

Final Report

Design of a Cuff System to Monitor the Blood Pressure of Western Lowland, Silverback Gorillas

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TABLE OF CONTENTS

TABLE OF CONTENTS.....	2
II. Project Description.....	5
a) Background.....	5
b) Description.....	5
c) Goals.....	6
d) Target Users and/or Subjects.....	6
e) Market Information.....	7
f) Potential FDA Product Classification and Regulatory Pathway.....	7
III. Design Research/Investigation Methodologies.....	8
a) Discussions with Advisor.....	8
b) Design Concepts.....	8
(i) Mechanism for detecting blood pressure.....	8
(ii) Monitoring System.....	9
(iii) Safety Mechanisms.....	9
c) Patent Review.....	10
(i) Mechanisms for Detecting Blood Pressure.....	10
(ii) Monitoring System.....	11
(iii) Safety Mechanisms.....	11
d) Literature Review.....	12
(i) Mechanisms for Detecting Blood Pressure.....	13
(ii) Safety Mechanisms.....	13
e) Patent and Literature Discussion.....	14
(i) Oscillometric Method.....	14
(ii) Cuff Inflation.....	14
(iii) Monitoring System.....	15
(iv) Magnetic Connection.....	15
(v) Air Connector.....	15
(vi) Sliding Rail System.....	16
(vii) Low-Noise Emission.....	16
f) Investigation of Similar Products.....	17
IV. Engineering Design Specification.....	17
a) Customer Requirements.....	17
(i) Expected Functional Parameters and Metrics.....	17
(ii) Human Factor Considerations.....	18
b) Engineering Characteristics.....	18
(i) Size, Weight, Materials, Mechanical Properties.....	18
(ii) Sterility.....	18
(iii) Electrical Requirements.....	18
c) Production methods.....	18
(i) Manufacturing Methods and Cost Analysis.....	18
(ii) Allowable Tolerance Levels.....	18
(iii) Packaging and Storage Requirements.....	20
d) Constraints.....	20
(i) Functioning With Other Products.....	20

(ii) Target Manufacturing Cost	20
V. Design Concepts	20
a) Design I.....	20
b) Design II	21
c) Design III	21
d) Design IV.....	21
VI. Proposed Design	22
VII. Plan of Work for 4601	23
VIII. References.....	24
IX. Addendum.....	26
IX. Addendum.....	26

I. Executive Summary

Cardiac disease is the leading cause of mortality and morbidity in captive, adult male gorillas. Zoo Atlanta currently monitors precursory signs to cardiac disease and is working to improve its detection in western lowland, silverback gorillas. Every three years, Zoo Atlanta anesthetizes gorillas in order to measure their blood pressure. Sedation is necessary due to the skittish and potentially dangerous nature of the animal. As of now, blood pressure readings have never been taken on awake, conscious gorillas. Therefore, an automatic device is being designed, capable of taking accurate, repeatable blood pressure measurements of awake gorillas.

The limiting factors affecting the proposed designs include user needs such as user safety and compatibility with cage attachment. The proposed designs were devised to address the following issues: a mechanism for detecting blood pressure, implementing the oscillometric method and automatic cuff inflation; a monitoring system with a digital readout of pulse, diastolic and systolic blood pressure; safety mechanisms which incorporate an easily detachable connector, a low-noise emission device, and a disengagement mechanism.

Using a weighted evaluation matrix with ten design criteria, all proposed designs underwent comparative analysis. The final design consists of a protective casing for the blood pressure cuff used to take measurements. The casing is attached to a rail system, acting as a disengagement mechanism, to unplug the air flow connector from the cuff to the Critikon Dinamap 8300 blood pressure monitor, under sufficient tensile force from the gorilla. The final design includes the following parts and features:

- Cuff Casing- composed of two attachable parts fasten by four latches; made of ABS plastic and attaches cuff to the rail system
- Rail System- composed of two four-sectioned ball bearing drawer sliders, plywood and fastened to the cage-mesh sleeve by eight L-brackets; attaches cuff casing to cage-mesh sleeve
- Air Flow Connector- smooth plug adapter comprised of two parts: 1) threaded female and smooth male connector 2) smooth female connector and threaded male connector; converts connection of monitoring system to cuff from threading to smooth plug

Future work will include building a training prototype and functional prototype, and a testing and redesign phase for each. Then a final design will be produced and used to collect physiological data from awake gorillas for comparison to anesthetized gorilla data. If successful, the final product will be redesigned for use with female and adolescent gorillas.

II. Project Description

a) Background

Adult male gorillas in captivity are highly susceptible to cardiac disease. Cardiac disease is any condition affecting the ability of the heart or blood vessels to function and circulate blood properly which in turn affects the supply of oxygen to vital organs. If oxygen does not reach the tissue of an organ, hypoxia will ensue and the organ will eventually die[1]. Blood pressure measures the force exerted by blood on the walls of blood vessels and thus indicates the pressure built by the contracting heart muscle. Blood pressure monitoring is a crucial step in early diagnosis of cardiac disease[1].

b) Description

Currently, veterinarians use human blood pressure cuff systems to measure gorillas' blood pressure. Human blood pressure monitors often utilize the oscillometric method which uses an electrically regulated pump and valve cuff[2]. The cuff is placed on the forearm of the animal and is subsequently inflated and released using an electrically regulated pump and valve. A pressure sensor measures the pressure, which varies periodically with cyclic expansion and contraction of the brachial artery[2]. The systolic and diastolic values are not directly measured. Rather, they are computed by a pre-programmed algorithm and displayed on a display screen[2].

Currently, a gorilla's blood pressure is only measured when the gorilla is fully anesthetized. Blood pressure measurements are only obtained during their health check-ups, which happen once every two to three years due to the unhealthy nature of anesthetics. Veterinarians have recently realized the importance of measuring an awake gorillas' blood pressure rather than an anesthetized gorilla's blood pressure. It is unknown how anesthesia and the gorillas' orientation (lying on its back) affect blood flow and the ensuing blood pressure readings. It is highly probable that the anesthetized

readings are far different than awake readings and thus do not provide representative values. Therefore, the team's advisor, Dr. Rivera, has requested the design of a device that is capable of measuring the blood pressure in awake gorillas.

The intended purpose of this product is to monitor blood pressure in awake, Western Lowland silverback gorillas in order to aid in the diagnosis of cardiac disease.

c) Goals

Since the blood pressure will be measured in awake gorillas, many design modifications must be made to human blood pressure cuff systems in order to design a blood pressure monitor for awake male gorillas. The new device will use the same oscillatory method as the current device; however, it will take into account the behavior of the gorilla and safety of the user by having the following features:

- Larger cuff size to fit the forearm of an adult male gorilla to aid in the gorilla's comfort level in order to prevent undesirable behavior
- Lower noise emission to keep the gorilla calm during the procedure to prevent undesirable behavior
- Automatic shut-off mechanism to prevent injury to a gorilla that becomes disturbed by the device while measurements are taken
- Emergency off-switch for the user to activate if the user notices a problem with the subject, device, or other users
- Durable to prevent damage by the gorilla
- Digital output display to make the measurement read-out easier to see
- Able to temporarily fasten to an existing cage-mesh sleeve attachment (refer to Figure 1 for the cage extension sketch) to prevent the device from entering the gorilla's cage and getting destroyed

To see the concept sketch that incorporates all of the above features, refer to Figure 2 in the addendum.

d) Target Users and/or Subjects

The proposed device will be used by a team of veterinarians and caretakers of gorillas at Zoo Atlanta. The device will be used inside a cage with a cage-mesh sleeve

extension by the veterinary and training team. The subjects of the device will be Western Lowland Gorillas. Use will only include turning on the device with an on/off switch, emergency off button, and a start button to initiate data acquisition. The cuff will be housed inside the cage-mesh sleeve, while the control console with the digital display will be outside the cage. This will keep the least expendable parts in a safe location.

e) Market Information

- Current market Size = 140 zoos in the world with gorillas[3, 4]
- Patient Population = 768 gorillas in captivity[5]
- Current Number of Procedures = 384 procedures/ year in the world
- Number Underserved = 384 patients

Before calculating the market sales price, the cost of each component of each device must be added together. After adding up all the components, the total came to \$121.00 USD outlined in Table 1 [6]. Due to the likelihood of the destruction of the device, a testing cost was added. After this, a manufacturing cost (labor) and a marketing cost were added. The total came to be \$550 USD. Since this device is a monitoring device, the sales price should be three to four times the product cost. Therefore, the market price per device should be approximately \$1,650- \$2,200 USD with a total market price of \$231,000-\$308,000 USD.

f) Potential FDA Product Classification and Regulatory Pathway

Although this blood pressure monitoring device is not intended for use on humans, it is treated as though a premarket notification (510(k)) will be filed in order to approve the device for market. This blood pressure monitoring system is a Class II device because it has special controls for which general regulations are not enough to guarantee the safety of the device[7]. Prior to applying for a 510(k), it must be proven that there is “substantial equivalence” between this device and another predicate device[7]. It can be proven substantially equivalent if it has the same intended use as a predicate device and has the same technological characteristics as the predicate device[7]. The device will also be subject to the following specific regulations to ensure its safety.

- Performance standards recognized by the FDA (approval of product) – tests efficacy and safety of product

- Post-market surveillance
 - Medical device reporting – monitors significant adverse effects of product use
 - Medical device tracking – used to locate products if recall of product is implemented
- Patient registries[7]

III. Design Research/Investigation Methodologies

a) Discussions with Advisor

Meetings with the advisor, Dr. Sam Rivera, were held on a bi-monthly basis at Zoo Atlanta or as deemed necessary. Furthermore, discussions and questions related to the project were addressed via email. The initial meeting to discuss the project was held on September 10th 2008 at Zoo Atlanta. Dr. Rivera provided a detailed description of the problem as well as information regarding the species that the device will be used on, Western Lowland gorillas. The second monthly meeting with Dr. Rivera occurred on November 14th 2008 at the zoo as well. At this meeting, the group was introduced to the environment in which the product will be used, the caging area for the gorillas. The team also met the gorilla training team that will be crucial once the prototype is completed. This provided the group with a visual understanding of the environment in which the device would be used and greatly aided the overall product development. On December 5th 2008, the team met again at the zoo to pick up the cage-mesh sleeve that was constructed by Christian Wright of the zoo maintenance team. The veterinarian staff also provided the team with a Critikon blood pressure cuff, reference no. 2647, which is currently used to test the blood pressure of anesthetized gorillas. The cuff provided is compatible and used with the Critikon Dinamap 8300 Blood Pressure monitor.

b) Design Concepts

(i) Mechanism for detecting blood pressure

The oscillometric method of blood pressure determination will be utilized in the final proposed device. Using an electronically regulated pump and valve cuff, the device occludes blood flow through the brachial artery. After occlusion, air is slowly released

and a pressure sensor is used to measure pressure exerted by blood flow. Blood flow through the brachial artery varies periodically with cyclic expansion and contraction of the artery. Using an algorithm, the blood pressure monitoring device is able to calculate the systolic and diastolic blood pressures based on the pressure readings.

(ii) Monitoring System

The monitoring system for the proposed device consists of two main components: the display screen and the control console. The display screen provides digital readouts of (1) systolic blood pressure, (2) diastolic blood pressure, and (3) pulse. The control console, which houses the display screen, also consists of several key components. The control console will contain (1) an emergency off button, (2) an on/off button, and (3) a start button. The control console will also have a user-friendly design making it simple and portable.

(iii) Safety Mechanisms

Several safety mechanisms also comprise a part of the proposed device design. Because of gorillas' behavior to new devices and sensations, the device has precautionary features to protect the user if any violent behavior is exhibited by the gorilla. First, a novel magnetic connection between the arm cuff and the console control was proposed to be utilized to increase the safety of both the user (veterinarian) and subject (gorilla.) However, the design team decided on a much simpler safety mechanism, a novel, releasable air flow connector between the arm cuff and the control console. The releasable air flow connection will release under enough tensile force (gorilla tries to rid arm of blood pressure cuff) and will salvage the cuff and the control console. Furthermore, the detachment of the air flow connection will serve as an emergency off mechanism for the monitoring system.

Another safety mechanism, the sliding rail system, was added to ensure that the gorilla would not harm itself and that the cuff would not be torn out of the cuff casing. The team developed this sliding rail system that provides the device with extra time to deflate if the gorilla exhibits excited behavior, and it ensures the cuff will not enter the cage and be destroyed. The device will be attached to the sliding rail system so that if the gorilla attempts to pull its arm out of the cuff system, the releasable air flow connector

will disconnect the cuff system from the control console. As the device slides with the gorilla's arm, air will be released from the cuff bladder, making it easier for the gorilla to remove its arm from the cuff without harming itself or the actual device.

Keeping the noise emission of the blood pressure monitoring system to a low level is a significant safety mechanism that will be considered for the proposed device. Gorillas are easily startled by loud noises and thus keeping the operating volume low will help lessen the natural response to unexpected noises.

c) Patent Review

A thorough patent search, using Google Patents search engine, was conducted to examine patented devices that are similar to the components of the proposed design. Similarities and differences between the prior patents and the components of the group's proposed device were examined in the following section. Table 2 was compiled to show details related to the patent searches.

(i) Mechanisms for Detecting Blood Pressure

(a) Oscillometric method

Patent No: 4889132 Inventor: Hutcheson, et al Date of Patent: 12/26/1989
Title: Portable Automated Blood Pressure Monitoring Apparatus and Method[8]

When designing an automated mechanism for measuring blood pressure, it is crucial to utilize the oscillometric method. This patent describes a portable oscillometric blood pressure and heart rate monitoring system. It measures systolic and diastolic blood pressure on command or at programmed time intervals. A flow chart of this method can be found in Figure 3.

(b) Cuff inflation

Patent No: 4109646 Inventor: Keller, et al Date of Patent: 8/29/1978
Title: Automatic Blood Pressure Cuff Applicator[9]

This patent is for the design of a flexible, inflatable cuff used in taking blood pressure measurements. It is applied to a body member such as an arm or leg. The arrangement includes a rotatable drum supported between a pair of end plates which have openings formed therein allowing the body member of the subject to be placed inside of the rotatable drum. A drawing of the device and its

components can be found in Figure 4. When the drum rotates, it encircles the body member and initiates the inflation of the cuff leading to the measurement of blood pressure.

(ii) Monitoring System

Patent No: D473308 Inventor: Nakanishi, et al Date of Patent: 4/15/2003

Title: Blood Pressure Monitor[10]

There are several designs for the display of various blood pressure monitoring systems. However, the design in patent no. D473308 is the most similar to the team's design specifications (see Figure 5). The screen on this device displays systolic blood pressure, diastolic blood pressure, and the pulse rate. The device also has a console which contains three buttons: an emergency off button, a start button and a stop button.

(iii) Safety Mechanisms

(a) Magnetic connection

Patent No: 7354315 Inventor: Goetz, et al Date of Patent: 4/8/2008

Title: Releasable Plug Connector System[11]

This patent is for a “break-away” plug connector system. It is mainly designed for audio outputs of MP3 players and consists of two parts. The first part is an audio jack in which one side is inserted into the MP3 player. The other side extends out of the player with a conducting pathway on the end. This conducting pathway is meant to match up with a complementary conducting pathway on the end of a headset. The point of contact of the conducting pathways is surrounded by a cap on one side (see Figure 6).

(b) Air Connector

Patent No: 5014716 Inventor: Ogawa, et al Date of Patent: 5/14/1991

Title: Sphygmomanometer Air Connector[12]

This patent is for an air connector used in association with a sphygmomanometer body. It is comprised of an air socket with an air plug acceptor and a pressure measuring air line. The connector has an exhaust air line communicating with the air plug acceptor and an air supply plug removably

connected to the air plug acceptor of the air socket. It contains an air tube joint at one end and an insert cylinder at the other end. Upon installation, the insert cylinder brings air supply into the monitor where it communicates with the pressure measuring air line and exhaust air line. Upon removal, the insert cylinder brings the air supply line of the air supply plug selectively into communication with the pressure measuring air line for pressure determination. A drawing of the components of this patent are shown in Figure 7.

(c) Rail Sliding System

Patent No: 5466060 Inventor: Hoffman, et al Date of Patent: 11/14/1995
Title: Drawer Slide with Access Holes[13]

This patent is for a drawer slide assembly with telescopically interfit drawer channels. This particular design includes screw mounting holes with an enlarged center channel in order to gain better access to these holes. The drawer system itself is comprised of two or more channel sections installed in cabinetry with matching draw slides attached to the drawer itself. Figure 8 shows a drawing of this patent.

(d) Low-Noise Emission

Patent No: 4832039 Inventor: Perry, et al Date of Patent: 5/23/1989
Title: Linear, Low Noise Inflation System for Blood Pressure Monitor[14]

This patent is for a compact, low noise inflation system for pressurizing occlusion cuffs, and is used with an automatic blood pressure monitoring system. The system is controlled by an electric pump which uses a pressure feedback control circuit that is closed-loop. The cuff pressure is constantly compared with the custom pressure set by the user and stored in the memory. This device uses an acoustic filter located at the intake and exhaust ports of the pump attenuating acoustic noise and pressure waves to more accurately measure blood pressure. The mechanism is displayed in Figure 9.

d) Literature Review

Researching prior literature allowed the group to examine previous studies relating to the proposed design concepts. Table 2 in the addendum shows the relevant articles discussed.

(i) Mechanisms for Detecting Blood Pressure

Literature research revealed several pertinent studies that examine the various mechanisms for detecting blood pressure. Literature was found describing both the auscultatory and oscillometric method for determining blood pressure[15]. This literature showed the similarities and differences between the two methods. This research helped confirm the group's decision to use an oscillometric blood pressure monitor due to its more accurate and user-friendly approach. Another source revealed common complications that may arise upon measurement of blood pressure with the proposed device[16]. This literature also provides recommendations to improve equipment in order to avoid these problems. Table 2 shows these complications and recommendations[16].

(ii) Safety Mechanisms

A prominent safety mechanism researched was the magnetic connector. Due to the novel nature of the magnetic connector, few pieces of literature were found discussing this device component. Furthermore, the group's idea to incorporate air flow, power supply, and electrical wiring within the connection decreased literature findings. However, literature was found to understand the magnetic connection of a power supply. The article found provides a description of the specific components and contacts necessary for this safety element in the proposed design[17]. When the magnetic components within the receptacle and plug are brought near each other, the attracting magnets cause the two separate components to interlock. Upon linking, electrical conductivity is initiated[17]. This research will aid in the design and development of the magnetic connection incorporating air flow, power supply, and electrical wiring. However, the design team decided not to use this connector due to its complexity and lack of literature findings.

Due to the novel nature of the plastic releasable air flow connector, there was also no literature found discussing the function of this component. There is not a large market for a device containing a releasable air flow mechanism due to the fact that most blood pressure monitors on the market are for human subjects, who typically do not have excited behavior when their blood pressure is measured. However, the design team

decided to use the literature findings from the magnetic connector to design a simplified releasable air flow connector.

Literature regarding the rail sliding system was also difficult to find because of the simple nature of the device. Rail sliding systems are often components of products such as drawers. Rail sliding systems are usually not the emphasis of the product or device, and thus literature published on rail sliding systems does not frequently appear in publication databases.

Researching literature and prior art allowed the group to determine the novelty and patentability of the proposed design concepts. The most relevant patents and literature reviews were examined thoroughly and compared to the proposed design concepts for similarities and differences.

e) Patent and Literature Discussion

(i) Oscillometric Method

The majority of patents found for digital blood pressure monitors utilized the oscillometric method for blood pressure measurements. After researching various patents, patent no. 4889132 best represented this design concept. This patent deals with a blood pressure and heart monitoring device that uses oscillometry to take measurements. Fagugli et al. supports the incorporation of the oscillometric method over the auscultatory method due to its higher accuracy. The proposed device does not infringe on the patent rights of this invention or any other oscillometric blood pressure monitoring system because oscillometry is a concept that is considered public knowledge.

(ii) Cuff Inflation

Various uni-body blood pressure cuff patents were found, and patent no. 4109646 best represented this pool of results. This patent describes a specific method for inflation of a flexible, inflatable blood pressure cuff. This design uses a rotary mechanism in order to make the cuff encircle the subject's body member. Next, the cuff inflates with air in order to apply pressure to take subsequent blood pressure measurements. However, the proposed design concept will only contain a single cuff size, and therefore, not have a rotational component. The design concept will utilize a similar inflation method for

filling the cuff with air. Also, the proximity of the electric pump to the cuff will be significantly greater in the proposed design concept than in the patent.

(iii) Monitoring System

Of the patents dealing with ease of use, patent no. D473308 most closely resembled the design concept of display and control features. The patent is for the outer casing of a blood pressure monitor, which contains a display screen, three buttons, and is sleek and compact in shape. The layout of the screen will be different when displaying systolic blood pressure, diastolic blood pressure, and pulse rate readings. Also, the proposed design concept will only have two buttons (start and emergency stop) along with an on/off switch in order to be user-friendly.

(iv) Magnetic Connection

The previously proposed design concept has a magnetic connection in the cord designed for safety purposes. When looking for literature and a patent regarding magnetic connections, a patent application by Rohrbach et al. and patent no. 7354315 was found to have the most applicable design for the proposed design concept. The proposed design concept has a large tube that contains two smaller tubes (one for electrical signals and one for air) that transfer signals between the console and the cuff. It uses a magnetic connector to join the tube half that relays the output from the console to the tube half that relays the input into the cuff. The difference between the design concept and the patent is that the patent is focused on a magnetic connector that links the output of an MP3 player to a headset. This patent uses the magnetic connector to relay auditory signals, whereas the magnetic connector in the design concept relays both air flow and digital signals. Also, the patent uses a jack to connect the headset cord to the MP3 player, while the cable of the console of the design concept is permanently attached to the console. The magnetic connection was initially part of the proposed design concept, but has since been removed due to its complexity and lack of literature and patent support.

(v) Air Connector

The final proposed design concept has an emergency release air flow connector designed for safety purposes. When looking for literature and patents regarding releasable air flow connections, a patent by Hiroshi Ogawa et al. was found. However, it was not

applicable to the team's proposed design because the patent is not a releasable connector. The proposed design will be similar to the function of the magnetic connector in that the connector will interlock a receptacle and plug together allowing air to flow to and from the cuff. The connector will also disconnect under sufficient tensile force to allow air to quickly escape from the cuff, providing easy release of the subject's arm. However, the proposed design will only incorporate plastic and tubing for air flow, as opposed to tubing, electrical wiring, and magnets as previously proposed in the magnetic connection component. The design will use the plastic connector to join the tubing together until there is enough tensile force to break the air flow connection.

(vi) Sliding Rail System

This proposed design concept has a sliding rail system connecting the cage-mesh sleeve and the cuff device to each other. The sliding mechanism allows the cuff more time to deflate when the air flow connection is broken and thus will help salvage the cuff should the gorilla try to rid its arm of the cuff. When searching for literature and patents relating to a similar sliding rail system, a patent by Keith Hoffman, et al. was found explaining the function of a drawer slide with access holes. This patent is very similar to what the design team is looking to insert into the cage-mesh sleeve and attach to the cuff apparatus. The proposed design will incorporate a similar sliding mechanism with holes that will attach the device to the sliding rails and temporarily attach the entire design to the cage-mesh sleeve.

(vii) Low-Noise Emission

A distinguishing feature of the design concept is the low-noise emission. This feature is crucial for devices used on gorillas because they are easily frightened by foreign noise such as the humming of a motor. Patent no. 4832039 is for a linear, low noise inflation system for blood pressure monitor. The device utilizes an acoustic noise filter to minimize the sound caused by the pump's air influx and efflux. The design concept implements a muffler system for minimizing noise emission caused by the pump's air influx and efflux. The group may decide to utilize a similar low-noise emission inflation system in the final device.

Significant differences were found between the existing patents and the proposed design concept while conducting prior art research. This research confirms that the proposed design concepts are substantially different from prior art. Thus, the patentability of the proposed device components should not be a hindrance in the overall product design.

f) Investigation of Similar Products

Upon meeting with Dr. Rivera and discussing the current method in which blood pressure is taken in gorillas, it was found that Zoo Atlanta uses the Critikon Dinamap 8300 Veterinarian Blood Pressure Monitor to record blood pressure readings. The Critikon Dinamap 8300 measures systolic blood pressure, mean arterial pressure, diastolic blood pressure, and pulse rate by the oscillometric method. Furthermore, the device encompasses an emergency off button as well as an on/off button and a start button to further satisfy the design requirements set forth by the team. The device is powered by a rechargeable battery, which makes the device portable. The unit itself is separate from the blood pressure cuff, which connect via a non-removable plastic air flow connector at the end of the tubing. Since the Critikon Dinamap 8300 satisfies the initial design specifications set forth by the group, it may be a good device to integrate within the overall design of the cuff system.

IV. Engineering Design Specification

a) Customer Requirements

(i) Expected Functional Parameters and Metrics

- Measures systolic and diastolic blood pressure
- Displays the output from the blood pressure system in mmHg on LCD
- Internal circumference of blood pressure cuff is at minimum 20"
- Fits into existing cage-mesh sleeve measuring 8" x 8" x 42"
- Detachable from cage-mesh sleeve so other medical devices can be inserted into sleeve
- Easily replicable for training purposes
- Disposable since gorillas are scared easily and tend to destroy unfamiliar objects

- Utilizes the oscillometric method

(ii) Human Factor Considerations

Physical, cognitive, and behavioral factors are considered in the design of the blood pressure monitoring system:

- Physical: size of fingers and hands of end-user; size of forearm of the subject[18].
- Cognitive: perception of the output, processing information listed on the display, memory, and motor response of the end-user; long-term memory of subject, size/shape/color recognition of device[18].
- Behavioral: awareness and long-term memory patterns of the end-user; conduct and attitude of subject[18].

All these human/animal factors will help the end-user and subject maximize safety, efficiency, and productivity, and minimize mistakes, misinterpretations, and costs[18].

b) Engineering Characteristics

(i) Size, Weight, Materials, Mechanical Properties

Table 3- Shows the size, weight, material, and relevant mechanical properties of each component

Part	Size	Weight	Material	Mechanical Properties
<i>Control Box Casing</i>	7" x 4" x 3" (WxLxD)	4-8 oz.	ABS (Acrylonitrile butadiene styrene)	Density: 0.35-1.26 g/cc Modulus of Elasticity: 1.52-6.10 GPa
<i>LCD</i>	5" x 3"	2 oz.	Nematic liquid crystals, silicon oxide glass, polarized material filter	N/A
<i>Vinyl Cuff and Tubing</i>	Double layered 30" x 6 " tubing: 19 Fr	2-6 oz.	Vinyl	Density: 0.55-2.50 g/cc Modulus of Elasticity: 0.00159-3.24 GPa
<i>Internal Circuitry</i>	N/A	8-12 oz.	Copper, Silicon, Solder, Steel	N/A
<i>Clam Shell Enclosure for</i>	7.25" x 8.5" x 7" (WxLxD)	5-9 oz.	ABS	Density: 0.35-1.26 g/cc

<i>Cuff</i>				<i>Modulus of Elasticity: 1.52-6.10 GPa</i>
<i>Sliding Rails</i>	2" x 20" x 0.5" (WxLxD)	10 oz.	Stainless Steel	<i>Density: 8.03 g/cc Modulus of Elasticity: 193 GPa</i>
<i>Air Flow Connector</i>	19 Fr	1 oz.	ABS	<i>Density: 0.35-1.26 g/cc Modulus of Elasticity: 1.52-6.10 GPa</i>

(ii) Sterility

Sterility is not a significant factor in product design because the device is a non- invasive monitoring system with low risk of disease transfer or infection.

(iii) Electrical Requirements

The proposed device requires an external power source with the ability to power an LCD screen, pump mechanism, and internal circuitry. Parts that do not require electricity to function include: rubber buttons, control console casing, vinyl arm cuff, tubing, plastic air flow connector and power switch.

c) Production methods

(i) Manufacturing Methods and Cost Analysis

When manufacturing the device, it will be made on a small scale. There will be no assembly lines or large manufacturing plants involved because the market size is so small. To create the product, CAD files were created and a contractor will be hired to create some of the parts via injection molding. These parts include the clam shells, battery case, buttons, and air flow connector. The cuff cover, cuff bladder, tubing, wires, battery, LCD screen and sensor for the cuff will be ordered from other companies. After all the parts have been received, the product will be assembled in house.

(ii) Allowable Tolerance Levels

The tolerance for all manufactured components of the device will be ± 0.001 inches.

(iii) Packaging and Storage Requirements

When packaging the device, a cardboard box with Styrofoam padding will be used. The device will have an operating and storage temperature of 10-40 °C.

d) Constraints

(i) Functioning With Other Products

The product must fit into the cage-mesh sleeve. It will be inserted into the cage-mesh sleeve through a door on the side of it. The cage-mesh sleeve is 8" x 8" x 42". Also, the designed device must be compatible and integrated with the Critikon Dinamap 8300. Other constraints include the customer requirements mentioned above.

(ii) Target Manufacturing Cost

The target manufacturing cost will be less than the target market sales price in order to make a profit from the device (see cost analysis for pricing breakdown in Table 1). After adding up the cost of each component, manufacturing costs and labor, the total came to be \$550 USD. Refer to section (II.e) to find the estimated market price.

V. Design Concepts

The design team explored four different design concepts during the design process. A comparison matrix showing how each was ranked for various important parameters can be viewed in Table 4.

a) Design I

This design concept uses a polyvinyl chloride (PVC) pipe to hold the actual blood pressure cuff bladder as shown in Figure 10. The design uses a magnetic connector as a safety mechanism to disconnect the power supply and air flow to the cuff. The wiring and tubing carries electrical signals from a sensor in the cuff back to the electrical control console and air flow from the pump in the console to the cuff for inflation. The display includes the following readings: systolic blood pressure, diastolic blood pressure, and pulse rate. There are three buttons on the console including the on/off switch, an emergency off button, and a start button. The design team would be designing all of these components including the electrical components within the console as well as the control console casing.

b) Design II

This design concept uses an acrylonitrile butadiene styrene (ABS) injected molded shell to hold the actual blood pressure cuff bladder as opposed to PVC pipe from design I. This is shown in Figure 11. The design team decided that a more rectangular shape would be easier to attach to the cage-mesh sleeve than a cylindrical tube as seen in design I. The design also uses the same magnetic connector, wiring, tubing, and console as design I.

c) Design III

Design III incorporates the use of the same ABS injected molded container as design II shown in Figure 12. However, this concept introduces two new safety mechanisms including a releasable air flow connector and a sliding rail system. The releasable air flow connector allows the cuff to deflate when the subject exerts a certain amount of tensile force on the two ends of the connector in order to safely remove the subject's arm from the device if the subject tries to pull away. Also, the sliding rail system allows the cuff extra time to deflate by sliding along the rail towards the cage if the subject pulls their arm back in fear. The rail stops at the edge of the cage-mesh sleeve, preventing the device from entering the cage itself and getting destroyed. Another addition to this design includes a console that sits on a flat surface and tilts towards the user at an angle to allow an easier view of the output on the display screen.

d) Design IV

This design concept incorporates all of the same components and mechanisms from design III except that the console will not be built by the design team. This design concept is shown in Figure 13. The blood pressure console described in section (III. f) that is currently in use at Zoo Atlanta (Critikon Dinamap 8300) will be used as the electrical control console for this proposed design.

Table 4- Shows the evaluation matrix used to assess the different designs.

<i>Criteria</i>	<i>Weight</i>	Alternatives							
		Design I		Design II		Design III		Design IV	
		<i>Rating</i>	<i>Score</i>	<i>Rating</i>	<i>Score</i>	<i>Rating</i>	<i>Score</i>	<i>Rating</i>	<i>Score</i>
<i>Target User: Veterinarians and Gorilla Caretakers</i>	9	9	81	9	81	10	90	10	90
<i>Visibility of displayed</i>	5	9	45	9	45	9	45	10	50

<i>information</i>									
<i>Human Factors Consideration</i>	4	4	16	6	24	6	24	7	28
<i>Easily Replicable</i>	2	4	8	5	10	5	10	6	12
<i>Fits into Cage-mesh Sleeve</i>	10	10	100	10	100	10	100	10	100
<i>Temporarily attaches to Cage-mesh Sleeve</i>	8	7	56	7	56	7	56	9	72
<i>Disposable</i>	3	4	12	5	15	5	15	6	18
<i>Automatic shut off mechanism</i>	7	5	35	5	35	9	63	9	63
<i>Safety</i>	6	5	30	5	30	7	42	9	54
<i>Cost Effective</i>	1	6	6	6	6	6	6	8	8
Total	55	63	389	67	402	74	451	84	495

VI. Proposed Design

The proposed design is comprised of three major design components: the cuff casing, the sliding rail system, and the air flow connector.

The cuff casing is composed of two large parts that complete the housing of the cuff and is securely fastened with four custom designed latches. The top portion of the casing contains more material and surface area that contacts the blood pressure cuff. The bottom portion of the casing contains the bored holes to allow for attachment to the rail system, a reverse lipped edge and holes to attach to the protruding lips and pins from the top portion of the casing. Specifications for top and bottom portions of the casing are included in Figures 14 and 15, respectively. Fastening the casing portions together are four latches composed of a latch handle and latch pin. The latch is assembled onto the bottom portion of the casing and after the top portion is fitted to the bottom, it is securely fastened by snapping shut the latches on the protruding lip on the top portion of the casing. Specifications for latch parts are detailed in Figures 16 and Figure 17.

The rail system includes two four-sectioned ball bearing drawer sliders with dimensions of 2"x 20"x 0.5" (width/length/thickness), a board of 0.250" plywood with dimension 6.500"x32", and eight L-brackets each fastened to the plywood by two 0.250" hex screws, two hex nuts, and two flat washers. The top of the sliders are fastened to the bottom portion of the cuff casing by 3/8" round screws, hex nuts, and flat washers.

The air flow connector is a smooth plug adaptor comprised of two parts. The first part has a threaded female connection that attaches to the threaded connectors of the cuff and a smooth male connector that attaches to the second part of the air flow connector. It is displayed in Figure 18. The second part of the airflow connector has a smooth female connection that attaches to the first part of the air flow connector and a threaded male connection that attaches to the threaded female connection on the tubing from the Critikon veterinary blood pressure monitor. It is displayed in Figure 19.

VII. Plan of Work for 4601

The next step in the development of the project will be to order or purchase any parts necessary to construct two prototypes of the design. The parts will be ordered over the winter break to allow time for shipment and delivery. Once the parts arrive in early January, the team will begin constructing a non-functioning prototype for the caretakers to train the gorillas. The non-functioning prototype will likely utilize a non-electric blood pressure monitor to help gorillas gain familiarity with the process. The testing of the prototypes will not occur until the caretakers have sufficiently trained the gorillas to allow for their blood pressure to be taken. After the construction of the non-functioning prototype is complete and while the caretakers are training the gorillas, the team will complete a Societal Impact Report. A Regulatory Report will also be completed by the team while the caretakers are training the gorillas.

A meeting will be held with the caretakers after the initial training to see if anything with the non-functioning prototype needs to be changed or addressed. If nothing is an issue with the non-functioning prototype, the team will build a functional prototype that differs only in functionality. If the caretakers have comments or concerns with the prototype, these will be addressed prior to the construction of the final prototype. After construction, the team will present the cuff system to Dr. Rivera and the caretakers, and they will begin the testing of the functioning device on the gorillas.

The Final Project Report will be written at the end of the semester to present the designed device as well as the experimental results obtained. A Gantt chart highlighting the team's milestones can be seen in Figure 20 of the addendum. A flow chart highlighting the testing and building of the prototypes can be found in Figure 21 of the addendum.

VIII. References

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IX. Addendum

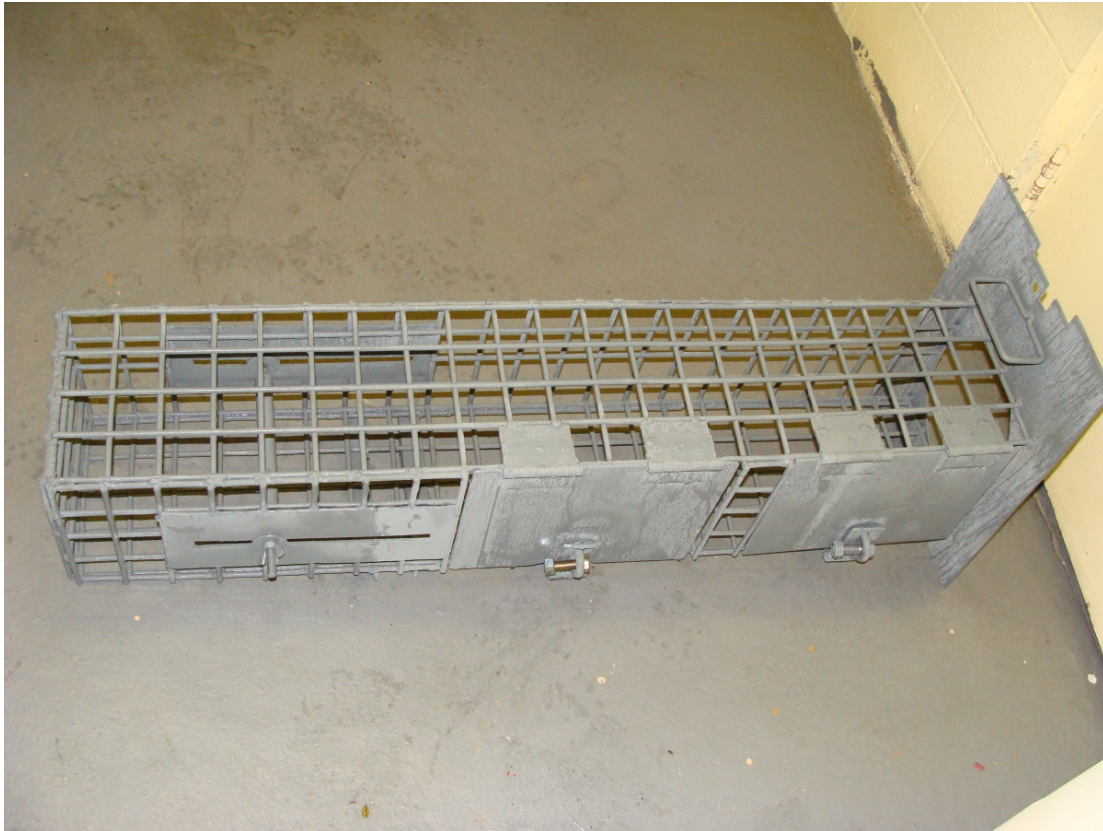


Figure 1. The cage-mesh sleeve that will house the cuff and attach to the gorilla's cage

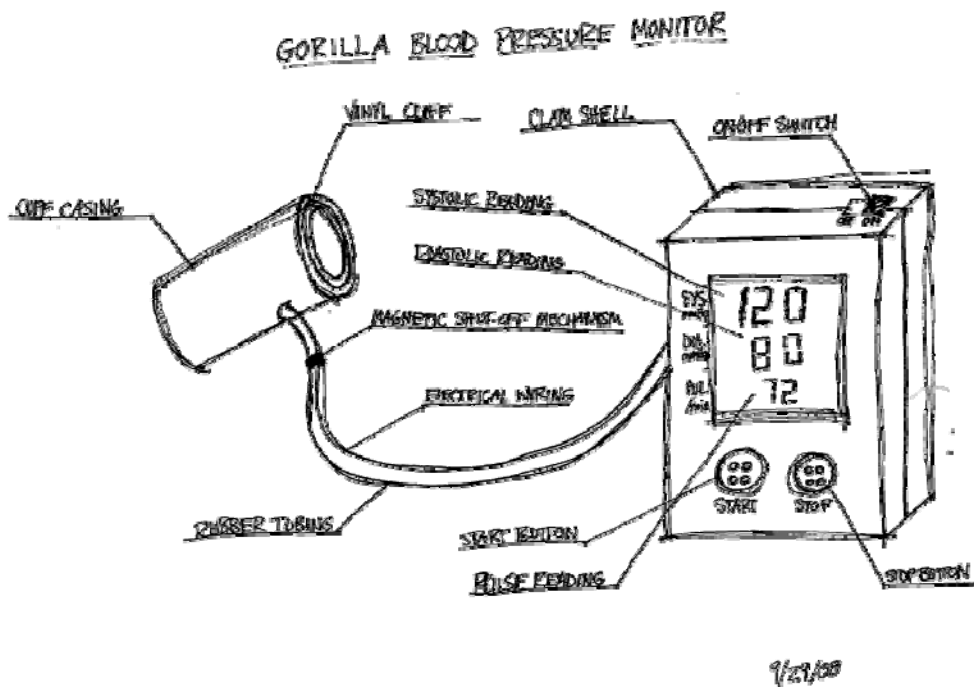


Figure 2. Complete concept Sketch of Features

Table 1. Manufacturing Cost and Production Method for design components

Component	Material	Manufacturing Process	Function	Cost per Component
<i>Cuff Apparatus</i>	ABS Plastic	Injection Molded	Holds cuff in place inside cage-mesh sleeve	\$7.00
<i>Clam Shell Latch</i>	ABS Plastic	Injection Molded	Holds two halves of clam shell together	\$3.00
<i>Handle and Latch Pin Tubing to Cuff</i>	Rubber	Molded	Allows pumped air to flow to and from cuff	\$6.00
<i>Cuff Bladder</i>	Rubber	Molded	Fills up with and releases air	\$7.00
<i>Air Flow Connector</i>	ABS Plastic	Injection Molded	Allows air to flow to and from cuff via tubing into and out of connector and releases under certain tensile force	\$4.00
<i>Sliding Rail System</i>	Stainless Steel	Machined	Allows cuff apparatus to slide inside cage-mesh sleeve while uninflating with air to safely release subject's arm	\$18.00
<i>Wood Attachment</i>	Ply Wood	Layered and glued	Attaches sliding rail system to cage-mesh sleeve	\$3.00
<i>Rail to Wood Screws</i>	Stainless Steel	Machined on a Screw Lathe	Attached wood to sliding rail system	\$12.00 (for 50)
<i>Control Console</i>	ABS Plastic	Injection Molded	Holds internal components inside the device	\$7.00
<i>Clam Shell Screw</i>	Stainless Steel	Machined on a screw lathe	Holds two halves of clam shell together	\$12.00 (for 50)
<i>Battery Cover</i>	ABS Plastic	Injection Molded	Covers battery	\$1.00
<i>Battery</i>	Alkaline	N/A	Power supply for device	\$7.00
<i>Buttons</i>	Rubber	Molded	Allows user to interact with device	\$1.00
<i>Wires</i>	Copper/Silver	Hot Rolled	Transfers current through device to	\$6.00

<i>LCD Screen</i>	Plastics	PECVD	and from cuff sensor Displays calculated blood pressure readings	\$20.00
<i>Circuit Board</i>	Metal and plastic	Copper etching, negative electroplating, photoengraving, tungsten carbide milling	Performs algorithms to calculate blood pressure from sensor readings	\$5.00
<i>Sensor</i>	Metal and plastic	N/A	Reads pulse in inflated and deflating bladder	\$2.00
Total = \$121.00				

Table 2. Patent and Literature Search- terms, results, and notes

Search Term	Search Engine	Title of Patent/ Article	Patent (P:#). Article (A).
"Blood", "Pressure" and "Monitor"	Google Patents	Blood Pressure Monitor	P: D473308
"Blood", "Pressure" and "Monitor"	Medline	Blood Pressure Measurement	A
"Portable", "Blood", "Pressure" and "Monitor"	Google Patents	Blood Pressure Monitor	P: D475137
"Oscillometric", "Blood" and "Pressure"	Medline	Oscillometric Blood Pressure Measurement: The Methodology, some Observations, and Suggestions	A
"Portable", "Blood", "Pressure" and "Monitor"	Google Patents	Blood Pressure Monitor	P: D338271
"Electronic", "Blood", "Pressure" and "Monitor"	Google Patents	Electronic Blood Pressure Monitor and Blood Pressure Data Processing System	P: 6699195
"Automated", "Blood", "Pressure" and "Cuff"	Google Patents	Automatic Identification of Cuff Size in Automated Blood Pressure Monitors	P: 4501280
"Noise", "Blood" and "Pressure"	Google Patents	Linear, Low Noise Inflation System for Blood Pressure Monitor	P: 4832039
"Magsafe" and "Connector"	Google Patents	Releasable Plug Connector System	P: 7354315
"Automated", "Blood", "Pressure" and "Cuff"	Google Patents	Automatic Blood Pressure Cuff Applicator	P: 4109646
"Portable", "Automated", "Blood", "Pressure" and "Monitor"	Google Patents	Portable Automated Blood Pressure Monitoring Apparatus and Method	P: 4889132
"Blood", "Pressure", "Problems" and "Measure"	Google Scholar	Human blood pressure determination by sphygmomanometry	A

"Apple", "Magnetic", and "Connector"	Google Patents	Releasable Plug Connector System	A
"Blood", "Pressure" and "Monitor"	Google Scholar	Arterial Stiffness as Underlying Mechanism of Disagreement Between an Oscillometric Blood Pressure Monitor and a Sphygmomanometer	A
"Blood", "Pressure", "Monitor", "Air" and "Pump"	Google Patents	Blood Pressure Cuff Automatic Deflation Device	P: 4116230
"Oscillometric" and "Auscultatory"	PubMed	Comparison Between Oscillometric and Auscultatory Methods of Ambulatory Blood Pressure Measurement in Hemodialysis Patients	A

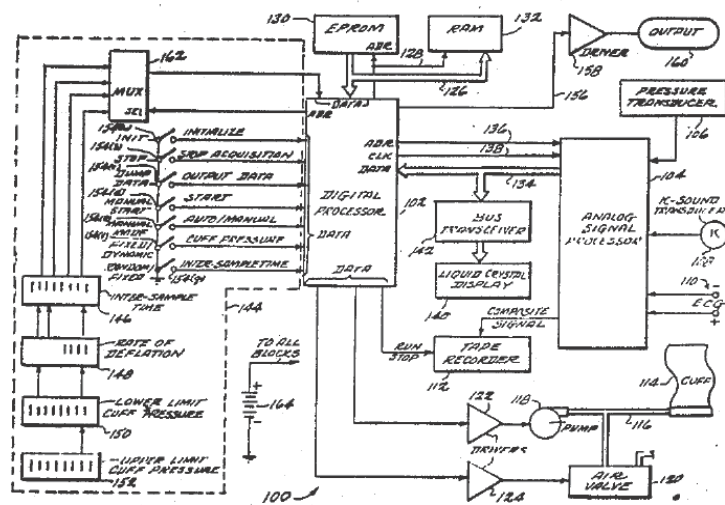


Figure 3. Shows flow chart of oscillometric method from patent no. 4889132

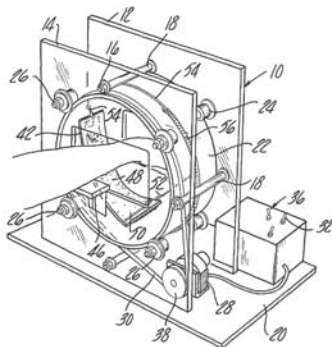


Figure 4. Shows cuff inflation mechanism in patent no. 4109646

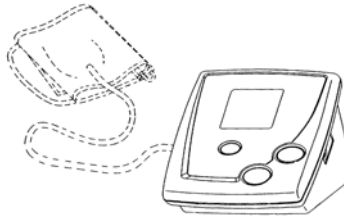


Figure 5. Shows casing design of blood pressure monitor from patent no. D473308

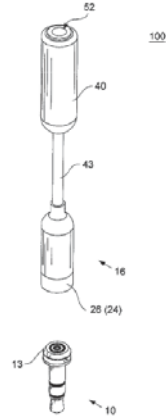


Figure 6. Shows magnetic connector for audio application in patent no. 7354315

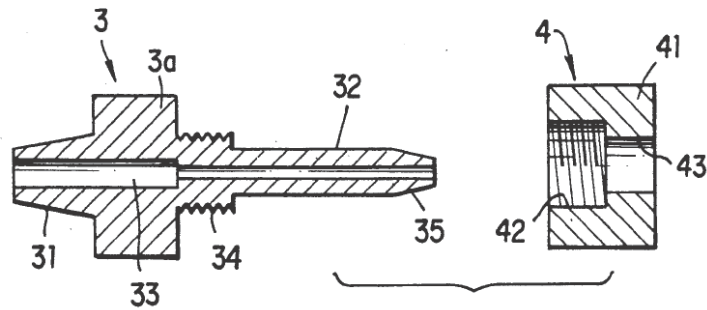


Figure 7. Shows air connector used in connection with sphygmomanometer in patent no. 5014716

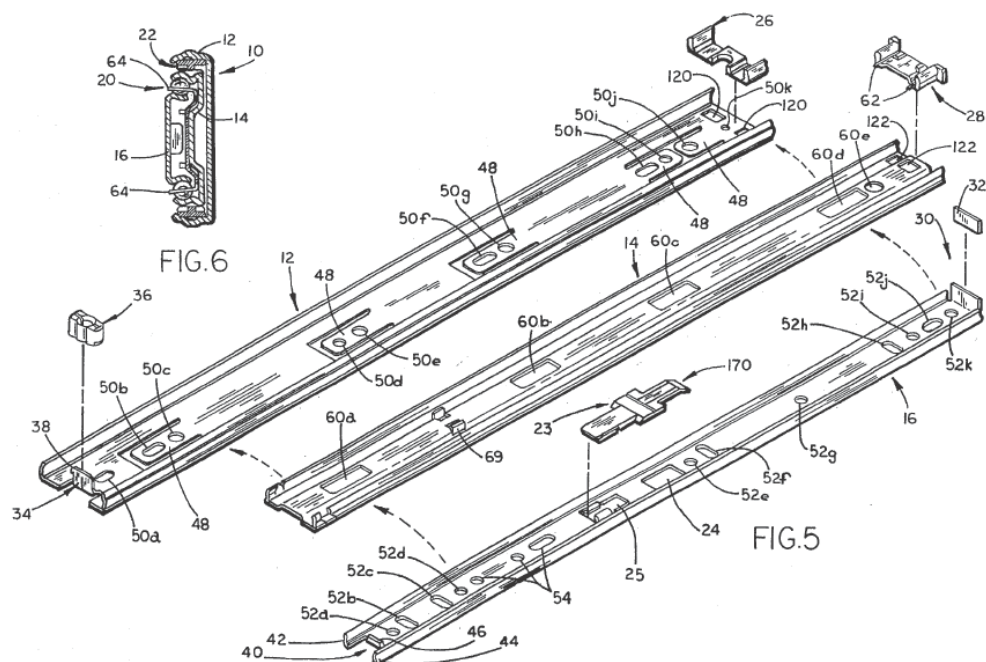


Figure 8. Shows drawer slider with access holes in patent no. 5466060

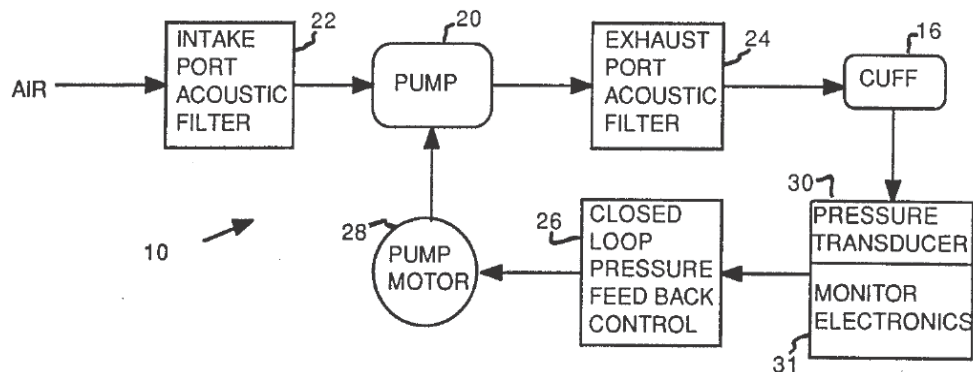


Figure 9. Shows the flow chart of a linear, low noise inflation system for blood pressure monitoring in patent no. 4832039

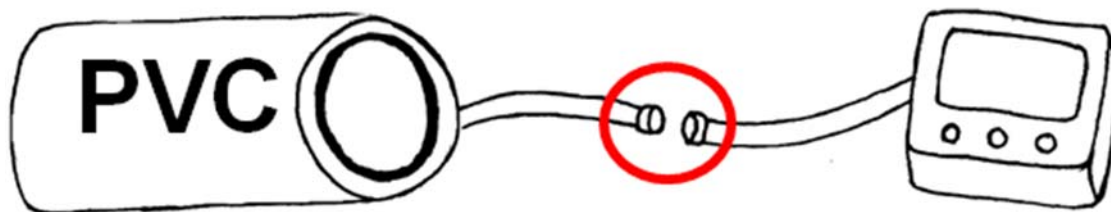


Figure 10. Shows a sketch of design I with PVC pipe casing and magnetic connectors (red)

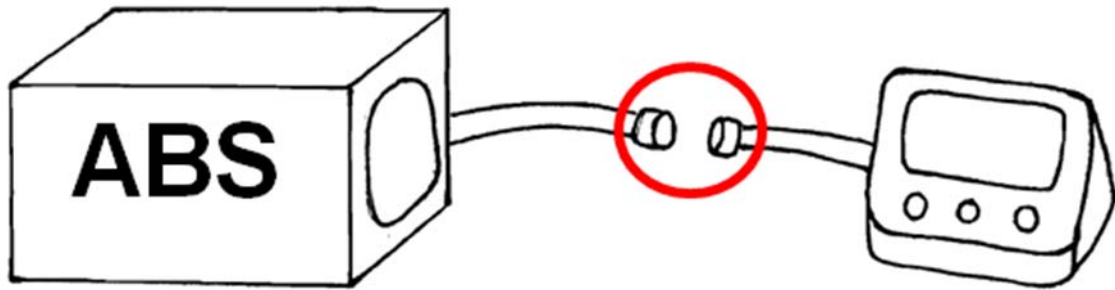


Figure 11. Shows a sketch of design II with ABS casing and magnetic connectors (red)

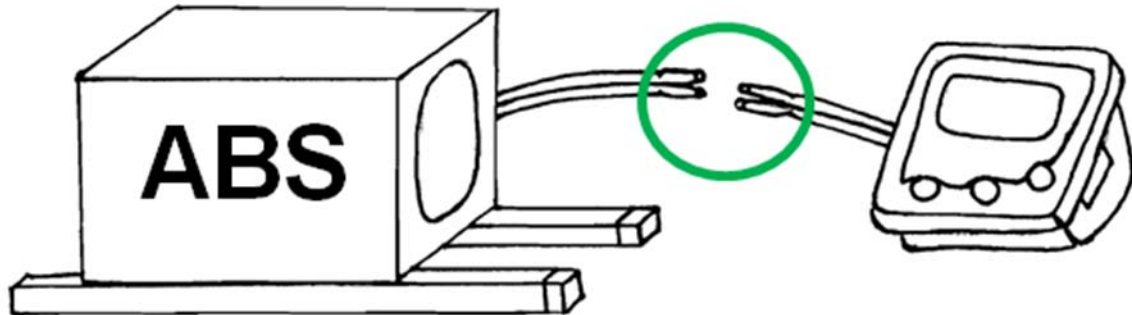


Figure 12. Shows a sketch of design III with ABS casing, plastic air connectors (green) and sliding rail system

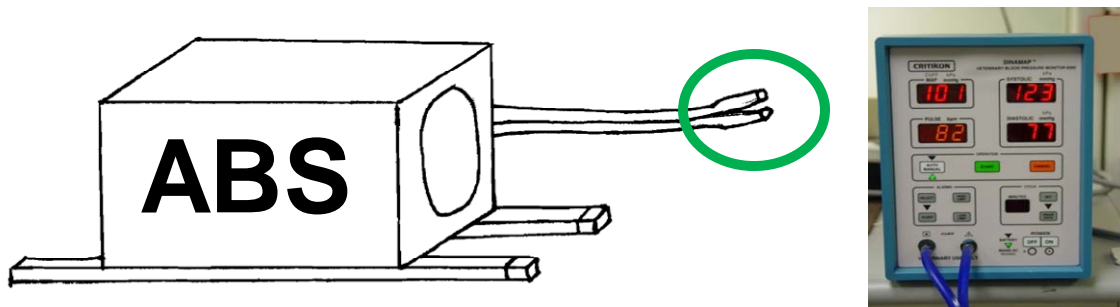


Figure 13. Shows a sketch of design IV with ABS casing, plastic air connectors, and sliding rail system. Design IV incorporates cuff system with Critikon Dinamap 8300 Veterinary Blood Pressure Monitor

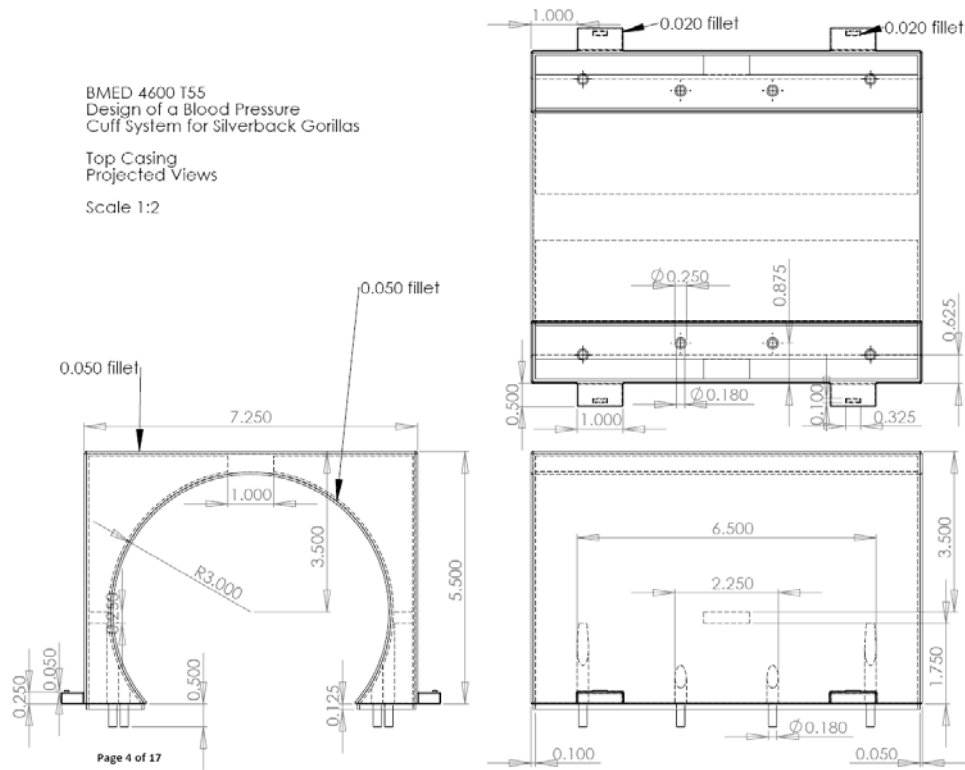


Figure 14. Top casing projection view with dimensions in IPS

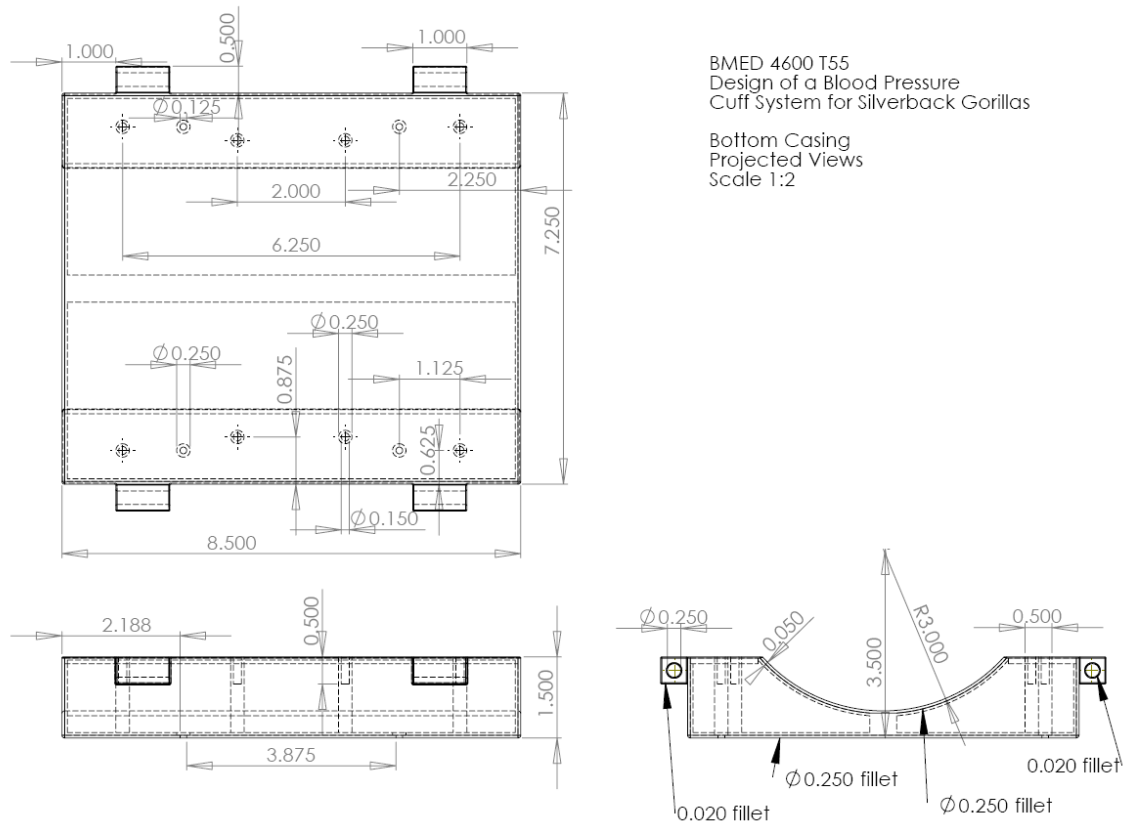


Figure 15. Bottom casing projection view with dimensions in IPS

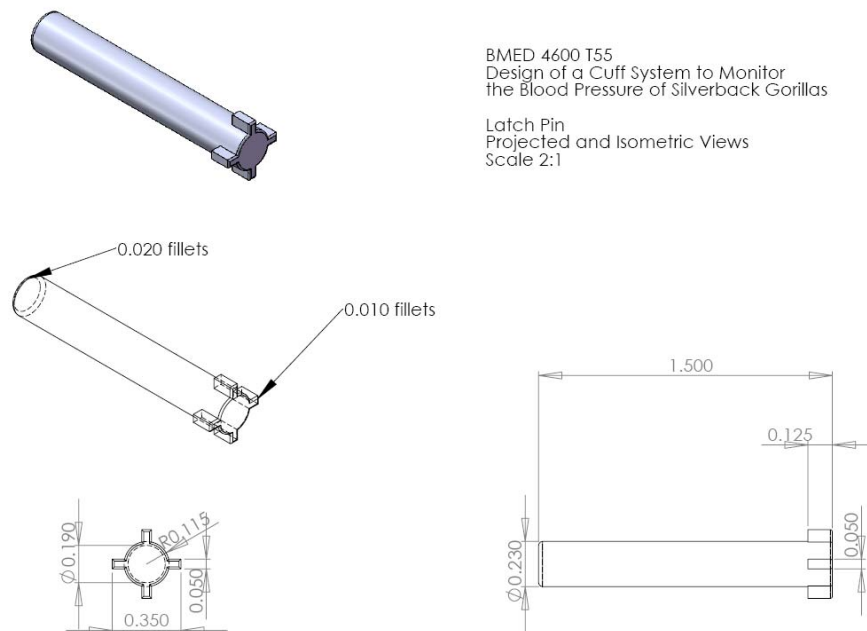


Figure 16. Latch pin projection and isometric views with dimensions in IPS

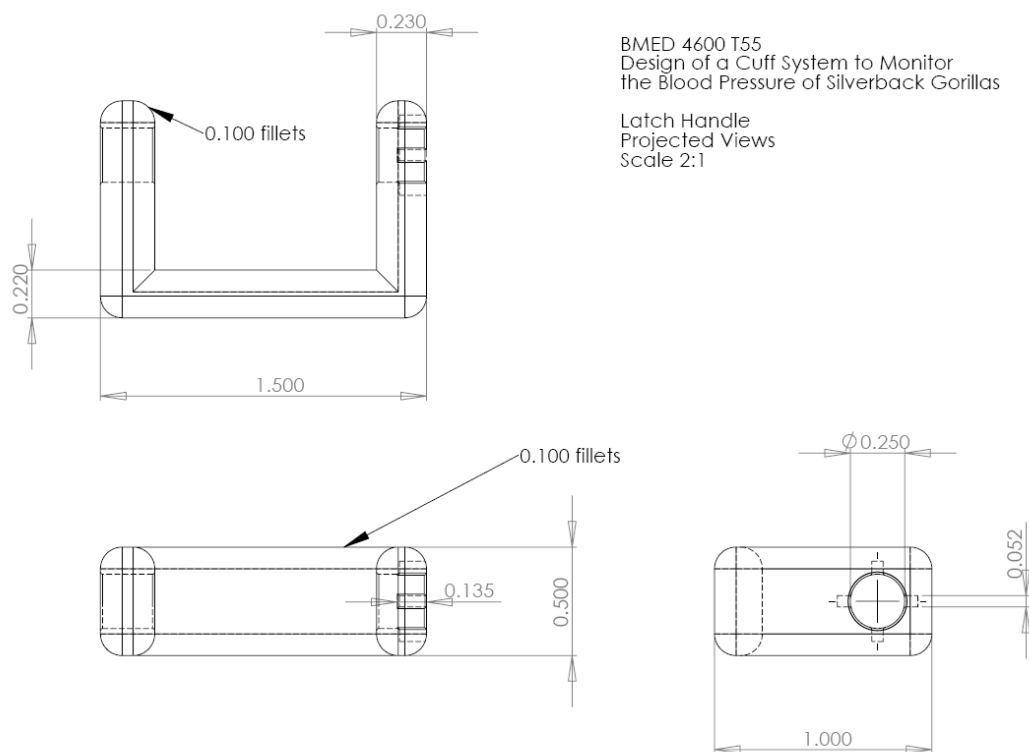
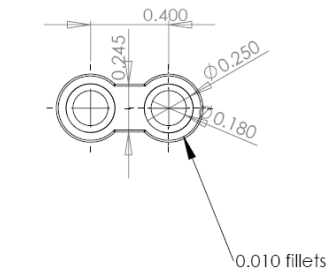


Figure 17. Latch handle projection view with dimensions in IPS



BMED 4600 T55
Design of a Cuff System to Monitor
the Blood Pressure of Silverback Gorillas

Air Flow Connector Part 1
Projected Views
Scale 2:1

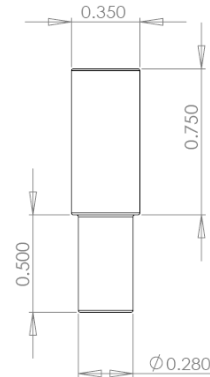
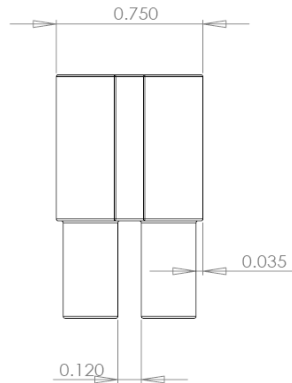
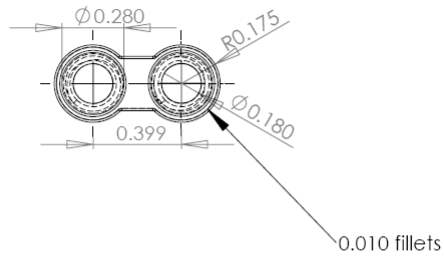


Figure 18. Connector 1 projection view with dimensions in IPS



BMED 4600 T55
Design of a Cuff System to Monitor
the Blood Pressure of Silverback Gorillas

Air Flow Connector Part 2
Projected Views
Scale 2:1

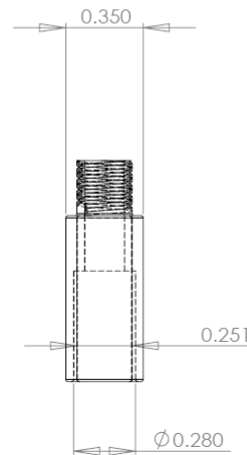
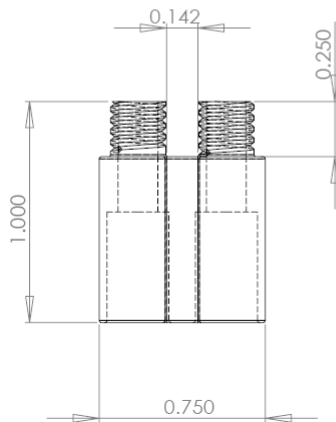


Figure 19. Connector 2 projection view with dimensions in IPS

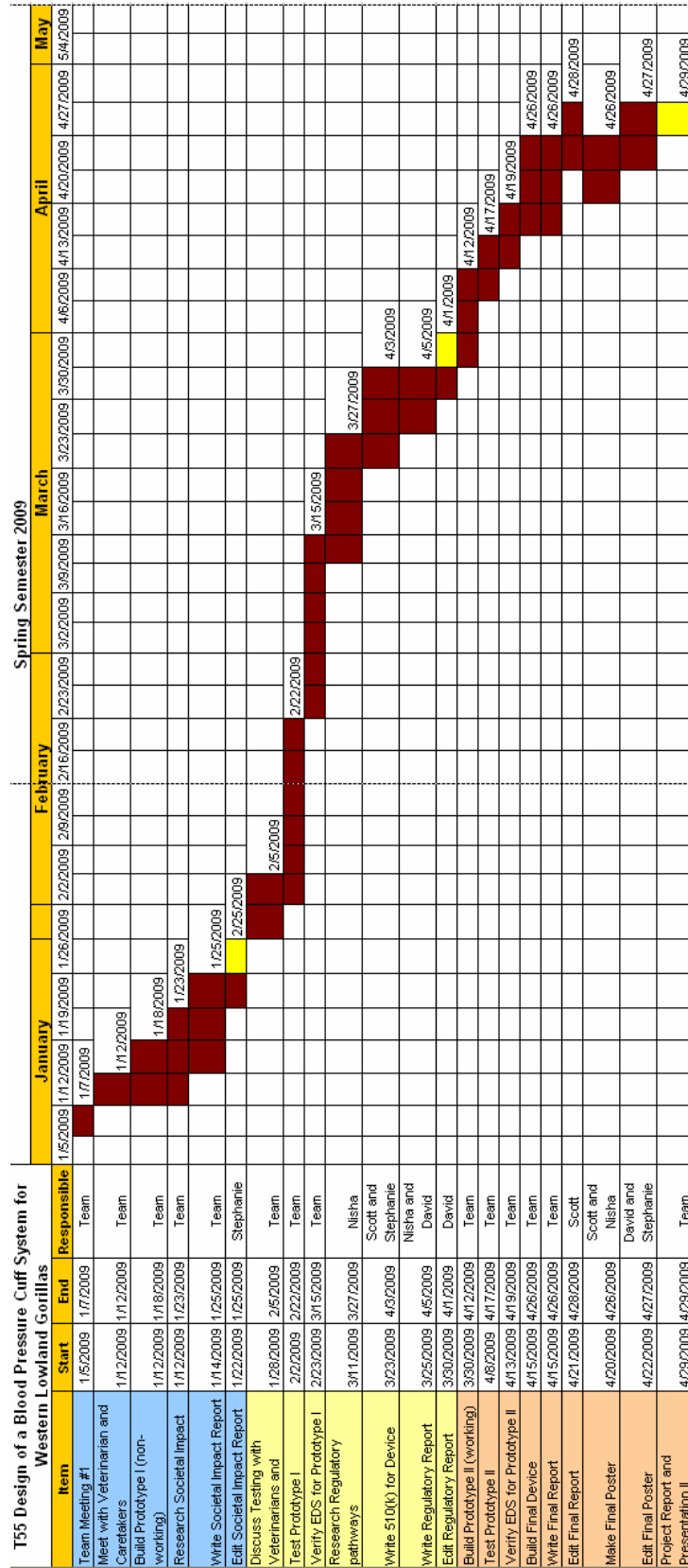


Figure 20. Gantt Chart with upcoming goals and milestones

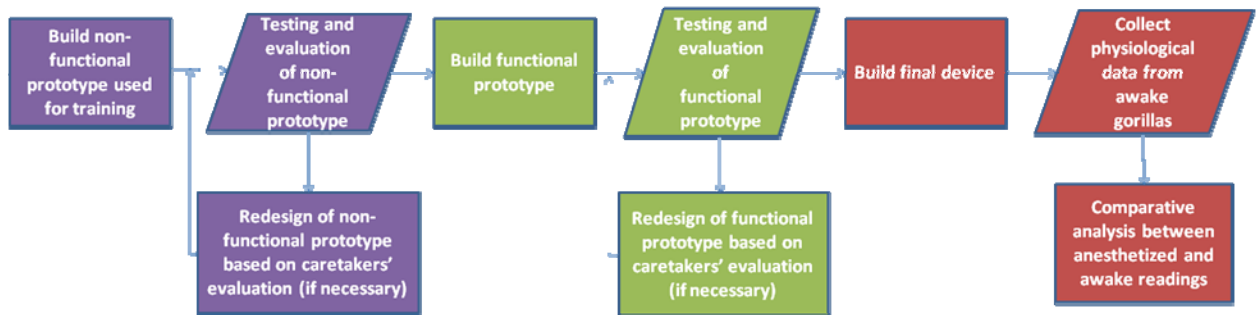


Figure 21. Flow Chart of Future Work