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Accurate electronic sphygmomanometer

Darshan Rane

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Accurate Electronic Sphygmomanometer

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Chapter 1

INTRODUCTION

An odyssey towards making of accurate sphygmomanometer began with a small talk with Dr. Sagar, a resident doctor at Rochester General Hospital, Rochester, NY. The small talk turned into a detailed question and answer session that paved its way to the most revealing talk I ever had. The fact that most of the electronic blood pressure monitors available in the market, including the ones used in hospitals have accuracy issues related with them, surprised me and made me think of the risks involved in such cases.

This would be the right point to investigate what is blood pressure and why is it required to measure in human beings.

Blood pressure is the force exerted by the blood on an area of wall of artery as it is pushed through the circulatory system. During the course of the cardiac cycle, the arterial blood pressure is constantly changing. The highest pressure in the cycle is recorded when the heart beats. This pressure is also called the Systolic blood pressure. Between the heartbeats is recorded the lowest blood pressure, also called the Diastolic blood pressure.
The systolic number is always stated first and the diastolic number listed next. E.g.: 132/77 (132 over 77) Systolic = 132, Diastolic = 77.

Fig. 1 shows the 2 pressures graphically.

The measurement of blood pressure is one of the most common and most important diagnostic procedures in the diagnosis of various heart related disorders, hypertension being the most likely of them. The measurement of blood pressure alone is the main indicator of hypertension and the need to start medication for a lifetime. Hypertension or high blood pressure is a common disorder, affecting approximately 50 million Americans. According to Dr. Mark Gelfer, Medical Director, VSM MedTech Ltd. in his article, *Addressing the Need for Accurate Blood Pressure Measurements*, it is estimated as many as 2 million people die in United States due to hypertension. Over time it has become essential, not only to detect hypertension but also to monitor it regularly and keep it in permissible limits.
How is blood pressure measured?

Blood pressure is measured through the use of a medical instrument called Sphygmomanometer. It is a quick, painless test.

fig. 2 Typical set-up of human blood pressure measurement

A compression cuff is wrapped around a person's upper arm and inflated. The large artery in the arm is compressed and the flow of blood is momentarily stopped.

As the air in the cuff is released, the person measuring the blood pressure listens with a stethoscope. When the blood starts to pulse through the artery, it makes a sound. This sound is heard continuously until pressure in the artery exceeds the pressure in the cuff.
As the person listens and watches the sphygmomanometer scale, he or she records two measurements. The systolic pressure is the pressure of the blood flow when the heart beats (the pressure when the first sound is heard). The diastolic pressure is the pressure between heartbeats (the pressure when the sound changes quality). This sound is called as Korotkoff sound as it was discovered by Dr. Korotkoff. Blood pressure is measured in millimeters of mercury, which is abbreviated mm Hg. The harder it is for blood to flow, the higher the numbers will be.

Diagnosis of hypertension affects the life of an individual at various levels. A continual monitoring and treatment follows the detection of hypertension. This has psychological and socioeconomic implications on the patient. Thus people identified incorrectly as having hypertension may have adverse effects of medication and have increased treatment cost and insurance. On the other hand if a truly hypersensitive patient is not diagnosed, it can lead to catastrophic event. Thus these reasons result in leaving no room for error in blood pressure measurements.

Consistently overestimating low blood pressure could increase the number of people suffering from hypertension leading to being exposed to inappropriate therapy. Whereas underestimating diastolic pressure could keep people having hypertension, from life saving treatment. These factors reinforce the importance of accurate blood pressure measurements.
Chapter 2

ERRORS IN BLOOD PRESSURE MEASUREMENT

It becomes important at this point to understand in detail the various kinds of errors associated with the measurement of blood pressure. There is extensive literature on the sources of error encountered with blood pressure measurement. These errors can be summarized as:

- Errors associated with the observer
- Errors associated with the measuring instrument
- Errors associated with the cuff

Errors associated with the observer

As blood pressure is considered a routine diagnostic procedure, it is not measured routinely by the physician; it is often performed by those with significantly less training, such as a nurse, technician, nurse’s assistant, paramedic or other healthcare provider. Other than lack of training and
improper methods of taking the readings factors enlisted below also lead to inaccurate measurements:

- Distraction and noise in a busy clinic or hospital
- Position of the person taking the reading relative to the manometer, resulting in improper angle of sight for reading the measurements, also called parallax
- Detecting and recording Korotkoff sounds requires considerable clinical expertise to obtain accurate readings

Based on these issues some guidelines have been developed that blood pressure measurements be conducted in a standardized form using equipment that meets certain criterion. The NIH Joint National Committee has set up following rules:

- Patients should be seated in a chair with their backs supported and their arms bared and supported at heart level.
- Blood pressure measurement should begin after at least five minutes of rest.
- The appropriate cuff size should be used.
- Measurement should be taken with a mercury sphygmomanometer, recently calibrated aneroid manometer or a validated electronic device.
- Both systolic and diastolic blood pressure measurements should be recorded.

- Two or more readings separated by two minutes should be averaged. If the first two readings differ by more than 5mm Hg, additional readings should be obtained and averaged.

A frequent cause for error in blood pressure measurement in the clinical setting is the "White Coat Effect". It is described as *isolated clinic hypertension* by the World Health Organization (WHO). This is a condition in which a patient's blood pressure is consistently elevated in the physician's office or clinic. This could happen because the patient may become anxious in the clinic in the presence of doctors or clinicians in order to know if he suffers from hypertension. The anxiousness results into hypertension. Thus the blood pressure may be elevated in the clinic, but normal at other times. Individuals with this condition are very likely to receive unnecessary expensive drug therapy.
Errors associated with the instrument itself

There are three types of blood pressure apparatus: the mercury gravity manometer, the aneroid gauge and the electronic devices.

Mercury Devices:

The conventional sphygmomanometer was first introduced in 1896 and later modified by Korotkoff in 1905. Since then, the sphygmomanometer has been considered as the gold standard in measuring blood pressure. However they are being phased out due to two concerns: mercury posing as a potential biohazard and the manometer being a source of observer error. Even though considered as a gold standard, these manometers are very difficult to use. Viewing the mercury column from different angles has been shown to generate errors in measurements. Given the age of many mercury devices, dirty columns, faded calibration marks and mercury oxidation have made many devices difficult to read.

fig. 3 Conventional mercury sphygmomanometer
Aneroid Devices:

Aneroid sphygmomanometers have replaced many mercury devices, but they have also been shown to be a source of error in blood pressure measurement. The aneroid gauge consists of a metal bellows and a watch-like movement connected to the compression cuff. Variations of pressure within the system cause the bellows to expand and contract. Movement of the bellows rotates a gear that turns a pointer pivoted on bearings, across a calibrated dial. The adjustment of the mechanical system of the aneroid gauge is more easily disturbed. For this reason, the aneroid gauge must be calibrated against a mercury manometer at regular intervals. Since the blood pressure recorded with the aneroid gauge depends upon the elasticity of the metal bellows, it is subject to errors inherent in the elastic properties of metal such as 'seasoning', hysteresis and drift.

According to Dr. Mark Gelfer, Medical Director, VSM MedTech Ltd. in his article, *Addressing the Need for Accurate Blood Pressure Measurements*, up to 60% of the aneroid devices tested are inaccurate due to improper calibration or maintenance.

fig. 4 Aneroid sphygmomanometer
Electronic Devices:

Over the past few years, blood pressure monitoring devices have become available for individuals to measure their blood pressure conveniently at home. A high percentage of these instruments are electronic and are popularly called Electronic Sphygmomanometers. The electronic devices operate on the extrapolation of deflections of a transducer coupled with an algorithmic derivation of a selected oscillation. They do not use the auscultation of Korotkoff sounds.

Despite studies purporting accuracies of these electronic sphygmomanometers, there are a significant number of patients recording inaccurate readings due to various reasons. Most of the reasons are related to the design of the device and the method of using the instrument.

fig. 5 Electronic Sphygmomanometer
Errors associated with cuff size

A cuff bladder that is too wide will underestimate actual blood pressure and one that is too narrow can overestimate the measurement. According to Dr. Mark Gelfer, Medical Director, VSM MedTech Ltd. in his article, Addressing the Need for Accurate Blood Pressure Measurements, the appropriate width of bladder should be at least 40% of the circumference of the arm and the length should be at least 80% of the arm circumference. Other errors related to cuff and bladder include a bladder not centered on the arm, a cuff placed over clothing and a cuff that is too loose.

fig. 6 Typical cuff used during human blood pressure measurement

This thesis aims to solve these issues by means of a newly designed, accurate electronic sphygmomanometer that can be used in the convenience of home and at the same time be suitable for retirement homes. In developing a solution to the problem, following conditions are important.

1. The principle task is to develop a highly functional, accurate, ergonomically efficient product, the visual statement of which is distinctive enough to generate sufficient customer interest.
2. Different materials and assembly methods will be discussed and considered during the design phase.

3. An interface will be designed to make the product approachable and easy to use for the consumer.

This thesis is a methodical, conscientious effort to tackle these issues and design an Accurate Electronic Sphygmomanometer.
Chapter 3

METHODOLOGY

The process to design an accurate electronic sphygmomanometer is methodical and involved the following steps.

**Step 1: Data collection**

This step was to collect data of available similar solutions, analyze them and find existing issues. It also helped in knowing the current trends in terms of aesthetics, functions and features. Interviews with the home users, patients, medical personnel were integral part of information collecting process.

**Step 2: Design Development**

In this step new product was defined in terms of function, form and aesthetics. After the basic configuration was established, alternate new design concepts for the sphygmomanometer were developed. Interface design issues were considered to assist the user in proper and easy handling.

**Step 3: Final Design**

As the design was finalized, fabrication and assembly methods were selected to fully define the product in terms of its forms, features and
manufacturability. A digital and a full-scale physical model were developed to convey the idea and define the product in totality.
Step 1: DATA COLLECTION

An extensive research about the existing solution revealed substantial information about current trends in market and issues related to the sphygmomanometers. A trend map as illustrated in fig. 7 was developed.

TREND MAP

fig. 7 Trend map illustrating a study of current electronic sphygmomanometers available in the market
Step 2: DESIGN DEVELOPMENT

Brainstorming

A mind map was developed to explore various ideas that could possibly eliminate the issues with current monitors. Fig. 8 shows the mind map developed to brainstorm new concepts and functions for new and accurate sphygmomanometer.

fig. 8 Mind map that was created to develop new ideas for accurate electronic sphygmomanometer
Initial Sketches

Further 2D and 3D sketch models were developed. The following illustrations show a sample of 2D and 3D sketches developed during this phase.

Each time a form was developed, manufacturing and assembly methods were considered. The aim was to develop a form that was easy to manufacture. Very simple forms as illustrated were considered.

fig. 9 Rough sketches to brainstorm ideas
fig. 10 Rough sketches to brainstorm ideas

fig. 11 Rough sketches to brainstorm ideas
Complex organic forms as shown in fig. 12 were also considered.

To better understand the manufacturing process and to get a feel of size and scale of the product, 3D sketch models were developed. These models as shown in fig. 13 and fig. 14 were made using materials like clay, putty, foam core, yellow foam or Styrofoam.
fig. 13 3D sketch models made using yellow foam or Styrofoam

fig. 14 3D sketch models made using yellow foam or Styrofoam
Step 3: FINAL DESIGN

In the final stages, a form that accentuated friendliness and expressed concern towards the user was developed. The final developed form emulated a shape of a pet. Pets are considered friendly towards their owners. They provide a sense of companionship and are means of compassion for many people. Since the larger segment of market for blood pressure monitor is the elderly, it was an aim to design a product that would serve more than just a simple medical device. Most of the available solutions in the market are just devices that are meant to be used at a particular time and then shoved back into the drawers or closets away from the user. It was the aim of the thesis to design a product that need not be hidden. And at the same time have a

fig. 15 Form development of the product and its accessories
conspicuous presence.

Fig. 16 illustrates 3D sketch models developed to understand the assembly of various accessories and their function. Yellow foam and ren were used for mock-up models.

fig. 16 3D sketch models developed to understand the assembly of various accessories
**Human Interface Development**

Interface development was also an integral part of this phase. Various combinations were tried to develop the Human Interface of the device. The interface menu was developed in MACROMEDIA FLASH software to simulate the working of the device. This menu is provided on the CD on the last page of the report.

Fig. 17 and fig. 18 illustrate the various attempts to develop a Human Interface of the device. These are preliminary sketches to understand the placement of buttons with respect to the menu shown on the screen. Both, the menu and the buttons and their placement on the product were developed simultaneously.
fig. 18 Developing human interface
Final Design of HI

Along with final form of the sphygmomanometer, its features and human interface were designed to ensure ease of handling and simplicity. Fig. 19 shows the final design of human interface of Spiggy. The first screen is shown below. It indicates the battery charge remaining and the last reading recorded. It also shows “WELCOME” which indicates a warm feeling towards the user. There are 2 buttons at the bottom that are used to execute functions shown on the screen.

fig. 19 Final HI design
Computer Aided Design

The next step was to develop a full scale physical model. A model with accurate dimensions was developed in Alias Studio Tools 11.0. Various colors were then applied before deciding the exact color for the product. Fig. 20 illustrates the main body of "SPIGGY" – the new Accurate Electronic Sphygmomanometer.
The files developed in Alias Studio Tools were transferred to SolidWorks for 3D printing purposes. A rapid prototype was then developed using resin - SLA-11120 and using the process of Stereo lithography. The prototype was provided by the courtesy of Design Prototyping Technologies, Inc. The model was then taken to a finished level by applying the appropriate colors. The full scale model helped to understand the form and gave a sense of scale to the product. Since the form was complex, the process of stereo lithography assisted in making a precise prototype.

Fig. 21 illustrates the physical model of the concept after appropriate colors were applied to the resin model provided by DPT Inc.

fig. 21 Physical model of conceptual Accurate Electronic Sphygmomanometer
For functional reasons, accessories were developed with main body of Spiggy. Full scale physical models were made to demonstrate the function and purpose of each accessory. The following accessories were developed:

1. Charging dock: The dock is used to charge Spiggy. It is also used to connect to the internet. All the readings recorded using Spiggy are saved on a central server when connected to the internet. These readings can be retrieved by the user or the user’s relatives and doctors by going online. The red LED indicates data transfer status.

2. Cuff Clip: The clip was developed to hold the cuff securely. It snaps into the sides of the charging dock to keep the units together.

Fig. 22 shows Spiggy and the accessories designed to function with it.
Chapter 4

HOW TO USE SPIGGY?

Hit any key.

Follow the self-explanatory menu.

Measure your blood pressure.

Other than measuring blood pressure Spiggy has features that make it unique and a better product than the other solutions available in the market.

**Spiggy features:**

- Maintains records
- Multi-user system
- Personalized settings for each user
- Uses rechargeable battery
- Connects to internet

![Start](image)

![Person sitting enjoying weather report](image)

![fig. 23 How to use Spiggy](image)
• Provides latest information regarding blood pressure

• Provides information regarding weather
Chapter 5

HOW DOES SPIGGY HELP?

The NIH Joint National Committee states its first two rules as:

- Patients should be seated in a chair with their backs supported and their arms bared and supported at heart level.
- Blood pressure measurement should begin after at least five minutes of rest.

The design of SPIGGY is such that the user follows the two rules without any special efforts.

For measurement purposes, the cuff is required to be connected to the main body of sphygmomanometer. This length can be critical when the user is not conscious of the importance of being seated while taking the measurements. During the research it was observed that users took readings while not being seated. This resulted into erroneous recordings. The length of the cuff tube that connects to “belly” of Spiggy is kept short so that the user has to sit down to take the blood pressure measurement. As a result the user cannot use Spiggy unless he is in the appropriate position.
It is very necessary that the user has calmed down before he takes any blood pressure readings. If the user has performed any rigorous exercises or has just returned after doing any activity that increases the rate of blood flow, (like running up the stairs, jogging) it is essential that he/she waits a few minutes, so that the blood flow has returned to normal. The electronic blood pressure monitors available in the market start the process of measurement in a few seconds after they are switched on. This sometimes leads to wrong measurements being recorded, if the patient hasn't waited for enough time to allow his blood pressure to return to normal. Spiggy functions in such a manner that the user has to wait before he can actually take any measurements. This is achieved with the help of menu options. The user has to undergo a series of menu options before he reaches a point where he/she can actually take a reading.

1. The user begins with a “WELCOME” screen.

2. When the user hits either of the two buttons, current date and time are displayed.

3. This is then followed by the current weather conditions like temperature and humidity.

4. The menu then comes to a point where the user has to select his profile.

5. After the user selects his profile, the past 10 recordings are displayed.
6. Then the user is instructed through the process of blood pressure measurement.

Thus by the time the user is actually recording a reading, a considerable amount of time is spent in a resting position. This reduces, if not completely eliminates the erroneous recordings. The intuitive menu (supplied on a CD with this report) keeps the user glued to the process he/she is performing.
Chapter 6

OTHER ADVANTAGES OF SPIGGY

In addition to working as an accurate blood pressure monitor, Spiggy has other advantages.

Remote monitoring

Spiggy can be used as a remote monitoring device in hospitals by doctors or nurses to check upon their patients at regular intervals. A central monitoring system established via means of Spiggy, to connect numerous patients to a single nurse helps to stay in touch with and monitor a large number of patients.

Internet Connections

With the purchase of Spiggy, the buyer gets a user account on the internet to keep record of readings. As Spiggy supports multiple user profiles, single Spiggy can be used by different family members and respective records can be set up on the internet. This information can be shared amongst responsible family members and family doctors. Each user profile on the internet is password protected for security purposes.
Visiting Nurses

Nurses who are not scheduled to visit their patients daily and take measurements can train them to take their own blood pressure and monitor the patients from clinics or their homes.
Chapter 7

CONCLUSION

The entire thesis completion process has been one of the best learning experiences that I have had. The first step taken at the start, thesis research involved searching a lot of data and information. It involved interviewing people and collecting relevant facts. The World Wide Web has been a great resource of information, wherein people did not want to reveal their identity but at the same time were glad to help and share all the information they had.

The second phase was the design development. In this phase I was able to use and enhance all the skills honed at RIT and my engineering experience to come up with a solution that could potentially be an answer to the problems discovered during the research phase. The concept of making the user wait for a while before he/she can actually start recording any readings could work very well for some users. The interactive menu successfully keeps the user engaged before any readings are taken. It provides a graphical overview of the past readings. In order to keep the user occupied in a fruitful manner, Spiggy gives the current temperature. The menu at all times engages user in the entire process.
Spiggy provides user profiles, thus giving a personal touch to the product and process. Providing user profiles allows a multiple users to use Spiggy. Each user can log on to his personal profile and thus access his data. However, there are certain issues that could cause problems. The multiple users could access each others data, thus invading privacy. This can however be tackled by proving passwords at the login screen. Increasing the buttons size on the human interface can provide further user comfort.

This thesis has taught me the essentials of design. The skills gained and the experiences during the making of Spiggy have instilled confidence in my design skills and will be useful to me for the rest of my design career.
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Fig. 4. Pg. 9. Aneroid Devices. Available from http://www.ackley-uniforms.com/images/prestige-79.jpg

Fig. 5. Pg. 10. Electronic Devices. Available from http://www.orthobionics.com/rehab1/bloodpressure/index.htm

Fig. 6. Pg. 11. Cuff Size. Available from http://www.cranlea.co.uk/bp2.8.jpg