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Belly Bundle Fetal Monitoring Assistant

BME 201
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Abstract

The goal of this project is to design an obstetric belly band that both provides ultimate comfort for the mother during labor and effectively holds the tocometer and ultrasound transducer in place. The tocometer, which measures uterine contractions, and the ultrasound transducer, which tracks the fetal heart rate, must be fastened securely to the mother's belly during labor to ensure accurate readings. The current belly band, used in many hospitals, tends to bunch up in the back during labor. This causes a great amount of discomfort to the mother. In an effort to improve the existing belly band, several factors were considered. These factors include: size and shape of the band, fastening methods, and other additional components. Design matrices were used to evaluate the advantages and disadvantages of each element of design. From this information, it was concluded that a two-piece band with gathering and without additional fastening mechanisms is the best basic design option. To further improve the comfort and monitoring reliability of this band, we have added two additional elements to the band. Small hooks are attached to the top of the band to pull it taut and increase pressure, and the back of the band is lined with stiff elastic to prevent any possibility of bunching or gathering. Testing was done to verify the functionality of the band. Future tasks include obtaining an IRB in order to test our product in a hospital setting, making final design adjustments based on results from hospital testing, and streamlining production.

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BACKGROUND

MOTIVATION

Every year, more than four million babies are born in the United States (Births, 2011). In order to ensure the health of the prenatal infant, electronic monitoring is used from the time an expecting mother arrives at the hospital, until she has given birth (Minton, 2011). During this monitoring, the ultrasound transducer and tocodynamometer (tocometer) are held in place using very basic bands and belts. Unfortunately, these means of securing the devices are neither efficient nor comfortable for the laboring women. In order to assist the hospital staff with their task of monitoring and keep women as comfortable as possible, a new obstetric belly band needs to be designed. Our mission is to redesign the obstetric belly band so that it has more rigidity in the transverse direction and will not roll up during use while still maintaining enough pressure on the transducers to ensure proper monitoring.

ELECTRONIC FETAL MONITORING

Continuous electronic fetal monitoring is used for all pregnancies and is especially important in pregnancies with increased risk of prenatal death, cerebral palsy, or neonatal encephalopathy. It is also used when oxytocin is being administered for the induction of labor. It is recommended that electronic fetal monitoring records be inspected and documented every fifteen minutes in the active phase, and every five minutes in the second stage of labor (Liston, 2002).

Fetal heart rate and contractions are the most important vitals to monitor during labor. These are most commonly measured using an ultrasound transducer and tocometer, respectively (Schifin, 1990).

Figure 1. Ultrasound and tocometer transducers (Tocometers, 2011).

Ultrasound transducers use high frequency sound waves to reflect mechanical actions of the fetal heart (Tucker, 2002). The transducer emits a beam that reflects off the moving fetal heart valves, and the changes in frequency are used to count heart beats (Sweha, 1999). This method is limiting because the sound waves can be reflected by any moving structure. It is essential to keep the mother and fetus steady to maintain the best signal. Any motion can cause distortion in the results (Afriat, 1989).

The tocometer is a pressure-sensing device that is applied to the maternal abdomen to monitor the frequency and duration of contractions (Tucker, 2002). During uterine contractions, the rigidity of the abdomen depresses a pressure sensitive button and the machine records the activity. Applying the accurate amount of pressure to the instrument is essential because a loose strap will miss contractions, and tightening the strap too much will be uncomfortable (Afriat, 1989). Tracking the contractions is an important tool in labor because it allows for the indication of fading contractions before the pain subsides (Fetal Monitoring, 2011).

PROBLEM STATEMENT

Our mission is to redesign an obstetric belly band so that it has more rigidity in the transverse direction and will not roll up during use. During delivery, obstetric belly bands are placed around the abdomen to keep the tocometer and the ultrasound transducer in place.

Current methods for securing the instruments are inefficient for nurses and uncomfortable for patients. The team's solution will not only fit the needs of health care professionals using the device for monitoring purposes, but also ensure comfort for laboring women.

COMPETITION

Our belly band will face competition from existing belly band and belly strap companies. Even with a design superior to that of the competition, we will have to compete at a very low price point. Our band will involve a design with more specific components and will be more difficult to produce. It will require more advanced stitching and a more complex belt design. To compensate for our product's higher cost, it is essential that the band is more comfortable for the patient than the existing competition.


Figure 2. Roll of belly band material to be cut into bands (Fetal Monitoring Bands & Straps, 2011).

The existing belly band is simply a cylindrical elastic band with no modifications. The woman steps into the band and pulls it around the pregnant belly. The transducers are then slid under the fabric and held against the belly by pressure. One of the largest benefits of this design is its cost. These bands can be easily mass-produced in rolls and then sold to hospitals in individual packages for a low cost of $2-$3 (Frigge, 2011). Another large benefit to the band is its simple design. No special stitching or cuts to the band itself have to be made during manufacturing. This universally simple design also allows for the belly band to be very inexpensive. Unfortunately, these bands tend to bunch up in the back. This can cause the laboring woman to become very hot and uncomfortable. Furthermore, if a woman decides to have an epidural, the band must be shifted down for it to be properly administered (Frigge, 2011).

Another competitor to our design is the belly strap. The straps are made out of a soft, elastic material. The transducers slide onto the straps, which are then wrapped around the belly, and secured by Velcro (Wendricks-House, 2011). This design is simple and universal, and therefore can be easily mass-produced. This mass production allows the straps to be sold at very low prices, which will be difficult for our team to match. The benefits of the straps are that they are too thin to bunch up: eliminating much of the discomfort that the belly bands produce. However, the straps could cause some discomfort by pinching the patient. The straps may be placed around the woman while she is lying down. While an epidural is being applied, the straps can be easily moved to expose the middle of the back. However, these bands do cause some trouble with placement. At times, it can be hard to place the traducers in the correct location due to the round belly. In some cases, the straps may even slide off the belly (Minton, 2011).

Figure 3. Belly straps to hold ultrasound and tocometer transducers(Fetal Monitoring Bands & Straps, 2011).

In order to make our product competitive with these inexpensive alternatives, we need to solve the issues produced by both products. We need to design a comfortable band that will not bunch up in the back and will provide secure placement of the transducers. Our product needs to have additional benefits that make it worth the higher price.

DESIGN CRITERIA

As with any product intended for medical use, the obstetric belly band must meet several different criteria. Because our product will be subjected to the stresses of labor, it is vital that the belly band be comfortable, reliable, and easy to use. In order for our product to be utilized by hospitals, the belly band must also be cost effective.

Our client was adamant that the patient's comfort is the primary concern for our project. During labor, the current belly band rolls and absorbs sweat causing a great amount of discomfort for the laboring woman. Therefore, our product must be stiff enough to prevent rolling. The belly band must also be elastic to increase patient comfort.

The obstetric belly band is worn for the entirety of labor. Our product must function properly and safely until it is removed after labor. The materials from which the band is made must be strong enough to withstand movements of labor such as walking and pushing. Allergic reactions are also a major concern for laboring women. Therefore, we must use fabrics that do not cause irritation and maintain strength during prolonged stresses.

Due to the large variance in the size and shape of womens' bellies, our product must be universal. In addition, multiples (such as twins) require two ultrasound transducers and two tocometers (Puccinelli, 2011). The band must be versatile enough to comfortably and reliably fit a very broad range of women.

To compete in the current market, our belly band must be cost effective. Hospitals can purchase belly bands for approximately 2-3 dollars per unit (Frigge, 2011). Therefore, our more expensive obstetric belly band must provide benefits that outweigh the additional costs.

FABRICS

When selecting a fabric for the belly band, patient safety and comfort must be considered. Many different fabrics cause discomfort or even allergic reactions. Fabrics such as wool and polyesters frequently cause rashes and irritation ("Formaldehyde," 2011). Since the belly band will be used in a hospital setting, Latex allergies must be considered. Polyester and Spandex, two common elastic fabrics, contain Latex (Groce, 1997). Therefore, these materials cannot be utilized in our band. To minimize the chance of an allergic reaction, we created our band using an elastic cotton blend. The cotton blend gives sufficient strength to hold the tocometer and ultrasound transducer during labor, while still allowing for a significant amount of stretch.

While the cotton blend has an advantage of being durable, it does have a disadvantage. The cotton blend does not wick moisture well and can get warm during labor. In order to circumvent these issues a mesh latex-free material was used in some prototypes. Unfortunately, the mesh material was not strong enough and did not hold up during testing. The cotton blend was chosen over the mesh because the durability and reliability of the band is more important than its water-wicking properties.

DESIGN ALTERNATIVES

The design options are split up into three categories: structure, fastening methods, and additional elements. The different structures, fastening methods, and additional elements can be combined in different ways to form many different design alternatives. The structure designs include: a full band with boning, a tapered band, a formed hemisphere band, a tracking system band, and a two-piece band with gathering on the sides. The fastening method options include: Velcro, zippers, small snaps, eye hooks, and no external fastening method. The additional elements include: stiff elastic, silicon, small hooks, and slits.

STRUCTURAL OPTIONS

The full band with boning is a uniform band, having a similar shape to the existing belly band, with thin wire boning integrated into the fabric to give it more structure and rigidity. This added structure would likely prevent the band from rolling up during use, but the boning could cause a great amount of discomfort due to its stiff, constricting nature.

The tapered band is approximately 12 inches in front and gradually tapers off towards the back, leaving only a thin band of about 5 inches. With less fabric in the back of the band, the bunching will be less problematic. In order to ensure that the fabric doesn't roll up as it begins to taper off, it is expected that a small piece of boning on each side will need to be introduced to this design.

The formed hemisphere band is made of two separate pieces of fabric. The front consists of a formed cup that fits snugly around the belly, and the back consists of a simple, slim band. This design would provide a lot of comfort to the patient; however, it would be very difficult to manufacture in sizes that would fit a wide variety of different belly sizes. The cupped component of this design would need to be custom made to fit the belly of nearly every mother.

The tracking system band consists of a network of thin pieces of fabric rather than one uniform band. There are several vertical straps running in-between two horizontal straps on the top and the bottom of the band. These vertical straps would allow for facilitated movement of the tocometer and ultrasound transducer during labor. However, having several straps could cause a lot of discomfort during labor. Due to the large amount of pressure the band must apply to the belly, these straps would fit very tightly, and could lead to pinched skin.

The two-piece band with gathering on the sides consists of two separate pieces of fabric. The front of the band is long, covering the whole belly, with a length of about 12 inches. The back of the band is shorter, measuring 5 inches. Where these two pieces of fabric meet, on the sides, the band is gathered. This gathering would prevent the band from rolling at the sides, where the band becomes shorter. However, it is possible that the gathered fabric would feel thick or uneven, and may cause the patient to feel discomfort.

FASTENING OPTIONS

A band with Velcro would allow quick and easy fastening and, if strong enough, would hold very well. However, Velcro could become very uncomfortable for the mother if not aligned well. A band with a zipper would be a very reliable and secure form of fastening, but could be extremely uncomfortable. Especially in larger women, the skin could be pinched in the zipper, causing pain and discomfort. Small snaps could be comfortable to the patient, but would not be very reliable, nor would they be fastened easily. As there is a lot of movement during labor, the snaps could very easily come undone. Furthermore, it could be a very tedious process for the nurses to have to snap the band into place on every patient. The use of eye hooks as a fastening method would be uncomfortable and unreliable. Hooks could easily come undone due to the stresses of labor and are not reliable enough to fasten the entire band. A band with no fastening method would be very comfortable to the patient because it would not pinch, poke, or irritate the skin. However, the need to step into the band in order to put it on could cause complications, especially when the band needs to be changed in the middle of labor.

ADDITIONAL ELEMENTS

In addition to these structure and fastening options, it is anticipated that other elements to maximize comfort and effectiveness will need to be added to the band as prototypes are made and tested. Such elements might include stiff elastic, silicon edges, small hooks, and slits. Sewing elastic into the edges of the back of the band would increase the rigidity of the band, and further prevent bunching and rolling of the fabric. Silicon edges would have a similar effect as the elastic. By adherence to the patient's skin, bands lined with silicon would be much less likely to experience bunching and rolling. The use of small hooks on the front of the band would be used to increase the pressure: holding the tocometer and ultrasound transducer more securely in place. Due to the wide range of belly sizes, the ability to change the pressure on each band would allow for a more secure fit for every mother. Finally, slits in the front of the belly band would allow for facilitated movement of the tocometer and ultrasound transducer during labor. These slits would resemble button holes, and allow health care professionals to adjust the devices as needed without disrupting the patient's comfort.

DESIGN MATRIX

After brainstorming numerous design options, design matrices (Table 1 and 2) were used to determine which ideas should be integrated into the final design. Two design matrices were created to narrow down both structural and fastening aspects. The combination of these two design matrices allowed us to choose parts of our design quantitatively with minimal subjective bias. The following seven criteria were used to rank the four structural design alternatives. The fastening options were ranked by comfort, ease of use, reliability, and cost.

Comfort was the most important aspect of our design because of the setting in which it is used. Laboring women are in significant pain and their skin is very sensitive. In order to ensure their comfort, proper materials must be used. The comfort of the patients is of ultimate importance.

Another very important facet of the design is reliability. Monitoring the fetus is very important during labor, so nursing staff needs to be assured that the belly band will properly secure the instruments and prevent inaccurate readings. Women can be very active during labor, so the band needs to maintain the proper positioning of the ultrasound transducer and tocometer under all types of movement. There can be no risk of the band coming off or allowing the instruments to shift.

Cost is yet another important feature of our design elements. It was highly weighted because obstetric belly bands currently being used in hospitals are very inexpensive. No matter how well our product works, unless it is affordable, hospitals will not purchase it. They are not willing to pay a premium unless our product presents exclusive benefits over the current band.

Another highly rated category was ease of use. It is important that health care professionals can use our design efficiently and effectively. The device should be easy to use in both initial placement and follow up adjustments. This category was ranked higher in terms of fastening because it is the main feature allowing or preventing the patient to put on the belly band.

Ease of production, while still important, was ranked lower than the aforementioned aspects. The final design must be easy to manufacture and produce on a large scale. The easier the product is to produce, the cheaper the cost of the product.

Versatility is not as highly ranked because it is an additional aspect of comfort. In hospitals, all types of women will be using the belly band. The design needs to accommodate all shapes of bellies, sizes of women, and positions of the fetus. In terms of position, sometimes fetuses are in different positions which means that tocometer and ultrasound transducer need to be in different positions to monitor properly. The final design needs to ensure that in all cases the instruments are able to monitor accurately.

Table 1. Design Matrix of Structural Elements

	Weight	Full Band with Boning	Tapered Band	Formed Hemisphere	Tracking System	Two Piece Band with Gathering
Comfort	1	2	4	5	3	3
Reliability	1	5	5	4	3	5
Cost	1	3	4	2	3	3
Ease of Use	0.75	3	4	3	3	4
Ease of Production	0.5	4	4	2	3	4
Versatility	0.5	3	4	2	2	4
Size Ranges	0.25	5	4	3	4	5
Total	**5**	**15.5**	**19**	**15**	**13.75**	**17**

Size is another design aspect that was considered. The device needs to be scaled to fit all pregnant women. This would increase the usability of our product.

Table 2. Design Matrix of Fastening Elements

	Weight	None	Zipper	Velcro	Snaps	Pegs
Comfort	1	5	2	3	3	1
Ease of Use	1	3	4	4	3	2
Reliability	1	5	5	3	2	2
Cost	1	5	3	3	2	2
Total	**4**	**18**	**14**	**13**	**10**	**7**

TESTING

We performed tests on three different prototypes and the original belly band. To perform the tests, we used a theater pregnancy belly to simulate a pregnant belly. The bands were initially placed properly and comfortably around the belly, exhibiting no rolling. Next, the wearer of the band initiated a series of movements. The movements included sitting up from the prone position, rolling from side to side, walking, and sliding back and forth on a bed. These tests were designed to simulate the movements that are observed during labor. Rectangular objects approximately 3x3", the same size as a tocometer and ultrasound transducer, were placed in between the band and the belly to test the pressure of the band and its ability to hold fetal monitoring devices in place.

Figure 4. Original belly band after movement tests displays a high degree of rolling and bunching

The first test was performed on the original belly band. After the movement tests, the band rolled in the back and caused slight discomfort. The back of the band compressed 28.6% following movement tests (Figure 4). The band also trapped a lot of heat. When the rectangular object was inserted near the top of the band, there was not enough pressure exerted on the object.

Figure 5. The second band, with stiff elastic lining the back, displayed much less rolling than the original belly band after movement tests

The second test was performed on a prototype band composed of two pieces of fabric with gathering at the sides. The back of the band was composed of a thin mesh fabric with stiff elastic sewn along the edges. This band significantly decreased the amount of rolling caused by the movements (Figure 5). Additionally, this band provided a cooler feel. However, this band also had a loose fit near the top.

The third band tested was composed of the two pieces of fabric with gathering at the sides, and a hook system on the side. The back of the band was composed of a thin

Figure 6. The third band, with a hook system, provided improved pressure and contact between the belly and the object mimicking the monitoring devices

mesh fabric with stiff elastic sewn along the edges. Upon placing the band around the belly, the back of the band began to tear. During the movement tests, this band reduced the amount of rolling compared to the original. Furthermore, the hook system on the band greatly increased pressure and improved contact between the tocometer and the belly (Figure 6).

After evaluating the performances of the first prototypes, a final prototype was created. It consists of a two-piece gathered band with elastic siding and a hook system. Both the front and the back of the band are an elastic cotton blend fabric. There was a 5.0% compression in the back of the band after the movement tests (Table 3).

Table 3. Fabric compression results of movement tests.

Band	Length Before Activity	Length After Activity	Percent Compression
Original Band	14”	10”	28.6%
Two-piece band with elastic	5”	4.75”	5.0%

Following the movement tests, 10 and 6 pound medicine balls were placed in each of the bands; the bands were then suspended for 1 minute. These tests were conducted to test the integrity of the fabric and stitching. During these tests, both the original belly band and the final prototype were able to support 10lbs (Table 4). The two prototypes that contained mesh fabric could only support six pounds, due to the tearing of the mesh material.

Table 4. Results of the weight tests on the four different bands.

Belly Band	Maximum Weight Supported
Original Band	10 lb.
Two-piece with gathering and elastic siding (mesh material)	6 lb.
Two-piece with gathering and hook system (mesh material)	6 lb.
Two-piece with gathering and elastic siding and hook system (belly band elastic)	10 lb.

FINAL DESIGN

Figure 7. Final prototype design: two-piece band with gathering at the sides, stiff elastic in back, and a hook system

After thoroughly evaluating our designs with matrices, and testing our prototypes, we decided our final design should include: a two piece band with gathering at the sides, a hook system to increase tension, and stiff elastic for support. The structure of this band meets all of the design criteria while reducing the unit cost. Due to its structure and purpose, it was named the Belly Bundle Fetal Monitoring Assistant.

The final design has a two-piece, gathered and tapered structure (Figure 7). The front of the band is fashioned from a rectangular piece of fabric that is 15x12". This piece of the fabric is gathered to form a half-hemisphere like shape. The front fabric is attached to a smaller piece of fabric, measuring 10x5" that contains two strips of stiff elastic running the length of the fabric on the top and bottom. Once the pieces are attached, the final belly bundle has an unstretched diameter of 8 inches. The smaller band on the back reduces the amount of material that rolls and absorbs water during labor. Additionally, the decreased amount of fabric in the back makes it easier for health care professionals to cut the band off after labor. The thin elastic bands provide more structure in the back to further reduce rolling and bunching. This design increases patient comfort compared to the original cylinder design.

Because the band has to be large enough to accommodate a wide variety of belly sizes, a mechanism to increase tension at the top of the band is needed. Two hooks have been placed on the front of the band; located two inches from the top of the band on each side. These hooks can be attached to latches just below the seam between the two pieces of fabric. These hooks provide a tighter fit, and ultimately a more accurate reading from the ultrasound transducer and tocometer.

The front and back of the band will be made from a latex-free elastic cotton blend. Although this blend does not possess the best water wicking properties, it has excellent strength and is sure not to fail during labor.

The final Belly Bundle Fetal Monitoring Assistant will have a per unit cost of $5.54 (Table 5). This cost will include the two materials: cotton-blend fabric, elastic, and latches and hooks. This price will not include the cost of manufacturing. If we were working in conjunction with a fabrics manufacturer, the price of the band could be further reduced.

Table 5. Total cost of materials in single prototype: $5.54. Labor for fabrication not included. Material price is expected to decrease during mass-production.

Item	Cost
Elastic cotton blend material	$2.00
Elastic strip	$1.59
Bra Back Extender (hooks)	$1.95

ETHICAL CONSIDERATIONS

There are several ethical considerations to keep in mind throughout the course of the design project. The preexistence of the belly band as a product requires that the team be very careful not to infringe upon any current copyrights or patents. It is critical that all design ideas be original and different from those that are already on the market (from companies such as FetaMed). In addition, it is of utmost importance that the product designed is safe and comfortable for the patients. Careful thought must be put into the fabrics, the sizing, and the structure of the band to avoid possible allergic reactions and injuries. Finally, in order to ethically test the product on human subjects Institution Review Board approval must be obtained before the design is implemented in a hospital setting.

FUTURE WORK

Even after constructing multiple prototypes, there is still some work to be done in order to integrate our product into a hospital setting. Further testing needs to be done in hospitals to ensure it accomplishes all of our goals under the stresses of labor. In addition, we need to work on streamlining the production of our product.

Throughout the semester, we have tried to obtain an IRB at some of the local hospitals. An IRB protects the rights and the welfare of the patients who are involved with a medical experiment. In order to obtain an IRB, you must obtain a primary investigator and submit your design to the Institutional Review Board. The review board then categorizes your design and approves or rejects your design. If you are to be approved, the review board needs to be kept up to date with your research on a regular basis (Michaels, 2011). Due to time constraints, we were unable to acquire an IRB, so we could not test our band on real patients. Given more time, it would be necessary to get an IRB because it would allow us to perform tests in an actual hospital with patients in labor. This would provide us with real-world feedback and confirm our beliefs that our product is the best on the market. We would correct any negative feedback and move on to the production of our Belly Bundle.

With our completed Belly Bundle, we would be ready to prepare the design for manufacturing and introduction to the competitive market. We would need to acquire the elastic cotton blend fabric in large quantities. In our current prototype, we used the existing belly bands to obtain the material. However, to mass-produce our design, we will need to purchase this material in bulk.

We would also like to build a belly bundle for all different sizes of women. Due to the constraint of the theater belly being relatively small, we made a smaller model for our prototype. In the future, we would like to have multiple sizes from which women can choose. The larger sizes would be made using the same design, simply using larger pieces of fabric fit to scale.

CONCLUSIONS

The construction of the new Belly Bundle Fetal Monitoring Assistant will aid nursing staff in proper fetal monitoring by allowing a more secure, accurate placement of the ultrasound transducer and tocometer. In addition, the band is designed to greatly increase patient comfort. By making changes to the current, rather elementary design, we will be able to positively affect many people. Additional effort must be taken to ensure the design has no ethical repercussions, is cost effective, and will function properly in the designated environment.

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APPENDIX A

Project Design Specifications

#43- Obstetric Belly Band

February 3, 2011

Team: Kelsey Duxstad, Michael Stitgen, Andrew Pierce, and Emma Weinberger

Client: Dr. John Webster

Advisor: Professor Willis Tompkins

Function:

Our mission is to redesign an obstetric belly band so that it has more rigidity in the transverse direction and will not roll up during use. Obstetric belly bands are placed around the abdomen, during delivery, to keep in place the tocometer and the ultrasound transducer.

Client Requirements:

- Cost effective
- Comfortable
- Effective

Design Requirements:

1) Physical and Operational Characteristics

a) *Performance requirements*

i. To hold the tocometer and ultrasound transducer in place during labor

ii. Breathable, durable fabric that ensures comfort for the user

ii. Must withstand a damp environment

iii. Must withstand stress and movement

iv. Can be adjusted to change location and angle

b) *Safety*

i. Can be easily removed

c) *Accuracy and Reliability*

i. Must secure instruments and allow for adjustments when necessary

d) *Life in Service*

i. 1-2 days

e) *Shelf Life*

i. 5-10 years

f) *Operating Environment*

i. Patient hospital rooms

g) *Ergonomics*

i. Easily placed

h) *Size*

i. Diameter: 8 inches

ii. Front height: 12 inches

iii. Back height: 5 inches

i) *Weight*

i. Less than 1 pound

j) *Materials*

i. No latex

ii. Elastic

iii. Breathable

iv. Quick drying

k) *Aesthetics*

i. Pleasing to the eye

2) Production Characteristics

a) *Quantity*

i. One model

b) *Target Product Cost*

i. under $5

3) Miscellaneous

a) *Standards and Specifications*

i. Must be tested to ensure patient comfort and product performance

b) *Customer*

i. Medical schools

ii. Hospitals

c) *Patient-related concerns*

i. Skin irritation

ii. Discomfort (bunching of fabric)

d) *Competition*

i. Feta Med

ii. Cooper Surgical

iii. Pedi Corporation