Frugal Engineering of a Sterile Docking Device

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Executive Summary

Our group was tasked with applying the principles of frugal engineering to develop a drastically cheaper alternative to a Sterile Docking Device (SDD) while maintaining the original functionality. We approached this task using Value Methodology Engineering (VM), a systematic approach to providing the necessary functions at the lowest possible cost. VM does this by first understanding its constituent components and their associated costs. It then seeks to find improvements to the components by either reducing their cost or increasing the value of the functions. There are eight phases we followed in VM: Preparation, Information, Function Analysis, Creativity, Evaluation, Development, Presentation, and Implementation. Through this process, we were able to design a functional, single-use SDD that will cost $2.67 per unit. In this paper we will walk through each of the phases of VM that we were able to execute and detail how each was applied in the context of our project.

1. Preparation Phase

The preparation for this design had two main areas of interest. Firstly, we found that we had to familiarize ourselves with the general workings of a Sterile Docking Device, and secondly, we needed to work through the previous group's findings and recreate the design where they had left off.

The primary purpose of an SDD is to transfer blood or other bodily fluids through IV tubing from one bag to another bag or similar container. The most common applications of an SDD are for use in a blood bank to allocate blood portions for use in a patient such that the remaining pint can be saved. Additionally, SDDs are heavily utilized in fluid exchanges during Continuous Ambulatory Peritoneal Dialysis (CAPD). After understanding the importance that SDDs have in these crucial medical applications, we began to examine why a redesign would be necessary. Most SDDs are very large pieces of machinery that slice and reattach the PVC tubing through a wafer heated up to 300℃ to create a sterile weld within the system. In addition to being bulky, this application can cost facilities upwards of $30,000 USD. This is of grave importance as the concept of an SDD could potentially be utilized across the globe to best cope with blood shortages and provide the best possible care for those on dialysis, but many of those who could benefit cannot afford the current market product.

To account for this disparity, the previous group came up with the design of a small plastic device that could theoretically cut, align, and reattach tubing by inserting the endcaps of two pieces of tubing for the desired bags to be connected, using a blunt end to slice open the tubing in a twisting motion, and re-align the now-opened tubing in an inner chamber accessed by the twisting motion. While we would later discover the extent of its flaws, we were excited by the prospect of a much smaller, single-use, easily manufacturable device to bypass the SDD's currently on the market.

Utilizing both our newfound knowledge of our ultimate design's purpose and predecessor, we were better able to understand the provided problem statement to best channel our efforts. We were set to 1. Assess the completeness of the previous design. 2. Account for any non-functional or underdeveloped features that would impede the purpose. 3. Create a detailed manufacturing plan while implementing the tenants of frugal engineering to ensure that our design is as affordable as possible for our identified user base.

We also took the opportunity to familiarize ourselves with common practices within value methodology and frugal engineering. These two workflows set us up with clear phases to work through in order to meet our necessary deliverables.

2. Information Phase

The Information Phase consists of gathering, organizing, reviewing, and transforming information about our product as well as finding our bearings regarding the product, each other, and the other VM study process. We gathered our information from the previous group's reports, online research, and through user and customer discovery.

Following our initial preparation surrounding the design thus far, the market device it was aiming to replace, and what our primary deliverables for the project would be, we wanted to collect more information on both the end user and the manufacturing process. To do this we made two separate lists of interview questions. The first could be discussed with any local or international blood bank to assess their current operating standards and how an SDD could be implemented if one did not already exist. If the facility did have an SDD, we were curious as to the frequency of use and the standards of that device that we may want to carry over to our own design. The second set of questions was written with local plastics manufacturers in mind to gain a better understanding of how plastics are utilized for medical or similarly sterile applications.

Our findings from the interview at the local blood bank showed that a design that emphasized ease-of-use, consistency, and ease-of-storage is favorable. The current device is used anywhere from zero to thirty times a day, and takes about 30 seconds to operate. The seals created with the current device have a 95% efficacy rate for leak-prevention and maintained strength from the original IV tubes. The information that Dr. Bidanda collected for us in Kenya truly emphasized the need for our project. They currently have no way to safely transfer blood into donor bags once they've been opened, which results in a large volume of wasted blood, especially when used for children who do not require the full amount of blood in a standard bag. The plastics manufacturers enlightened us on the differences between plastics that are used in medical applications compared to their non-medical counterparts.

3. Function Analysis Phase

In this phase, we defined the functions of a SDD, allocated resources and performance, and prioritized functions to best improve value. The Function Analysis Phase is perhaps the single most important and useful technique in VM and was instrumental in helping us optimize our design.

Based on the answers from our interviews and prior-art research, we translated the gathered information into user needs. Our necessary functions for our design were cutting the IV tubing, aligning the cut-ends, maintaining sterility, and being easy to use. These branched out of the most basic identified function, which was to split aliquots. This aspect was important as it comprehensively summarized the product's purpose as a medical device, not defined by any particular fluid or facility.

Activity/Phase	Verb	Noun	Function Type
Primary Design	Split	Aliquots	Basic
Primary Design	Cut	Tubing	Secondary
Optimization	Prevent	Harm	Secondary
Primary Design	Align	Tubes	Secondary
Primary Design	Seal	Connection	Secondary
Optimization	Maintain	Sterility	Higher Order

Table 1. Random function identification. This is a basic technique for identifying functions and is recommended to serve as a brainstorming exercise for the team.

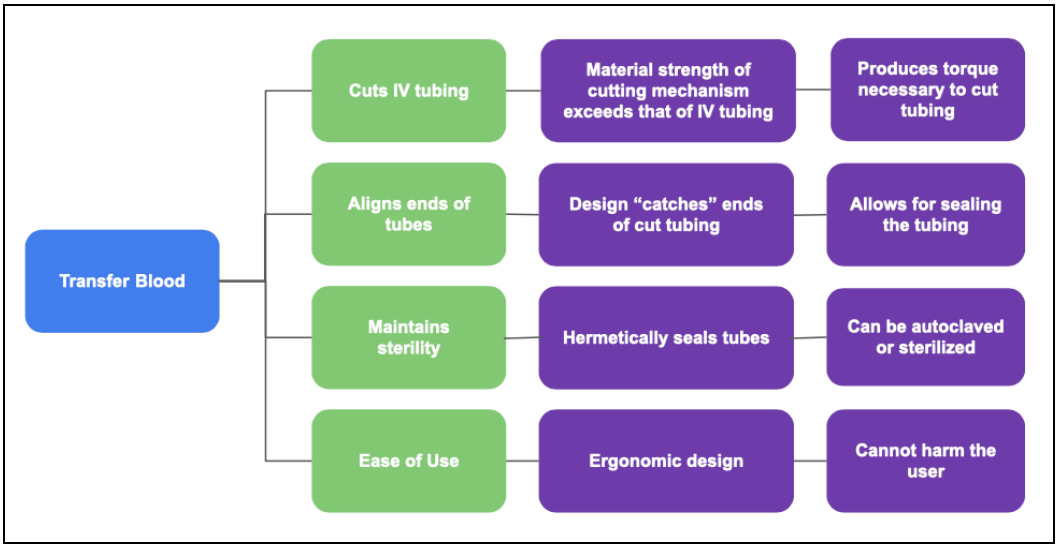


Figure 1. FAST Diagram. FAST Diagrams show the specific relationships of all functions with respect to one another.

The first function we sought to accomplish, and the one we ascribed the highest priority, was to cut the IV tubing. This was partially due to the fact that the previous group had not been able to demonstrate that this was possible with their design. We further elaborated that successfully designing for this function would require a clean, complete cut through the entirety of a section of 5 mm PVC tubing. Prior to any design work, we considered the possible ways to later test this function in our prototypes, as we knew we could easily gain access to identical PVC tubing.

Unfortunately, our second function of sterility would be much harder to test in the same setting. We based our definition of meeting this function around our engineering specification of the same nature, a steam sterilization test result showing that the design is able to withstand temps of 140 C, in which the Sterility Assurance Level (SAL) is 10^-6 [1]. This test however, was not something that we would be able to accomplish with the resources at our disposal. In light of this, we sought to research all of the input materials in the context of whether they could be sterilized by traditional methods, and whether they were biocompatible.

The function of proper alignment was mostly accounted for in the design we received from the previous group. However, we would need to test this alignment more concretely once the cutting function was achieved, as well as choosing our design modifications carefully such that this function would never be impeded.

Ease-of-use is a function that we needed to incorporate into several different aspects of our design. We would need to ensure that any adult individual, regardless of their size or strength, could operate the device seamlessly. The design also needed to be intuitive to use such that operation could be learned quickly and performed at a competitive time compared to market SDDs. Additionally, we wanted the final design to be as ergonomic as possible, given the necessary motion. The testing to determine if our final design met this function would be much more subjective, and primarily a matter of opinion.

By defining these primary functions and thinking in advance about how we would test each of them, some ideas about implementation in the design quickly came to mind and would be very influential in the creativity phase of our process.

4. Creativity Phase

The purpose of the Creativity Phase is to generate a plethora of ideas that can perform the aforementioned functions in order to optimize value in our design. Our project is unique in that we inherited ideas from the previous group. Due to the precedent that was set for us by the previous group's design, we wanted to focus our creative efforts towards implementing each of the necessary functions into a similar design. This required us to identify areas of incompleteness in the previous design, which we took to be our clearest path forward. Upon printing the original CAD files provided to us, we immediately noticed additional aspects within the design that would need to be fixed outside of our chosen functions. Primarily, we needed to add tolerances to the design such that the separate parts could be assembled as intended. Once the device was assembled, we began brainstorming methods of implementing the required functions into the previous design.

As previously stated, our primary non-basic function was to cut the tubing. Our brainstorming efforts led us to a variety of design concepts centered around this function, including:

1. Testing the previous group's blunt edge.
2. Adjusting the thickness of the edge to be much thinner and blade-like.
3. Creating an angle on the edge to slice across the tubing rather than pinching through it.

4. Creating a sharp puncture point, an example of biomimicry inspired by one of our group member's cat, whose naturally pointy teeth could reliably cut through the PVC tubing he found with minimal force.
5. Creating a press-down design for the cutting motion to mitigate the lack of torque that could be generated.
6. Inserting a metal blade rather than relying on the plastic main carriage of the design to perform the cutting.

Each of these design iterations had varying levels of success in performing the assigned function, as well as different opportunities for the successes of the other necessary functions. These differences are later highlighted in the evaluation phase of our process, where we were able to actually prototype and test our ideas, after weighing the pros and cons of each. Exploring our creativity to satisfy our necessary functions led us to trying new ideas which deviated from the previous group's. For example, by evaluating the basic function of cutting the tube, we decided to pivot from a twisting motion to a press-down motion for the cutting mechanism. It also led us to reevaluate the sealing mechanism in the previous group's design when assessing the function of sealing the connection.

5. Evaluation Phase

This phase is intended to systematically reduce the large number of ideas generated during the creativity phase to those that best optimize the value of our product. Evaluation requires comparing options, in this case the differing ideas we have for satisfying a function. We evaluated several blade iterations and sealing mechanisms to find which design best balances function and cost.

I. Testing the previous group's blunt edge.

This initial iteration was wrought with shortcomings right off the bat. The blunt edge squeezed down on the PVC tubing but no puncture was ever observed. It became immediately clear that this idea would not meet our needs for the final design.

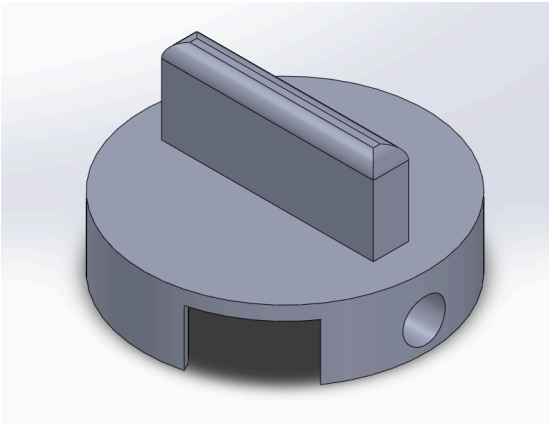


Figure 2. Previous group's design

II. Adjusting the angle and thickness of the edge to be much thinner and blade-like.

Our second iteration was designed with a thinner edge to model a blade that would hopefully cut through the material. This thin edge was achieved by using a TAZ 3-D printer, as it has a higher resolution than the Ender Pro printer we had used for previous prints. The blade was also angled to mimic the shape of an X-Acto knife. However, when testing this design, the PVC tubing would get caught under the cutting point, jamming the device. This made the attempts to cut unsuccessful.

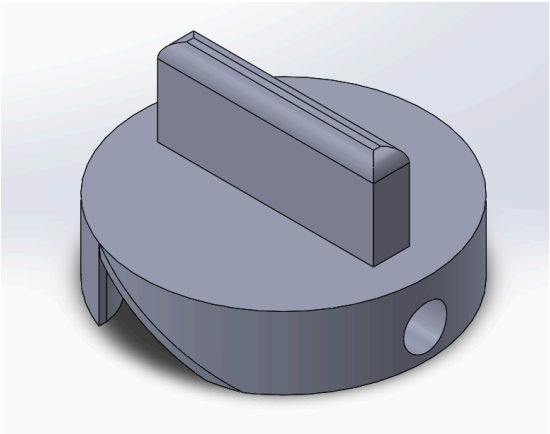


Figure 3. Angled edge design

III. Creating a V-like space for tubing to pass through.

To address the issue of the tubing getting caught, the third iteration included a second angled edge on the bottom to create a pathway for the tubing to enter the cutting point. While this approach solved the issue of stuck tubing, it still failed to cut through the tubing.

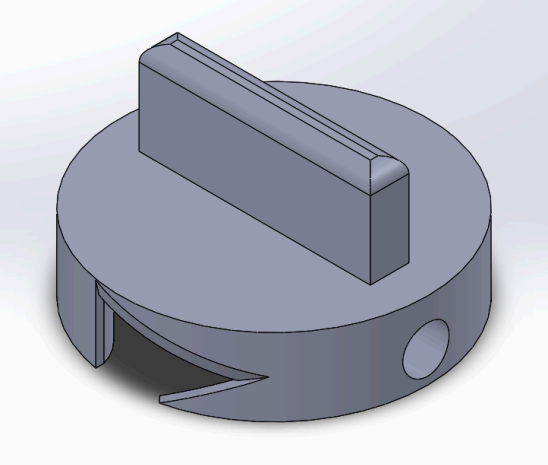


Figure 4. Angled plow-like design

IV. Creating a serrated edge.

Biomimicry was used to create the fourth iteration. When working on the design at home, it was observed that one group member's cat was able to cut the tubing by chewing through it. This inspired our fourth iteration to be modeled after a cat tooth while still keeping the bottom incline to prevent the tubing from getting stuck. While this design was able to pierce the tubing, it did not cut through it completely.

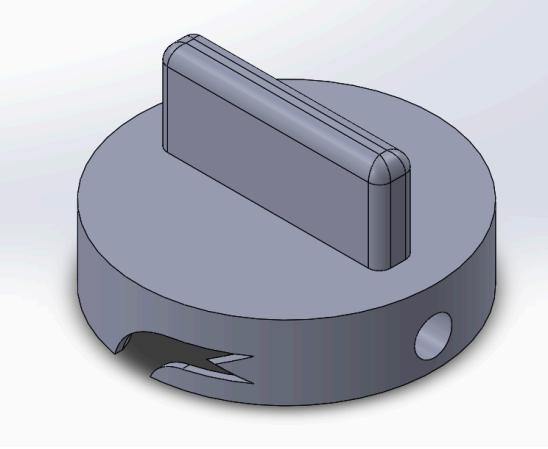


Figure 5. Biomimicry design

V. Inserting a blade and pressing downwards to cut.

It was ultimately decided that the plastic itself would not be sharp enough to cut all the way through the tubing no matter the configuration, due to the insufficient torque that we were able to generate with the twisting mechanism. We then decided that more force could be generated by pushing down onto the tubing as opposed to attempting to twist through it. The design does, however, still utilize a twisting motion to align the ends of the tubes for fluid flow. The initial design held the blade captive within the wall of the lid, though we found that the small overhang from the blade to the outer edge of the wall prevented the lid from being able to twist into place to align the tubes. This was mitigated by gluing the blade flush to the outer wall of the lid to ensure twisting clearance.

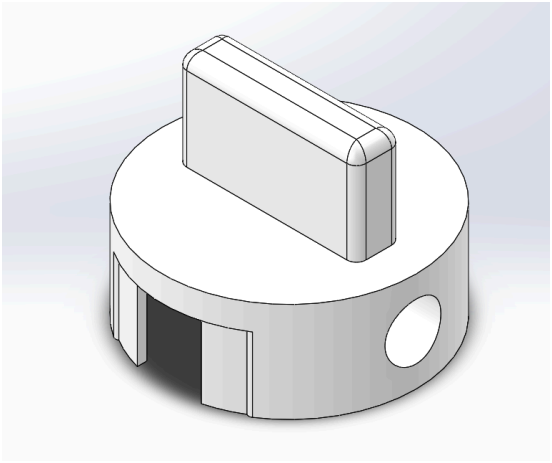
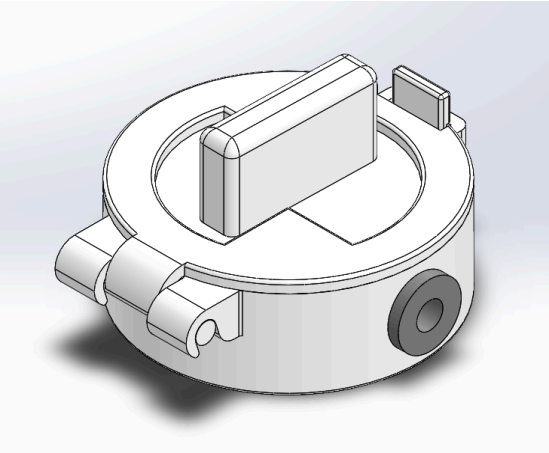
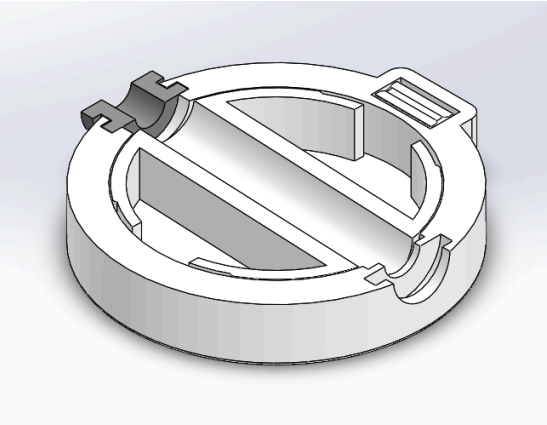


Figure 6. Blade-insert design

VI. Adding grommets for sealing.

The previous group's design had no mechanism for sealing, relying solely on absolutely perfect alignment to prevent leakage. As this proved to be ineffective, we opted for rubber grommets to be inserted at each of the outer holes to both hold the tubing in place, and to prevent fluid leakage. The grommets are secured by wrapping around both sides of the wall, but to ensure that the inner side of the wall would remain clear for twisting the lid, a cavity was created through the middle of the wall for the grommet to wrap around as seen in Figure 8. We were successfully able to easily push IV tubing through the grommets, but with a snug enough fit that it did not move by itself.





Figures 7 and 8. Final design with grommets inserted, and Cross section showing the grommet cavity in the middle of the wall

6. Development Phase

At this phase in the process, the bulk of the VM study has been completed and our group prepared to present our findings. Our team documented our VM proposals with written descriptions, narratives providing justification, sketches, performance and risk assessments, and cost comparisons.

As part of the development phase, our team created a manufacturing plan for our single use SDDs. After consulting with plastics manufacturers and other experts, we decided to utilize injection molding of polypropylene for the manufacturing of our device. Polypropylene has similar material properties to that of the resin used for our prototypes, so we felt confident that no major structural differences would be found in a final manufactured version. After researching the labor costs for an average factory worker in the U.S. and finding it to be $16.82/hour, Dr. Bidanda advised us to explore foreign labor costs instead. Finding China's rate to be $3.93/hour and India's to be $2/hour, a cost analysis was performed comparing the price of production in these countries at 10,000, 25,000, and 50,000 units. Taking into account the costs of manufacturing molds, raw material (polypropylene), grommets, blades, adhesive for the blades, and labor costs our final prices per unit were found as seen in Table 2. A more in-depth look at the values that went into these calculations can be seen in the first item of the appendix.

	U.S.A.	China	India

10,000 Units	$2.80	$2.69	$2.67
25,000 Units	$2.86	$2.75	$2.73
50,000 Units	$2.80	$2.69	$2.67

Table 2. Price per unit cost analysis

India's price per unit of $2.67 was found to be our cheapest option. The higher prices for the 25,000 unit run were the result of the lifecycle of a typical manufacturing mold used in the injection molding process. Molds need to be replaced or recalibrated every 10,000 cycles, so manufacturing an amount not evenly divisible by 10,000 results in the loss of potential for 5,000 units which drives up cost.

Estimating usage of this device to be ten times a day, every day of the year, results in 3,650 uses which comes out to $9,745.50 spent on our device a year. This figure is less than a third of the cost of current market options, and is flexible depending on frequency of use.

7. Presentation Phase

The presentation phase is where a design and VM proposals are introduced to stakeholders who were not part of the VM study. In our case, the stakeholders we presented to were our professor, Dr. Winter, and our project mentor, Dr. Bidanda, as well as the rest of our Product Realization classmates. As this is a class project, the presentation phase also involved preparing materials for our design EXPO. Presentation materials included a video demonstration of the product in action from start to finish. It showed the insertion of IV tubes into the device, cutting the tubes, joining the tubes, and lastly, successfully transferring lab-made fake blood between the tubes. In addition to the demonstrative video, we created a poster which outlined the nine steps of our VM process and how we used it in the context of our product. Lastly, we displayed prints of all of our iterations for our audience to interact with as they walked by.

8. Implementation Phase

In this phase, we had to determine the state of our VM proposals and validate their effect on the value of the product. After our stakeholders have a chance to review our VM proposals,

we will consult with them to agree on next steps. Ideally, our design will be used at blood banks in third world countries where current SDD models are unaffordable.

Additional testing is required before our design can be implemented. First and foremost, our product should be tested for sterility. Since our product is single use and only uses materials that are currently used in other medical applications, we expect that this will not be an issue. However, it is important to test for sterility in order to validate the expectation that blood will not be contaminated by our device. Sterility testing can be done using ISO 11737-2 [1].

When implementing our design, there are still a few things to consider. One of the main considerations is that there must be an alternative method of sealing after the blood transfer is complete. Since one of the main purposes of this device is to minimize blood waste by providing the opportunity to split donor blood bags into smaller aliquots, it is important to reseal the original donor bag so that its blood can be used later. This could be done by placing a clip on the tubing of the donor bag after transfer, or by sealing it with heat.

Another consideration for our device is sustainability. Since our device is mostly made of single-use plastic, the environmental effects of its disposal should be taken into account before it is implemented on a large scale. This could be done by looking into a recycling program for this product or using more environmentally friendly materials, such as bioplastics. Alternatively, it may be feasible to make our device reusable. Future groups could look into the possibility of resterilization so that each device can be reused.

Acknowledgements

We would like to give special thanks to Dr. Eric Winter and Dr. Bopaya Bidanda for their guidance and knowledge through our entrance into Value Methodology Engineering. We would also like to thank the staff at Open Lab for getting us set up for our prototyping needs.

References

[1] Degen, Jörg. “Sterility Testing of Medical Devices: An Overview.” *Eurofins*, https://cdnmedia.eurofins.com/corporate-eurofins/media/12154151/9433_sterlity-test-medical-devices_web-ready.pdf

Appendix

1. In-depth cost breakdown

MATERIAL	**COST**		**QUANTITY / UNIT**	**COST / UNIT**
polypropelyene	$0.020	per gram	21.31	$0.426
blade	$0.050	per unit	2	$0.10
grommet	$0.160	per unit	2	$0.32

ADHESIVE			
$40/bottle	45 mL bottle	estimated 0.012 mL needed per unit	3750 units per bottle

Units	*Bottles needed*	*Total bottle cost*	*Cost per unit*
10,000	2.67 (3)	$120	$0.012
25,000	6.67 (7)	$280	$0.0112
50,000	13.3 (14)	$560	$0.0112

MOLD			**LABOR**
$3000 good for every 10,000 cycles			Estimated 30 second assembly time

Units	*Molds needed*	*Cost per unit*	*Country*	*Hourly Rate*	*$/second*	*Total Assembly Cost*
10,000	1	$0.30	U.S.	$16.82	$0.00467	$0.14017
25,000	3	$0.36	India	$2	$0.00056	$0.01667
50,000	5	$0.30	China	$3.93	$0.00109	$0.03275

TOTAL			
	U.S.	*India*	*China*
10,000 Units	$2.7982	$2.6747	$2.69075
25,000 Units	$2.8574	$2.7339	$2.74995
50,000 Units	$2.7974	$2.6739	$2.68995