DEVELOPMENT OF AN ENDOSCOPIC IRRIGATION PUMP

EXPERIENCE WITH BYRNE MEDICAL, INC.

A Record of Study

by

LUI CHENG

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF ENGINEERING

May 2007

Major Subject: Engineering

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ABSTRACT

Development of an Endoscopic Irrigation Pump

Experience with Byrne Medical, Inc. (May 2007)

Lui Cheng, B. S., Texas A&M University;

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As an intern with Byrne Medical Inc., I took part in several development and validation projects for medical products. A design project for a medical irrigation pump for endoscopic procedure is the focus for my Doctor of Engineering degree. This project represents the scope and depth of a typical design project for a medical device.

In this dissertation, a summary of motors used in current medical irrigation pumps available in the market, as well as their flow rates, is presented. A procedure of typical product design process is followed and a working prototype of endoscopic irrigation pump is designed and fabricated.

The objective of the project was to design and fabricate a working prototype of a medical irrigation pump to be used for endoscopic procedures with standard videoscopes in the medical field. Currently there are no irrigation pumps that satisfy physicians' needs. By manufacturing their own pump, Byrne Medical would be able to select a host of the positive features noted on other pumps and combine those features into a single pump that fits both the technical and user needs. The author made improvements in the areas of

appearance, size, usability, functionality, product life, and ability to vary motor speed, and therefore the flow rate.

Flow rate of the prototype was tested by measuring the amount of water it was able to pump per minute (milliliter per minute). Each tubing set was attached and secured onto the prototype unit and adjust the speed control to the maximum flow. The power switch was turned on and the pump was running continuously for twenty seconds. Water was collected and weighted with a digital scale. The amount of water (in pound) per twenty seconds was then converted to milliliter per minute.

Physicians in the GI (Gastroenterology) suites prefer an irrigation pump that rotates backward when they turn the power off to prevent the sterile water from dripping. A Multi-function Timer (model H3DE-M2) manufactured by **Omron** was selected for future improvement. A working prototype (previously fabricated) was tested with this DPDT timer and the result proved the improvement was achievable.

DEDICATION

This record of study is dedicated to my parents and sisters, for their love and support.

ACKNOWLEDGEMENTS

By the time I was working on this record of study, my study for the Doctor of Engineering degree is approaching the end. It was two years ago when I decided to pursue the Doctor of Engineering degree at Texas A&M as an important step for my transition from academia to industry. Thanks to my advisor, Dr. Charles Lessard, and other committee members, I learned a lot from this program and the degree well prepared me to work effectively in industry.

Internship with Byrne Medical in Conroe, Texas, was an invaluable experience for me. Mr. Don Byrne brought me in to this small but fast growing company. Ms. Dawn Burks served as my internship supervisor who taught me how to be a good product development engineer. Alan Smith and Rusty Smith gave me opportunities to work on several exciting projects through which I gained some hands-on experience in project management, technical problem solving skills and management responsibilities.

Special thanks to Krista Oakes, Principal of Amica Solutions, who helped me prepare documents for 510(K) throughout my internship with Byrne Medical, Inc.

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1. INTRODUCTION

1.1 Internship with Byrne Medical, Inc.

Byrne Medical, Inc. is a privately held medical device manufacturer headquartered in Conroe, Texas. The company produces a line of disposable, patented products that cater to Endoscopy departments of hospitals and clinics. Byrne Medical employs over 30 diverse team members including assemblers, engineers and sales support staff and is ISO (International Organization for Standardization) certified.

The idea for the Endo SmartCap™ came when the company began researching the cleaning process required for reusable water bottles used in Endoscopy procedures. The company found that

1) there were no industry-wide guidelines and,
2) a potential risk to patients due to cross contamination.

Byrne Medical realized the need for disposable water bottles; thus, the Endo SmartCap™ was created and received FDA 510(K) approval in 1997.

This Record of Study follows the style and format of *IEEE Transactions on Biomedical Engineering.*

Later, the same concern for infection control led Byrne Medical to invent the Endo Gator™ a product designed to end the potential risk of back flow via the irrigation units used when an irrigating flush is needed or while performing electro-surgical procedures. In the tradition of their first discovery, and now as the leader in disposable endoscope irrigation systems, Byrne's research and development team continues to strive for greater efficiency and patient safety. The company responds to the needs of the care providers by persistent customer follow up, prompt delivery and a consistency of product performance. In doing so, Byrne Medical continues to look for ways to improve patient care while offering uncompromising service from the provider's perspective.

The author had an opportunity to work on a new product development project when he joined the company. His task was to design and fabricate a working prototype of a medical irrigation pump to be used for endoscopic procedures in hospitals or medical settings. He was also given the opportunity to work on several other validation and protocol testing for current products. The main project will be discussed extensively in later sections; additionally, various testing protocols and validation projects that he worked on during his internship are listed below:

1. Tensile strength test of bottle cap - To investigate the cap strength of the nozzle, the effect of applying different percentages of alcohol (70 % and 91%) on the nozzle during assembling procedure and whether or not the sterilization plays a role on weakening the nozzle strength.

2. Bond Testing (long tube subassembly): Comparing a.) the amount of pressure and b.) force the long tube subassembly could sustain between the use of Cyclohexanone as bonding agent and use of alcohol as wetting agent. The goal was to eliminate the use of Cyclohexanone as bonding agent if the test result shows no significant difference on pressure and force the two agents were able to sustain.
3. Determine the maximum force the BMP-100130 tubing set was able to sustain: To find the maximum force (pressure) the tubing set (BMP-100130) could sustain, and compare the maximum force it sustained after applying a different agent, (glue (Cyclohexanone, to secure the connection) and alcohol (as a lubricant)). Further to determine the effect of sterilization acting on the components.
4. To determine the flow rate of existing irrigation pumps, Universal Generator-Irrigator, ERBE EIP-2, Olympus OFP and ViraPump, in the market.
5. To compare the flow rate of BMP-100130 by using original material DOW 350LH (silicone) and DOW Q7-4750 (silicone) in making component BMP-077 per Vesta's request.

Besides these validation projects, the author visited Texas Children Hospital in Houston on July 12, 2005 with Rusty Smith, the Director of Research and Development, to investigate the reasons there was no air flow when the physicians were using the Endo

Smartcap™ with the new Pentax processor. Another purpose of this trip was to become familiar with both the facility and the set up in the GI (Gastroenterology) room.

2. The EGP-100 PROJECT

The endoscopic irrigation pump is used to clear debris and improve the physicians' ability to observe, maneuver, and diagnose during endoscopic exams. Many irrigation pumps are specifically designed for use with specific videoscopes/endoscopes that incorporate a dedicated auxiliary water channel to supply sterile water at the touch of a button or a foot-switch.

The objective of the project was to design and fabricate a working prototype of a medical irrigation pump to be used for endoscopic procedures with standard videoscopes in the medical field. Currently there are no irrigation pumps that satisfy physicians' needs. By manufacturing their own pump, Byrne Medical would be able to select a host of the positive features noted on other pumps and combine those features into a single pump that fits both the technical and user needs. Targeted features included: compact design, pump safety system, easy loading pumphead and self-contained footswitch, and disposable EndoGator™ tubing for safety and compliance. The author made improvements in the areas of appearance, size, usability, functionality, product life, and ability to vary motor speed, and therefore the flow rate. A working prototype was important for Byrne Medical since this would give them a new business opportunity – Byrne's first electro-mechanical product.

To manage the project more effectively, the author divided the whole project in into four primary phases through completion: Technical Analysis, Design, Fabrication and Validation.

2.1 Technical Analysis Phase

The Technical Analysis phase stressed the knowledge of the technical data for current medical irrigation pumps and involved investigation into product specifications and requirements. Focus areas included:

a) flow rate ranges
b) flow rate averages
c) pressure ranges
d) pressure averages
e) common dimensions
f) input mechanism
g) control methods
h) components cost

The information collected at this initial phase was necessary for the following three phases. Specifically, for the Design phase, the sizes provided a volume constraint, the inputs provided an interface requirement, and the control methods determined any necessary appendages. For Fabrication, the flow rates and pressures determined the

principal internal components, and the cost of components limit the usable materials. Finally, the ranges of values supplied adequate Validation specifications.

2.2 Design Phase

The main Design items are comprised of the motor and user interface. The motor information is derived from the Technical Analysis phase, while the user interface requires innovation of design and some degree of ergonomics.

Motor

The process to design the internal pump began by using the information previously derived to develop optimal parameters of the motor. Thereafter, various motors underwent investigation to establish the most appropriate motor based on efficiency and cost-effectiveness. Finally, the overall schematics of the pump were outlined. The process follows and is graphically shown in Fig. 1.

1. Define optimal motor parameters for the pump.
2. Investigate existing motors for efficiency and cost-effectiveness.
3. Outline overall pump schematics.
4. Select the most appropriate casing.
5. Assemble the pump using the components.

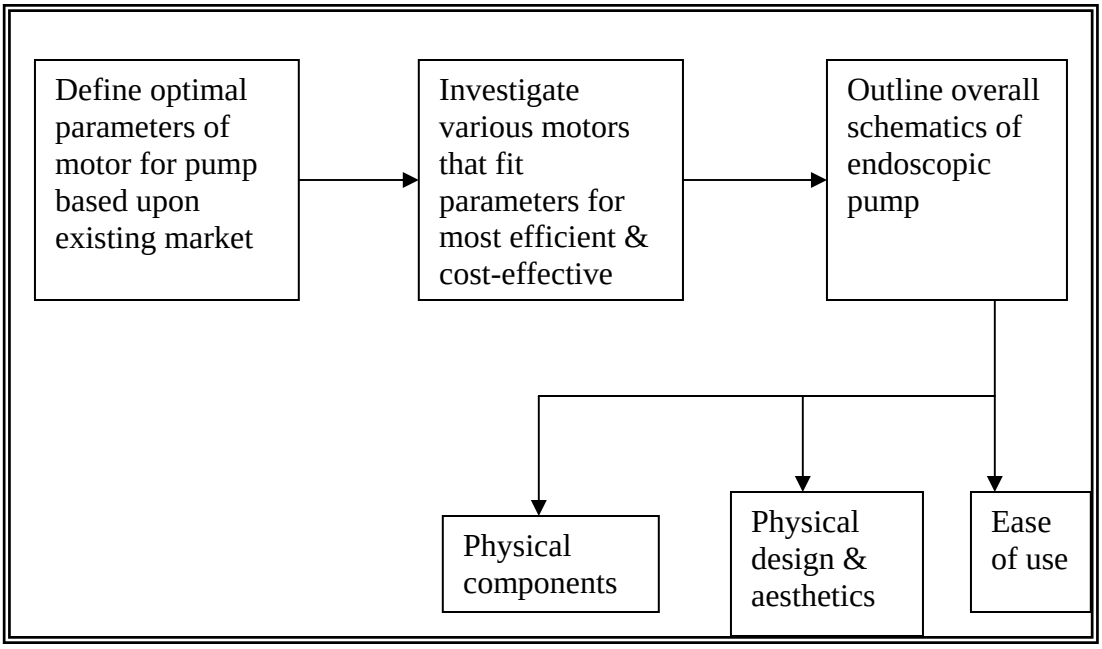

Fig. 1. Development Process.

Interface

Considerations for the interface included aesthetics, accessibility and the ease of use. Due to the diversity of users, the device must be simple to operate and control, yet stylish enough to appeal to the potential customers, who are typically different than the end-users.

The current blueprint for the project (Fig. 2) depicts the flow of the device's basic operation from the user's perspective, while Fig. 1 represents the path the author took to reach the process of Fig 2.

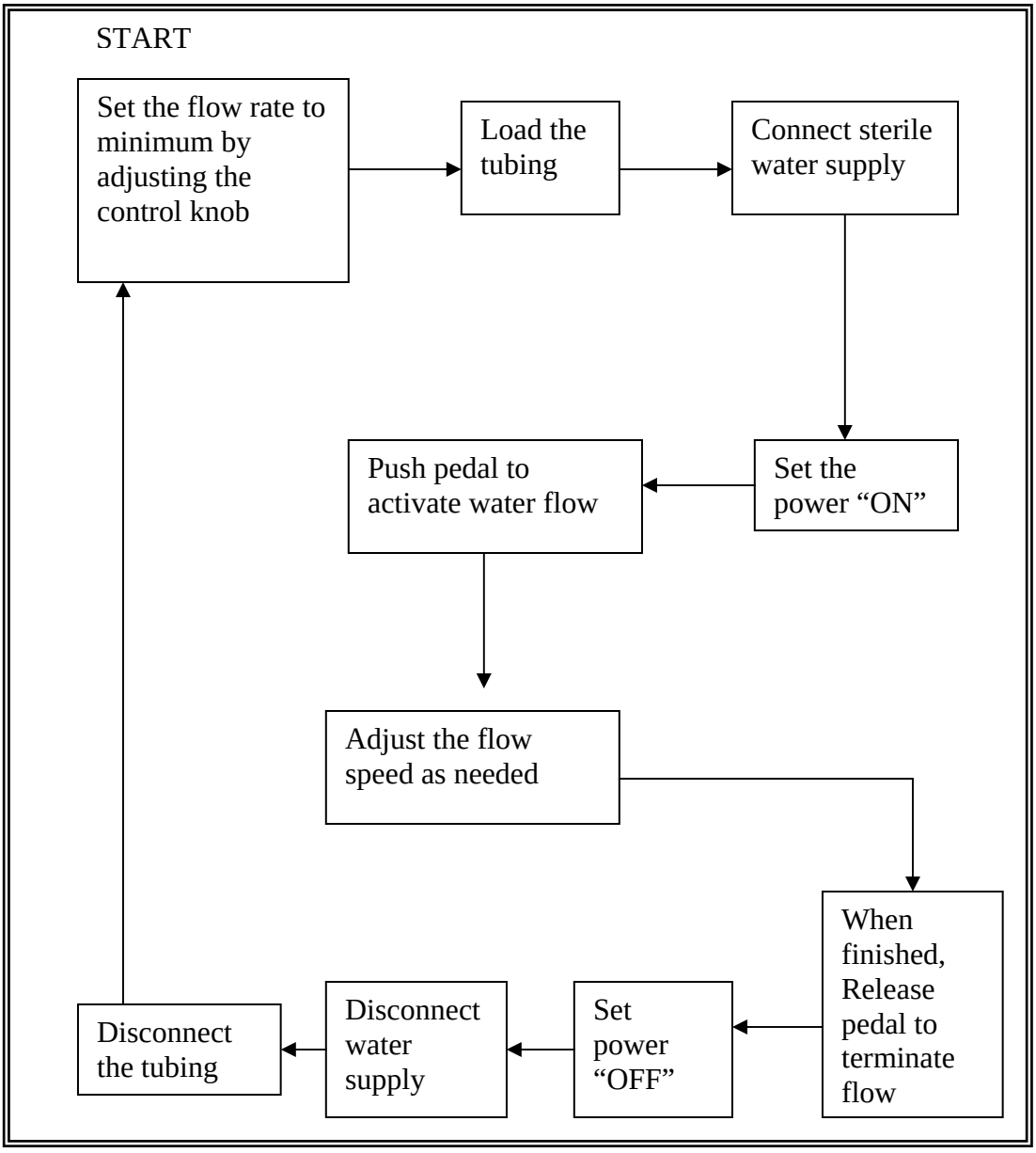

Fig. 2. Basic Operating Procedure.

2.3 Fabrication Phase

The fabrication phase consists of the actual assembly of an irrigation pump (a prototype). The optimal parameters for the design are based on the design phase. Prior to assembly, various components needed are to be purchased.

2.4 Validation Phase

Following production of the prototype, all parameters were tested to insure that the design met required mechanical and electrical specifications, i.e.:

1. electronics (switches)
2. minimum and maximum pressure
3. durability
4. usability
5. flow rate

If validation of the prototype failed, the prototype was returned to the design phase for modifications. Time constraints, however limited the amount of repeated trials following this phase and all findings were reported to the supervisor for further investigation.

2.5 Human Factors/Risk Analysis

Since the final product would be used by physicians, nurses, and other hospital staff, the device had to be kept compatible with existing equipment and similar in operation. These qualities a) reduce training time in addition to b) promoting product acceptance.

The current outer design plan, represented by Fig. 3, uses the control knob to adjust the flow rate at various speeds and the special shape provides a firm grip. The design also used a foot switch pedal for hands-off on/off function. The current design plan also incorporated a front-loading area for the pumphead, to function correctly with pumpheads presently being used for endoscopy devices. Moreover, the tubing attaches to the motor via the same mechanism as current leading irrigation pumps. By using characteristics of an already proven design, the project plans ensure consistent results and fewer risks associated with improper loading.

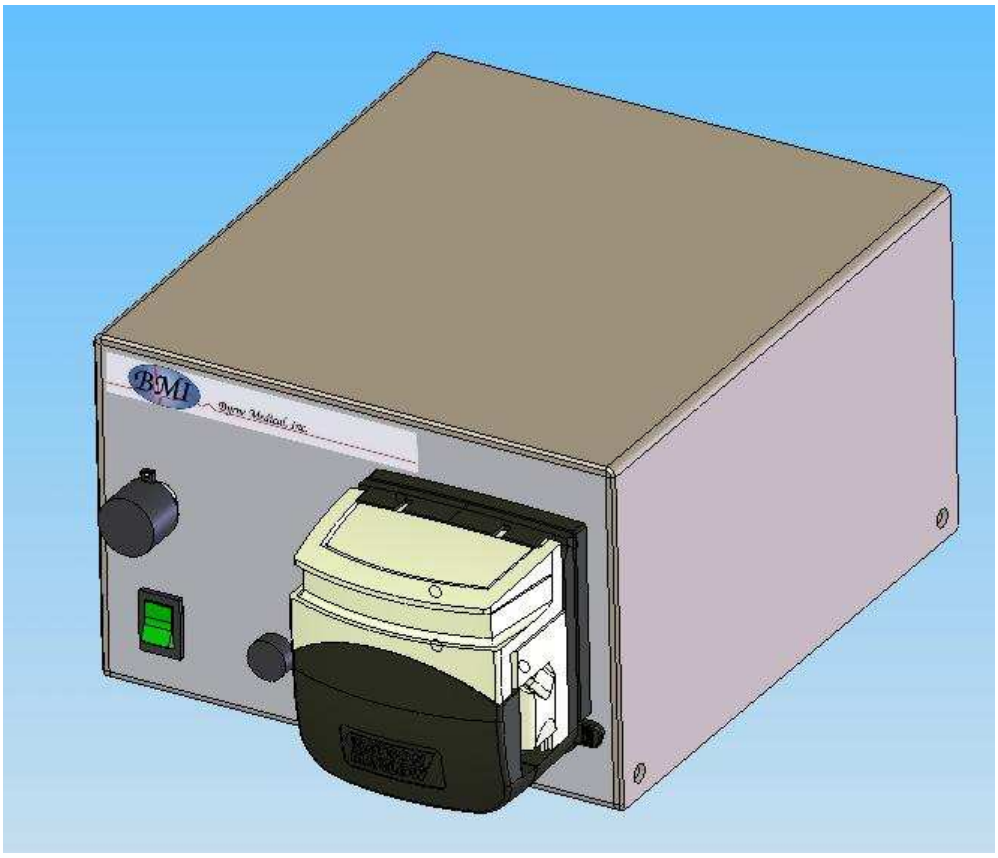

Fig. 3. Representation of Final Product.

The design of this compact, high flow rate irrigation pump posed no greater safety risk (minimal at most) than pumps presently being used in hospitals. Every pump on the market runs the risk of operating at a dangerously higher or lower pressure than it is specified to run at a certain level within the device. Other features of the planned device in planning, such as the proposed back-flow component and the shut off mechanism, could also cause other malfunctions. However, in the rare case of a malfunction, the medical professional performing the procedure must always have the option of a manual device shut-down.

3. DESIGN SPECIFICATIONS

To meet the Byrne Medical goals several vital specifications were set for the new irrigation pump. The pump had several criteria set that needed to be either revised or implemented from scratch. These specifications include:

I. Internal features:

A. Pump Motor must have:

1. Variable speed from 500-3000 rpm to achieve an appropriate flow rate.
2. 0 to 24V DC voltage.
3. Maximum current less than 3 A.
4. Maximum diameter of 3”.
5. Wire leads.
6. Permanent Magnetic Direct Current for the motor type.
7. Magnetic Coupling for pump head compatibility.

B. Variable Speed Motor Driver (Control Card) must have:

1. Ability to control the flow rate from 0 to 700 mL/min or greater with appropriate rpm.
2. An internal AC to DC converter.
3. Compatibility with the potentiometer for external flow control.
4. Compatibility with the On/Off power switch.
5. Minimal size to fit inside pump casing.

C. Transformer must have:

1. The ability to convert 120VAC to 24VDC.
2. A heatsink to decrease its contribution to the temperature rise inside the casing.
3. A straight AC voltage input and DC voltage output for ease of use

II. External features:

A. Speed Control Knob must have:

1. Easy to grip grooves on knob.
2. Customizable number tab for number of instruments being cleaned.
3. Optional locking rotation for off position.

B. Potentiometer must have:

1. Nominal resistance of 10K.
2. Shaft size compatible with control knob.

C. Rocker Switch must have:

1. Compatibility with 115VAC.
2. Water Resistance.
3. Illumination capability.
4. Durability up to 100,000 cycles of use.

D. M/F Power Cord must have:

1. Approximately 18/3 AWG wire gage.
2. 10 A, 115 VAC rating.
3. UL Listed and CSA Certified rating.

4. Hospital grade rating.

E. AC Receptacle must have:

1. Compatibility with 115 VAC.
2. Hospital grade rating.

F. Pump head must have:

1. Peristaltic type pump head.
2. Compatibility with PMDC motor.
3. Nominal flow rate of 700 mL/min.
4. Maximum rpm that is greater than the maximum motor rpm.
5. Pressure release system that is adjustable from 0.7 bar to 3.5 bar (max differential pressure).

G. Tubing: using in-house product

H. Casing must be:

1. Painted.
2. Aesthetically pleasing in appearance.
3. Made with Byrne Medical's logo on the front.
4. Made with minimal size.
5. Built with 4 non-slip feet on bottom of casing.
6. Made with screws positioned facing inward.

3.1 Description of Components

After searching for acceptable parts that fit the technical specifications, the author compared and selected the optimal parts for the project. A part by part summary of the choices is described in this section per the outline of the specifications, including figures and tables for explicit part specifications. The figures and diagrams in this section are for visualization of the parts alone.

DC motor with brush

Fig. 4 is a picture of the DME 44 B6 HPB from **Japan Servo** for the first prototype and specifications of the motor are listed in Table I [1]. The motor specifications were taken directly from their websites. The specification regarding mount code is the type of shaft head the motor possesses, which for our motor and pump head was the A type mount code.

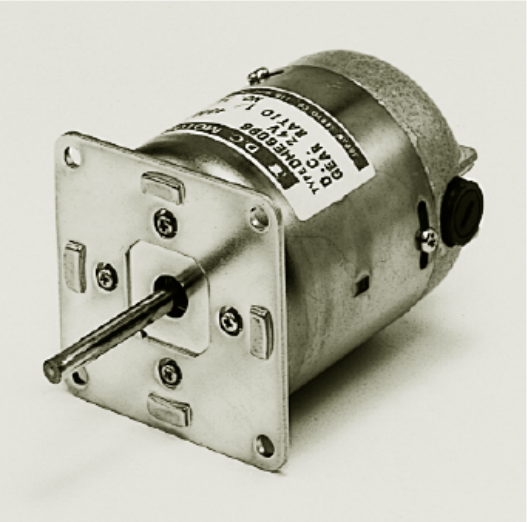

Fig. 4. DME 44 B6 HPB Brush Motor.

TABLE I
JAPAN SERVO DC MOTOR SPECIFICATIONS (WITH BRUSH)

●with 6DGF TYPE GEARBOX MOTOR MODEL DME44S6HFP☆, DME44B6HFPB & GEARBOX MODEL 6DG□F

Model	Gear ratio		5	*12.5	*15	*25	*30	50	75	100	150	180
	Rated speed	r/min	720	288	240	144	120	72	48	36	24	20.6
DME44S6HFP☆ & 6DG□F	Rated torque	N·m	0.1	0.22	0.27	0.44	0.53	0.80	1.2	1.6	2.4	2.4
		oz·in	13.89	30.55	37.50	62.49	74.99	113.87	166.65	222.19	333.29	347.18
DME44B6HFPB & 6DG□F	Rated speed	r/min	720	288	240	144	120	72	48	36.3	25.7	21.8
	Rated torque	N·m	0.16	0.35	0.43	0.72	0.85	1.3	1.9	2.4	2.4	2.4
		oz·in	22.22	49.99	59.71	101.38	120.82	180.53	263.86	347.18	347.18	347.18

Speed control board - adjustable voltage regulator (LM317T)

The motor in the pump design is a DC motor that runs off of 24 volts direct current. The voltage is controlled using the variable speed control board with a LM317T (variable voltage regulator) chip. The LM317T is a monolithic integrated circuit containing an adjustable 3-terminal positive voltage regulator designed to supply 2.2A typical of load current with an output voltage adjustable over a 1.2 to 37V. It employs internal current limiting, thermal shutdown and safe area compensation. A schematic of motor speed controller is shown in Fig. 5 [2].

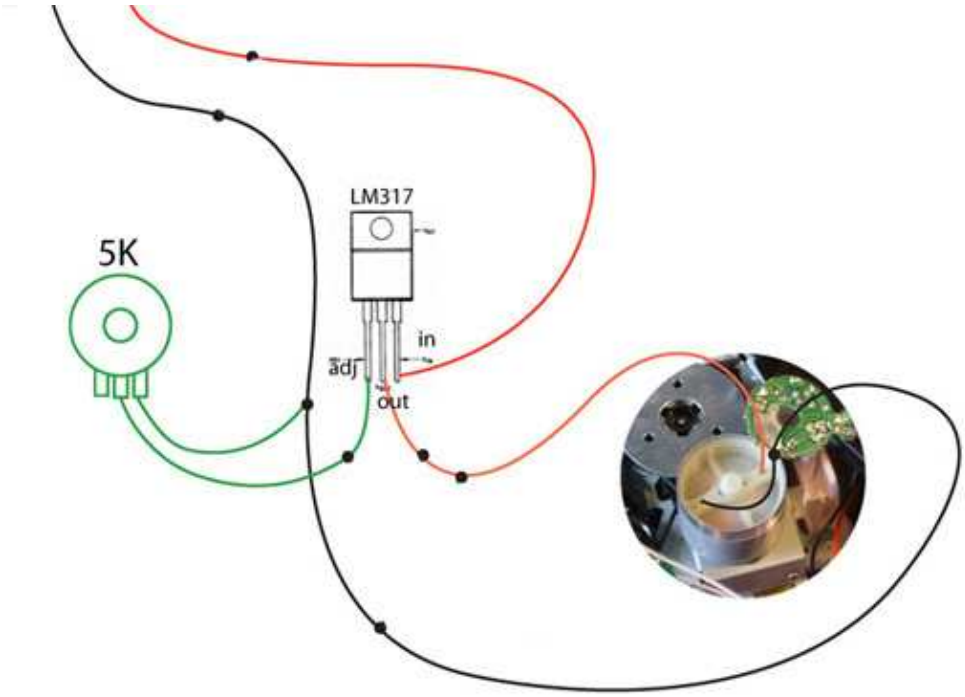

Fig. 5. The Schematic of LM317T as a Speed Controller.

AC/DC converter

The transformer in the author's design provides power to the motor to pump the water. The device selected was a FSK-S15-24U AC/DC converter (Fig. 6), as it had the necessary 24VDC output to provide up to 0.65 amps of current. This unit could output 24V DC consistently with wide input range of AC between 85V and 264V. The main advantage of the converter is its encapsulated compact case design plus an industry standard pin out for easy connection. The built-in electromagnetic interference filter suppressed the undesired conducted EMI.

What is EMI?

Within an electronic unit, common-mode currents flow in the same direction from both active and neutral leads to earth ground. When common-mode currents flow to ground along paths outside the unit, the noise is called common-mode electromagnetic interference (EMI). Fortunately, conducted common-mode noise is a correctable form of EMI by using an EMI filter.

Fig. 6. FSK-S15-24U AC/DC Converter.

Air switch (manufacturer: Herga, part number: 6871-0C)

The one pole C/O momentary air switch (Herga, 6871-0C) was selected for the final switch to turn the pump on/off by stepping on/release, respectively, of the foot pedal.

The dimensions of the air switch are shown in Fig. 7 [3] and its specifications are shown in Table II [3].

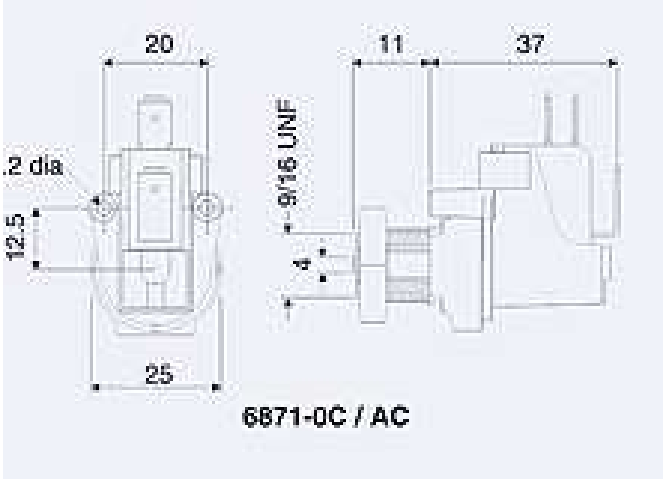

Fig. 7. Herga Air Switch.

TABLE II
HERGA AIR SWITCH SPECIFICATIONS

Model No	6871-0C
Switch Details Number of Poles & Action	1 pole C/O momentary
Air Connection	Back entry
Air Spout Diameter	4mm
Connecting Tube Part Numbers	2311-08/2311-01
Alternative Air Connection Model Number	Back entry 2mm spout 6871-0K side entry 4mm spout 6871-01
Body Material	Acetal
Diaphragm Material	Silicone
Electrical rating @ 250V ac	16A Res 4A Ind 1/2 HP
Special Approvals Upon request	UL CSA
All European electrical switch approvals apply.	

Power entry module

The Corcom AC Receptacle was chosen because

a) it fit the specification set, plus

b) was the least expensive available straight plug receptacle

for the appropriate voltage (115 VAC) and current rating (15 A). The receptacle also had a medical durability rating. The diagrams of the receptacle dimensions are included in Fig. 8 [4] and the specifications are included in Table III [4].

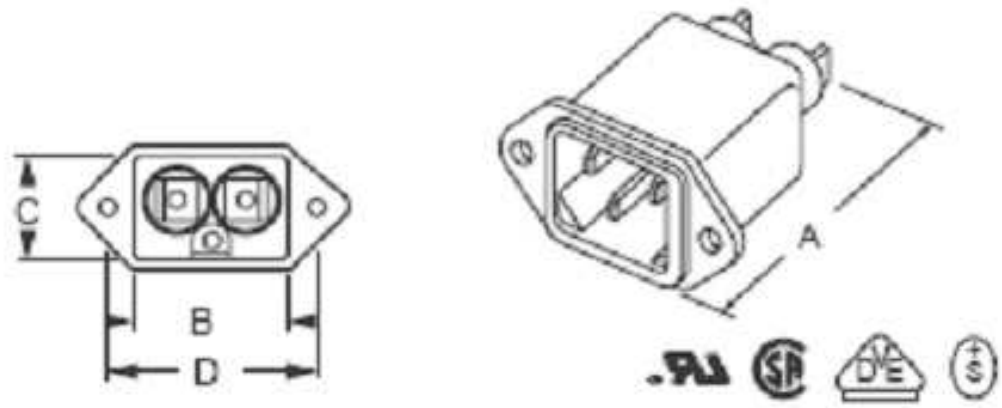

Fig. 8. Corcom AC Receptacle.

TABLE III
CORCOM AC RECEPTACLE PART SPECIFICATIONS

Fig.	Rated Current 120V (Amps)	Termination	Dimensions (mm) A	B	C	D	E	F	Digi-Key Part No.	Pricing 1	25	100	Corcom Part No.
2	15	Faston, Straight	66.50	30.20	20.60	40.01	—	—	CCM1636-ND	20.34	355.75	1188.00	15EF1F

The rugged international power entry module incorporates the special IEC (the International Electrotechnical Commission) power line connector. They are UL (Underwriters Laboratories Inc.) recognized, CSA (Canadian Standards Association) certified, and VDE (the Association for Electrical, Electronic & Information Technologies, founded in Germany) and SEV approved. It is also SEMKO (a division of Intertek plc, a world-wide company specializing in testing and certification) approved and complied with BSI (British Standards Institution) standards.

Rocker switch

A rocker switch was chosen as the best type of On/Off switch for the applications of our device. The main advantages in the rocker switch are its ease of use and clearness in each state of on and off. Fig. 9 [5] shows an image of the Cannon rocker switch model that was selected. The switch has “ON” and “OFF” marked on the surface for ease of use. Fig. 10 [5] shows the dimensions and connection points for the switch.

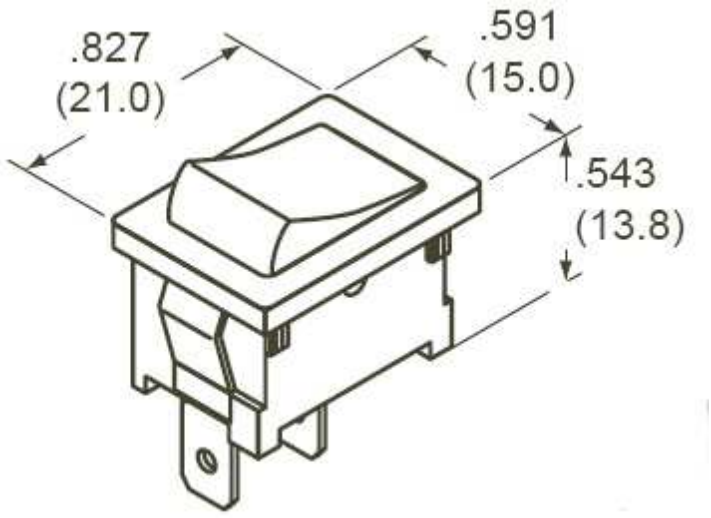

Fig. 9. Cannon Rocker Switch.

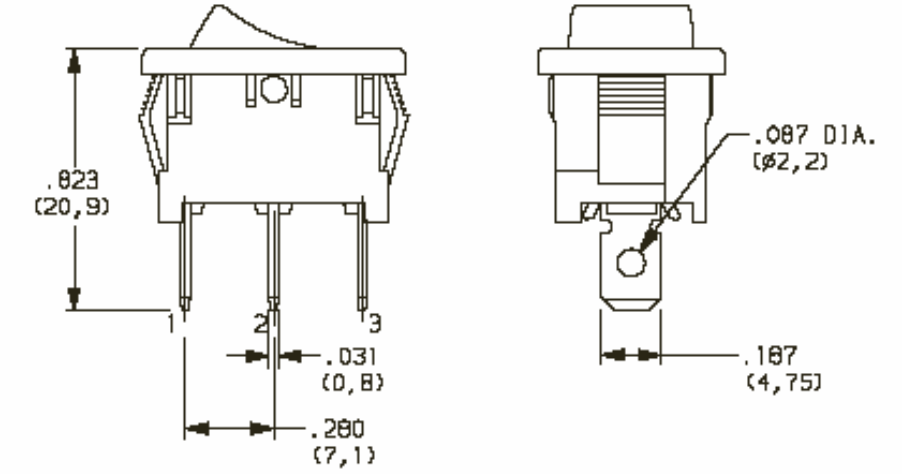

Fig. 10. Cannon Rocker Switch Dimensions.

The 5K potentiometer (RadioShack: 2711714)

The 5 Kilo-ohm potentiometer gives the control range the motor to operate within required specified motor speeds. With 1K and 10K potentiometers, the range was insufficient for controlling the speed of the motor. The advantages of the 5K potentiometer include:

1) reasonable price compare to other vendors
2) the size of this potentiometer is more desirable than others to mount on the front panel of the device, and
3) easier to wire with other electrical components because of its size

Peristaltic pump head by Watson-Marlow

Peristaltic pumps use rotating rollers pressed against special flexible tubing to create a pressurized flow (Fig. 11) [6]. The tube is compressed at a number of points in contact with the rollers. The fluid is moved through the tube with each rotating motion. The individual components of peristaltic pumps include a pump head, drive, and tubing. Peristaltic pumps are also referred to as flexible member pumps, flexible tube pumps, dispensing pumps, or dosing pumps.

The advantages of peristaltic pumps are that the components of the pump may be chosen when the integrity of the media is a requirement of the application since the fluid type does not contact any internal parts. Seals and valves are not needed as in other pumps. Nothing but the hose or tube touches the fluid which eliminates the risk of the pump

contaminating the fluid, or the fluid contaminating the pump. Peristaltic pumps are also reversible and can be flushed to clean out the tubing or hose. They are used in pharmaceutical, chemical, and food and beverage applications [7].

The tubing in peristaltic pumps is often replaceable or disposable. Peristaltic pump does not have valve, seal or glands and the fluid contacts only the bore of the hose or tube. The fluid is drawn into the pump, trapped between rollers and expelled from the pump. The complete closure of the hose, which is squeezed between a roller and the track, gives the pump its positive displacement action, preventing backflow and eliminating the need for check-valves when the pump is not running. It is easy to install, simple to use and quick to maintain. There are no metal parts in contact with the tubing so the tubing will last longer.

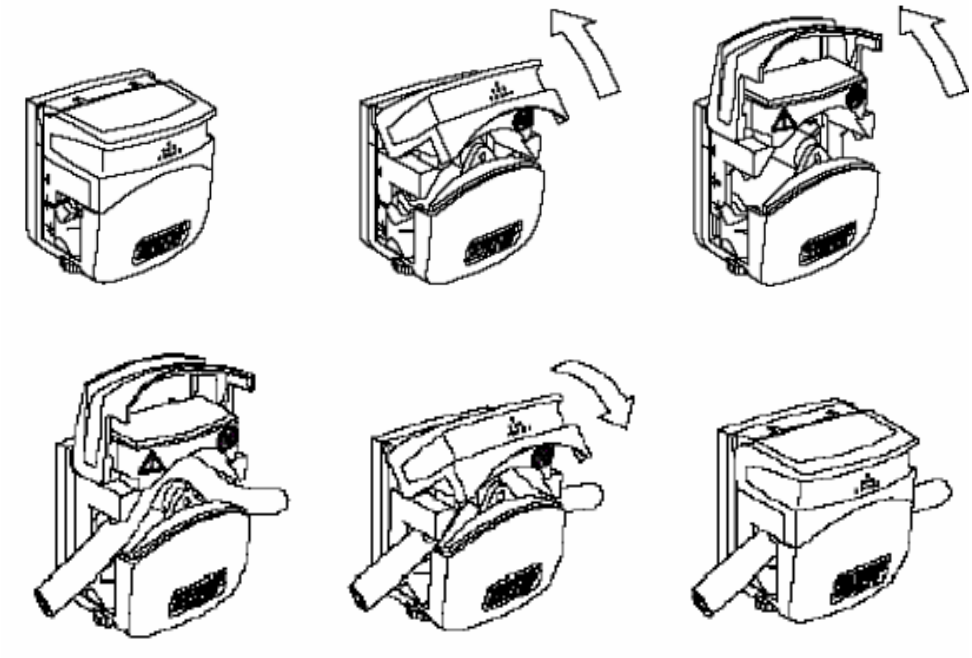

Fig. 11. Open and Close Mechanism of a Peristaltic Pump.

Another advantage is freedom from internal leakage. Fluid in the tube can only leak if the tube should rupture. Displacement is determined by tube size, so delivery rate can be changed only during operation by varying pump speed. However, some models have an adjustable track height, so flow rate can be changed by stopping the pump, changing the tube, adjusting track height, and restarting the pump.

Housing

The housing was an aluminum built casing manufactured by Bud Industries. After receiving the parts and making appropriate the author laid out the internal design and was able to determine the room necessary for the interior of the pump. From calculations of the intended dimensions of 12” W x 7” H x 4” D, he selected the part number of CU-2111-B to house all pump internal components.

3.2 Implementation/Manufacturing/Testing

In selecting optimal features from other irrigation pumps and combining those features to create a concept for a single pump that fits both the technical and user needs, it was necessary to examine the existing products in the market and determine the desirable features of these individual pumps with their flow rates. A summary of flow rates of current products available in the market are compiled in Table IV.

TABLE IV
FLOW RATES OF CURRENT PRODUCTS ON THE MARKET

Flow Rate ml/min	Meditron Univeral Generator Irrigator	Olympus Flushing Pump w/ olympus tubing	Olympus Flushing Pump w/100130	ERBE EIP-2	Vira Pump
Low	300	25	100	95	900
Medium	590	200	400	245	900
High	918	250	500	490	900

The next phase was researched the motor to provide desired flow rate based on the information gathered from the first phase of the project; and the data are presented in Table V.

TABLE V
MOTOR USED IN CURRENT PUMPS ON THE MARKET

Pump	Meditron EL-100C	ERBE EIP-2	Olympus OFP	ViraPump
Type of Motor	DC Motor	DC Motor	DC Motor	DC Motor
Input Voltage	12V	24V	12V	120V
RPM	3600 RPM	3100 RPM	2500 RPM	1550 RPM

The motor and gear box that met design specifications were finally purchased after comparing prices among different vendors. Several simple fixtures were made to assemble the pump in order to test the flow rate when the motor and gearbox were

arrived. Since the motor is a DC input device, a power supply was bought to do the test. According to the motor's specifications, the maximum voltage input is 24V DC and with that the flow rate is about 700ml/min (higher than the competitors, OFP and ERBE, their flow rates are about 500ml/min and 400ml/min respectively). The simple structure of the pump is shown in Fig. 12.

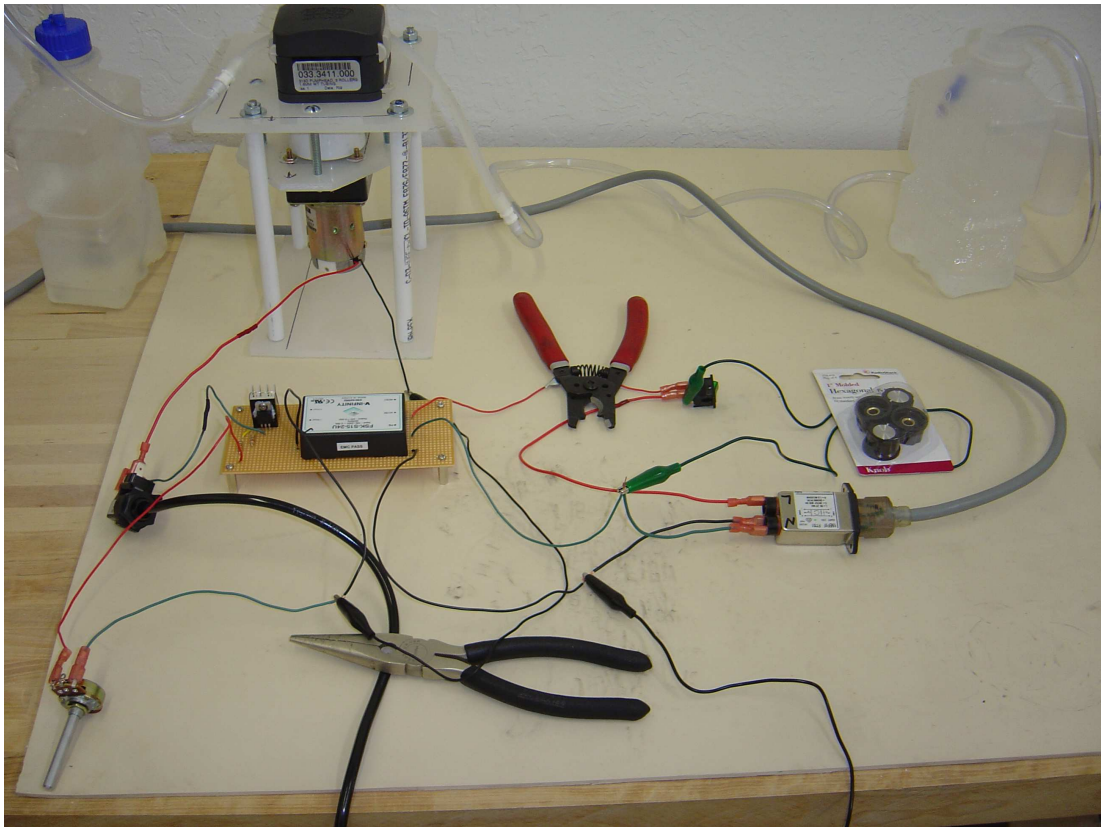

Fig. 12. A Simple Pump to Test the Motor.

While the simple model of the pump has assembled, electrical components for motor speed controller to properly control the motor speed and desired flow rate were under investigation and selection process.

All the electrical components were wired on a breadboard to test if the motor speed control board would function properly as designed. The speed control board is shown in Fig. 13 and the wiring of power switch is shown in Fig. 14.

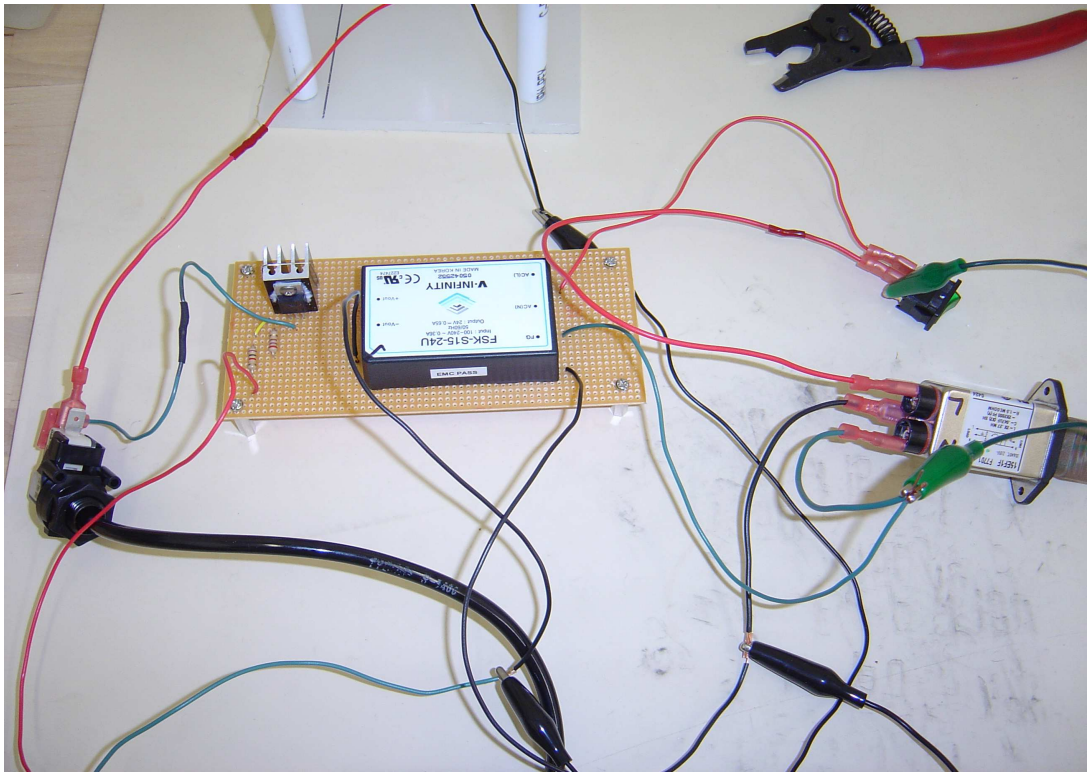

Fig. 13. A Simple Speed Control Board.

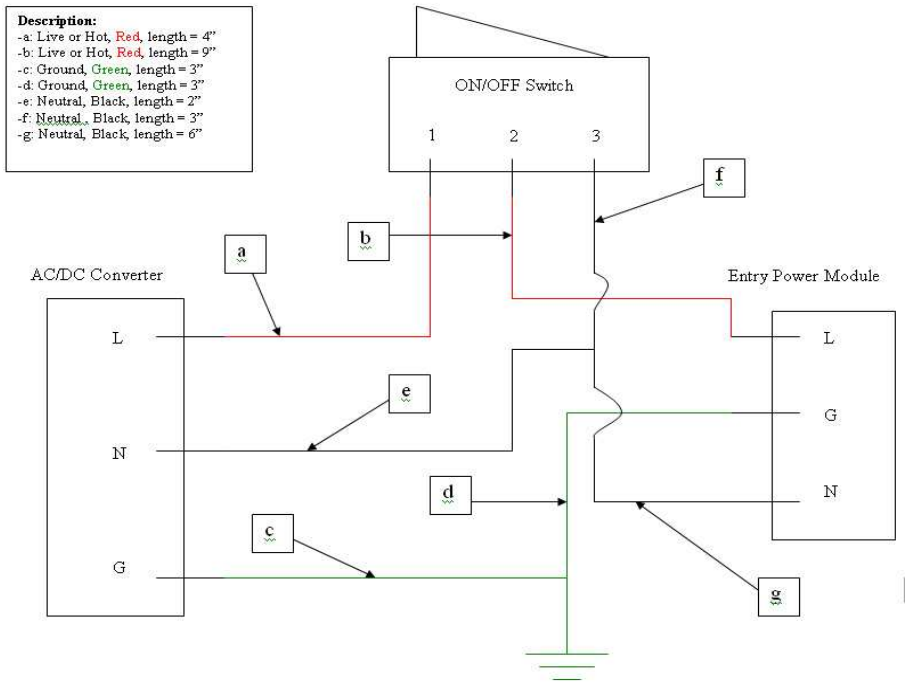

Fig. 14. Wiring of the Power Switch, Power Supply and AC/DC Converter.

After validating that the board was functioning within specifications, the controller was miniaturized by soldering the components onto a circuit board. The prototype was completed when all the necessary components were assembled and placed into the aluminum casing and tested to ensure proper operation. The first working prototype is shown in Fig.15 and 16, and the cost of the first working prototype is shown in Table VI. Dimensions of the first working prototype was 12”W x 7”H x 4”D.

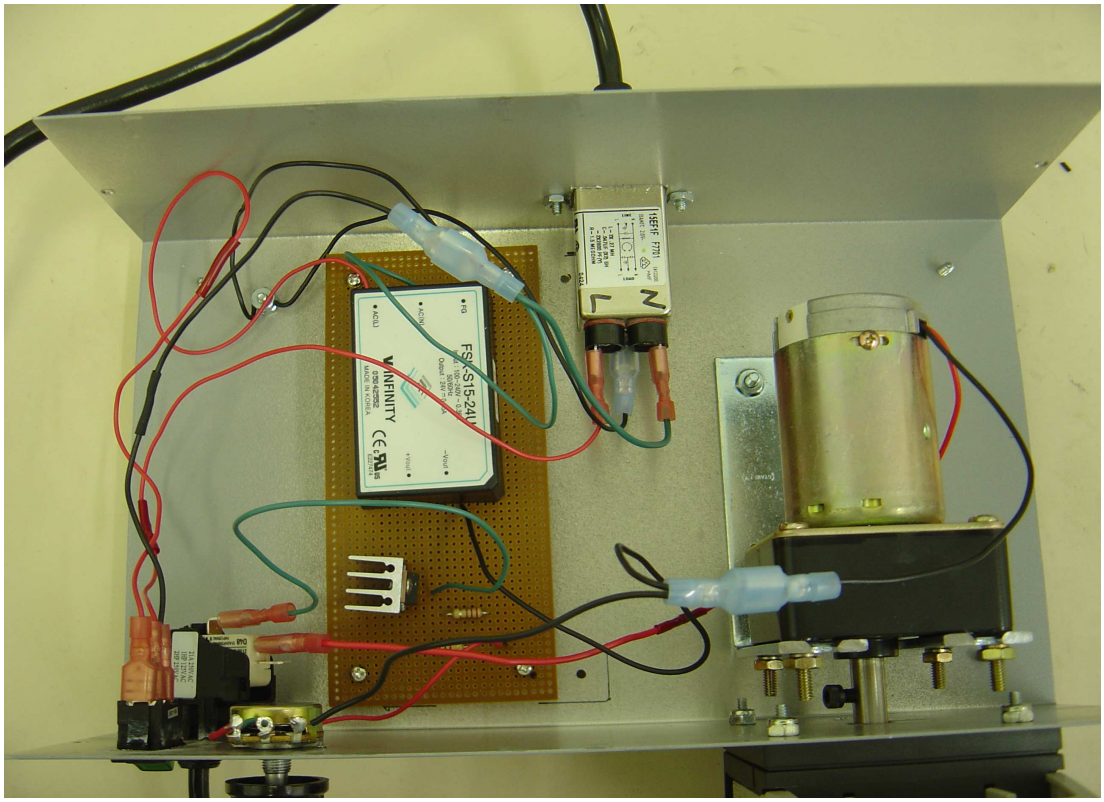

Fig. 15. The Interior Appearance of the First Working Prototype.

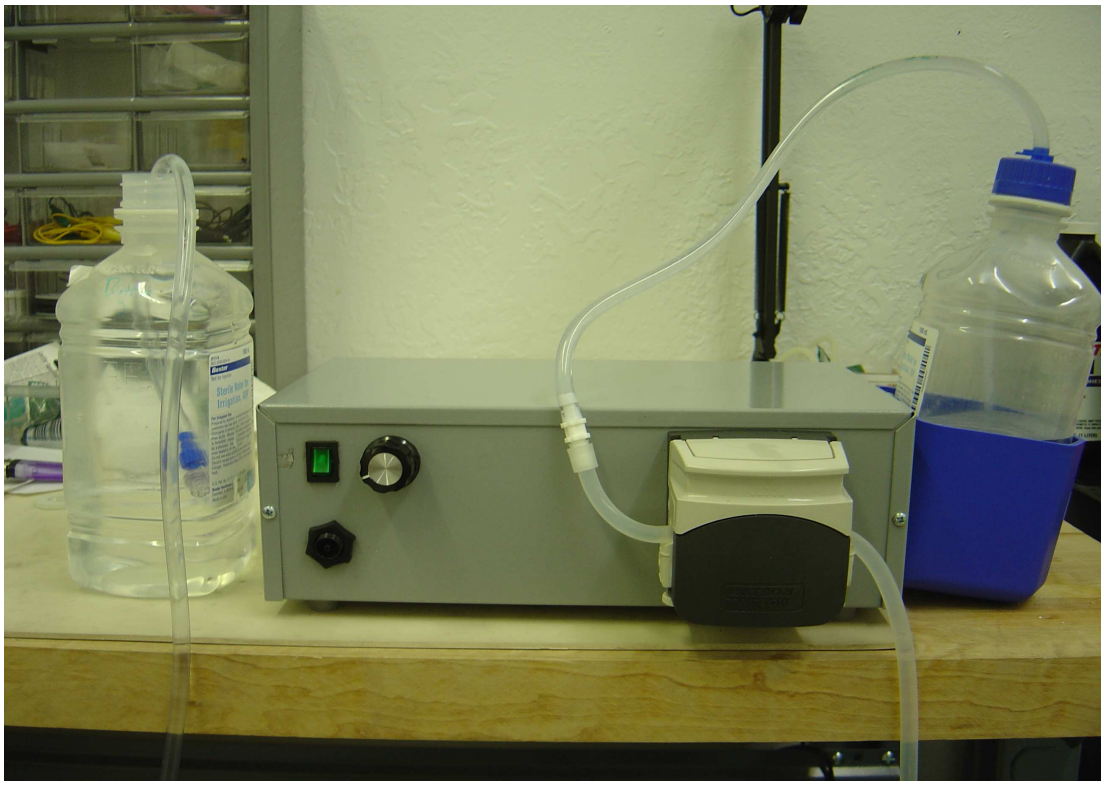

Fig. 16. The Exterior Appearance of the First Working Prototype.

TABLE VI
BUDGET FOR THE FIRST WORKING PROTOTYPE

Parts	Distributor Part Number	Distributor	Quantity	Price
Motor	DME 44 B6 HPB	Japan Products Corp	1	74.45
Gearbox	6DG 12.5-21	Japan Products Corp	1	33.40
Pump head	313D	Watson Marlow	1	157.00
AC/DC Converter	102-1167-ND	Digi-Key	1	43.06
Rocker Switch	401-1292-ND	Digi-Key	1	1.41
Power Entry Module	CCM 1636-ND	Digi-Key	1	20.34
Potentiometer 5K	2711714	RadioShack	1	2.89
Control Knob	2740416	RadioShack	1	0.83
Air Switch	6871-0C	Herga	1	5.95
Footswitch Pedal	from unused part in-house, estimated price		1	50.00
Voltage Regulator	2761778	RadioShack	1	2.29
Circuit Board	2761395	RadioShack	1	2.59
Heatsink	2761368	RadioShack	1	1.69
Housing	377-1086-ND	Digi-Key	1	32.70
Shaft adaptor	made by machinist in CA		1	18.00
Miscllaneous				5.00
			Total	451.60

After validating the first prototype was functioning according to specifications, Byrne Medical wanted their new product, EGP-100, to be small and lightweight in design; hence, changes in components were made accordingly. The first major change was the motor, instead of using a DC motor with brush (DME 44 B6 HPB), a brushless DC motor was selected (AXHM 15K-05). The AXHM 15K-05, manufactured by Oriental Motor, is a brushless DC motor adopting a thin, high torque motor and a 24 volt DC

open case type high-precision drive. Fig. 17 and Table VII [8] show the AXHM 15K-05 motor manufactured by Oriental Motor and its specifications, respectively.

Fig. 17. AXHM 015K-05 Brushless DC Speed Control System.

TABLE VII
ORIENTAL MOTOR AXHM 015K-05 BRUSHLESS SPEED CONTROL SYSTEM

Gearmotor — Torque Table (Geared Type/Combination Type) Unit = Upper values: lb-in/Lower values: N-m

Model	Speed Range * r/min	20~500 (20~600)	10~250 (10~300)	6.7~167 (6.7~200)	5~125 (5~150)	3.3~83 (3.3~100)	2~50 (2~60)	1~25 (1~30)	0.5~12.5
	Gear Ratio	5	10	15	20	30	50	100	200
AXH015K-□		2.0 0.23	3.9 0.45	6.0 0.68	7.6 0.86	11.5 1.3	17.7 2.0	17.7 2.0	—

As this brushless motor comes with speed control system, the speed control board was also eliminated. The original potentiometer and scale dial were also replaced by the products manufactured by **Oriental Motor** since they are designed for use with one other. Using **Oriental Motor**'s potentiometer and control knob eliminated a compatibility problem.

The Oriental AXHM 015-05 motor provides one of the most important features to make Byrne's medical pump stands out in the market with its run/brake control which stops the motor instantaneously. The advantage of AXHM 15K-05 includes:

1. compact size
2. brushless DC speed control motor and board-level driver packages provide space savings,
3. high power output
4. cable protected leads with connector for fast and convenient connection.

The second working prototype was fabricated with incorporation of this new DC speed control motor (Fig. 18 and 19).

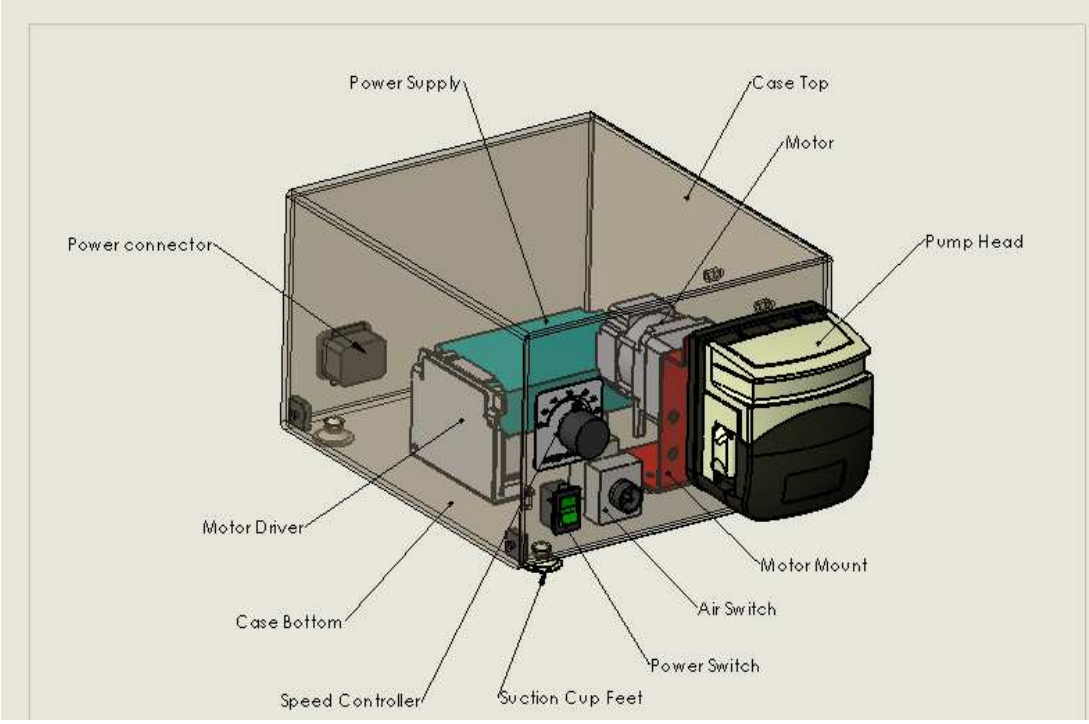

Fig. 18. The Placement of Each Component of the EGP-100 Irrigation Pump.

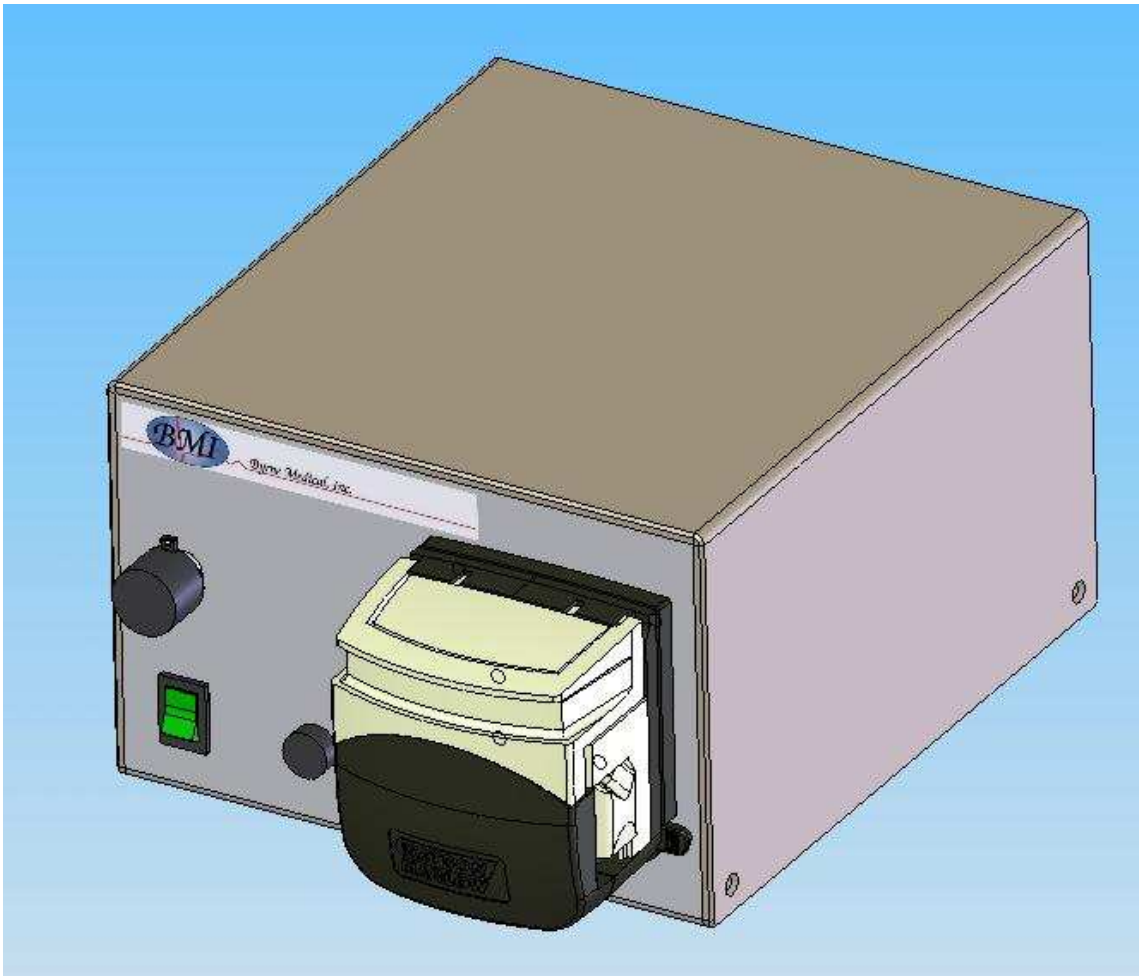

Fig. 19. The Final Appearance of EGP-100 Irrigation Pump.

TABLE VIII
COST FOR THE SECOND PROTOTYPE

Parts	Manufacturer Part Number	Manufacturer	Quantity	Price
Motor Gearbox	AXHM15K-05	Oriental Motor	1	317
Pump head	313D	Watson Marlow	1	162
AC/DC Converter	FSK-S15-24U	V-Infinity	1	43.06
Rocker Switch	DA102J3GS215QF7	IIT Industries	1	1.41
Power Entry Module	15EF1F	Corcom	1	14.04
Potentiometer 20K Control Knob	PAVR-20KZ	Oriental Motor	1	15
Air Switch	6871-OCO-U126	Herga	1	5.95
Footswitch Pedal	6448-ABAB	Herga	1	8.95
Circuit Board	2760158	RadioShack	1	3.29
Housing	CU-3009-A	Bud Industries	1	14.1
Shaft adaptor	made by machinist in CA		1	18
Mounting Bracket	SOL0B	Oriental Motor		23
Miscellaneous				5
			Total	630.8

The cost for the second prototype (Table VIII) was substantially higher than the first because the cost of AXHM 15K-05 motor was higher than the first motor. However, the cost will decrease to approximately four hundred dollars each when motors are ordered in large quantities. The result of flow rate testing for the EGP-100 is presented in Table IX. The test was done by using 5 sets of tubing (same bore size) with each set consisting of five tubing sets. The resulting flow rate met and exceeded the required specifications defined during the design phase.

TABLE IX
FLOW RATE OF EGP-100

12/29/2005

	RUNS	lb/ 20sec	ml/min
SET 1	1	0.46	627.27
	2	0.46	627.27
	3	0.46	627.27
	4	0.46	627.27
	5	0.44	600.00
SET 2	6	0.46	627.27
	7	0.46	627.27
	8	0.46	627.27
	9	0.46	627.27
	10	0.46	627.27
SET 3	11	0.44	600.00
	12	0.46	627.27
	13	0.44	600.00
	14	0.46	627.27
	15	0.46	627.27
SET 4	16	0.46	627.27
	17	0.46	627.27
	18	0.46	627.27
	19	0.44	600.00
	20	0.46	627.27
SET 5	21	0.46	627.27
	22	0.46	627.27
	23	0.46	627.27
	24	0.46	627.27
	25	0.46	627.27
	Average	0.46	621.82

4. FUTURE IMPROVEMENT

Physicians in the GI (Gastroenterology) suites prefer an irrigation pump that rotates backward when they turn the power off, i.e. when they release the footswitch, to prevent the sterile water from dripping. To meet this specification, extensive literature research was conducted plus Oriental Motor was consult. After several productive discussions with Mr. John Wong, a Senior Engineer at **Oriental Motor**, a Multi-function Timer (model H3DE-M2) manufactured by **Omron** was selected to achieve the goal. H3DE-M2 is a DPDT (Double Pole Double Throw) Timer which meets the design criteria perfectly. A working prototype (previously fabricated) was tested with this DPDT timer and the result proved the improvement was achievable. Fig. 20 is the schematics of the wire connection of the DPDT and Fig. 21 shows the wiring to the potentiometer provided by Oriental Motor. A picture of the testing is shown in Fig. 22.

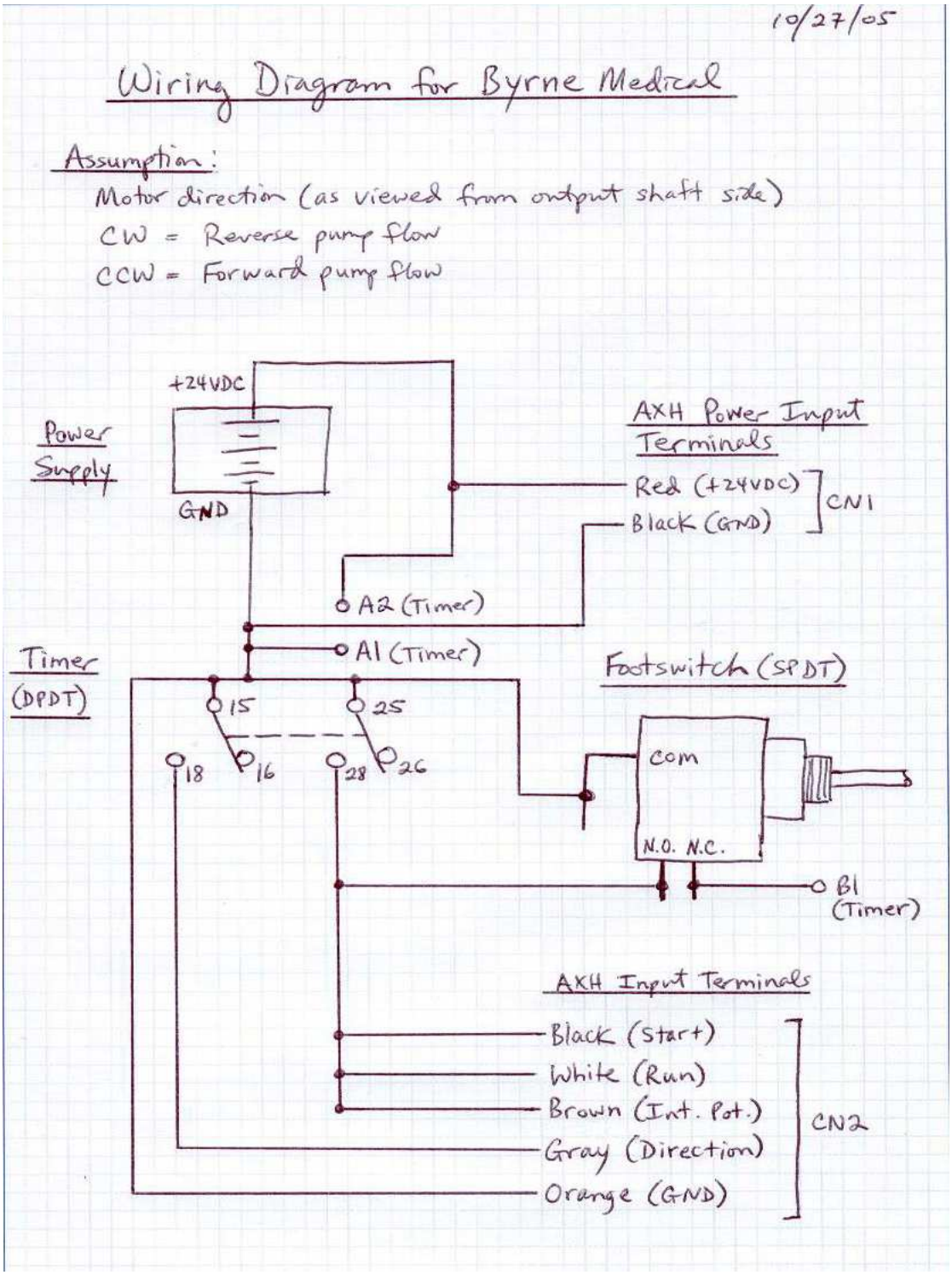

Fig. 20. Wiring Diagram for the DPDT.

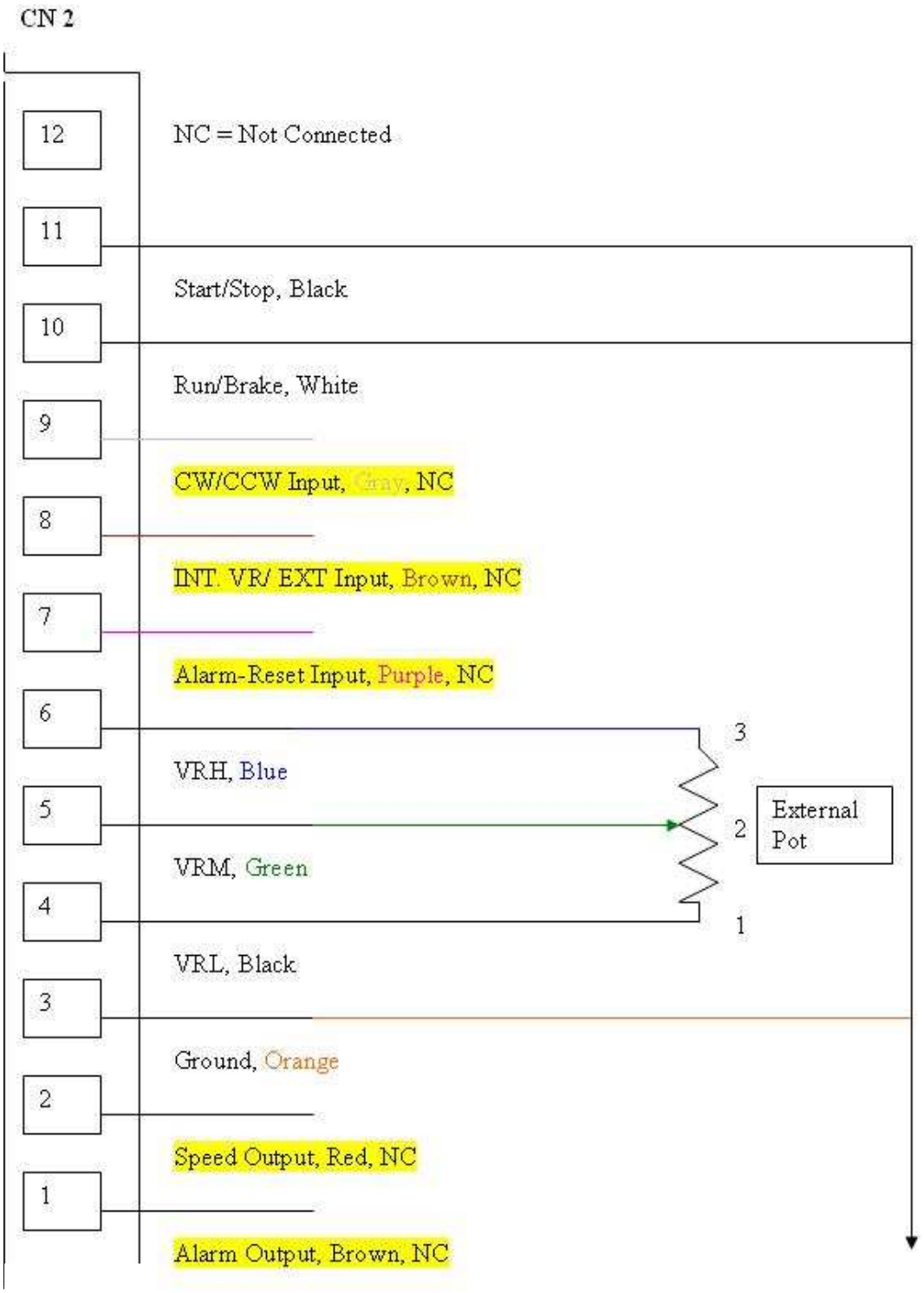

Fig. 21. Detail Wiring for the Potentiometer.

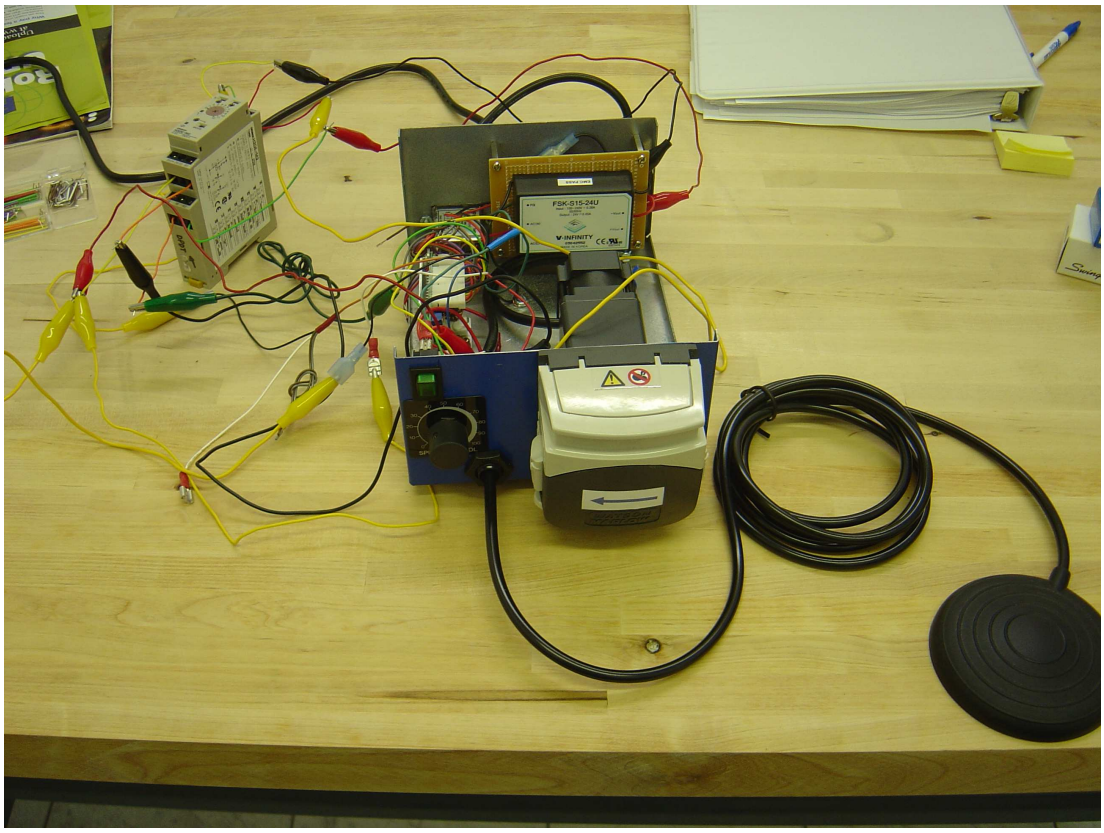

Fig. 22. A Working Prototype with DPDT.

Byrne Medical, Inc, would decide how to implement and incorporate this timer into the second generation casing of their EGP-100.

5. PREPARATION FOR 510(K)

In order to sell the medical device (EGP-100) product in the US market, FDA approval is required; hence, documentation for a 510(K) was prepared from the beginning of the project. The preparation for a 510(K) is a lengthy process; the author's contribution was significant through out the duration of his eight month's internship. All the information, from the design phase to the validation phase, was collected and documented, thus, allowing Byrne Medical to use this for the 510(K) approval. A typical 510(K) premarket notification contains the following contents in the application package:

Section 1 - Medical Device User Fee Cover Sheet (Form FDA 3601)

Section 2 - CDRH Premarket Review Submission Cover Sheet

Section 3 - 510(k) Cover Letter

Section 4 - Indications for Use Statement

Section 5 - 510(k) Summary or 510(k) Statement

Section 6 - Truthful and Accuracy Statement

Section 7 - Class III Summary and Certification (not applicable)

Section 8 - Financial Certification or Disclosure Statement

Section 9 - Declarations of Conformity

Section 10 - Executive Summary

Section 11 - Device Description

Section 12 - Substantial Equivalence Discussion

Section 13 - Proposed Labeling

Section 14 - Sterilization and Shelf Life (not applicable)

Section 15 - Biocompatibility

Section 16 - Software (not applicable)

Section 17 - Electromagnetic Compatibility and Electrical Safety

Section 18 - Performance Testing – Bench

Section 19 - Performance Testing – Animal (not applicable)

Section 20 - Performance Testing – Clinical

A sample 510(K) submission is attached in the Appendix A. The complete documentation of Byrne Medical's 510(K) is not included in this Record of Study because of its proprietary information.

6. PROJECT MANAGEMENT

The EGP-100 project was easy to manage, especially during the pump design and prototype fabrication phases, as it was an individual project. At the beginning, the project was divided into 4 distinct phases: Technical Analysis, Design, Fabrication and Validation, for easy management. A Gantt Chart is attached in the Appendix B. Project management for the pump project was achieved and managed by the President of Byrne Medical. The target date for the first EGP-100 to be available in the market was the end of May 2006. FDA approved the EGP-100 and it has been on the market since early June 2006.

7. LESSON LEARNED

The author liked the project that he worked on because this is a device that is

a) actually needed and

b) could improve the safety of a medical procedure.

Projects will be more interesting when you are aware that your final product might have some real world usefulness. He enjoyed working with Byrne Medical and learned a lot about what a product development engineer working in the industry actually does. This was knowledge not gained in any of his engineering courses. Coming up with his prototype designs seeing that this really works has probably been the most exciting part of the project. He realized that to make a successful prototype the team has to consider different designs and possibly integrate different elements of each to come up with a truly successful design.

Regarding project management, he learned that this involved an incredible amount of communication between colleagues as well as with the company's superiors. He also discovered the fact that for a project to be successful it required adhering to a strict schedule as closely as possible. Also, it is important to have a plan in case something goes wrong such as a delay in getting an essential component.

While working on the pump project and others, the author had opportunities to interact with colleagues in other departments to get things accomplished. He learned that good

communication is important to complement the management techniques by improving his ability to foster a friendly environment with other workers and convey ideas effectively. Dawn Burks, his internship supervisor, taught him the importance of forward thinking from day one when he joined Byrne Medical. A product development engineer not only needs to design and build a device that works, but also he needs to think forward (e.g. how to design the device ease of manufacturing so that easy for assembly workers to assemble) – this is important as it is how engineers make both employer and fellow colleagues happy and create a harmonious work environment.

8. CONCLUSION

Finishing this internship fulfilled a part of the requirements for the Doctor of Engineering Program at Texas A&M University. The following were the author's objectives and accomplishments and/or contributions:

1. To demonstrate and enhance his abilities and to apply the knowledge gained from technical training in making a significant contribution or practice concern to Byrne Medical, Inc. and the medical device industry:
    - This objective was fulfilled by working on the EGP-100 (medical irrigation pump) project. The objective of the project was to design and fabricate a working prototype of a medical irrigation pump to be used for endoscopic procedures in the hospitals and/or medical environments, since current pumps designs do not satisfy physicians' needs. By manufacturing their own pump, Byrne Medical would be able to select all the positive features they see in other pumps and combine those features to make a single pump that fits both the technical and user needs. The author had an opportunity to make contributions in the areas of appearance, size, usability, product life, and ability to vary motor speed and therefore flow rate. A working prototype was important for Byrne Medical since it would give them a new business opportunity – their first electro-mechanical product. By the time he left the company, three

working prototypes were designed, fabricated, and flow tested. These prototypes have shown promising features that Byrne Medical specified from the beginning of the project.

2. To enable him to function in a nonacademic environment and become familiar with the organizational approach to problems in addition to traditional engineering design or analysis, for instance, problems of management, environmental protection, labor relations, public relations and economics, and

    - While working on the pump project and others, he had an opportunity to interact with colleagues in other departments to get things done. I learned that good communication is a key to complementing the management techniques by improving his ability to foster a friendly environment with other workers and convey ideas effectively. Dawn Burks, his internship supervisor, taught the importance of forward thinking from day one when he joined Byrne Medical. An R&D engineer not only needs to design and build a device that functions properly, but he must also think forward (e.g. how to design the device easy for assembly workers to assemble) – to make both employer and fellow colleagues happy.

3. To be familiar with the federal regulatory guidelines on medical devices such as FDA 510(k) and current Good Manufacturing Practices (cGMP) Requirements.
    - Along with working on the pump project, he composed documents for master records and technical files for FDA 510(K) exemption with the guidance of Krista Oakes from Amica Solutions. The current Good Manufacturing Practices (cGMP) were reviewed during the first two weeks of internship and revised occasionally during the internship.

During the internship, the author had opportunities to attend the Management Review Meeting and Material Review Board Meeting several times, and learned the structures of management team at Byrne Medical and how they collaborate with each other to run their business. He believes that good management skill is an essential element. To facilitate the design work, Byrne Medical sponsored his attending the SolidWorks courses (Essentials and Advanced Part Modeling) in Houston and obtained certificates for both courses. With the knowledge in SolidWorks, it makes the design work and CAD drawings easier and faster, especially when the design needs to be reviewed and modified. He was able to manage the project and finished it in a timely fashion after a timeline was developed and followed. However, he didn't get to manage people as he was the only one working on the project. This made it much easier to follow the schedule.

REFERENCES

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APPENDIX A

Byrne Medical Irrigation Pump
510(k) Premarket Notification

Contents

Section 1 - Medical Device User Fee Cover Sheet (Form FDA 3601)

The Medical Device User Fee Form may be obtained at www.fda.gov/oc/mdufma/coversheet.html. See also **Guidance for Industry and FDA Staff – User Fees and Refunds for Premarket Notification Submissions (510(k)s)** at www.fda.gov/cdrh/mdufma/guidance/1511.html.

Section 2 - CDRH Premarket Review Submission Cover Sheet

See: www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf for the cover sheet

Section 3 - 510(k) Cover Letter

<on a separate page, on company letterhead, print the following>

<Date>

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

Re: 510(k) Premarket Notification

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, our firm is notifying FDA of our intent to market a non-sterile, software-controlled irrigation pump for endoscopy/gastroenterology procedures.

The principal factors and use of our device is described as follows:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		No
Does the device contain components derived from a tissue or other biologic source?		No
Is the device provided sterile?		No
Is the device intended for single use?		No
Is the device a reprocessed single use device?		No
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		No

Does the device contain a biologic?	No
Does the device use software?	No
Does the submission include clinical information?	No
Is the device implanted?	No

Information required by 21 CFR 807.90, and recommended by appropriate FDA guidance documents, is included within this premarket notification. If any additional information is required, please contact Chris Meador, Regulatory Affairs Manager, at the following contact information:

Byrne Medical Inc.

2021 Airport Road

Conroe, TX 77301

Telephone: (936) 539-0391

Facsimile: (936) 539-0392
Email: cmeador@byrnemedical.com.

We look forward to your reply.

Regards,

Chris Meador

Regulatory Affairs Manager

Section 4 - Indications for Use Statement

I.

Indications For Use:

For general irrigation during flexible endoscopy within a healthcare environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use

(Per 21 CFR 801.109)

Indications for Use

510(k) Number (if known): _____

Device Name: Irrigation Pump

Indications for Use:

Irrigation and removal of debris during endoscopy/gastroenterology procedures

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 - 510(k) Summary or 510(k) Statement

510(k) Summary

Submitter Information
Byrne Medical, Inc.
2021 Airport Road
Conroe, TX 77301

Contact
<name, telephone, fax>

Date Prepared
<date>

Product Name
Byrne Medical Irrigation Pump

Predicate Device
<name & 510k reference>

Product Description

Intended Use

Comparison to Predicate Device
<insert comparison matrix>

II.

Performance Data & Conclusions

Section 6 - Truthful and Accuracy Statement

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as <position> of <company>, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____ _____

<name> <date>

Section 7 - Class III Summary and Certification (not applicable)

Section 8 - Financial Certification or Disclosure Statement – not applicable

Section 9 - Declarations of Conformity

The subject devices meet applicable sections of the following standards:

Standard	Deviations	Test Laboratory or Certification Body

Section 10 - Executive Summary

Description

Indications for Use

Device Comparison Table
<insert comparison table>

Summary of Testing

Section 11 - Device Description

We recommend that you describe the performance specifications and include a brief description of the device design requirements in this section. We also recommend that you identify all models, as well as all accessories or components, included in the submission.

If diagrams, dimensions, tolerances, and/or schematics are useful to fully describe and characterize the device, we recommend that you include them for each device, accessory or component included in the 510(k) submission. We also recommend that you provide a list of all patient contacting components and their respective materials.

Section 12 - Substantial Equivalence Discussion

These devices are substantially equivalent to the following:

510(k) Reference	Description	Submitted By

A comparison of devices is provided below:

	<Subject Device>	<Predicate>	<Predicate>
Intended use			
Patient population			
Dimensions			
Weight			
Max. Vacuum			
Suction bottle description			
Pump type			
Microbial exhaust filter			
Vacuum gauge			
Suction bottle/bag overflow protection			
Power supply			
Power consumption			
Suction bottle capacity			
<other features as appropriate>			

<add any discussion of major similarities and differences, and how differences do not raise new safety/effectiveness questions>

Section 13 - Proposed Labeling

<add labeling, including instructions for use, product labels, and (if available) promotional materials>

Section 14 - Sterilization and Shelf Life

For devices sold as sterile, we recommend that you follow the guidance, Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA , at www.fda.gov/cdrh/ode/guidance/361.html.

For devices that are reprocessed single use devices, please refer to **Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices** at www.fda.gov/cdrh/ode/guidance/1216.html.

For a submission that identifies a shelf life for the device, your shelf life should be supported by appropriate bench tests and/or sterilization (packaging) validation.

Section 15 - Biocompatibility (not applicable)

Section 16 - Software

This section should include the appropriate software documentation as described in the guidance titled Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices at www.fda.gov/cdrh/ode/337.html. As discussed in the guidance, we recommend that you identify the "level of concern," (minor, moderate, or major) associated with your device and provide documentation consistent with that level.

Section 17 - Electromagnetic Compatibility and Electrical Safety

This device has been tested for electromagnetic compatibility and electrical safety in accordance with EN 60601-1 and EN 60601-1-2.

Section 18 - Performance Testing – Bench

list the specific bench tests conducted

- describe each test protocol
- summarize the results
- describe your analysis
- discuss your conclusions

The description of test protocols should identify the:

- objective of the test
- test articles used in the test
- test methods and procedures (including any specific test conditions)
- study endpoint, i.e., the specific parameter measured
- pre-defined acceptance or pass/fail criteria.

In the summary of your results and analysis, we recommend that you briefly present the data derived from testing in a clear and concise form, such as a table.

We also recommend that your conclusions describe any comparison testing with the predicate in terms of substantial equivalence.

Section 19 - Performance Testing – Animal (not applicable)

Section 20 - Performance Testing – Clinical (not applicable)

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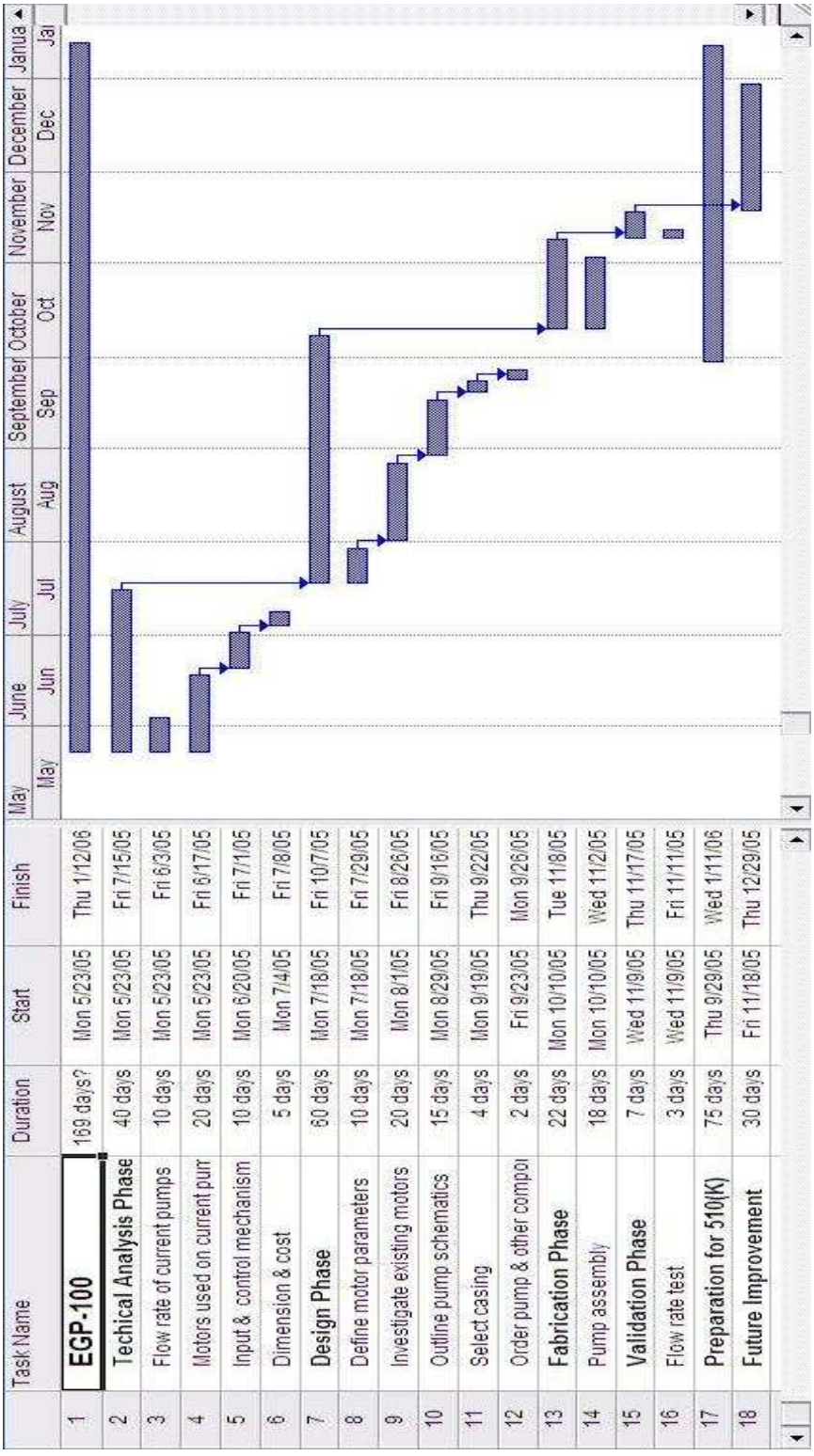
APPENDIX B



	Task Name	Duration	Start	Finish
1	**EGP-100**	169 days?	Mon 5/23/05	Thu 1/12/06
2	**Techical Analysis Phase**	40 days	Mon 5/23/05	Fri 7/15/05
3	Flow rate of current pumps	10 days	Mon 5/23/05	Fri 6/3/05
4	Motors used on current purr	20 days	Mon 5/23/05	Fri 6/17/05
5	Input & control mechanism	10 days	Mon 6/20/05	Fri 7/1/05
6	Dimension & cost	5 days	Mon 7/4/05	Fri 7/8/05
7	**Design Phase**	60 days	Mon 7/18/05	Fri 10/7/05
8	Define motor parameters	10 days	Mon 7/18/05	Fri 7/29/05
9	Investigate existing motors	20 days	Mon 8/1/05	Fri 8/26/05
10	Outline pump schematics	15 days	Mon 8/29/05	Fri 9/16/05
11	Select casing	4 days	Mon 9/19/05	Thu 9/22/05
12	Order pump & other compol	2 days	Fri 9/23/05	Mon 9/26/05
13	**Fabrication Phase**	22 days	Mon 10/10/05	Tue 11/8/05
14	Pump assembly	18 days	Mon 10/10/05	Wed 11/2/05
15	**Validation Phase**	7 days	Wed 11/9/05	Thu 11/17/05
16	Flow rate test	3 days	Wed 11/9/05	Fri 11/11/05
17	**Preparation for 510(K)**	75 days	Thu 9/29/05	Wed 1/11/06
18	**Future Improvement**	30 days	Fri 11/18/05	Thu 12/29/05

APPENDIX C

Protocol #

Date:

Testing protocol for Olympus auxiliary water port (part number: 100115)
Study to be performed by Lui Cheng and Rusty Smith of the R&D.

1.0 **Purpose:** To design a stronger auxiliary water port fitting and to eliminate the reinforcement of an applied cable tie in the original product.

2.0 **Anticipated design change:** To replace the existing connector and cable tie configuration with a more aggressive barbed fitting and locking collar, further reducing the opportunity for water leakage during use.

3.0 **Equipment:** Pressure gauge, Olympus Flushing Pump (OFP), original OFP tubing.

4.0 **Product samples:** Olympus auxiliary water port (finished product, part number: 100115).

5.0 **Pressure test methodology:** Two groups, original design and new proposed design, of auxiliary water port will be sampled and each group will have 5 samples. The original OFP tubing along with the OFP pump will be used to determine how much pressure the Olympus auxiliary water port fitting (both new proposed design and original design) can withstand. The auxiliary water port tubing will attach to one end of the pressure gauge and the other end will be connected to the original OFP tubing. Water will be pumping through the original OFP tubing, the pressure gauge and the Olympus auxiliary water port. The port will be blocked to let the pressure build up inside the tubing and the maximum of pressure the tubing could stand will be determined by visually observing the pressure gauge reading. The effect, due to the pressure building up inside the tubing, to the product will be studied.

6.0 **Result:** For the new proposed design have a larger and more aggressive barbed fitting and a locking collar. We expect the new auxiliary water port will be able to sustain a higher pressure than the original design, and with no water

leakage. The benchmark will be set at 40 psi which is 10 psi higher than the maximum pressure of the Olympus Flushing Pump can generate.

7.0 See Attachment A for drawing of original design of 100115
See Attachment B for new proposed new design of 100115

APPENDIX D

Reference Protocol #

Date:

Testing result of the protocol for Olympus auxiliary water port (part number: 100115)

Protocol results: Pressure test has been conducted based on the method described in the "Pressure test methodology" section, and test has been done on 5 samples of each group.

Original Design

During the test, the original auxiliary water port fitting could withstand the pressure up to 80 psi. When the pressure reached at 80 psi or higher, the water port was pressurized to move outward and stopped at the cable tie (see Fig. D-1 and D-2). At the test, one sample (out of five) of the original design was actually blown off after several trials. Also, water tends to leak at the v-section of the cable tie since it is not completely circular around the tubing.

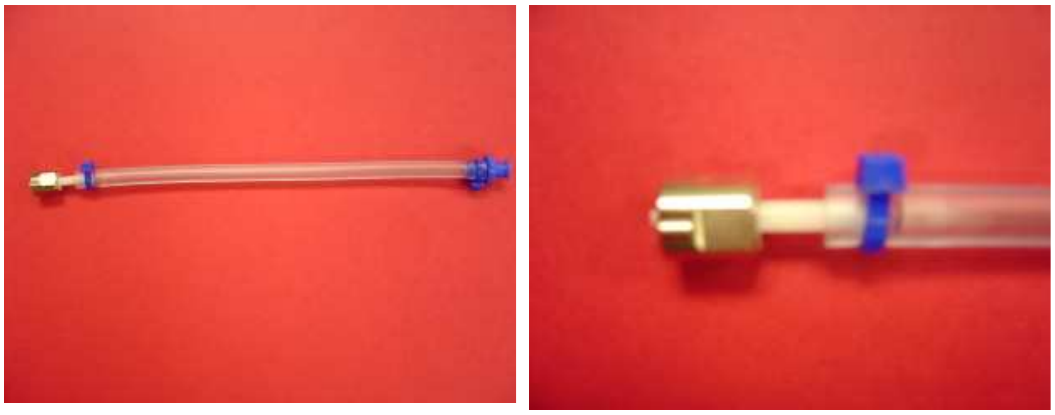


Fig. D-1 and D-2. The auxiliary water port fitting after the pressure test.

New Proposed Design

The new auxiliary water port fitting could withstand a higher pressure (higher than 100 psi, see Attachment C, column 5) with a very slight movement of the port (see Fig. D-3 and D-4) when pressure reached above 90 psi with no water leakage (see Attachment C, column 3).

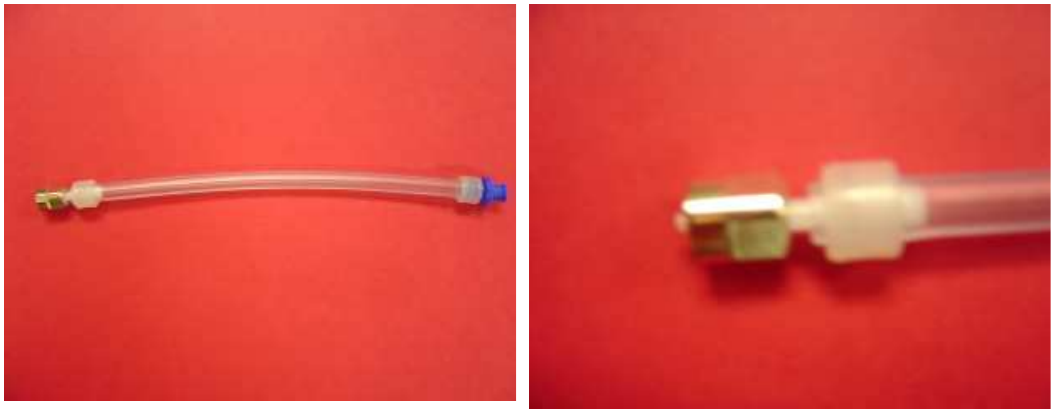


Fig. D-3 and D-4. The new auxiliary water port fitting after the pressure test.

Recommendation: Both new and original products exceeded the benchmark that was set for the pressure test. However, the new auxiliary water port fitting is a better product and meets our technical specifications. The new auxiliary water port can withstand a higher pressure and would not be blown off under proper usage. Therefore, replace the original cable tie method with the new barbed connector and locking collar configuration for all future work order.

Change authorized by:

_____ _____

(Lui Cheng, R&D) Date

_____ _____

(Rusty Smith, R&D Manager) Date

TABLE D-I

THE RESULT OF PRESSURE TEST OF ORIGINAL AND NEW DESIGN AUXILIARY WATER FITTINGS

Pressure Test Result of auxiliary water port fitting				
Unit: PSI				
	Pressure to move the fitting		**Pressure the fitting withstands**	
Sample	**Original**	**New**	**Original**	**New**
1	76	91	88	100
2	78	93	90	100
3	75	94	87	100
4	79	92	91	100
5	78	91	89	100

Note: The maximum reading from the pressure gauge is 100 psi, and the pressure the new auxiliary water port fitting could withstand was higher than 100 psi when the test was conducted.

APPENDIX E

Protocol # (ECN 052-05)

Date:

A protocol to test the (part number: 100116)

Study to be performed by Lui Cheng and Rusty Smith of the R&D.

1.0 **Purpose:** To test the new proposed design

2.0 **Anticipated design change:** To replace the existing (BMP-016), which have the elbow barb fitting creates high pressure at the junction and might cause water leakage during use with Pentax scope. The new proposed design replaces the elbow barb fitting with a straight one which significantly reduces the pressure at the junction when connected with the scope. Hence there will be no leakage problem.

3.0 **Equipment:** Meditron Universal Generator-Irrigator (model UGI-3000), Olympus Flushing Pump, male-male luer connector (made in house), Pentax scope (EC-3830L), an analog pressure gauge, (100125) and (100130).

4.0 **Product samples:** (part: 100116).

5.0 **Test methodology:** Two groups of new proposed design (part #100116) will be tested and each group will have 20 samples. One group will be tested using Meditron Generator-Irrigator and another group will be tested using Olympus Flushing Pump (OFP), respectively.

The straight barb fitting of each sample will be hooked up to the Pentax Scope. The other end of the sample will be connected to the pressure gauge which is then connected to the (name) (part number:100125) for Meditron (part number:100130 for OFP).

We will test the new proposed design with Olympus® Flushing Pump, which could produce higher pressure than Meditron with maximum flow rate and determine if it could withstand the pressure and is there any water leakage.

6.0 **Expected result:** In general, the new proposed design with a straight barb fitting should withstand a higher pressure, maximum flow rate with no water leakage than the original design. The maximum operating pressure Meditron Universal Generator-Irrigator, under maximum flow with Pentax scope connected, is 34 PSI. Hence we will choose that as the benchmark for this protocol. The OFP could put out 42 psi when its flow rate goes to maximum. The new proposed design should also withstand 42 psi pressure and we will establish the 8 psi difference as an applicable safety window.

7.0 **See Original Drawing –** Attachment A.

See New Proposed Design Drawing – Attachment B.

APPENDIX F

Reference Protocol #

Date:

Protocol results:

Bench test has been conducted followed the methodology described in the protocol. Totally 40 samples were tested, half with Meditron Universal Generator-Irrigator and the other with Olympus Flushing Pump. The results are presented as follow and data is in Table F-I:

III. Meditron Universal Generator-Irrigator

Twenty samples of new proposed design were tested using Meditron Universal Generator. Each sample was running with maximum flow under maximum operating pressure, 34 psi, when connected with the Pentax scope for twenty seconds. Test results show that each sample withstood the pressure with no water leakage.

IV. Olympus Flushing Pump (OFP)

Since OFP outputs higher pressure when it runs at maximum speed, we would like to see if the new proposed design could sustain at higher pressure, 42 psi. Based on the result of the test, each sample of the new proposed design did not show any leakages when the pump is running with maximum flow and maximum operating pressure.

Conclusion

After testing the new proposed design with maximum flow under different maximum operating pressure (using two different pumps, Meditron and OFP). Each sample of this new proposed design did not show any leakages from the result. The new proposed design could sustain both 34 psi and 42 psi, pressure Meditron and OFP could output, respectively, with maximum flow rate.

Recommendation: Replace the original ( ) design with the proposed design in all applicable production orders.

Change authorized by:

_____ _____

(Lui Cheng, R&D) Date

_____ _____

(Rusty Smith, R&D Manager) Date

If applicable, ref ECN# _____

Reference Protocol #

Attachment C

TABLE F-I
THE RESULT OF BENCH TEST ON

	Meditron Universal	**Olympus**
	Generator-Irrigator	**Flushing Pump**
	34 PSI	42 PSI
	20 sec	20 sec
Samples	Max Flow	Max Flow
1	X	X
2	X	X
3	X	X
4	X	X
5	X	X
6	X	X
7	X	X
8	X	X
9	X	X
10	X	X
11	X	X
12	X	X
13	X	X
14	X	X
15	X	X
16	X	X
17	X	X
18	X	X
19	X	X
20	X	X

Note: X means no leakage

APPENDIX G

Protocol #: 001-05

Date: 05-02-2005

A protocol to test the tensile strength of the cap's nozzle (part number: BMP-016)

Study to be performed by Rusty Smith of the R&D.

8.0 **Purpose:** To find out the strength of the nozzle on the caps, the effect of applying different percentages of alcohol (70 % and 91%) on the nozzle during the assembly procedure, and determine whether or not the sterilization plays a role on the strength of the nozzle.

9.0 **Anticipated design change:** To replace the existing cap (BMP-016), which does not have any fillet or strengthening radius added to the cap and nozzle intersection at the outer diameter, with a new proposed design. The new proposed design includes a small fillet or strengthening radius added to outer diameter of the nozzle at the cap intersection to reinforce the strength of the nozzle.

10.0 **Equipment:** A digital force gauge (manufactured by Extech Instruments Co.) and an aluminum fixture (made in house).

11.0 **Product samples:** Caps (component, part number BMP-016)

12.0 **Tensile strength test methodology:** Two groups of caps, original design and new proposed design, are to be sampled. Each group will have 3 batches of caps and each batch will have 25 caps. For each group, one batch will contain the cap itself, one batch will have caps with (alcohol is used during the assembly process). These sterilized samples will arrive in two conditions, some will arrive in loose bulk and some will arrive in pouch as they are ready to ship to the end user. 10 caps will be randomly selected from each batch and tested. The selected sample (the cap) will be put on to an aluminum fixture which is mounted to the base of the stand to stabilize the cap. Compression force will be

exerted on the nozzle of the cap and the peak force (the maximum force to break the nozzle or deflect it) will be recorded.

13.0 **Expected result:** In general, the new designed cap should withstand a higher force than the original design and the nozzle should not be broken off under proper handling and/or usage. The maximum force that a person exerts on the nozzle when processing and handling the product is about 7.5 lb. So the benchmark for the cap with tubing will be set at 15 lb, two times the maximum amount of force a person would normally exert on the nozzle, establishing an applicable safety window.

APPENDIX H

Reference Protocol #: 001-05

Date: 07-11-2005

Protocol result of the tensile strength test of the cap's nozzle (part number: BMP-016)

Study is performed by Lui Cheng and Rusty Smith of the R&D.

Protocol results:

V. Non-sterilized

A. Original caps: Based on the result of tensile strength test, all the nozzles of the original caps (without tubing) broke (snapped) at an average force of 33.56 lb with a standard deviation of 3.56 (see Attachment C, Table 1 for the result data and Fig. H-1 and H-2 for the resultant caps after the test).

B. New proposed design caps: Instead of breaking, the new design deflected the applied force. The average force was deflected by the nozzle of the new proposed design was 29.86 lb with 1.92 of standard deviation (see Attachment C, Table 1 for the data and Fig. H-3 and H-4 for resultant caps after the test).

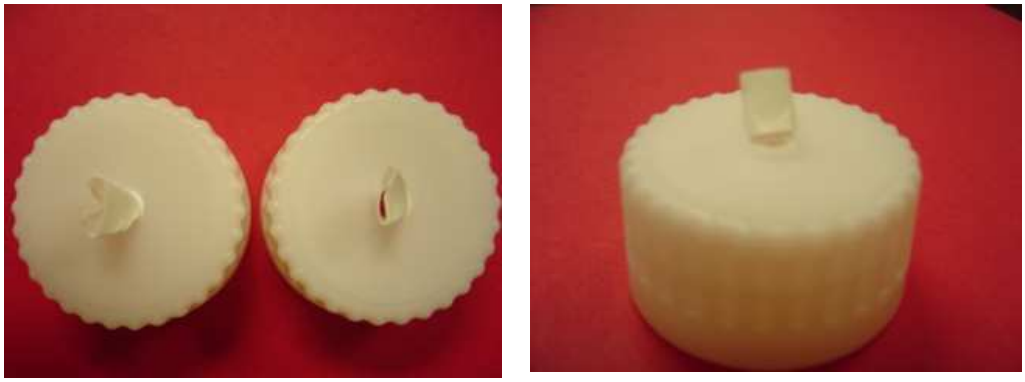


Fig. H-1 and H-2. Result of the original caps after the tensile test.

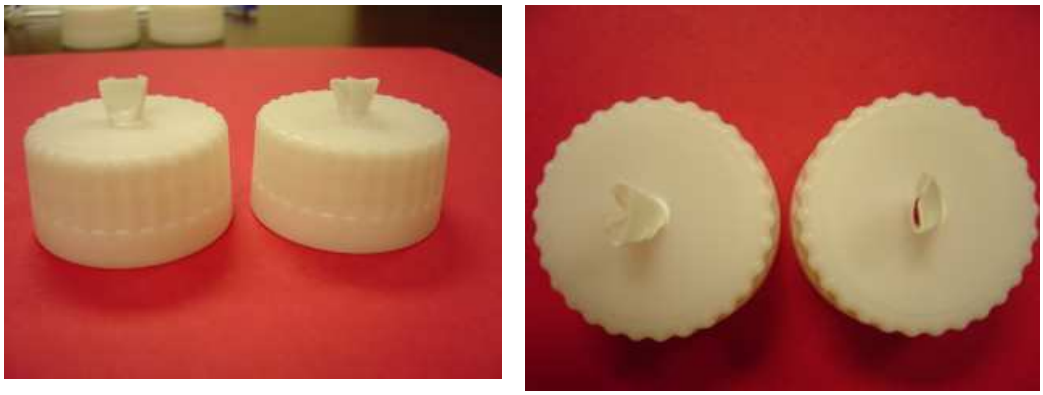


Fig. H-3 and H-4. Result of the new caps after the tensile test.

C. **Original caps with tubing (70% alcohol used):** The average force to break the nozzle was 23.47 lb and the standard deviation was 7.28.

D. **New proposed design with tubing (70% alcohol used):** The average force to break the proposed design caps assembled with tubing was 25.80 lb with 4.61 of standard deviation.

E. **Remarks:** The difference in the amount of force breaking the nozzles seems to be insignificant. However, the way these nozzles broke is somewhat different. When the original caps broke, they just snapped apart and the whole nozzle almost fell off. For the new proposed design caps, the tip was stretched and torn apart (see Fig. H-5 and H-6, and H-7 and H-8 for comparison).

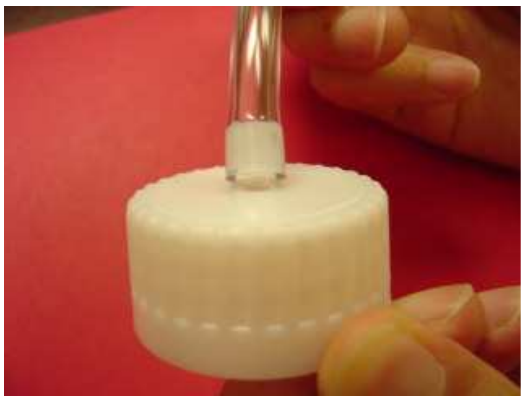



Fig. H-5 and H-6. The result of the original caps with tubing after the tensile test (the nozzle was snapped apart).

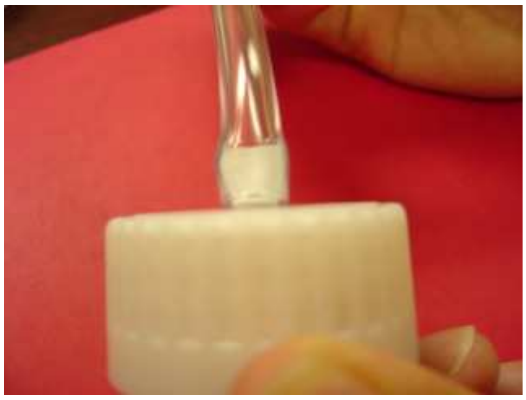



Fig. H-7 and H-8. The result of the new caps with tubing after the tensile test.

F. **Original caps with tubing (using 91% of alcohol during assembly):** The minimum force to break the nozzle was 4.29 lb while the maximum was 33.60 lb with the average of 16.91 lb (see the data in Attachment C, Table H-I column 6).

G. **Remarks:** It appears that the higher percentage of alcohol did weaken the strength of the intersection of the nozzle and the cap (compare to 70% of alcohol), which may cause the nozzle to break during transportation or use. It is recommended that 91% of alcohol should not be used during the assembly process. Current procedure calls for 70% alcohol only. The result also shows that the proposed design with small fillet added to the outer diameter of

the nozzle at the cap intersection has a better sustaining strength. The benchmark for the cap with tubing was arbitrarily set at 15 lb, which is twice the average simulated amount of force that a person would exert on the nozzle when handling the products. From the testing result, 90% of original product passed the benchmark whereas the new design has a 100% passing rate (Attachment C, Table H-I, column 4 and 5), which shows that the proposed design has increased the strength of the nozzle and the cap intersection significantly. We did not set the benchmark for the cap itself because the proposed design did not break, but deflected the force when it exceeded the 29 lb mark. The average amount of force is lower for the cap with tubing due to the tubing provides a better grip for the extension rod to break the nozzle off.

VI. Sterilized

The same testing methodology was performed on new and original design caps with 70% of alcohol used during assembly, and both were sterilized. These sterilized samples arrived in two conditions, some came in loose bulk and some arrived in pouch.

A. Caps in loose bulk:

1. **Original caps:** The average force to break the nozzle off the caps was 14.74 lb with 4.59 of standard deviation.
2. **New proposed design caps:** The average force to knock off the nozzle was 23.48 lb and the standard deviation was 2.41.

3. **Remarks:** The difference between he sterilized caps and non-sterilized caps was insignificant when comparing the results of these two categories in Attachment C, Table 1(column 4 and 7, and column 5 and 8).

B. Caps in pouch:

1. **Original caps:** The average force to break the nozzle off the original caps was 17.09 lb and the standard deviation was 8.94.
2. **New proposed design caps:** The average force to break the nozzle off the proposed design caps is 24.69 lb with standard deviation of 4.78.
3. **Remarks:** Comparing the results between sterilized and non-sterilized caps, it appears that the sterilization does not weaken the strength of the nozzle.

Conclusion

After testing the old and new proposed design caps in various conditions, the result shows that the new proposed design performs better than the original caps in each aspect. It also indicates that the use of 91% of alcohol during assembly does affect the strength of the nozzle when compare to 70% of alcohol under same conditions.
Recommendation: Replace the original cap design with the proposed design in all applicable production orders, and continue use of 70% alcohol as lubricant in the assembly line.

Change authorized by:

_____ _____

(Lui Cheng, R&D) Date

_____ _____

(Rusty Smith, R&D Manager) Date

If applicable, ref ECN# _____

Reference Protocol #: 001-05

Attachment C

TABLE H-I

THE RESULT OF TENSILE STRENGTH TEST ON ORIGINAL AND NEW PROPOSED DESIGN CAPS

	Tensile Strength Test on cap								
	Force unit: lb								
	Testing Equipment: Digital Force Gauge								
	NON-STERILIZED CAPS					**STERILIZED CAPS**			
	No Tubing		**With Tubing**			**With Tubing**			
	No Alcohol		alcohol used during assembly			70% alcohol			
	*Cap only		70%	70%	91%	Loose bulk		In pouch	
Sample	New**	Original**	New**	Original**	Original**	New**	Original**	New**	Original**
1	31.32	35.60	29.28	23.54	11.31	25.47	26.37	22.81	21.74
2	29.61	39.83	22.59	26.56	7.68	24.82	20.37	23.16	30.27
3	25.57	28.56	30.82	31.45	26.78	26.64	24.05	32.23	15.83
4	29.04	28.67	28.30	36.68	30.14	22.72	15.80	31.11	13.43
5	32.46	31.91	24.77	10.96	18.34	23.90	14.76	23.20	5.81
6	28.45	34.81	25.77	20.40	33.60	22.52	33.95	22.86	6.10
7	30.04	31.47	25.67	19.50	14.53	22.97	34.66	24.57	7.99
8	30.71	33.71	23.58	19.66	15.15	25.78	14.27	17.59	28.00
9	31.42	35.43	31.42	18.96	7.23	21.58	11.39	N/A***	24.74
10	30.02	36.62	15.80	26.95	4.29	34.10	15.63	N/A***	17.00
Average	29.86	33.66	25.80	23.47	16.91	25.05	21.13	24.69	17.09
Std Dev	1.92	3.56	4.61	7.28	10.17	3.57	8.33	4.78	8.94

Note:

Cap only: no tubing, no alcohol.

** "Original": Original caps
"New": Proposed design with radius fillet added at the base (the intersection of the nozzle and cap).

*** N/A: There are only 8 samples available from vendor for testing.

APPENDIX I

Flow Rate (BMP-100130):
The effect of changing the material on BMP-077

Testing Done By: Lui Cheng

R&D Intern Engineer

Flow Rate Testing Protocol

Date: 01/05/2006
Protocol # P001-06

Flow rate testing

This test plan was requested by Don Byrne.

Purpose

Comparing the flow rate of BMP-100130 by using original material DOW 350LH (silicone) and DOW Q7-4750 (silicone) in making component BMP-077 per Vesta's request on material change.

Testing Device Descriptions

BMP-100130 Endo Gator Irrigation Units

DOW 350LH (original silicone material)

DOW Q7-4750 (new silicone material)

2 Baxter® 1000 ml Water Bottle

Olympus® OFP-1

Timer

Digital Scale (model: SK-20K, manufactured by A&D Co., Ltd). The increment size of this scale is 0.02 lb.

Test Procedure

Comparing the maximum flow rate of BMP-100130 using original material (DOW 350LH, silicone) and new material (DOW Q7-4750, silicone) in making the component BMP-077. Five tubing sets with new material for BMP-007 and one control tubing set with old material are used, and each set will run for five tests.

Open Air Flow

Attach and secure each tubing set onto Olympus® OFP-1 pump unit and adjust the speed control to the maximum flow.

Turn the power on and the run the pump continuously for 20 seconds.

Water will be collected and weighted with a digital scale.

The weight (in lb) per 20 seconds will then be converted to milliliter per minute.

Data are recorded on an Excel spreadsheet.

Attach collected results to the test protocol

Conclusion or Summary

** The increment size of the digital scale is 0.02 lb and it does not read out any changes below 0.02 lb.

The result shows that there is no significant difference in the flow rate (only) between the materials used in making the component BMP-007 for BMP-100130. The average maximum flow of the BMP-100130 with BMP-077 using original material was 480 ml/min, while the maximum flow of the BMP-100130 with BMP-077 using new material was 474 ml/min.

TABLE I-I
RESULTS

BMP-007 Flow test 1/5/2006

Original Material: DOW 350LH (silicone)

New Material: DOW Q7-4750 (silicone)

	Original Material		New Material									
	Control		Tubing Set 1		Tubing Set 2		Tubing Set 3		Tubing Set 4		Tubing Set 5	
RUNS	lb/20 sec	ml/min	lb/20 sec	ml/min	lb/20 sec	ml/min	lb/20 sec	ml/min	lb/20 sec	ml/min	lb/20 sec	ml/min
1	0.34	463.64	0.36	490.91	0.36	490.91	0.34	463.64	0.34	463.64	0.34	463.64
2	0.36	490.91	0.36	490.91	0.36	490.91	0.34	463.64	0.34	463.64	0.34	463.64
3	0.36	490.91	0.36	490.91	0.36	490.91	0.34	463.64	0.34	463.64	0.34	463.64
4	0.34	463.64	0.36	490.91	0.36	490.91	0.34	463.64	0.34	463.64	0.34	463.64
5	0.36	490.91	0.36	490.91	0.36	490.91	0.34	463.64	0.34	463.64	0.34	463.64
Average	0.35	480.00	0.36	490.91	0.36	490.91	0.34	463.64	0.34	463.64	0.34	463.64

Average of 5 sets = 474.55 ml/min

VITA

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