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Development and Prototyping of Automated Laparoscopic Irrigation and Suction Pump

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ABSTRACT: In this paper current scenario of medical device industry is discussed. There are several challenges for manufacturing of medical device in India and some are discussed in this paper. In this paper we have discussed current scenario of medical device manufacturing in India. Further we have developed automated irrigation and suction pump which will help doctors in their surgery. The Automatic irrigation system is implemented using pressure sensor and some signal processing. We have design enclosure for this system as a two-body design. We have used N-channel MOSFET to drive 2 pumps in the product. During entire development process we have focused on reducing the manufacturing cost of the device.

KEYWORDS: Medical Devices, Laparoscopy Irrigation pump, Automatic Pump, Photolithography, Laparoscopy Suction pump, Instrument Manufacturing, Casing Design.

I. INTRODUCTION

Medical devices are an integral component of the health care system with a mandate of access and equity. A Medical device is an instrument which is applied for diagnosis, therapy, or alleviation of diseases in human beings or animals. India is the 4th largest market of medical devices in Asia and counted amongst the top 20 markets in the world. In 2020, the total market was estimated to be US\$5.2 billion and is projected to reach US\$50 billion by 2025. However, most demand for medical devices in the country is currently met through imports, comprising ~80% of the total sales^[1]. This high import dependency offers an attractive proposition for domestic manufacturers. At present, the Indian companies are largely involved in manufacturing low-end products for local as well as international consumption. The challenge therefore for companies in India is to produce medical devices that are both cost effective and competitive to increase penetration and use. It is in this context that the Make in India initiative becomes significant for the medical devices industry.

II. CHALLENGES FOR MEDICAL DEVICE MANUFACTURING IN INDIA

India mostly depends on imports- 75% of the total devices are generally imported and are treated as drugs under the Drugs and Cosmetics Act^[1]. India is a net importer and emerging as a market for medical devices and equipment with a 1.2% share in the total value of the global import of medical devices and equipment. There is also a continuous growth of import of medical devices and equipment in India. During the four-year period from 2010 to 2014, the export of medical devices from India has grown by 15% per annum and import of medical devices has grown by 12% per annum^[1]. The devices are designed in other countries so the device can fail to perform because devices are not designed to perform in Indian environmental conditions. Proper maintenance of device is not done in Indian laboratories.

Deficiency of training and education is another challenge for medical device manufacturing. Most private organizations employ technicians with no education and training, therefore there is a high chance of error in assembly process^[2]. Unlike developed countries, the medical devices market in developing countries like India is price sensitive. As a result, there is a strong emergence of the market for refurbished medical devices. Thereby, the task of any government in developing countries like India is not only the promotion of domestic production of medical devices, but also equipping its regulatory framework to monitor the quality of the imported and domestically produced medical devices to protect people's health from profit-seeking "fly by night" manufacturers or vendors^[2].



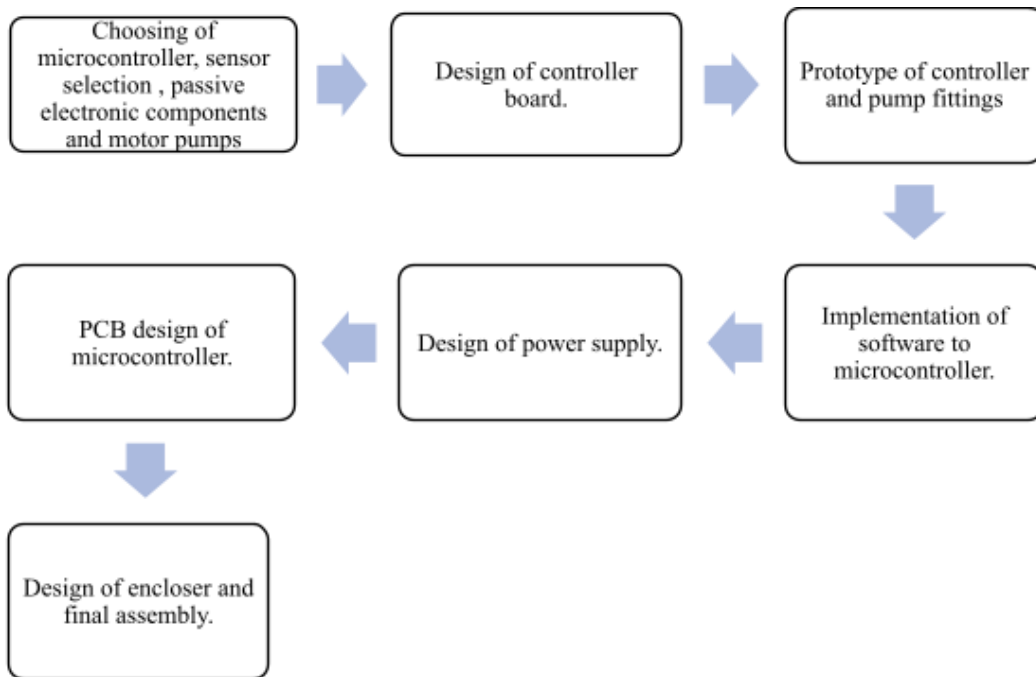
III. METHODOLOGY

We started by designing the controller board around PIC 24 microcontroller which would be able to handle all the computation and processing. The pressure sensor was chosen to match the pressure range of 2 bars. The controller circuit has 4 major parts to it which are the basic microcontroller Interfacing, noise filters for sensor, pump driver circuit and programming circuit. The PCB for the circuit is made of 2 layers.

The pressure sensor used in this instrument is manufactured by Honeywell. It has a pressure range of 2 bars. Push and pull type of connectors to be used for the whole piping network because they are available in different dimensions and in a variety of types for multiple applications also it has less prone to leaks.

Enclosure for this instrument is U shaped 2 body design. This type of design provides easy assembly of internal components. Material used for Fabrication is CRCA (Cold Rolled Closed Anneal) sheet metal of thickness 2mm. CRCA sheet metal has precise and accurate dimensional tolerances, improved mechanical and physical properties, improved draw-ability, etc.

In the encloser, two elevated mounts above base, for pumps, had been designed to prevent any tampering from outside like loosing of screw. All electronic components are mounted separately above the two pumps. This will prevent electronics components from damage due any kind of leakage from pumps or piping system.

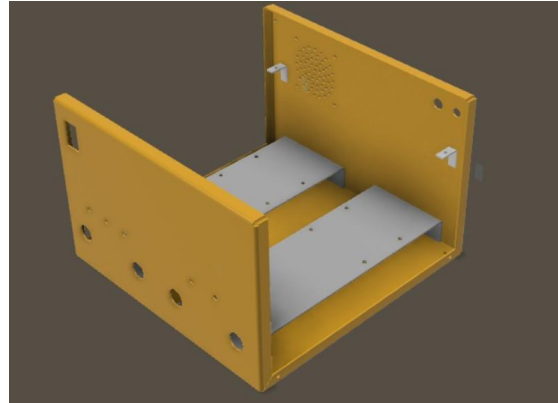
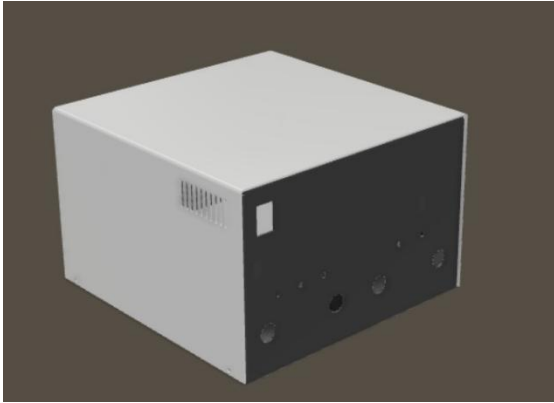


IV. IMPLEMENTATION

For this instrument we designed an enclosure, PCB, and software. We have used 2 mm thick metal sheet for fabrication of this enclosure. The design of this enclosure follows two body design. In this type of design, it is easy to maintain and repair the instrument.

The enclosure is made up of CRCA that is cold roll closed annealed material. The advantages of this material are:

1. Precise and Accurate Dimensional Tolerances.
2. Robust surface finish.
3. Improved mechanical & physical properties.
4. Improved Draw-ability



In this design, the pumps and electronic components are separate from each other, which ensures there is no damage to electronic components from any kind of leaks in piping system.

For manufacturing this enclosure laser cutting technology was used. Powder coating has been done on the enclosure to make it corrosion resistant.

V. PCB MANUFACTURING TECHNIQUE

The photolithography is one of the process used to fabricate electronic circuits. This process is well optimised to produce close traces in circuits so that the circuits can be smaller, faster, and more reliable. Photolithography is also used to make sensors and actuators in Micro Electromechanical Systems (MEMS). The process is so flexible that it can be scaled to nano meter level to create nano structures or traces. There are different ways to produce this each has their advantages and disadvantages. Here provided with one such procedure.

The below method is inexpensive and most of the raw materials can be sourced locally. A disadvantage is that number of PCB layers is limited, and extremely high frequency PCB manufacturing is difficult. But since this method is inexpensive and less complex, the less complex circuit can be manufactured in huge quantity with less errors.

VI. PROCEDURE USED FOR PCB MANUFACTURING

1. Double layer copper clad is drilled for through hole components and Vias.
2. Then it is electro plated for the Vias.
3. The copper clad is thermally pressed with Photoresist laminate.
4. It is Exposed through negative PCB design layout print by UVB light.
5. And it's dipped in alkaline with 10.5PH to strip the unexposed portion of the Photoresist layer.
6. It is dipped into ferric chloride solution for etching to remove unwanted copper.
7. Then dipped into tin solution to coat the copper with tin layer.
8. And finally solder mask is applied and dried using UVB light.



VII. ELECTRONIC CIRCUITS

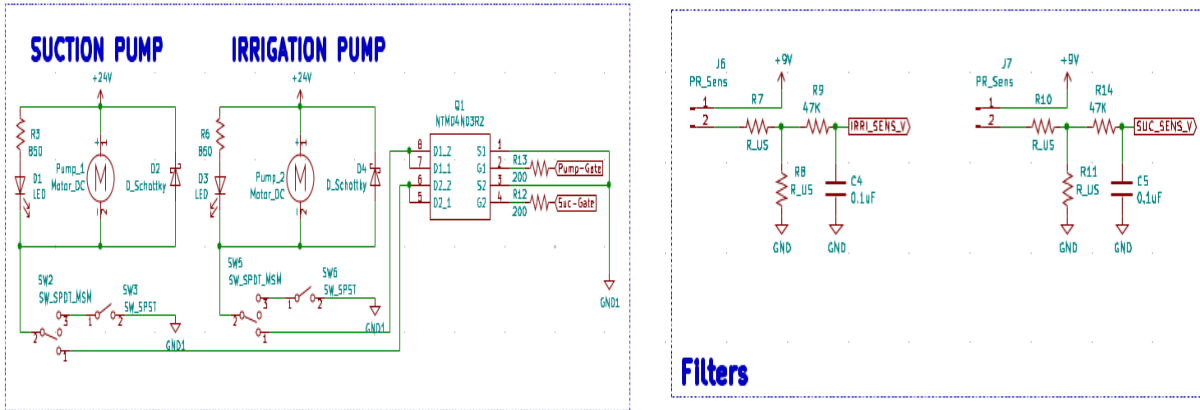


Figure 5: Nositie filter for pressure sensor

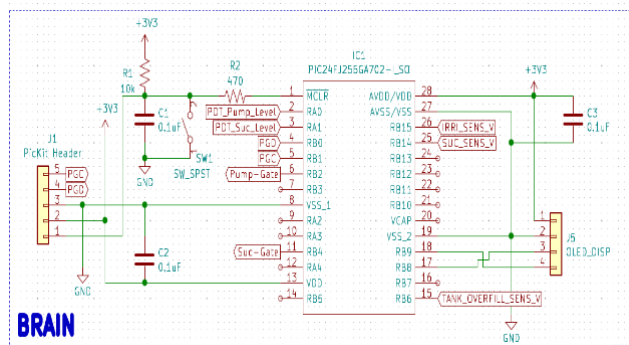
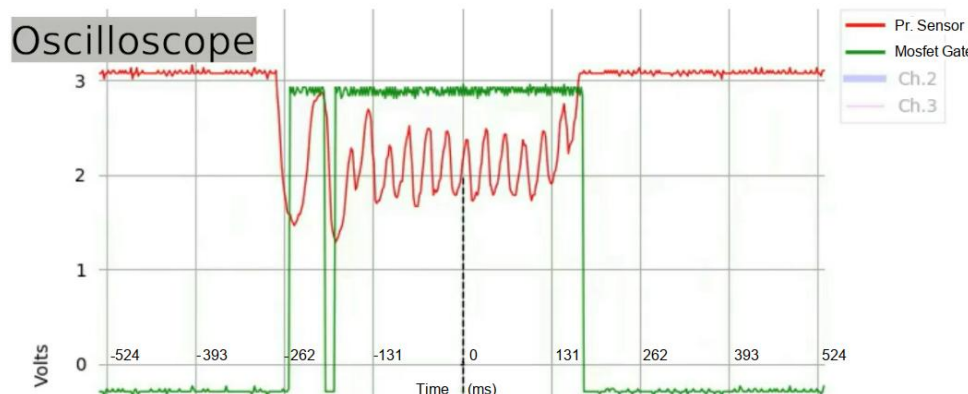


Figure 6: Microcontroller interfacing

The circuit presented above shows PIC24FJ256GA702 configured with a reset circuit, IOs for Pump signal, ADC inputs for pressure sensor and programming header. J1 is used for programming the microcontroller, using a PICkit 3 programmer.

The motor driver circuit used mosfets to control the pumps. The pumps draw about 0.6Amp of current at 24V DC. As an alternate way to use the pump, a manual override is available. It can be used in cases such where the user is not comfortable with its auto turn on/off functionality, or in cases of controller failure. The Pressure sensor data has noise, which need to be removed before we process it further.

To do so we have implemented a RC low pass filter. It's cut off frequency is around 33 Hz. Value of R7 is 0 Ohm. The sensor creates a voltage drop across the resistance R8. This voltage drop gets sampled by the microcontroller.





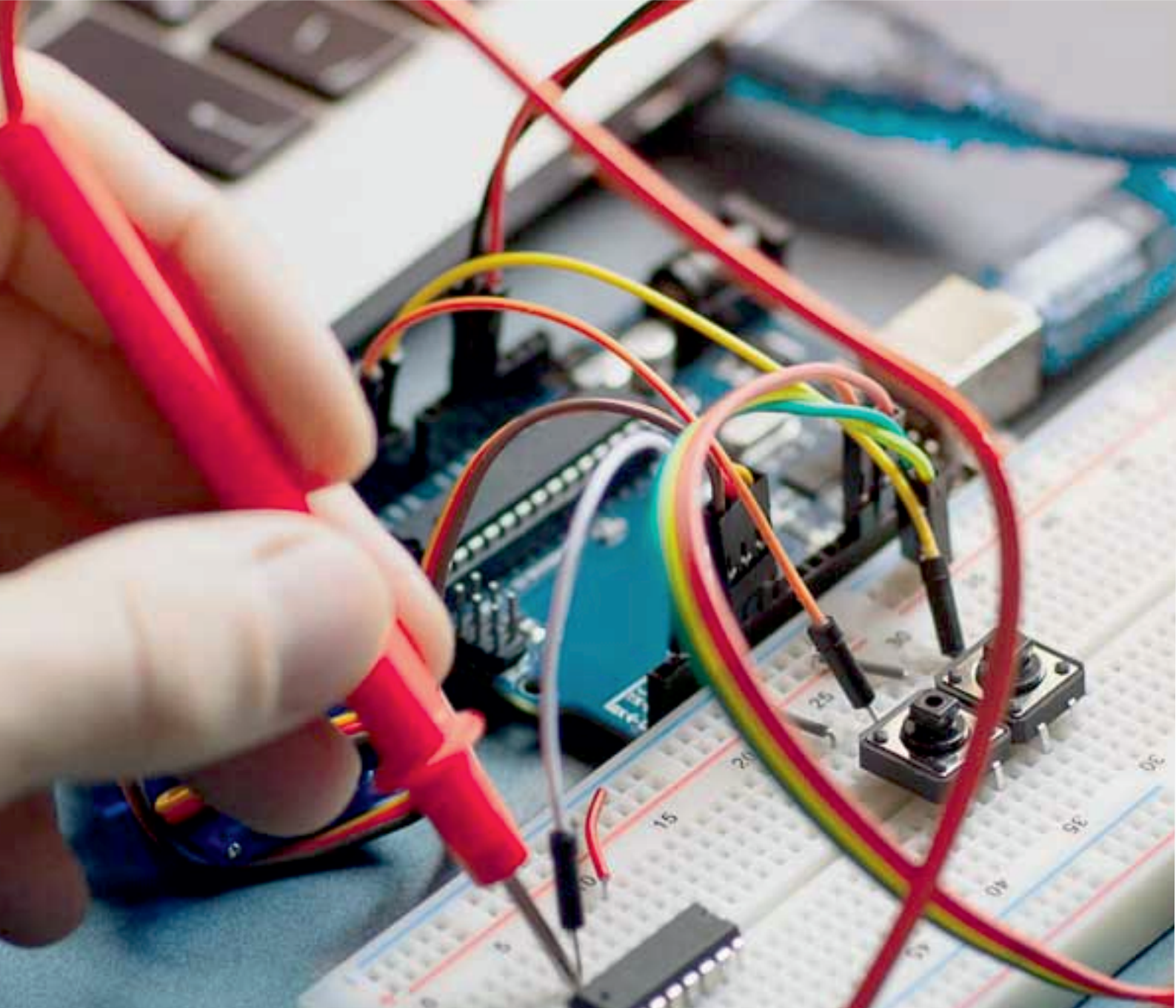
In figure 7 with an oscilloscope, we have measured the sensor voltage, when the outlet hose was opened and then closed again in a matter of about 131 milliseconds.

VIII. CONCLUSION

After carrying out detailed exploration of the subjects mentioned above, we have found methods to keep the cost of medical equipment low, making it easier for medical practitioners to make use of the best available technology. The analysis also revealed to us the deficiency in the region of medical equipment's in India.

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