DEVELOPMENT OF A MATERIAL HANDLING SYSTEM FOR CATHETER MANUFACTURING PROCESS

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To my beloved family Shahri , Hamidah , Norsyaridah , Hairudin, Halizah, Mohd Fitri, my son Harun Al-Rasheed , my daughter Aina Syafiqah and my wife Noraini Ahmad. Thank for all your support .

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ABSTRACT

In this thesis, a systematic approach to design and develop a model of a stripping handling system for a urological latex folex catheter tube manufacturer. The design is based on Design and Development Standard Karl Ulrich Steven Eppinger and Boothroyd Dewhurst Design for Manufacturing and Assembly Methodology. The system applies programmable Logic Controller to control all the switches from main control panel or Human Machine Interface. The output of the system is the movement of actuators that strip out the Catheter tube from the former or mold with respect to the pneumatic system. The measurements of the performance also being analyze by calculating the design efficiency. The resulting generalized model is validated through computer simulations and experimental analysis of variance with parameters such as hot water dipping temperature, distance between gripper to table and gripper pressure to material on working prototype.

ABSTRAK

Dalam laporan tesis ini, pendekatan sistematik dalam mereka bentuk dan membangunkan model sistem pengendalian bahan dalam pembuatan tiub urologi kateter latek. Bedasarkan sistem automasi, aplikasi konsep merekabentuk adalah berdasarkan kepada standard rekabentuk dan pembangunan berserta kaedah Boothroyd Dewhurs iaitu rekabentuk untuk pembuatan dan pemasangan. Sistem ini menggunakan pengaturcaraan kawalan logik yang mana ianya akan mengawal semua kemasukan suis pada panel kawalan utama atau panel pengantaramuka mesin manusia. Keluaran sistem ini pula adalah pergerakan penggerak yang melucutkan tiub kateter daripada pembentuk atau acuannya dengan merujuk kepada sistem pneumatik. Prestasi rekabentuk ini diuji dengan analisa pengiraan kecekapan. Hasil keputusan model ini disahkan dengan simulasi berkomputer dan kaedah eksperimen menggunakan analisis varian dengan beberapa parameter seperti suhu rendaman kateter dalam air, jarak antara pengepit ke meja dan tekanan pengepit pada bahan dalam prototaip kerja ini.

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LIST OF SYMBOLS

$Ø$	-	diameter
Q	-	air flow
ΔP	-	pressure drop
$\boldsymbol{V}$	-	velocity
N_s	-	number of stripped material
N_u	-	number of unstripped material
N_X	-	number of dented found on material during testing
N_Y	-	number of indented found on material during testing
E_{ma}	-	Design efficiency
N_{min}	-	Minimum theoretical number of part
T_{ma}	-	Total assembly time

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CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter is arranged as the following sub-chapters and intentions:

i. Overview of the Product
ii. Overview on the Material of the Product (Catheter)
iii. Case Study at CR Bard Sdn. Bhd.
iv. Problem Statements
v. Objectives
vi. Scopes
vii. Outline of the Thesis

In this project in design and development of semi automation stripping jig and fixture system for improvement process in Catheter manufacturing industry environment.

1.2 Overview of the Product

Catheter in medical is a tube that can be inserted into a body cavity, duct or vessel. Catheters thereby allow drainage, injection of fluids or access by surgical instruments. The process of inserting a catheter is catheterization. In most uses a catheter is a thin and flexible tube, although in some uses it is a larger and solid tube. A catheter left inside the body, either temporarily or permanently, may be referred to as an indwelling catheter. Catheter is placed into a particular part of the body may allow draining urine from the urinary bladder as in urinary catheterization, drainage of urine from the kidney by percutaneous nephrostomy, drainage of fluid collections and others.[9] Refer figure 1.1 folex catheter asembly pack.

Figure 1.1: Folex Catheter Asembly Pack

In this sub-chapter, the overview of the product (catheter assembly) is briefed. Foley catheters are soft and thin latex tubes that are passed through the urethra during urinary catheterization and into the bladder to drain urine. They are retained by means of a balloon at the tip which is inflated with sterile water. The balloons typically come in two different sizes: 5 cc and 30 cc. A Foley catheter is typically used when normal urination is disrupted by an infection, a swollen prostate gland, bladder stones, or, sometimes, an injury. In very sick people, a catheter may be used to keep track of urine production.

They were designed by Frederic Foley, a surgeon working in Boston, Massachusetts, in the 1930s, when he was a medical student. His original design was adopted by C. R. Bard of Murray Hill, New Jersey, who manufactured the first prototypes and named them in honour of the surgeon.[25]

A typical Foley catheter has drainage lumen, and an inflation lumen for inflating and deflating the balloon. The balloon is normally deflated until properly positioned in a patient's bladder. Once the catheter is properly positioned, the inflation lumen delivers fluid to inflate the balloon. The inflated balloon holds the catheter in place. A Foley catheter having redundant temperature sensors includes a catheter body with a proximal end and a distal end, an inflatable balloon disposed near the distal end, an inflation lumen extending from the proximal end to the balloon for inflating and deflating the balloon, a drainage lumen extending from the proximal end to the distal end, at least one temperature sensor lumen extending from the proximal end to the distal end, and at least two temperature sensors, each having a wire and a sensor element, the sensor elements being disposed in the distal end of the catheter body and the wires extending through the catheter body drainage lumen.

The temperature sensors electronically couple with a control unit, which obtains a primary temperature reading from one of the temperature sensors and obtains a secondary temperature reading from the other temperature sensors. The control unit compares the primary and secondary temperature reading to determine a difference.

The control unit establishes a threshold. The threshold is the maximum acceptable difference between the primary and secondary temperature readings. This threshold, according to one aspect of the invention, is set manually by an operator. The control unit also includes an alarm so that when the difference between the primary and secondary temperature readings exceeds the threshold, the control unit activates the alarm. The alarm is audible according to one aspect of the invention and is sounded on a speaker in communication with the control unit. According to

another aspect of the invention, the alarm includes a video display and activation of the alarm provides a video signal to the video display. In yet another embodiment, the alarm simply shuts the control unit off.

A method of using a Foley catheter with redundant temperature sensors in accordance with the invention includes the steps of introducing a Foley catheter into the bladder of a patient and using the Foley catheter to drain urine from the bladder. The method also includes electronically coupling the temperature sensors to a control unit and activating the control unit to obtain the primary temperature reading and the secondary temperature reading from the redundant temperature sensors. Obtaining two, or more, temperature readings facilitates redundancy. One aspect of the invention includes the step of comparing the primary temperature reading and the secondary temperature reading to determine whether both sensors are operational.[9]

Another aspect of the invention includes three temperature sensors and an appropriate methodology for detecting sensor failure. Three sensors enables continued operation of the control unit to achieve meaningful temperature readings notwithstanding the failure of one of the temperature sensors. It can be appreciated that there are a variety of control and feedback methods that can accomplish continuous operation of the catheter, sensors and control unit during a failure of one of the sensors. According to an aspect of the invention having two sensors, determining whether both sensors are operational is accomplished by comparing the primary temperature reading and the secondary temperature reading to determine a difference between the primary and secondary temperature readings. The control unit deactivates when the difference exceeds the threshold. Preferably, the sensors operate with an accuracy of ± 0.1 degree Fahrenheit. Accordingly a temperature difference of a whole degree, for example, or more would typically indicate failure of one of the sensors.

According to an embodiment of the invention the controller establishes a temperature threshold within the range of 0.5 to 2 degrees Fahrenheit. More

preferably, however, the temperature threshold is about 1 degree Fahrenheit so that the redundant sensors would operate safely in conjunction with a heat exchange catheter system for regulating patient body temperature.

A major problem with Foley catheters is that they have a tendency to contribute to urinary tract infections (UTI). This occurs because bacteria can travel up the catheters to the bladder where the urine can become infected. To combat this, the industry is moving to antibiotic coated catheters. This has been helpful, but it has not completely solved this major problem. An additional problem is that Foley catheters tend to become coated with time with a biofilm that can keep them from properly draining the bladder. This increases the degree of static urine left in the bladder, which further contributes to the problem of urinary tract infections. When a Foley catheter becomes clogged, it must be flushed or replaced. Thus keeping Foley Catheters from clogging may help reduce UTIs as well.

Foley catheters are used during the following situations:[25]

i. On patients who are anesthesized or sedated for surgery or other medical care
ii. On comatose patients
iii. On some incontinent patients
iv. On patients whose prostate is enlarged to the point that urine flow from the bladder is cut off. The catheter is kept in until the problem is resolved.
v. On patients with acute urinary retention.
vi. On patients who are unable due to paralysis or physical injury to use either standard toilet facilities or urinals.
vii. Urethral surgeries

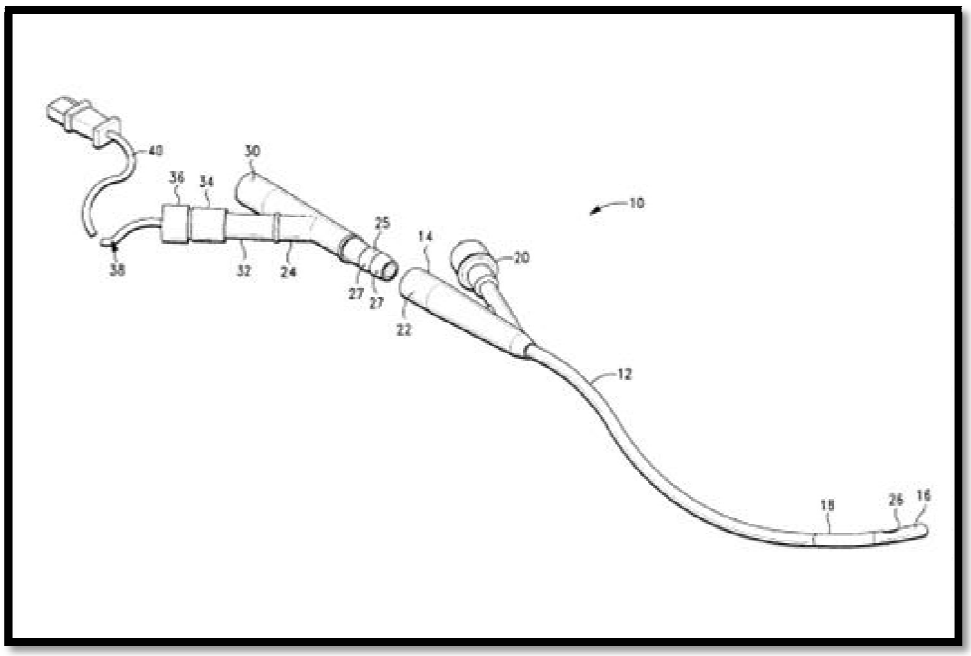

Figure 1.2: Foley Catheter Designated with Reference Numeral 10 [9]

Figure 1.2 shows a Foley catheter generally designated with the reference numeral 10. The catheter 10 includes a catheter body 12 with a proximal end 14 and a distal end 16. The catheter 10 also includes a balloon 18, an inflation lumen 20, a drainage lumen 22, and an adapter 24. The balloon 18 is deflated for insertion into a patient. The balloon 18 is disposed near the distal end 16. The inflation lumen 20 extends within the catheter body 12 from the proximal end 14 to the balloon 18, in fluid communication with the balloon 18, for inflating and deflating the balloon 18.

The catheter drainage lumen 22 extends from the proximal end 14 to the distal end 16. The distal end 16 includes an opening 26 in fluid communication with the drainage lumen 22 to facilitate drainage of urine from the bladder of a patient. The adapter 24 has a drainage lumen 30, a temperature sensor lumen 32 and a connector 25. The connector 25 attaches to the proximal end 14 of the catheter body 12. The connector 25 establishes fluid communication between the adapter drainage lumen 30 and the catheter drainage lumen 22. Preferably the connector 25 is tapered and includes ribs 27 for insertion and press-fit into the proximal end 14 of the catheter body 12. The adapter temperature sensor lumen 32 includes a fitting 34 and a cap 36. [9]

1.3 Overview on the Material of the Product (Catheter)

In this sub-chapter, the overview of the material of the product (catheter) is briefed. Materials used for the construction of catheters including silicone rubber latex and thermoplastic elastomers. Silicone is one of the most common choices because it is inert and unreactive to body fluids and a range of medical fluids with which it might come into contact. On the other hand, the polymer is weak mechanically, and a number of serious fractures have occurred in catheters. It is widely used, for example, in breast implants where failures by rupturing of the silicone shell are well attested. They are commonly made in silicone rubber or natural rubber.

Latex refers generically to a stable dispersion (emulsion) of polymer micro particles in an aqueous medium. Latexes may be natural or synthetic. Latex as found in nature is a milky sap-like fluid within many plants that coagulates on exposure to air. It is a complex emulsion in which proteins, alkaloids, starches, sugars, oils, tannins, resins, and gums are found. In most plants, latex is white, but some have yellow, orange, or scarlet latex.[1]

The word is also used to refer to natural latex rubber; particularly for non-vulcanized rubber. Such is the case in products like latex gloves, latex condoms and latex clothing. It can also be made synthetically by polymerizing a monomer that has been emulsified with surfactants. The term *latex* is attributed to Charles Marie de la Condamine, who derived it from Latin *latex*, fluid.

The cells or vessels in which latex is found make up the laticiferous system, which forms in two very different ways. In many plants, the laticiferous system is formed from rows of cells laid down in the meristem of the stem or root. The cell walls between these cells are dissolved so that continuous tubes, called latex vessels, are formed. This method of formation is found in the poppy family, in the rubber

trees (Para rubber tree and *Castilla elastica*), and in the Cichorieae, a section of the Family Asteraceae distinguished by the presence of latex in its members. Dandelion, lettuce, hawkweed, and salsify are members of the Cichorieae. It is also present in another member of the Asteraceae, the guayule plant.

In the milkweed and spurge families, on the other hand, the laticiferous system is formed quite differently. Early in the development of the seedling latex cells differentiate, and as the plant grows these latex cells grow into a branching system extending throughout the plant. In the mature plant, the entire laticiferous system is descended from a single cell or group of cells present in the embryo.

The laticiferous system is present in all parts of the mature plant, including roots, stems, leaves, and sometimes the fruits. It is particularly noticeable in the cortical tissues. Several members of the fungal kingdom also produce latex upon injury. Notable are the milk-caps such as *Lactarius deliciosus*.[1]

1.4 Case Study at CR Bard Sdn. Bhd.

Study is carried out at CR Bard Sdn. Bhd. Kulim, Kedah. C.R. Bard focus is on specific Disease State Management needs, both diagnostic and interventional, in three key areas which are Vascular, Urology and Oncology. Main head quater is in Murray Hill, New Jersey, USA. This company produce Latex Folex Catheters and Urological Procedural Kits for medical users.[25]

In BARD latex folex catheter manufacturing process, some of the process producing the part is still can be improved. One of the current process conditions that can be improved is stripping the rubber (latex folex catheter) from its catheter mould

stick. The process is done manually by operator which is require amount of an energy to strip out the part after came out from chamber.

The current process is quite tedious and fully rely on the manpower who are doing the job. Replacing humans in this task may improve efficiency and productivity of the production and at the same time the manpower doing the task can be trained or upgrade to some useful and important task.

Rationale to create automated system in this task is to get constant quality force or energy of movement that are difficult or impossible to archive for human energy.

Thus, beginning from conceptual design, development, fabrications and measurement of the semi automatic stripping jig and fixture system, a systematic procedure of Design and Development Standard and Boothroyd Dewhurst Design for Manufacturing and Assembly (DFMA) methodology are chosen as a guideline in order to achieve the target.

Simulation of processes, principle of operation, arrangement of Input and output devices (sensors, switches, valves etc) will be showed as well.

1.5 Problem Statements

How the manual stripping process of latex folex catheter can be improved by using an automatic material handling system.

Related Questions

What are the important needs to be considered?
What are suitable concept designs to develop the model?
How to quantify the performance of the design model with several variables?

1.6 Objectives

The main objectives of this project is to design and development of an automatic handling system in latex folex catheter manufacturing process by using a PLC based system and quantify the performance of the design model.

1.7 Scope of project

This project will be focus on automating industrial processes.

Area will be focus on:

i. Identify the characteristics of the existing process and the need to develop an automatic stripping system.
ii. Design and Develop a material handling system that stripping out latex folex catheter from its former (mold).
iii. Characteristics of the existing process & the need to develop an automatic stripping system.

iv. Evauate the productivity and reliability of the existing process and how can the new developed automatic stripping system will improve the handling of this process.
v. Analyze the performance of the design model.

The mechanism or conceptual design model need to be generated at the begining. Then the best design concept model will selected and tested as well as the analysis will taking place after selection has been made.

The analysis will consist of identifying and quantifying the area(parameters) that contribute to the improvement in production area. Then correlating those parameters and establish the mathematical model to represent the variable interaction.

The project will be utilized a PLC (Programmable Logic Controller) with appropriate mechanism design to make an improvement in chosen production process (Stripping out catheter body from it former).

1.8 Outline of the Thesis

The thesis presents the implementation of the design and development prototype model of material handling system which is stripping mechanism for catheter from the former based on the design and development standard principle.

Chapter 2 focuses on the literature review, which introduces the overview of the manufacturing proceses of producing the catheter. The explanation begins with

the critical process that most required need to be studied. This chapter is then described by related researches on stripping mechanism efficiency and some standard for design and development, which is found to be related and facilitate to this project.

Chapter 3 provides the methodology that is used through out the work of this project. It covers the technical explanation of design and development standard based on Karl Ulrich Steven Eppinger starting with gather raw data until design for manufacturing and assembly. The model also been verified with the simulation of stress and strenght of it former by using CosmosXpress software .

Chapter 4 deals with the generating of Computer Aided Design (CAD) drawing complete with bill of material. Testing the performance results then done thru an experimental method analysis of varians (ANOVA). The obtained results are determine the effectiveness of the design prototype model.

Chapter 5 presents the conclusions of the project as well as some constructive suggestions for further development and the contribution of this project. The project outcome is concluded in this chapter. As for future development, some suggestions are highlighted with the basis of the limitation of the effectiveness of the prototype model development.