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DEVELOPMENT OF AN ELECTRONICALLY-CONTROLLED, MULTIDOSE, NASAL, DRUG-DELIVERY DEVICE

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ABSTRACT OF THE THESIS

DEVELOPMENT OF AN ELECTRONICALLY-CONTROLLED, MULTI-DOSE, NASAL, DRUG-DELIVERY DEVICE

In recent years, the nasal route has received a great deal of attention as convenient and reliable method of systemic administration of drugs, due to its benefits of reduced pain, precise drug delivery and eliminated risk of intravenous needles. The pharmaceutical industries are facing a competitive challenge introducing novel devices for the nasal drug delivery, which is better than commercially available, unit dose and squeeze bottle sprayers. The purpose of this study is to develop such a device for the nasal drug delivery that would satisfy the needs of the patients, physicians and pharmacist. An electronically controlled multi-dose nasal drug delivery device is developed as a result of the study. The parts of the device are designed to satisfy customer needs. The developed parts are redesigned for manufacture and assembly, considering the DFMA principles. The conceptual design was tested for its functionality by developing working prototypes of using rapid prototyping techniques. Suitable materials and manufacturing processes for parts of the device are determined, and the manufacturing and assembly cost of the device is estimated to justify affordability.

Keywords: Design, Manufacturing, Nasal device

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29TH JULY 2002

DEVELOPMENT OF AN ELECTRONICALLY-CONTROLLED, MULTI-DOSE, NASAL, DRUG-DELIVERY DEVICE

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THESIS

Aravind Balasubramanian

The Graduate School

University of Kentucky

2002

DEVELOPMENT OF AN ELECTRONICALLY-CONTROLLED, MULTI-DOSE, NASAL, DRUG-DELIVERY DEVICE

THESIS

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Manufacturing Systems Engineering from the College of Engineering at the University of Kentucky

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2002

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Chapter 1 INTRODUCTION TO THESIS

1.1 INTRODUCTION

The two primary methods used for delivering medication are tablets and intravenous injections with the needles. The second method is painful, produces bio-hazardous materials, and the first method takes time for the medication to perform its action. Nasal drug delivery eliminates these disadvantages. In nasal drug delivery, the drug is sprayed into the nasal cavity, and the highly permeable tissue in the nasal cavity, which is very receptive to medication, absorbs it quickly and efficiently. According to Intranasal Technology Inc. [1], administering drugs through the nasal cavity is a highly effective and safe delivery method that benefits patients, physicians, health care workers and medical institutions. The other advantages of nasal drug delivery according to Intranasal Technology [1] are as follows:

- Nasal drug delivery reduces patient anxiety since it is less painful and invasive than injections.
- Delivering drugs nasally in smaller doses produces fewer side effects (e.g., in the stomach and intestines) than medication delivered in tablet form.
- Nasal delivery devices allow medication to be administered in precise, metered doses that allow for greater flexibility.
- Patients or healthcare workers can administer the drugs.
- Nasal delivery devices do not generate bio-hazardous waste or pose the accidental risks of intravenous needles.

- Nasal delivery offers an attractive alternative to deliver the formulation ot the appropriate site (nose associated lymphoid tissues) [2]

Due to the above advantages of nasal delivery, Intranasal Technology is formulating drugs that can be administered through the nose. Administering drugs through the nose requires some mechanism for controlling the dosage of the medication to prevent over dosage. The nasal sprayers currently available in market are meant for single doses or two doses. Multi-dose models have no means to regulate the frequency of dosing. Photographs of some nasal sprayers are shown in Figure 1-1. The different types of nasal adapters available are shown in Figure 1-1 (a), (b) and (c), which can be used for administering the drugs through nose.

Figure 1-1: Nasal Sprayers [1] (a), (b)two piece nasal adapter (c) Three piece nasal adapter (d) Unit dose nasal sprayer

(Borrowed from www.intranasal.com & www.calmar.com/Products/Pharma/nasaladapters)

The Figure 1-1 (d) shows a unit dose nasal sprayer, it has a container for storing a unit dose of medicine, pump for atomizing the medication which has to be sprayed in to the nose and a nose cap for spraying the medication. Unit dose of the drug is sealed in the container by a rubber stopper and the pump for delivering the drug is attached to the nose cap. The drug is sprayed in the nose by pressing the container against the pump in the nose cap, so that the needle of the pump pierces the rubber stopper and pushes it to the bottom of the container. Drug between the rubber stopper and the container is forced out as the rubber stopper is pushed down, and the drug is sprayed in to the nose through the nose cap.

A nasal drug delivery system that could regulate the dose and period between successive doses for drugs would have a distinct advantage over the existing commercially available devices.

Therefore, the hypothesis of this thesis is:

> *An economical, handheld device capable of regulating and delivering multiple doses of liquid medication to the nasal tissue will enable new treatment methods preferred by patients, pharmacist and physicians.*

This thesis validates the hypothesis by designing and prototyping an electronically controlled, multi-dose, novel nasal drug delivery device. The remainder of this thesis describes the design and manufacture of the device.

The picture of the final device developed to satisfy the above requirements are shown in Figure 1-2 (a) and the picture of the different parts in the device is shown in Figure 1-2 (b).

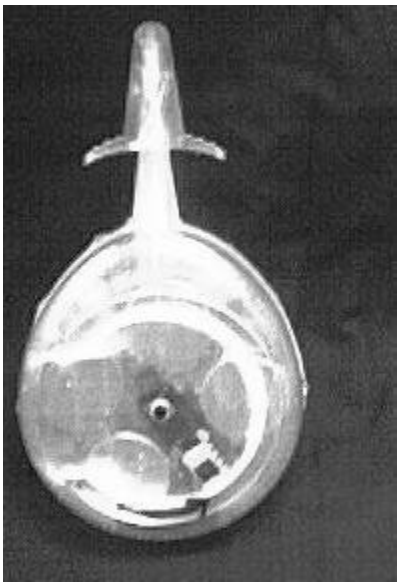


Figure 1-2: Nasal Sprayer

1.2 AXIOMATIC PERSPECTIVE OF DESIGN PROCESS

The above-mentioned device was designed following the axiomatic design theory [3]. According to the axiomatic design theory, the design involves zigzagging between the four domains: the customer domain, the functional domain, the physical domain and the process domain to identify the customer needs and develop design parameters and process variables to achieve those needs.

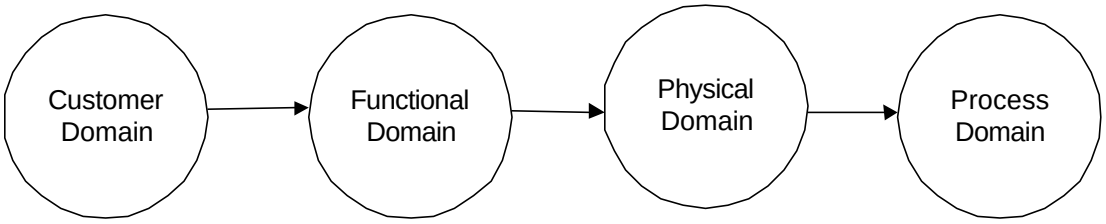


Figure 1-3: Axiomatic Process [Adopted from Nam.P.Suh [3]]

The domains in the left relative to the domain on the right represents (Figure 1-3) ‘what we want to achieve’, whereas the domain on the right represents the design solution for ‘how we propose to satisfy the requirements specified in the left domain [3]. This thesis

emphasizes on determining the design parameter and process variables from the physical and process domain, gathering the inputs from the customer and the functional domain. The functions of each domain and the activities performed in each of them are described in detail below.

Customer Domain: The customer domain characterizes the need or the expectations of the customers in the product [3]. Therefore, the customer expectation in this product is defined in this domain. This information can be gathered by means of surveys from the customers of the product.

Functional Domain: In the functional domain the customer needs are specified in terms of Functional Requirements (FRs) and Constraints (Cs), where, functional requirements are a minimum set of independent requirements that completely characterizes the functional needs of a product and constraints are bounds on acceptable solution [3]. Therefore, independence of functional requirements should be maintained while specifying the functional requirements. The main point to be concentrated while framing the functional requirements is that it should be determined in the solution neutral environment, that is the functional requirement should be specified before thinking about the possible solutions. The system is classified as large or small system only based upon the number of functional requirements it has to satisfy, rather than the physical size of the system.

Physical Domain: In the physical domain design parameters are defined to satisfy the functional requirements. The design parameters are the variables in the physical domain that characterizes the design satisfying the specified FR's [3]. The design parameters

should be selected with care, so that it does not conflict with the constraints. The design parameters (DPs) may be parts, assemblies or dimensions of a part, etc.

Process Domain: In the process domain, the process variables (PVs) are used to develop the process from the design parameters. The process variables are the variables in the process domain that characterizes the process, which can generate the specified DP's [3]. For an existing system, the process variables of the system are already defined and hence they act as constraints for the system. Some examples of the process variables of a system may be the capacity of the system, and the resources available to the system. Therefore, while designing the new system, the process variables should be chosen in such a way they satisfy the design parameters and constraints.

The axiomatic design theory states that the two axioms, the independence axiom and the information axiom should be used as guideline in defining the above parameters.

> *Independence axiom:* The independence axiom states that independence of functional requirements should always be maintained [3].
>
> *Information axiom:* The information axiom states that among those designs that satisfy the independence axiom, the best design has the smallest information content and therefore has the highest probability of success [3].

The remainder of this chapter employs the principles of axiomatic design theory to describe the design and manufacture of the device. The following sections briefly outline the customer needs, functional requirements, constraints, design parameters and process variables.

1.2.1 CUSTOMER NEEDS

The first step in framing the customer need is to identify the customers of the device. The three customers considered in this case are the patients, physicians and the pharmacist. The needs for each class of customer are listed below,

Customer needs from the patient's perspective are:

- It should be easy to operate.
- It should provide effective treatment with minimal side effects.
- The device should insure safety.
- It should be portable, so that it can be carried in the shirt pocket.
- It should have privacy during use, so that other cannot use it by mistake.

Customer needs from physician perspective are:

- It should deliver accurate amount of the dose.
- It should promote patient's safety.
- It should enhance efficacy of treatment i.e., medication should be delivered directly to the target area.
- It should be designed to control prescription frequency.

Customer needs from the pharmacist perspective are:

- The cost of the device should be less.
- The device should have novel features that would attract the patients to buy the device, like over dosage prevention, tamper evident, etc.

The above customer needs are condensed and organized hierarchically in Figure 1-4. The three major branches of needs are to enhance efficacy of treatment, to promote compliance, and to ensure safety.

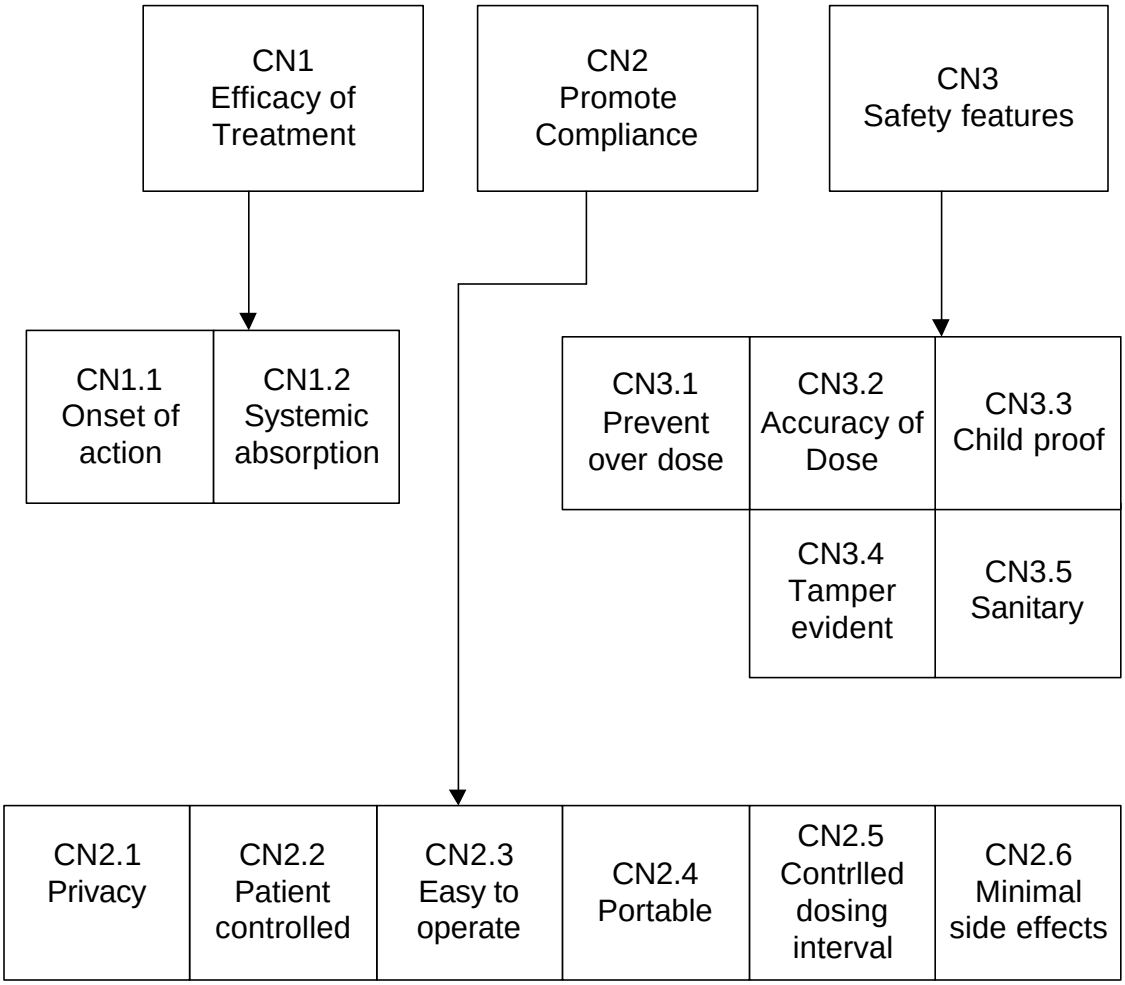


Figure 1-4: Customer Needs

The major branches are then subdivided further to give the second level of customer needs as shown in the Figure 1-4. Some of the customer needs like efficacy of treatment are satisfied by the nasal delivery, as it delivers the drug to a highly permeable tissue that is receptive of medication and also the time for the drug to perform its action is less in

nasal delivery compared to other means of medication. Therefore, the customer needs like onset of action and systemic absorption are achieved by the nasal drug delivery. The device for the nasal delivery has to satisfy the rest of the needs except minimal side effects. The customer needs that are focused for developing the device are preventing the overdose, accuracy of dose, controlling the dosing interval, portable, patient controlled, easy to operate and privacy. The other needs like child proof, tamper evident and sanitary were given little attention during the development of the device.

1.2.2 FUNCTIONAL REQUIREMENTS AND CONSTRAINTS

According to the axiomatic design theory, the functional requirements and the constraints should be defined in the functional domain. As discussed above, some of the customer needs are satisfied by the nasal drug delivery. The functional requirements for the rest of the customer needs are discussed below. The nasal delivery in itself gives rise to the functional requirement of delivering the drugs to the nasals tissue. Functional requirements are framed for the customer needs that are not satisfied by nasal drug delivery.

Customer Needs	Functional Requirements
CN2.1, CN3.3: Privacy during use and childproof	Authorizing the use of the device with security codes.
CN2.2: Patient controlled	Intake method should be less complex, unlike injections.
CN2.3: Easy to operate	Minimizing the number of controls in the device.
CN2.5: Controlled dosing interval	Incorporate programming of the device so that the pharmacist can vary the dosing interval.
CN3.1: Prevent overdose	Regulating the dosage interval by preventing the access to the drug before the dosage interval expires.
CN3.2: Accuracy of dose	Controlling the amount of drug dispensed.

The customer need that the device needs to be portable imposes the following constraints to the device:

- The shape of the device should be compact to fit the shirt pocket.
- Size of the device should fit the pocket.
- Weight of the device should be less so that it can be easily carried.

The other constraints from the manufacturers point of view are:

- Cost of the device should be less than $10.00.
- 10-30 doses should be accommodated in a device.

The customer needs like tamper evident and sanitary were not given much importance during the design of the device. The customer needs like minimal side effects depends on the drug rather than on the device for the drug delivery, and so it is neglected. Some customer needs are obtained through a single functional requirement that is the customer needs childproof and privacy is obtained through single functional requirement of authorizing the use of the device. Similarly, the customer needs onset of action and systemic absorption is obtained through nasal drug delivery. Figure 1-5 shows the functional requirements mapped to the customer needs.

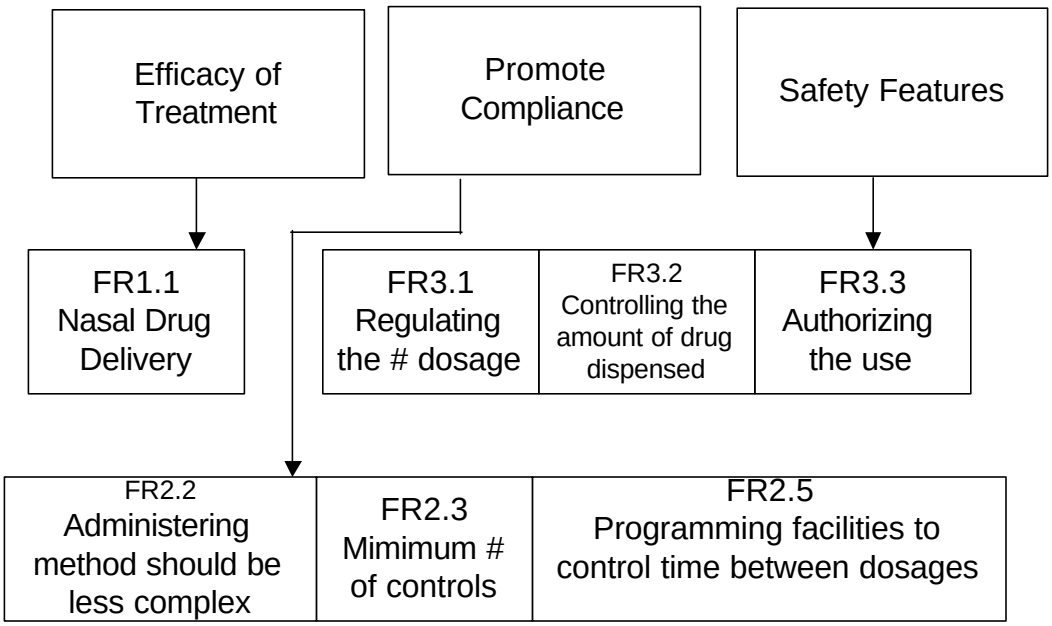


Figure 1-5: Functional Requirements

1.2.3 DESIGN PARAMETERS

The next step in the axiomatic design theory is to define the design parameters in the physical domain from the functional requirements. The functional requirement of controlling the amount of drug dispensed is achieved by designing a drug storage system that would control the amount of drug dispensed. The functional requirements like developing a programmable device and regulating the dosage can be achieved by designing a regulatory system. The other functional requirements like delivering the drugs to the nose are achieved by developing a drug dispensing system. Figure 1-6 shows the top-level design parameters. The design parameters are further decomposed in to sublevels and are discussed in detail in Chapter 2.

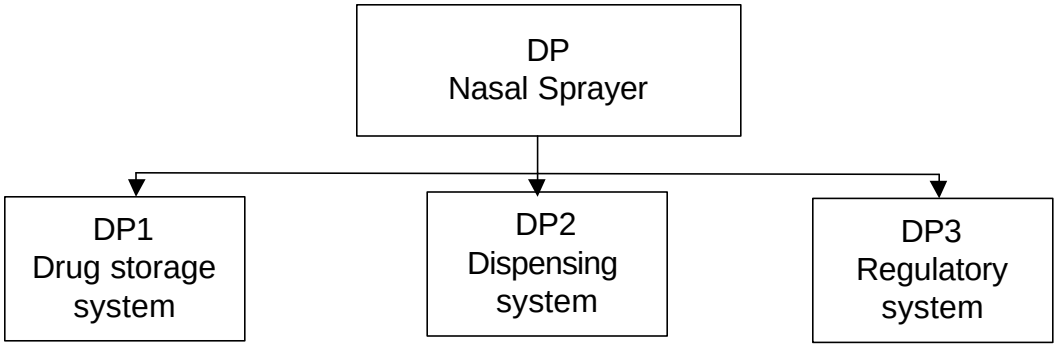


Figure 1-6: Design Parameters

1.2.4 PROCESS VARIABLES

The next step in the axiomatic design theory is to identify the process variables in the process domain from the design parameter (DP's). The process variables of this system are the resources needed to achieve the framed design parameters. The process variable to achieve the top level design parameters are the resources needed for sterilizing the container and filling the drugs, manufacturing the component of the device and assembling the components. The process variables will be discussed in detail after discussing the design parameters in detail.

1.3 OVERVIEW OF THE THESIS

The customer needs and the functional requirements of the device were framed in the first chapter. The second chapter focuses on the mapping the functional requirements to the design parameters. An electronically controlled device is developed as a result of the mapping. The behavior of the NiTi wire was studied, and a NiTi actuator is developed for regulating the drug delivery in the nasal sprayer. The developed device was tested by producing a prototype using rapid prototyping techniques. The device developed

following the axiomatic design theory is redesigned for efficient assembly in the third chapter. The design for manual assembly guidelines framed by Boothroyd et al [9] is used for redesigning the device for the manual assembly. The materials and manufacturing process for the parts of the device are determined in the fourth chapter, and the parts are redesigned to suit their manufacturing methods. The process variables of the device are identified in the fifth chapter 5, and the manufacturing and assembly cost for the device is calculated from the resources required.

Chapter 2 DESIGN PARAMETERS

2.1 INTRODUCTION

This chapter focuses on designing the parts of the nasal sprayer and testing the various designs to find the best one. In this chapter, the design parameters are mapped to the functional requirements, and the functional requirements are further decomposed into subfunctional requirements by zigzagging through the functional and physical domains. The functional requirements are decomposed until they cannot be further decomposed, and design parameters are framed for the new functional requirement. The mapping of the design parameters to the functional requirements is discussed in detail in the following sections. The design parameters in this case are the parts of the device and the features of the parts, through which the functional requirements identified in Chapter 1 are achieved. The prototype of the working model of the nasal sprayer is produced from the parts designed to test the functioning of the device. The tree in Figure 2-1 shows the design parameters decomposed into sublevels. The remainder of this chapter discusses in detail, the sublevel design parameters and analysis conducted on the functional parts to determine their optimal dimensions.

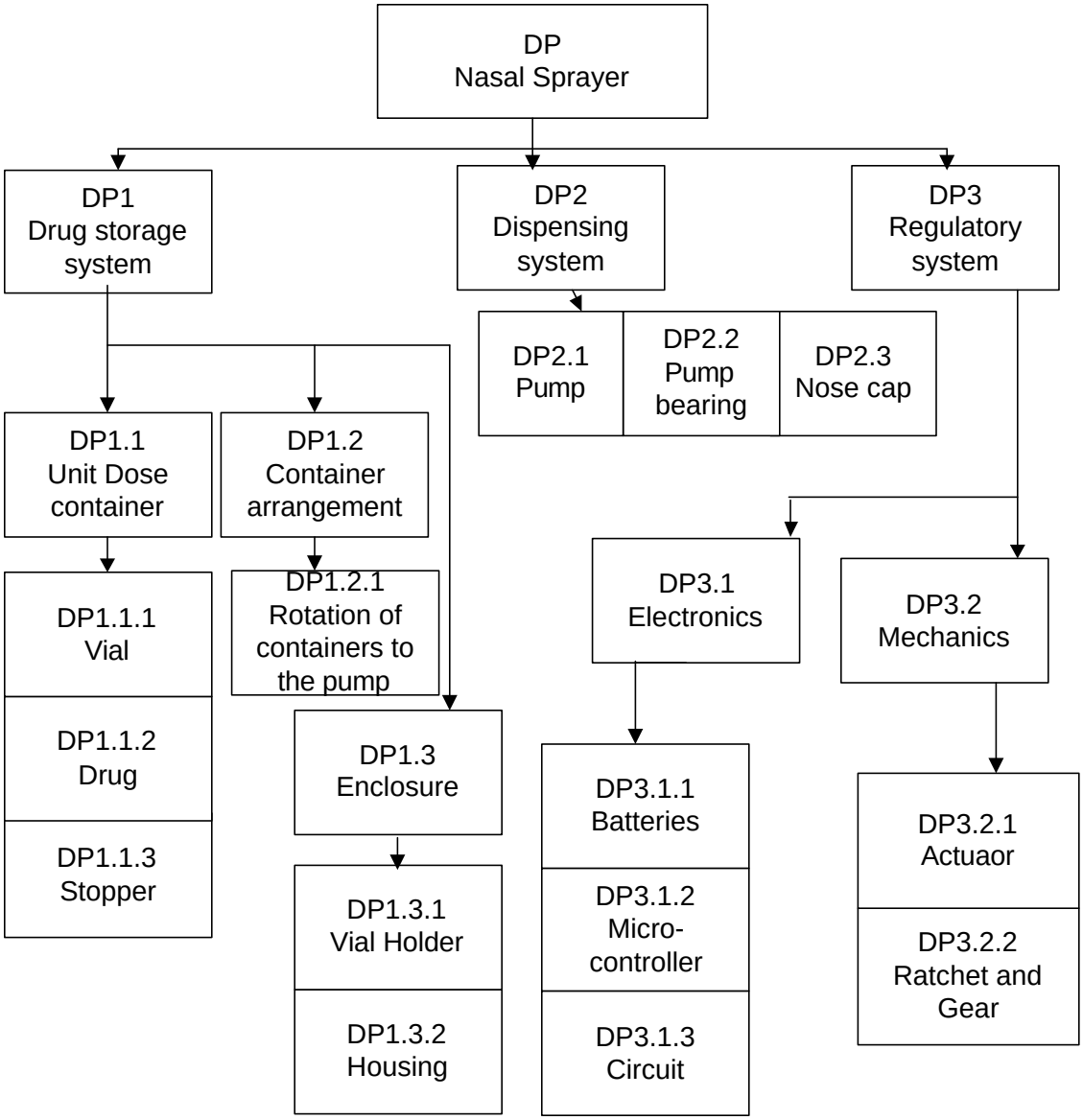


Figure 2-1: Design Parameter Tree

2.2 DRUG STORAGE SYSTEM

The primary requirement for delivering multiple doses of medication is storage. The two possible means of storing multiple doses of medication are by using a single bottle that contains multiple doses of medication or by using multiple containers (crucibles) to store

a unit dose of medication. Both approaches are currently commercially available. The latter choice is preferred because the glass vials can be easily sterilized compared to the polymer bottles. The accuracy of dosage is also easily achieved in the latter choice due to the following reasons. The dispensed volume of the drug in the unit dose containers is equal to the filled volume in the unit dose containers, and therefore dose accuracy is determined by the filling accuracy. The dose accuracy determined by the filling volume is higher compared to the multiple dose drops [4], and therefore the unit dose containers have higher dosage accuracy compared to the multi-dose bottles. Priming the pump makes the accuracy of dosage difficult in the former choice. The variability in the volume of dosage from one device to another is achieved by designing the unit dose containers for maximum dosage amount, so that the lower volumes of dosages can be automatically accommodated, and the variability in the number of dosages is accommodated by varying the number of vials in the device. Hence, the unit dose container is preferred for storing the medication due to the above advantages.

2.2.1 UNIT DOSE CONTAINER

The medication is stored by filling the crucibles (glass vials) with the unit dose of medication and sealing it with the rubber stopper. The spraying of the medication is achieved by puncturing the rubber stopper using a pump. The primary design parameters for the vials (unit dose containers) are its diameter and length. The design parameters are constrained in this case as the unit dose containers are commercially available; hence, it is appropriate to buy the commercially available ones rather than manufacturing them. Considering the arrangement of the vials, the advantages of designing the customized

vials for this application are analyzed in the next section. The vial along with the rubber stopper is shown in the Figure 2-2.

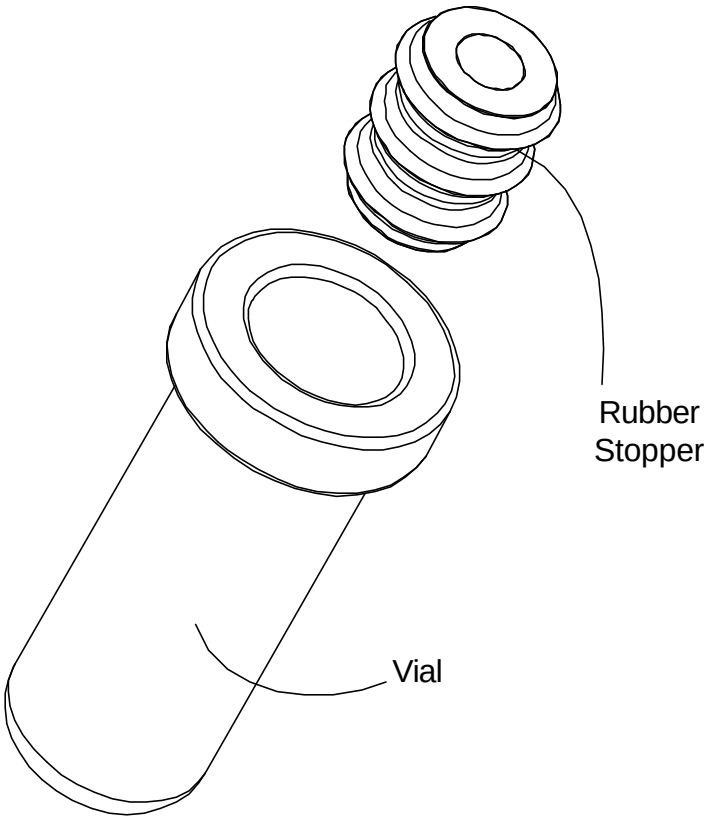
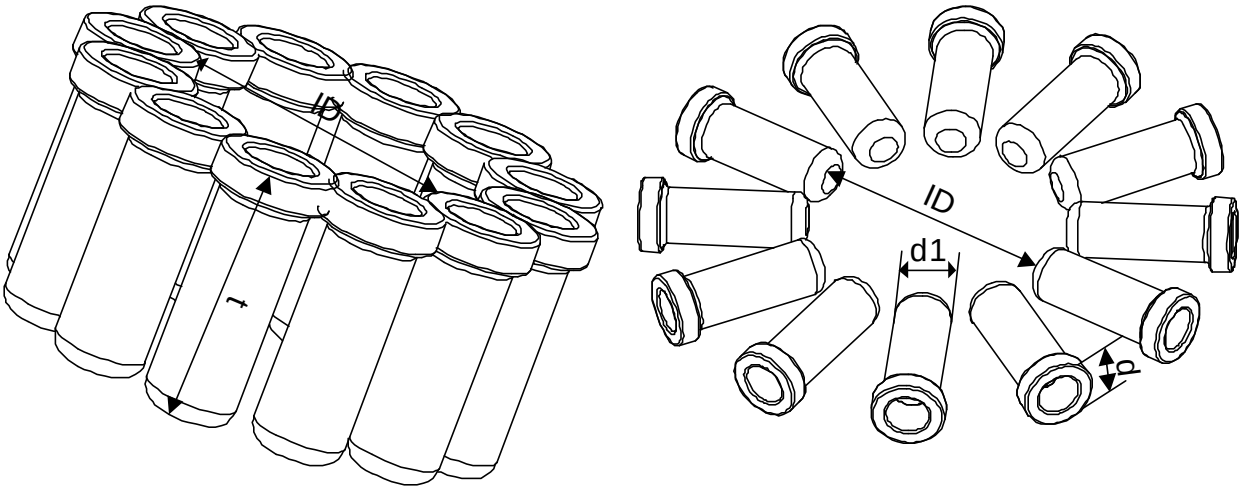


Figure 2-2: Vials and Rubber Stopper

2.2.2 ARRANGEMENT OF CONTAINERS

The two factors that have to be considered while deciding the arrangement of the vials are the shape and size of the device. The vial should be arranged and enclosed in a manner that fits inside the shirt pocket (portable). The two means of arranging the vials are arranging them axially around a center or arranging them radially, as shown in Figure 2-3. They can be enclosed in a flat enclosure by arranging them in a radial manner, whereas the axial arrangement gives rise to the need for a cylindrical or bottle-shaped enclosure. Both the arrangements are analyzed by comparing their packing efficiency for

a corresponding number of vials. The volume of the container is also compared, as it should fit inside the shirt pocket. Both the arrangements are cylindrical in shape with the thickness and the inner diameter being different.



(a) Axial Arrangement of Vials

(b) Radial Arrangement of Vials

Figure 2-3: Vials Arrangement

Therefore, volume for the axial arrangement is given by

$$V_a = p * (ID + d)^2 * t / 4 \quad (2\text{-}1)$$

The volume for radial arrangement is given by

$$V_r = p * (ID + t) * d / 4 \quad (2\text{-}2)$$

The number of vials that can be accommodated is given by

$$\#\text{ of vials} = p * (ID + d) / d \text{ (vertical arrangement)} \quad (2\text{-}3)$$

$$\#\text{ of vials} = p * ID / d1 \text{ (radial arrangement)} \quad (2\text{-}4)$$

$$PackingEfficiency = \#of\ vials / Volume \quad (2\text{-}5)$$

The graphs are plotted to compare the packing efficiency and volume of the arrangement.

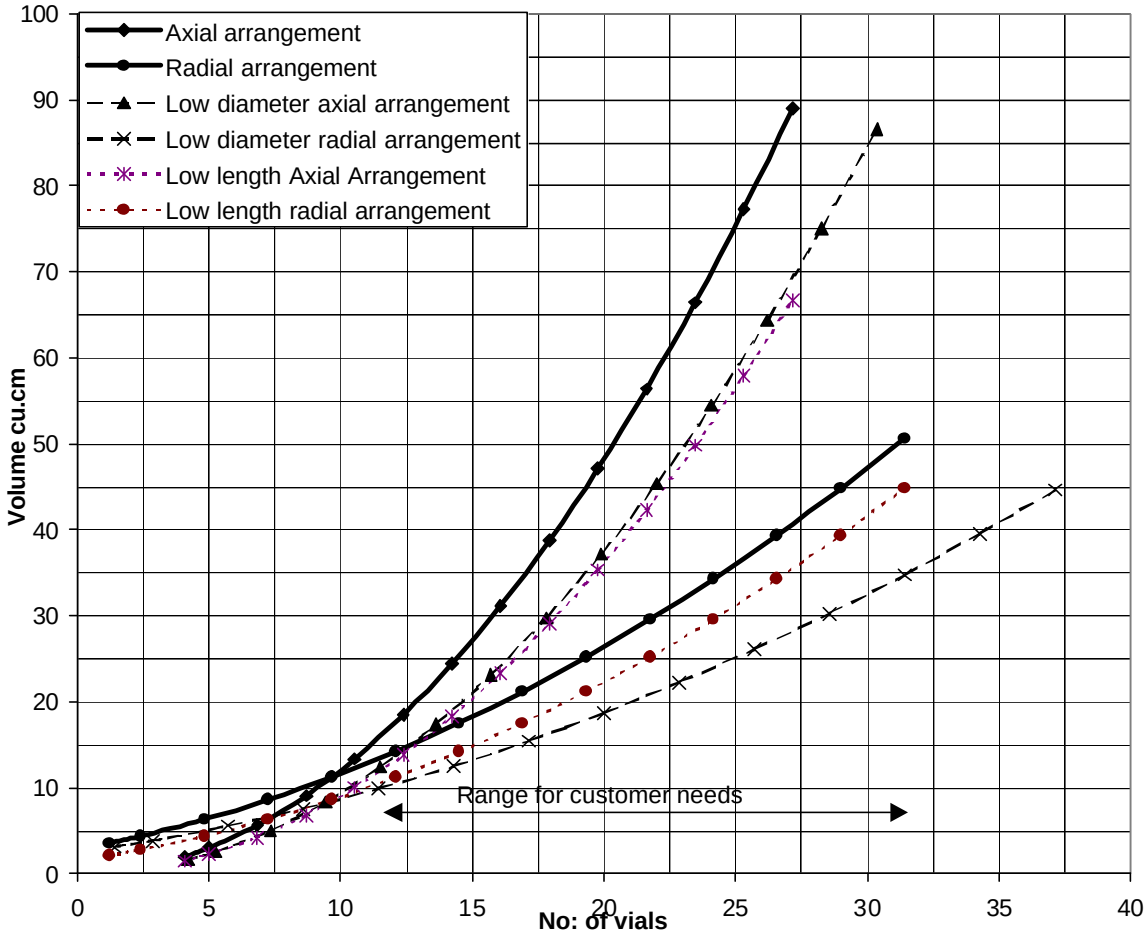


Figure 2-4:Number of vials Vs Volume of Container

Figure 2-4 shows the relationship between the number of vials and volume of the enclosure and Figure 2-5 shows the relationship between the number of the vials and the packing efficiency. The above graphs were plotted for the different volumes of the vials to analyze the effect of designing the customized vials. The volume of the vials is decreased to 80% of its original volume (vials commercially available) by decreasing its diameter in first case, and decreasing its length in the next, to see its effects on the packing efficiency and the volume of the arrangement. It is evident from the graph that decreasing the volume of the vials does not have any significant effect on the

arrangement of the containers for a fewer number of vials, but a decrease in volume of the container and increase in packing efficiency is achieved for larger number of vials (20-30). Therefore, it indicates that designing custom unit dose containers does not have any perceivable advantage if the number of vials is fewer than 20, but it would be advantageous if the number of vials were more.

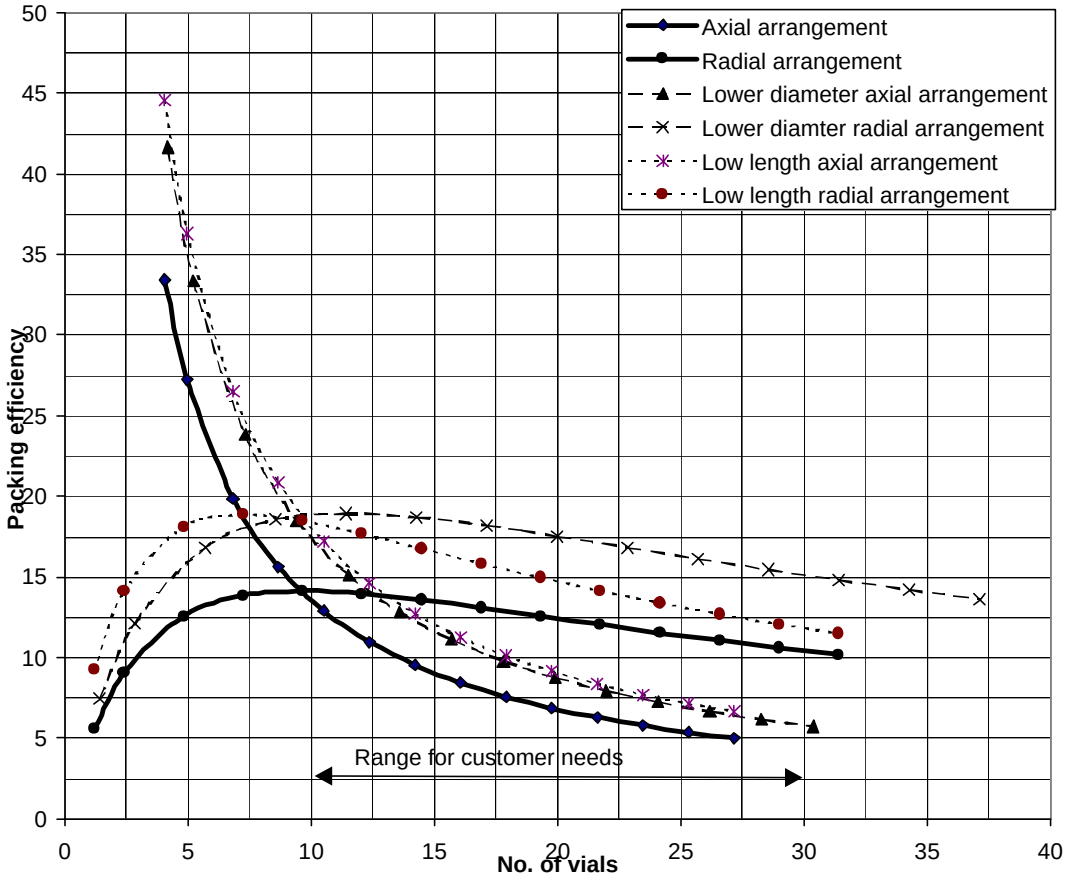


Figure 2-5: Number of vials Vs Packing efficiency

It is evident from the above figures that axial arrangement of the vials is a better option only if the number of vials to be accommodated is fewer than nine, and radial arrangement is the better option if more than nine vials are used. The radial arrangement of the vials is preferred as the constraint for this system is to accommodate 10-30 vials.

2.2.3 ENCLOSURE FOR THE VIALS

The functional requirement that needs to be satisfied while designing the enclosure for the vials are that all the vials should be accessible, and axial bearing for the vials should be provided so that they are not displaced from their position. A lid-shaped base with protrusions and slots as shown in Figure 2-6 is designed to accommodate the vials. Cutouts are provided along the periphery of the lid so that all the vials are accessible. This enclosure is called vial holder, which is shown in Figure 2-6.

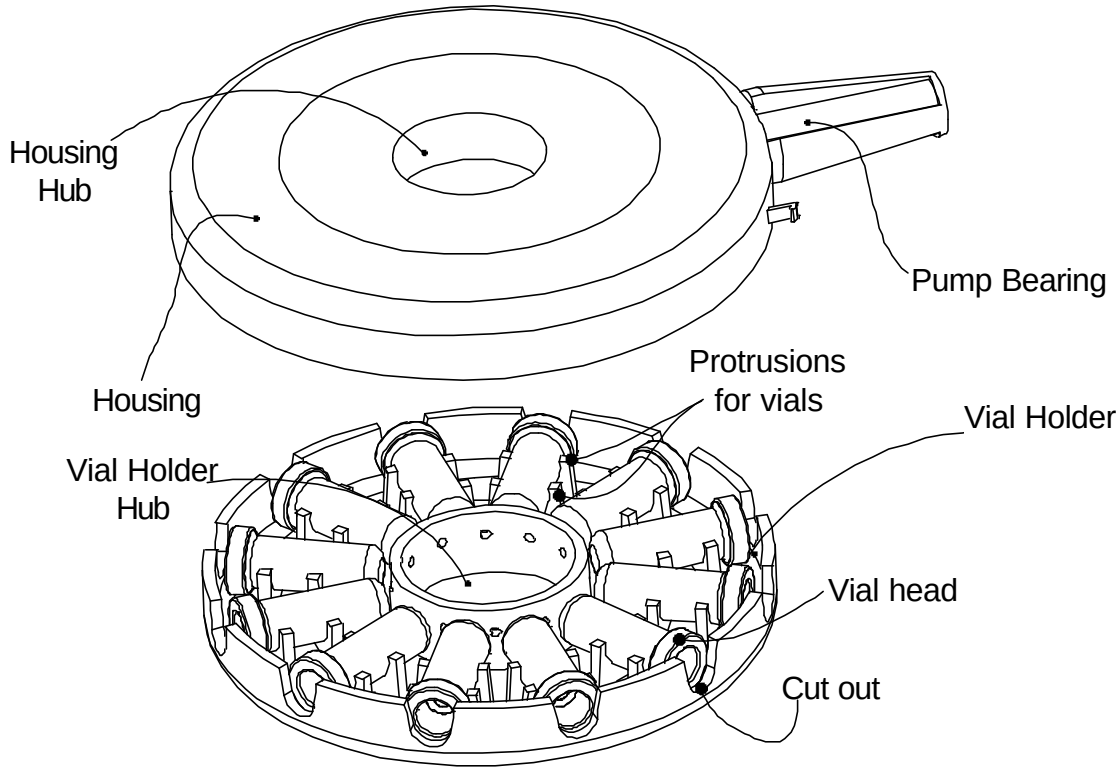


Figure 2-6: Vial Holder and Housing

The vial holder is protected by an outer cover, which is referred to as housing (Figure 2-6). The vials are first packaged into the vial holder in their positions, and then the housing is press-fitted to the vial holder, thus enclosing the vials. The central hub of the

housing and that of the vial holder acts as the radial and axial bearing between them. The protrusion for the vials (Figure 2-6) in the vial holder and its outer periphery provides axial bearing for the vials, i.e., the vial head is constrained between the two surfaces as shown in Figure 2-6. The protrusions for the vials are also used to position the vial, so that they are accessible through the cutouts provided and the medication in the vial is then accessed through the cutouts in the vial holder. The pump bearing in the housing makes sure that the pump is inline with the cutouts in the vial holder, when the pump is pressed to dispense the drug. The housing, along with the pump, rotates to access the vials in the vial holder for the medication. As mentioned above, the vial holder hub and the housing provide their bearing for the rotation. Thus, the enclosure for protecting the vials is designed for satisfying the functional requirements.

2.3 DISPENSING SYSTEM

A longer pump has to be used to reach the vials, as they are enclosing in the vial holder. This requirement is satisfied by designing a pump connector to connect two pumps, which is shown in Figure 2-8. The top surface of the pump connector has a hole to accommodate the needle of the first pump, and the bottom surface of the pump connector has the profile of the pump head to accommodate the second pump. The pump pusher (nose cap) is designed with protrusions for radial bearing as shown in Figure 2-8. The pump pusher in combination with the pump bearing in the housing (Figure 2-6) provides the radial and torsional bearing for the movement of the pump. Figure 2-7 shows the cross-sectional view of the pump along with the vial and rubber stopper. The pump is adopted from the unit dose nasal sprayer discussed in Chapter 1, and it was extended in length by using a pump connector. The working mechanism is the same as the unit dose

nasal sprayer; that is, the rubber stopper is punctured and pushed to the bottom of the vial by the pump, which ejects the drug out.

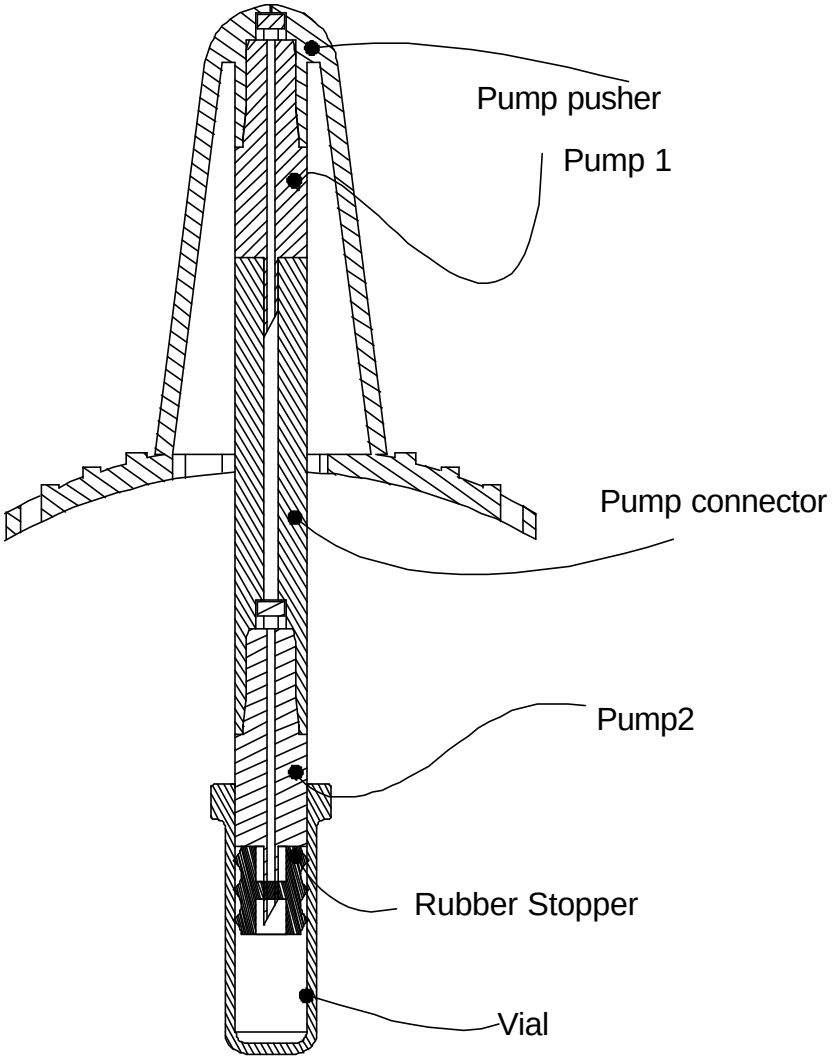


Figure 2-7: Cross-sectional View of the Pump

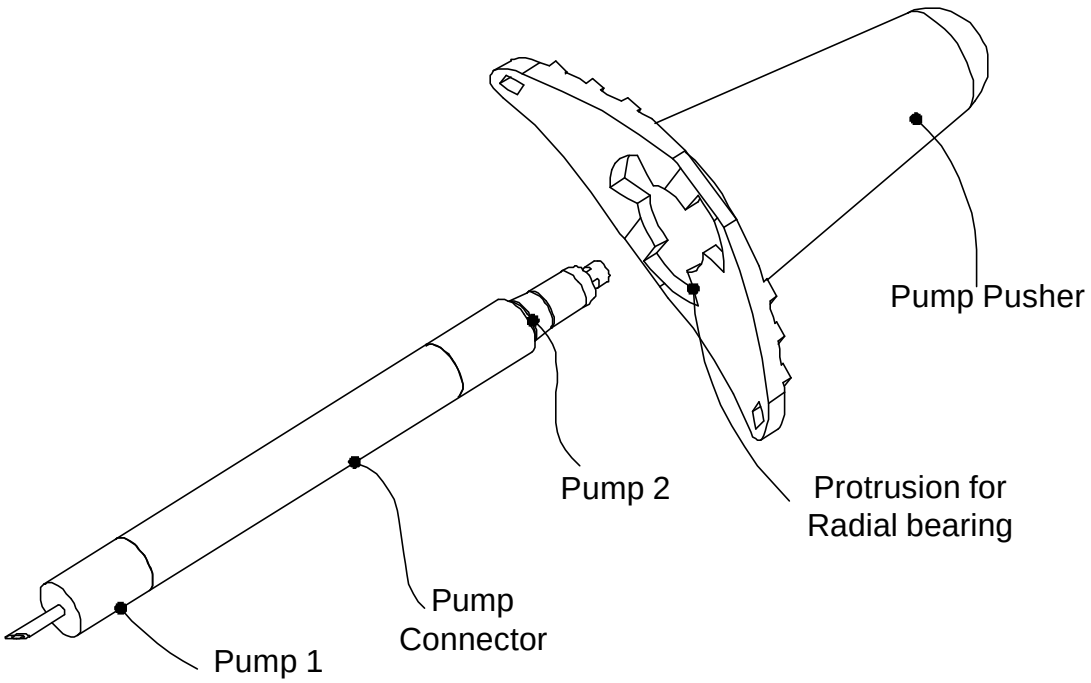


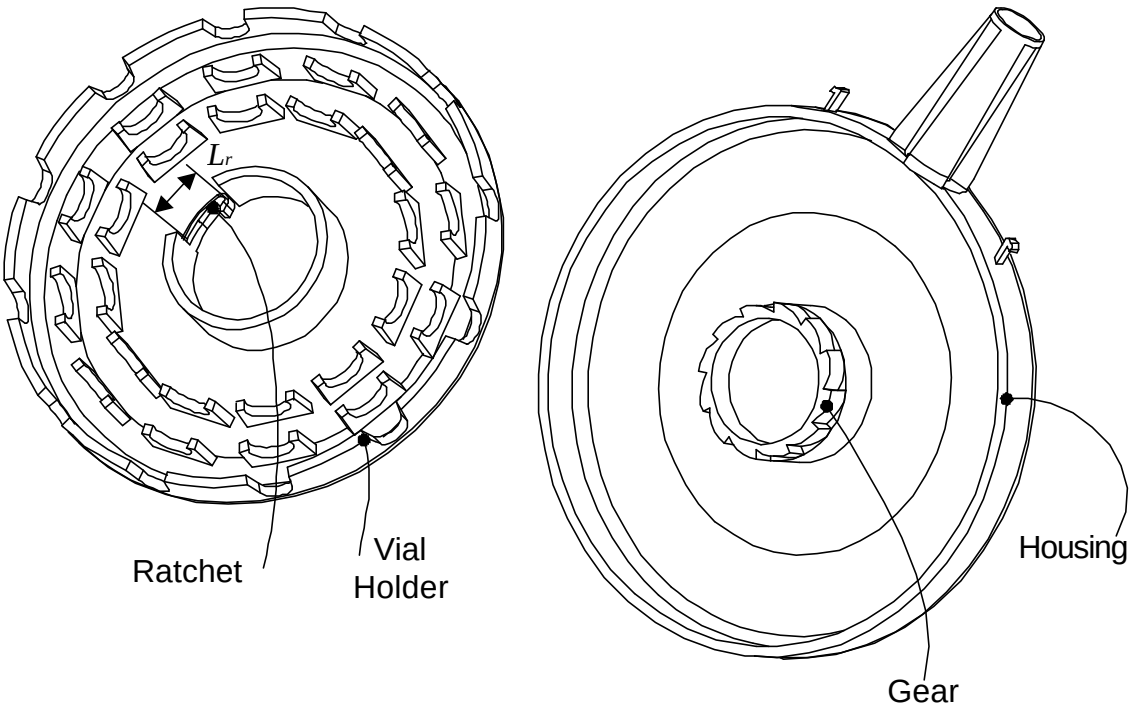
Figure 2-8: Pump Connector and Pump Pusher

2.4 REGULATORY SYSTEM

The rotation of the housing to access the next vial gives rise to the functional requirements of preventing the rotation of the housing in the reverse direction so that it does not access an empty vial, and controlling the forward rotation so that it rotates one vial at a time. The ratchet and gear mechanism is used for preventing the rotation in the reverse direction, which is discussed in detail in the following subsection. The regulatory system should also help in regulating the dosage by allowing only one vial to be accessed at a time. This is achieved by locking the rotary motion between the vial holder and the housing after indexing a vial. Shape memory alloy actuators are used for locking the rotation in the forward direction, which is discussed in detail in the next subsection of the chapter. The design parameter tree shown in Figure 2-1 lists the different components of the regulatory system.

2.4.1 PREVENTING ROTATION IN REVERSE DIRECTION

This is accomplished by modeling a ratchet and a gear, where the ratchet is incorporated into the vial holder, and the gear into the housing as shown in Figure 2-9.



(a) Vial holder with Ratchet (b) Housing with Gear

Figure 2-9: (a) Vial Holder (b) Housing

The ratchet locks into the gear and prevents the rotation of the housing in the reverse direction, whereas the ratchet bends allowing the housing to be rotated in the forward direction. The ratchet is a small hook-shaped structure attached to the hub of the vial holder. The gear is incorporated into the hub of the housing and the number of teeth in the gear corresponds to the number of slots in the vial holder for holding the vials (# of vials).

The dimension of the ratchet is computed from the equations below [5] so that the required deflection (amount of bending to allow forward rotation of the housing) is obtained. The ratchet along with its design parameter (length, width) and its meshing with gear is shown in Figure 2-9 and Figure 2-10.

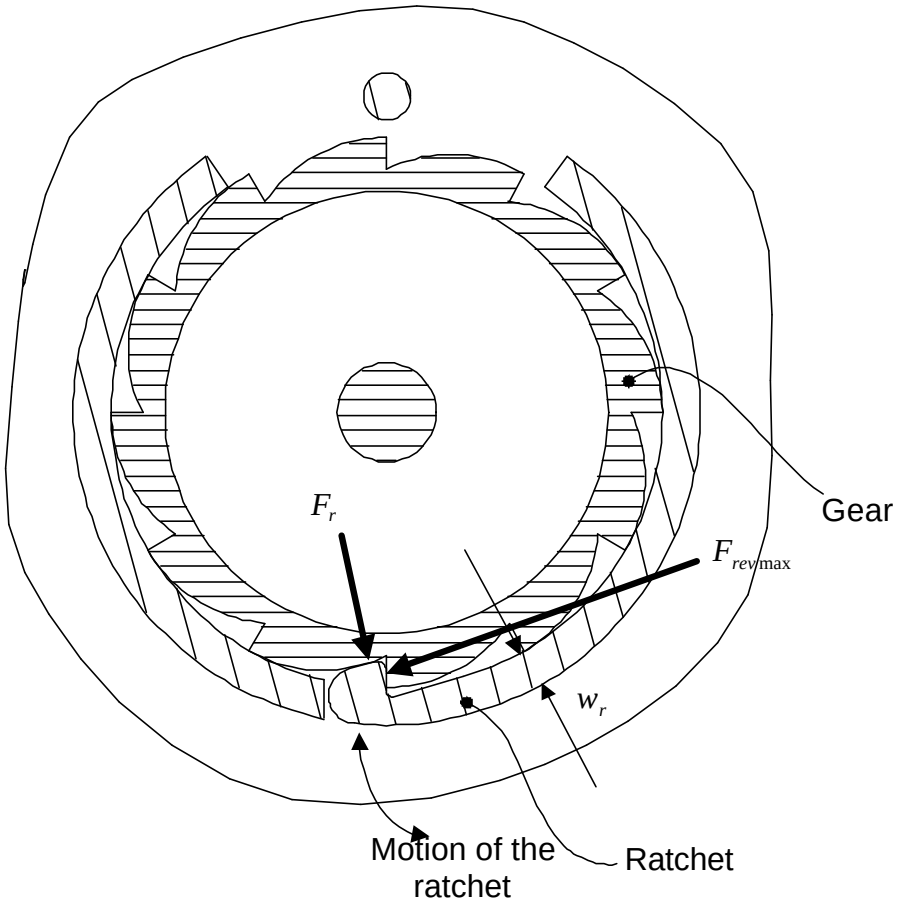


Figure 2-10: Ratchet with Dimensions

Considering the ratchet as a cantilever beam, the force acting on the ratchet beam (F_r) is directly proportional to the modulus of elasticity of the material of the ratchet (E), required deflection (y, i.e., depth of the gear teeth) and moment of inertia (I) and inversely proportional to the length of the ratchet (L_r).

$$F_r = 3 * y * E * I / L_r^3 \quad (2\text{-}6)$$

The moment of inertia of the ratchet (I) is proportional to the width (w_r) and the cube power of the thickness (t_r) of the ratchet.

$$I = w_r * t_r^3 / 12 \quad (2\text{-}7)$$

From the bending stress equation, maximum Stress that the piece can withstand (strength of the ratchet ($[s_{br}]$)) is proportional to the yield strength of the material (S_y) considering the factor of safety (N)

$$[s_{br}] = S_y / N \quad (2\text{-}8)$$

From the equation of the bending stress for the cantilever beam, the bending stress acting on the ratchet (s_{br}) is proportional to the force acting on the ratchet (F_r), length and thickness of the ratchet hook and inversely proportional to the moment of inertia.

$$s_{br} = F_r * L_r * t_r / 2\ I \quad (2\text{-}9)$$

Equating the stress acting on the ratchet (s_{br}) and the strength of the ratchet ($[s_{br}]$) (Eq. (2-8) & (2-9)), the equation for the thickness of the ratchet beam can be developed,

$$t_r = 4 * S_y * L_r^2 / 9 * y * E \quad (2\text{-}10)$$

The thickness of the ratchet can be found by varying the length of the ratchet. The dimension of the ratchet varies depending upon the material chosen.

Considering locking of the rotation in the reverse direction, the torque that the ratchet can withstand while preventing the rotation is given by the equations given below. The maximum force ($f_{rev\max}$) the ratchet can withstand while preventing the rotation in reverse direction is given by the product of the cross-sectional area and yield strength of the material of the ratchet

$$f_{rev\max} = w_r * t_r * S_y / N \quad (2\text{-}11)$$

Therefore, the maximum torque $t_{\max}$ that the ratchet can withstand is the product of the maximum force that the ratchet can withstand ($f_{rev\max}$), and the diameter of the hub of the vial holder (D_h).

$$t_{\max} = f_{rev\max} * D_h / 2 \quad (2\text{-}12)$$

The maximum force exerted while rotating in the reverse direction should be less than $f_{rev\max}$ for the ratchet to be safe. Thus, the rotation of the housing in the reverse direction can be prevented. The next functional requirement to be dealt with is preventing the over-dosage, which requires controlling the rotation of the housing in the forward direction.

2.4.2 CONTROLLING THE FORWARD ROTATION

The over-dosage is prevented by allowing the user to access one vial at a time, and the next vial after the stipulated time elapses. This gives rise to a new functional requirement of controlling the forward rotation of the housing. The housing should rotate once to the next vial, and it should be locked after advancing. The housing should be released only during the time of the next dosage, so that it can be advanced to the next vial for medication and thus the cycle continues. This requirement is achieved by providing slots

in the hub of the housing as shown in Figure 2-11. The number of slots and the slot dimensions correspond to the number of vials in the vial holder. The housing with slots is shown in Figure 2-11. The rotation of the housing is prevented by inserting a block into the slots, and the housing is free to rotate when the block is removed from the slot. Therefore, the next functional requirement is to block the slot in the housing at the required time, which is done by using an actuator.

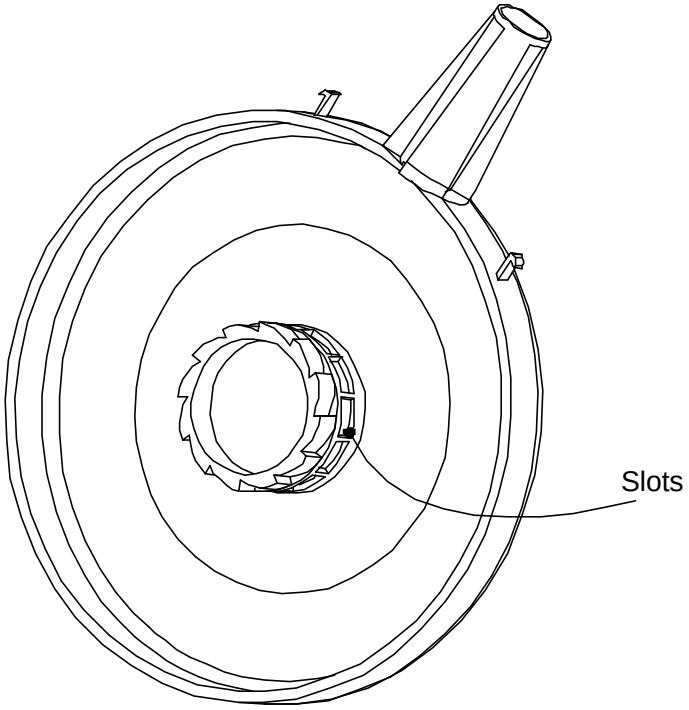


Figure 2-11 : Housing with Slots

2.4.2.1 ACTUATOR MECHANISMS

This portion of the chapter will describe the different actuation mechanism designed for blocking the slots, and the advantages and disadvantages of each method are highlighted. The actuator to be designed also has constraints on it size, as it has to be accommodated in the space available between the vials. The different actuators designed to block the slot in the housing are as follows:

- Flexural bearing actuator
- Tension spring linear actuator
- Compression spring linear actuator

The basic concept of all the three actuators is to excite a shape memory alloy (SMA) wire, so that it contracts in length and releases the block, and one of the mechanisms (flexural bearing or tension spring or compression spring) extends the SMA wire back to its original length and blocks the slot. The mechanism behind this is that the SMA wire contracts by about 4-5% of its original length when heated to a particular temperature, and it can be extended back to its original length when cooled. The bias force for extending the SMA wire back to its original length is provided by one of the above mechanisms. The wire is heated to the required temperature inductively by passing current through it. The amount and the duration of the current are controlled by the microprocessor to prevent overheating of the wire. The microprocessor is programmed to actuate the wire in the stipulated intervals of time and to remove the block. The housing is then rotated to the next vial, and one of the actuator mechanisms pushes the blocks into the next slot, which prevents the user from rotating more than one vial. The other available options for blocking the slot in the housing are using solenoids or piezo electric crystals to block the slot by passing the current through them. The advantages of using the SMA actuators compared to the above two options are that it consumes less power and the SMA actuators can be developed in relatively small sizes compared to the other options. Thus, the space constraint for the actuator is easily met with the SMA actuators rather than the other options. As the power requirement is directly proportional to the number of batteries needed, it should be kept at a minimum level to minimize the cost of

the device. Therefore, the shape memory alloy actuators are preferred compared to the other two options. According to the study of W.Huang [6] on the selection of material for the shape memory alloy actuators, NiTi wire is found to be the best choice with respect to the thermo-mechanic related performances. The characteristics and properties of the different diameter NiTi wire are briefly discussed below.

2.4.2.2 WIRE CHARACTERISTICS

Figure 2-12 gives the percentage change in length of the NiTi wire, with change in temperature. It is evident from the graph that 5% change in length can be achieved by heating the wire from 25^{o} C to 80^{0} C and the change in length is reversible. The top curve shows the path followed while heating the wire and the bottom curve shows the path followed during cooling. The residual strain in the wire is removed by stretching back the wire with the help of the actuators.

The data collected from the wire suppliers (Dynalloy [7]) regarding the behavior and properties of the wire are listed as follows:

- Wire can be stretched 4-5% of its length below its transformation temperature by a force of only 692 kgf/cm^2 (10000Psi) or less
- The wire contracts (4-5%) when heated through the transformation temperature exerting a stress of 1730 kgf/cm^2 (25000Psi)
- The normal working temperature of the NiTi wire is 60-110^{o} C.
- Straining more than 4-5% of the original length causes dislocation movement throughout the structure and degrades the recovery as well

- Maximum force that a single wire can exert is 3460 kgf/cm^2 (50000Psi), and to repeat cycling no more than 1384 kgf/cm^2 (20000Psi) would be effective.

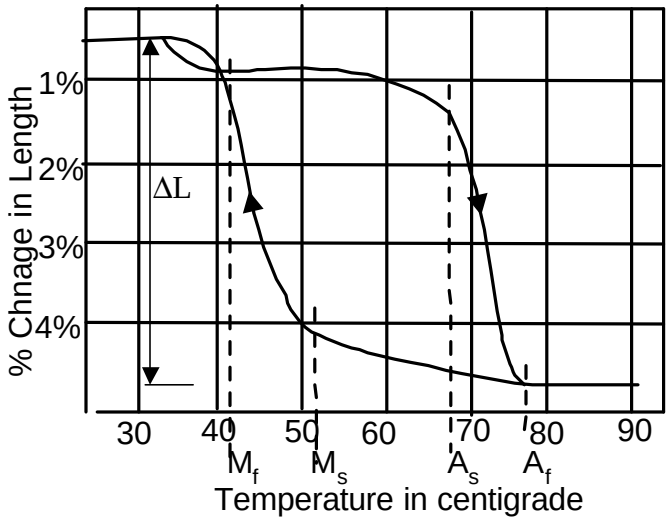


Figure 2-12 :NiTi wire behavior (Refer [7] for graph toscale)

The table below [3] gives the properties of different diameters of NiTi wire

Table 2-1: NiTi Wire Properties [7]

Wire Diameter	**Resistance Ohms/inch**	**Max. Pull force Gms**	**Current at room temperature mA**	**Contraction time sec**
0.0015”	21	17	30	1
0.002”	12	35	50	1
0.003”	5	80	100	1
0.004”	3	150	180	1
0.005”	1.8	230	250	1
0.006”	1.3	330	400	1
0.008”	0.8	590	610	1
0.010”	0.5	930	1000	1
0.012”	0.33	1250	1750	1
0.015”	0.2	2000	2750	1

2.4.2.3 FLEXURAL BEARING ACTUATOR

In this mechanism, the NiTi wire is attached to a toggle, which is fixed to a torsion post. The torsion post acts as a fulcrum for the toggle, so that it can move in and out of the slot when pulled and released by the NiTi wire. The deflection obtained from this mechanism is the sum of the deflection caused due to the torsional bending of the post and bending of the toggle. The torsion post is secured to the vial holder, and the height of the torsional post is adjusted so that the toggle blocks the pockets (slots) in the housing. Figure 2-13 shows the toggle and the post.

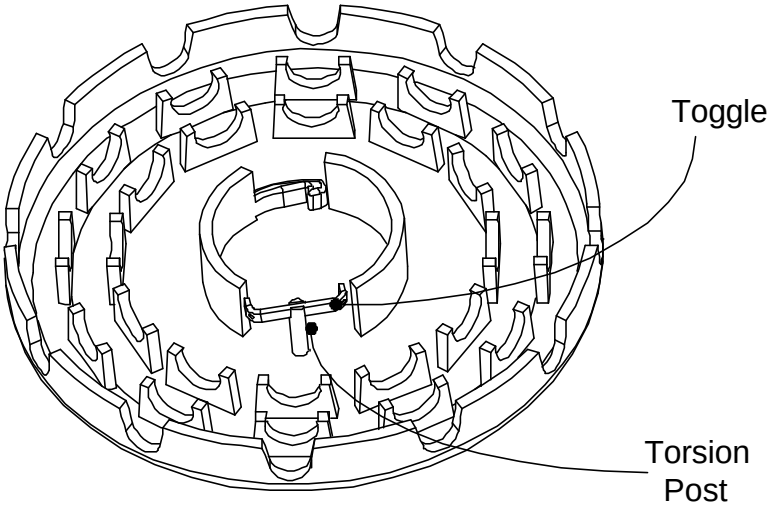
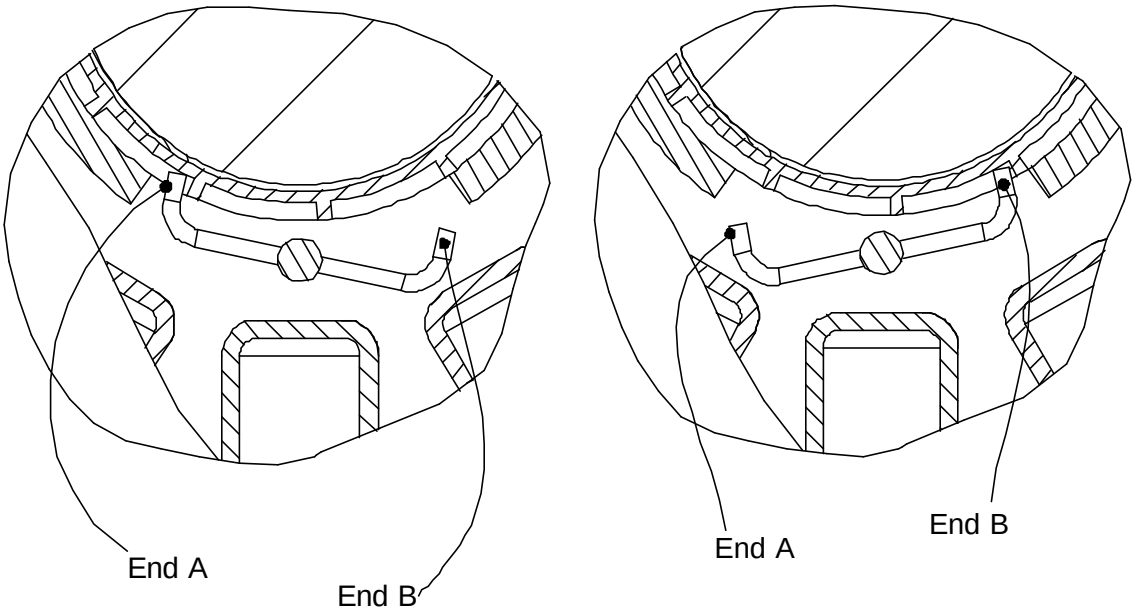


Figure 2-13 : Toggle and Torsion Post

The working of this mechanism is explained as follows. First, one end of the toggle will engage with the slot in the housing as shown in Figure 2-14. The NiTi wire is attached to tip of the toggle at one end, and secured tightly to post in the other, and the electrical connections are given to both the ends. When the current is passed through the NiTi wire

it contracts in length, pulling one end (end A) of the toggle out of the slot. Due to the pivoting action of the torsion post, the other end (end B) of the toggle is forced (pushed) into the next slot (shown in Figure 2-14), allowing the housing to turn partially. The wire is then cooled, and the elastic modulus of the toggle and the torsion post pushes back the toggle (end A) into the slot by stretching the NiTi wire to its original length. The energy required for stretching back the wire is provided by the stiffness (elastic modulus) of the material of the toggle and post. As mentioned above, due to the pivoting action of the torsion post, the other end (end B) is pulled out of the slot, allowing the housing to be turned until the slot hits end A of the toggle. Thus, this completes a cycle, and the pump, along with the housing, is indexed to the next vial. The access to the drug can be controlled by controlling the excitation of the NiTi wire.



(a) Toggle State 1 (b) Toggle State 2

Figure 2-14 : Toggle State

The dimension of the toggle and the torsion rod has to be figured out so that the necessary deflection (depth of the slot in the housing) is obtained. The deflection from the toggle and the post should be greater than the depth of the slot in the housing, otherwise the end of the toggle will not be completely pulled out, and the housing will still be restricted from rotating. The equations for calculation of the dimensions of the torsion post and the toggle are given below. The dimensions of the toggle and the torsion post are shown in Figure 2-15. The total deflection from this assembly is given by

Total deflection = Deflection due to the torsion of the post + Deflection due to bending of the toggle.

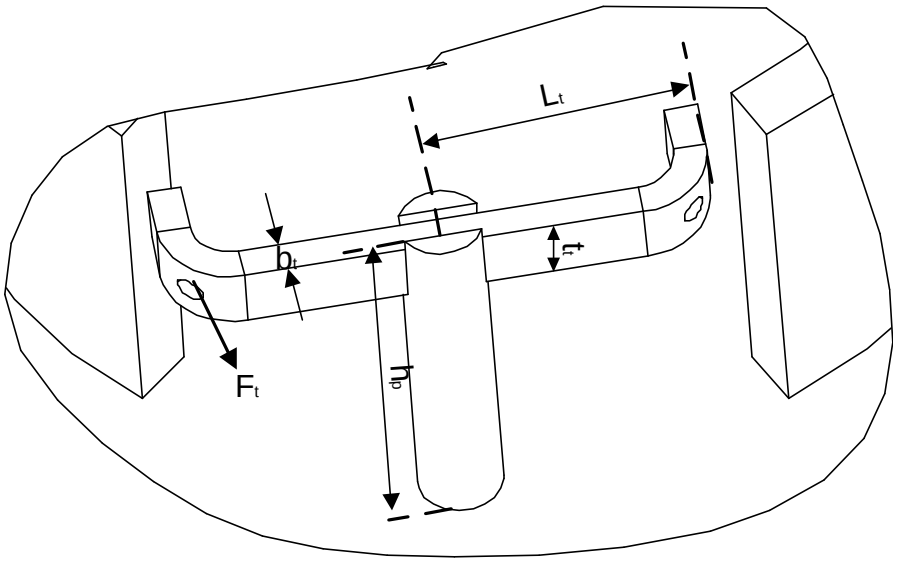


Figure 2-15 : Dimensions of Toggle and Torsion post

Deflection due to the torsion of the post

The torque acting on the torsion post (t_p) is given by the product of the force acting on the toggle (F_t) and one half length of the of toggle (L_t), where, the force acting on the

toggle is the pull force exerted by the NiTi wire, which can be obtained from the Table 1 corresponding to the diameter of the wire used. The torque acting on the post is given by product of the force and length.

$$t_p = F_t * L_t \tag{2-13}$$

The shear stress acting on the post is calculated for both hollow and the solid post from the torque acting on the toggle and diameter of the post (d_p, in the case of solid post and d_o, the outer diameter in case of the hollow post).

$$Shear\ Stress = (t_p * d_p / 2) / J \qquad (for\ Solid\ rod) \tag{2-14}$$

$$Shear\ Stress = (t_p * d_0 / 2) / J \qquad (for\ hollow\ post) \tag{2-15}$$

The polar moment of inertia (J) of the post is given by the equations (2-16) and (2-17), where d_i is the inner diameter of the post in the case of hollow post.

$$J = p * d_p^4 / 32 \qquad (inch^4) \quad for\ solid\ rod \tag{2-16}$$

$$J = p / 32 * (d_o^4 - d_i^4) \qquad (inch^4) \quad for\ hollow\ post \tag{2-17}$$

The angular deflection of the post (q) due to torsion is directly proportional to the torque acting on the post (t_p) and the height of the post (h_p), and inversely proportional to the polar moment of inertia (J) and modulus of rigidity (G) of the material of the post.

$$q = t_p * h_p / J * G \tag{2-18}$$

Then the corresponding linear deflection is given by the equation (2-19).

$$Linear\ deflection\ due\ to\ torsion = L_t * q \tag{2-19}$$

Deflection due to bending of the toggle

The stress induced in the metal due to bending (s_{bt}) is directly proportional to the force acting on the toggle (F_t), one half length of the toggle (L_t) and thickness of the toggle (t_t), and inversely proportional to the moment of inertia of the toggle (I).

$$s_{bt} = (F_t * L_t * t_t / 2) / I \quad (2\text{-}20)$$

The moment of inertia of the toggle (I) is proportional to the width of the toggle (b_t) and the cube power of the thickness of the toggle (t_t).

$$I = b_t * t_t^3 / 12 \quad (2\text{-}21)$$

The deflection due to bending (y_t) is directly proportional to the force acting on the toggle (F_t) and cubic power of the one half length of the toggle (L_t), and inversely proportional to the modulus of elasticity (E) of material of the toggle and its moment of inertia (I).

$$y_t = F_t * L_t^3 / 3 * E * I \quad (2\text{-}22)$$

Therefore the total deflection is given by sum of deflection due to torsion of the post and bending of the toggle, i.e., sum of Equations (2-19) & (2-22).

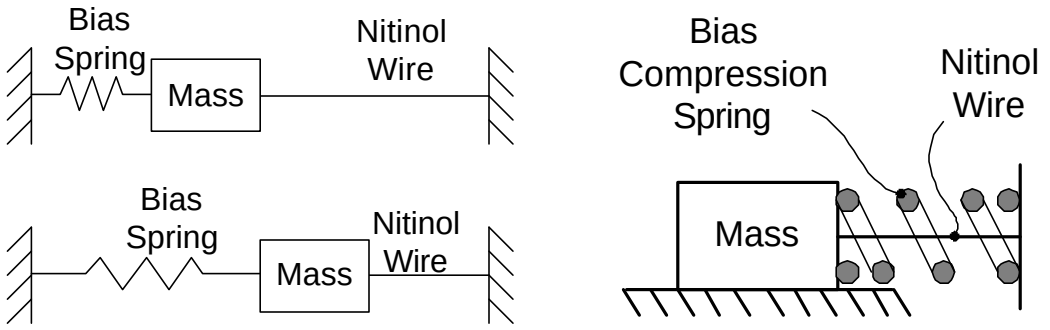
$$Total\ Deflection = (L_t * q) + (F_t * L_t^3 / 3 * E * I) \quad (2\text{-}23)$$

The dimensions of the toggle, torsion post and the depth of the slot should be adjusted to the desired value, by choosing the appropriate materials for them. This mechanism would only work if the toggle and the torsion post were strained within their elastic regions, that is the shear stress and the bending stress acting on the torsion post and toggle due to the

pull force created by NiTi wire, should less than their yield strength. The torsion post and toggle will be plastically deformed, if the stress acting on them exceeds their strength, and hence they will not be able to stretch the NiTi wire back to its original length. Therefore, tensile test and the fatigue test should be conducted on the materials of the post and toggle, before deciding the dimensions of the piece. The spreadsheet showing the calculation of the dimensions of the post and toggle and the corresponding deflection is shown in the Appendix A for a particular material. It was found from that sufficient deflection is not achieved from the solid torsion post, and hollow post is very fragile that it would fail. Therefore, the bias spring actuators were considered as the best choice for the actuation.

2.4.2.4 BIAS SPRING ACTUATORS

In this mechanism, the toggle and the torsion post are replaced by the springs. This mechanism involves modeling a bearing and a slider. The NiTi wire pulls the slider back from the slot and the spring pushes it back into the slot, instead of the toggle and torsion post. The working of the tension spring and the compression spring actuators are discussed in detail in the later part of this chapter. The basic principle is that when the wire is heated inductively by current, the recovery force generated by the shape memory effect compresses (in case of compression spring) or stretches the spring (in case of tension spring) and stores the energy in the spring. When the wire is cooled, the energy stored in the spring is used to strain the wire back to its initial position [8]. The principle described is illustrated in Figure 2-16 for the tension spring actuator and compression spring actuator respectively.



(a) Tension Spring Concept (b) Compression Spring Concept

Figure 2-16: Bias Spring Concept

The stiffness of the springs and the diameter of the NiTi wire that can be used along with the spring have to be determined for the bias spring actuators. The equations discussed below are developed to choose the right spring and the wire for the bias spring actuators. Two sets of equations were developed; in the first set of equations, the spring stiffness is taken as the input and the NiTi wire diameter is calculated, whereas, in the second set of the equations based on the NiTi wire diameter, the stiffness of the spring is determined. The advantages and disadvantages of the two models will be discussed after discussing the models. The effects of friction force and additional load were not considered in the first model, whereas they are accounted in the second model.

MODEL WITHOUT ACCOUNTING THE FRICTION FORCE

The Figure 2-17 shows the different states of the spring and the NiTi wire like free state, actuated state, preloaded state etc. The equations are developed considering the tension spring actuator and it has to be modified appropriately for the compression spring actuators.

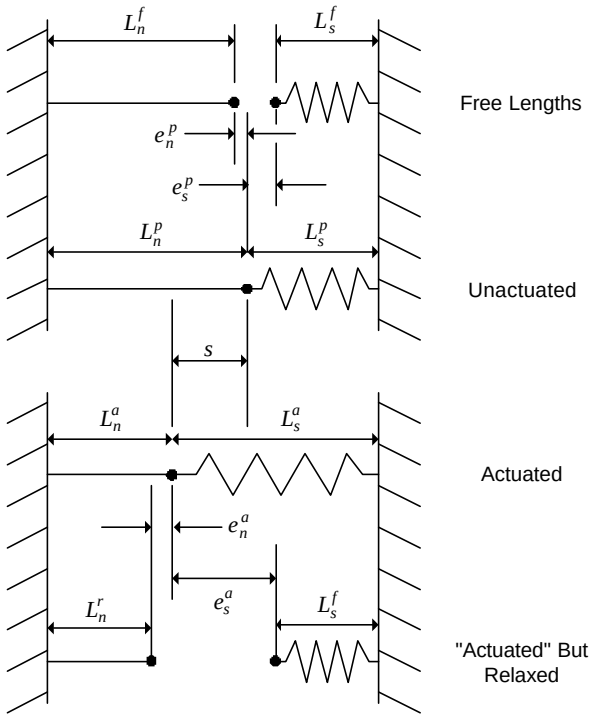


Figure 2-17 : States of NiTi Wire

The different dimensions shown in the Figure 2-17 are explained below,

L_n^f = Length of the NiTi wire before preloading

L_s^f =Length of the spring before loading.

L_n^p =Length of the NiTi wire after being preloaded

L_s^p =Length of the spring after being preloaded

L_n^a =Actuated length of the NiTi wire

L_s^a =Actuated length of the spring

L_n^r =Length the NiTi wires would be if it is not preloaded with spring after actuation

e_n^p =Elongation of the NiTi wire due to pre-loading

e_s^p =Elongation of the spring due to preloading

s = Elongation of the NiTi wire due to actuation, which is equal to the stroke needed.

e_n^a = Elongation of the NiTi wire if the preload is removed after actuation

e_s^a =Elongation of the spring if the preload is removed after actuation.

With these variables the following equations are arrived at as follows:

From the Hooke's law we know that, Young's modulus = stress/ strain

Considering,

σ_p as the stress in the wire after preloading and

σ_a as the stress in the wire after actuation

By Hooke's law, the strain due to preloading e_p is given by the ratio of the stress in the NiTi wire after preloading (σ_p) and the young's modulus of the wire before actuation (E_{low}).

$$e_p = s_p / E_{low} \quad (2\text{-}24)$$

Similarly, the strain due to the actuation (e_a) is given by the ratio of the stress in the NiTi wire after actuation (σ_a) and the young's modulus of the wire after actuation (E_{high}).

$$e_a = s_a / E_{high} \quad (2\text{-}25)$$

The young's modulus is different for the NiTi wire before and after actuation because, when the current is passed through NiTi wire, phase transformation occurs as shown in

Figure 2-12, from martensite to austenite and back when cooling. This phase change causes the difference in young's modulus.

Also, Strain = Elongation / original length

Therefore the elongation of the NiTi wire before (e_n^p) and after (e_n^a) the actuation are given by equations (2-26) and (2-27)

$$e_n^p = \mathrm{L}_\mathrm{n}^\mathrm{f} * e_p \quad (2\text{-}26)$$

$$e_n^a = \mathrm{L}_\mathrm{n}^\mathrm{r} * e_a \quad (2\text{-}27)$$

Therefore, the final length is the sum of the original length and elongation if there is an increase in length (while extending after cooling) or difference between the two if there is decrease in length (while contracting after actuation).

$$L_n^p = L_n^f + e_n^p \quad (2\text{-}28)$$

$$L_n^r = L_n^a - e_n^a \quad (2\text{-}29)$$

The stroke (s) is the difference between the actuated length (L_n^a) and the preloaded length (L_n^p)

$$L_n^p = L_n^a - s \quad (2\text{-}30)$$

From the definition of the stress as force per unit area, the equation of the preload force (F_p) and the actuation force (F_a) on the NiTi wire is given by equations (2-31) and (2-32), where A_w is the cross sectional area of the wire.

$$F_p = s_p * A_w \quad (2\text{-}31)$$

$$F_a = s_a * A_w \quad (2\text{-}32)$$

The cross sectional area of the NiTi wire (A_w), is directly proportional to the square of the diameter of the NiTi wire (d).

$$A_w = p * d^2 / 4 \quad (2\text{-}33)$$

The force required for the elongation of the spring is given by the product of the stiffness of the spring (k) and its elongation length (e_s^p). Therefore, the preload force and the actuation force from the spring perspective is given by the equations (2-34) and (2-35).

$$F_p = k * e_s^p \quad (2\text{-}34)$$

$$F_a = k * (e_s^p + s) \quad (2\text{-}35)$$

Equating, the preload forces (Eq (2-31) & (2-34)) and the actuation forces (Eq (2-32) & (2-35)) the area of the wire can be determined, thus, the diameter of the wire can found. The length of the NiTi wire is given from the elongation of the wire (e) as

$$L_n^f = s / e \quad (2\text{-}36)$$

Rearranging and solving the above equations with $E_{low}, E_{high}, s, s_p, s_a$ and k as the input parameter, we can arrive at the optimum values for the other variables, like preload length of the spring and other parameter that needs to set can be determined. The disadvantage of this model is that, the forces that the NiTi wire needs to pull in addition to the spring stiffness were not considered. This led to the failure of these equations in the practical cases where friction is involved or where some load needs to be pulled. However, the above equation produces reliable results for the experimental setup, to

study the behavior of the different combination of springs and NiTi wire, because in the experimental setup the springs are directly connected to the NiTi wire.

MODEL ACCOUNTING THE FRICTION FORCE

In this model, the effects of the friction were considered, and the equations were framed, and the graphs were plotted illustrating the effects of the friction on the other parameters. In this model optimal, preload stress and actuation stress, were got from the suppliers of the wire (Dynalloy Inc [7]) to repeat cycling and to make sure that the wire is not overloaded, which might deprive its characteristics.

Therefore,

Preload stress or Stress before actuation [7] σ_p = 692 kgf/cm^2 (10000 PSI)

Actuation stress or Stress after actuation [7] σ_a = 1384 kgf/cm^2 (20000 PSI) (Refer wire characteristics section (Section 2.4.2.2 of the thesis))

The force NiTi has to be preloaded (F_p) by the spring to overcome the friction, is given by equation (2-37), where f is friction force between the bearings in this case or the load the bearing has to pull.

$$F_p = s_p * A_w + f \quad (2\text{-}37)$$

The actuation force (F_a) that NiTi wire can generate is the product of the actuation stress and the cross-sectional area of the NiTi wire (A_w).

$$F_a = s_a * A_w \quad (2\text{-}38)$$

The main condition here is the actuation force generated by the NiTi wire should be greater than force the NiTi wire has to be preloaded, otherwise the wire will not be able to pull the slider back. Therefore if the actuation force is lesser the wire diameter needs to be increased. The correct wire diameter for the application is found by increasing the wire diameter step by step from the smallest wire diameter, until the actuation force generated by the wire is greater than the force to which it is preloaded. The equation for the stiffness of the spring that is used in conjunction with the wire selected is derived as follows. The preload force that would be produced by a spring is given by,

$$F_p = k * (L_s^f - L_s^p) \quad (2\text{-}39)$$

The actuation force produced by the spring is given by,

$$F_a = k * (L_s^f - L_s^a) \quad (2\text{-}40)$$

$$L_s^a = L_s^p - s \quad for\ compression\ spring \quad (2\text{-}41)$$

$$L_s^a = L_s^p + s \quad for\ tension\ spring \quad (2\text{-}42)$$

Subtracting equation (2-39) from equation (2-40), the equation for the stiffness of the spring (k) can be obtained as

$$k = F_a - F_p / s \quad (2\text{-}43)$$

As the preload force and the actuation force are same for the NiTi wire and the spring, the stiffness of the spring is obtained by substituting the preload force and actuation force from Equation (2-37) & (2-38) in Equation (2-43). The preload length of the spring

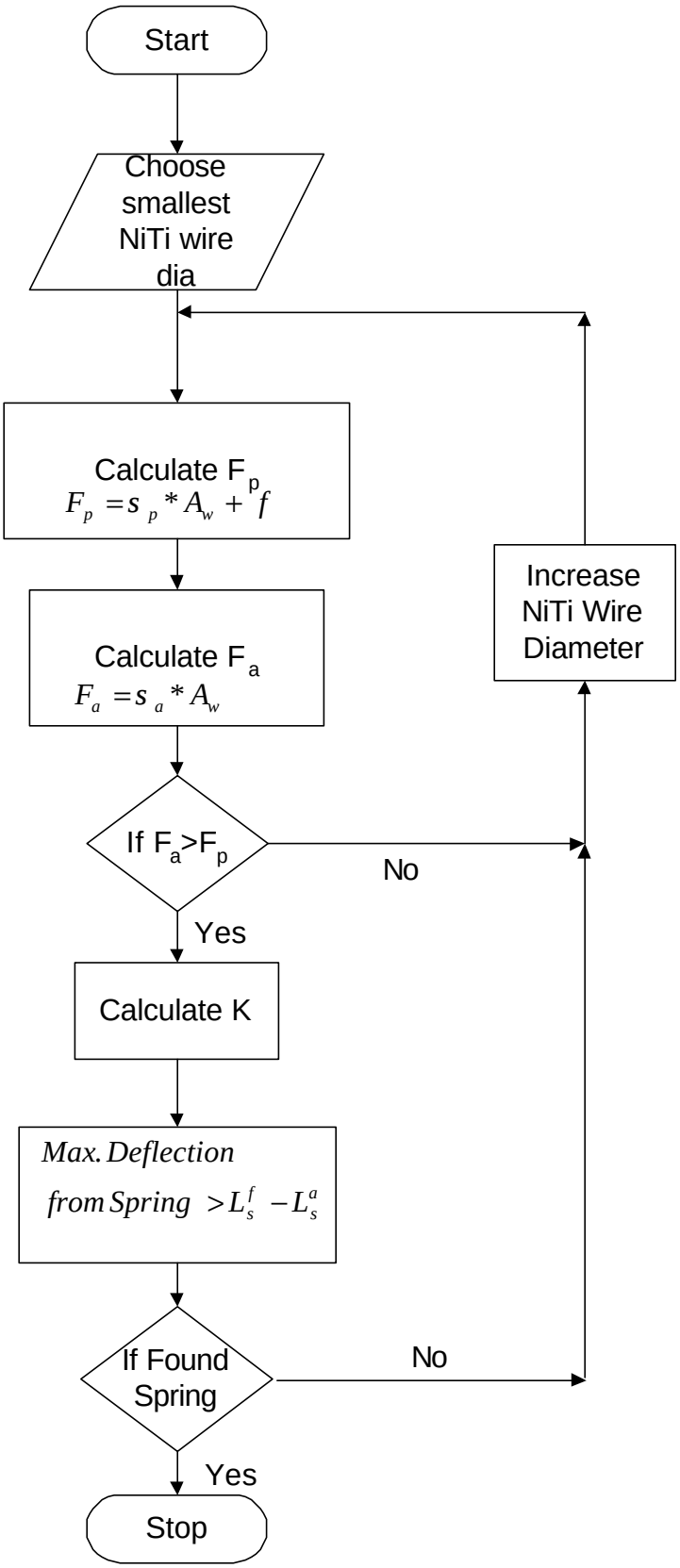
(L_s^p) can be determined from Equation (2-39), after calculating the stiffness and selecting the spring. The maximum deflection of the selected spring should be greater than the difference between free length (L_s^f) of the spring and its actuated length (L_s^a). If the spring is not available with the required deflection then different spring with the same stiffness has to be selected, or the wire diameter has to be increased to find the next match.

$$Max.\,Deflection\ from\ Spring\ > L_s^f\ - L_s^a \tag{2-44}$$

Thus in this method, the correct wire and the spring is found accounting for the friction force. The next step is to find the length of the wire that should be used. The length of the wire depends on the percentage change in length that can be obtained from the from the NiTi wire when heated inductively which is referred here as elongation, and the expected stroke of the bearing. Therefore, the length of the NiTi wire is given by,

$$L_n^f = s / \varepsilon \tag{2-45}$$

The flow chart below explains the concept described above in a better manner. The steps to be followed in the selection of the correct NiTi wire diameter and calculation of the spring stiffness for the selected wire is shown the flow chart graphically.


Start
Choose smallest NiTi wire dia
Calculate F p
$F_p = s_p * A_w + f$
Calculate F a
$F_a = s_a * A_w$
If F a>F p
No
Yes
Increase NiTi Wire Diameter
Calculate K
Max. Deflection from Spring $> L_s^f - L_s^a$
If Found Spring
No
Yes
Stop

The figures below shows the effect of the friction force on the actuation force (which is proportional to diameter of the wire chosen according to equation). These graph are plotted based on the above equations, to help the user to select the NiTi wire and the spring.

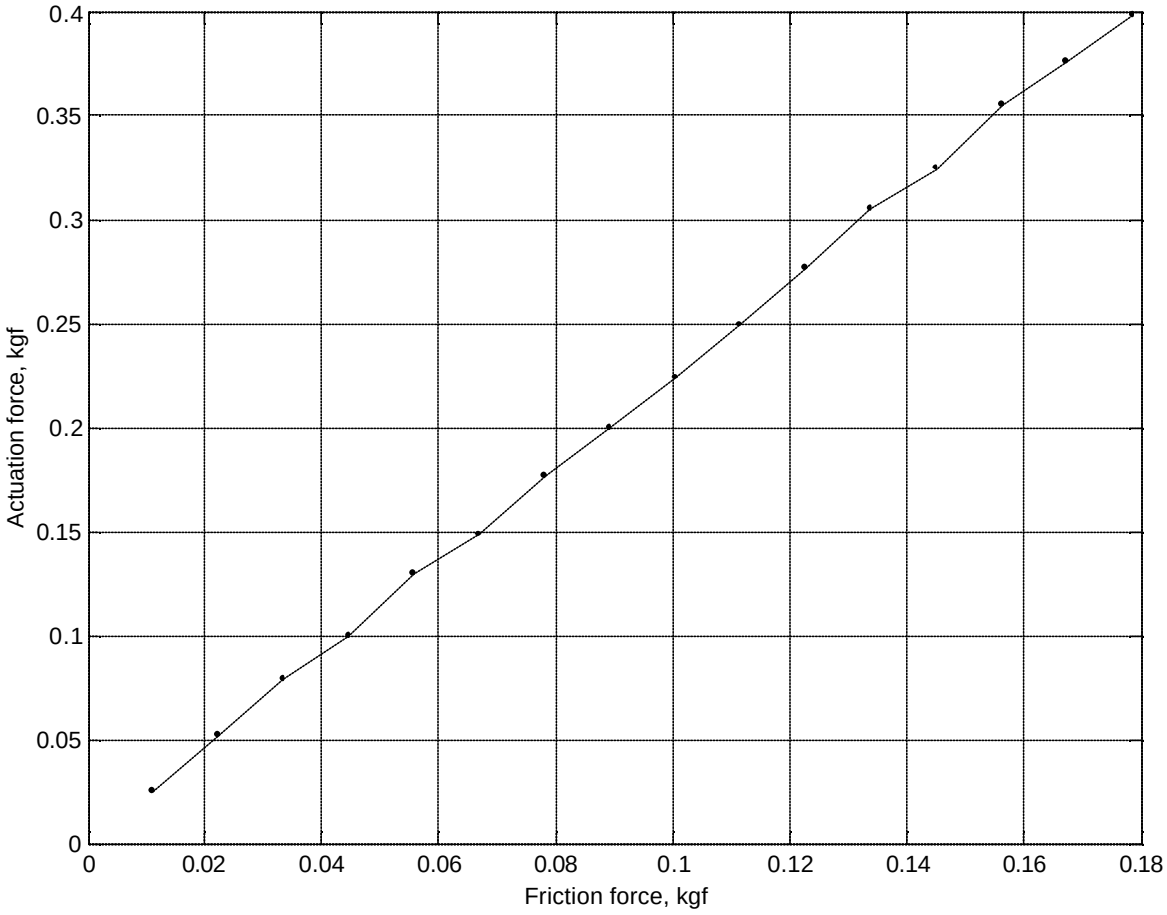


Figure 2-18: Friction force Vs Actuation force

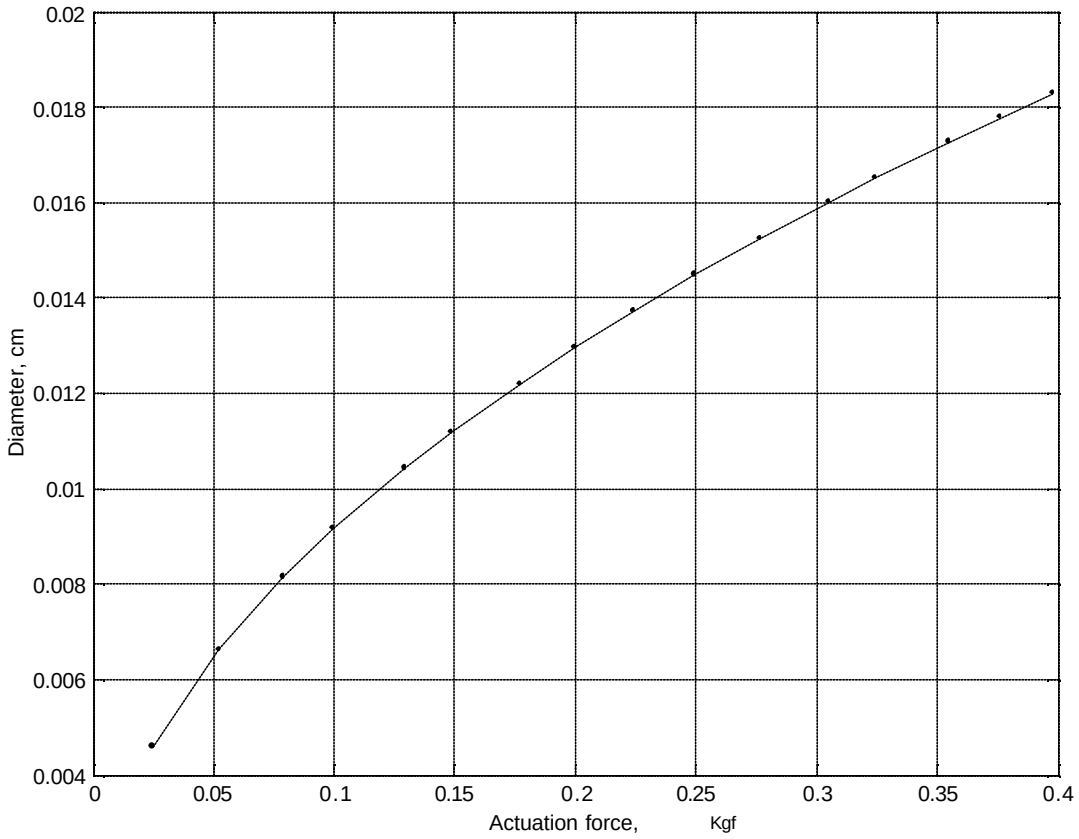


Figure 2-19: Actuation force Vs Diameter

The procedure of using the graphs is as follows.

1. Determine the friction force in the system and select the actuation force corresponding to the friction force from the Figure 2-18.
2. Select the wire diameter from graph corresponding to actuation force, if wire diameter is not available in the market perform step 3, else step 4.
3. Choose next available, wire diameter, and reverse track the actuation force corresponding to the diameter from Figure 2-19.
4. Compute Preload force from Eq (2-37)
5. Compute Stiffness of spring from Eq (2-43).

6. Check Eq (2-44), if spring is not available go to step3.

Thus, the above procedure helps in determining the spring and the wire diameter needed.

2.4.2.5 TENSION SPRING ACTUATOR

The components of the tension spring actuator and their assembly are discussed first, followed by the working mechanism of the actuator. The components needed to accommodate the tension spring actuator in this system are sliders, rear-bearing covers, front bearing cover, connectors, NiTi wire, steel cable, and tension spring. First, a steel cable is passed through the sliders and both the sliders are bonded to the wire in the fixed positions. The ends of the steel cable passing through the sliders are terminated with two connectors. The tension spring is connected to the one connector (Connector 1) at one end and secured to a post at the other end. The NiTi wire is secured to the second connector (Connector 2) at one end and to another post at the other end. The sliders are enclosed within two part bearings (top cover and base). The arrangement of the slider and other component in the vial holder is shown in Figure 2-21. The working mechanism of the actuator is that, when the NiTi wire is contracted by passing current, one slider (slider 2) is pulled back from the slot and the other slider (slider 1) is pulled into slot as the length of the wire between the two sliders is fixed. The housing slot that was previously in contact with slider 2 partially rotates and engages with slider 1. When the NiTi wire is cooled, the stored energy in the spring pulls the slider 1 back from the slot, which inturn pulls the slider 2 in to the next slot. The housing rotates and engages with slider 2. Thus, this completes the cycle and the pump is indexed to the next vial. The length of the steel cable between the two sliders is critical because if the length is less, the sliders cannot be

assembled into the bearing, whereas if the length is more, the coupled action (the other slider being pulled front, when one slider is pulled back) will not take place.

Two models were developed for this concept to control the trajectory followed by the steel cables; one is routing the cable under the vials as shown in the Figure 2-21, and other is looping the cable vertically above the bearings as shown in the Figure 2-22. The Figure 2-20 shows the path followed by the steel wire for the first model. The major problems of this model were as follows: the friction in the system was very high, which forces the use of larger diameter NiTi wires, and the control of the length of the cable between the sliders is difficult and a fixture has to be designed to assemble or bond the parts at required lengths.

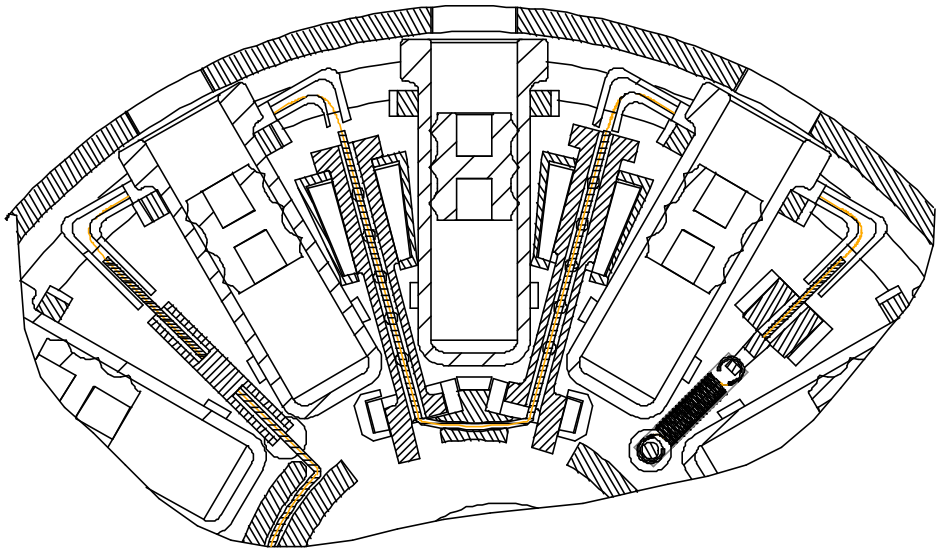


Figure 2-20 : Path of Steel Cable

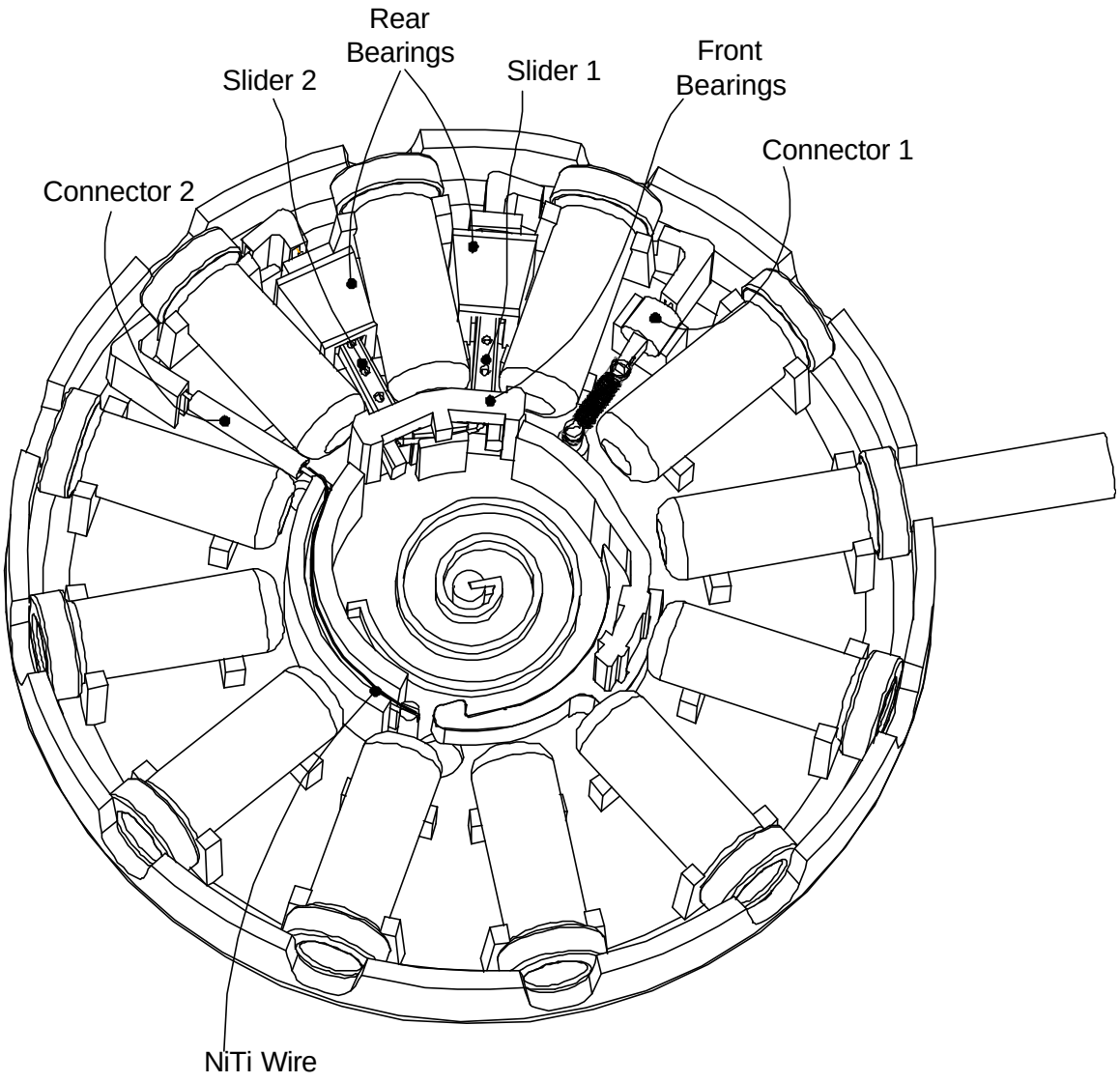


Figure 2-21 : Tension Spring Model with Under the Vial Looping

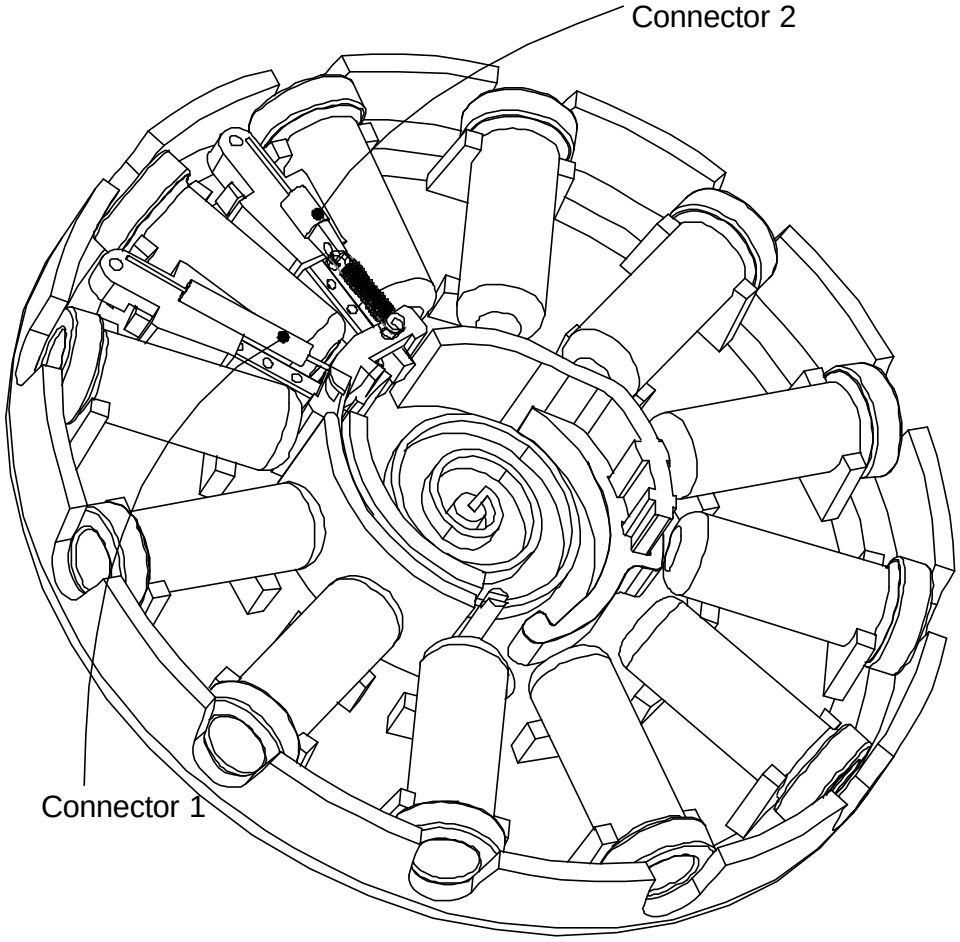


Figure 2-22 : Tension Spring Model with Vertical Looping

2.4.2.6 COMPRESSION SPRING ACTUATORS

The number of parts is reduced in the compression spring actuator model compared to the tension spring model. The compression spring is accommodated between the front and the back bearing, unlike outside the bearing in the tension spring actuators. The compression spring is coiled around the slider; and it is compressed by the bearing surface at the back when the NiTi wire is exited. The coupling between both the sliders is removed in this model, and they function independent of each other (the other slider is not pulled front when one is pulled back). The steel cable used in the previous model is

eliminated, hence removing the unnecessary connectors. In this model, the NiTi wire is crimped at one end of the slider, and it passes through the slider and the other end is crimped to the front bearing cover as shown in the Figure 2-23. The working mechanism of this model is that initially both the slider blocks the successive slots in the housing. Slider 1 (shown in Figure 2-23) is exited first, and the slot of the housing, which was previously engaging with slider 1 is rotated and engaged with slider 2. Slider 1 is then cooled and pulled back into the next slot, and the slider 2 is exited allowing the slot to be rotated again to engage with slider 1. Finally, slider 2 is cooled and stretched back into the slot by the compression spring. Thus, a cycle is completed, allowing the rotation of the housing. Therefore, two independent actuators are used in this model and hence two compression springs are needed compared to one tension spring in the previous model. The order of actuation is very critical as the two NiTi wires have to be actuated to complete the cycle compared to one in the previous models; the NiTi wire passing through slider 1 is actuated first, followed by the next. The order and timing of the actuation of the NiTi wires are controlled by the microprocessor. The preload length of the spring is controlled by the distance between the front and back bearing. Whereas, in the previous model, the steel cable length between parts and trajectory followed by the cable controlled the preload length of the spring, which is very difficult to control precisely. The model of the actuators assembled in the vial holder is shown in Figure 2-23, and Figure 2-24 shows the different states of the actuator during the cycle.

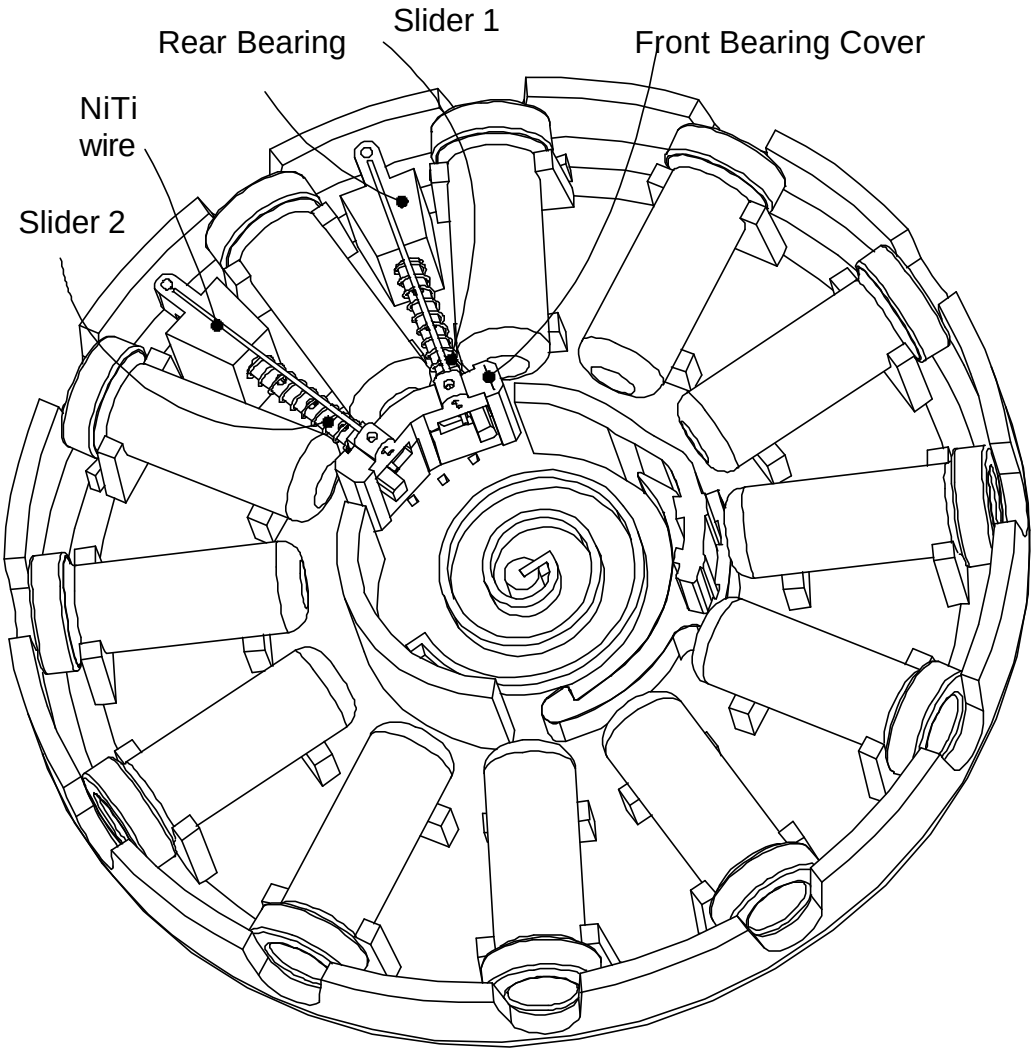
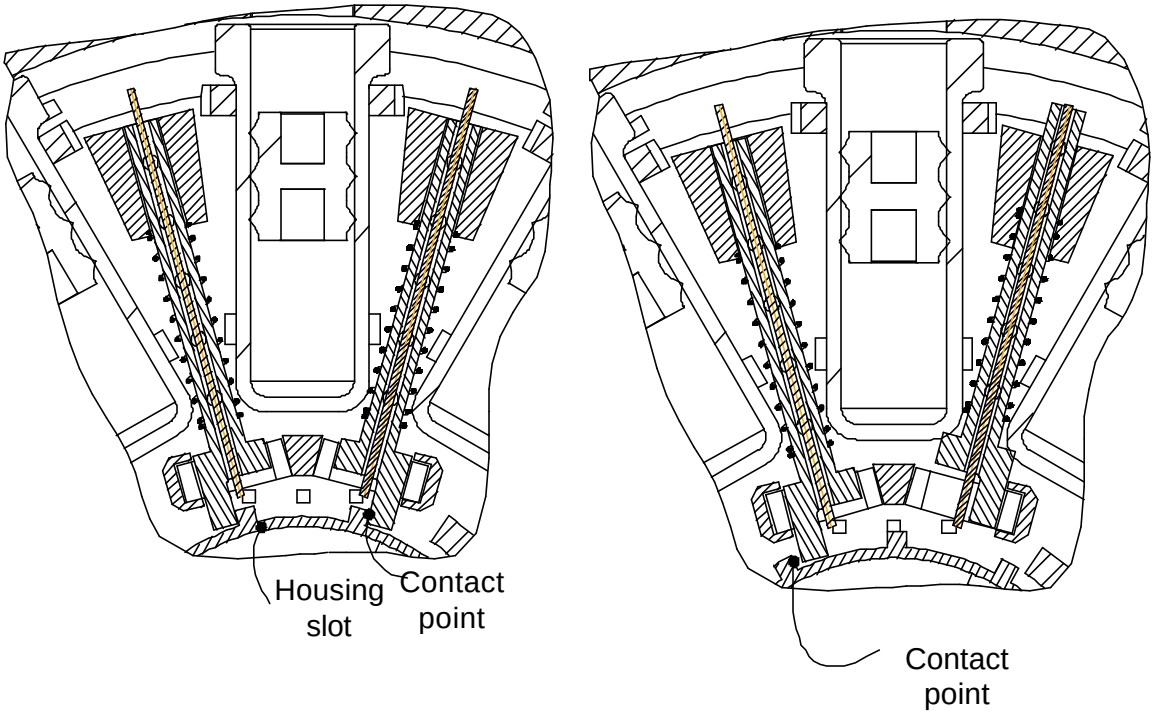


Figure 2-23 : Compression Spring Actuator Model



(a) Actuator state 1

(b) Actuator state 2

Figure 2-24: (a) Actuator State 1 (b) Actuator State 2

The assembling methods of the parts for the above models will be discussed in detail in the next chapter.

2.4.3 ACCOMODATING ELECTRONICS

Obtaining the functional requirement of controlling the rotation in the forward direction gives rise to a new functional requirement of accommodating the electronics to excite the actuators. This requirement is obtained by providing slots for the batteries and the circuit at the back of the vial holder. Currently, slots are provided for the four batteries as shown in Figure 2-25, to make a working model with a SLA material. The friction force from the stereo-lithography parts forces the use of four batteries; hence, decreasing the friction force helps us in decreasing the actuation force needed (as lower diameter wire and lower stiffness spring can be used) as shown in Figure 2-18. Therefore, the number of batteries

can be reduced by selecting the materials with a low coefficient of friction for the actuators. Accommodating the electronics at the back of the vial holder gives rise to another requirement of protecting them. Therefore, the housing is split into two parts, top housing and bottom housing, and the vial holder is enclosed within the housing. The vial holder rotates now and the housing with the pump bearing remains stationary; that is, the vials are indexed to the pump compared to the pump being indexed to the vials in the previous case. The housing along with the vial holder and electronics is shown in Figure 2-26.

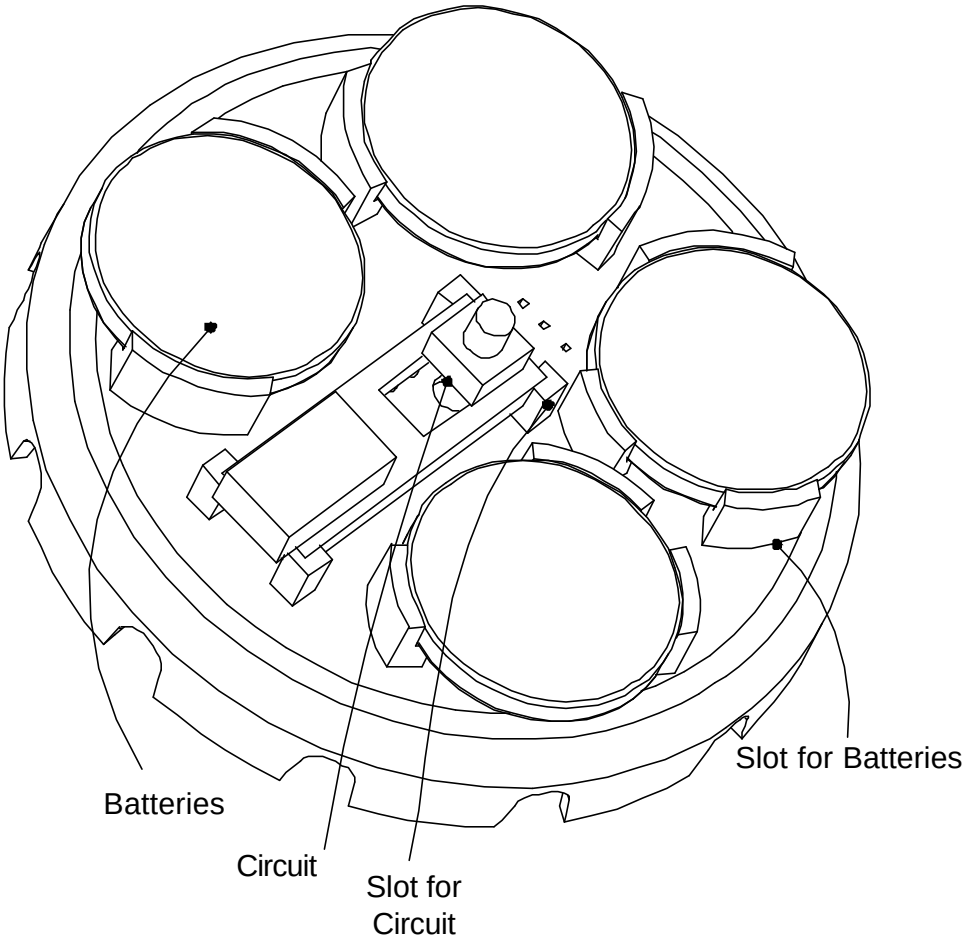


Figure 2-25 : Vial Holder with Electronics

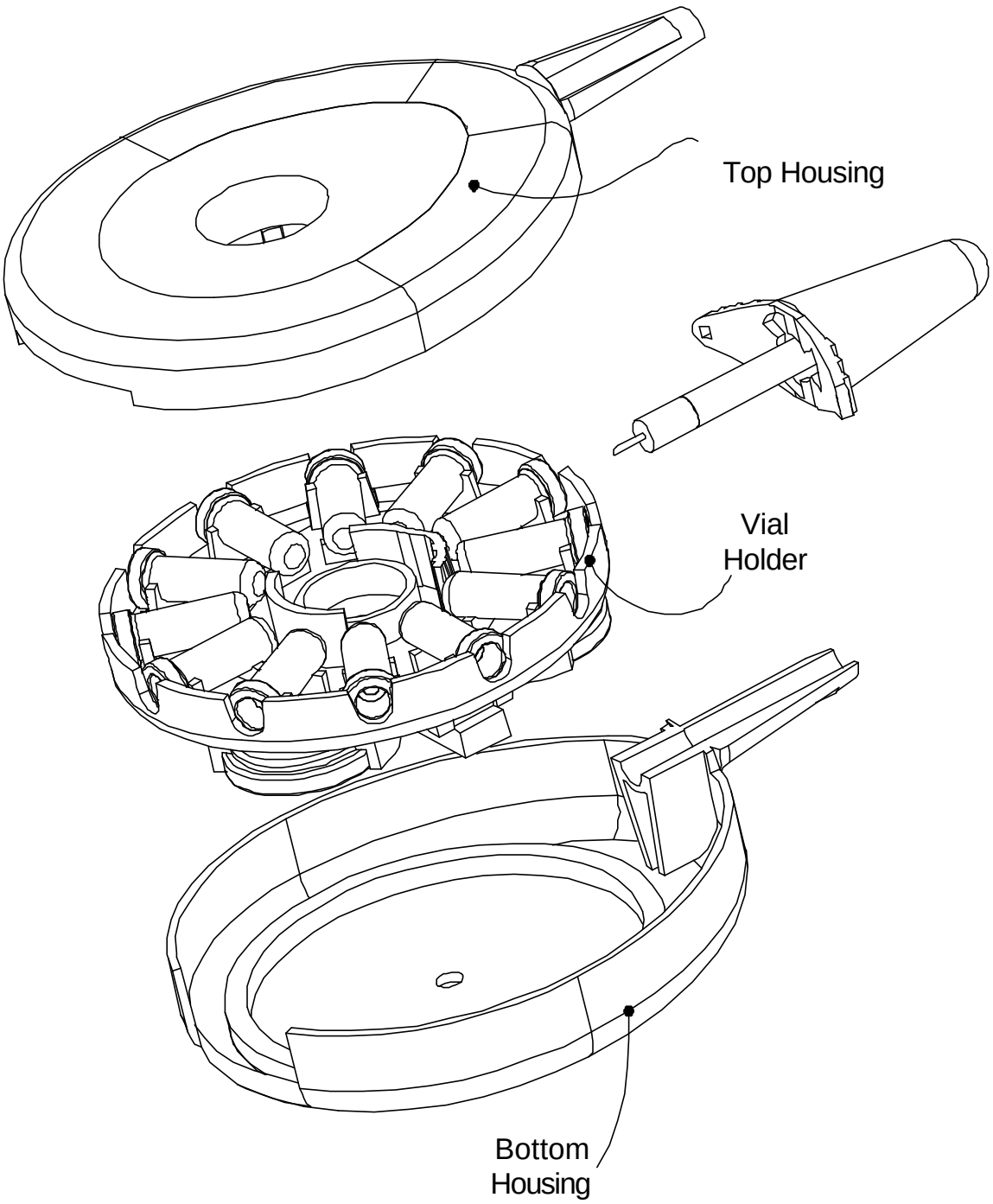


Figure 2-26 : Top Housing and Bottom Housing

2.5 TESTING OF CONCEPTUAL DESIGN

The parts of the nasal sprayer are designed according to the axiomatic design theory to satisfy the functional requirements. The next stage in the design process is to test the parts developed for its functionality. The degree to which the parts serve its function can be determined by testing the design. One way of testing the design is to make a working model of the device and analyze the problems. Rapid prototyping serves as the best and affordable way of testing the design. In this case, stereo lithography was used for producing the prototypes of the parts designed. The working model of the design was successfully produced resolving the problems, which is shown in Figure 2-27. From the working models produced, the compression spring actuator model was found to have a higher probability of success compared to the other actuator model. Therefore, in the next chapter the model with the compression spring actuator is analyzed for further redesigning possibilities to reduce the assembly time and to decrease the manufacturing cost.

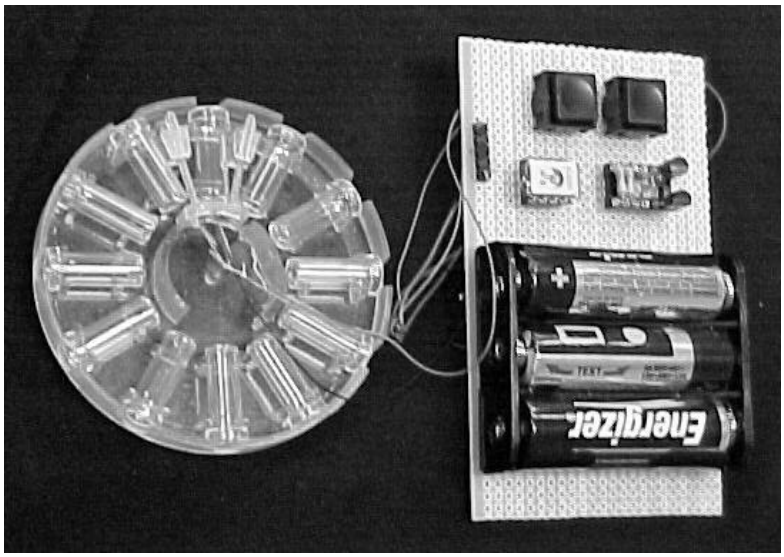


Figure 2-27: Prototyped Model

Chapter 3 REDESIGNING FOR ASSEMBLY

3.1 INTRODUCTION

The parts for the nasal sprayer were designed satisfying the different functional requirements. This chapter and the remaining chapters concentrate on making the device affordable. The cost of the device is mostly decided by the manufacturing methods, material cost, assembly time, and assembly methods. This chapter will deal with redesigning the device for easy assembly. The assembling method (manual or automatic) should be determined before redesigning the device for assembly. The assembling method highly depends on the volume of the device to be produced in a day. The detail provided by the Intranasal Technology Inc on the initial target volume is one hundred thousand devices per month. Therefore, filling the vials and packaging them in the vial holder is automated and the rest of the assembly processes like assembling the actuators, pump, and electronics are performed manually. Therefore, the product is redesigned for manual assembly, considering DFA principles [9]. Some of the factors that are considered for the product design for manual assembly are [9]

- Minimizing the number of parts, which involves identifying the necessary parts in the assembly considering its functionality and avoiding unnecessary connectors and fasteners.
- Preventing the assembly operations in restricted areas.
- Assembly time
    - Symmetry
    - Size of the parts and handling difficulties

- Insertion difficulties

Each of the above factors will be discussed in detail below and an assembly tree will be formed for the redesigned parts.

3.2 MINIMIZING THE NUMBER OF PARTS

The number of parts is drastically reduced in the compression spring model compared to the tension spring model, i.e., unnecessary connectors are discarded as the steel wire is eliminated in the compression spring model. The compression spring actuator model is considered for further improvement as it has fewer numbers of parts. The exploded view of different parts in the compression spring actuator model is provided in Appendix B. The parts of the nasal sprayer are to perform a particular function, as designing using axiomatic design theory involves the design of the part for functionality. The different parts and their functionality are summarized again from chapter 2 in the table below.

Table 3-1: Parts and its functionality

Parts	Functionality
Vials	Contains medication
Rubber Stopper	Seals the medication in the vials
Vial Holder	Holds the vial in position
Top housing	Protects the vials from being exposed
Bottom Housing	Protect the electronics
Rear actuator bearing, Front actuator bearing cover, sliders	For controlled the drug delivery.
Pump pusher	For dispensing the drugs
Pump connector	For joining two pumps

Therefore, no parts can be eliminated based on the functionality as they are designed to perform a particular function. The only way of minimizing the number of parts is by

integrating two or more parts. Even though integrating the parts decreases the assembly time, the disadvantages of integrating the parts together, like increased manufacturing complexity, should also be taken into account. Considering the pump connector (shown in Figure 2-8), it can be eliminated if the pump is manufactured longer, thus this avoids the use of the pump connector, which would save lot of time and resource involved in manufacturing and assembling it.

3.3 ASSEMBLY OPERATIONS IN RESTRICTED AREAS

The parts that are assembled in the restricted areas of the device are sliders, rear bearings, and the front bearing cover. The vial holder contains the bottom half of the front bearing, and protrusions for snap-fitting the rear bearing as shown in the Figure 3-1. The sequence that is followed for assembling the actuator to the vial holder is described below. The rear bearings are first snap-fitted in their position in the vial holder (Refer to Appendix B for exploded view of parts of the compression spring actuator model). The compression spring is then inserted on the slider preassembled with the NiTi wire, and they are inserted into the rear bearing cover. Finally, the head of the slider is rested on the bottom half of the front bearings compressing the springs, and the front bearing cover is pressed in its position (Figure 3-1). The other end of the NiTi wire that has been passed through the sliders is then pulled and glued to the top of the front bearing cover. This assembly operation is complicated and consumes considerable time, and also the vial holder will be occupied while assembling the actuators and it cannot be used for any other purpose (like packaging the vials).

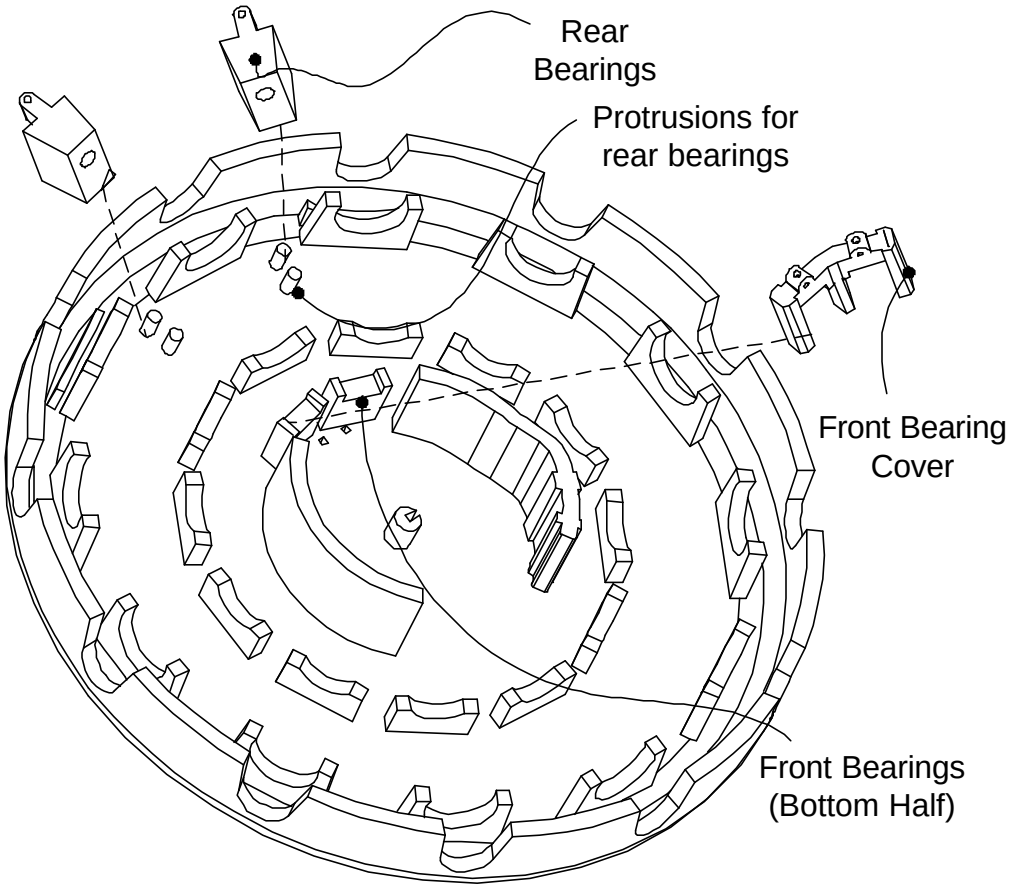


Figure 3-1 : Vial Holder with Front Bearing and Rear Bearing Slots

The actuators are redesigned independent from the vial holder inorder to eliminate the assembling of the actuator in the restricted space between the vials in the vial holder and to decrease the assembly time. The rear bearing, front bearing cover and the bottom half of the front bearing is combined to form a single actuator bearing and the shape of the actuator bearing is modeled to fit the space between the vials. The actuator that is designed independent from the vial holder is shown in Figure 3-2. The new assembly sequence after redesigning the actuator bearings is as follows. The NiTi wire is first pinched with a ball at one end, and is routed through the slider; then, the compression

spring is slid on the slider and finally they are pushed into the actuator and the other end of the NiTi wire is crimped with a ball and pushed into the slot below the actuator. The slot at the bottom of the actuator is kept open (Figure 3-2) so that the NiTi wire can be crimped at the required length and then it can be pulled and locked into the slot, rather than pulling the wire and crimping it in position. This decreases the assembly time of the actuator and the actuator can now be assembled parallelely while the vial holder is being packaged with vials, and finally the actuator can be pressed in position in the vial holder.

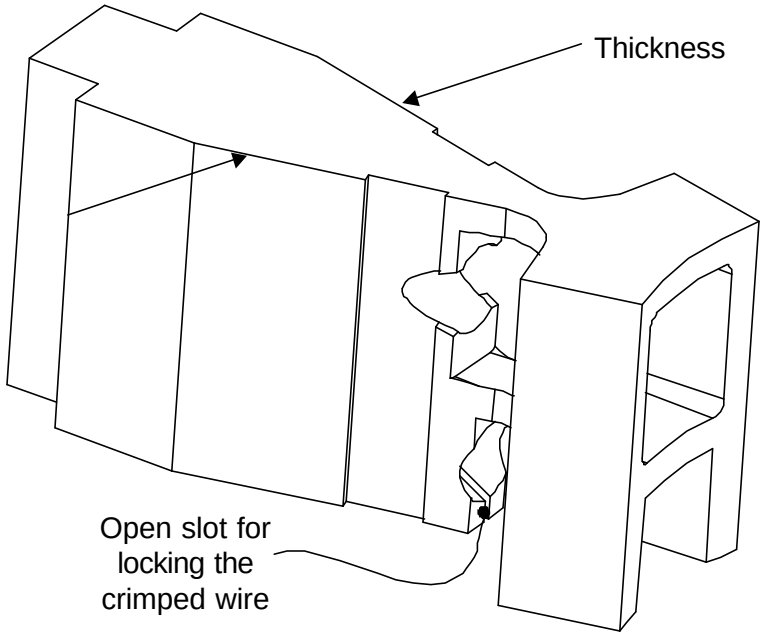


Figure 3-2 : Actuator Bearing

3.4 REDUCING ASSEMBLY TIME

The parts of the nasal sprayer are analyzed for their assembly time and redesigned for the possible improvements. The factors that determine the assembly time are the handling time of the parts and the assembly time after picking up the parts. The factors like

symmetry of the parts and size of the parts are considered to decrease the handling time of the parts, and the insertion difficulty is considered to reduce the assembly time. The effect of the weight of the parts in the handling time is not considered, as the parts are made of thermoplastics, which are very light and does not increase the handling time significantly.

3.4.1 SYMMETRY

One of the principal design features that affect the time required to grasp and orient the part is its symmetry [4]. According to Boothroyd [4], there are two types of symmetries for a part, alpha symmetry and beta symmetry. Alpha symmetry depends on the angle through which a part must be rotated about an axis perpendicular to the axis of insertion to repeat its orientation. Beta symmetry depends on the angle through which a part must be rotated about the axis of insertion to repeat its orientation. Figure 3-3 clearly illustrates the alpha and beta symmetry.

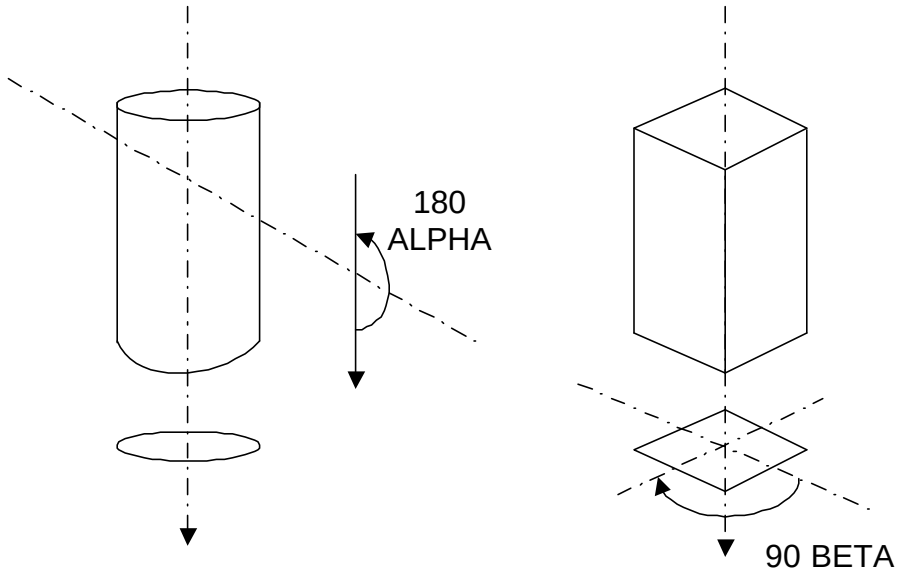


Figure 3-3 : Alpha and Beta Symmetry

The symmetry plays a critical role only for the sliders, and the other parts have low symmetry angle (less than or equal to 180) and less possibility for redesign. Considering the parts for the symmetry, the springs are cylindrical in shape and they have an alpha symmetry of 180^0 and a beta symmetry of 0^0 because if the springs are picked up by grasping it on its ends, it needs to be rotated 180^0 before insertion. It not possible to redesign the spring for low symmetry angle; similarly, the other parts have low symmetry angle as mentioned. Therefore, the slider is concentrated for improving symmetry. The slider has a cylindrical tube and a rectangular head with a protrusion to block the slots in the housing. The shape of the slider is shown in Figure 3-4. The rectangular piece with a protrusion has an alpha symmetry of 360^0 and a beta symmetry of 360^0 [4]. The total angle of the symmetry is the sum of the alpha symmetry and the beta symmetry, which is 720^0. Therefore, the slider has to be rotated in all possible angles before insertion. The handling time for the slider is highly variable depending upon how it is being picked. Figure 3-5 shows the effect of symmetry on the handling time. It is evident from Figure 3-5 that the square section with a total symmetry of 720^0 has the highest handling time and therefore modifying the shape of the slider head can reduce the handling time. The slider head is designed square in cross-section to provide a radial bearing for constraining the slider tip (at the bottom of the slider head Figure 3-4) that blocks the slot in the housing, so that it does not rotate and move to the top. The height of the slider tip from the vial holder surface must match the height of the slot in the housing for it to lock the housing, and this forces us to constrain its position.

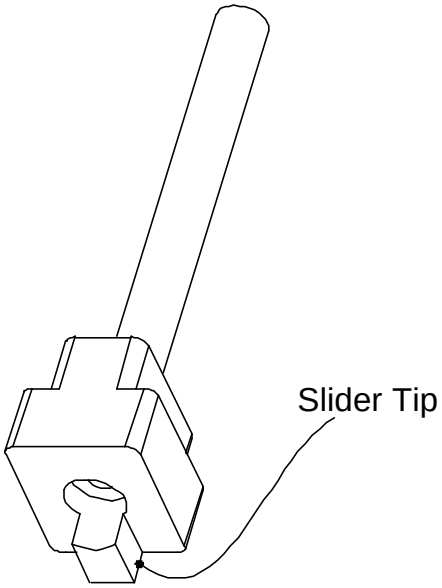


Figure 3-4 : Slider

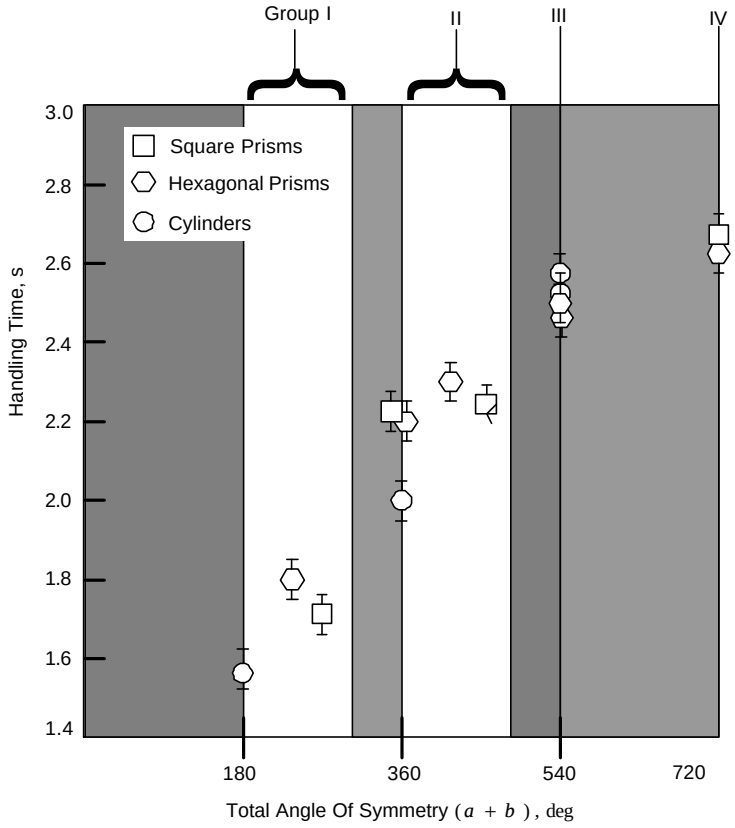
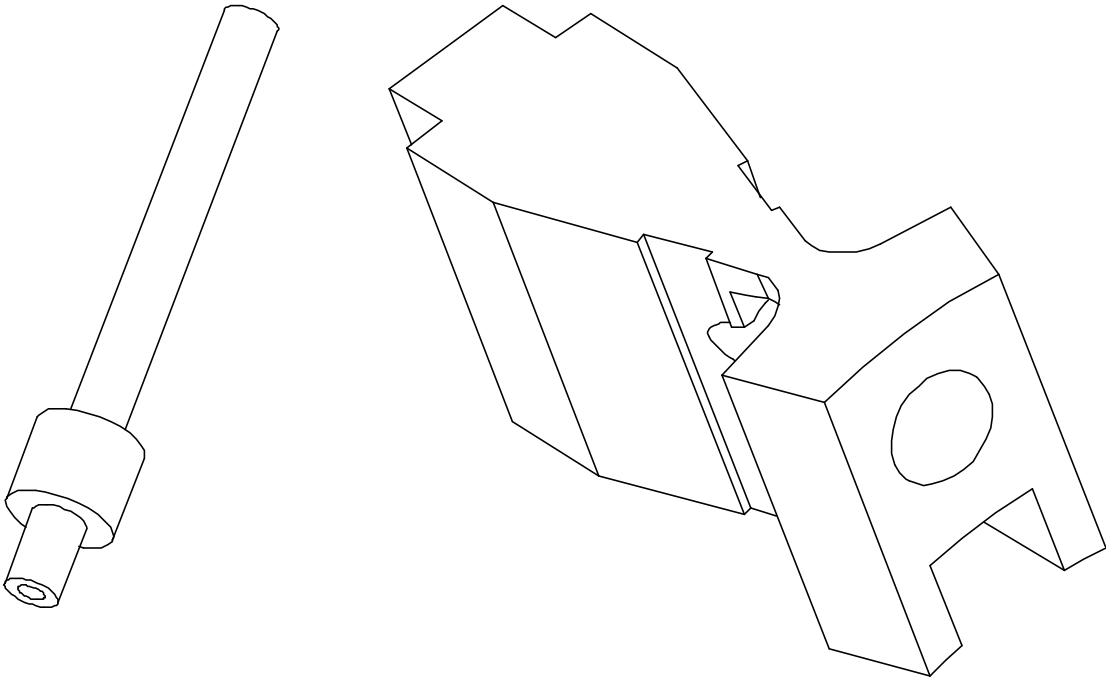


Figure 3-5: Angle of Symmetry Vs Handling Time (Refer [9] for graph to scale)

This problem is avoided by moving the protrusion (slider tip) axial to the cylindrical portion of the slider, so that the rotation of the slider does not shift the position of the slider tip. Therefore, the slider is redesigned to be a cylindrical tube, with a cylindrical head as shown in Figure 3-6, eliminating the necessity for radial bearing. The alpha and beta symmetry for a cylindrical tube with a head is 360^0 and 0^0 respectively [4]. The total symmetry of the slider is decreased to 360^0. Therefore, from Figure 3-5, it is evident that the handling time is reduced to 2 sec, thus saving 0.75 sec per slider handling. This is an appreciable time as a device involves two actuators; it saves 1.5 sec per device. Modifying the shape of the slider creates a necessity to modify the shape of the actuator; the redesigned slider and actuator are shown in Figure 3-6.



(a) Slider

(b) Actuator Bearing

Figure 3-6: Redesigned Slider and Actuator Bearing

Vials, similar to the slider, have a cylindrical head and body. Therefore, the vials also have an alpha symmetry of 360^0 and a beta symmetry of 0^0 and they have the same handling time due to symmetry. The handling time of a part due to the part size is discussed in the next section.

3.4.2 SIZE OF THE PARTS AND HANDLING TIME

The dimensions that play a major role in the size of the parts are the thickness and the length of the part. The thickness of the non-cylindrical part is defined as the maximum height of the part with its smallest dimension extending from a flat surface [9], and the thickness of the cylindrical part is defined as the radius of the part [9]. The length of the part is defined as the largest non-diagonal dimension of the part's outline when projected on a flat surface [9]. The effect of the thickness of the part on the handling time is shown in Figure 3-7. The thickness of the parts in the device and their handling time penalties are shown in Table 3-2. The handling time for a rubber stopper is not considered as it is inserted automatically into the vials after filling it with the medication. The handling time penalties tabulated below are developed for the manual assembling and will not suit the automated assembly. The thickness dimension for the actuator bearing is shown in Figure 3-2 as it is not evident. The thickness of the pump pusher varies along its length and therefore considering the average thickness, its penalty accounts to zero. The only two parts that have handling penalty are the sliders and the springs.

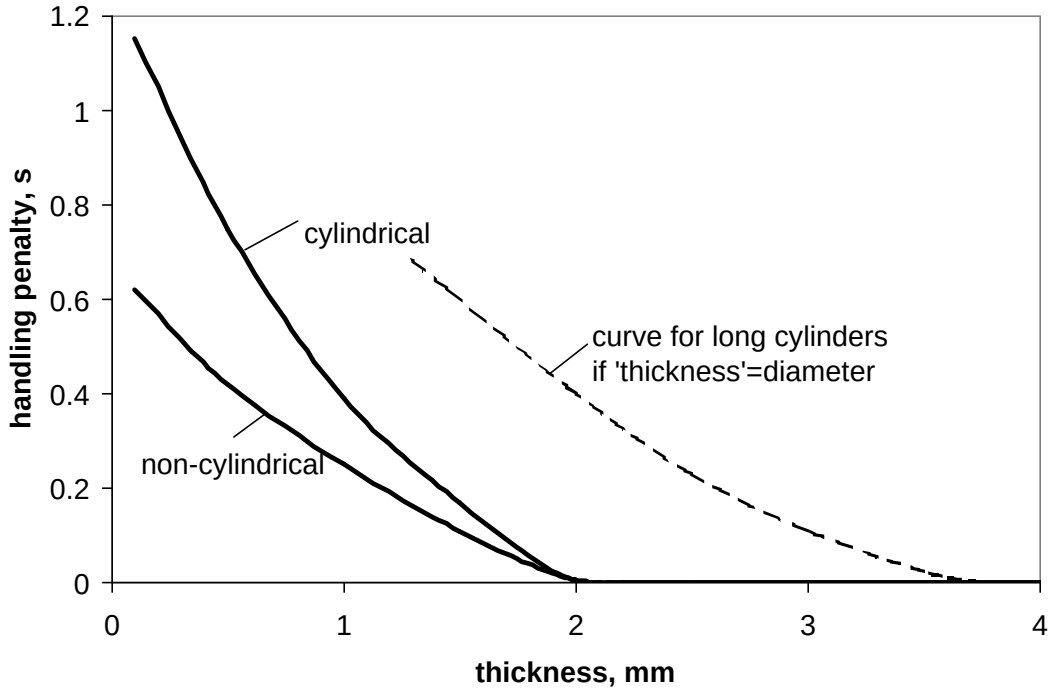


Figure 3-7: Thickness Vs Handling Penalty (Refer [9] for graph to scale)

Table 3-2: Size and Handling penalty of the parts

Parts	**Thickness dimension, mm**	**Handling Penalty, sec**
Slider	1.5, Radius of the slider head	0.2
Actuator bearing	7.62, Shown in figure 3.8	0
Springs	1.2, Radius of the spring	0.3
Vials	4.3, Radius of vials	0
Vial Holder	9.6	0
Top housing	9.6	0
Bottom Housing	15.2	0
Pump connector	3.81,Radius of connector	0

The handling penalty due to the length of the part is analyzed below, as it also contributes to the handling penalty due to the size. Figure 3-8 shows the handling time penalty for the

different length of the parts. It is evident from the figure that the handling time penalty is negligible when the length of the part is above 10mm. All the parts in this device are more than 10mm in length; therefore, the parts do not have handling penalty due to their length. Therefore, only two parts in the device will have handling time penalties due to their size. The handling time penalty of these parts due to size is neglected as the space constraint does not permit redesigning the parts, and as appreciable time is not saved by redesigning. The handling time penalty due to size would be much less (almost zero) for the sliders if it had a square or rectangular head, but that would increase the handling time due to the symmetry by 0.75 sec as seen above. Therefore, the sliders are not redesigned as the handling penalty of 0.2 sec is better compared to 0.75 sec.

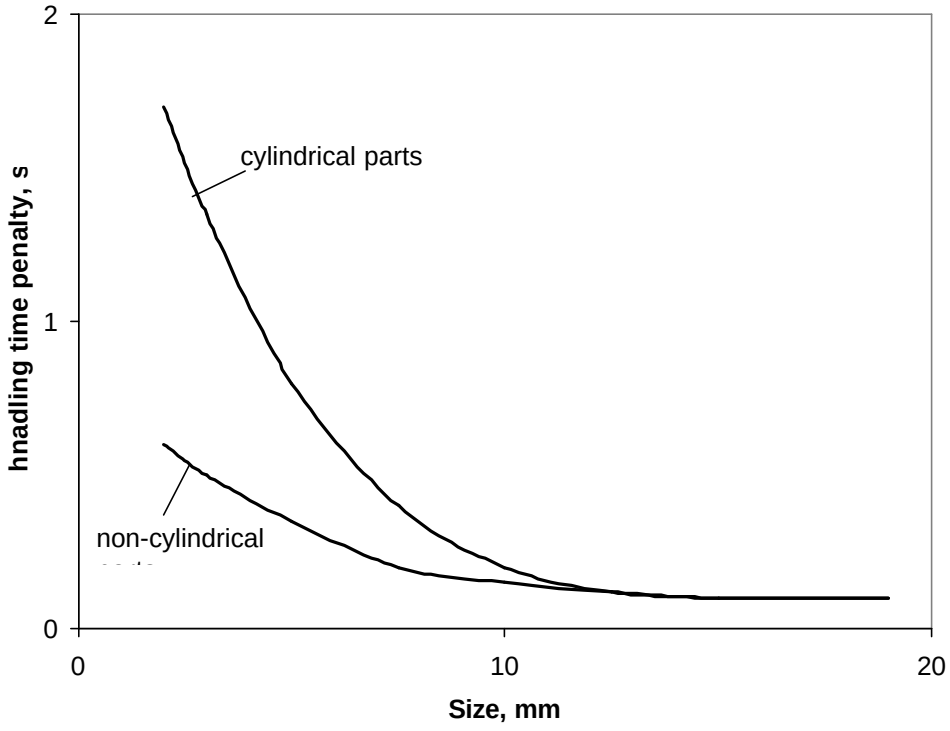


Figure 3-8: Length Vs Handling penalty (Refer [9] for graph to scale)

3.4.3 INSERTION DIFFICULTIES

The insertion time mainly depends on the diametrical clearance and the provision of the chamfer on the hole and the peg. If the proper clearance is not provided, it may lead to the jamming of the peg into the hole increasing the assembly time. The effect of the chamfer and diametrical clearance on the insertion time is given by the equations below. The insertion time (t_i) for the part is given by the highest value either equation (3-2) or (3-3). The insertion time is the function of the diametrical clearance (c), insertion length (L) and diameter of the peg (d) in equation (3-2) and it is just the function of the insertion length in equation (3-3). The diametrical clearance is the ratio of the difference in diameter of the hole and peg and the diameter of the hole (D).

$$c = D - d / D \qquad [4] \tag{3-1}$$

$$t_i = -70 \ln c + f(chamfers) + 3.7L + 0.75d \qquad ms[4] \tag{3-2}$$

$$t_i = 1.4 * L + 15 \qquad ms\,[4] \tag{3-3}$$

The value of f(chamfer) is the given in the Table 3-3.

Table 3-3: Chafer state [9]

Chamfer state	**Value**
No chamfer	-100
Chamfer on hole	-220
Chamfer on peg	-250
Chamfer on peg and hole	-370

The insertion time for the parts in the device are computed and analyzed for necessary redesign, so that the perceivable amount of assembly time could be reduced. However,

there is a tradeoff between increase in manufacturing cost due to changes in the design and the cost saved in reducing the assembly time. The only part that is being inserted in this assembly is the sliders. It is very difficult to provide chamfer on the sliders as the diameter of the slider is small; also, providing chamfer on the slider would increase its manufacturing cost. Providing chamfer on the slider makes no difference in the insertion time as the spring is first inserted on the slider and the spring –slider assembly is inserted on the actuator bearing, and it will be anunnecessary functionality. The actuator bearing can be redesigned with a chamfer, as introducing the chamfer does not affect its manufacturing method; but first, the effect of the chamfer on the insertion time should be computed before redesigning the actuator bearings. From the insertion time calculated from the equations (3-2) & (3-3), it was found that the time from equation (3-3) is higher, therefore the insertion time due to the length of the sliders dominates the insertion time of the sliders due to the diameter. Thus, introducing the chamfers in the actuator bearing will not have any effect on the insertion time and would just be an added functionality.

3.5 ASSEMBLY SEQUENCE

The next requirement is determining the sequence for the assembling the parts together. The logical sequence for assembling the device is assembling parts as subassemblies and then finally assembling the subassemblies to the main assembly. The assembly tree in Figure 3-9 shows the sequence of assembly of the parts and subassemblies of the nasal sprayer.

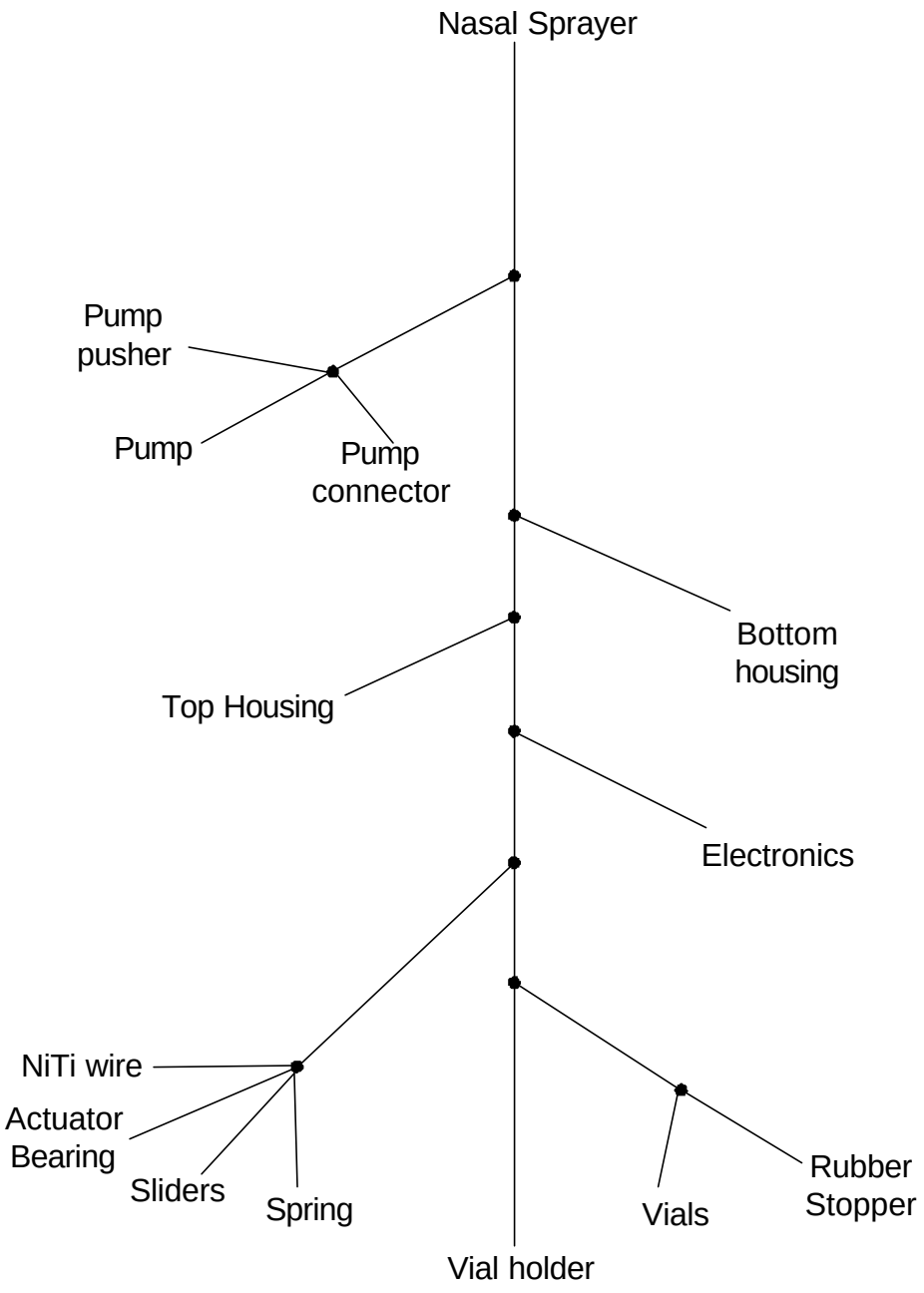


Figure 3-9 : Assembly Tree

The assembly sequence shown in Figure 3-9 is explained below. The sealed vial with medication and rubber stopper is pressed on the vial holder first in the assembly sequence. The actuator (slider, spring, NiTi wire) is then assembled as a separate

subassembly and then finally snap-fitted onto the vial holder. The electronics is fabricated as a separate subassembly and it is fixed to the vial holder. Followed by the electronics the top and the bottom housing are assembled. Finally, the pump subassembly (pumps, pump connector and pump pusher) is assembled to the device, completing the assembly. The sequence of assembling the vials, actuator subassembly and the electronics can be varied for balancing the line, assembling the parts, or each device may be assembled in a different sequence if line balancing cannot be achieved through a single assembly sequence.

Chapter 4 MATERIALS AND MANUFACTURING

4.1 INTRODUCTION

The parts are redesigned in the previous chapter considering the design for assembly principles to decrease the assembly time of the device. The other factors that contribute to the cost of the device are the material of the parts and manufacturing methods. Therefore, in this chapter, the different alternative manufacturing methods for producing the parts are discussed and suitable one is selected. The features of the parts are analyzed and redesigned from the manufacturing perspective, so that parts can be produced economically. Due to the complex features and size of the parts, injection molding and plastic extrusion are the two manufacturing methods analyzed for the production of the parts. Therefore, the parts will be examined for possible redesign considering injection molding or plastic extrusion as the manufacturing method. The materials are then selected for the redesigned parts and the manufacturing method is finalized after redesign.

4.2 INTRODUCTION TO THE MANUFACTURING METHODS

This section of the chapter introduces the probable manufacturing process for the manufacturing the parts of the device. The purpose of this section is to introduce the resources needed for the process so that they can be compared to select the most economical method.

4.2.1 INJECTION MOLDING

Injection molding is the most important plastic molding process. Molding machines range in sizes from injection capacity of 12000 mm^3 to 2.2 x 10^6 mm^3. The locking forces applied to the mold range from 0.1MN to 8MN [10]. The cycle of operation of the injection molding technique is shown in Figure 4-1.

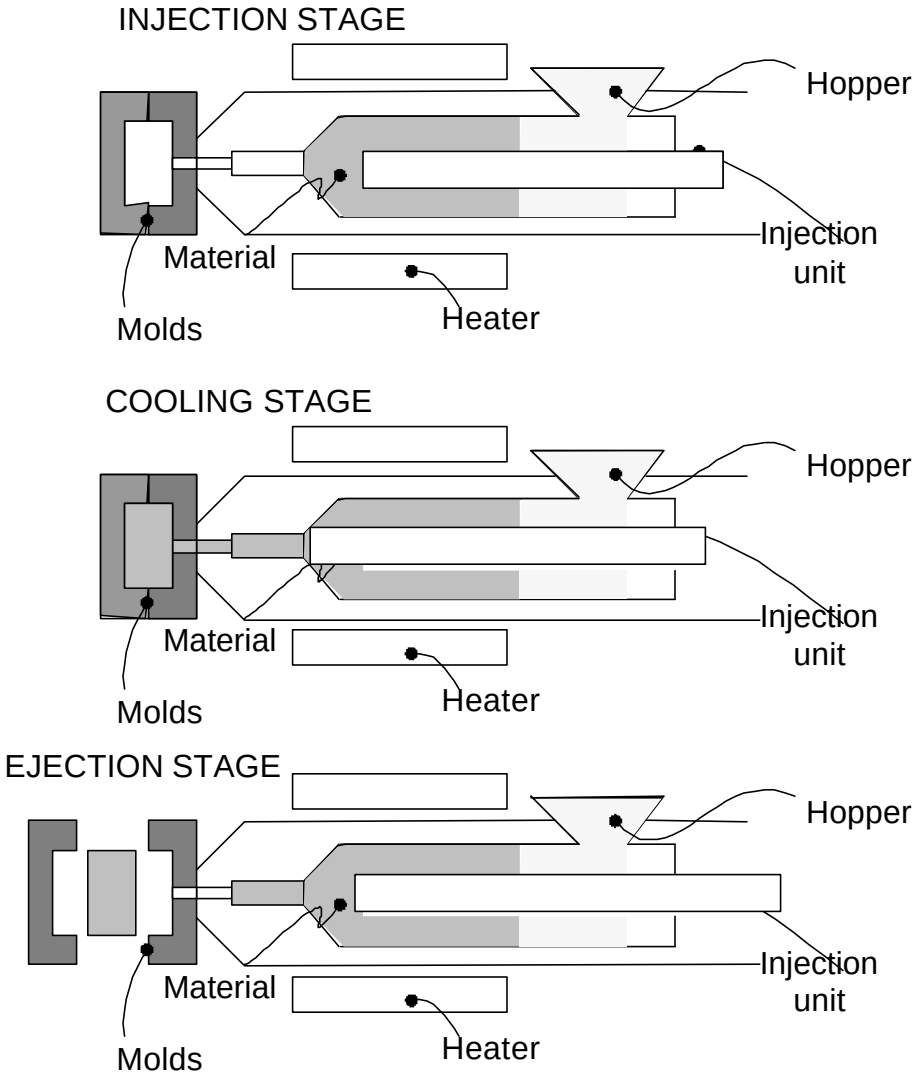


Figure 4-1: Stages of Injection Molding

The injection molding stages shown in the above figure are explained below. First, a metered amount of material is fed at the cold end of the injection cylinder, and the

injection ram or the screw plasticizer forces the material into the heating section. The amount of material transferred into the mold is referred to as shot. The injection stage is accompanied by a gradual increase in pressure during injection, and a drop in pressure when the injection plunger is withdrawn. The injection stage is followed by the cooling stage; due to the pressure drop in the cooling stage the reverse flow of material might occur in this stage, which is minimized by the proper design of the gates. The final stage of the injection molding is ejection and resetting, during which the mold is opened, the part is ejected and the mold is again closed ready for the next injection. Therefore, the different resources for injection molding are the injection unit, the clamp unit and the mold. The first two units are common for all parts and the molds differ from part to part.

4.2.2 PLASTIC EXTRUSION

The plastic extrusion often serves the function of producing the plastic in an intermediate form; that is, they need tobe cut in to pieces of required size after extruding. The plastic extrusion process is similar to the metal extrusion; that is, the material flows through the dies orifice of the required shape under pressure. The material is forced under pressure into the orifice by the ram injection or screw plasticizer similar to that of the injection molding (Figure 4-2). Finally, the polymer extruded through the die has to be cooled and hardened. The problems with the plastic extrusion are the swelling of the part after extrusion and this swelling depends on the shear rate and molecular weight of the polymer [10]. Therefore, the different resources needed for the plastic extrusion are an injection unit, and dies for the parts.

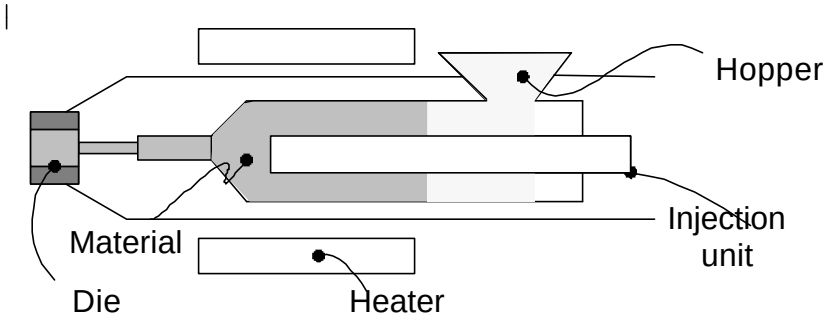


Figure 4-2: Plastic Extrusion

4.3 SELECTING THE MANUFACTURING METHOD

The parts like the top housing, the bottom housing, the vial holder, the actuator bearing and the pump pusher have to be manufactured by injection molding due to their complex shape. The remaining parts, the ratchet and the gear (split from vial holder and housing, discussed in the detail in the redesigning section of this chapter, refer to Figure 4-3 and Figure 4-4), can be manufactured by injection molding or plastic extrusion. The injection molding is preferred for the ratchet and gear too, as both injection molding and plastic extrusion involves die (mold) cost, and both require a material injection unit as discussed in the previous section of this chapter. The plastic extrusion process requires an extra band saw or cutting machine to cut the extruded solids into small parts, as it produces the parts in the intermediate form. The only cost involved by opting for injection molding is the cost of the molds, as injection-molding machines are already purchased for molding the other parts. Whereas, the plastic extrusion process requires a separate material injection unit, as it is not easy to interchange the material injection units between the injection molding machine and the plastic extrusion machine. Injection molding also saves the operation time involved in cutting the extruded parts to the required size. Therefore, injection molding is opted for manufacturing the ratchet and gear.

4.4 REDESIGNING FOR INJECTION MOLDING

The factors to be considered while redesigning the parts for injection moldings are [11]:

- The parts should have uniform wall thickness.
- Sharp corners should be avoided and fillets should be incorporated wherever possible.
- Abrupt changes in wall thickness should be avoided. When changes in wall thickness are necessary, the transition should occur gradually without sharp change.
- Holes in the parts should be designed so that they are perpendicular to the parting line. If it is not possible to accommodate holes perpendicular to the parting line it can be parallel to the parting line. Holes at an angle to the parting line and holes intersecting with each other in an angle should be avoided for economical mold cost.
- Thick sections should be avoided to prevent the problems due to shrinkage and to decrease the cooling time.
- The depressions on the inner surface of the walls should be avoided, as it requires the use of moving the core pin inside the main core.

The parts of the nasal sprayer are redesigned considering the above recommendations. The wall thickness for all the parts is almost uniform except for the actuator bearing and pump pusher. The pump pusher is not redesigned as its shape should fit the nose. Even though uniform wall thickness is difficult to achieve for the actuator bearings, as it should

fit in the gap between the vials, it is redesigned to eliminate the abrupt changes in the wall thickness in the subsection of this section. Redesigning considering factors like filleting the sharp corners and avoiding thick sections (shrinkage problems) are also discussed in the subsection of this section of the chapter. Redesigning for factors like holes at an angle to the parting line and depressions on the inner surface of the walls are not necessary, as the parts of the nasal sprayer do not have the above features.

4.4.1 SPLITTING THE PART FOR INJECTION MOLDING

The features in the parts that make the injection molding difficult are considered first for redesign. The feature that prevents the parts from being injection molded in this case are the ratchet that is incorporated to the vial holder, the gear that is incorporated in the top housing, and the protrusion for radial bearing in the pump pusher. The ratchet needs to have an air gap between its bottom surface and the surface of the vial holder, as it should deflect to allow the forward rotation of the housing (discussed in chapter 2). This makes the injection molding of the vial holder difficult, and therefore the ratchet is made as an independent part from the vial holder, which would make the vial holder injection moldable. Figure 4-3 shows the ratchet and the vial holder as separate parts. The protrusions are provided in the vial holder for accommodating the ratchet and the corresponding slots are provided in the ratchet. This type of engagement of the ratchet prevents it from being pulled out while preventing the rotation in the reverse direction.

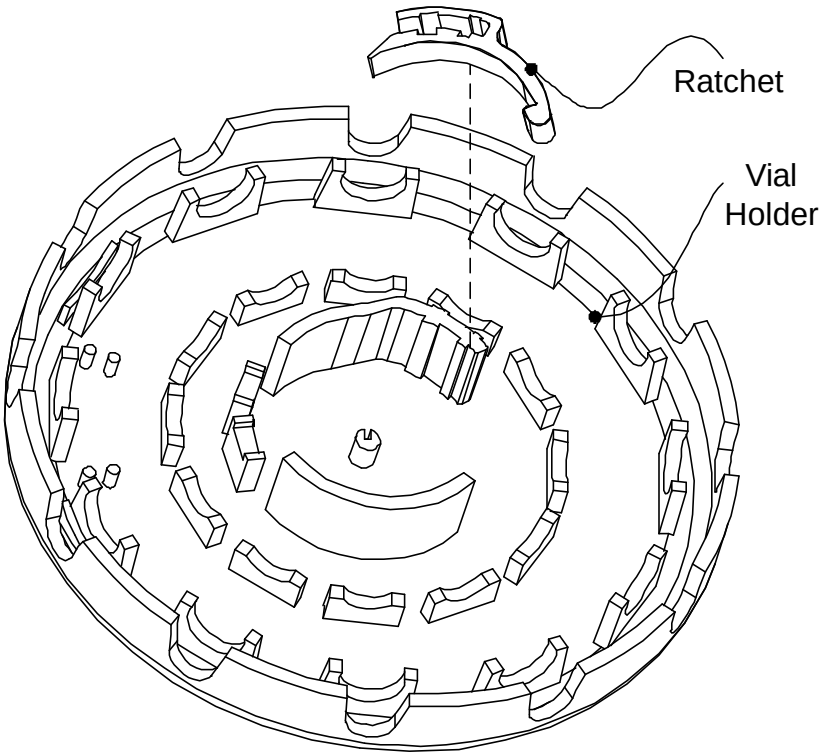


Figure 4-3 : Vial Holder and Ratchet

The next feature is the gear in the housing. The problem with this feature is that the mold cannot be drawn out after injection molding, as the diameter of the gear is larger than the pockets (slots) in the housing (for locking the rotation). Therefore, the gear needs to be made into a separate part for the housing to be injection molded. The gear is made into a separate part and protrusions for snap fitting the gear are provided in the housing. Figure 4-4 shows the redesigned housing and the gear that can be injection molded. Manufacturing the ratchet and the gear as separate parts adds an extra step in the assembly process of assembling them to the vial holder and housing respectively.

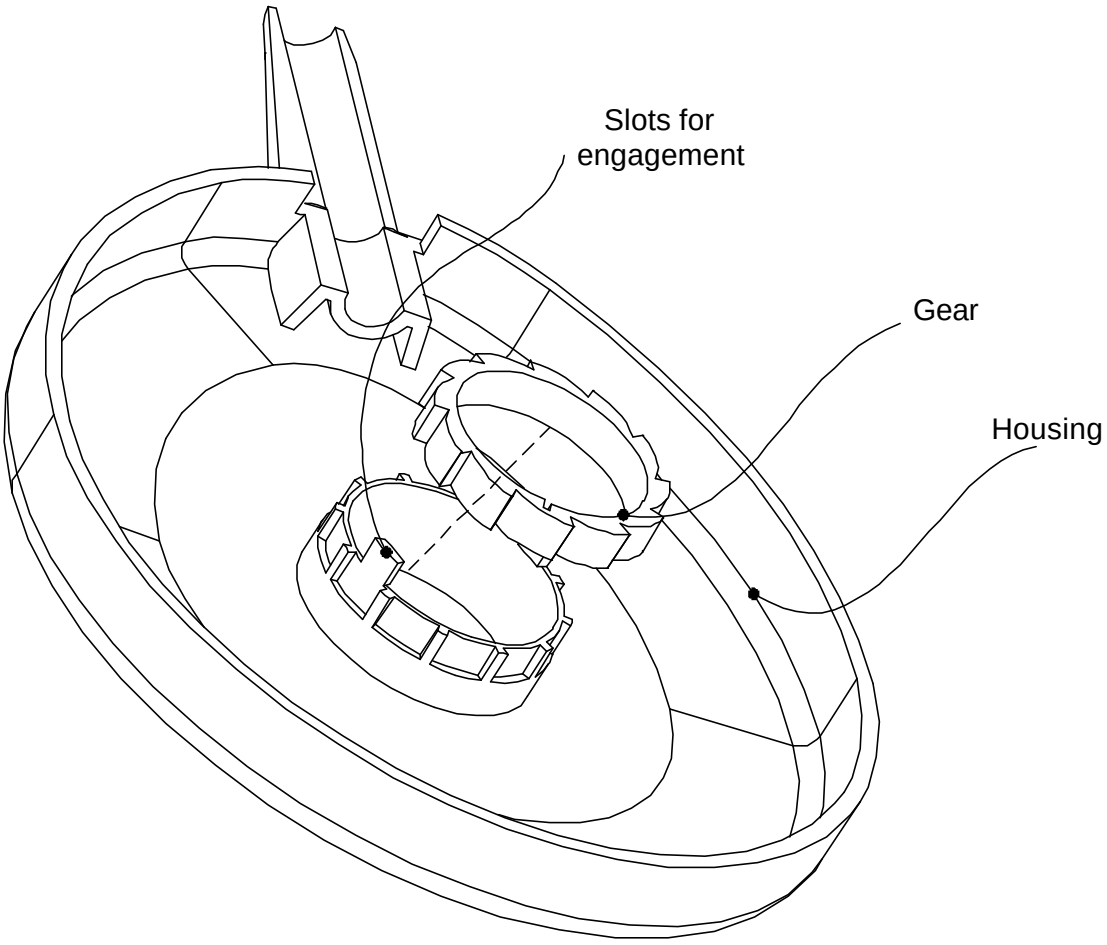


Figure 4-4: Housing and Gear

The radial bearing of the pump pusher shown in Figure 2-8 prevents the part from being injection molded, as the mold cannot be designed to access the inner features. Therefore, the pump pusher has to be redesigned by splitting it into two parts as shown in Figure 4-5. Protrusions are provided in the pump pusher for locating the bearing and corresponding slots are provided in the pump bearings. Thus, this adds one more step to the assembly process, but no trade-offs can be made, as all the parts need to be made manufacturable.

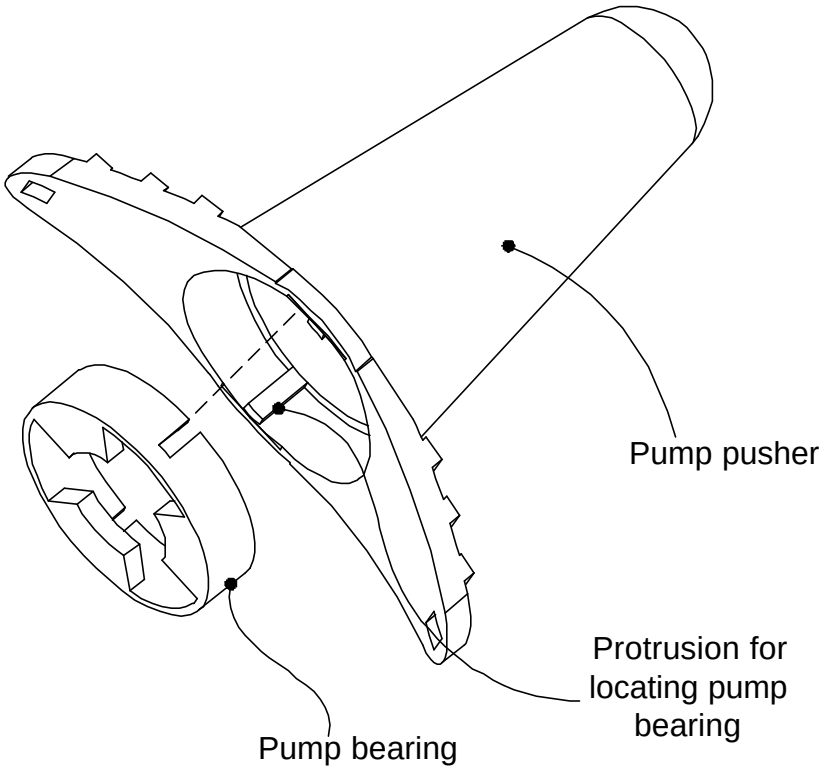


Figure 4-5 : Pump pusher and Radial Bearing

4.4.2 AVOIDNG WARPING PROBLEMS FROM SHRINKAGE

The next improvement focuses on eliminating the unnecessary solid material to avoid warping problems due to the shrinkage, and to decrease the cooling time of the part after injection. This can be achieved by eliminating the thick sections or by making them hollow. Consider the protrusion in the bottom housing for guiding the motion of the pump, and the protrusion on the bottom housing for adjusting the height of the vial holder, which are shown in Figure 4-6.

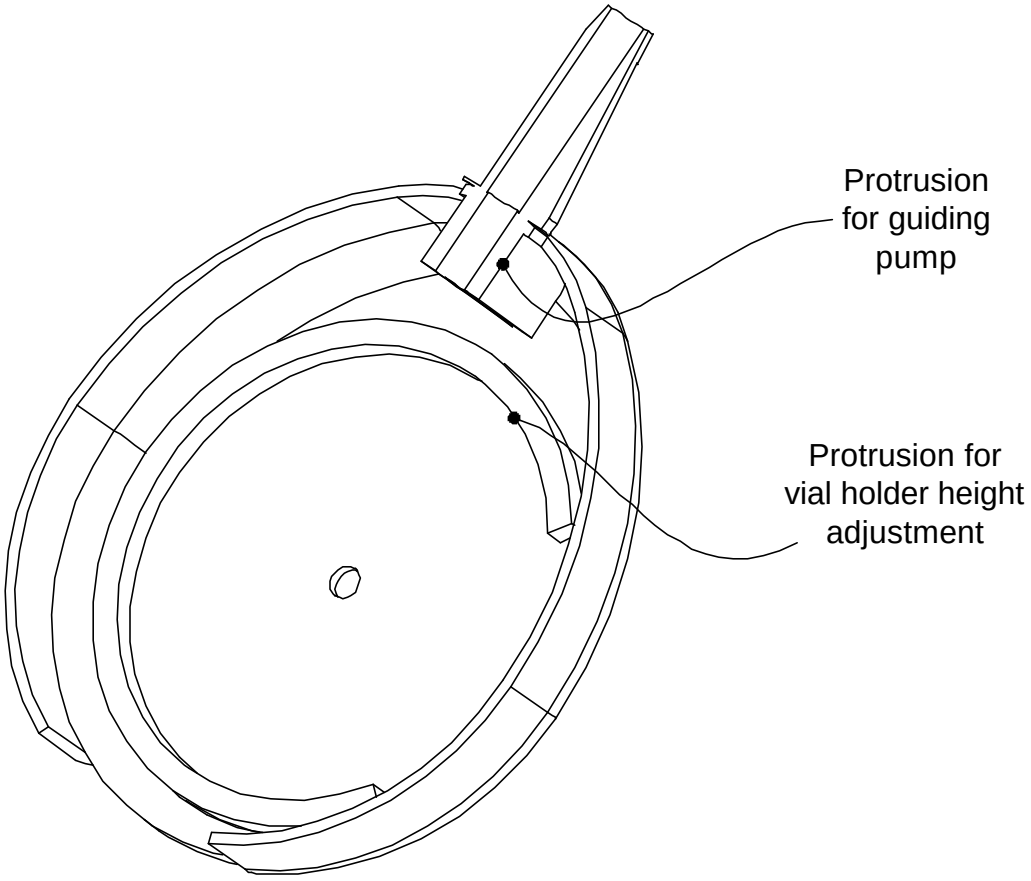


Figure 4-6 : Bottom Housing before Redesigning

The bottom housing is redesigned providing cuts in the protrusion for adjusting the height of the vial holder as shown in Figure 4-7, which removes the unnecessary material. Similarly, a cut is provided in the protrusion guiding the pump. They still serve their function after making the above design changes. The thick sections would cause the feature to deform (warp) due to the shrinkage of material during the cooling stage of the injection molding. Thus, implementing the above design changes helps in avoiding the shrinkage problems. Similar change can be accommodated in the protrusion for guiding the pump in the top housing, which is shown in Figure 4-8.

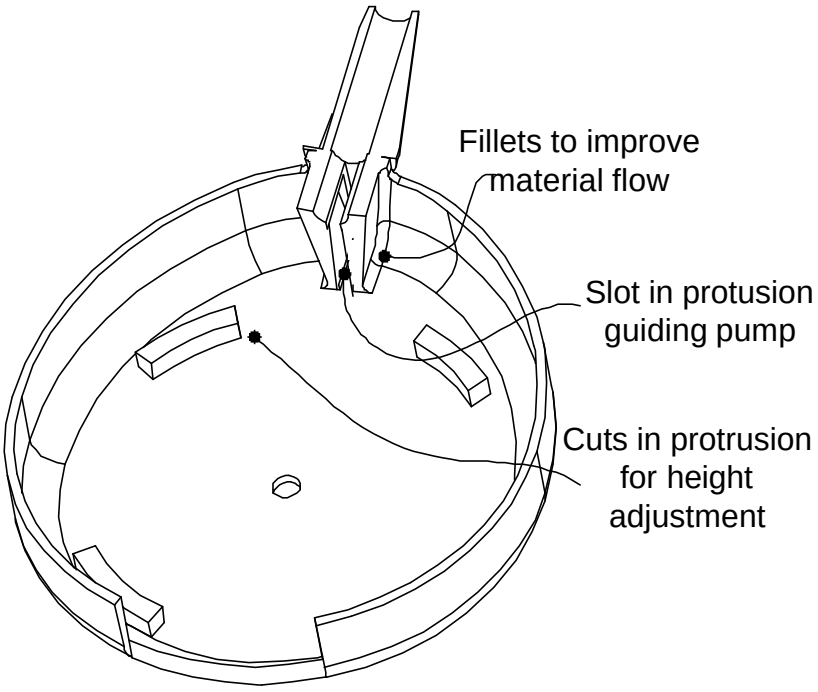


Figure 4-7: Bottom Housing after Redesigning

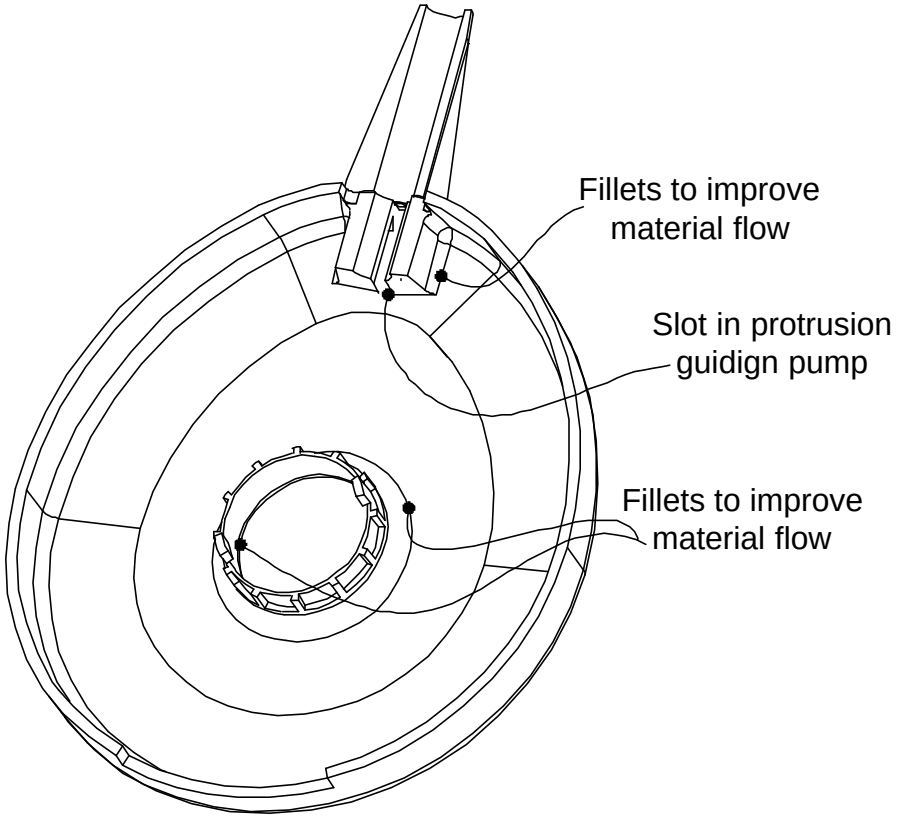


Figure 4-8: Top Housing after Redesigning

4.4.3 ELIMINATING SHARP EDGES USING FILLETS

The sharp edges in the parts should be filleted to obtain a smooth flow of the material in the mold. Considering the bottom housing, the edges between the protrusion for guiding the pump and the walls of the bottom housing are filleted as shown in Figure 4-7. Similar changes are done to the protrusion for guiding the pump in the top housing too, and the edge between the hub and the top housing is filleted as shown in Figure 4-8. The other part, which needs to be concentrated for filleting the edges, is the vial holder. The edges of the protrusion that locate the vials are filleted to ease the flow of the material in the mold. The edge between the hub of the vial holder and its base wall and the edges of the slot for the batteries and the circuit at the back of the vial holder are also filleted. The redesigned vial holder with fillets is shown in Figure 4-9.

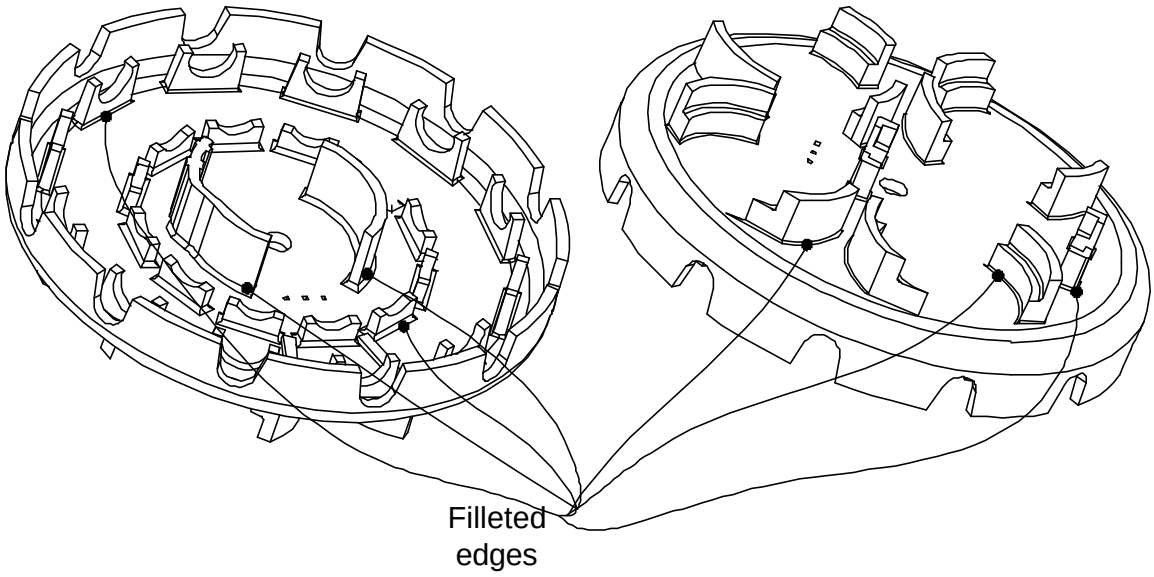


Figure 4-9 : Redesigned Vial Holder

Filleting the edges ensures a smooth flow of the material during the injection stage and prevents the formation of cavities in the parts.

4.4.4 ELIMINATING ADDITIONAL INSERTS

The only part that requires an additional insert other than the molds is the actuator bearing. The actuator bearing requires a hole in the top along the parting plane for the slider and the spring, and another hole and a slot in the bottom for the NiTi wire. This forces the use of two inserts other than the molds. In the cases where the inserts cannot be eliminated, it is better to keep the number of inserts to minimum, so that the manufacturing time can be reduced. Therefore, the features in the bottom half of the actuator bearing are redesigned to eliminate the insert for the hole and the slot for the NiTi wire. The redesigned actuator bearing is shown in Figure 4-10, and it consists of a protrusion with a spherical slot into which the terminating ball of the NiTi wire is locked. Thus, the insert required for molding the part can be reduced from two to one, but this gives rise to another problem of adopting a new method for attaching the actuator bearing to the vial holder. The actuator bearing is designed with the rectangular protrusion at its bottom as shown in the Figure 4-10 and the vial holder is redesigned with a corresponding rectangular slot to accommodate the actuators. Thus, the protrusion with the spherical slot serves the same function of locking the NiTi wire in its place, but reduces the manufacturing cost perceivably as the number of inserts used is reduced. It also saves manufacturing time, as only one insert needs to be inserted. Therefore, it is worth redesigning the actuators, due to the above advantages.

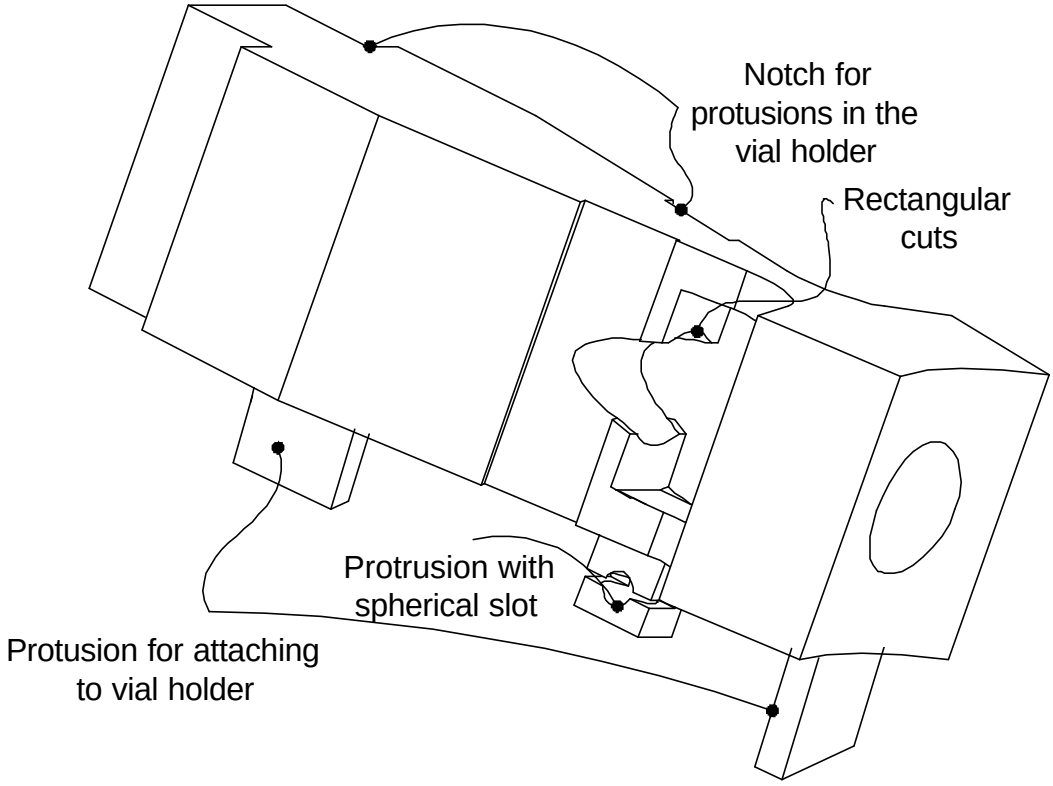


Figure 4-10: Redesigned Actuator Bearing

4.4.5 ELIMINATING SHARP CHANGES IN CROSS SECTIONAL AREA

The only part in which there is a sharp change in the cross sectional area is the actuator bearing. The actuator bearing shape has to be modified to eliminate the drastic changes in the cross-sectional area. The feature that creates sharp changes in the cross section area of the actuator bearing are the notches in the bearing to accommodate the protrusion for the vials in the vial holder (Figure 4-10). The notch in the middle of the actuator bearing is eliminated, reshaping the actuator bearing, so that the transition in shape is achieved gradually and it is ensured that it still fits in the space between the vials. The actuator is decreased in size to eliminate the notch at the end of the actuator bearing. The protrusion for locking the NiTi wire is moved to the front to maintain the length of the NiTi wire, even though the actuator is decreased in size, which is shown in Figure 4-11. The

rectangular cut in the actuator bearing (Figure 4-10) is also redesigned into a circular one, so that it can be accommodated with a cylindrical insert. The redesigned actuator in which the change in shape is gradual is shown in Figure 4-11.

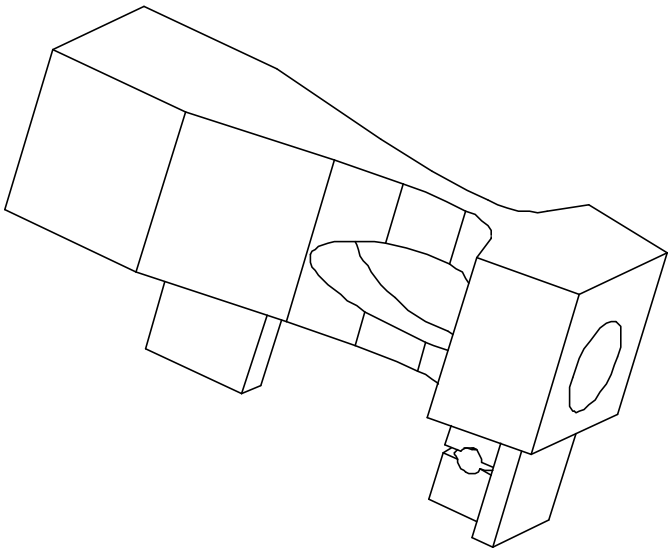


Figure 4-11: Actuator Bearing

4.5 MATERIALS

The next step after redesigning the parts is to select the materials for them. Some parts of the nasal sprayer need materials of minimum strength to ensure that they do not fail during their life. The parts that need materials of minimum strength are the ratchet and sliders. The equations for the calculation on the material strength of the ratchet were presented in chapter 2 and the spreadsheet showing the strength and dimensions of the ratchet is attached in Appendix A. From the spreadsheet, it is evident that the ratchet material should have minimum strength of 55N/mm^2 (Mpa). It is found from the material database shown in Table 4-2 that polycarbonate, polyamide and acetal satisfies the strength requirements. The acetal is eliminated due to its low melt flow value and the polyamide is eliminated due to its high water absorption rate (10%) and therefore,

polycarbonate is found to be the most appropriate material for the ratchet. The commonly used polymers for injection molding are shown in Table 4-1, and their properties are given in Table 4-2.

Table 4-1 : Commonly used polymers in Injection Molding [12]

Thermoplastic	**Elastic Modulus (MN/m^2)**	**Heat Deflection Temperature (^oC)**	**Cost ($/kg)**
High density polyethylene	925	42	0.90
High-impact polystyrene	1900	77	1.12
Acronitrile butadiene styrene(ABS)	2100	99	2.93
Acetal (Homopolymer)	2800	115	3.01
Polyamide (6/6 nylon)	2800	93	4.00
Polycarbonate	2300	130	4.36
Polycarbonate (30% glass)	5500	143	5.54
Modified polyphenylene oxide (PPO)	2200	123	2.75
Polypropylene (40% talc)	3300	88	1.17
Polyester teraphthalate (30% glass)	11000	227	3.74

Table 4-2 : Polymer properties [13]

Materials	Melt flow g/10min	% Elongation at yield	Tensile yield strength (Mpa)	Density g/cc	Water absorption
High density polyethylene	0.1-90	6.9-15%	25.2	0.918-1.4	0.01-1.5%
High Impact polystyrene	4.7		23	1.04	0.10%
Acronitrile Butadiene Styrene (ABS)	0.5-45	1.7-6%	48	1.02-1.21	0.05-1.8%
Acetal (homopolymer)	1.0-39	8-23%	64.9	1.34-1.44	0.2-0.44%
Polyamide	4.0-130	18.50%	62.4	1-1.17	0.3-10%
Polycarbonate	2.0-71	6-8%	62	1.17-1.45	0.09-0.35%
Polycarbonate (30% glass filled)	8.0-19	2-4%	120	1.33-1.45	0.08-0.26%
Modified PPO (30% glass)		3-4%		1.28	0.06%
Polypropylene (40%talc)	1.0-12	4.50%	27.3	1.21-1.26	0.025-0.04%
Polyester teraphthalate		1.5-4%	140	1.5-1.69	0.05-0.06%

Considering the slider, the preload force of the compression spring acts continuously on it even at its free state, as the slider head compresses the springs to the preload length even at the free state. This force tends to buckle the slider over time; therefore, the fatigue failure of the slider has to be considered. It has been observed from the prototypes that the tube of the slider tends to buckle with time due to the preload force of the compression spring. Therefore, the tube of the slider has to be made of steel, and the head of the slider can be a polymer or a rubber. Another factor which encourages the use of the steel tube for the sliders is the friction offered by the steel slider and the jewel bearings; it helps in reducing the power requirements to half, i.e., the actuators can be operated with two batteries instead of four, which would drastically reduce the cost of the device. This gives rise to a new requirement of incorporating the jewel rings inside the actuator bearing due to its advantage of reduced friction. The disadvantage of incorporating the

jewel rings is that an extra insert is needed for molding the bearing, as the hole in the actuator bearing changes in diameter to accommodate the jewels. Therefore, one insert is inserted from the front and one from the back compared to a single insert in the previous case. The wire return guide is made into a separate piece to facilitate the insertion of the extra insert in the back, and slots are provided in the actuator bearing to assemble the jewels and protrusions for assembling the wire return guide. The modified actuator bearing accommodating the jewels and wire return guide is shown in Figure 4-12. Figure 4-13 shows the picture of the assembled actuator.

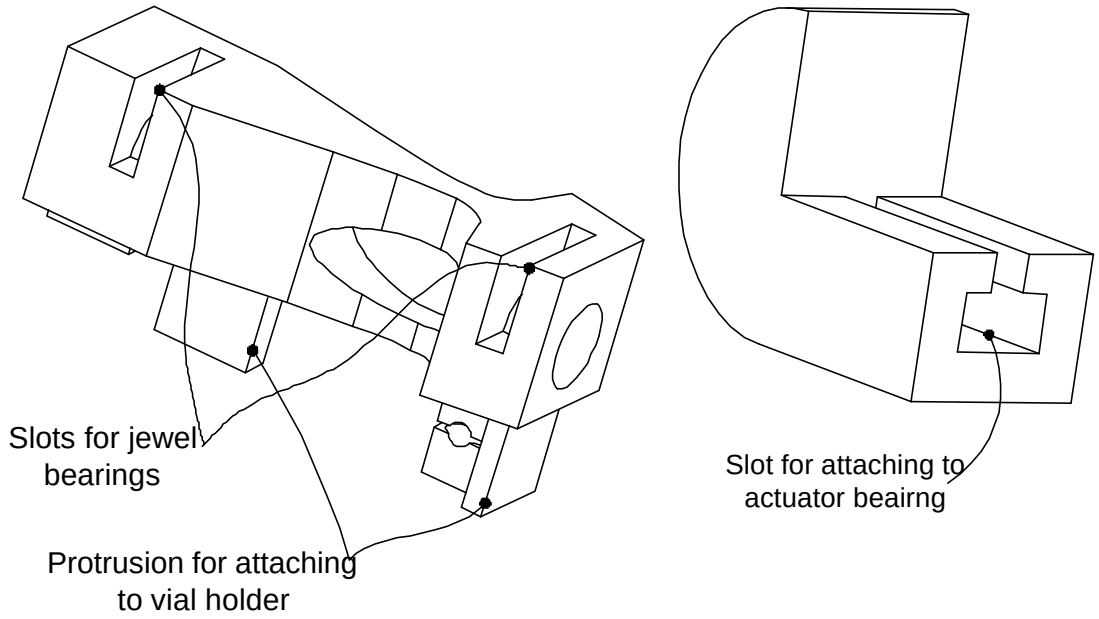


Figure 4-12 : (a) Actuator Bearing (b) Wire Return Guide

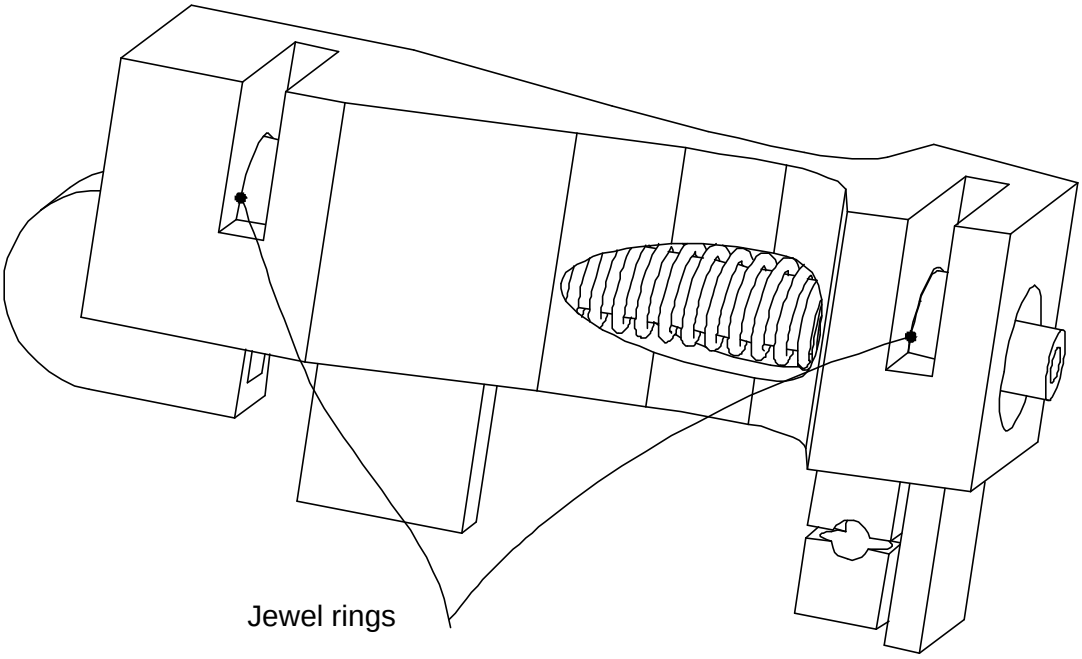


Figure 4-13: Actuator with Jewel Bearings

The materials for the other parts do not require particular strength. The only requirement is that the material should not be brittle, as the device should not break if it is dropped accidentally. Therefore, different polymers commonly used for injection molding were selected from Table 4-1[12] and the selected polymers were analyzed comparing their properties from Table 4-2 [13]. The different properties of the polymers considered for comparison are the melt flow values, to ensure the efficient flow of the polymers in the mold, and percentage elongation at yield is compared to ensure that the material is not brittle. Density cost and water absorption rate were the other properties that were compared. The ductility of material is given priority in the material selection; as mentioned before, the device should not break if it is dropped accidentally. Therefore, percentage elongation at yield is compared for different polymers, and high-density polyethylene, acetal and polyamide were found to have good ductility values. High-

density polyethylene is found to be the most appropriate material for the other parts as it had the advantage of low cost and high melt flow value over acetal and polyamide.

4.6 FINALIZING MANUFACTURING METHODS

The different manufacturing methods considered for the parts are buying the components off the shelf, injection molding and plastic extrusion. The parts like vials, rubber stoppers, and the pump were adopted from the products available in the market; therefore, they can be bought from the sub-contractor rather than manufacturing them in-house. Similarly, the electronics can also be subcontracted, so that it can be purchased as a single unit and assembled in the device. The steel tubes of required length can be purchased from the subcontractors and the slider head can be assembled to it, as the slider is redesigned to be a steel tube with a head. The other parts namely, the top housing, the bottom housing, the vial holder, the actuator bearing, the pump pusher, the ratchet and the gear are manufactured by injection molding as discussed. Injection molding is found to be the best method for the new parts, the wire return guide, and the pump bearing also.

4.7 TOOLS FOR INJECTION MOLDING (MOLDS)

Molds for the injection molding vary in design, degree of complexity, size and cost depending upon the parts to be produced from them. The mold consists of two parts, stationary half to which the molten polymer is injected and a moving half which is attached to the closing side of the injection molding machine. In this case, the parts are grouped into families, so that a group of parts can be manufactured from a single-family mold. The parts for a family are selected such that the volume of the parts in a single family is approximately the same, as the material flowing from the injection point to

cavities for the parts will be approximately the same. Therefore, it is better to group the parts with the same volume into a family. The parts, the top housing, the bottom housing and the vial holder have same volume approximately and they are grouped into a single family so that they can be manufactured from single-family mold. Similarly, the parts ratchet, gear, and pump bearing are grouped into a single family. The actuator bearing and the wire return guide are manufactured from a single-family mold. A separate mold is used for manufacturing the pump pusher, as the wall thickness of the mold needed for manufacturing it varies along its length. Thus, four sets of mold are required for manufacturing the parts of the nasal sprayer. The different molds considered for manufacturing the product are the prototype mold and the production mold. The difference between the prototype mold and the production mold is that the prototype mold is made up of soft steel compared to the hardened steel in the case of production mold; the prototype mold would yield around a half-million parts before it wears out [14], compared to the millions of parts of the production mold. The advantage of the prototype mold is that it is much cheaper than the production mold. Therefore, the prototype mold is opted for manufacturing the parts of the nasal device, as the product would undergo numerous design changes during the introduction phase depending upon the response from the customers, and so does the mold. The quote for the cost of the family mold obtained from a tool manufacturing company [14] is shown in Table 4-3.

Table 4-3: Mold cost

FAMILY MOLD	COST
Family mold 1: Vial holder, Top-Housing, Bottom Housing	$35,000
Family mold 2:Ratchet, Gear, Pump Bearing	$8000
Family mold 3: Pump pusher	$9,000
Family mold 4: Actuator bearing, Wire return guide	$20,000

Thus, in this chapter, the parts are optimized for manufacturing, material for the parts are assigned, the manufacturing methods for the parts are determined, and the cost of the tooling is estimated. The next step is to determine the capacity of the machines required and resources required for manufacturing and assembling the device, which are analyzed in the next chapter.

Chapter 5 PROCESS VARIABLES

5.1 INTRODUCTION

The parts of the nasal sprayer and the features of the parts were finalized in the previous chapter. The next step is to map the process variables to the design parameters. As discussed above, the process variables are the resources needed to manufacture the device. The different resources needed for manufacturing the device and the quantity of each resource is determined in this chapter. The different tasks that need to be done to produce a finished product are sterilizing the vials, filling the vials with medication, inserting the rubber stopper into the vials, arranging the vials in the vial holder, and assembling the device. The unit cost of device is calculated from the cost of resources required, cost of the subcontracted parts and the material cost.

5.2 PROCESS VARIABLES

The resources needed for accomplishing the above tasks are: a sterilizer for sterilizing the vials, a vial filling machine for filling the medication, a machine for inserting the rubber stopper, and a pick and place robot for arranging the vials in the vial holder. The resources needed for manufacturing are injection-molding machines for manufacturing the parts and the molds. The resources needed for assembling the parts are an operator, tools, and fixtures required for assembling. The process variables for the device are shown in Figure 5-1. The process variables are divided in to major subdivisions: resource needed for filling the vials, manufacturing the parts, and assembling the device. The sub-process variables for the major divisions are then determined as shown in the Figure 5-1.

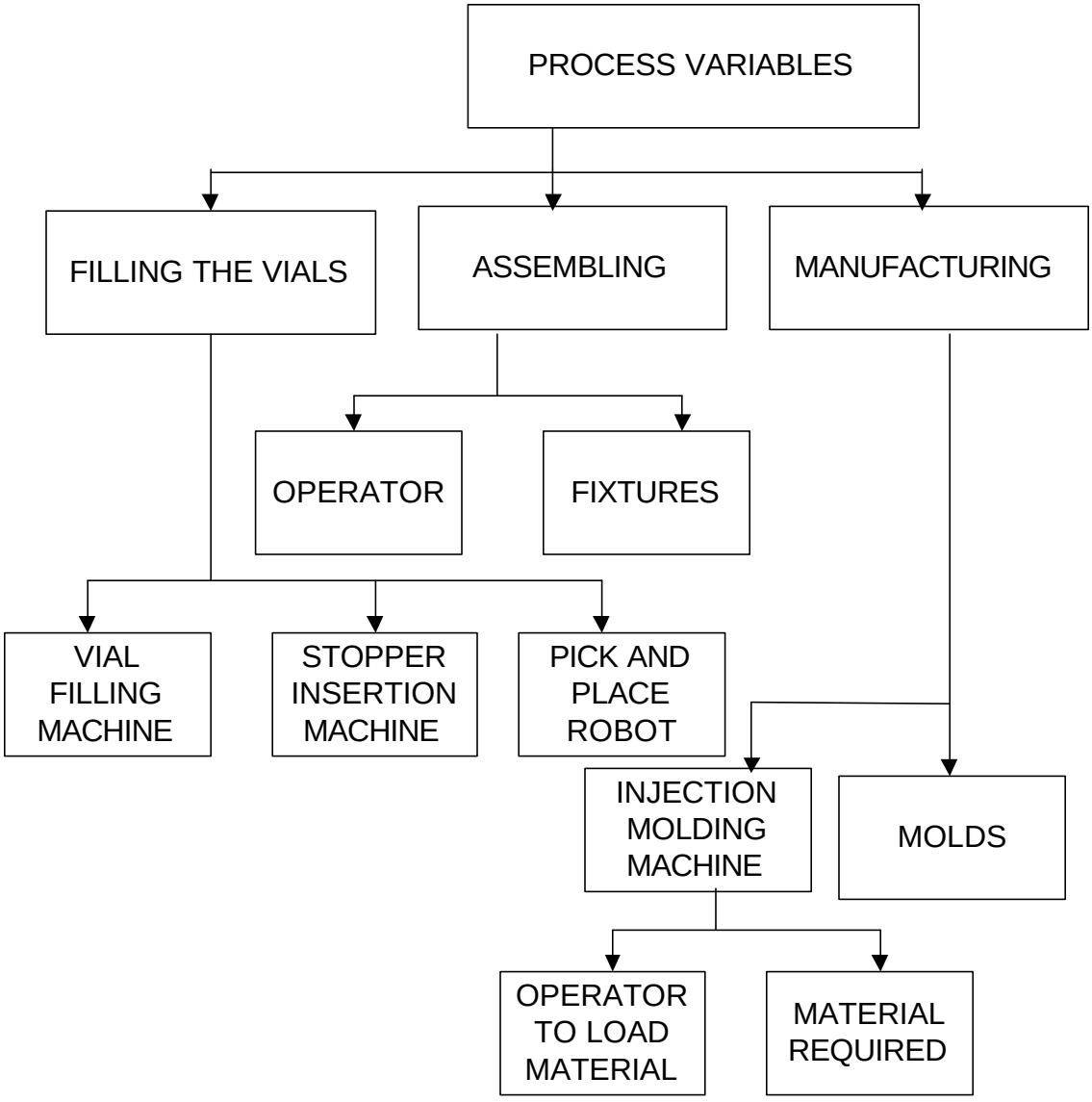


Figure 5-1: Process Variables

The process variables for filling the vials with the medication and loading it in the vial holder are already mentioned above and are not discussed in detail, as this thesis focuses on the resources required to manufacture and assemble the parts of the device, rather than the resources required for filling the medication in the vials.

5.2.1 PROCESS VARIABLES FOR MANUFACTURING THE DEVICE

As discussed above, the process variables for manufacturing the device are injection molding machine, molds, and operators to load the material and maintain the machine. The cost of each process variable is calculated in this section. First, the type of injection molding machine required and its cost is determined. Next, the capacity of the machine (# of machines) required to meet the demand of 1.2 million parts per year is determined.

5.2.1.1 DETERMINING THE SPECIFCATIONS OF THE INJECTION MOLDING MACHINE

The next step after determining the required process variables is to determine the specification of the process variable to be able to approximate the cost of it. The appropriate size of the injection-molding machine is determined based on the required clamping force, and a good estimate of the clamping force is obtained from the projected area of the parts in the direction of the mold opening [12]. The project area of the parts in the direction of the mold opening for all the parts is calculated from the part model in the Pro-Engineer modeling software and is tabulated in Table 5-1.

The size of the runner system depends upon the size of the part. The final projected area is calculated by adding the projected area of the runner system as the percentage of the projected area of the part. The percentage of the runner system project area is calculated for different parts from their volumes, which is given in Table 5-2. The projected area of all the parts in the family (manufactured by a single mold) needs to be determined in this case to calculate the maximum clamping force.

Table 5-1 : Projected area and Volume of parts

SNO	Part	Projected Area ‘cm^2’	Final Projected area‘cm^2’	Volume ‘cm^3’
1	Top Housing	52.07538	71.34327022	11.41998
2	Vial Holder	42.47733	58.19394813	12.21983
3	Bottom Housing	54.47279	74.62772816	14.15023
4	Ratchet	0.505805	0.692953453	0.168213
5	Pump Bearing	0.769031	1.053572086	1.549086
6	Gear	1.058708	1.450429357	0.385604
7	Pump pusher	4.036	5.529485715	1.942
8	Actuator bearing	1.343	1.840215674	0.4765
9	Wire return guide	0.107	0.146	0.029

Table 5-2 : Percentage Projected area of runner system [12]

Part or Family volume ‘cm^3’	Shot size ‘cm^3’	Runner %
16	22	37
32	41	27
64	76	19
128	146	14
256	282	10
512	548	7
1024	1075	5

The total project area of the family of parts is the sum of the final projected area of the different parts in the family. The total projected area and the total volume of the different family are given in Table 5-3.

Table 5-3 : Projected area and Volume of part family

Family Name	**Parts**	**Volume of the family 'cm^3'**	**Total projected area with Runner system 'cm^2'**
Family 1	Top housing Bottom Housing Vial Holder	37.79	204.16
Family 2	Ratchet Gear Pump Bearing	2.102	3.196
Family 3	Pump pusher	1.924	5.529
Family 4	Actuator bearing Wire return guide	0.504	1.986

The minimum clamp force that the machine should have for manufacturing the above family of parts is given by the product of the total projected area and the maximum cavity pressure. Assuming 50% of the pressure generated by the injection unit is lost due to the flow resistance in the sprue and runner systems [12], the maximum cavity pressure is assumed half the recommended injection pressure. The recommended injection pressure is obtained from the processing data table.

$$Min.Clamp\ force = Total\ project\ area\ of\ family * Max.cavity\ pressure \quad (5\text{-}1)$$

From the equation(5-1), the clamp force required for the different families is calculated.

Family 1: 985 KN

Family 2: 15.5 KN

Family 3: 26.5KN

Family 4: 11.6KN

Table 5-4 : Processing Data for Polymers [12]

Thermoplastic	**Specific gravity**	**Thermal (mm^2/s)**	**Injection temp (^0c)**	**Mold temp (^0c)**	**Ejection temp (^0c)**	**Injection pressure (bars)**
High density polyethylene	0.95	0.11	232	27	52	965
High-impact polystyrene	1.59	0.09	218	27	77	965
Acronitrile butadiene styrene(ABS)	1.05	0.13	260	54	82	1000
Acetal (Homopolymer)	1.42	0.09	216	93	129	1172
Polyamide (6/6 nylon)	1.13	0.10	291	91	129	1103
Polycarbonate	1.20	0.13	302	91	127	1172
Polycarbonate (30% glass)	1.43	0.13	329	102	141	1310
Modified polyphenylene oxide (PPO)	1.06	0.12	232	82	102	1034
Polypropylene (40% talc)	1.22	0.08	218	38	88	965
Polyester teraphthalate (30% glass)	1.56	0.17	293	104	143	1172

Based on the clamp force, the machine is selected from the machine selection table (Table 5-5), and it is found that for the calculated clamp force, the 22 KW driving power machine is appropriate for family 1 and 5.5KW machine is appropriate for the other families. The next step is to check whether the total volume of the family is less that the shot size of the machine before deciding on the machine; if not, the machine with the higher shot size has to be considered. In this case the total volume is less than the shot size.

Table 5-5: Machine selection table [12]

Clamping force (KN)	**Shot size (cc)**	**Operating cost/hr ($/hr)**	**Dry cycle times (s)**	**Max. clamp stroke (cm)**	**Driving Power (KW)**
300	34	28	1.7	20	5.5
500	85	30	1.9	23	7.5
800	201	33	3.3	32	18.5
1100	286	26	3.9	37	22.0
1600	286	41	3.6	42	22.0
5000	2290	74	6.1	70	63
8500	3636	108	8.6	85	90

5.2.1.2 DERTERMINNG THE REQUIRED CAPACITY OF THE MACHINES

The next step is to find the capacity or the number of machines of a particular type required. From the information on the estimated number of parts to be manufactured in a year (1.2 million/year) provided by Intranasal Technology Inc, the capacity of the machines required is calculated. A single nasal sprayer requires two actuator bearings and one of the other parts. Therefore, to assemble 3350 sprayers in a day, 3350 parts have to be produced from family molds 1, 2, and 3 and 6700 parts have to be produced from Family mold 4. The injection molding time depends on the volume of the parts and inserts required. The injection molding cycle time for the parts of Family 1 would be 45 sec as it has high volume and it would be 15 sec for Family 2 and 3. The cycle time for Family 4 (20 sec) would need an extra 5 sec for the insertion of the inserts. Therefore, the total machine time required for each family of parts is calculated and displayed below.

$$Total\ machine\ time\ /\ family = no.of\ \ family\ parts\ req * cycle\ time \qquad (5\text{-}2)$$

Family 1: 42 Hrs

Family 2: 14 Hrs

Family 3: 14 Hrs

Family 4: 37 Hrs

Total hours: 107 Hours

From the total number of machine hours required per day, it is evident that 5 machines can be used for 23 hours to manufacture required parts in a day. Therefore two 22 KW (as machine hours for Family 1 is less than 42 hrs) and three 5.5 KW injection molding machines are required for manufacturing the required parts.

5.2.2 PROCESS VARIABLES FOR ASSEMBLING THE DEVICE

As discussed above, the resources needed for assembling the device are fixtures for assembling the parts, operators for the manual assembly and other miscellaneous resources like assembly tables and tools. The fixture for snap fitting the slider tube with the slider head is shown in Figure 5-2. First, the slider tube is inserted into the slot and then the slider head is pushed on the slider tube until it hits the shoulder.

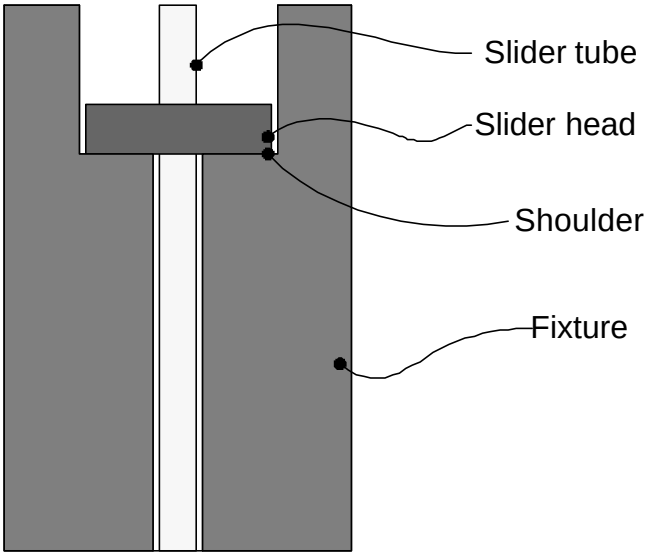


Figure 5-2: Slider Fixture

The next step is to estimate the number of operators required for assembling the device. It is estimated that five operators are required to work for 24 hours assuming a 10 sec cycle time for each task. The task is split among the operators as follows: one for assembling the slider, one for the assembling jewels in the actuators, one for assembling actuators with a slider and spring, one for assembling the ratchet and the gear to the housing and vial holder respectively, and one for assembling the final device. Thus, the process variables required for assembling the device are determined.

5.3 MANUFACTURING AND ASSEMBLY COST

The next step is to determine the manufacturing and the assembly cost of the machine. The cost is determined from the process variables determined above. The process variables for manufacturing and assembling are divided into two categories: fixed cost (does not depend on # of units produced) and variable cost (depends on # of units produced). The process variables contributing to the fixed cost are, the injection molding machines, fixtures for assembling, machines for filling and loading the vials, and other

resources need for assembling. The process variables contributing to the variable cost are the material cost, cost for the operators, mold cost (distributed over half a million parts) and the cost of the parts bought from the suppliers (sliders tubes, NiTi wires, Springs, Electronics, pump).

5.3.1 CAPITAL OR FIXED COST

The costs of the machines are estimated for the calculation of the fixed cost. The estimated cost is shown in Table 5-6.

Table 5-6: Fixed cost table

Resources	**Cost ($)**
4 Injection Molding machine	500000
Resource for filling and loading vials	200000
Fixtures and Resources for assembling	25000
Total	**725000**

Assuming each machine's life to be five years and 3350 products are produced per day by the machine, the capital cost can be distributed over all the parts produced in five years and the distributed capital cost per part is $0.12 per part.

Mold Cost

The mold cost is already estimated in the previous chapter. The mold can be used to produce up to half a million parts. For manufacturing the device, 3350 parts are manufactured from Family molds 1, 2, 3, and 6700 parts are manufactured from Family mold 4. Therefore, the cost of the mold for parts produced in a day is calculated below.

Cost per day for Family molds 1,2 &3 = (35000+8000+9000)*3350/500000 = $348.5

Cost per day for Family mold 4 = 20000*6700/500000 = $268

Total mold cost/day = 348.5 +268 = $616.4

The mold cost per unit is calculated by the dividing the above cost by number of units manufactured in a day and it accounts to $0.18.

5.3.2 ESTIMATION OF VARIABLE COST

Cost of the operators

The total number of operators required is five for assembling the device and one for the injection molding. Assuming an hourly pay of $15, cost for the operators per day is $2160. The operator cost per unit is found by distributing the above cost over the number of units produced per day and it accounts to $0.64.

Material cost

The total volume of material required for the family is calculated by adding a 10 % extra volume to the total volume of the family. The 10% extra-volume accounts for the volume of the material that is wasted in the runner. The material cost is then calculated by figuring the weight of the material from its volume, and multiplying its cost from Table 4-1.

$$Material Cost = Volume\ of\ the\ material * Density * \cos t / kg \qquad (5\text{-}3)$$

Volume of material used by Family mold 1 /day : 37.79 * 1.1*3350 = 139256 cc

Volume of material used by Family mold 2/day : 2.102* 1.1*3350 = 7745 cc

Volume of material used by Family mold 3/day : 1.924*1.1*3350 =7090 cc

Volume of material used by Family mold 3/day: 0.504*1.1*6700 = 3715 cc

The parts of Family mold 1,3 and 4 use the same material (high density polyethylene), whereas the parts of Family mold 2 require a specific strength so polycarbonate is used for those parts as discussed in Chapter 4. Therefore, the volume of the material required is 150060 cc of HDPE and 7750 cc of polycarbonate per day.

Weight of HDPE = 150060 *0.95 = 142.5 Kg

Weight of polycarbonate= 7750*1.25 = 9.7 Kg

Cost of the material/day = cost of HDPE + cost of polycarbonate

Cost of material/day = 142.5*0.90 + 9.7*4.36 = $171

Similarly, the cost of the material per unit is obtained by dividing the above cost by the number of units produced per day and it accounts to $0.05

Cost of the Outsourced parts

The different parts bought from the suppliers for this device are the slider tubes, the springs, the NiTi wire, the jewel bearings, the electronics, the vial, the rubber stopper and the pump. The cost of the subcontracted parts and the suppliers for them are listed in the Table 5-7.

Table 5-7: Estimated Cost of Outsourced parts

SNO	Part	Requirement	Cost/day	Supplier Name
1	Slider tube	6700 pieces	$1200	Microgroup Inc
2	Springs	6700 pieces	$670	Century springs
3	Jewel Bearings	13400 pieces	$8710	Swiss Jewel Co.
4	NiTi wire	302 m	$504	Dynalloy Inc
5	Electronics	3350 pieces	$5025(approx)	Estimated
6	Vials, Rubber Stopper and Pump	40200 (vials and stopper) 3350 pumps	$4300 (Approx)	Estimated
		Total	$20409	

The cost of the subcontracted parts per day is calculated by adding all the cost from Table 5-7 and is found to be $20409, and the cost of the subcontracted parts accounting for a single device is found to be $6.09.

Interest of the capital cost

Considering the fixed cost is borrowed as a loan, interest accounting to the capital is included in the variable cost. Assuming 20% interest as the interest rate on the fixed cost, the variable cost due to the interest per day is calculated as $403/day, and the cost due to interest par part is $0.12.

5.3.3 TOTAL COST OF A DEVICE

The total cost of the device presented in this section excludes the cost of the medication to be filled in the vials. The total cost of the device is given by the sum of all the unit cost calculated above. Therefore, the cost of a device is,

$$Cost/device = Sum\ of\ the\ costs \quad (5\text{-}4)$$

$$= \$7.21/\text{piece}$$

Thus including the cost of the medication would provide us with the cost of producing a complete device. The appropriate price for the device would be $10, considering the cost of the medication, the utilities, the overhead cost and the profit; this is economical.

Chapter 6 CONCLUSION

The parts were conceptually designed in Chapter 2 using the axiomatic design theory, and optimized for manual assembly in Chapter 3, and finally optimized for manufacturing, i.e., injection molding in Chapter 4. The manufacturing and assembly cost of the device was calculated in Chapter 5 and the cost was found to be within acceptable limits. If the product cost is beyond the expected range, then the product has to be redesigned for the cost by giving up some less important functional requirements to make the product affordable. Thus, an economical, handheld device capable of regulating and delivering multiple doses of liquid medication to the nasal tissue is developed following axiomatic design theory and design for assembly and manufacturing principles. Thus, the hypothesis of this thesis is validated by designing and prototyping a nasal drug delivery device that satisfies the required functional requirements and which could be manufactured at an affordable cost.

6.1 FUTURE WORK

The FDA regulations on the materials of the parts of the nasal sprayer are not considered in the selection of the material for the parts. Therefore, the materials of the nasal sprayer have to be analyzed considering FDA regulations and reselected if necessary. The assembly sequence provided in Chapter 3 is the logical sequence that would suit the assembly of the device. Therefore, the manufacturing and assembly sequence of the parts of the device has to be developed conisidering the flow of the parts in the shop floor and the utilization of the machine and the workers. The tools and fixtures for manufacturing and assembling the parts need to be developed. The transition from manual assembly to

automated assembly should be considered once the product design stabilizes after the introduction stage of the product. The means to test the performance of the low friction actuator and optimize its performance should be developed; this can be accomplished by designing a test stage to inspect the performance of the actuator. Thus, the future works that can be done based upon this thesis were listed above.

APPENDIX A

Sample Spread Sheets

Sample spread sheet for calculation of dimensions of toggle and post

RP6461					
DES. OF SYMBOLS	**INPUTS**	**VALUE**	**UNITS**	**VALUE**	**UNITS**
Youngs Modulus	E	1786.944	N/mm^2	246000	psi
Yield Strength	Sy	56.6592	N/mm^2	7800	psi
Shear Strength	[Ss]	28.3296	N/mm^2	3900	psi
Modulus of Rigidity	G	666.6097	N/mm^2	94615.38462	psi
FOR SOLID TORSION ROD					
DES. OF SYMBOLS	**OUTPUT**	**UNITS**	**VALUE**		
Lever Length	L	3.556	mm	0.14	inch
Post Height	h	7.62	mm	0.3	inch
Actuation Force	F	0.71168	N	1.60E-01	lbf
Post Diameter	d	2.032	mm	0.08	inch
Polar Moment of Inertia	J	1.673766	mm^4	4.02124E-06	inch^4
Torque on Post	T	2.530734	N*mm	0.0224	lbf*inch
shear stress	Tau	1.536192	N/mm^2	222.8169203	psi
Twist Angle	theta	0.017284	rad	0.990279442	deg
Deflection Due to Torsion	y_tors	0.061461	mm	0.002419709	inch
FOR HOLLOW TORSION ROD					
DES. OF SYMBOLS	**INPUTS**	**UNITS**	**VALUE**		
Post Outer dia	do	2.032	mm	0.08	inch
Post Inner dia	di	1.905	mm	0.075	inch
Polar Moment of Inertia	J	0.380822	mm^4	9.14928E-07	inch^4
Shear Stress	Tau	6.751786	N/mm^2	979.3125673	psi
Twist Angle	theta	0.075964	rad	4.352421268	deg
Deflection Due to Torsion	y_tors	0.270128	mm	0.010634971	inch
BENDING OF THE METAL PIECE					
	INPUT	**UNITS**	**VALUE**		
Width	b	0.7493	mm	0.0295	inch
Thickness	h	1.4986	mm	0.059	inch
Bending Moment of Inertia	I	0.210151	mm^4	5.0489E-07	inch^4
Young's Modulus (Steel)	Esteel	2.06E+05	N/mm^2	3.00E+07	psi
Max. deflection	y	2.46E-04	mm	9.66E-06	inch
Bending Stress	Sb	9.023408	N/mm^2	1308.799829	psi
TOTAL DEFLECTION					
Solid Torsion Rod With Metal	y_total	0.061707	mm	0.00242941	inch
Hollow Torsion Rod with Metal	y_total	0.270512	mm	0.010650067	inch

Sample Spreadsheet for ratchet dimension calculations

BENDING OF THE RATCHET					
	INPUT	**VALUE**	**UNITS**	**VALUE**	**UNITS**
length	l	10.16	mm	0.4	inch
Modulus of Elasticity	E	1734	N/mm^2	246115.6	lbs/inch^2
Tensile Strength	[Sb]	54.95	N/mm^2	7799.339	lbs/inch^2
Max. deflection	y	1.27	mm	0.05	inch
Factor of Safety	N	1.5	--	1.5	--
depth of Beam	d	3.175	mm	0.125	inch
Hub Diameter	D	22.098	mm	0.87	inch
	OUTPUT	**VALUE**	**UNITS**	**VALUE**	**UNITS**
Height of Beam	t	1.144774	mm	0.04507	inch
Force	F	2.50043	N	0.550095	lbs
FEA Force Per Unit Length				5.500947	lbf/inch
Tension Analysis					
	Input	**VALUE**	**UNITS**	**VALUE**	**UNITS**
stress	St	54.95	N/mm^2	7799.339	lbs/inch^2
Output		**VALUE**	**UNITS**	**VALUE**	**UNITS**
Area	A	3.634658	mm^2	0.005634	inch^2
force(tensile)	Ft	133.1496	N	29.29292	lbs
Torque	T	2367.4	Nmm	12.74242	lbs-inch
FEA Pressure				8615.564	lfb/inch^2

Sample spreadsheet for design of NiTi actuators without friction

	Material Properties							
	Preload Stress in Nitinol	SigmaP	30000	psi	2E+08	Pa	206.9	N/mm^2
	Maximum Stress in Nitinol	SigmaMax	80000	psi	6E+08	Pa	551.6	N/mm^2
	Young's Modulus of Nitinol Tlow	E_low	5.00E+06	psi	3E+10	Pa	34475	N/mm^2
	Young's Modulus of Nitinol Thigh	E_high	1.20E+07	psi	8E+10	Pa	82740	N/mm^2
	Desired Change in Strain	Delta_Eps	0.04					
	Spring Stiffness	k	1.60	lbf/inch	280.19	N/m	0.28	N/mm
	Actuated Stress in Nitinol Wire	Sigma_a	5.00E+04	psi	3E+08	Pa	344.8	N/mm^2
	Functional Requirements							
	Stroke	Delta_L	0.0400	inch	0.001	m	1.016	mm
	Calculations							
		E	4.00E-02					
	Preload strain in nitinolwire	eps_p	6.00E-03	-		-		-
	Length of nitinol wire(L)	ln1	1	inches	0.254	m	25.4	mm
		delta_ln1	6.00E-03	inches	0.0015	m	0.152	mm
	Actuated Strain in Nitinol Wire	eps_a	4.17E-03	-		-		-
	length of preloaded nitinol wire(L)	l1	1.01	inches	0.2555	m	25.55	mm
	length of nitinol after actuation	l2	9.66E-01	inches	0.2454	m	24.54	mm
	length the nitinol(not preloaded) after actuation	ln2	9.62E-01	inches	0.2443	m	24.43	mm
		delta_ln2	4.01E-03	inches	0.001	m	0.102	mm
	Preload Force	Fp	9.60E-02	lbf	0.43	N		
	Force in Wire While Actuated	Fa	1.60E-01	lbf	0.71	N		
	Wire Cross-Sectional Area	Aw	3.2E-06	inches^2	2E-09	m^2	0.002	mm^2
	Wire Diameter	d	0.00202	inches	0.0005	m	0.051	mm
		delta_ls1	6.00E-02	inches	0.0152	m	1.524	mm
	Design Parameters							
	Length of Nitinol Wire	L	1	inches	0.254	m	25.4	mm
	Wire Diameter	d	0.00202	inches	0.0005	m	0.051	mm

Sample spreadsheet for design of NiTi actuators with friction

Stroke	0.05	inch	0.127	cm
Friction Force	0.2	lbf	0.089286	Kg
Assumed Wire Diameter	0.006	inches	0.01524	cm
Area of Wire	2.82743E-05	in^2	0.000182	cm^2
Assumed Percent Elongation	0.03			
Stress before Actuation	10000	psi	691.9657	kgf/cm^2
Stress after Actuation	20000	psi	1383.931	kgf/cm^2
Preload Force	0.483	lbf	0.21551	kgf
Actuation Force	0.565486678	lbf	0.252449	kgf
Spring Stiffness	1.654866776	lbf/inch	0.290858	kgf/cm
Wire Length	1.666666667	inch	4.233333	cm
Spring Specs				
Stiffness	1.654866776	lbf/inch	0.290858	kgf/cm
Max Force (at solid length)	0.565486678	lbf	0.252449	kgf
Free Length	0.75	inch	1.905	cm
Preload Length	0.4582887	inch	1.164053	cm
Actuation Length	0.4082887	inch	1.037053	cm

APPENDIX B

Exploded view of the different nasal sprayer models

EXPLODED VIEW OF FLEXURAL BEARING ACTUATOR MODEL

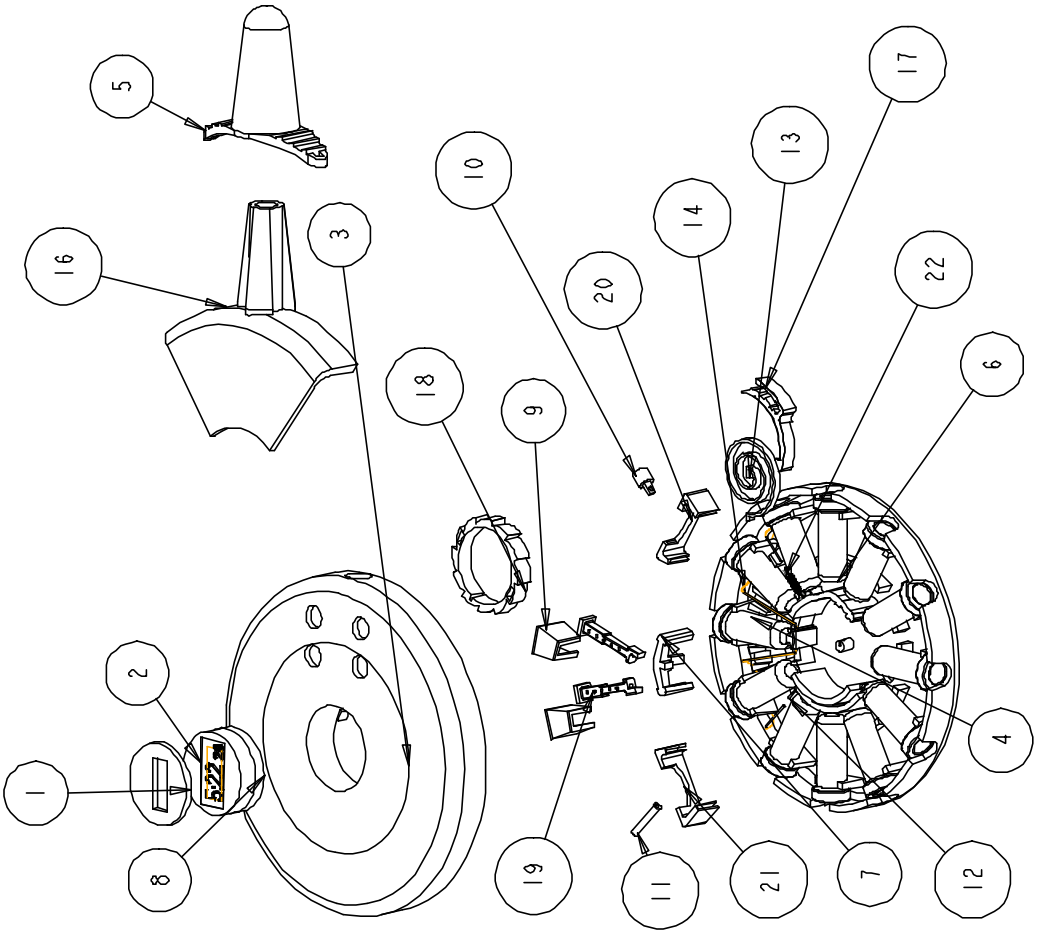
EXPLODED VIEW OF TENSION SPRING ACTUATOR MODEL

FILENAMES:	MODEL	NASAL-GATLIN-ASSY
	DRW	PACONSULTING

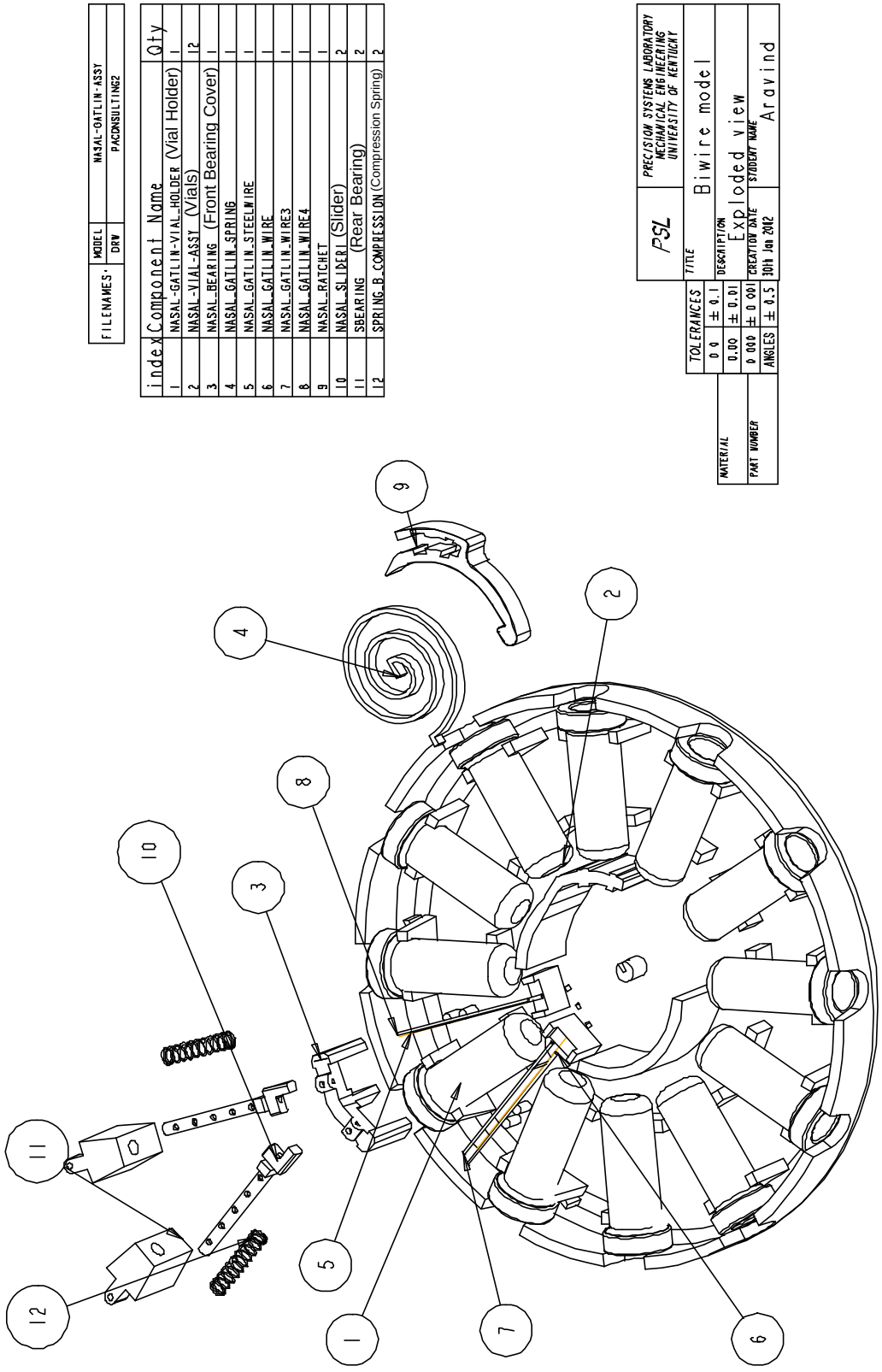
index	Component Name	Qty
1	NASAL-CLEAR_PLATE	1
2	NASAL-CLOCK	1
3	NASAL-GATLIN-HOUSING (Housing)	1
4	NASAL-GATLIN-VIAL_HOLDER (Vial Holder)	1
5	NASAL-PUMP_PUSHER (Pump pusher)	1
6	NASAL-VIAL-ASSY	12
7	NASAL_BEARING (Front Bearing cover)	1
8	NASAL_ELECTRONICS-PLATE	1
9	NASAL_ESCAPEMENT_BEARING_COVER2 (Rear Bearing Covers)	2
10	NASAL_GATLIN_CRIMP1 (Connector 1)	1
11	NASAL_GATLIN_CRIMP2 (Connector 2)	1
12	NASAL_GATLIN_MITINGKNIFE	1
13	NASAL_GATLIN_SPRING	1
14	NASAL_GATLIN_STEELWIRE	1
15	NASAL_GATLIN_STEELWIRE2	1
16	NASAL_PUMP_BEARING	1
17	NASAL_RATCHET	1
18	NASAL_RATCHET_TOOTH	1
19	NASAL_SLIDER1 (Slider)	2
20	NASAL_WIRECOVER (Wire guide)	1
21	NASAL_WIRECOVER2 (Wire guide)	1
22	OEM-CENTURY-80000 (Tension Spring)	1

PSL	PRECISION SYSTEMS LABORATORY MECHANICAL ENGINEERING UNIVERSITY OF KENTUCKY	
TITLE	Monowire Model	
DESCRIPTION	Exploded view	
CREATION DATE	31 Jan 2002	
STUDENT NAME	Aravind	

MATERIAL	TOLERANCES	
	0.0	± 0.1
	0.00	± 0.01
PART NUMBER	0.000	± 0.001
	ANGLES	± 0.5



EXPLODED VIEW OF COMPRESSION SPRING ACTUATOR MODEL



FINAL REDESIGNED
COMPRESSION SPRING
ACTUATOR MODEL

FINAL REDESIGNED
ACTUATOR ASSEMBLY

FILENAMES:	MODEL	TEST_JEWEL_ASSY
	DRW	THESIS

index	Component Name	Qty
1	JEWEL_BEARING_SLIDER (Slider)	1
2	JEWEL_WIREGUIDE (Wire return guide)	1
3	JEWELBEARING (Ruby Ring Jewels)	2
4	JEWELBEARING_ACTUATOR (Actuator Bearing)	1
5	NASAL-ACTUATOR-SPRING (Compression spring)	1

PSL	PRECISION SYSTEMS LABORATORY MECHANICAL ENGINEERING UNIVERSITY OF KENTUCKY
TITLE	Actuator
DESCRIPTION	
CREATION DATE	23 may 2002
STUDENT NAME	Aravind

TOLERANCES	
0.0	± 0.1
0.00	± 0.01
0.000	± 0.001
ANGLES	± 0.5

MATERIAL	
TBD	
PART NUMBER	
TBA	

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VITA

Aravind Balasubramanian was born in Bangalore, India on 15th May 1979. He received his high school diploma from Madras, India in 1996. He earned his Bachelor's degree in the field of Mechanical Engineering from University of Madras, India in 2000. He joined Master's program in Manufacturing Systems Engineering at University of Kentucky in Fall semester of 2000. He worked as Research Assistant under Dr Ryan Vallance at Precision Systems Laboratory in the department of Mechanical Engineering during his Master's degree on the development of an electronically controlled nasal drug delivery device.

Achievements:

- He was one of the inventors of programmable multi-dose intranasal drug delivery device. International publication number **(Patent No.) : PCT WO 02/13886 A2**
- He has filed a disclosure for the application of patent for low friction bias spring SMA linear actuator to University of Kentucky.