

**UNIVERSITY OF CAPE TOWN**

**DEPARTMENT OF HUMAN BIOLOGY:**

**BIOMEDICAL ENGINEERING**



**DESIGN AND IMPLEMENTATION OF AN  
APPARATUS FOR HYDRODYNAMIC AND FATIGUE  
TESTING OF PROSTHETIC AORTIC VALVES**

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN IN PARTIAL FULFILMENT OF  
THE REQUIREMENTS FOR THE DEGREE  
MSc MED IN BIOMEDICAL ENGINEERING

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I     **Abstract**

Aortic valve replacement in humans may be needed due to pathology leading to valve stenosis and regurgitation. Replacement is by either mechanical or soft tissue prosthetic valves. Before new valves are medically approved and introduced into the market they are required to undergo rigorous testing to verify performance and product life expectancy. Performance testing is done in a hydrodynamic test apparatus and life expectancy verified in an accelerated test apparatus. The Cardiology Department at Tygerberg Hospital has proposed a project for the design and implementation of a prosthetic aortic valve test apparatus. This device is to be used primarily for fatigue, but also limited hydrodynamic, testing of prosthetic heart valves.

The design of the test apparatus was based on the four-element Windkessel model of the arterial system. This simple lumped parameter electrical analogy of the arterial system takes aortic and arterial resistance, arterial compliance, and blood inertance into account to simulate total arterial impedance. This model was developed with physiological reference and thus the element parameters only hold for physiological simulation as the equation governing impedance is speed sensitive. The model was adapted to provide theoretical physiological loads from physiological speeds of 60BPM through to accelerated speeds up to 1000BPM through mathematical optimisation of the Windkessel.

The test apparatus was designed and built taking into account the varying Windkessel parameters where possible. Both compliance and resistance could be varied within an acceptable range, inertance however, could not be varied due to the limitations of the project. The apparatus was controlled and pressures on either side of the valve monitored with a LabView® graphical user interface. The apparatus was able to mimic *in vivo* closely and satisfied the ISO requirements for valve testing up to speeds of 230BPM.

Various modifications are proposed to both the Windkessel model and the physical test apparatus to compensate for hydrodynamic effects at high testing speeds in order to improve performance, as well as increase the maximum testing speed.

## II Declaration

I declare that this entire dissertation contains only my work and that each significant contribution to, and quotation in this report from the work, or works, of other people has been attributed and has been cited and referenced. The Harvard convention for citation and referencing has been used.

I have not allowed and will not allow anyone to copy my work with the intention of passing it off as his or her own work.

Signed by candidate

on 08-05-2009

Hugo Krynauw

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## VII Glossary

### Pressure

AP: Arterial Pressure - The fluid pressure in the aorta. On the test apparatus the pressure measured downstream from the aortic valve, before the compliance chamber

VP: Ventricular Pressure - The fluid pressure in the left ventricle. On the test apparatus the pressure measured upstream from the aortic valve

Diastolic: Lowest arterial pressure during heart beat

Systolic: Peak arterial pressure during a heart beat

Valve pressure gradient: Pressure drop across the valve due to resistance

### Load elements

C Capacitance (electrical) or compliance (hydrodynamic)

L Inductance (electrical) or inertance (hydrodynamic)

R Resistance

Z Impedance

### LabView Terminology

VI: Virtual Instrument, the name for a program written in LabView

Sub VI: A VI called from within another VI

GUI: Graphical User Interface

### Heart valves:

Aortic valve: Outlet from the left ventricle.

Mitral valve: Inlet valve into the left ventricle

Test valve: The bi-leaflet aortic valve used for all the testing

**General terminology**

BPM     Beats Per Minute

CNC     Computer Numerical Control

DAQ     Data Acquisition device

EIB     Electronic Interface Board

*In vivo*   Conditions in the living body

*In vitro*   Conditions in laboratory simulation of *in vivo* scenarios

ProE     PTC ProEngineer 3D CAD software

PTFE     PolyTetraFluoroEthylene

$\omega$      Operating angular frequency. Given in rad/s

# Chapter 1

## Introduction and Problem Definition

### 1.1 Background to the project

The Cardiology Department at Tygerberg Hospital has proposed a project for the design and implementation of a prosthetic heart valve test apparatus. This device is to be used primarily for fatigue and limited hydrodynamic testing of prosthetic heart valves. Hydrodynamic testing simulates physiological conditions as closely as possible whilst monitoring detailed valve behaviour. Fatigue testing accelerates the physiological heart rate to simulate several years of use in a shorter space of time.

## 1.2 Purpose and importance of the project

The test apparatus is to be used to assess prosthetic heart valve performance as well as to estimate the life expectancy of these valves. These are the two main components of *in vitro* testing for prosthetic heart valve evaluation, and are important to ensure the correct operation of the valves over a long period of time where unexpected valve failure can lead to serious medical complications and death. The project was suggested as a masters project due to the expense of a commercially available testing apparatus being beyond the financial scope of the Tygerberg research group.

## 1.3 Project objectives and specifications

The objectives outlined by the Tygerberg Cardiology Unit were to design, build and test an apparatus that can:

- 1) Allow for testing up to three aortic valves simultaneously
- 2) Allow the assessment of aortic valves under physiological conditions to ensure that the valve behaves similar to a native valve
- 3) Allow for accelerated testing at speeds up to 1000BPM in order to test for cyclical load failure such as fatigue
- 4) Enable the set-up of various tests that meet the relevant ISO5840 standards (as seen in Table 1.3.1), and internally defined testing constraints laid out in 1.5.1

Due to time constraints, objectives two and four were modified for the M.Sc. project as follows:

- 2) Implementation of only one testing line with the capability of expanding to three
- 4) Accelerated speeds up to 230BPM with the capability of increasing this to a 1000BPM

| Parameter                                                          | Description                   |                         |                                                |
|--------------------------------------------------------------------|-------------------------------|-------------------------|------------------------------------------------|
| Surrounding medium:                                                | Human heart/Human blood       |                         |                                                |
| Temperature:                                                       | 34 °C to 42 °C                |                         |                                                |
| Heart rate:                                                        | 30 beats/min to 200 beats/min |                         |                                                |
| Cardiac output:                                                    | 3 l/min to 15 l/min           |                         |                                                |
| Stroke volume:                                                     | 25 ml to 100 ml               |                         |                                                |
| Blood pressures and resultant pressure loads by patient condition: | Systolic pressure mmHg        | Diastolic pressure mmHg | Differential pressure across closed valve mmHg |
| Normotensive                                                       | 100 to 130                    | 65 to 85                | 95                                             |
| Hypotensive                                                        | 60                            | 40                      | 50                                             |
| Hypertensive                                                       |                               |                         |                                                |
| Stage 1 (mild)                                                     | 140 to 159                    | 90 to 99                | 123                                            |
| Stage 2 (moderate)                                                 | 160 to 179                    | 100 to 109              | 138                                            |
| Stage 3 (severe)                                                   | 180 to 209                    | 110-119                 | 155                                            |
| Stage 4 (very severe)                                              | >210                          | >120                    | 185.                                           |
| Extreme (expected maximum pressure for a single cycle)             | 300                           | 160                     | 230                                            |

Table 1.3.1 ISO valve testing requirements (ISO 2005, p. 12)

The ISO specifications further states that the required differential pressure across the valve must be present for at least 5% of the beat duration and must occur in at least 95% of the beats during testing.

Furthermore, rigid valves are required to be tested for 400million cycles. This translates into approximately 10 simulated years at 75BPM and 0.76 testing years (6700hours) at 1000BPM. Test requirements for flexible leaflet valves is half that of rigid valves (ISO 2005, p. 18).

## 1.4 Scope of the project

Areas that were covered in the project included the design, building and implementation of the test apparatus, as well as basic testing to show the functionality of the test apparatus. The project did however not include extensive testing and evaluation of prosthetic heart valves. Aspects of the design included:

### 1. Mechanical design:

Housing: Apparatus chassis mounting points and stationary components.

Fluid flow: Fluid composition, reciprocating pump and flow regulation.

Assembly: Building apparatus, valve replacements, sensor changes, fluid changes, cleaning and maintenance.

## 2. Electrical design

Power: Supply and distribution.

Signal measurement: Sensors, signal handling and signal acquisition.

**Actuation: Motor selection and electronic interfacing.**

Fluid temperature control: Measurement and heating.

## 3. Software

GUI design: LabView interface

Monitor: Apparatus and valve performance.

Data logging: Record data during testing

## 4. Measurements

Pressure sensors: Monitor pressure across valve

Fibre optic scope portal: Optical inspection of valve

Echo probe for Doppler imaging interface: Measuring flow through valve

## 1.5 Limitations and constraints of the project

There were three main limitations or constraints that occurred during the design and development of the valve test apparatus. They are as follows:

### 1.5.1 Machine constraints

Firstly the minimum life expectancy for the entire test apparatus set out by project sponsors is 10 000 hours, which would be sufficient for testing three batches of flexible leaflet valves. Secondly the primary use of the machine will be for fatigue analysis. Hydrodynamic testing will be done on exactly the same system but at physiological speeds, i.e. between 60 and 80

beats per minute. This implies that the flow waveform will be the same for hydrodynamic and fatigue testing.

### **1.5.2 Budget constraints**

The sponsor of this project approved the initial tender of R21 000 with an end limitation at R30 000. This amount of money was for the construction of a three line test apparatus, however due to various difficulties and time limitations this was reduced to one line and thus the budget was not expended. The remaining budget is sufficient to construct the remaining two testing lines.

### **1.5.3 Time limitation**

The intention of commissioning the apparatus was for actual medical testing. As a result there were time limitations imposed by the end user as they wished to continue with their own projects. However, due to various unforeseen, practical problems with the manufacturing and commissioning of the apparatus, the original deadline of April 2008 was extended until such time when the issues were resolved, which was August 2008. From then on the apparatus was handed over to the end user and is now being used for further research.

## **1.6 Plan of development**

This report discusses the design, implementation and evaluation of the test apparatus. Chapter 2 gives a summary of important literature followed by a description of the design and implementation process in Chapter 3. Testing and the evaluation of operating conditions are then discussed in Chapter 4 upon which conclusions and recommendations are made in Chapter 5. References are listed in Chapter 6.

## Chapter 2

### Literature Review and Relevant Background Theory

#### 2.1 Introduction

The main sources for this literature review were journals pertaining to biomedical engineering, specifically the cardiovascular branch thereof. Other sources included textbooks and journals concerning various aspects of valve testing. This literature review begins with a brief introduction to cardiac physiology and valve pathology as well as valves currently available to replace pathogenic valves. This is followed by a section pertaining to valve testing, discussing the two analogies used in valve testing, as well as their application and implementation.

## 2.2 Introduction to cardiac physiology and valve pathology

The human circulatory system is a transport system for oxygen, carbon dioxide, nutrients, waste and hormones in the human body. It consists of the heart - a muscular, four chamber double pump; blood - the liquid for transportation; and blood vessels which forms a network throughout the body. The blood flow through the body is illustrated in Figure 2.2.1 where oxygenated blood from the lungs enters the left atrium, after which it passes through the bicuspid valve (mitral) into the left ventricle.

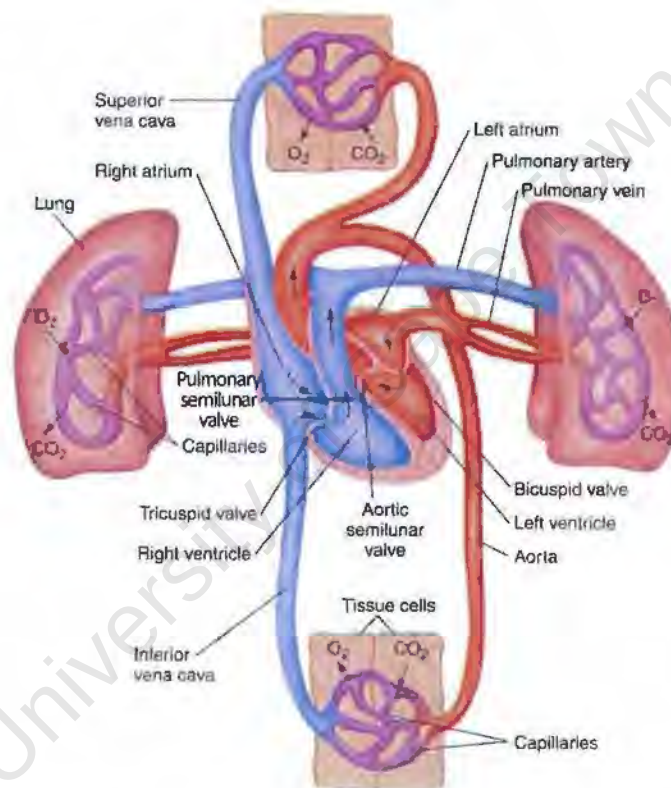


Figure 2.2.1 Cardiovascular flow through the body (Fox 2006)

When the muscular left ventricle contracts, the blood is ejected through the aortic valve into the aorta from where it is spread throughout the body via the arterial system. Blood returns to the heart via the venous drainage vessels and enters the right atrium. After this the blood enters the right ventricle through the tricuspid valve and is ejected through the pulmonary semilunar valve back into the lungs (Fox 2006).

This study deals mainly with the aortic valve which is a three cusped valve as shown in the inserts in Figure 2.2.2. When the left ventricle contracts (systole period, marked on Figure

2.2.3 and illustrated in (b) on Figure 2.2.2), the pressure inside the ventricle exceeds that in the aorta and the blood pushes past the cusps. After contraction (diastole period, marked on Figure 2.2.3 and illustrated in (a) of Figure 2.2.2), the blood in the aorta attempts to re-enter the relaxed ventricle, but instead fills the cusps of the aortic valve, forcing them to close against each other.

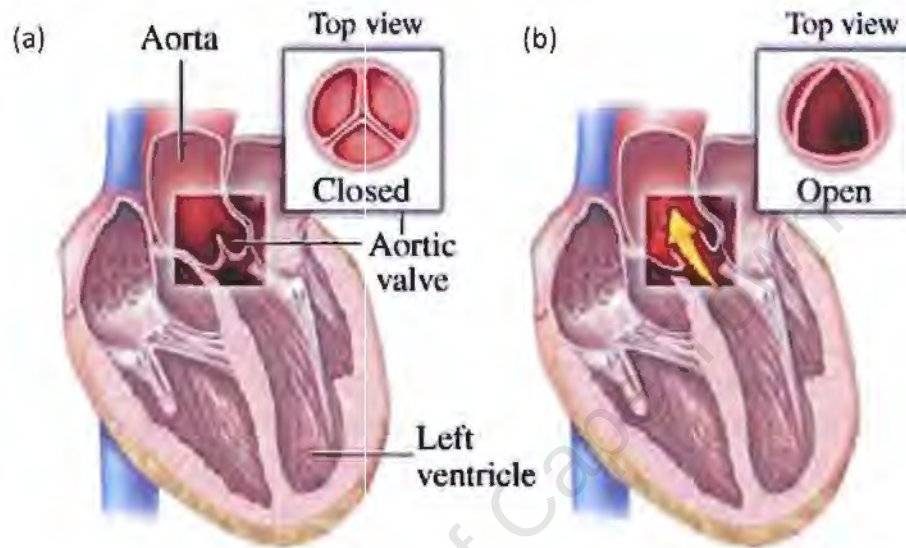


Figure 2.2.2 Three cusped aortic valve (Hayden)

The small dip and rise in the arterial pressure (AP) after the systole in Figure 2.2.3 is known as the dicrotic notch (Klabunde 2007). At the end of the systole the blood has momentum down the aorta but no more blood is being supplied. This causes a pressure drop, which, combined with the energy stored due to compliant vessels, pushed the blood back towards the valve, closing it and causing a small rise in pressure. This same effect is known as waterhammer in hydraulic systems where a valve in a pipe containing flowing liquid is closed suddenly. The waterhammer in the human heart is very small and the pressure fluctuation does no damage to the valve.



Figure 2.2.4 Aortic valve stenosis (Parks)

The effect of this restricted flow is a greater pressure loss across the valve and thus a greater demand on the left ventricle to produce the required pressure in the aorta (Klabunde 2007). This is best illustrated in Figure 2.2.5 where the shaded area between the ventricular (VP) and arterial pressure (AP) during systole represents pressure drop across the valve due to stenosis.

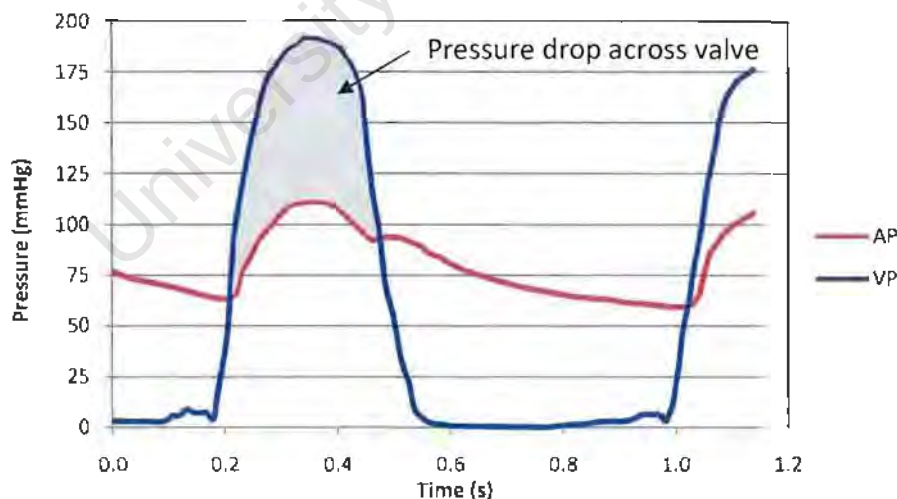


Figure 2.2.5 Effect of valve stenosis on ventricular pressure (Klabunde 2007)

Furthermore it is important to note the coronary arteries' orifices out of the aorta are situated close to the valve leaflets. This positioning is critical to the heart receiving oxygenated blood as the aortic valve shuts. Valve stenosis can lead to the coronary arteries

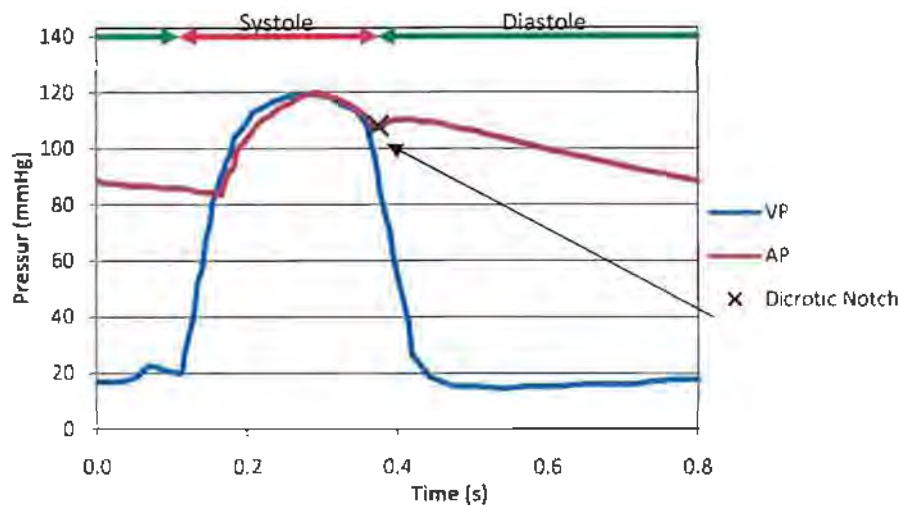


Figure 2.2.3 Heart pressure in healthy heart (Klabunde 2007)

Since this study is focussed on the aortic valve performance, it is required to simulate the pressure and flow waveforms through it. To do this the systems influencing these waveforms must be mimicked in an *in vitro* scenario. This system consists of various components which include: the left ventricle, a single pump chamber; the pump inlet (mitral) and outlet (aortic) valves; the arterial and capillary system which has compliance due to stretching vessel walls and also offers resistance to flow due to friction; and the blood which has momentum as it flows through the system. The simulation of these components is further discussed in Section 2.4.

The replacement of heart valves in humans is due to various valve pathological states which render the human valve insufficient. These include aortic stenosis and regurgitation. Stenosis is the obstruction and narrowing of the aortic valve, preventing blood from flowing freely into the aorta (Parks). Aortic insufficiency, also a result of stenosis or of valve damage, is the regurgitation of the blood from the aorta back into the left ventricle (Hayden). Both these conditions are degenerative and may require an aortic valve replacement (Sacks and Smith 1998). The causes of stenosis include valve calcification, plaque build-up on valve leaflets, as illustrated in Figure 2.2.4, and leaflets fusing together.

being starved of blood due to blocking of their exits from the aorta and thus starving the heart of oxygenated blood.

Regurgitation, the second condition, occurs when the valve does not shut completely and blood leaks back into the ventricle when it relaxes, shown in Figure 2.2.6. It can be caused by stenosis or by the valve leaflets suffering damage.



Figure 2.2.6 Aortic valve regurgitation, blood leaking back into heart (Hayden)

Any blood leaking back into the heart through the aortic valve decreases the stroke volume and thus diminishes the volume of oxygenated blood delivered to the body. For these reasons it is necessary to replace defective valves with prosthetic valves.

## 2.3 Prosthetic valves currently available

There are various types of prosthetic valves currently available on the market. The two main categories are rigid leaflet and flexible leaflet valves. Rigid leaflet valves are manufactured from metals and carbon composites (Yoganathan, Chandran and Sotiropoulos 2005; Zilla *et al.* 2008), whilst flexible leaflet valves are either made from natural tissue such as pericardium or of synthetic polymers. Both types have advantages and disadvantages and the choice of which to use is patient specific. The test apparatus in this project was designed to test both.

### 2.3.1 Rigid leaflet valves

Rigid leaflet valves are made from rigid materials such as stainless steel and carbon composites. They have a distinct lifespan advantage over tissue valves and are thus used for

younger patients. The drawbacks include audible mechanical noise and the need for lifetime use of anti-coagulating medication to prevent calcification and clot formation (Yoganathan, Chandran and Sotiropoulos 2005). Figure 2.3.1 shows several rigid leaflet valves, both discontinued and in production. Rigid leaflet valves are generally inserted during open heart surgery and attached to the aortic wall by means of a material suture ring (the white perimeter on the valves in Figure 2.3.1)



Figure 2.3.1 Examples of rigid leaflet heart valves (Zilla *et al.* 2008)

The valve used for testing during the design of this apparatus was a rigid, bi-leaflet valve, similar to the two indicated in Figure 2.3.1.

### 2.3.2 Flexible leaflet valves

Flexible leaflet valves closely resemble human aortic valves in shape and material properties. Currently there are two main divisions in the market, namely stented versus unstented and natural tissue versus polymer products. Advantages of using flexible leaflet valves include their quiet operation, the fact that they operate more like human valves than rigid leaflet valves and that patients do not need to use anti-coagulant medication (Cacciola, Peters and Baaijens 2000; Mackay *et al.* 1996; Yoganathan, Chandran and Sotiropoulos 2005). The largest drawback is their shorter lifespan, which is highlighted by the reduced ISO testing requirements, and they are thus primarily used on patients with a shorter life expectancy. Figure 2.3.2 shows various flexible leaflet heart valves.



Figure 2.3.2 Flexible leaflet valves: (a) polymer valve (b) natural tissue valve (Zilla *et al.* 2008)

## 2.4 Cardiovascular simulation

One of the major requirements of a valve test apparatus is its ability to simulate physiological flow and pressure waveforms in the aorta, as shown in Figure 2.4.1, as closely as possible. In order to simulate these waveforms in the aorta, both the pump and the systemic load needs to be analogous to the heart and arterial system, their physiological counterparts.

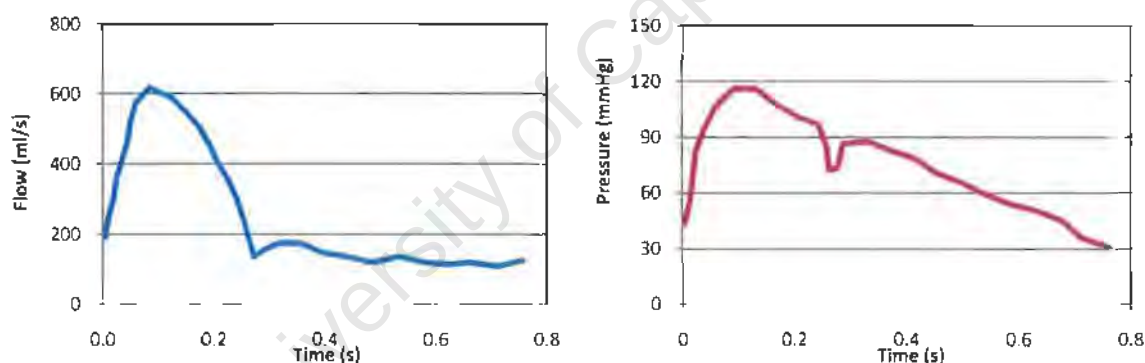


Figure 2.4.1 Simulated aortic flow and pressure waveforms (Stergiopoulos, Westerhof and Westerhof 1999)

This has been achieved by several means in the past, depending on the exact requirements of the testing device. The flow has been controlled by: a cam driven by a rotary shaft (Davila *et al.* 1956); a linear motor (Dynatek Delta); or pneumatics (Liu *et al.* 2006). The reciprocating action from these was then in turn used to drive either a cylinder inside a piston (Dynatek Delta) or a membrane pump (Liu *et al.* 2006). Simulating the load is more critical and complex than the pump, as the load simulation has the largest impact on pressure and flow propagation through the system. Load simulation has primarily been done in two ways as discussed below.

#### 2.4.1 Simulation by wave propagation model

This load simulation in which a replica of the human arterial system was built with tubes of varying diameters and wall thicknesses, as illustrated in Figure 2.4.2, is used to study the pressure and flow propagation throughout the body (Beul *et al.* 1974; Segers, P. *et al.* 1998). This model is overly complex for the use of only simulating conditions in the aorta. Thus it was not used in this design project.

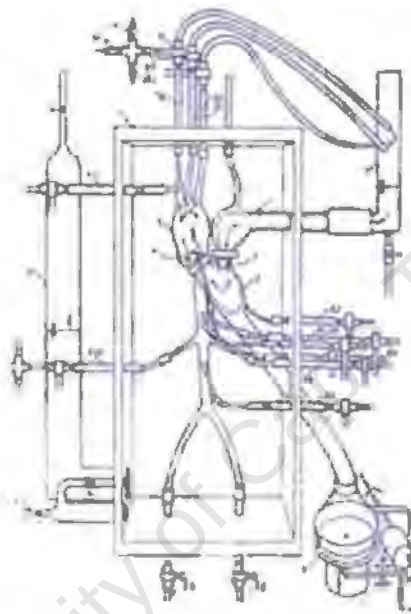


Figure 2.4.2 Arterial bed for wave propagation study (Beul *et al.* 1974)

#### 2.4.2 Simulation by lumped parameter model

In 1899 the first attempt was made to simulate the systemic vascular load by means of a two-element electrical lumped parameter model (Stergiopulos, Westerhof and Westerhof 1999). This model has been significantly improved over the years by means of the four-element Windkessel, as illustrated in Figure 2.4.3 (Milnor 1989; Segers, Patrick, Stergiopulos and Westerhof 2002; Stergiopulos, Westerhof and Westerhof 1999).

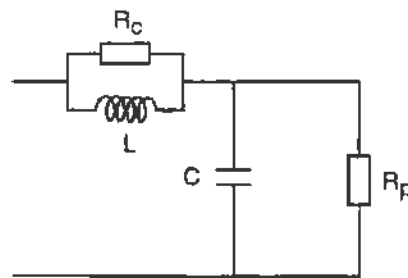


Figure 2.4.3 Electrical four element windkessel (Stergiopoulos, Westerhof and Westerhof 1999)

In this electrical analogy the total impedance can be calculated from the individual impedances, given by Equations 1-4, to yield Equation 5 (Horowitz and Hill 2004).

$$Z_{R_c} = R_c \quad (1)$$

$$Z_{R_p} = R_p \quad (2)$$

$$Z_c = \frac{1}{j\omega C} \quad (3)$$

$$Z_L = j\omega L \quad (4)$$

$$Z = \frac{j\omega L R_c}{R_c + j\omega L} + \frac{R_p}{1 + j\omega R_p C} \quad (5)$$

Where Z is impedance, R is resistance, C is Capacitance (compliance in a flow system), L is Inductance (inertance in a flow system) and  $\omega$  is operating frequency in rad/s

An illustrated hydrodynamic equivalence of this electrical system is depicted in Figure 2.4.4. Compliance (C) is modelled by a partially filled chamber and is governed by Equation 6 (Liu *et al.* 2006). It must be noted that the equation holds only if the pressure indicated in the denominator has units of Pa as opposed to mmHg. The standard unit in the medical field for compliance is however ml/mmHg, thus a factor converting the units has been included in Equation 7. Here only mmHg is used.

The flow loop resistance ( $R_p$ ) and aortic characteristic resistance ( $R_c$ ) are modelled by tube resistance and can be calculated by Equation 8 (Beneken and Bergel 1972; Milnor 1989; Sheffer, Santamore and Barnea 2007) and measured as a pressure drop in mmHg. Other means of providing flow resistance for  $R_p$  include pipe constrictors and shut-off valves

(Davila et al. 1956; Liu et al. 2006). Inertance ( $L$ ) is a function of the fluid density and tube diameter as in Equation 9 (Beneken and Bergel 1972; Sheffer, Santamore and Barnea 2007) and can thus not easily be changed independently of  $R_c$  (Stergiopoulos et al, Milnor, Segers et.al., Sheffer et. al.) except possibly by changing the fluid, which is impractical as the testing fluid needs to behave as closely to blood as possible.

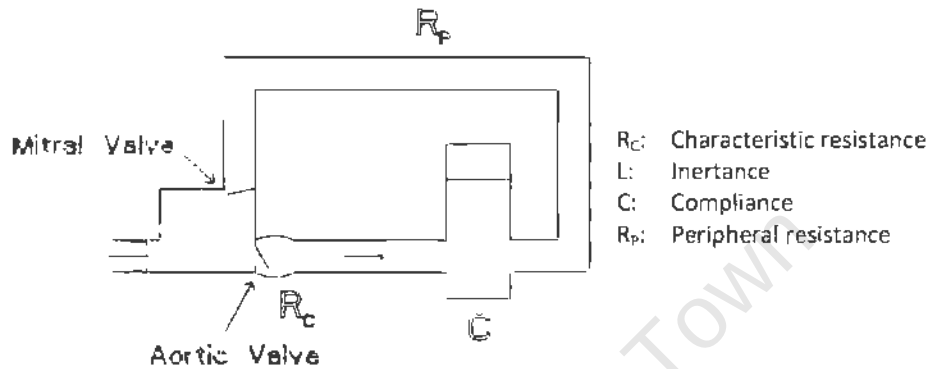


Figure 2.4.4 Illustrative hydrodynamic analogy of four element windkessel

$$C = \frac{V_{air}}{P_{air}} = \frac{V_{comp} - A_{comp} h_{fluid}}{P_{fluid} - \rho g h_{fluid}} \quad (6)$$

$$C = \frac{V_{air}}{P_{air}} = \frac{V_{comp} - A_{comp} h_{fluid}}{P_{fluid} - \frac{\rho g h_{fluid}}{1.35}} \quad (7)$$

Where  $V_{comp}$  is the compliance chamber volume in ml;  $A_{comp}$  is the chamber cross sectional area in  $\text{cm}^2$ ;  $h_{fluid}$  is the fluid height in the chamber in cm;  $P_{fluid}$  is the pressure measured in the aorta in mmHg, and thus also at the bottom of compliance chamber;  $\rho$  the testing fluid density in  $\text{g/cm}^3$ ; and  $g$  the gravitational constant  $980\text{cm/s}^2$ .

$$R = \frac{8 \times \mu \times l}{\pi \times r^4} \quad (8)$$

$$L = \frac{\rho \times l}{\pi \times r^2} \quad (9)$$

Where  $\mu$  is the fluid viscosity in mmHg·s;  $l$  is the length of tube in cm;  $r$  is tube internal radius in cm; and  $\rho$  the testing fluid density in  $\text{g/cm}^3$ .

Appendix D provides conversions between various units used when describing blood flow studies.

By using a Windkessel load and controlling the input (current in the electrical analogy and volume flow in hydrodynamic analogy) as shown in Figure 2.4.5, a close approximation to physiological pressure loading on the valve can be achieved (Cochrane 1991).

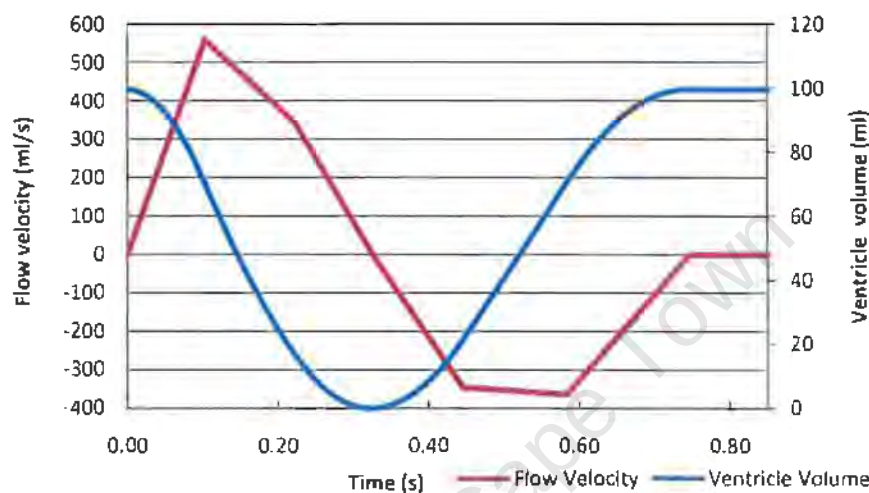


Figure 2.4.5 Required ventricular flow velocity and flow volume as modelled in Excel

In the electrical model, the total impedance ( $Z$ ) is governed by Equation 5.  $Z$  is dependent on the frequency ( $\omega$ ) that the circuit is operating at. This model has mainly been used for studies under physiological conditions, which implies a frequency of around 70 beats per minute (Stergiopoulos et al). In order to maintain the same operating load on the pump at accelerated speed as in this design project, the equations governing physiological studies must be modified. As  $\omega$  increases, compliance, inertance and resistance must be varied in order to keep impedance constant. This is required in order to maintain physiological pressures during high speed testing. It should be noted that this model and the associated equations governing the various components were developed for physiological testing and ignore factors such as wave rebound and friction which play an increasing role as fluid velocity increases. A valuable tool for correctly setting the load would be to obtain mathematical functions relating the desired values of  $C$  and  $R$  to  $\omega$ , whilst keeping both these values in a feasible range. Although the mathematical work has been done and is discussed in Section 3.3.1, the correlation and calibration between the mathematical model and the physical implementation has not been thoroughly researched and implemented.

### 2.4.3 Waterhammer on the valve

Another aspect to keep in mind is the effect of waterhammer on the valve. Although waterhammer under physiological conditions is negligible, the force with which the valve is closed increases considerably as the fluid momentum increases with increased speeds. The absorption of large pressure waves in the fluid by the valve when it closes places a large load on the valve itself (Wu, Hwang and Lin 2002). This effect is amplified at accelerated testing speeds as the fluid velocity increases dramatically and can cause valves to fail after fewer cycles than if only submitted to physiological flow velocities. (Wu, Hwang and Lin 2002) has shown that at testing speeds of 550 beats per minute and above, the effect of waterhammer becomes overwhelming and deteriorates the quality of the test. In order to make better lifetime prediction for valves, it is important to not overload the valves with non-physiological pressure loads. An investigation into various methods to compensate for waterhammer may prove to provide improved lifetime prediction for prosthetic valves whilst testing at very high speeds, however, this is beyond the scope of this design project.

### 2.4.4 Evaluating the performance of a cardiovascular simulation

There are several aspects with which the performance of the testing apparatus can be evaluated. As the objective is to test heart valves, it is important to note proper valve functioning during testing. At accelerated speeds the flow over the leaflets can cause abnormal behaviour which must be avoided. These include micro cavitations in rigid leaflet valves and fluttering in flexible leaflet valves; valves not opening and closing completely; and valves vibrating whilst moving. These scenarios can all be assessed visually (Conti 1990). Furthermore the pressure across the valve and the flow through it should simulate physiological standards as closely as possible. To validate the pressure and flow in an *in vitro* scenario the load impedance of the test setup must be compared with that of known human data. Input impedance is calculated by Equation 10, using a single pulse with both pressure and flow in the frequency domain (Gessner and Bergel 1972).

$$Z_{Load} = \frac{\text{Pressure}}{\text{Flow}} \quad (10)$$

Where  $Z_{Load}$  is input impedance; *Pressure* is pressure spectrum in mmHg; and *Flow* is flow spectrum in ml/s

Figure 2.4.6 shows the input impedance modulus of hydrodynamic model (Segers, P. *et al.* 1998) as well as *in vivo* data (Murgo *et al.* 1980; Nichols *et al.* 1977).

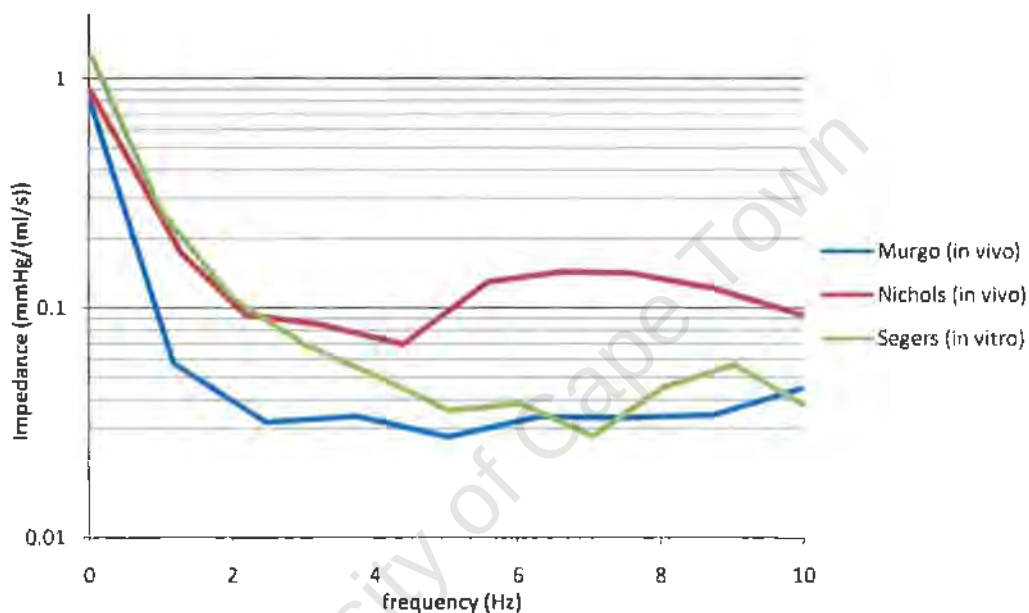


Figure 2.4.6 Input impedance modulus at physiological speeds

If the input impedance at high speed can resemble the trend in Figure 2.4.6 the load on the pump and thus the pressure and flow profiles through the valve will be close to physiological. It should be noted that the data for these plots was acquired at physiological speed of 60BPM and that the frequency range for accelerated tests will be scaled according to speed increase.

It is especially the pressure gradient across the valve during diastole which is of importance when conducting fatigue testing (ISO 2005). In the absence of ultrasound flow measurements, as is the case in this project, where load impedance cannot be determined, this becomes the only concrete way of validating valve performance. The shape of the pressure traces can be compared to physiological norm, however quantifying differences and the effect on the valve cannot be done conclusively by this comparison.

## 2.5 Concluding remarks

In order for valves to be medically accredited for human implantation, they have to undergo rigorous tests. This literature review has provided valuable insight into the various types of available heart valves as well as testing methods, in particular the Windkessel simulation of the arterial system. The ability to adjust the Windkessel parameters for high-speed testing was of particular interest, as this design project required a large operating speed range. Consequently the Windkessel model was used in the designing of the test apparatus.

## Chapter 3

### Materials, Equipment and Methods

#### 3.1 Introduction

This chapter deals with the materials and methods employed in the design and building of the test apparatus. It starts with a basic design process overview followed by the investigation of arterial load variation over a wide operating range and the proposed design for compensating for this. This is followed by a brief overview of the various design aspects, including mechanical, electrical and software after which the chapter is concluded by basic instructions for apparatus operation and maintenance.

### 3.2 Test apparatus design overview

The design of the test apparatus was based on the Windkessel model proposed by Liu *et al.* (2006). Major differences included the use of a cam to drive a piston instead of a pneumatically powered membrane, as well as the exclusion of the pulmonary blood flow loop since only aortic valves were to be tested. The system comprised of the control PC, the control and power box and the main test apparatus. Figure 3.2.1 shows a photo as well as a ProE illustration of the entire system with fluid flow and motion respectively indicated by green and red arrows on the ProE illustration. From here on ProE illustrations are used in this report to demonstrate the various components of the mechanical design as they offer a clearer and simplified view of the essential components.

The design process began with an assessment of the impedance of the Windkessel model across the speed range and theoretical load element variations across the range. Then the drivetrain was analysed by means of an Excel simulation to obtain the power requirements for driving three testing lines, leading to the specification of a motor and major drive components. The apparatus was then designed and modelled in ProE. Detailed part and assembly drawings are in Appendix E. From this drawings were created and the components manufactured in the UCT Mechanical Engineering Workshop. During the manufacturing of the mechanical components the electrical and control system was developed and built. Whilst the mechanical components were being assembled the basic control software was written to test the electrical and mechanical systems as components were completed. The control software was further developed during apparatus testing and modification.

- |                 |                       |
|-----------------|-----------------------|
| a) Computer     | e) Aortic valve       |
| b) Control box  | f) Compliance Chamber |
| c) Drive system | g) Flow Resistance    |
| d) Ventricle    | h) Fluid Reservoir    |

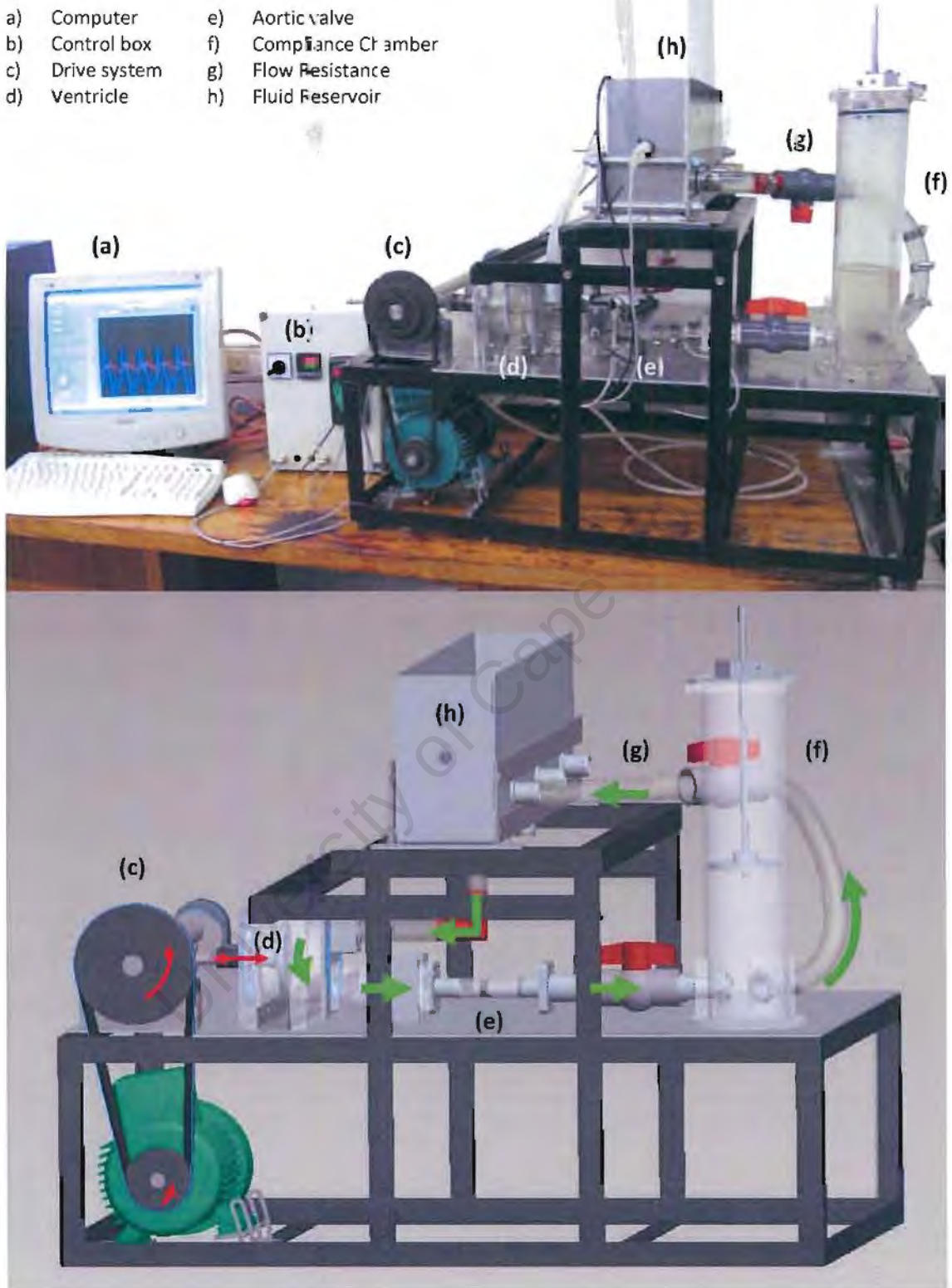


Figure 3.2.1 Photoc and ProE illustration of test apparatus

### 3.3 Arterial simulation

One of the aims of this project was to simulate heart beats across a speed range. As mentioned in Section 2.4.2 the load magnitude is dependent on the operating speed. It is thus important to investigate the theoretical influence which the speed spectrum has on the load and how to compensate for this.

#### 3.3.1 Arterial load variation across pump speed spectrum

In order to optimise arterial load on the heart pump across the initial operating speed range of 60 to 1000BPM, the total impedance, governed by Equation 5 in Section 2.4.2, was modelled in MatLab. The effect of peripheral resistance ( $R_p$ ), compliance ( $C$ ) and inertance ( $L$ ) on the real and complex components of the impedance were investigated. These three load elements were then optimised across the speed range using a Nelder-Mead unconstrained nonlinear minimization algorithm (The MathWorks Inc) to attempt to match the impedance at the fundamental frequency across the speed range to that at 60BPM (see Appendix C.3 for MatLab code). The starting point for the iterative solver was the impedance obtained by using the physiological values for  $C$ ,  $R_p$  and  $L$  obtained from various journals (Liu *et al.* 2006; Luo *et al.* 2007; Nitenberg 2003; Segers, Patrick, Stergiopoulos and Westerhof 2002; Stergiopoulos, Westerhof and Westerhof 1999) Figure 3.3.1 shows the real, complex and absolute components of the impedance with and without optimising the load elements.

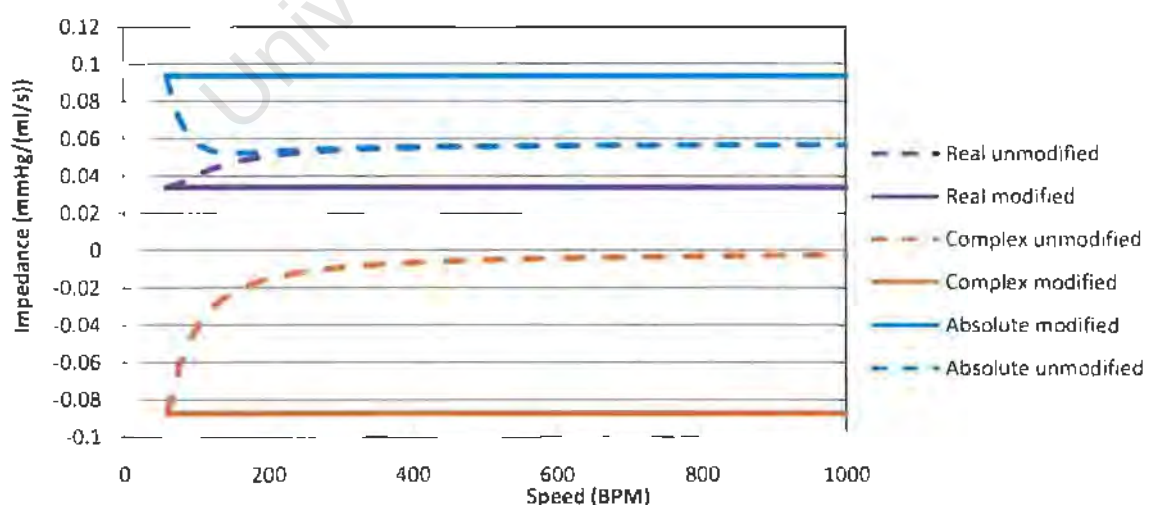


Figure 3.3.1 Effect of optimising load elements across the speed range on impedance

To obtain the ideal scenario shown in Figure 3.3.1 where the real and complex components remain constant across the speed range, the load elements must be varied across the speed range as in Figure 3.3.2. These curves were obtained numerically from the above-mentioned MatLab optimisation.

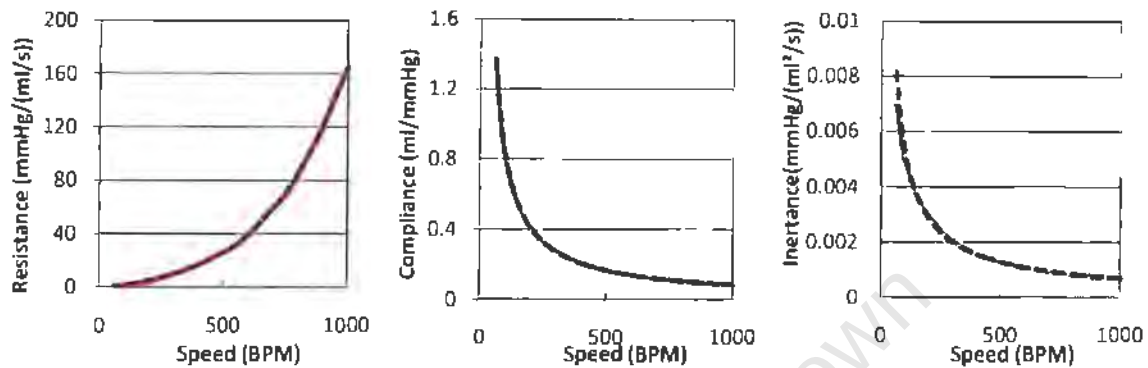


Figure 3.3.2 Load elements varied across the speed range in MatLab simulation

From the data in Figure 3.3.2, curve fits in Excel (in black dashed lines on the graphs) revealed that the optimised load elements can be expressed in terms of operating speed by Equations 11-13

$$R_p = 2 \times 10^{-07} x^3 - 0.0001x^2 + 0.0676x - 4.4434 \quad (11)$$

$$C = 81.101x^{-0.997} \quad (12)$$

$$L = 0.2963x^{-0.877} \quad (13)$$

Where x is testing speed in BPM

These modified values for the load components gave a theoretical approach on improving testing operation at speeds greater than physiological norms. The practical approach is discussed in the next section.

### 3.3.2 Designed resistance, inertance and compliance

The design of load elements to yield resistance, inertance and compliance was largely driven by the practicality of manufacturing, assembling, operating and maintaining of the apparatus. As mentioned in Section 3.5.2, inertance cannot be separately controlled from resistance without changing the testing fluid across the speed range, which was not a viable solution. L was thus not considered a variable. The pipe section determining  $R_c$  and L (Figure

3.3.3) serves many purposes, including the: interface with the ventricular chamber (a); flow rectification (b); optical scope port (c); the valve mount (d); two pressure transducer mounts (e), hidden in the view; and the shutoff valve for compliance adjustment (f). Its length of 220mm from the valve mounting position to inlet into the compliance chamber and diameter of 20mm was thus determined to facilitate these functions. Sealing between sections was by o-rings compressed in between components.

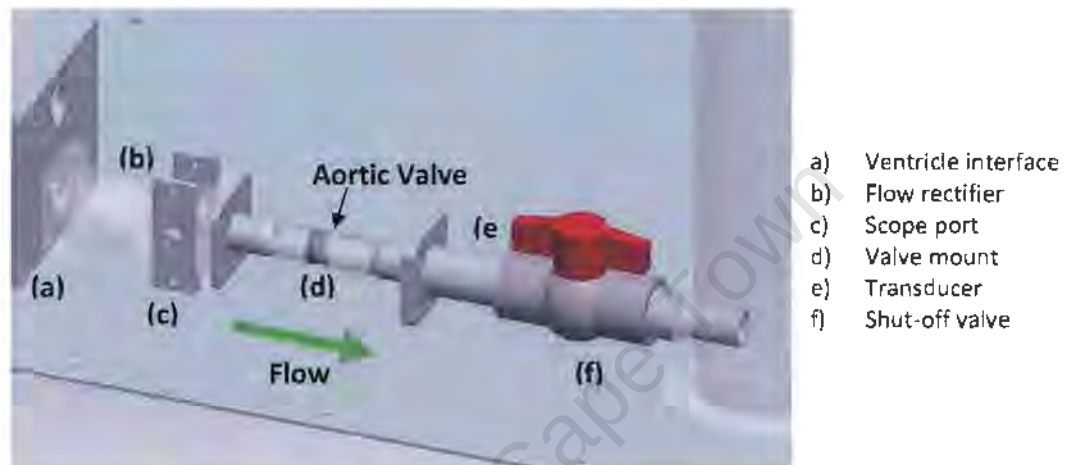


Figure 3.3.3 ProE illustration of section determining L and  $R_c$

The compliance chamber was designed in a similar manner to Liu *et al.* (2006) and is shown in Figure 3.3.4. The chamber (a) is 400mm high with a 90mm inner diameter in order to adjust the compliance across the wide range reported by various journals (Coleman 1985; Segers, Patrick, Stergiopulos and Westerhof 2002; Stergiopulos, Westerhof and Westerhof 1999). The Perspex allows the user to monitor the air and water ratio in the chamber. This ratio determines the level of compliance and is adjusted either by changing the water level in the chamber or by lowering the plunger (b) and clamping it in place at the top of the chamber (c). Compliance is set according to Equation 14 when the compliance plunger is 350mm from the bottom of the chamber and the reservoir is filled to 30mm above the float switch. In other chamber set-ups, or when the exact compliance is desired, Equation 7 in Section 2.4.2 must be used.

$$C = -0.084H + 2.9 \quad (14)$$

Where  $C$  is the compliance in ml/mmHg  $H$  is water level in the compliance chamber mm

The inlet and outlet of the chamber were not placed in line to improve the path of the return flow pipe. In retrospect they should have been in line to offer minimal resistance to the flow and to reduce pressure waves rebounding back into the aorta.

The peripheral resistance  $R_p$  was governed by a  $\varnothing 25\text{mm}$  PVC pipe (d) and a ball valve (e) in this pipe section which returns flow from the compliance chamber to the reservoir (f), shown in Figure 3.3.4. The overall resistance could be varied in order to yield physiological resistive loads at speeds up to 230BPM. A larger diameter pipe is however required for higher speed sections.

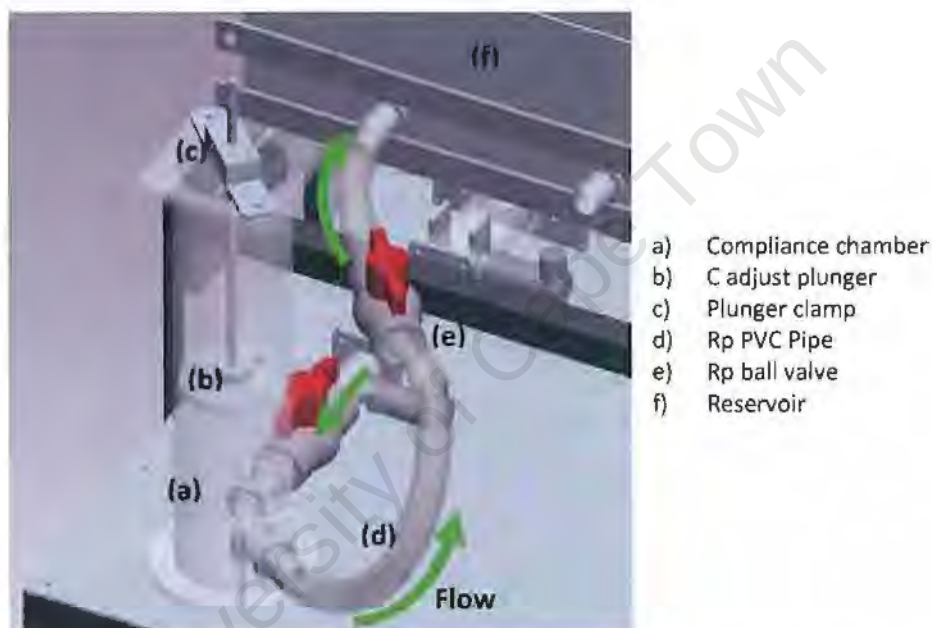


Figure 3.3.4 ProE illustration of compliance, peripheral resistance pipe and valve

The combined loading elements were sufficient for low speed testing. However these results are discussed and illustrated in the next chapter, with various recommendations to improve testing across the speed range as well as to extend the maximum speed to above 230BPM.

### 3.4 Mechanical components of the apparatus

The design started out with a single testing flow loop, from the heart ventricle to the compliance chamber. After this a mounting base for three of these testing loops was created with a frame to support this base, the reservoir and the drive system.

### 3.4.1 Ventricle and piston

The flow was controlled by a piston in a Perspex cylinder driven by a cam and spring (discussed later in this section). Figure 3.4.2 shows the ventricle, piston and their attachments. As the cylinder diameter affected the stroke length and thus also the force required to oscillate the piston, the diameter needed to be optimised for the reciprocating force, thus also lowering the required motor power to run the apparatus. The diameter was optimised by means of a force analysis in Excel (see Appendix A.6 for details), taking into account estimated friction, acceleration for reciprocating motion, fluid compression and the return spring. The spring (Figure 3.4.4) was designed such that the total force on the cam would always be positive, thus ensuring contact with the cam at all times. Figure 3.4.1 shows these forces at the original design speed of 1000BPM. The optimisation, combined with small modification for material availability limitations, yielded an internal diameter of 90mm for the best combination of low motor power requirements as well as minimising cam force.

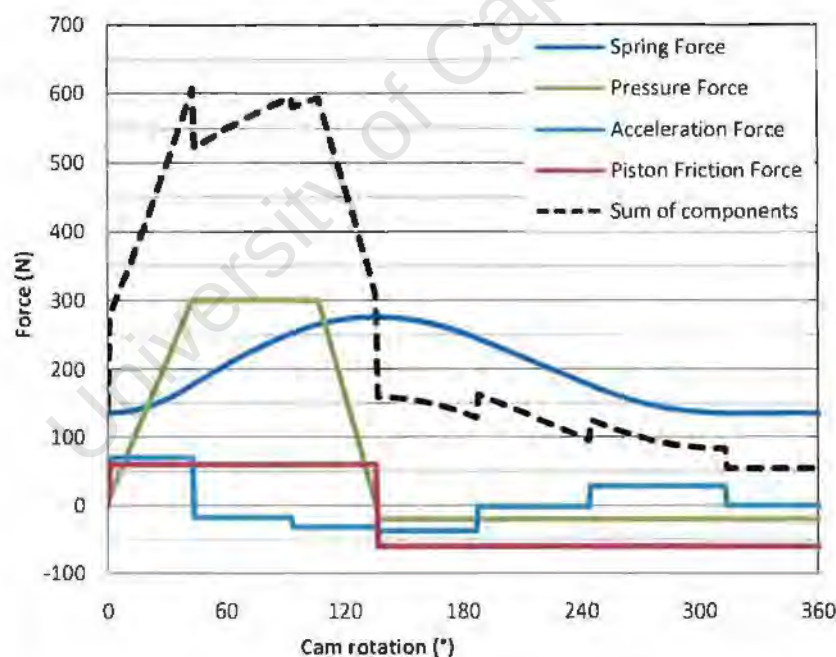


Figure 3.4.1 Force components on the cam

The cylinder (a) was glued to the mounting flanges (b) using chloroform and *Tensol*, as in Figure 3.4.2. Chloroform was used as it provided a quick-setting, penetrating bond and *Tensol* for extra strength. The one side was sealed by an o-ring in the 4mm aluminium plate (c) with an inlet (top) and outlet (bottom) for the pump.

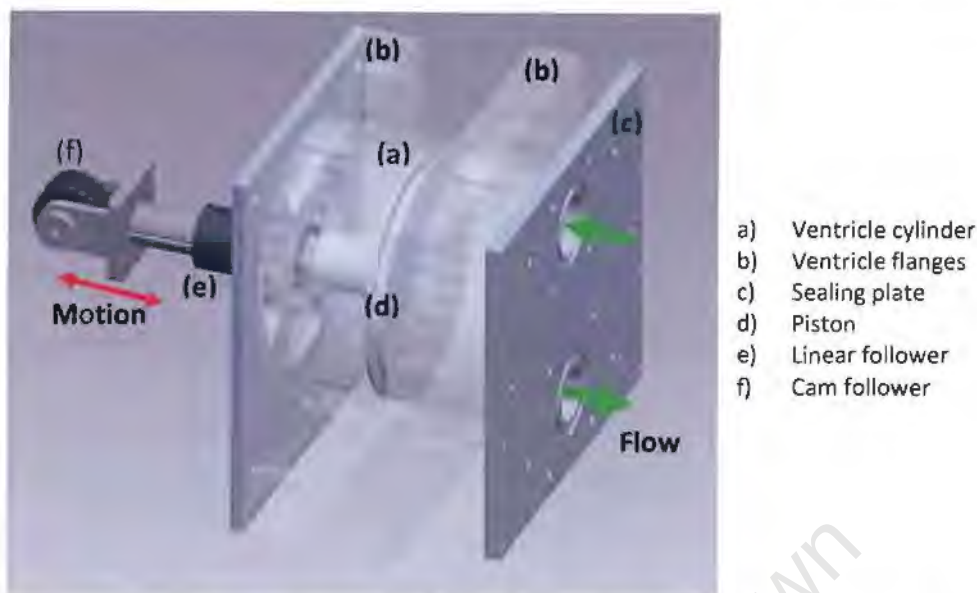


Figure 3.4.2 ProE illustration of ventricle with piston and driving components

The piston (d) was inserted from the open side and sealed in the cylinder by means of a PTFE seal energised by a compressed o-ring, as illustrated in the cross section in Figure 3.4.3. A PTFE seal was used as various other sealing materials did not slide smoothly over the *Perspex*. PTFE was however not elastic enough to form a seal by itself, hence the energising o-ring was inserted to maintain contact between the seal and cylinder wall. Assembly into the cylinder was assisted by a 15° taper on the cylinder point of insertion.

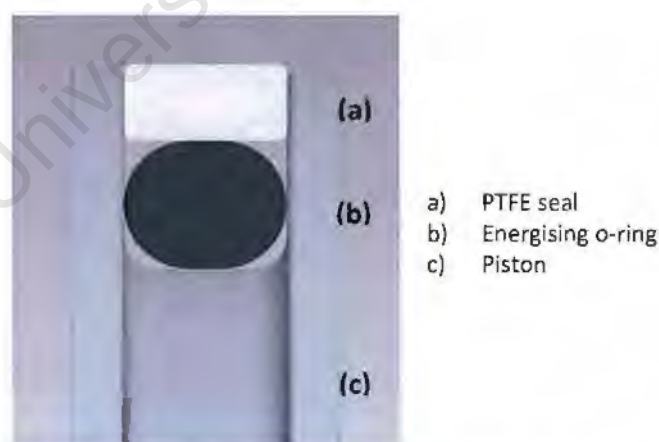


Figure 3.4.3 Cross section of piston with PTFE and o-ring seal

The piston was held in line with the cylinder by means of an IKO LSAGF 15 (e) linear follower (IKO 2001a LSAG) which was mounted to a 4mm aluminium plate. The linear follower tracked the cam by means of an IKO NART 8 VUUR (f) non-separable, crowned cam follower

(IKO 2001b Roller Followers). A 9kN/m spring was placed between the linear follower mounting plate and the cam follower mount (see Figure 3.4.4) with a 10mm spacer which maintained the follower on the cam during the return stroke. See Appendix A.6 for details on the spring design.

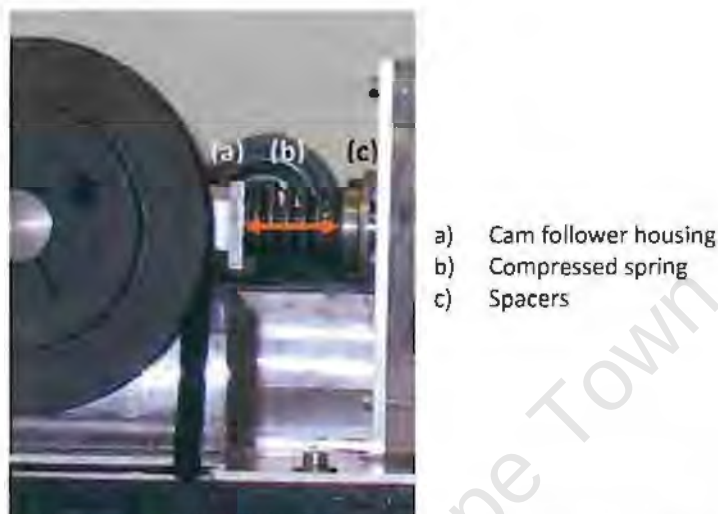


Figure 3.4.4 Spring compressed between spacers and cam follower housing

### 3.4.2 Base and frame

The 4mm aluminium base was designed for the mounting of the three testing lines and was laser-cut for accurate mounting hole locations. The frame was designed around the mounting requirements of the testing base with the three testing lines, the motor and the reservoir and was welded from 30mm angle iron and spray-painted with *Hammerite™* heavy duty paint. Figure 3.4.5 shows the frame (a) with the motor mount plates (b); the base plate (c) with stainless steel channel (d) to mount the testing lines; as well as the reservoir (e).

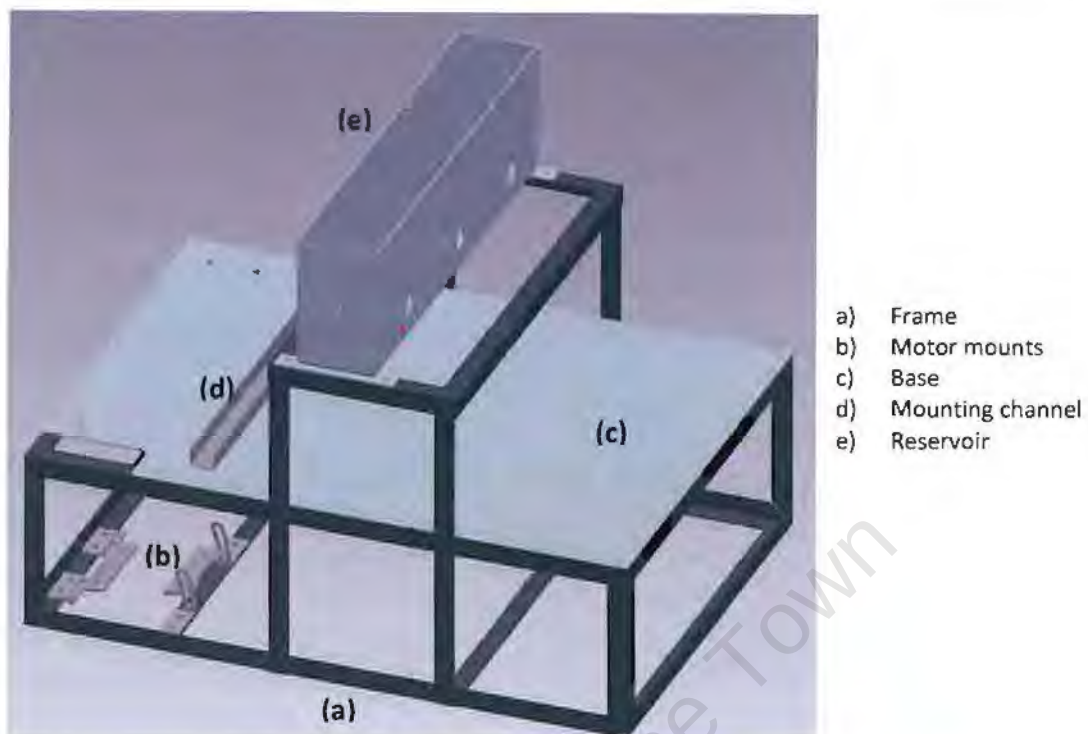


Figure 3.4.5 ProE illustration of frame with base, reservoir and motor mounts

The motor mount was hinged on the one side and slotted on the other to enable belt tensioning and adjustment. The motor was then fixed in position by M6 nuts on the threaded rods on the motor mount.

The original frame did not support the heart chamber and plumber-block bearings sufficiently, thus it was further braced in two places. The ventricular chamber was being pushed forward by the piston and thus it was rotating slightly about its mounting at the base and was braced as shown by (c) in Figure 3.4.6 to prevent this. The bearings were braced by adding a simple angle iron construction underneath the plumber-block mounts.

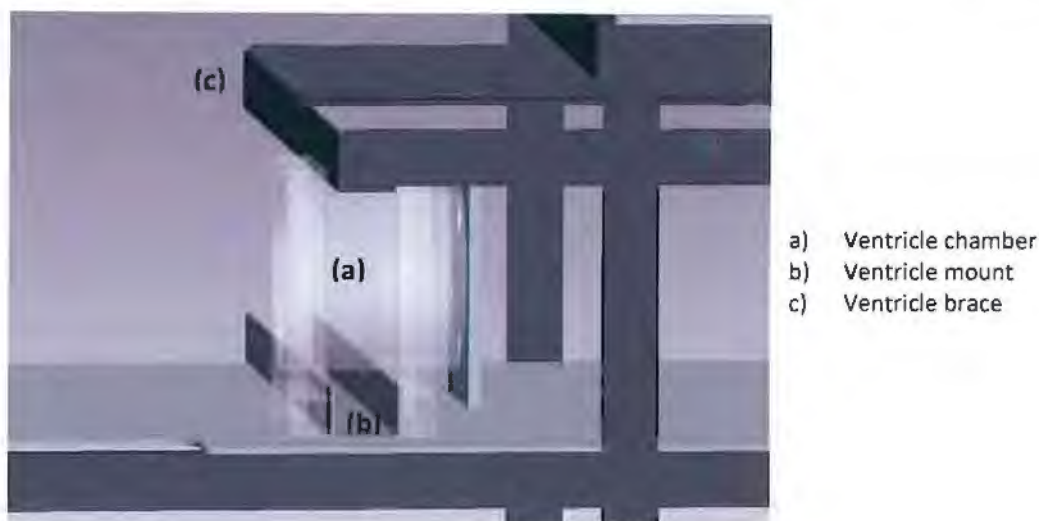


Figure 3.4.6 ProE illustration of chamber bracing

### 3.4.3 Drivetrain design

#### 1. Cam design and manufacture

As discussed in Section 2.4, it is important to control the volumetric flow from the left ventricle in order to simulate physiological conditions. The cam shape was obtained by scaling the graphical integration of the flow velocity from the left ventricle (Cochrane 1991) for the required flow volume. This profile, as seen in Figure 3.4.7 on the left, was then transposed onto the circular cam with a base diameter of 50mm, starting at the red line on the right of Figure 3.4.7 moving clockwise. The cam was then made with the UCT CNC milling machine

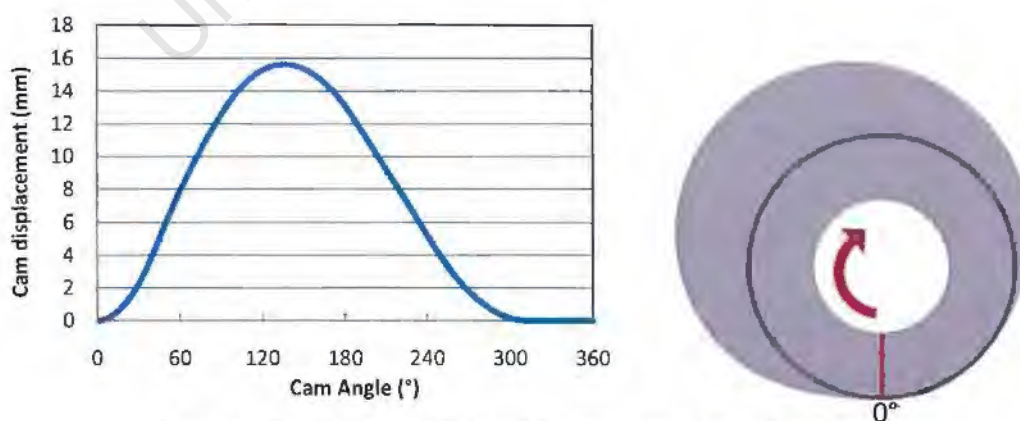


Figure 3.4.7 Cam displacement and this transposed unto circular cam

Due to the absence of lubrication and the cam material hardness, the cam underwent heat treatment according to *Böhler Steel* specifications (BÖHLER-Uderholm) at the *UCT Centre for Materials Engineering* in order to increase its hardness sufficiently to avoid damage.. For further detail the cam design and heat treating, see Appendix A.5

## 2. Motor to driveshaft

The full drive train is illustrated in Figure 3.4.8 below with labelled components. The cam (a) was located on the 25mm silversteel driveshaft (b) by means of a springpin. The shaft was seated in two plumberblock bearings (c) and attached to the apparatus base via two mounting blocks (d). Power transmission from the motor (e) to shaft was by a 1:2 pulley ratio (f), connected by a single 800mm Fenner SPZ V shaped belt (g).

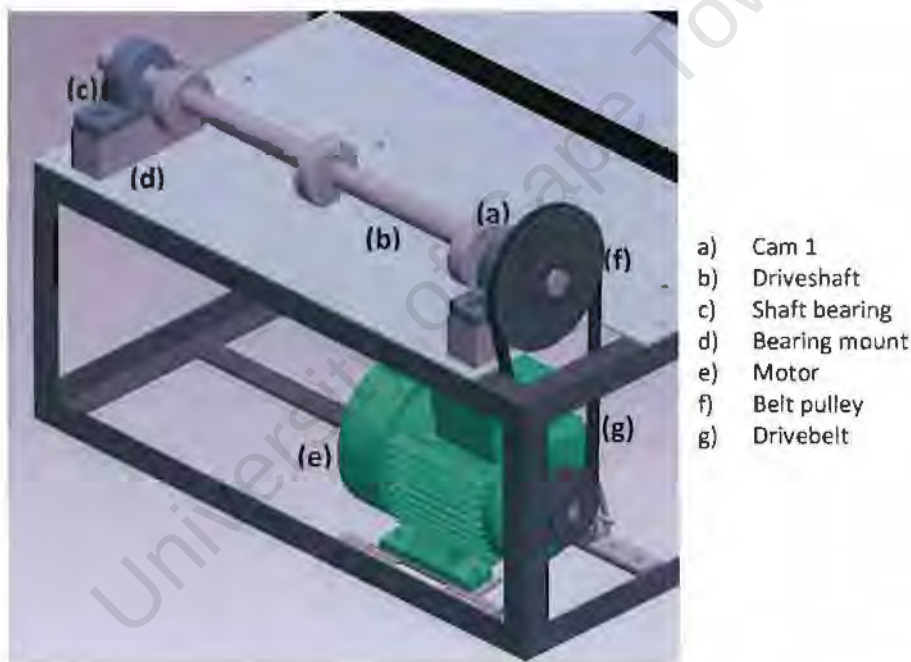


Figure 3.4.8 ProE illustration of drivetrain with three cams

In order to reduce the load on the motor the three cams were set  $120^\circ$  apart. This resulted in the three testing lines not being in phase, however the control software can be modified to shift the pressure traces on the output monitor and in the data log files to enable easy comparisons between testing lines.

3.5 Electrical components of the apparatus

This section starts with a brief overview of the overall electrical system of the test apparatus, followed by low the voltage electronic interface; data acquisition hardware; pressure sensors; motor power and control; and temperature control. For more detailed descriptions, see Appendix B.

3.5.1 Overall electrical overview

The three main electrical systems of the test apparatus are the Control PC, the Apparatus Controller and the mechanical testing base, interconnected as shown in Figure 3.5.1.

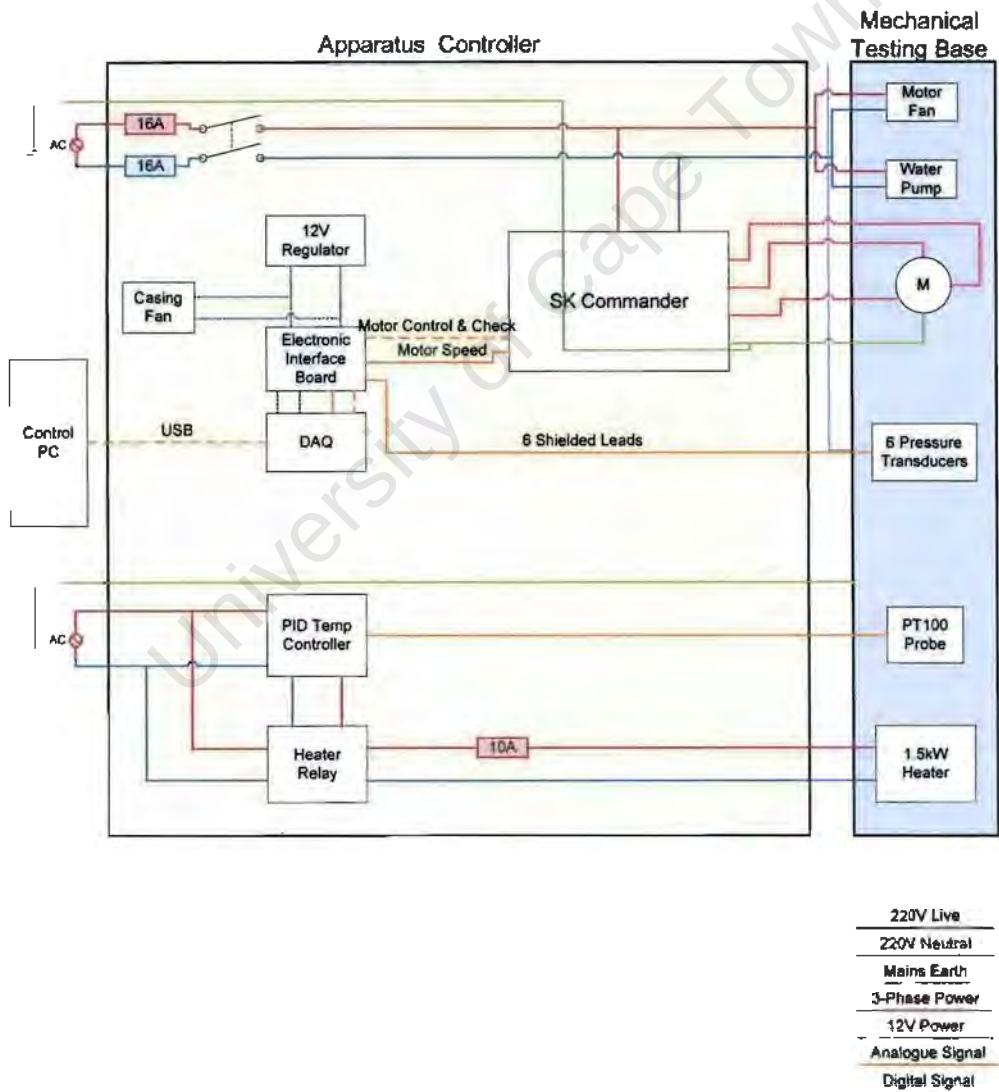


Figure 3.5.1 Schematic overview of electrical systems

The apparatus controller was powered from two separate 220V mains supplies, one for the motor and control electronics and another for the heater. This was due to the limitation that some mains power points are fused to 13A and that the entire apparatus can draw more than this when all three testing lines are installed. The other components are discussed in the following sections.

### 3.5.2 Electronic DAQ to apparatus interface

For the DAQ to communicate with various apparatus components it was required to modify both input and output signal types and ranges. This was done by means of the Electronic Interface Board (EIB), built on vari-board. From the interface board connections to the apparatus components was made by Molex connectors. The signal type modifications are listed in Table 3.5.1 and connections in Table 3.5.2 with numbered references in the photo in Figure 3.5.2.

|    | Apparatus component         | DAQ Signal  | Apparatus Signal   | Method                     |
|----|-----------------------------|-------------|--------------------|----------------------------|
| a) | Motor controller Stop/Start | 5V DC logic | 10V DC Logic       | ICL7667 Mosfet driver      |
| b) | Motor controller Speed      | 0-5V DC     | 0-10V DC           | LM358 non-inverting op-amp |
| c) | Pressure transducers        | 0-5V DC     | 4-20mA             | 300Ω resistors             |
| d) | Float switch                | 5V DC logic | Open/closed switch | 5kΩ resistor               |

Table 3.5.1 DAQ to apparatus interface signal type modifications

|       | Line description            | Source     | Destination        | Signal       |
|-------|-----------------------------|------------|--------------------|--------------|
| 1.1-6 | Pressure transducers signal | EIB        | DAQ                | 0-5V DC      |
| 1.7   | Motor speed setting         | DAQ        | EIB opamp          | 0-5V DC      |
| 2.2   | Float switch                | EIB        | DAQ                | 5V DC Logic  |
| 3.1-6 | Pressure transducer power   | 12V Supply | Transducers power  | 12V          |
| 4.1-4 | Pressure transducer ground  | RIB Ground | Transducers ground | Ground       |
| 5.1   | Float switch power          | 5V Supply  | Float switch       | 5V DC        |
| 5.2   | Float switch ground         | EIB Ground | Float switch       | 5V DC        |
| 6.1   | Motor speed                 | EIB opamp  | Motor controller   | 0-10V DC     |
| 6.2   | Motor enable                | ICL7667    | Motor controller   | 10V DC Logic |
| 6.3   | Motor start                 | ICL7667    | Motor controller   | 10V DC Logic |

Table 3.5.2 Electronic interface board molex connections

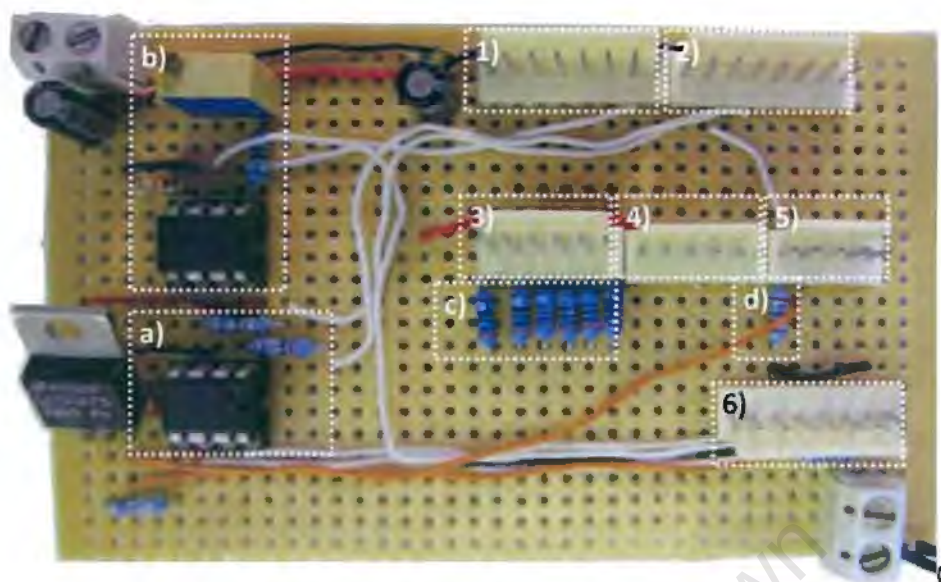


Figure 3.5.2 Photo of Vari-Board electronics

### 3.5.3 Data acquisition hardware

The interface between the PC and the test apparatus was a *National Instruments USB6008* DAQ, shown in Figure 3.5.3. The device provided a simple, low-cost, multifunction interface. Table 3.5.3 gives some of the important specifications (National Instruments).



Figure 3.5.3 Photo of National Instruments USB6008 DAQ

| Feature                     | Quantity | Used        | Used for                     |
|-----------------------------|----------|-------------|------------------------------|
| 12 bit analogue in channels | 8        | 6           | Pressure transducers         |
| Max sampling per channel    | 1kS/s    | 150-1000S/s |                              |
| Analogue outputs            | 2        | 1           | Motor speed control          |
| Digital I/O                 | 12       | 3           | Motor control, float switch, |

Table 3.5.3 Relevant DAQ specifications

### 3.5.4 Pressure sensing

In order to test the valve performance the pressure up- and downstream from the valve needed to be measured. For this two Wika A10 pressure transducers (see Figure 3.5.4) were installed in 20mm diameter sections a short distance before and after the valve. The maximum expected pressure range was between 0 and 400mmHg (0-53kPa). The lowest pressure range for which the A10 transducer is supplied in is 0-100kPa. These transducers provide a 4-20mA signal and can be powered from 8-30V (Wika). The transducers have a 4ms rail to rail response time, which translates into 760mmHg/ms (Wika). This is fast enough for measuring the pressure in the test setup.



Figure 3.5.4 Photo of Wika A10 pressure transducer mounted in apparatus

As discussed in Section 3.5.2 the DAQ required a 0-5V signal which was measured across a resistor in series with the transducer. As the transducer's full range was not required for the test apparatus, it was limited by a 300Ω resistor to 600mmHg (80kPa) which yielded a 16.8mA current from the transducer. This current through the resistor gave a 5V signal. In LabView the 0-5V signal was converted to mmHg by a linear scale with Equation 15 and then plotted in the GUI.

$$P_{mmHg} = 156.25 \times P_V - 187.5 \quad (15)$$

Where  $P_{mmHg}$  is the pressure reported in the software in mmHg and  $P_V$  is the voltage from the signal conversion board in V.

### 3.5.5 Motor power and control

A *Leroy Somer* asynchronous three-phase AC motor was selected to drive the system. It was powered and controlled by a *SK Commander* inverter based speed controller, depicted in Figure 3.5.5.

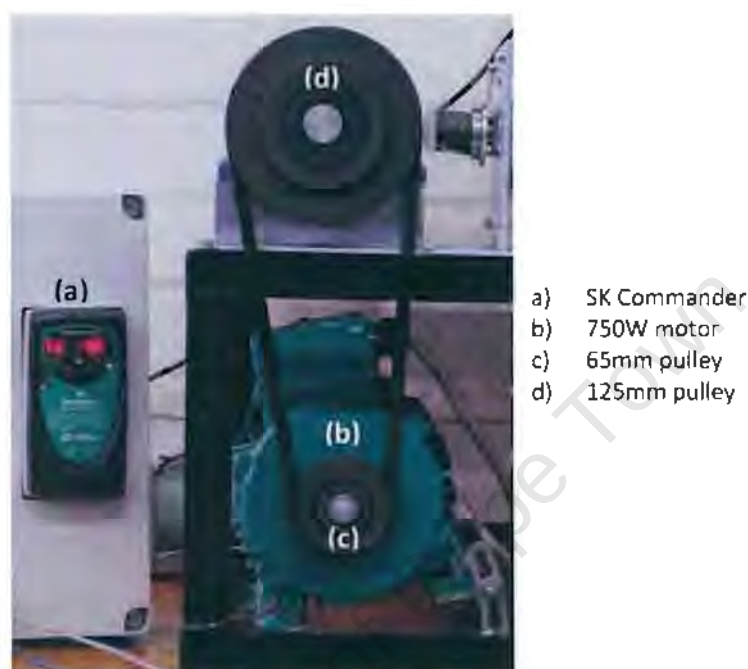


Figure 3.5.5 Photo of SK Commander and Leroy Somer Motor

Motor work calculations on a single testing line were performed by graphically integrating the approximated piston force (see section 3.4.1) over the distance travelled. To this, estimates of work done to overcome the cam and belt friction were added. From the total work for one cycle the motor power requirements was calculated. The initial calculations on which motor selection was made were considering testing speeds of up to 1000BPM, which yielded a motor power requirement of 540W with torque requirements as in the Figure 3.5.6 below.

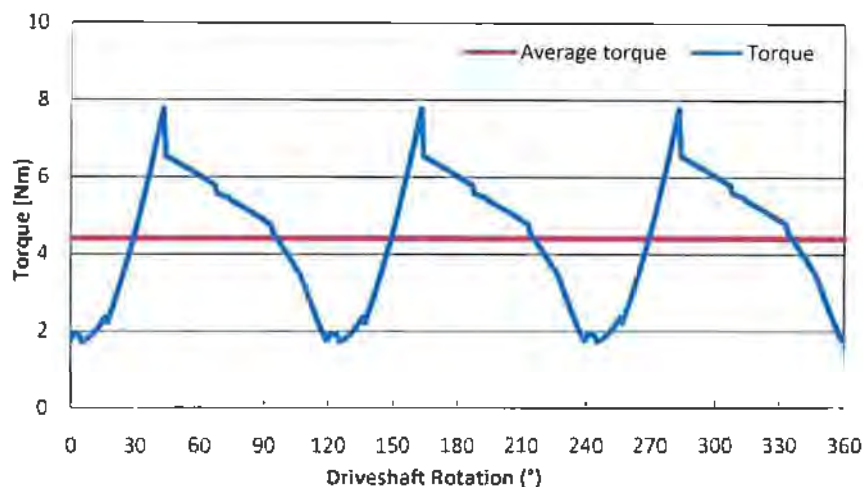


Figure 3.5.6 Motor torque requirements during one cycle at 1000BPM

The Leroy Somer 550W motor can only supply 3.8Nm and the 750W 5.1Nm (Leroy Somer). The 750W motor was selected as the average required torque for three testing lines, 4.4Nm and the peak value of 7.8Nm, was within its specifications. When the system was started the first time with only one testing line the motor was unable to supply the peak torque at low speeds. Due to other system constraints, discussed in Chapter 4, the maximum testing speed was lowered to 400BPM. This enabled the drive to be geared down as the motor's rated speed of 1400RPM was not required, thus the original 1:1 belt drive ratio was changed to a 1:2.

The motor suppliers recommended using the SK Commander from *Control Techniques* to power the motor. The controller inverts 220V 50Hz single phase power to 220V 3-phase. The SK Commander receives a 0-10V signal to control the motor speed in the set range of 60-800RPM, resulting in a final drive range from 30-400BPM.

### 3.5.6 Heater and temperature control

Controlling the temperature under which heart valve tests are conducted is important as the fluid viscosity changes with temperature change and can thus load the valve leaflets differently than at room temperature. The material properties of flexible leaflet valves can also change with temperature.

To maintain a fluid temperature between 34 and 42°C the fluid reservoir is heated by a 1500W Silica heater from *Specific Heat*. The heater is insulated from the 6mm stainless steel clamping plate by *FibroFrax* furnace insulation. The heater is powered via 220V mains and switched by a *Delta* DTA PID temperature controller. The temperature control loop was completed by a PT100 temperature probe submerged in the fluid. The PID controller has an automatic calibration setting which was executed whilst the drive and reservoir fluid agitation pump were in operation. With the resulting PID constants the heating rate was 2°C/minute, with no overshoot. Heating time from 15 to 37°C is 24min. As the systems runs above ambient temperature cooling takes place by heat dissipation through all fluid containing components.

### 3.6 Control and logging software

*National Instruments'* LabView is a visual programming language specifically designed for data acquisition and instrument control and provides a platform for a stable graphical user interface and reliable communication with the DAQ and was thus used for the control and logging software. The software is the main user interface with the test apparatus. This section is an overview of its structure and functioning. For an in depth description of all the components, see Appendix C.

#### 3.6.1 LabView graphical user interface

Through the graphical user interface the user can adjust and monitor the test apparatus. Figure 3.6.1 shows a screenshot of the GUI during operation. The numbered boxes refer to various sections discussed later in the next section.

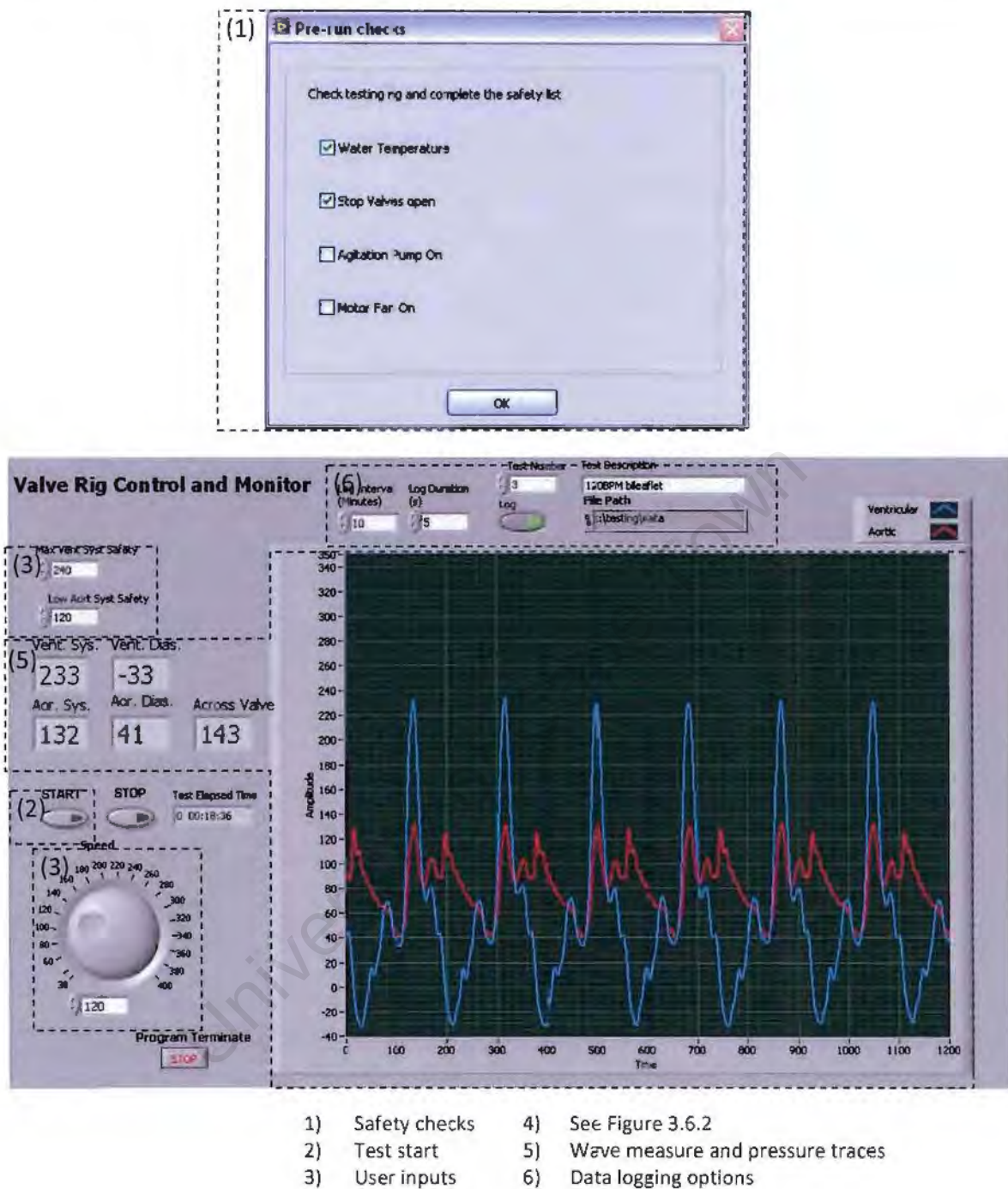


Figure 3.6.1 Screenshot of GUI

Behind the front panel of the GUI is the block diagram which contains the code and is discussed next in 3.6.2.

### 3.6.2 Basic code overview

LabView makes use of dataflow programming where code is created by placing operational nodes on the block diagram and then wiring the nodes to form a sequential structure. Nodes in LabView can be built in functions such as mathematical operations; built-in SubVIs such as data acquisition assists; or user made SubVIs. Figure 3.6.2 shows a simplified flow chart of the main VI where main program nodes and sections are shown. The numbered components in the flowchart are further explained below.

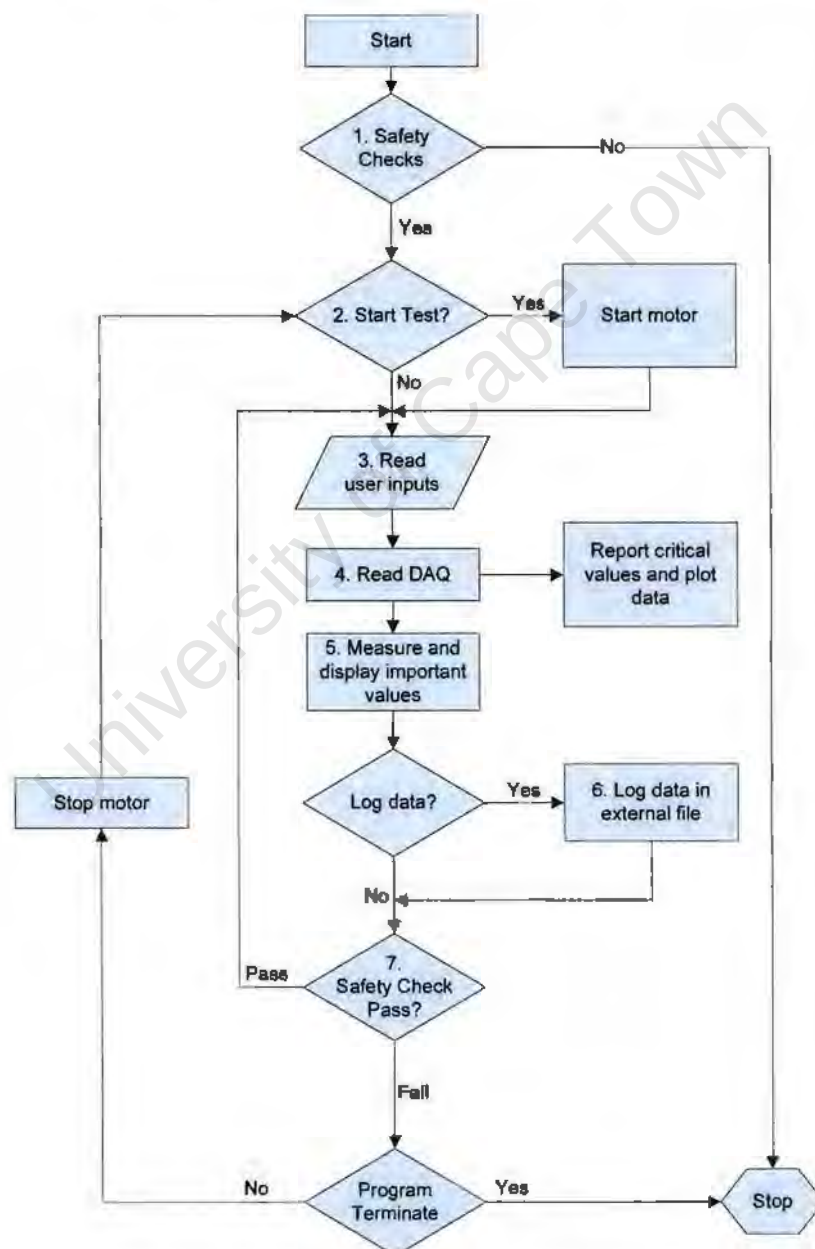


Figure 3.6.2 Simplified flowchart of main LabView code

### 1. User checks

User checks are safety checks performed and ticked off by the user. They include: water temperature; stop valves must be open; reservoir agitation must be operating; and the motor fan must be switched on. If all the tick boxes, shown in Figure 3.6.1, are not completed the user is warned and the program does not execute, displaying the warning shown below in Figure 3.6.3. These are to ensure the apparatus is ready for operation.



Figure 3.6.3 Pre-run checks warning

### 2. Motor start

After the user safety checks have been completed testing is ready to commence. By pressing the start button the motor is started at the speed set on the speed control knob. The default start-up speed when opening the testing software is 70BPM. It is important to set the starting speed to a low setting when commencing new tests.

### 3. User input

The user input for the apparatus include the two safety pressure values, the speed control knob and test start and stop buttons. These controls can be adjusted during testing.

### 4. DAQ read

The DAQ Read sub VI captured pressure and float switch data from the DAQ in one second durations into arrays. The data sampling rate per channel was dependent on the operating speed and was determined by the piecewise Equation 16. This implied 300 samples per simulated heart beat up to a speed of 200BPM where the maximum DAQ sampling speed was reached. This sampling speed adjustment kept log file size down to a minimum at lower speeds whilst maintaining enough samples for accurate representation.

$$\begin{aligned} N_{s/s} &= \frac{Speed_{BPM}}{60} \times 300 \quad \text{if } Speed_{BPM} < 200BPM \\ N_{s/s} &= 1000 \quad \text{if } Speed_{BPM} \geq 200BPM \end{aligned} \quad (16)$$

Where  $N_{s/s}$  is the number of samples per second

The pressure data is stored in a matrix whilst float switch data was exported in a separate array. From here they were first checked to ensure the apparatus was still performing as expected and whether a safety stop was required.

#### 5. Trace measurements

Various aspects of the pressure traces are important to monitor, especially whilst setting up the load components of a test. These include the systolic and diastolic values of the ventricle and aorta, as well as the maximum aortic valve gradient.

#### 6. Data logging

It is important to be able to log valve data during tests to be able to evaluate valve performance over time. Logging all pressure values the whole time can be cumbersome and results in very large log files. To overcome this problem the logging section can be configured to log data in time intervals for a set time period. The default time between log intervals is one minute and the default logging period for each interval is 60 seconds. The default will thus log continuously. Estimated file size for one minute of continuous logging at a speed of 200BPM (for maximum sampling rate and thus the largest possible file) is 1.88MB. The logging software has also been configured to continue logging for 10 seconds after a safety stop in order to maintain the pressure trace after the stop

#### 7. Safety stops

Safety stops were put in place to prevent damage to the apparatus and the valve being tested. They include:

**Ventricle over pressure:** Measures maximum pressure in ventricle and compares this with a setpoint and stops the drive if the value exceeds the setpoint. The default value is 250mmHg. This protects the mitral valve as it shuts when the pressure in the ventricle rises. Possible reasons for ventricular over pressure failure are increases in the resistive or compliance loads, or incorrect load settings for operating speed. As discussed later in Section 4.5, this failsafe was also instrumental in detecting valve failures at high speeds.

**Aorta under pressure:** Extracts maximum pressure in the aorta and compares it with a setpoint. Stops the testing if maximum pressure is below setpoint. The default value is

OmmHg as this failsafe must be set after the test has been fully configured and the pressure traces are stable. It is used only for detecting valve failure as discussed later in Section 4.5.

Float switch: Monitors the fluid level in the tank and trips if the fluid drops below the float switch level, opening the float switch circuit and dropping the float switch value from 5V to 0V.

Test Stop: User selects to stop the testing.

All safety stops, except the Test Stop, display a warning message on the screen indicating the reason for the stop, the date and time of the stop as well as the test duration at time of the stop.

### 3.7 Apparatus operation

This section deals briefly with the main aspects of operating the apparatus, including preparation, running valve tests and apparatus maintenance.

#### 3.7.1 General notes

The apparatus controller and heating should always be switched off until the control software has been opened in LabView. Failure to do this could lead to incorrect motor starting signals to be sent to the motor as well as to burning of the glycerol if there is no agitation in the reservoir.

#### 3.7.2 Preparation for starting

The first step of any test is ensuring that there is a clean mixture of the testing fluid. The volumetric fluid ratio is a 42% glycerol and 58% distilled water mix and to which NaCl is added to for a 0.9% saline solution (Sung *et al.* 1994). Converted to a mass ratio this results in 48% glycerol 52% distilled water and 9g salt per kilogram of final solution. Shake or stir solution well to mix glycerol, salt and water.

Ensure that the apparatus is clean throughout and rinse with distilled water after cleaning and before adding new fluid. Insert the aortic valve to be tested and clamp in place, ensuring that valve direction is correct. Clamping method depends on the type of valve to be tested.

Rigid valves can be held in place by a hose clamp, whilst valves with a flexible perimeters need customised retaining methods. Insert the testing section into the apparatus and bolt it in place insuring the o-rings are in the grooves.

Close the bleeding holes on the top and bottom of compliance chamber and fill the reservoir with the testing fluid. Tilt the entire frame in order to remove all air which may have been trapped in the ventricular chamber. Any remaining air can be bled from the ventricular compliance tubes. Adjust the ventricular and systemic compliance. Ensure that the lock-off and systemic resistance valves are both fully open.

### 3.7.3 Running tests

Open and run the Valve Testing VI in LabView. Complete the preliminary safety check list as shown in Figure 3.6.1. Complete the test number and description for data logging purposes, as well as the logging interval and duration. Ensure the test speed and all the safety parameters are set correctly before starting the test. When all is ready start the test and adjust the systemic resistance until the pressure trace is as desired.

### 3.7.4 Apparatus maintenance

Apparatus maintenance mainly comprises cleaning and bearing lubrication. Use lukewarm water to wipe and rinse the apparatus and diluted dishwashing soap to clean when water is insufficient. Ensure all soap is rinsed out before the next test.

The three sets of bearings all have different lubrication intervals. All bearings use the same Lithium Polymer soap grease. The linear followers must be lubricated every 48 hours of running by means of syringe with a short, wide needle, applying the grease in both the grooves on the linear rod. Cam follower bearings must be lubricated every 7 days of running and shaft bearings every 14 days. Both these sets are greased by means of the grease gun.

## 3.8 Concluding remarks

This then concludes the design, implementation and operation of the test apparatus. One of the main aspects of the project was validating whether the apparatus produced sufficiently realistic heart beats and whether it could operate as required by ISO valve testing

specifications. To do this various tests were completed across the operating speed range. The overall speed range was divided into physiological (30-80BPM) and accelerated (90BPM and up) speeds. At these speeds the compliance and resistive loads were adjusted in order to fine tune machine design and to establish the test apparatus's operating range.

Chapter 4 presents and discusses the test results from across the operating range, with conclusions and recommendations in Chapter 5

## Chapter 4

### Results and Discussion

#### 4.1 Introduction

This section deals with various tests completed to demonstrate the test apparatus performance and capabilities, showing relevant results and giving a brief discussion of each test. It starts with the temperature response of the system and how this influenced the valve testing, followed by performance in the various testing speed ranges. Next is a section dealing with valve failure detection, ending with ventricular compliance testing.

4.2 Initial system heating and effect of temperature on pressure

In order to start testing the testing fluid was first heated to an operating temperature of 37°C. As mentioned in Section 3.5.6 heating was done with the system running and the tank circulation pump switched on. The first test started with the fluid at 15.7°C and the target temperature set to 37°C. As can be seen in Figure 4.2.1 the fluid heats up at a rate of 2.2°C/min and reached within 2°C of the target in 9min35s. After this the heating rate drops and reaches within 0.5°C from the target temperature in another 1min 30s and then reaches the target after another 12 minutes. As long as the drive is running the temperature remained stable at the setpoint. If the drive is stopped whilst the heater remains on, the temperature fluctuates by 0.6°C over the setpoint.

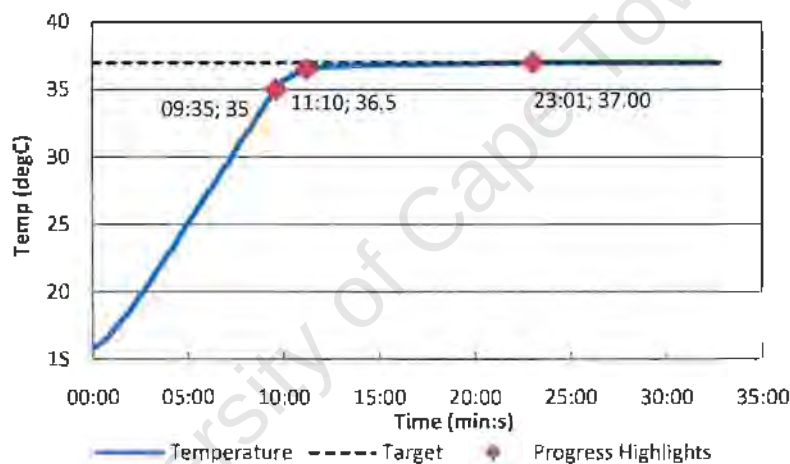


Figure 4.2.1 Temperature response when heating from 15.7 to 37°C at 72BPM

Although the PID controller was tuned at 72BPM, as can be seen in Figure 4.2.2, there was little difference in the heating curve when running at 150BPM. The heating slowed down with 2°C remaining and then reached the setpoint in 13 minutes. Once again there was no overshoot and the temperature remained constant without fluctuations for as long as the drive continued running.

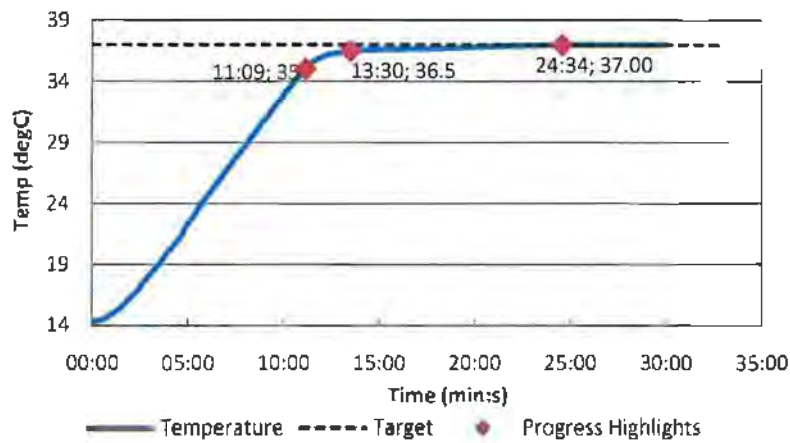


Figure 4.2.2 Temperature response when heating from 14.2 to 37°C at 150BPM

Figure 4.2.3 shows the ventricular and arterial pressure traces at 72BPM before heating the fluid (blue) and after the target temperature has been reached (red) and Figure 4.2.4 the same traces but at 150BPM. At both speeds the peripheral resistance valve was left completely open, hence the low pressure values.

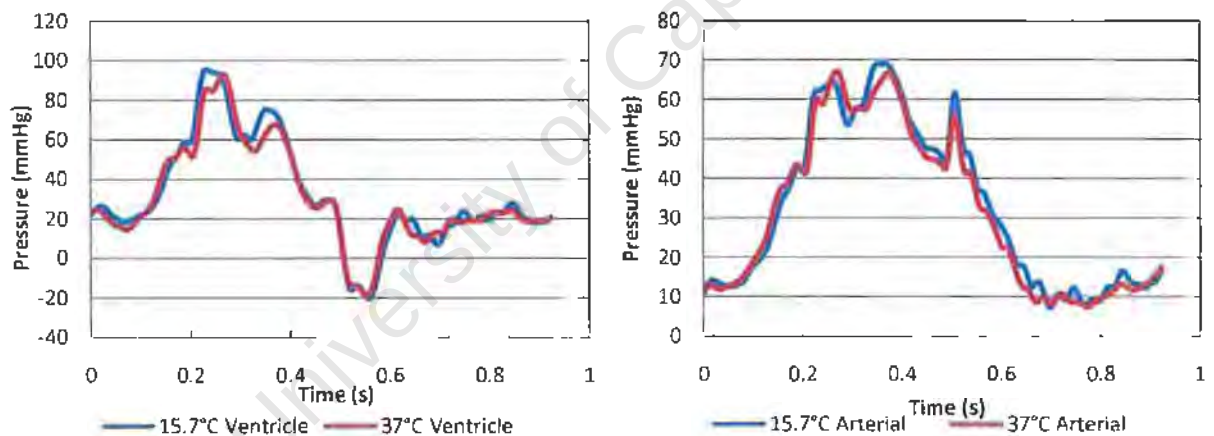


Figure 4.2.3 Pressure traces at start-up and target temperature, 72BPM

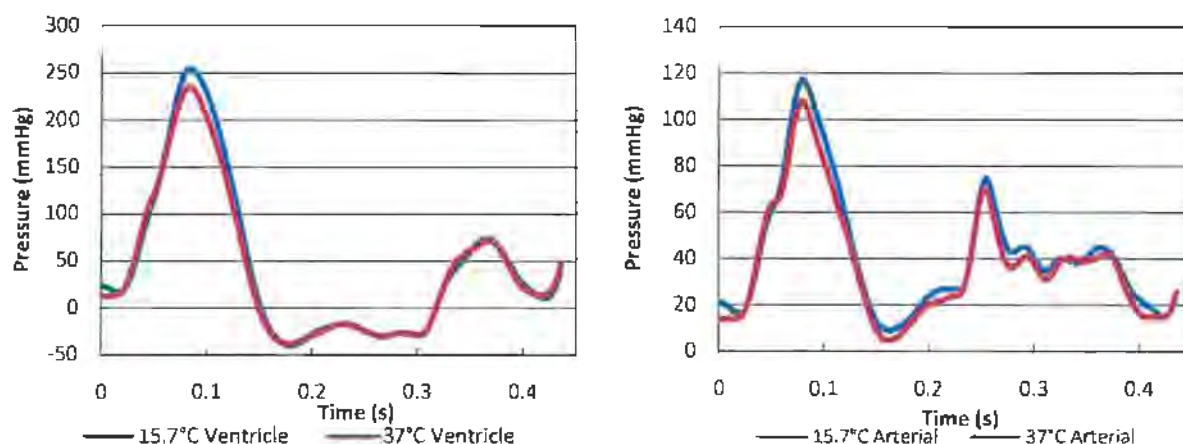


Figure 4.2.4 Pressure traces at start-up and target temperature, 150BPM

In both scenarios arterial pressure traces were slightly higher when cold than when hot, whilst the ventricular traces were closer together. This higher pressure drop between the two pressure transducers at low temperature shows the higher fluid viscosity. The difference in pressure traces between running cold and on temperature is within the same range as wave to wave variation at normal testing temperature. Because of this the valve can be inserted into the apparatus before testing is started as there are no abnormal pressure loads during heating. Although the pressure traces are very similar, testing at the correct temperature is important as the fluid viscosity as well as the valve leaflets, in the case of flexible leaflet valves, change with temperature. It is thus further advised to run at low speeds until operating temperature has been reached.

### 4.3 Testing of valves

The apparatus was designed to operate across a wide range of speeds, from the very low physiological 30BPM to accelerated speeds up to 400BPM for fatigue testing. This section briefly explains how to configure the test apparatus for testing valves at various speeds. For each speed the compliance must be set and the test started with the peripheral resistance valve open. After this the peripheral resistance valve must be closed slowly until the desired pressure is reached. The compliance setting for each test is given in parenthesis after the test speed in ml/mmHg as well as in fluid height in the chamber.

### 4.3.1 Low speed testing: 30-80BPM

From 30 to 45BPM the motor, with the fitted belt drive, was unable to supply enough torque to drive the system at a constant speed. A larger pulley ratio was unfortunately not possible as the driven pulley was already the largest the drive could accommodate without major modifications and the driver the smallest stocked by the supplier. Tests at these low speeds are however not required for long durations as they are purely for inspecting valve performance at such speeds and not for valve life expectancy calculations.

Figure 4.3.1 shows the pressure traces at 30BPM (2.3ml/mmHg, 70mm liquid). These traces correlate with the actual traces in the human heart shown in Figure 2.2.3 in Section 2.2. The ventricular pressure rose almost instantaneously as the forward stroke started until it surpassed the arterial pressure when the aortic valve opens.

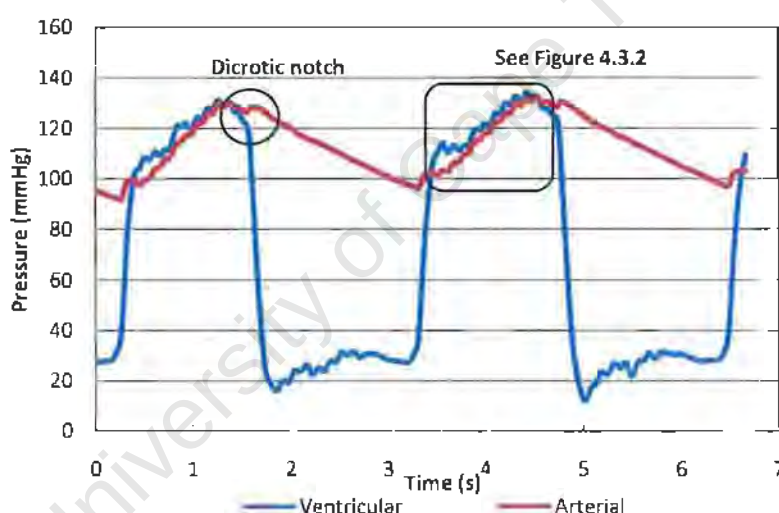


Figure 4.3.1 Pressure traces at 30BPM (2.3ml/mmHg, 70mm liquid) see Figure 2.2.3

Both traces then rose together with only a small pressure drop across the valve section as shown by the green plot in Figure 4.3.2 on the secondary axis, an enlargement of the section highlighted by the rectangle in Figure 4.3.1. The mean pressure drop between the pressure transducers at this cardiac output of 3 litres per minute was 4.21mmHg for the duration that the aortic valve is open. This is on par with results obtained during in vitro testing of valves of similar size with similar flow velocities (Bottio *et al.* 2004). Bottio *et al.* reported values ranging between 2.64 and 4.55mmHg at cardiac out of 2 litres per minute and 7.65 and 11.20mmHg at 4 litres per minute. As the piston return stroke started the ventricular

pressure fell sharply whilst the arterial pressure slowly dropped until the next stroke. The small dicrotic notch should also be noted at the start of the return stroke, highlighted by the circle in Figure 4.3.1.

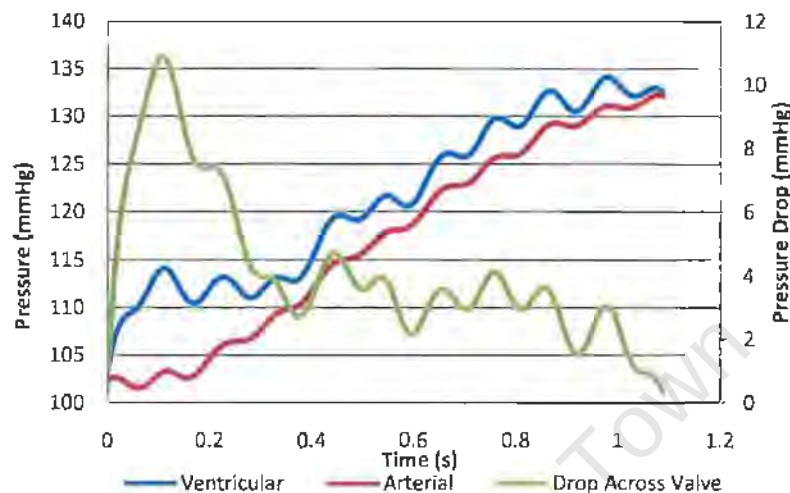


Figure 4.3.2 Pressure drop across the valve during piston forward stroke

Although testing at this very low speed was difficult due to the motor torque limitation, the results were sufficient to deduce proper valve operation.

The next testing at 50BPM (2.3ml/mmHg, 70mm liquid) presented similar pressure traces with two main differences: a larger spike in the ventricular and aortic values, highlighted by the rectangle in Figure 4.3.3; and a larger dicrotic notch, indicated by the circle. Since the dicrotic notch is formed by waterhammer, it was expected to increase with an increase in fluid velocity. By adding ventricular compliance it was possible to minimise these spikes. See Section 4.6 for more detail.

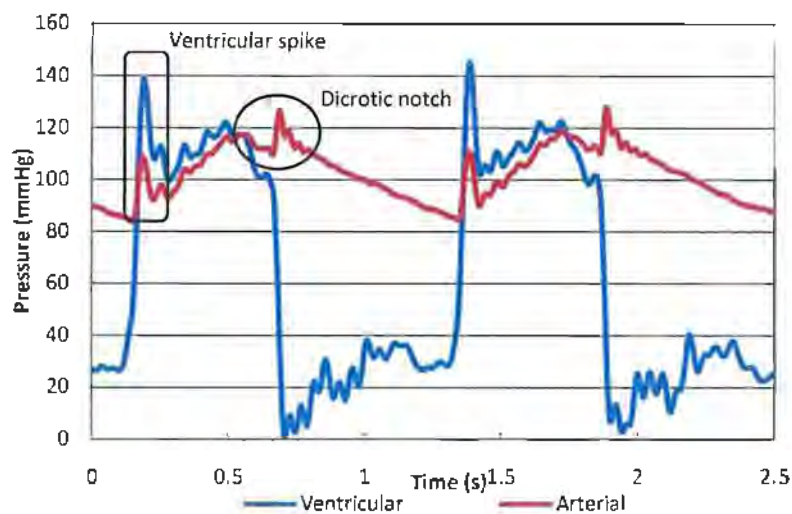


Figure 4.3.3 Pressure traces at 50BPM (2.3ml/mmHg, 70mm liquid)

Testing at 72BPM presented the threshold for physiological approximation. Here the ventricular spike and dicrotic notch were further emphasised and arterial pressure started losing its characteristic shape.

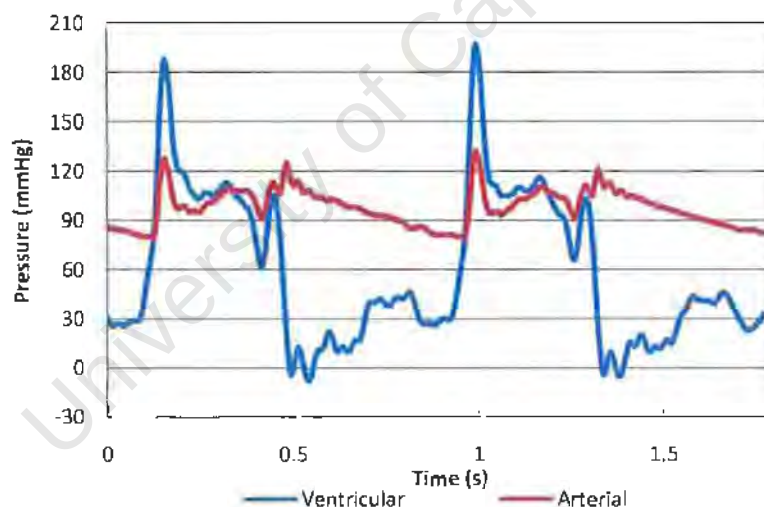


Figure 4.3.4 Pressure traces at 72BPM (2.2ml/mmHg, 80mm liquid)

#### 4.3.2 Accelerated testing: 90-230BPM

Testing speeds from 90BPM and up presented increasing deviations from physiological norms, as can be seen from Figure 4.3.5 through Figure 4.3.7. The pressure dropped significantly and for a long duration before the dicrotic notch and ventricular pressure showed unexpected behaviour as well as large spikes.

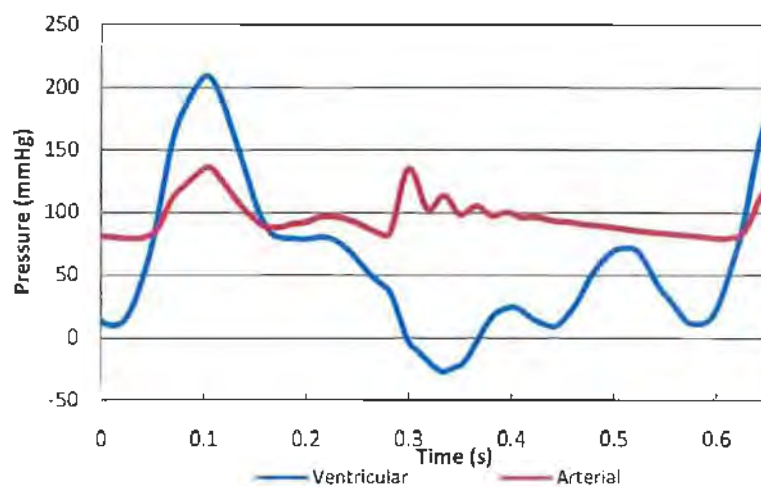


Figure 4.3.5 Pressure Traces: 96 BPM (2.1ml/mmHg, 90mm liquid)

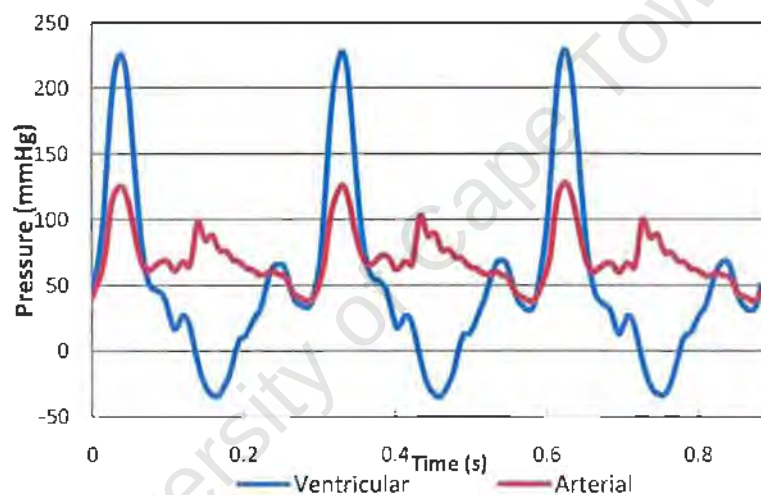


Figure 4.3.6 Pressure Traces: 120BPM (1.3ml/mmHg, 190mm liquid)

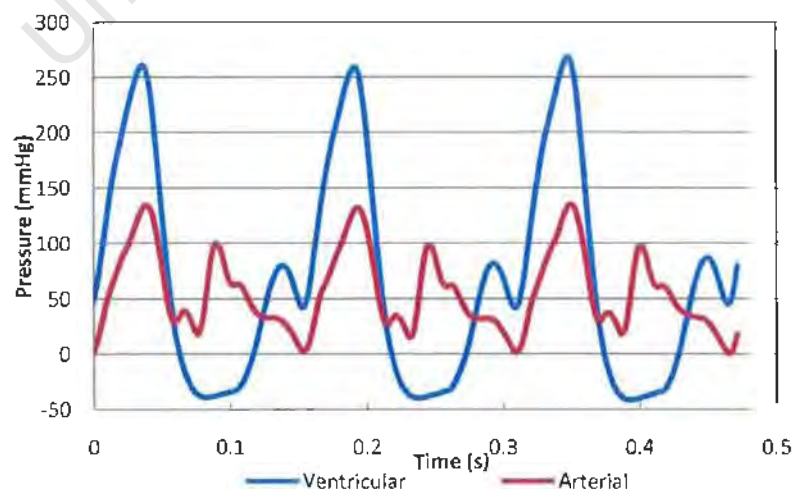


Figure 4.3.7 Pressure Traces: 230BPM (0.4ml/mmHg, 300mm liquid)

In this speed range the focus thus shifted to the ISO requirements for testing valves for fatigue. As stated in Section 1.3 the ISO requirements for fatigue testing involves a designated pressure across the closed valve for at least 5% of the cycle duration. The required pressure ranges from hypotensive states of 50mmHg across the valve to extreme hypertension of 185mmHg and a single 230mmHg beat, depending on the designation of the valve undergoing testing. The apparatus was thus set up to produce such pressures. Figure 4.3.8 shows the results of testing at 180BPM with the valve gradient exceeding 230mmHg. Figure 4.3.8 only shows the valve gradient during diastole as this is the pressure considered for ISO certification. In this test the pressure was maintained above 230mmHg for 5.2% of every beat and above 200mmHg for 20% of each cycle, as indicated in the figure.

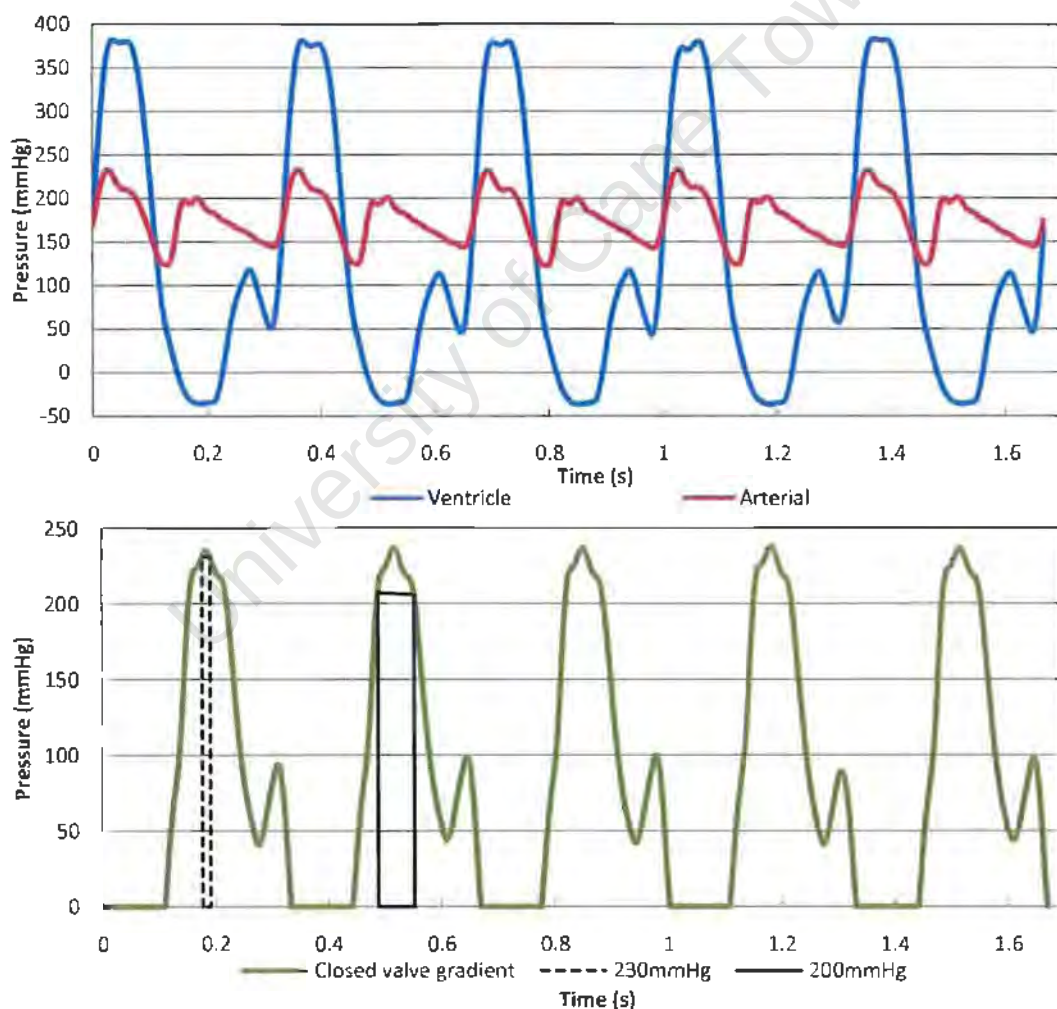


Figure 4.3.8 Ventricular, arterial and pressure gradient at 180BPM

These are extreme pressures and exceed the ISO testing requirement and demonstrate that the apparatus can operate under these conditions. Full testing comprised of a speed range of 90-230BPM with pressure gradients ranging from hypotensive 50mmHg to extreme hypertension as shown in Figure 4.3.8. The pressure drop during systole is due to an increase in flow resistance in the section between the pressure transducers with the increased fluid velocity. This pressure drop is in itself not an extra load on the valve since it is open during systole. The increased flow velocity associated with accelerated testing plays a larger role in unnatural wear of the valve.

#### 4.4 The effect of R, C and L on testing

Although it was mentioned in Section 4.3.2 that the focus for testing speeds above 90BPM was on valve pressure gradient, this section is an independent investigation and demonstration of the effect of R, C and L on the testing system. As discussed in section 3.2 the Windkessel model upon which the design of this test apparatus was based is sensitive to change in operating speed. Several measures have been put in place to attempt to compensate for this in order to test across a range of speeds. This section shows how the variables  $R_p$ , C and L (see Figure 4.4.1) in the Windkessel model affect the desired results of obtaining a plausible heartbeat. 16 tests were run, grouped according to the 4 speeds (70, 120, 190, 230BPM) with 4 compliance settings (2.2, 1.3, 0.8, 0.4ml/mmHg, which corresponds to compliance chamber fluid levels of 80, 190, 250 and 300mm) for each. The pressure traces across the compliance range for each speed was then plotted over time to illustrate the effect of compliance. Inertance L was fixed as the pipe section determining it as well as the fluid remained constant for all the tests. The peripheral resistance  $R_p$  was modified for each test with the aim of keeping the peak arterial pressure within a 20mmHg range for all compliance settings at that speed. Note the pipe sections  $R_p$  also contributes inertance.

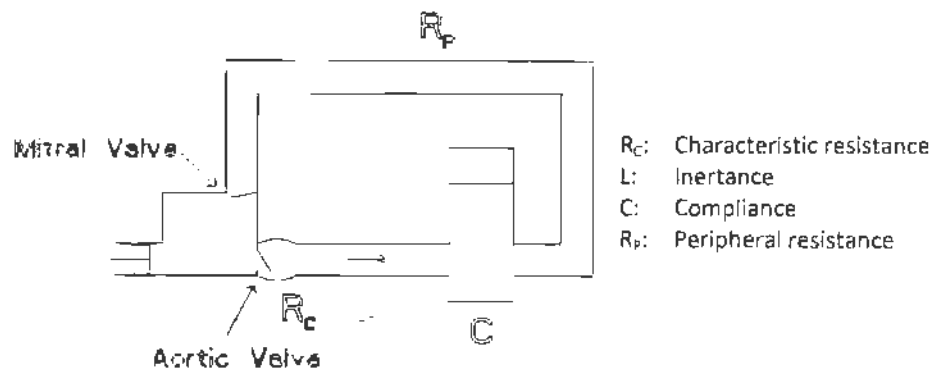


Figure 4.4.1 Illustrative hydrodynamic analogy of four element windkessel

#### 4.4.1 Characteristic and peripheral resistance

As discussed in Section 3.3.2, the section governing characteristic resistance ( $R_c$ ) remained fixed. As the flow velocity increased the friction and thus loads of this section increased, causing large pressure drops across the section. This effect can be reduced by shortening or widening the section which will in turn lead to better accelerated performance.

Equation 11 in Section 3.3.1 showed how an exponential increase in resistance was required to maintain physiological impedance, however, as the testing speed increased the resistance valve had to be opened to give less resistance. This was due to the increased pipe resistance at high flow rates. By increasing the diameter of the pipe containing flow from the compliance chamber to the reservoir, the adjustment of  $R_p$  will be more dependent on the resistance valve which will result in a more predictable system.

#### 4.4.2 Compliance

As discussed in Section 3.3.2 the compliance chamber was designed for physiological compliance settings of 2.0ml/mmHg and can be dropped to zero by completely eliminating all air from the chamber.

#### 4.4.3 Inertance

As discussed in Section 3.3.2, the section governing inertance ( $L$ ) remained fixed. As the operating frequency increased the effect of  $L$  on impedance increased as there was no way of lowering it within the testing requirements. Designing this pipe section with an impedance and characteristic resistance for a specific testing speed will improve testing at

that speed. Compensation over a large range is however impractical. The inertance due to the  $R_p$  section should also be minimised such that the physical test apparatus remains as close as possible to the electrical model.

#### 4.4.4 Testing results

Each of the following figures in this section shows the arterial and ventricular pressure traces of a single beat on separate axes. Each set also shows the plots for the four compliance settings. Figure 4.4.2 shows the effect of compliance where the rate of pressure drop after systole increases with decreasing compliance. Figure 4.4.3 and 4.4.4 show that the same compliance setting cannot be used for all testing speeds. The necessity for compliance to decrease at higher speeds can be seen in these figures as the pressure drop before the diastolic notch increases with more compliance. A decrease in inertance would also have decreased the pressure drop before the diastolic notch.

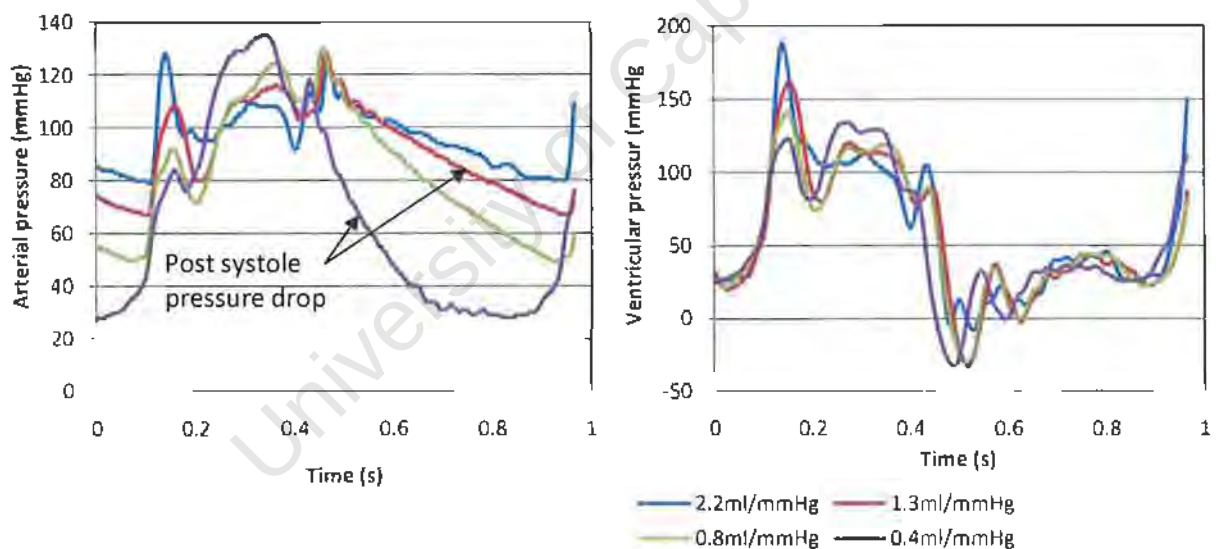
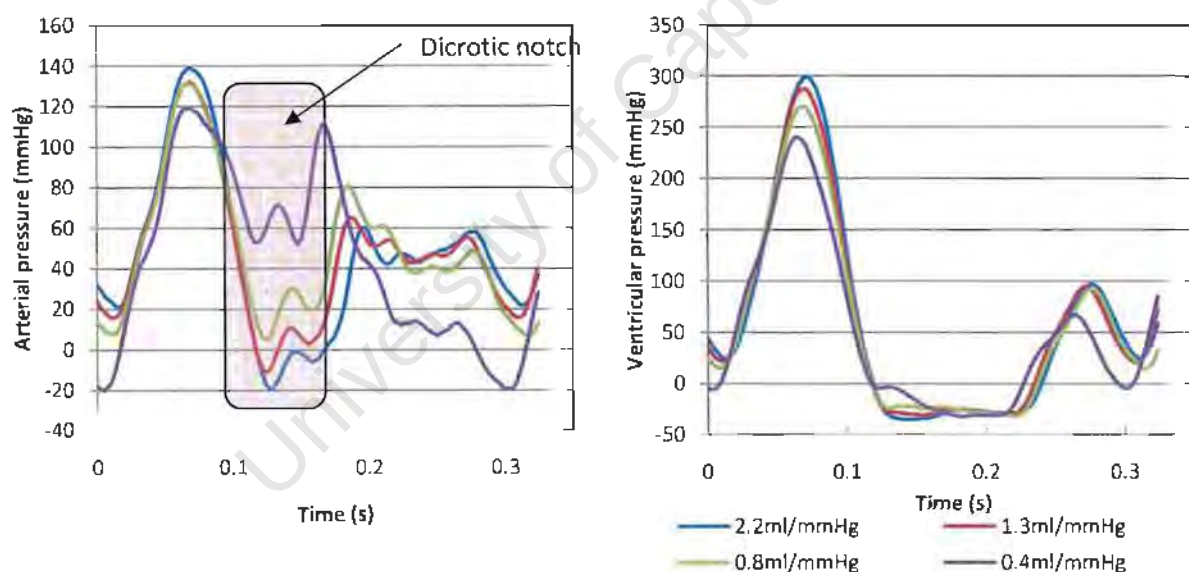
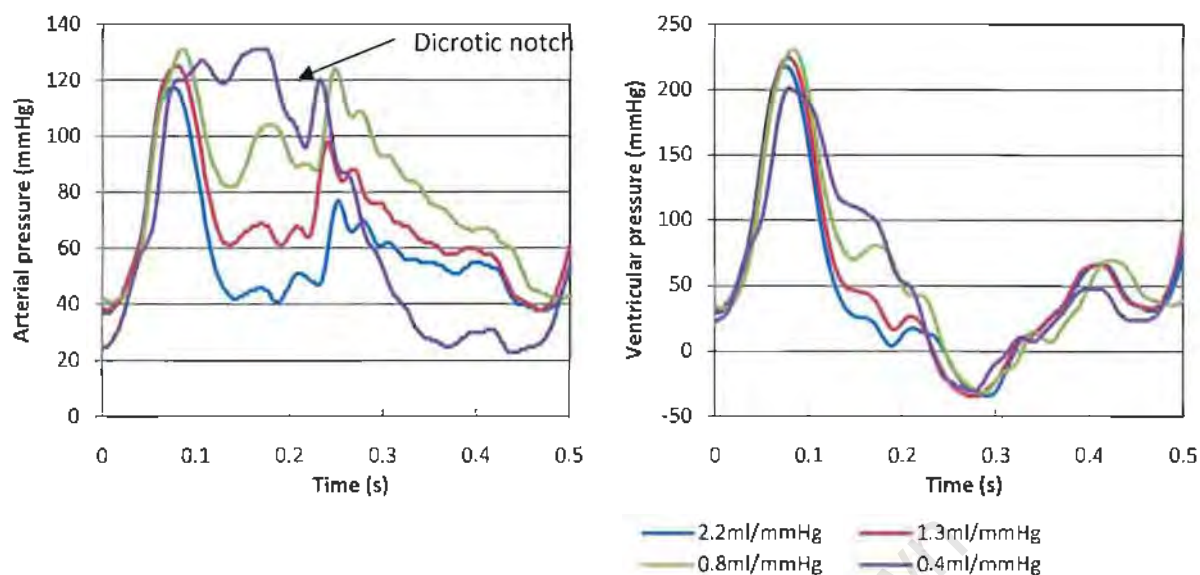


Figure 4.4.2 Pressure with varying compliance at 70BPM



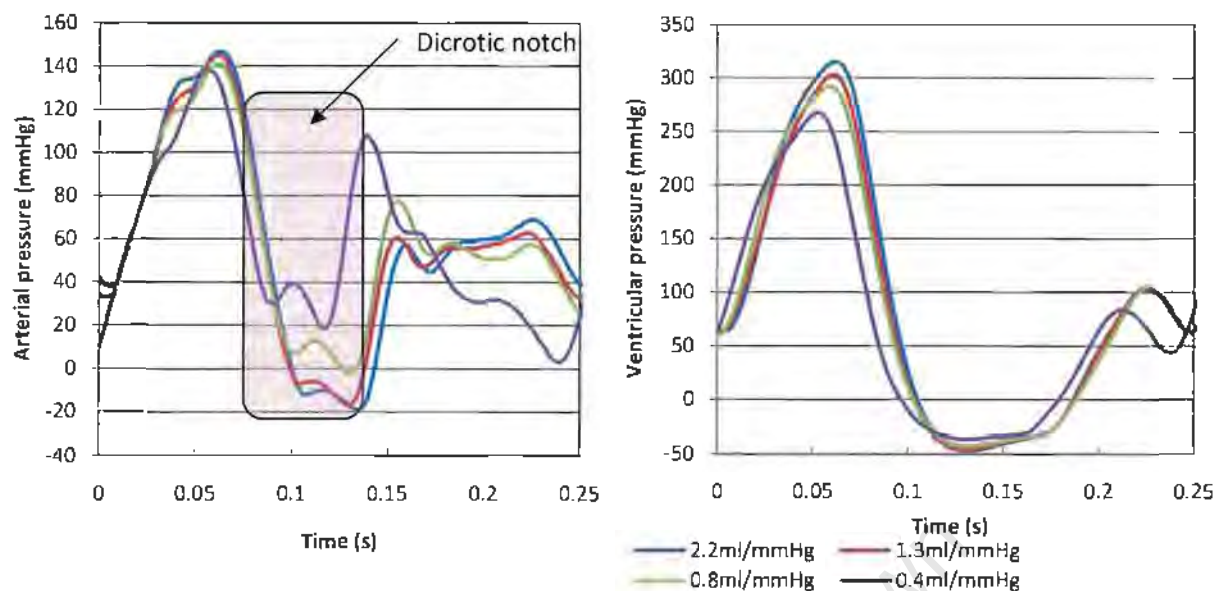


Figure 4.4.5 Pressure with varying compliance at 230BPM

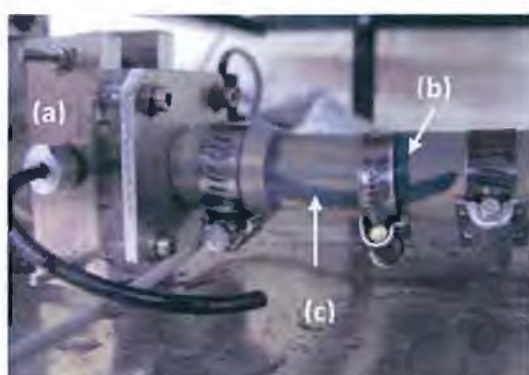
#### 4.5 Valve failure detection

During valve testing it is crucial to know when the valve has failed, and to keep it as intact as possible after failure in order to examine the reason for failure. For this reason the operating software can detect valve failures and stops the test testing to prevent the broken valve from further damage.

Valve failure was simulated by means of obstructing one of the test valve's leaflets with a piece of 4mm o-ring cord inserted through the optical scope port, as illustrated in Figure 4.5.1 and Figure 4.5.2. This replicated the effect of a cusp or leaflet breaking off as the test valve was unable to close completely. The effect of this on the pressure traces is dependent on the testing speed and system load. This failure was detected by the software if the safety pressures were set correctly. The values for the various safety pressures are also indicated on each of the graphs.



Figure 4.5.1 Valve obstructed by o-ring cord



- a) Optical scope port
- b) Valve
- c) O-ring

Figure 4.5.2 Obstructed valve in test apparatus

Figure 4.5.3 shows the result of a low speed failure where both ventricular and arterial pressures dropped as the leaflet was held open at the vertical green line.

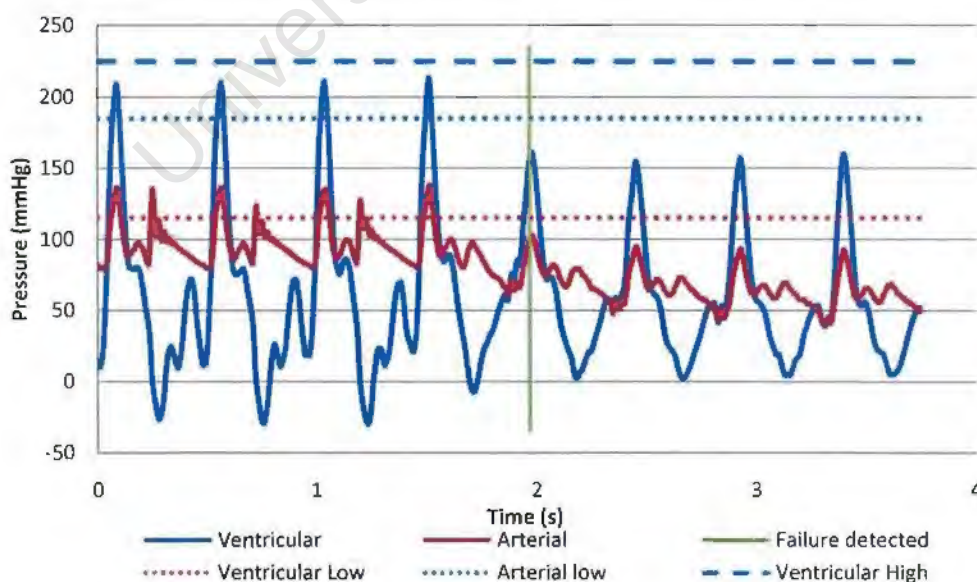


Figure 4.5.3 Valve failure simulation at 96BPM without safety stop

Figure 4.5.4 shows failure at 150BPM, falling in the medium speed category. Valve failure was simulated at the green vertical line, shortly before the third pressure peak, causing the aortic peak to drop below the set safety pressure and the testing to stop. The pressure trace after the green line still oscillates as the motor comes to a halt and the pressure waves die down.

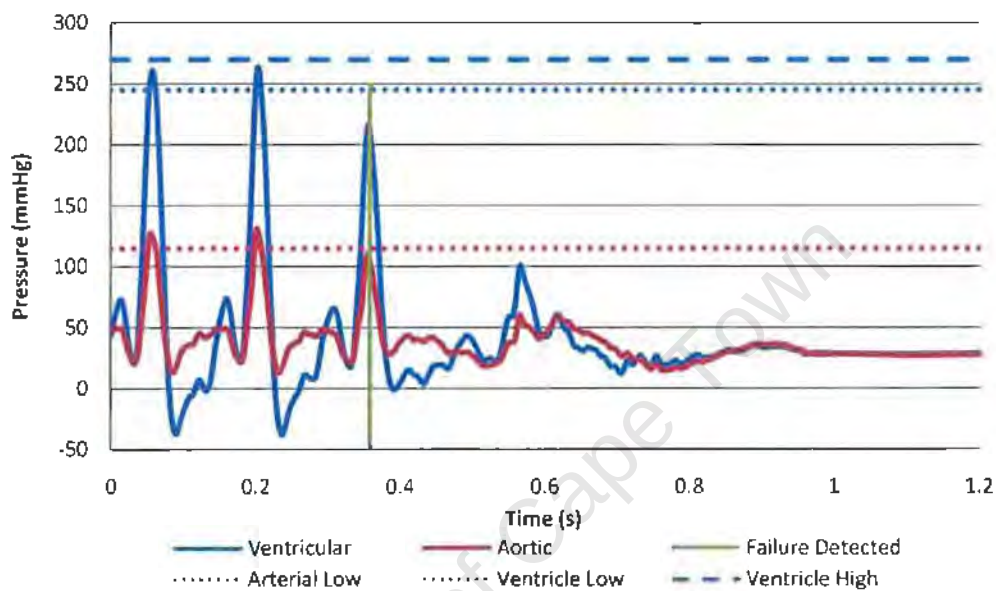


Figure 4.5.4 Valve failure simulation at 150BPM with safety stop

At higher speeds the failure has different effects on the system. Figure 4.5.5 indicates that the arterial pressure is virtually unaffected by the failure after the vertical green line, but that the ventricular pressure rises sharply. The change in failure mode is most likely a result of the effect which operating speed has on the compliance.

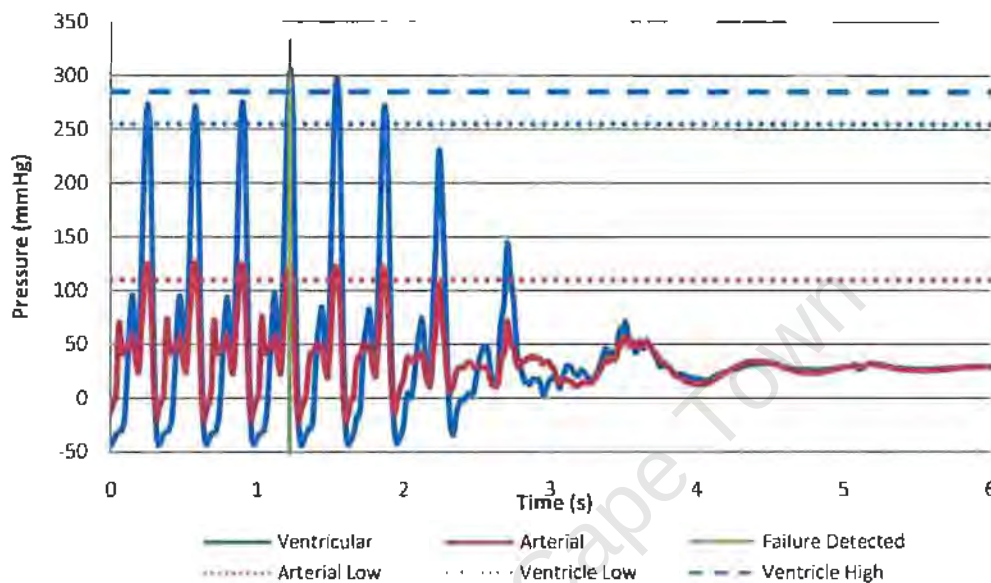


Figure 4.5.5 Valve failure simulation at 190BPM with safety stop

This emphasizes the importance of setting all safety checks correctly once pressure traces have stabilised after the start of a new test. Values for the safety pressures depend on the test setup. The margins between the peak pressures reported in the GUI and the safety values should be kept to a minimum to ensure accurate valve failure detection.

#### 4.6 Effect of added ventricular compliance

When operating the apparatus at above 100BPM, the ventricular pressure spiked much higher than the physiological norm. The human heart is not made from a rigid material, as is this Perspex simulation thereof. When the left ventricle of a human heart contracts it inherently has compliance in the heart walls. The lack thereof in the Perspex cylinder causes the pressure to spike as the piston starts its forward stroke. To compensate for this, compliance was added to the ventricle by means of two flexible tubes, photographed in Figure 4.6.1. The tubes were partially filled with air to offer extra compliance over that of the tube, and were sealed at the top with clamps.

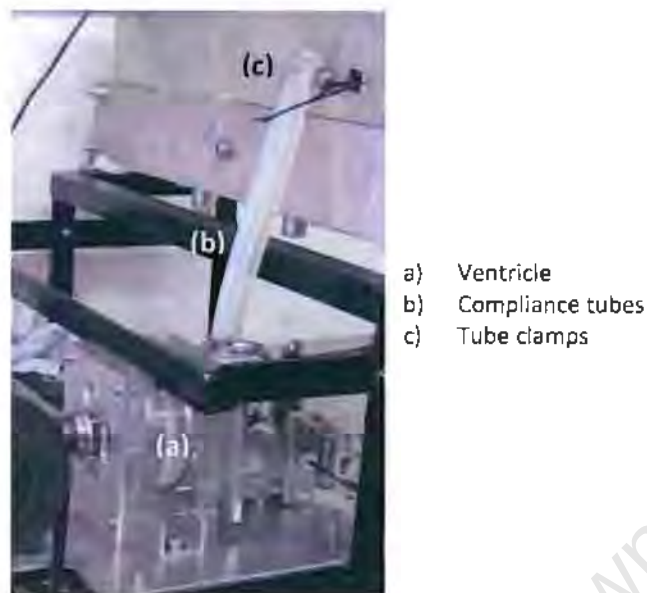


Figure 4.6.1 Ventricular compliance tubes

In this section the effect of the ventricular compliance was examined. As was mentioned in Section 3.3.1 the effect of compliance in the system is related to pulse frequency, thus the effect of the added ventricular compliance was examined under various speeds, ranging from 72 to 180BPM. Each test is accompanied by two pressure trace charts, the first of ventricular and the second of arterial pressure. Throughout the results the blue plot resembles testing with the extra compliance and the red without.

#### 4.6.1 Added compliance at 72BPM

This is the lowest speed at which this test was performed. As shown in Figure 4.3.1 in Section 4.3, very low speed testing did not suffer from the ventricular spike.

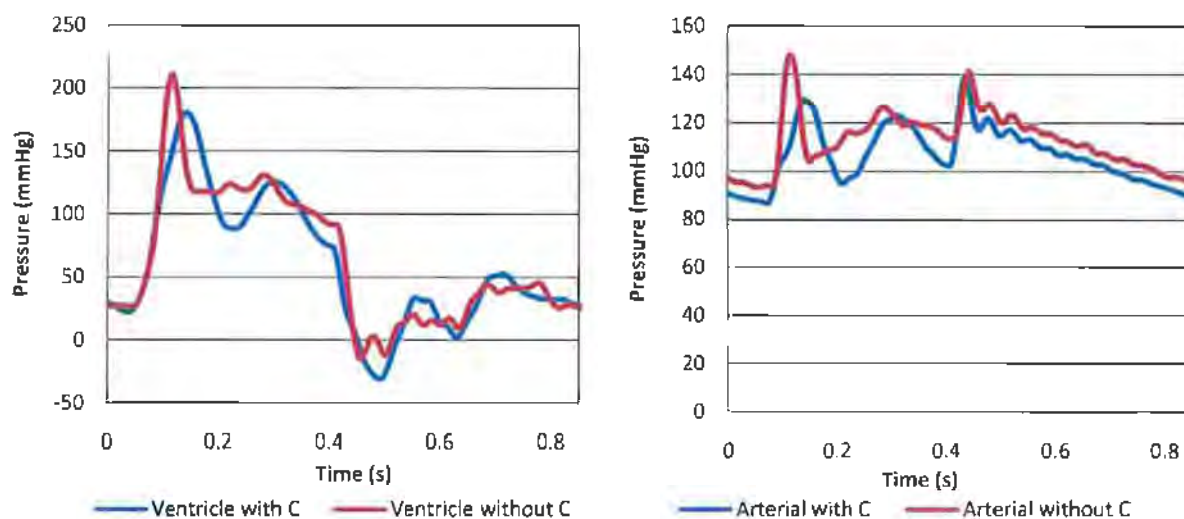


Figure 4.6.2 Pressure traces with and without ventricular compliance at 72BPM

Figure 4.6.2 shows that the added ventricular compliance affects the shape of the pressure trace, causing it to dip lower after the initial spike, thus deviating further from physiological norm. At low testing speeds the ventricular spike is small enough to rather maintain the pressure trace without adding ventricular compliance.

#### 4.6.2 Added compliance at 120BPM

The next step was to increase the testing speed. For this test at 120BPM the systemic resistance valve is slightly shut to attempt a plausible pressure trace.

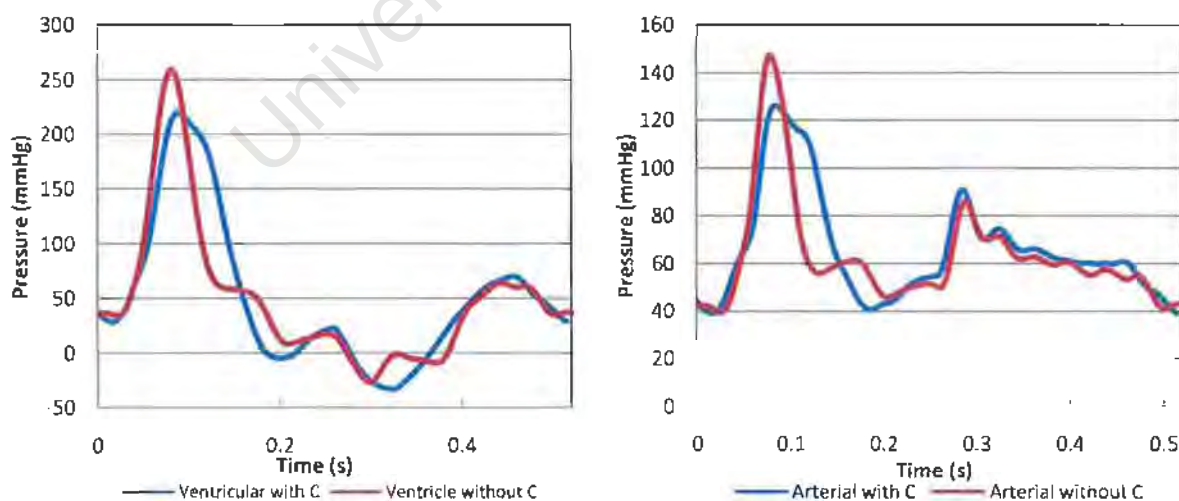


Figure 4.6.3 Pressure traces with and without ventricular compliance at 120BPM

Figure 4.6.3 shows that there is little difference between the shapes of the two traces. The main difference however is the 16% drop in ventricular spike, and 32% drop in the aortic spike. This drop is a significant decreased load on the valves with a minimal effect on the traces, thus it is recommended to use the added ventricular compliance at speeds greater than 120BPM

#### 4.6.3 Added compliance at 180BPM

At high testing speeds (180BPM) the systemic load of the system is too great to have extra resistance from the resistive ball-valve. As mentioned in section 4.3.2 the emphasis is not on accurate pressure reproduction, but rather faster testing without excessive loads on the valves.

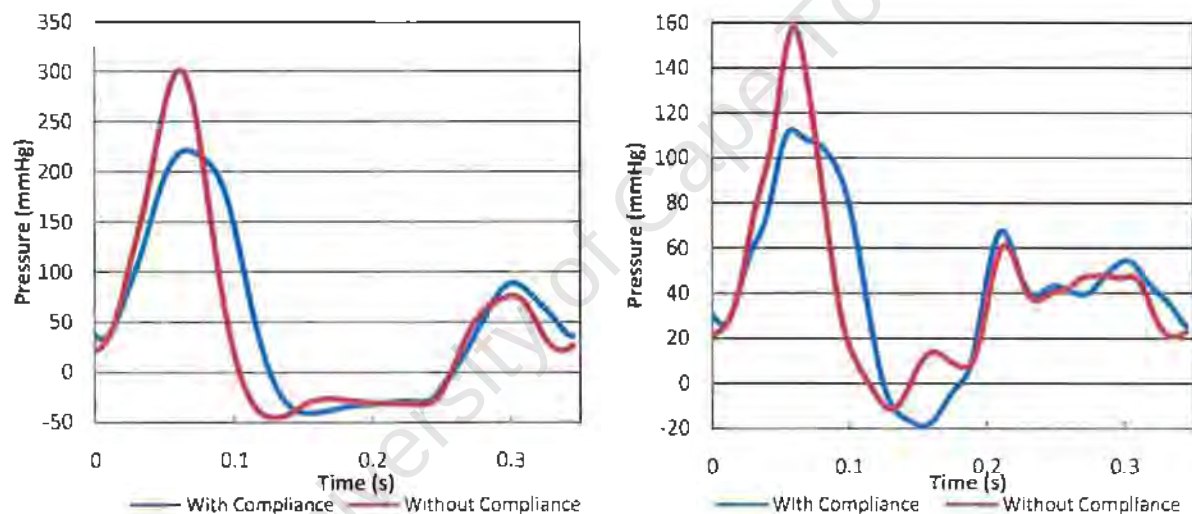


Figure 4.6.4 Pressure traces with and without ventricular compliance at 180BPM

Figure 4.6.4 shows a 30% decrease in ventricular and 26% in aortic pressure by making use of the extra ventricular compliance. This is a significant drop and will more accurately portray the valve lifespan by avoiding unusual high loads on the valves.

#### 4.6.4 Summary of added compliance

Adding compliance to the ventricle at high testing speeds reduced ventricular and arterial pressure spikes which could damage both the mitral and aortic valves. At low speeds the effect of spike reduction was not required and distorted the pressure curves. It is thus recommended to use the ventricular compliance at speeds greater than 120BPM.

In all the high speed tests in this chapter ventricular compliance was set up to achieve the best possible pressure traces.

#### 4.7 Concluding remarks

The testing fluid heats up at a rate of 2.2°C/min with no overshoot if the drive is running during heating. Fluid temperature makes little difference to the pressure traces

Physiological simulation is possible at speeds under 90BPM. At higher speeds the inertance and characteristic resistance alters the system impedance to the extent that the compliance and peripheral resistance are not able to compensate for the load change. Testing requirements for fatigue testing are however met up to the maximum speed of 230BPM. At higher speeds the spring was unable to maintain contact between the cam and cam follower.

Valve failure caused different effects at different speeds. At low speeds the arterial pressure dropped, whilst high speed failures caused a rise in ventricular pressure. The control software was able to detect both scenarios if set up correctly.

Ventricular compliance was introduced to compensate for a sharp spike in ventricular pressure during high speed tests. This compliance greatly reduced the spike without fundamentally affecting the pressure traces otherwise.

## Chapter 5

### Conclusions and Recommendations

#### 5.1 Introduction

This chapter highlights important conclusions from the design project and states recommendations for future development of the testing system. Conclusions and recommendations follow a similar progression to Chapters 3 and 4, starting with general notes followed by mechanical components, electrical components, software design and ending with valve testing.

## 5.2 Conclusions

Not all of the desired outcomes for the test apparatus were reached. Many of the problems were encountered due to the large operating speed range desired for the apparatus. Results at low speeds were close to the physiological norms and deviated as the speed was increased. Some of the simplifications of the Windkessel model of the arterial system play an increasing role as flow velocity increases. The Windkessel model is an electrical model and a hydrodynamic analogy inherently has complications as the model is translated from one-dimensional current flow to three-dimensional fluid flow.

### 5.2.1 Mechanical design

#### 1. Overall apparatus structure

The overall structure of the test apparatus was able to support and combine all the required components. If parts of the flow loop are to be redesigned, the overall structure may need to be altered to accommodate these changes.

#### 2. R, C and L components

The peripheral resistance had a sufficient range for physiological speeds. At higher speeds the pressure in the system was always higher than physiological standards. This is most likely caused by flow restrictions due to narrow pipe diameters in the section from the ventricle to the compliance chamber and the pipe from the compliance chamber to the fluid tank. Making fine adjustments of peripheral resistance was difficult as the ball valve did not allow for small adjustments.

The compliance chamber offered the correct range for C to be varied across a very large speed spectrum. The inlet and outlet were not put in line to accommodate the pipe returning flow to the reservoir. This could however have added resistance, deviating from the Windkessel model.

The inertance in the system was the largest source of error as speed increased. There was no way of changing it within the requirements of the apparatus, thus, as the testing speed increased, the inertance increased impedance and the waterhammer effect. The return flow from the compliance chamber to the reservoir added another impedance effect to the

system. Although negligible at low speeds, this could have played a major role in deviation from physiological impedance at high speed.

### 3. Drive system

The drive system was sufficient for the 50-230BPM testing speed range. Although the motor's low speed torque was not enough to drive the system reliably below 45BPM, these speeds will seldom be used. After the system has been modified to reduce pressure at high speeds to physiological values, the motor is capable of driving the system up to 400BPM.

The cam follower started losing contact with the cam at speeds above 300BPM. This was most likely due to the flow resistance from the reservoir to the ventricle.

#### 5.2.2 Electrical and electronic design

The electrical and electronic system performed as desired.

#### 5.2.3 Software design

The control and logging software fulfilled the requirements. The test apparatus was successfully controlled and data presented to the user and logged as required.

#### 5.2.4 Valve Testing

The testing fluid heats up at a rate of 2.2°C/min with no overshoot if the drive is running during heating.

Fluid temperature makes little difference to the pressure traces. Correct operating temperature remains important as forces on the valve leaflets as well as flexible leaflet material properties can change with fluid temperature.

Physiological simulation is possible at speeds under 90BPM.

Testing requirements for fatigue testing are met up to the maximum speed of 230BPM. At higher speeds the spring was unable to maintain contact between the cam and cam follower.

Valve failure caused different effects at different speeds. The control software was able to detect this if set up correctly.

Introducing ventricular compliance at high testing speeds lowers the large ventricular pressure spike without fundamentally affecting the pressure traces otherwise.

### 5.3 Recommendations

This section draws recommendation from the conclusion in Section 5.2. As the apparatus was to be focussed on fatigue testing, recommendations are aimed at improving high speed performance. This comes at the price of low speed performance and separate setups should be considered for high and low speed testing if both are to be achieved successfully. All the recommendations were considered but not implemented due to either time or workshop manufacturing constraints.

#### 5.3.1 Mechanical design

##### 1 Overall apparatus structure

Alterations to the overall apparatus structure may be required to accommodate changes in the flow loop.

##### 2. R, C and L components

Characteristic resistance  $R_c$  (the pipe section from the ventricle to the compliance chamber), and the minimum value of peripheral resistance  $R_p$  (the pipe section from the compliance chamber to the reservoir), should be minimised by making use of the largest diameter pipe practically possible. The distance from the ventricle to the compliance must be as short as possible and taper down from the ventricle to the aortic valve. This will drastically lower the inertance and resistance to flow and thus lower the pressure required in the ventricle to drive the system at high speeds. Figure 5.3.1 shows a cross section of the current setup as well as a proposed alteration where the narrow section length was reduced from 480 to 170mm and the section from the aortic valve to the compliance chamber reduced from 300 to 110mm. Changing the  $R_p$  resistance valve to another with finer adjustment resolution and the capability to be controlled electronically will greatly benefit fine-tuning apparatus operating conditions as well as total apparatus automation. The return from the compliance chamber to the reservoir and from the reservoir into the ventricle should also be of large diameter pipe to minimise resistance. The alterations in Figure 5.3.1 also allows both the

pressure transducers to be closer to the valve, thus giving more relevant readings as the pressure loss through the pipe section between the transducers is minimised. These changes will also reduce the inertance value of the flow loop, as well as reduce the effect as waterhammer.

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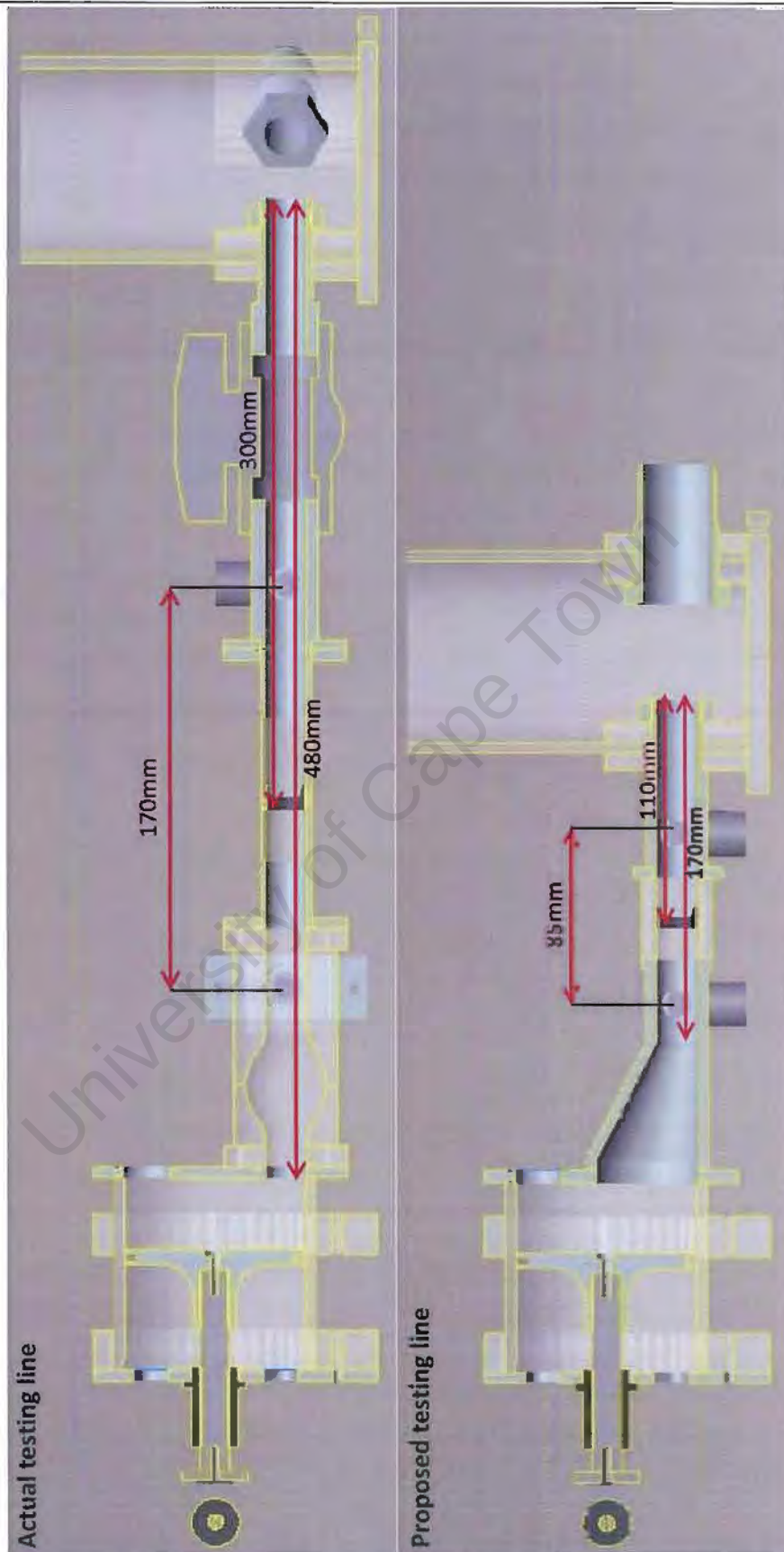


Figure 5.3.1 Current and proposed cross section between ventricles and compliance

Aligning the inlet and outlet of compliance chamber will reduce resistance and minimise wave rebound, also illustrated in Figure 5.3.1.

The compliance chamber does not need the plunger as varying compliance by means of water level adjustment is easier than adjusting the plunger. Adding a feature where compliance can be controlled via the control software would facilitate automation and simplify test procedures. This can be done by a small compressor regulating the air volume in the chamber.

Conducting a further investigation into the load variation over the speed range and linking the optimisation with the hydrodynamic analogy of the electronic Windkessel will help to improve the applied Windkessel model. This could include adding another inductor to the electrical analogy of the Windkessel model as in Figure 5.3.2 to closer represent the actual test apparatus and then optimising the load elements to closer match total impedance without the need to vary inductance.

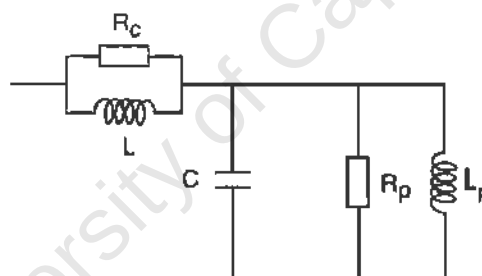


Figure 5.3.2 Proposed Windkessel

### 3. Drive system

If very low speeds are to be used frequently, the drive system must be modified to provide the required torque, either by changing the pulley ratio or by replacing the motor for one with a constant torque across its speed range.

The cam and follower design is ideal for accurate flow velocity control, however the increased piston momentum and energy required to return the piston at high speed was too much for the spring system. A crank system will eliminate this problem with the sacrifice of flow accuracy.

### **5.3.2 Electrical and electronic design**

The wiring for the other two testing channels and design electronics for the interface with automatic  $R_p$  and C adjustment instruments must be completed

### **5.3.3 Software design**

Further extend the software capabilities by:

Implementing code to identify each wave separately. This will improve data display and logging.

Improve the logging system to log continuously and detect changes during testing. If no change has occurred during a time period, the software can discard a portion of that data in order to save disk space whilst maintaining any important trends in the data.

Expand the software to encompass the control and monitor of the other two lines.

Including bearing lubrication interval calculations dependant on operating speed and inform user when lubrication is required.

### **5.3.4 Valve Testing**

By following the recommendations outlined above the speed range under which valves can be tested could be greatly extended.

## Chapter 6

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## Appendix A

### Mechanical Design

#### A.1 Introduction

This Appendix covers the mechanical design aspects not discussed in detail in the main document. These include the cam design and manufacture; force calculations; motor power and torque calculations; and piston diameter optimisation.

## A.2 Table of contents

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## A.5 Design and manufacture of cam

The driving cam profile was based on ventricular flow data from literature. The flow velocity from and into the ventricle can be given by the values in Table A.1 (Cochrane 1991) and illustrated in Figure A.1. The flow values in Table A.1 are expressed in terms of the maximum flow velocity. This enables the graph to be scaled if the pulse volume or heartbeat is to be changed. The curve formed by these segments was then integrated in Excel making use of the slope of the flow velocity graph to determine the ventricle volume, shown in Figure A.1. This, combined with the pressure characteristics discussed in Section A.6.1, led to the choice of a systole of 38% of the cycle.

| Segment | % of cycle | End Time (s) | % of maximum flow velocity |
|---------|------------|--------------|----------------------------|
| 1       | 12         | 0.10         | 100                        |
| 2       | 26         | 0.22         | 61                         |
| 3       | 38         | 0.32         | 0                          |
| 4       | 52         | 0.44         | -61                        |
| 5       | 68         | 0.58         | -64                        |
| 6       | 87         | 0.74         | 0                          |
| 7       | 100        | 0.85         | 0                          |

Table A.1 Segmentation of flow during single beat

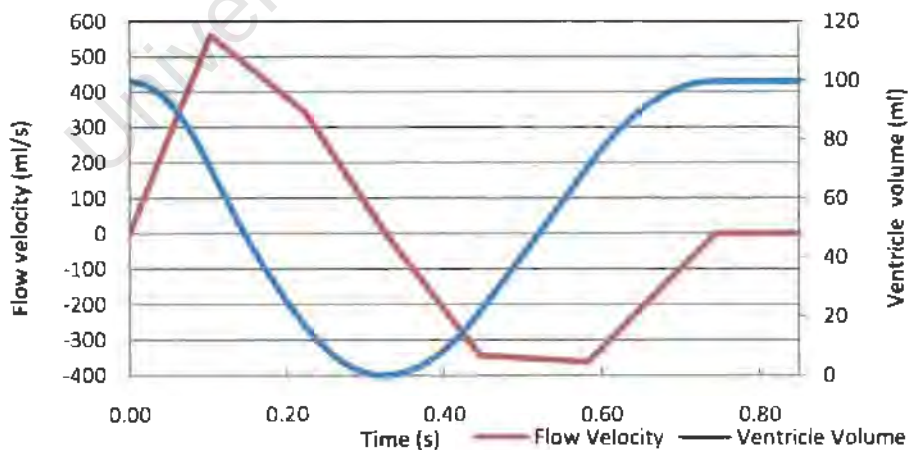


Figure A.1 Ventricular flow velocity and flow volume

The cam profile was then based on this volumetric flow and the ventricular piston cross sectional area. The piston diameter was optimised as explained in Section A.6 and was thus a

variable during initial cam design. Once the piston diameter was fixed the cam displacement profile was fixed and transposed onto the base diameter of 50mm as in Figure A.2.

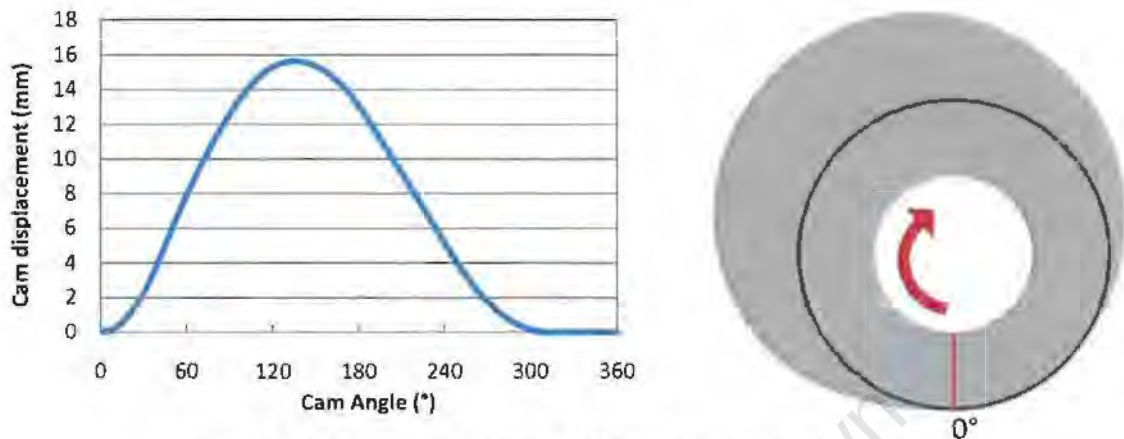


Figure A.2 Cam displacement and this transposed unto circular cam

The cam suffered damage after the first overnight run due to lack of lubrication and the M300 steel, of which it was made, being too soft. According to *IKO* specifications for their roller followers, a hardness of 30HRC is enough to avoid damage to the cam in the testing apparatus' loading conditions, assuming sufficient lubrication. The cam however ran unlubricated, causing it to be more prone to damage. A micro-indentation test on the cam showed a hardness of 28HRC. Consequently, the cam underwent heat treatment according to *Böhler Steel* specifications (BÖHLER Uderholm) at the UCT Centre for Materials Engineering. The treatment was done by a multi-phase process: the cam was placed in a preheated furnace at 400°C, was then heated to 1040°C and left at that for one hour. After this it was momentarily dipped in a salt bath preheated to 220°C and then quenched in oil. Following this it was placed in a preheated furnace at 200°C for an hour and then left to cool in air. The ultimate tempering hardness of 48HRC for M300 was obtained, as opposed to the original cam hardness of 28HRC. The apparatus then underwent several more long duration tests without further damage to the cam.

## A.6 Excel analysis of drive system

An Excel spreadsheet analysis was used to model forces and the power requirement of the drive system. This analysis was used to design and optimise the drive system.

### A.6.1 Excel analysis of cam forces

An Excel analysis was used to estimate the cam forces in one-degree angle intervals for a full rotation of the driveshaft. Calculations were based on the original specified speed of 1000BPM. The forces considered included: piston pressure; piston acceleration; piston friction; and return spring. The calculation and theory behind each force component is first discussed after which their combined effect on motor and piston diameter selection discussed.

#### 1. Force due to pressure on piston

During the piston forward stroke the pressure in the ventricle increases. In previous simulation studies (Cochrane 1991; McIlroy, Seitz and Targett 1986) the human ventricular pressure was simplified to a rise, plateau and drop for systole and a constant pressure assumed to be zero during diastole. This shape, shown in Figure A.3, was used and scaled for the maximum design pressure of 350mmHg instead of physiological values. The pressure during the cycle was calculated using the slope of this simplified model. The force due to the increased piston pressure during systole was obtained by Equation A-1.

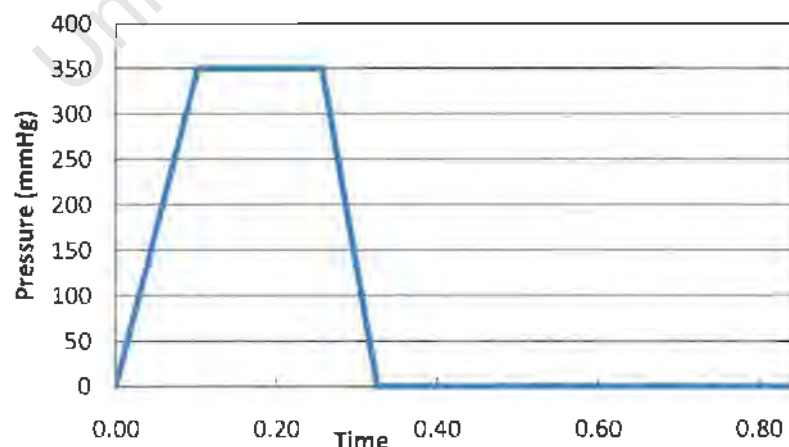


Figure A.3 Simplified ventricular pressure

$$F_{pres} = P \times A \quad (A-1)$$

Where  $F_{pres}$  is the force on the piston due to pressure in the piston in N;  $P$  is the pressure in Pa; and  $A$  is the piston cross sectional area in  $m^2$ .

Although the pressure in the human ventricle remains positive during diastole, the cylinder used as the ventricle in the test apparatus needed to draw fluid in from the reservoir through a pipe section and 90° elbow which yields resistance. The pump pressure inside the ventricle during diastole was thus assumed to average 30mmHg below gauge. This was later confirmed during testing when the ventricular pressure dropped to 40mmHg below gauge at times. The resulting force on the piston and thus on the cam due to the pressure is then given by Figure A.4.

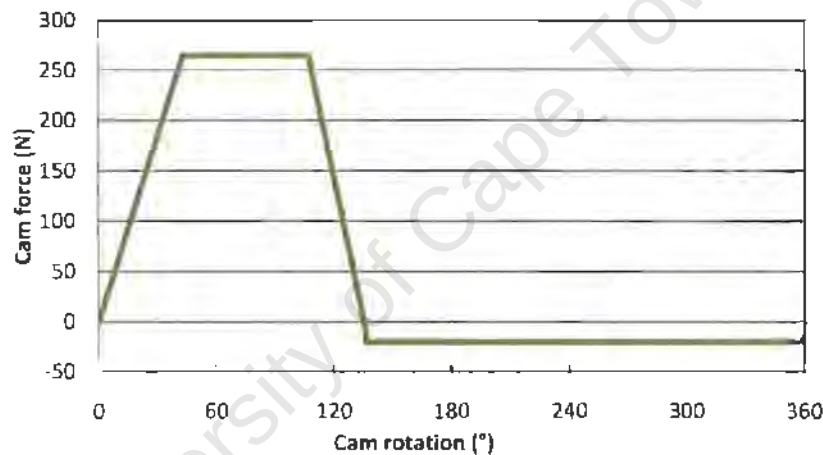


Figure A.4 Force on cam due to pressure

As the force due to pressure is related to cross sectional area, this force component played a role when optimising the piston diameter. This is further discussed in A.6.3.

## 2. Force required to accelerate piston

The reciprocating motion of the pump requires constant acceleration and deceleration of both the reciprocating components and fluid. Acceleration during a full cam revolution can be divided into four phases as in Table A.2.

| phase | Period   | Components       | Direction | Mass |
|-------|----------|------------------|-----------|------|
| 1     | Systole  | Piston and fluid | Positive  | 400g |
| 2     | Systole  | Piston           | Negative  | 300g |
| 3     | Diastole | Piston and fluid | Negative  | 400g |
| 4     | Diastole | Piston and fluid | Positive  | 400g |

Table A.2 Acceleration components

Acceleration values were obtained by differentiating the piston velocity curve, shown here with the resulting acceleration forces in Figure A.5. Acceleration force values were obtained by Equation A-2

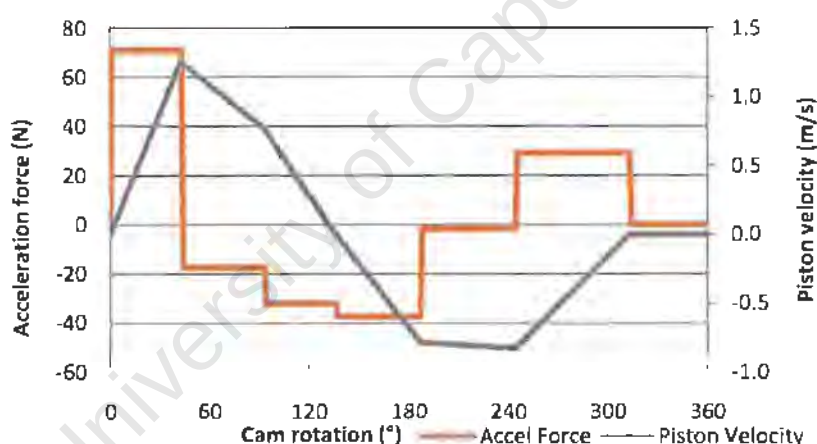


Figure A.5 Force on cam due to mass acceleration

$$F_{Acc} = m \times a \quad (A-2)$$

Where  $F_{Acc}$  is the force due to acceleration in N;  $m$  is the reciprocating mass in kg; and  $a$  is the acceleration in  $m/s^2$ .

As the ventricle diameter determines the stroke length and thus the piston speed, a larger piston diameter shortens the stroke and required less acceleration. This force component thus played a role when optimising the piston diameter. This is further discussed in A.6.3.

### 3. Force due to piston friction

Piston friction was estimated to be 60N opposing the direction of motion. The friction was however very dependent on the material used as a seal. The value of 60N was later confirmed for Viton o-rings by tests conducted on an *Instron* compression test apparatus. Due to trouble with the o-rings twisting in the groove and then locking up, the seal material was changed to Teflon. As the apparatus was already built by this stage and the fact that Teflon has a lower coefficient of friction than the Viton o-rings, the friction force in the Excel analysis was left as is.

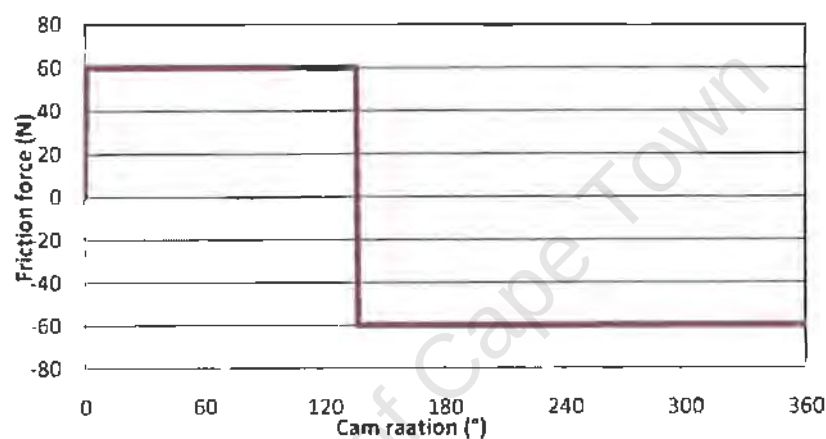


Figure A.6 Force on cam due to piston friction

#### 4. Force by piston return spring

The spring was designed to ensure that the cam follower remains on the cam. To accomplish this it was necessary for the resultant force unto the cam to always be positive. Spring force was calculated by Equation A-3 (Shigley, Mischke and Budynas 2004). It was found that a spring with a stiffness of 9kN/m and an initial offset of 15mm will ensure a minimum force of 55N onto the cam. This was 9% of the maximum cam force and was deemed enough to maintain contact.

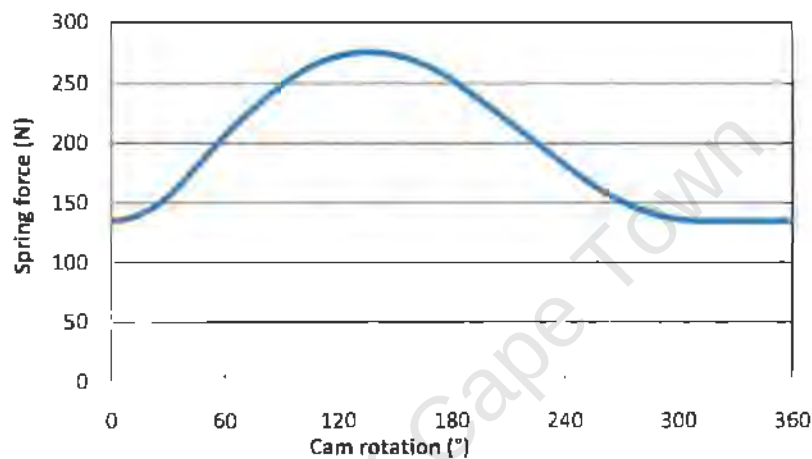


Figure A.7 Force on cam due to spring

$$F_{Spr} = k(x_{off} + x_{cam}) \quad (A-3)$$

Where  $F_{Spr}$  is the spring force in N;  $k$  is the spring stiffness constant in N/m;  $x_{off}$  is the spring offset distance in m; and  $x_{cam}$  is the cam displacement in m.

The spring was then designed according to Equation A-4 (Shigley, Mischke and Budynas 2004). The material used was standard EN45 springsteel. Design parameters to obtain a stiffness of 9kN/m are giving below in Equation A-4. Uncompressed length was 75mm. The spring was located on the linear bearing housing and compressed between the spacers and the cam follower housing as shown in Figure A.8.

$$k = \frac{d^4 G}{8D^3 N} \quad (A-4)$$

$$d = 3mm \quad D = 24mm \quad G = 77.2GPa \quad N = 6$$

Where  $k$  is spring stiffness constant in N/m;  $d$  the spring wire diameter in m;  $G$  the material shear modulus in Pa;  $D$  the inner spring diameter in m; and  $N$  the number of coils.

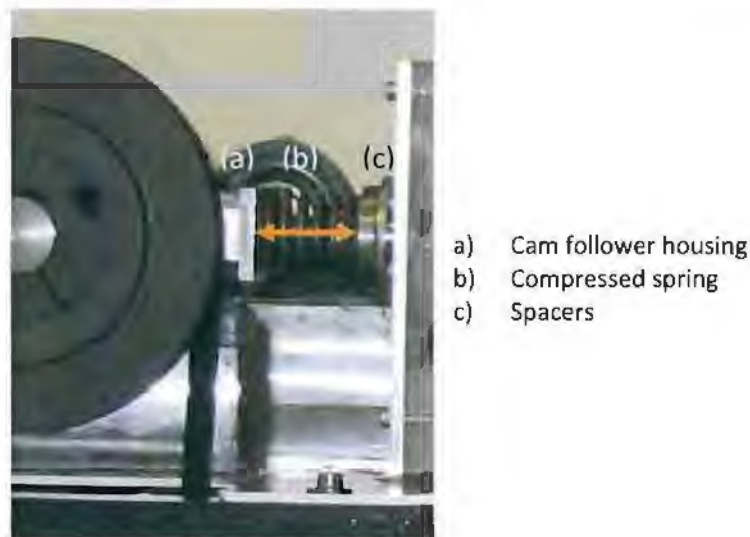


Figure A.8 Spring compressed between cam follower housing and spacers

### 5. Summary of forces

All the components contributing to the total force on the cam were then summed in order to design the spring, calculate motor requirements and optimise the piston. The summed forces are shown in Figure A.9 to give a perspective of the contribution of various forces.

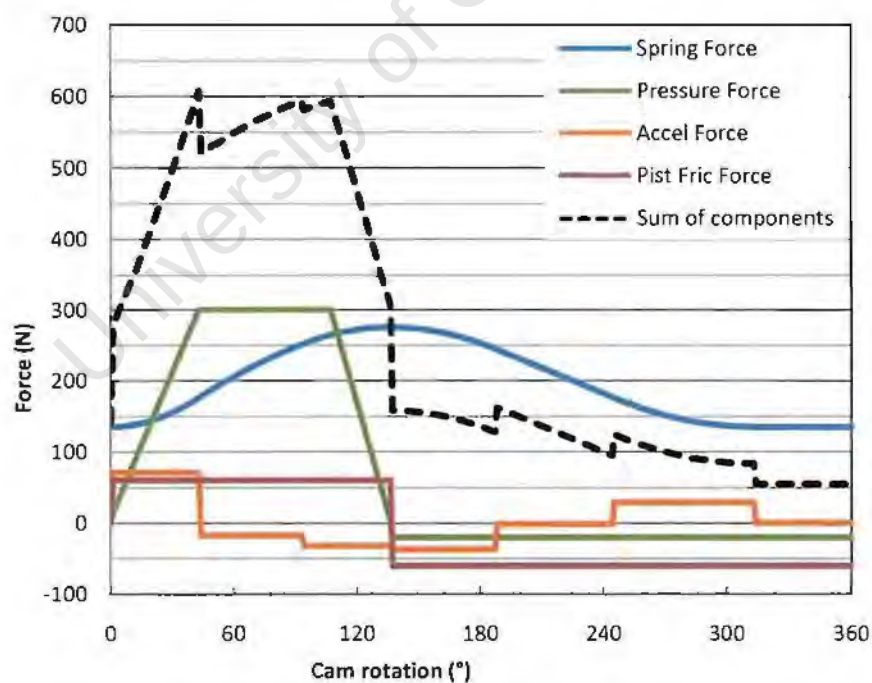


Figure A.9 Force components on the cam

### A.6.2 Excel analysis to calculate drive power requirements

In order to specify a motor to drive three testing lines the power requirement of three lines needed to be calculated. For this the work done against a force over a distance was calculated for each 1 degree increment of cam rotation by Equation A-5. Motor power was then calculated from Equation A-6 and the torque for each step obtained by Equation A-7 (Shigley, Mischke and Budynas 2004) The work, total cam force and torque for a single line was then copied by means of a *VLOOKUP* function and offset by 120° and 240° for the other two line. This comprised the total loading of the driveshaft.

$$W_i = F_{cam} \times (x_i - x_{i-1}) \quad (A-5)$$

$$P = \frac{W_{rev}}{t_{rev}} \quad (A-6)$$

$$T_i = \frac{P_i}{\omega} = \frac{W_i}{\omega \times t_i} \quad (A-7)$$

Where:

$i$  is timestep number

$P$  is total power in W

$P_i$  is power required for a timestep in W

$t$  is time for an entire revolution in s

$t_i$  is length of one timestep in s

$T_i$  is torque for a timestep in Nm

$W_i$  is work performed during a timestep in J

$W_{rev}$  is summed work for an entire revolution in J

$x_i$  is cam displacement at timestep  $i$  in m

### A.6.3 Optimising the piston diameter

The piston diameter affects the piston travel and thus the forces onto the cam. This was investigated to minimise both the required motor work as well as the total force unto the cam.

The built in *Solver* function was used to investigate the effect that piston diameter has on the total cam force. A 70mm diameter piston returned the lowest maximum cam force of 560N. The Solver was again used to investigate the effect of piston diameter, this time to investigate the effect on motor power requirements. A diameter of 200mm was reported to minimise the required motor power and torque. Table A.3 shows the effect of a transition from a small piston diameter to a large one.

|   | Diameter (mm) | Peak force (N) | Motor power (W) | Motor torque (Nm) |
|---|---------------|----------------|-----------------|-------------------|
| 1 | 70            | 560            | 420             | 9.2               |
| 2 | 90            | 610            | 340             | 6.5               |
| 3 | 150           | 1070           | 270             | 4.6               |
| 4 | 200           | 1700           | 260             | 4.2               |

**Table A.3 Effect of piston diameter on cam force and motor power**

The selection of a 90mm diameter was based on practicality and availability of materials. As the piston was to be made from Perspex to allow for inspecting for trapped air, material availability limited the outside diameter of the piston to 100mm. The smaller 70mm diameter was not chosen as the motor torque requirement was too high.

## A.7 References

- BÖHLER Uderholm *M300 Specification Sheet*, <[http://www.bohler-uddeholm.co.za/b\\_2566.htm](http://www.bohler-uddeholm.co.za/b_2566.htm)>.
- Cochrane, T 1991, 'Simple model of circulatory system dynamics including heart valve mechanics', *Journal of Biomedical Engineering*, vol. 12, pp. 335-40.
- McIlroy, M, Seitz, W and Targett, R 1986, 'A transmission line model of the normal aorta and its branches', *Cardiovascular Research*, vol. 20, pp. 581-7.
- Shigley, JE, Mischke, CR and Budynas, RD 2004, *Mechanical Engineering Design*, 7th edn, McGraw Hill.

## Appendix B

### Electrical Design and Calibration

#### B.1 Introduction

This Appendix covers the electrical design aspects not discussed in detail in the main document. This includes a detailed discussion of the electronic interface board as well as the calibration of various electronic components.

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**B.5 Electronic DAQ to testing apparatus interface**

For the DAQ to communicate with various apparatus components it was required to modify both input and output signal types and ranges. This was done by means of the electronic interface board (EIB), built on vari-board. From the interface board connections to the apparatus components was made by Molex connectors. The signal type modifications are listed in Table B.1 and connections in Table B.2 with numbered references in the photograph in Figure B.1 and the detailed schematic in Figure B.2.

|    | Apparatus component         | DAQ Signal  | Component Signal   | Method                     |
|----|-----------------------------|-------------|--------------------|----------------------------|
| a) | Motor controller Stop/Start | 5V DC Logic | 10V DC Logic       | ICL7667 Mosfet driver      |
| b) | Motor controller Speed      | 0-5V DC     | 0-10V DC           | LM358 non-inverting op-amp |
| c) | Pressure transducers        | 0-5V DC     | 4-20mA             | 300Ω resistors             |
| d) | Float switch                | 5V DC Logic | Open/closed switch | 2.2kΩ resistor             |

**Table B.1 DAQ signal modifications**

As each testing line is to have two pressure transducers, a total of six was required. Figure B.2 only shows the circuitry for one of these transducers, labelled (c). The other five connections are exactly the same.

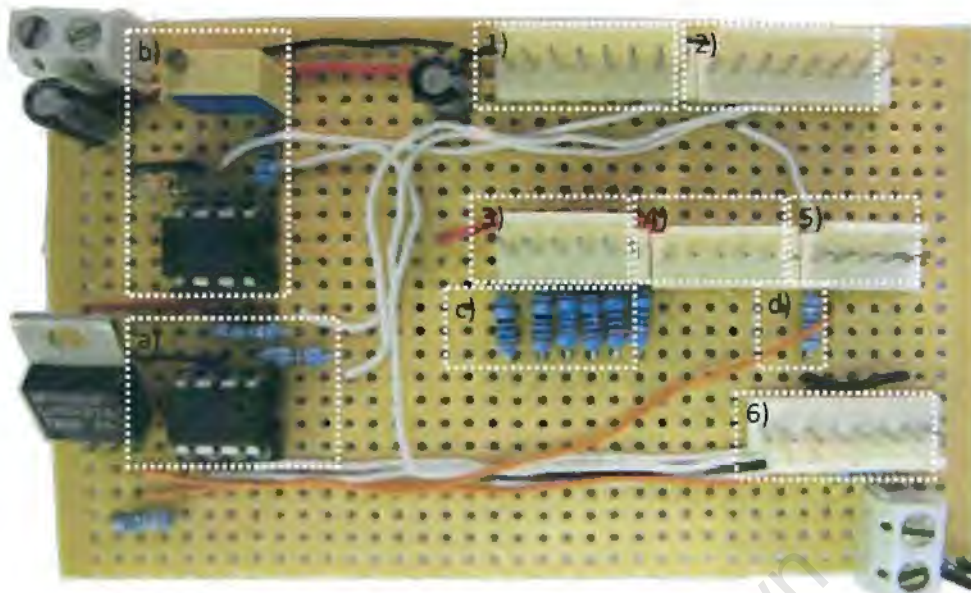


**Figure B.1 Photograph of Vari-Board electronics**

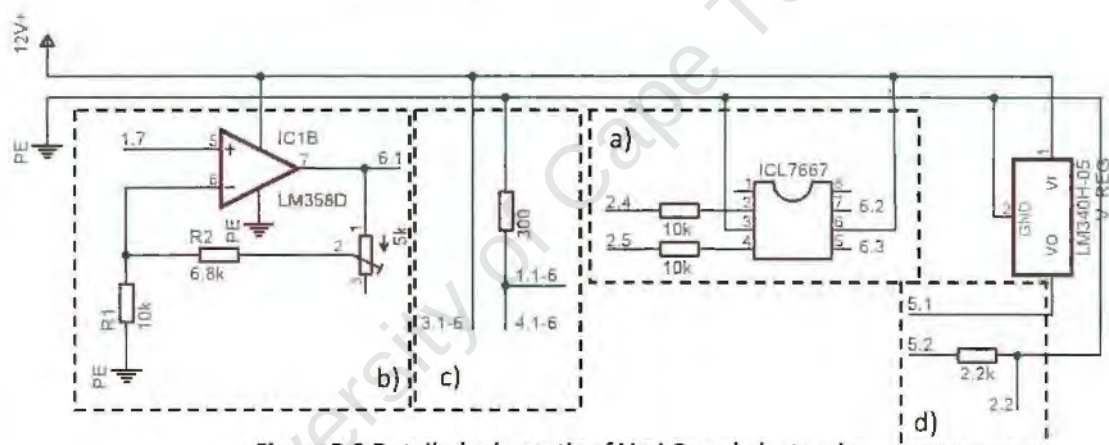


**Figure B.2 Detailed schematic of Vari-Board electronics**

|       | Line description            | Source     | Destination        | Signal       |
|-------|-----------------------------|------------|--------------------|--------------|
| 1.1-6 | Pressure transducers signal | EIB        | DAQ                | 0-5V DC      |
| 1.7   | Motor speed setting         | DAQ        | EIB Op-amp         | 0-5V DC      |
| 2.2   | Float switch                | EIB        | DAQ                | 5V DC Logic  |
| 3.1-6 | Pressure transducer power   | 12V Supply | Transducers power  | 12V          |
| 4.1-4 | Pressure transducer ground  | EIB Ground | Transducers ground | Ground       |
| 5.1   | Float switch power          | 5V Supply  | Float switch       | 5V DC        |
| 5.2   | Float switch ground         | EIB Ground | Float switch       | 5V DC        |
| 6.1   | Motor speed                 | EIB opamp  | Motor controller   | 0-10V DC     |
| 6.2   | Motor enable                | ICL7667    | Motor controller   | 10V DC Logic |
| 6.3   | Motor start                 | ICL7667    | Motor controller   | 10V DC Logic |

Table B.2 Molex interface

## B.6 Component calibration

Various components of the test apparatus required calibration. These included the motor speed setting circuitry; pressure transducer signal; and temperature controller constants. This section discusses these three calibration processes.

### B.6.1 Motor speed calibration

The motor is controlled by the SK Commander Motor Drive Unit. The drive unit configurations included minimum and maximum speed settings as well as motor speed ramp rates. The minimum speed was set to a final drive equivalent of 30BPM and the maximum to 400BPM. Speed is then varied between these two limits by a 0-10V DC signal. This signal is generated by the DAQ in the form of a 0-5V signal and then amplified with a non-inverting opamp with a fine tuning potentiometer as shown in Figure B.2 in block (b). The amplification of such an opamp circuit is given by Equation B-1 (Horowitz and Hill 2004).

$$G = \frac{R_1 + R_2 + R_v}{R_1} \quad (\text{B-1})$$

Where  $G$  is amplifier gain;  $R_1$  is 10k $\Omega$ ;  $R_2$  is 6.8k $\Omega$ ; and  $R_v$  is 0-5k $\Omega$

The gain range was thus 1.68-2.18. The potentiometer was used to obtain a gain of 2, tested by setting the motor speed to its maximum in the GUI and then measuring the voltage to the drive unit to be 10V

As there were several speed setting conversions from the GUI to the test apparatus, the accuracy of the speed control setting in the GUI needed to be verified. To do this a test was run at 120BPM and the data logged. The time elapsed for 7 consecutive beats was 3.57s as opposed to the expected 3.50s, thus the actual speed was 2% over the set speed.

### B.6.2 Pressure transducer calibration

The pressure transducers operate from a 12V supply with a 4-20mA signal for a pressure range of 0-100kPa. This had to be converted to a 0-5V signal for DAQ, and then to a pressure in mmHg in the software. As the apparatus was not designed to operate at over 80kPa the pressure range was modified to 0-80kPa to improve the DAQ resolution. This was done by routing the transducer current through a 340 $\Omega$  resistor. This resulted in the 4-20mA signal from the transducer producing a 1.2-6V for the DAQ.

This signal was sampled by a DAQ-assist in LabView. The scaling was done by Equation B-2, yielding a pressure Range from 0 to 750mmHg.

$$P_{mmHg} = 156.25P_V - 187.5 \quad (B-2)$$

Where  $P_{mmHg}$  is the pressure reported in the software in mmHg and  $P_V$  is the voltage from the signal conversion board in V.

### B.6.3 Temperature controller PID calibration

The Delta temperature controller features a built in auto-tuning for the PID constants. The auto-tune function was enabled with the drive running at 70BPM and the submersible agitation pump on and then left to complete the tuning. With the determined PID constants set and the drive running the temperature never overshoot the set temperature. The temperature was also limited to a maximum temperature setpoint of 45°C as a safety measure to avoid damage to the testing apparatus, the testing valve and to prevent the glycerol from burning.

### B.6.4 Reference

Horowitz, P and Hill, W 2004, *The Art of Electronics*, 3rd edn, Cambridge University Press.

## Appendix C

### Software Design

#### C.1 Introduction

This appendix covers the software design in detail with printouts of the main VI, all the Sub VIs designed for this project as well as description of all. The MatLab code used for optimising the load variables is also included and described

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## C.4 LabView code and descriptions

National Instruments' LabView is a visual programming language specifically designed for data acquisition and instrument control. It provides a platform for a stable graphical user interface and reliable communication with the DAQ and was thus used for the control and logging software.

All VIs consist of a front panel and a block diagram. The front panel contains the inputs and outputs to and from the VI. The block diagram is the functional connection and processing of the variables. The main VI's front panel serves as a graphical user interface (GUI) whilst SubVI front panels are not seen during program execution. This section is an in depth description, with screenshots, of the main VI and its major components and all SubVIs.

### C.4.1 Main VI and GUI: Valve Rig.vi

Figure C.1 shows a simplified flow chart of the main VI with the main program nodes. The numbered components in the flowchart correspond with the screenshot of the GUI and its block diagram.

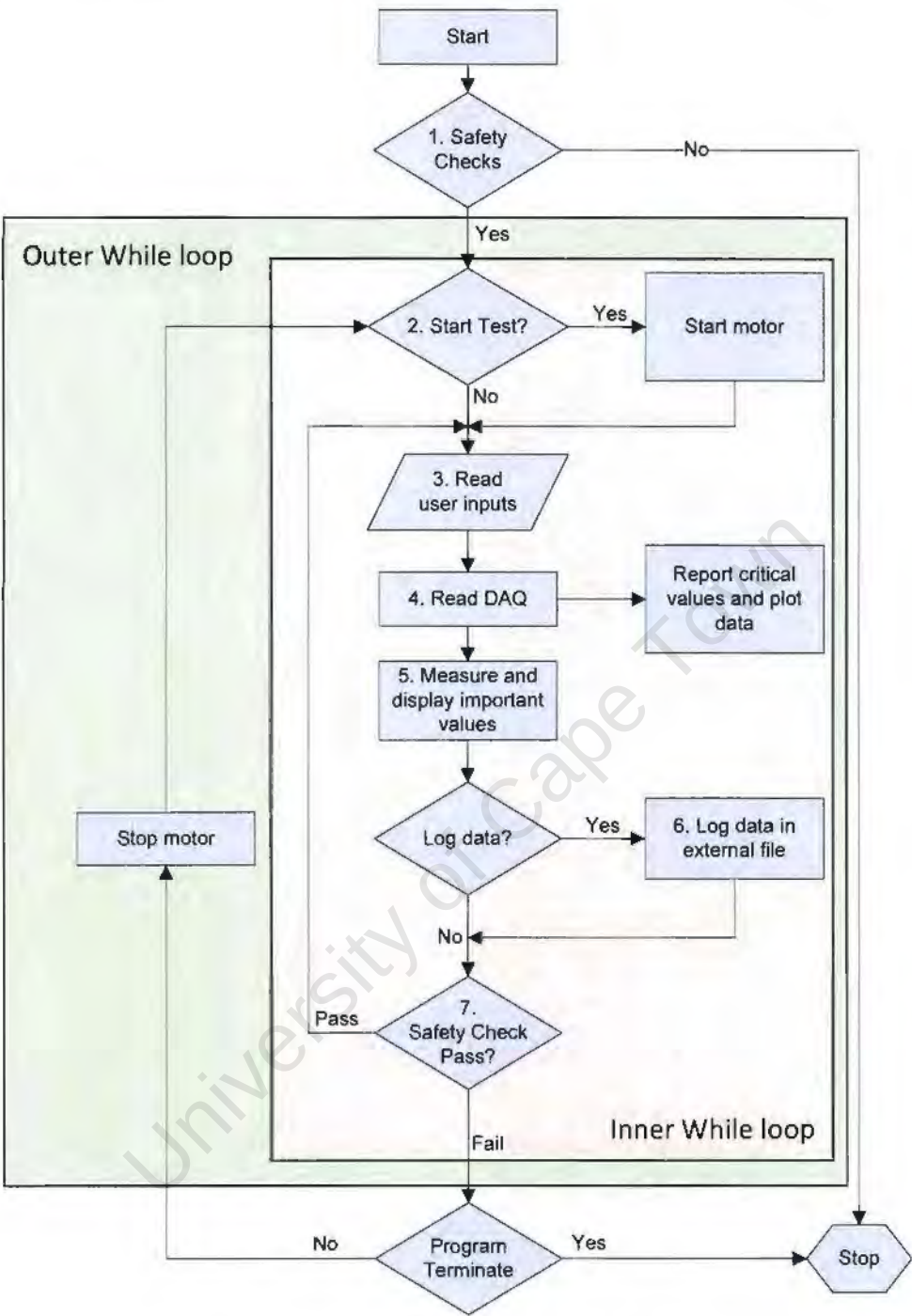


Figure C.1 Simplified flowchart of main LabView code

Through the graphical user interface (GUI) the user can adjust and monitor the test apparatus. Figure C.2 shows a screenshot of the GUI during operation. The numbered boxes refer to various sections discussed in the next section.

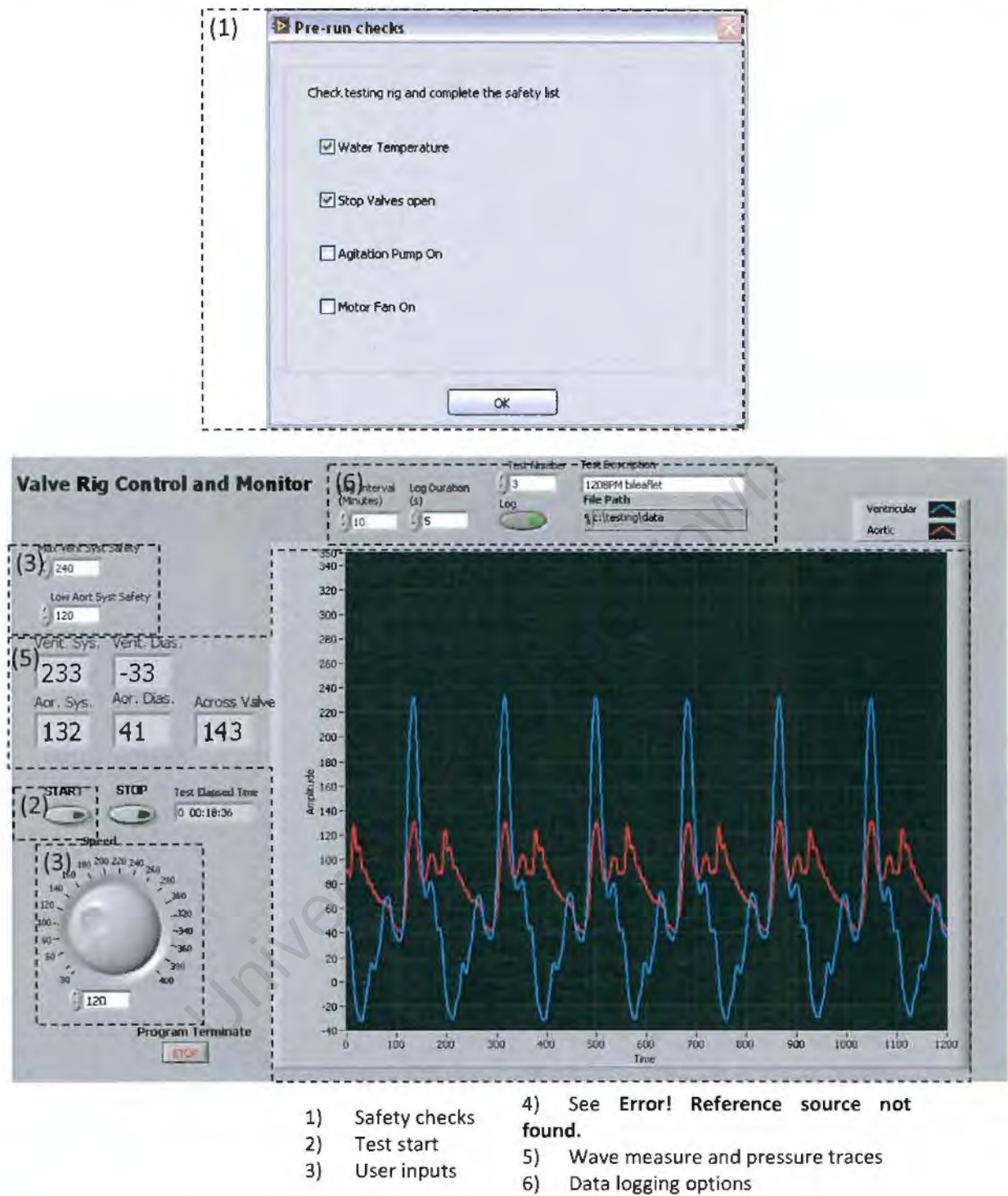


Figure C.2 Screenshot of main VI front panel, the graphical user interface



**Figure C.3 Screenshot of main VI block diagram**

### C.4.2 User checks

User checks are safety check performed and ticked off by the user. They include: water temperature; stop valves must be open; reservoir agitation must be operating; and the motor fan must be switched on. If all the tick boxes, shown in Figure C.2, are not completed the user is warned and the program does not execute, displaying the warning as shown in Figure C.4 below.

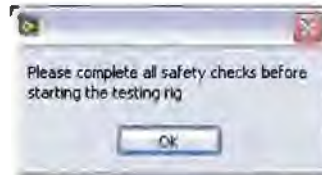


Figure C.4 Pre-run checks failed warning

After safety checks are completed the code enters the outer While loop until the program is terminated with the Stop button.

### C.4.3 Motor start

After the user safety checks have been completed testing is ready to commence. By pressing the Start button the motor is started at the speed set on the speed control knob. It is thus important to set the starting speed to a low setting when commencing new tests. When the motor is started the program enters the inner while loop which exits when a safety stop is executed (see C.4.8). The motor speed ramp is done by the SK Commander motor controller.

### C.4.4 User input

The user input includes the two safety pressure values; the speed control knob; and test start and stop buttons. These values can be adjusted during testing as they are read on each execution of the inner while loop.

### C.4.5 DAQ read: Pressure sampling.vi

The DAQ Read sub VI captured pressure and float switch data from the DAQ in one second durations and stores it in arrays. The data sampling rate per channel was dependent on operating speed and was determined by the piecewise Equation C-1. This implied 300 samples per simulated heart beat up to a speed of 200BPM where the maximum DAQ

sampling speed was reached. This sampling speed adjustment kept log file size down to a minimum at lower speeds whilst maintaining enough samples for accurate representation.

$$N_{S/s} = \frac{Speed_{BPM}}{60} \times 300 \quad \text{if } Speed_{BPM} < 200BPM$$

$$N_{S/s} = 1000 \quad \text{if } Speed_{BPM} \geq 200BPM \quad (C-1)$$

Where  $N_{S/s}$  is the number of samples per second

The pressure data is stored in a matrix whilst float switch data was exported in a separate array. Data is then sent to the Measure Sub VI (C.4.6); Logging SubVI (C.4.7) and to the Safety Stop SubVI (C.4.8).

The front panel receives as inputs the speed, filter, duration of test and any errors, as shown on the left of Figure C.5. It then returns the pressure wave matrix, float switch array, speed, sampling rate and error messages to the main VI, as shown on the right of Figure C.5. This SubVI also sets the motor speed.



Figure C.5 DAQ Read front panel

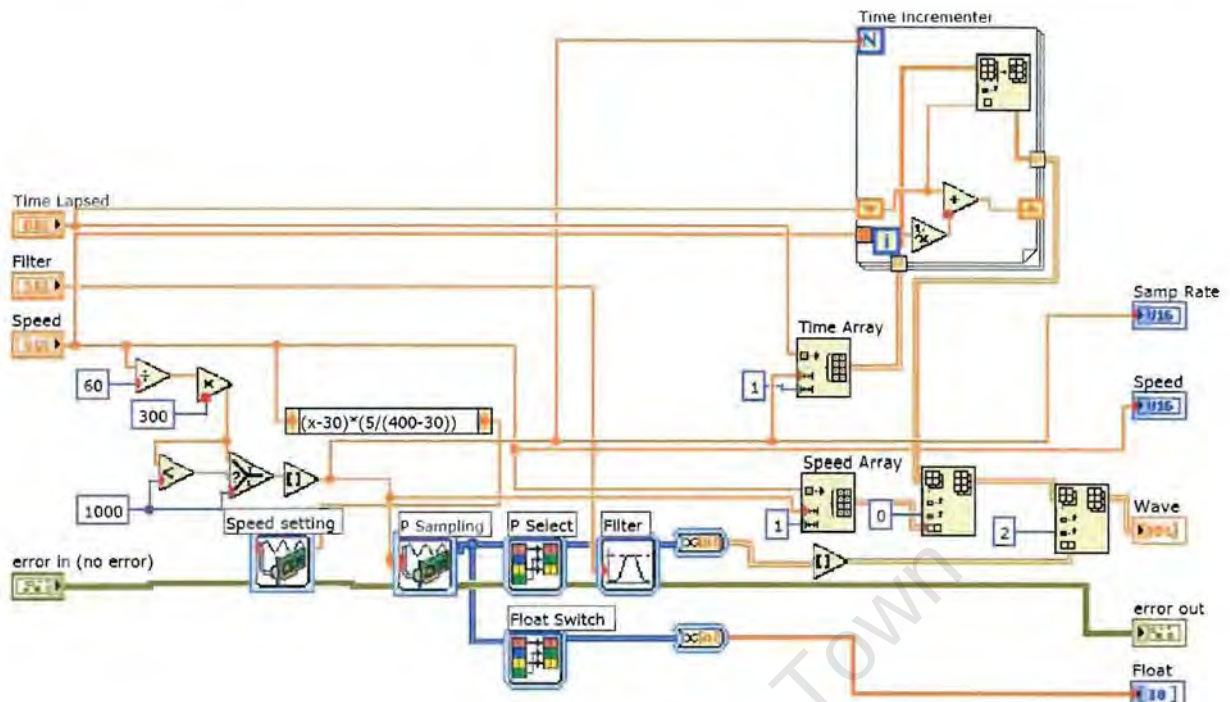


Figure C.6 DAQ Read block diagram

#### C.4.6 Trace measurements: Wave measure.vi

Various aspects of the pressure traces are important to monitor for setting up tests as well as for safety monitoring. These include the systolic and diastolic values of the ventricle and aorta, as well as the maximum aortic valve gradient. These are all reported in the GUI. This SubVI receives the wave matrix and outputs the measures as well as the wave matrix without the testing speed column ("Wave w/o speed" on front panel) in order for it to be plotted in the GUI.

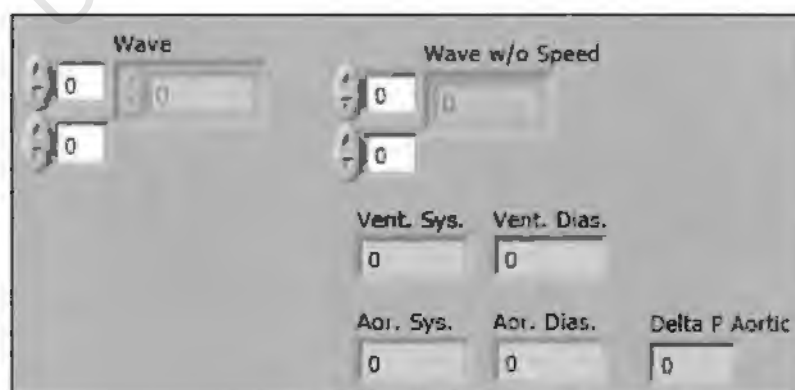


Figure C.7 Wave Measure front panel

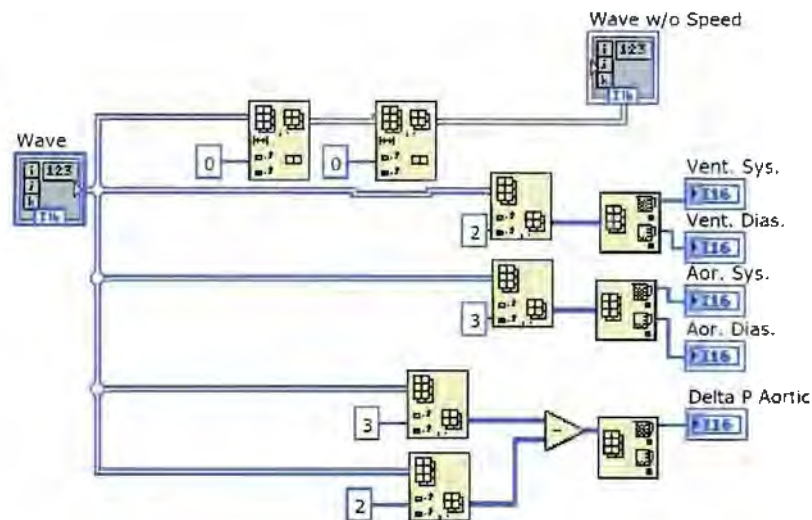


Figure C.8 Wave Measure block diagram

#### C.4.7 Data logging: Logger.vi

It is important to be able to log valve pressure data during tests in order to validate valve performance over time. Logging all pressure values continuously can be cumbersome and results in very large log files. To overcome this problem the logging section can be configured to log data in intervals for a set time period. The default time between log intervals is one minute and the default logging period for each interval is 60 seconds. The default will thus log continuously. Estimated file size for one minute of logging at 200BPM (for maximum sampling rate and thus the largest possible file) is 1.88MB. The logging software has also been configured to continue logging for 10 seconds after a safety stop in order to maintain the pressure trace after the stop.

All items on the front panel in Figure C.9 are inputs to the SubVI. It has no outputs back to the main program, only the output to a file.

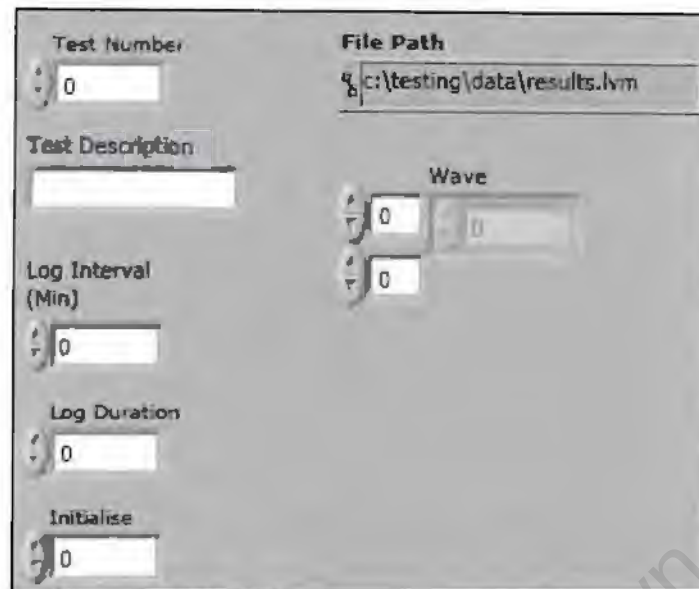


Figure C.9 Logger front panel

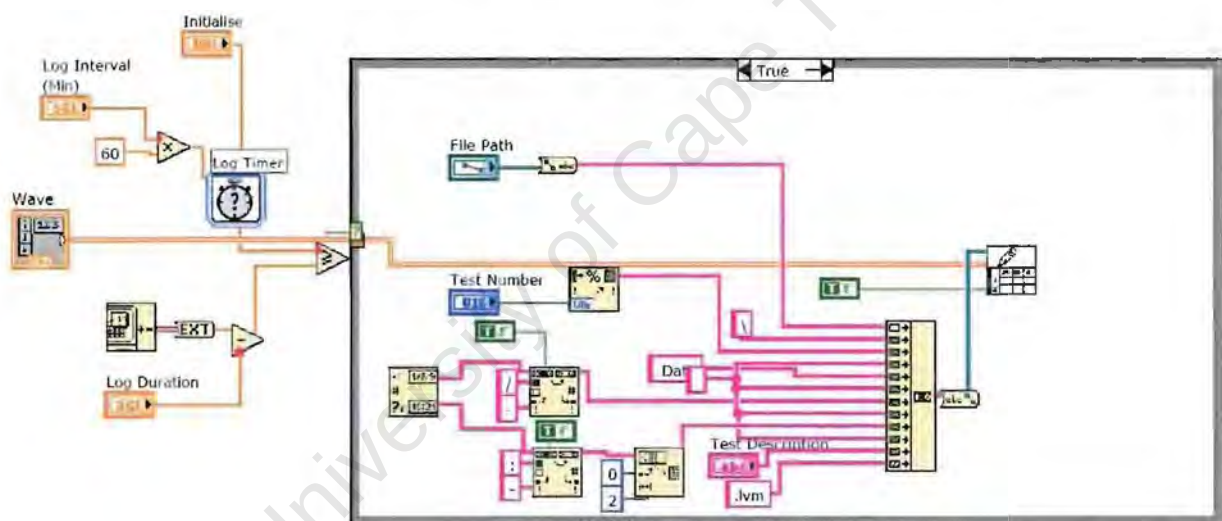


Figure C.10 Logger black diagram

#### C.4.8 Safety stops: Safety Checks.vi

Safety stops were put in place to prevent damage to the apparatus and the test valve. They include:

##### Ventricle over pressure:

Extracts maximum pressure in ventricle and compares with a setpoint. Stops the testing if maximum pressure exceeds setpoint. The default setpoint value is 250mmHg. This protects the mitral valve as it shuts when the pressure in the ventricle rises. Possible reasons for ventricular over pressure are increases in the resistive or compliance load or incorrect load

settings for the operating speed. This failsafe was also instrumental in detecting valve failures at high speeds.

**Aorta under pressure:**

Extracts maximum pressure in the aorta and compares it with a setpoint. Stops the testing if maximum pressure is below setpoint. The default value is 0mmHg as this failsafe must be set after the test has been fully configured and the pressure traces are stable. It is used only for detecting valve failure.

**Float switch:**

Monitors the fluid level in the tank and trips if the fluid drops below the float switch level, opening the float switch circuit and dropping the float switch value from 5V to 0V.

**Test Stop:**

User selects to stop the test.

All safety stops except, the Test Stop, display a warning message on the screen indicating the reason for the stop, the date and time of the stop as well as the test duration at time of the stop. Figure C.11 shows the Safety Stop front panel and Figure C.12 its block diagram



Figure C.11 Safety Stop front panel

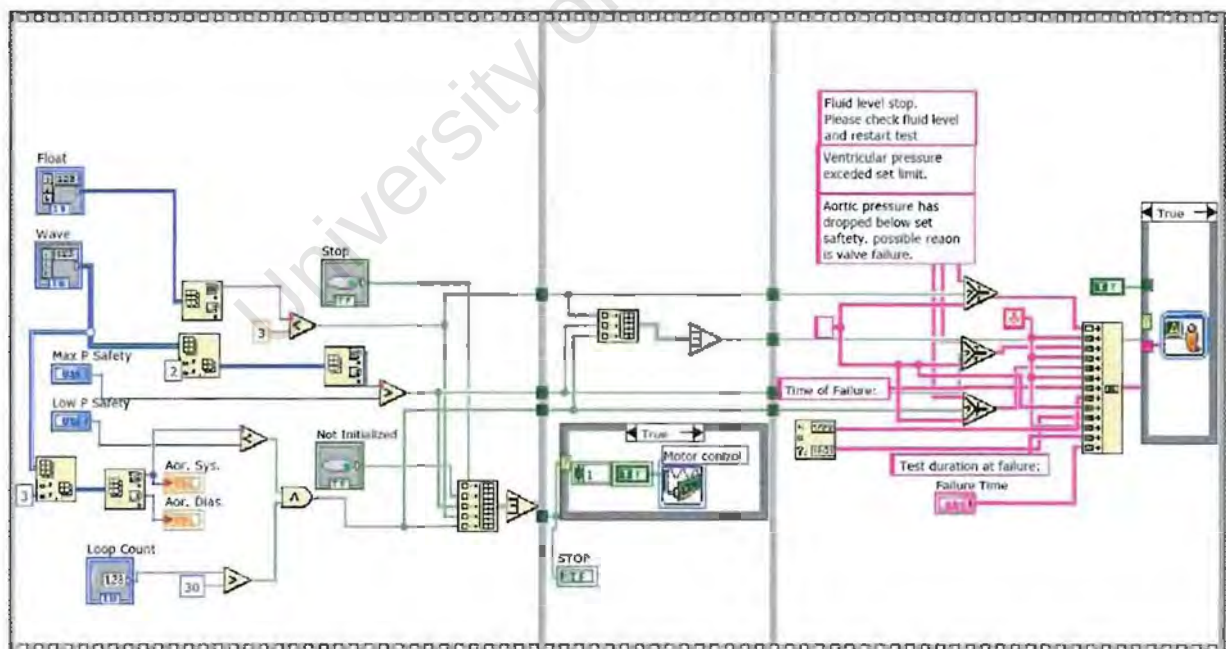


Figure C.12 Safety Stop black diagram

## C.5 Load optimisation software

In order to optimise arterial load on the heart pump across the initial operating speed range of 60 to 1000BPM the total impedance, governed by Equation C-2, was modelled in MatLab

$$Z = \frac{j\omega L R_c}{R_c + j\omega L} + \frac{R_p}{1 + j\omega R_p C} \quad (\text{C-2})$$

The effect of peripheral resistance ( $R_p$ ), compliance ( $C$ ) and inertance ( $L$ ) on the real and complex components of the impedance were investigated. These three load elements were then optimised across the speed range using a Nelder-Mead unconstrained nonlinear minimization algorithm (The MathWorks Inc) to attempt to match the fundamental frequency's impedance across the speed range to that at 60BPM. The starting point for the iterative solver was the impedance obtained by using the physiological values for  $C$ ,  $R_p$  and  $L$  obtained from various journals (Liu *et al.* 2006; Luo *et al.* 2007; Nitenberg 2003; Segers, Stergiopulos and Westerhof 2002; Stergiopulos, Westerhof and Westerhof 1999)

### C.5.1 Main program code: physload.m

This program defines all variables, optimises the load elements and plots the results as shown in the screenshot in Figure C.13

```
clear all
tic
%Set up load element parameters obtained from literature
Rp = 1.05;
Cp = 1.37;
L = 0.007;
Rc = 0.057;

%Define minimum, maximum and linearly spaced array from min to max speed
spd = 60;
spdAccMax = 1000;
spdvar = linspace(spd, spdAccMax, 60);

%Define constant and variable parameters and initialise arrays
param = [Rp Cp L Rc];
paramMod = [Rp Cp L];
paramConst = [Rc];

%%Vector for optimised load elements
paramVar = zeros(size(paramMod,2),size(spdvar,2));
%%Physiological load elements to 1st vector element
paramVar(:,1) = paramMod;
```

```

%%Vector for optimised impedance
Zmod = zeros(1,size(spdvar,2));
%%Vector for optimisation value
fval = zeros(1,size(spdvar,2));

%Load Calculation
%%Calculate impedance across speed range with unaltered load elements
Zunmod = loadcalc(param, spdvar);
%%Calculate impedance value to be compared to
Zmod(1) = loadcalc(param,spd);

%Load optimisation
optimise = @loadopt;

for step = 2:size(spdvar,2);
    %Optimise for the current speed array element with previous optimised
    variable as starting point
    [paramVar(:,step),fval(step)] = fminsearch(@(paramMod) ...
        optimise(paramMod, paramConst, spdvar(step), ...
        Zmod(1),paramVar(:,step-1)'));
    %Calculate load for newly optimised parameters
    Zmod(step) = loadcalc([paramVar(:,step); paramConst'],spdvar(step));
end;

%Plot optimised parameters as well as optimised and non-optimised loads
figure(1)
subplot(2,3,1), plot (spdvar,paramVar(1,:), 'b')
    title ('Rp over speed')
subplot(2,3,2), plot (spdvar,paramVar(2,:), 'r')
    title ('Cp over speed')
subplot(2,3,3), plot (spdvar,paramVar(3,:), 'g')
    title ('L over speed')
subplot(2,3,4), plot
    (spdvar,real(Zunmod),spdvar,imag(Zunmod),spdvar,abs(Zunmod)) ...
    title ('non-optimised Z over speed')
subplot(2,3,5), plot
    (spdvar,real(Zmod),spdvar,imag(Zmod),spdvar,abs(Zmod)) ...
    title ('optimised Z over speed')
    legend ('Real' , 'Imag', 'Abs');

```

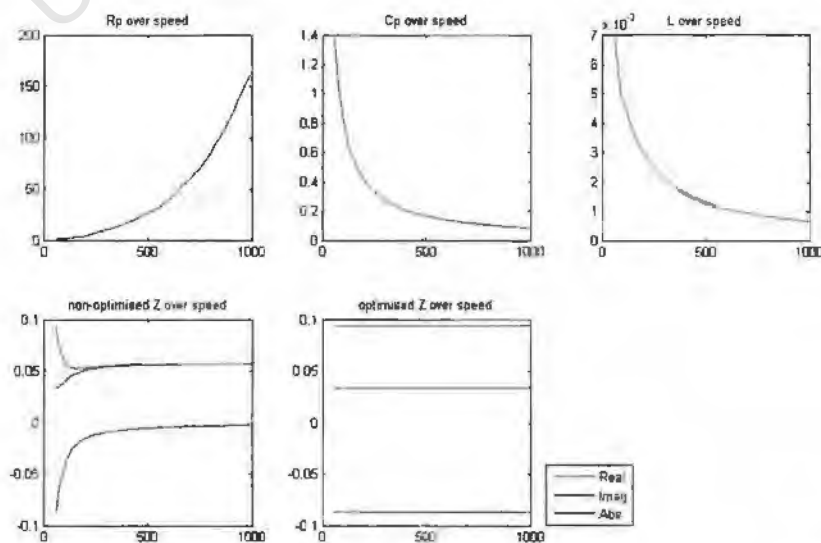


Figure C.13 Screenshot from optimisation plot

**C.5.2 Load optimisation function code: loadopt.m**

This is the function called by the multi-parameter minimisation function *fminsearch* built into MatLab. The value to be minimised is the difference between the original impedance vector and the optimised impedance vector. Since *fminsearch* is an iterative solver, *loadopt.m* is called repeatedly with updated load elements until the original and optimised impedance match.

```
%Function to calculate the factor to be minimised
function F = loadopt(paramMod,paramConst,spd, Z)

% Initialises the parameters
param = [paramMod paramConst];

%Calculate the load at input speed
ZAcc = loadcalc(param,spd);

%Calculate the difference in vector length between the desired load and
%the load obtained with the parameters being optimised
Diff = (real(Z)-real(ZAcc))^2+(imag(Z)-imag(ZAcc))^2;

%Prevent negative parameters by increases optimisation value by 10 if any
%parameters are negative.
if paramMod<0, F = Diff + 10;
else F=Diff;
end
```

**C.5.3 Load calculation function code: loadcalc.m**

This function calculates the impedance according to Equation 2 for a vector containing speed elements in BPM

```
%Function to calculate load when given load elements from Windkessel model
function Zout = loadcalc(param,spd)

%Assign variables
Rp = param(1);
Cp = param(2);
L = param(3);
Rc = param(4);

%Convert speed from BPM to rad/s
W = spd*pi/30;

%Calculate load for each element of speed matrix
for t = 1:size(W,2)
    Zout(t) = (j*W(t)*L*Rc)/(Rc+j*W(t)*L) + (Rp)/(1+j*Rp*W(t)*Cp) ;
end
```

## C.6 References

- Liu, Y, Allaire, P, Wu, Y, Wood, H and Olsen, D 2006, 'Construction of an Artificial Heart Pump Performance Test System', *Cardiovascular Engineering: An International Journal*, vol. 6-4, pp. 153-60.
- Luo, C, Ware, DL, Zwischenberger, JB and Jr, JWC 2007, 'Using a Human Cardiopulmonary Model to Study and Predict Normal and Diseased Ventricular Mechanics, Septal Interaction, and Atrio-Ventricular Blood Flow Patterns', *Cardiovascular Engineering: An International Journal*, vol. 7-2, pp. 17-31.
- Nitenberg, DCIAYLA 2003, 'Contribution of systemic vascular resistance and total arterial compliance to effective arterial elastance in humans', *American Journal of Physiology - Heart and Circulatory Physiology*, vol. 285, pp. H614-H20.
- Segers, P, Stergiopoulos, N and Westerhof, N 2002, 'Relation of effective arterial elastance to arterial system properties', *American Journal of Physiology - Heart and Circulatory Physiology*, vol. 282, pp. H1041-H6.
- Stergiopoulos, N, Westerhof, BE and Westerhof, N 1999, 'Total arterial inertance as the fourth element of the windkessel model', *American Journal of Physiology - Heart and Circulatory Physiology*, vol. 276, pp. 81-8.
- The MathWorks Inc, MATLAB® Documentation - fminsearch, viewed 05/11/2008, <[http://www.mathworks.com/access/helpdesk/help/techdoc/index.html?/access/helpdesk/help/techdoc/ref/fminsearch.html&http://www.mathworks.com/cgi-bin/texis/webinator/search\\_spt?db=MSS&prox=page&rorder=750&rprox=750&rdfreq=500&rwfreq=500&rlead=250&sufs=0&order=r&is\\_summary\\_on=1&pr=SPT&cq=1&collection=1&ResultCount=10&query=fminsearch&x=0&y=0](http://www.mathworks.com/access/helpdesk/help/techdoc/index.html?/access/helpdesk/help/techdoc/ref/fminsearch.html&http://www.mathworks.com/cgi-bin/texis/webinator/search_spt?db=MSS&prox=page&rorder=750&rprox=750&rdfreq=500&rwfreq=500&rlead=250&sufs=0&order=r&is_summary_on=1&pr=SPT&cq=1&collection=1&ResultCount=10&query=fminsearch&x=0&y=0)>.

## Appendix D

### Unit conversions

#### D.1 Introduction

This appendix gives a table for unit conversions between the three measuring standards used for flow studies pertaining to cardiovascular research. These are: the centimetre-grams-second (CGS) convention; the Standard International (SI) convention; and modern-day physiological standards. Only units pertaining to the design project were considered.

## D.2 Table of unit conversions

| Measure    | Symbol                           | CGS units                                                 | SI Units                                           | Physiological units             | SI → CGS                                                | SI → Physiological                                                          |
|------------|----------------------------------|-----------------------------------------------------------|----------------------------------------------------|---------------------------------|---------------------------------------------------------|-----------------------------------------------------------------------------|
| Length     | $l$                              | $cm$                                                      | $m$                                                | $cm$                            | $1m = 100cm$                                            | $1m = 100cm$                                                                |
| Volume     | $v$                              | $cm^3$                                                    | $m^3$                                              | $ml$                            | $1m^3 = 1 \times 10^6 cm^3$                             | $1m^3 = 1 \times 10^6 ml$                                                   |
| Mass       | $m$                              | $g$                                                       | $kg$                                               | $g$                             | $1kg = 1000g$                                           | $1kg = 1000g$                                                               |
| Density    | $\rho$                           | $\frac{g}{cm^3}$                                          | $\frac{kg}{m^3}$                                   | $\frac{g}{ml}$                  | $1 \frac{kg}{m^3} = 0.001 \frac{g}{cm^3}$               | $1 \frac{kg}{m^3} = 0.001 \frac{g}{ml}$                                     |
| Viscosity  | $\mu$                            | $Poise = \frac{Dyne \cdot s}{cm^2}$                       | $\frac{N \cdot s}{m^2} = Pa \cdot s$               | $mmHg \cdot s$                  | $1 \frac{N \cdot s}{m^2} = 10 Poise$                    | $1 Pa \cdot s = 0.0075 mmHg \cdot s$                                        |
| Force      | $F$                              | $Dyne = \frac{g \cdot cm}{s^2}$                           | $N = \frac{kg \cdot m}{s^2}$                       | $Dyne = \frac{g \cdot cm}{s^2}$ | $1N = 10^5 Dyne$                                        | $1N = 10^5 Dyne$                                                            |
| Pressure   | $P$                              | $\frac{Dyne}{cm^2}$<br>$= \frac{g}{cm \cdot s^2}$         | $Pa = \frac{N}{m^2}$<br>$= \frac{kg}{m \cdot s^2}$ | $mmHg$                          | $1Pa = 10 \frac{Dyne}{cm^2}$                            | $1Pa = 0.0075 mmHg$                                                         |
| Resistance | $R = \frac{8\mu \cdot l}{\pi^4}$ | $R = \frac{Poise}{cm^3}$<br>$= \frac{Dyne \cdot s}{cm^3}$ | $R = \frac{Pa \cdot s}{m^3}$                       | $\frac{mmHg \cdot s}{ml}$       | $1 \frac{Pa \cdot s}{m^3} = 10^{-5} \frac{Poise}{cm^3}$ | $1 \frac{Pa \cdot s}{m^3} = 7.5 \times 10^{-9} \frac{mmHg \cdot s}{ml}$     |
| Inertance  | $L = \frac{\rho}{Area} l$        | $\frac{g}{cm^4}$                                          | $\frac{kg}{m^4} = \frac{Pa \cdot s^2}{m^3}$        | $\frac{mmHg \cdot s^2}{ml}$     | $1 \frac{kg}{m^4} = 10^{-5} \frac{g}{cm^4}$             | $1 \frac{Pa \cdot s^2}{m^3} = 7.5 \times 10^{-9} \frac{mmHg \cdot s^2}{ml}$ |
| Compliance | $C = \frac{3\pi r^3}{2Eh} l$     | $\frac{cm^5}{Dyne}$                                       | $C = \frac{m^3}{Pa}$                               | $\frac{ml}{mmHg}$               | $1 \frac{m^3}{Pa} = 10^5 \frac{cm^5}{Dyne}$             | $1 \frac{m^3}{Pa} = 133.3 \times 10^6 \frac{ml}{mmHg}$                      |

(Beneken and Bergel 1972; Milnor 1989; Rideout and Dick 1967; Sheffer, Santamore and Barnea 2007)

### D.3 References

Beneken, JEW and Bergel, DH 1972, Cardiovascular Fluid Dynamics: Some computer Models in Cardiovascular Research, vol. 1, 2 vols., Academic Press.

Milnor, WR 1989, Hemodynamics, Second edn, Williams & Wilkins.

Rideout, VC and Dick, DE 1967, 'Difference-Differential Equations for Fluid Flow in Distensible Tubes', IEEE Transactions on Biomedical Engineering, vol. BME-14, no. 3, pp. 171-7.

Sheffer, L, Santamore, WP and Barnea, O 2007, 'Cardiovascular Simulation Toolbox', Cardiovascular Engineering: An International Journal, vol. 7-2, pp. 81-8.

## Appendix E

### Drawings

#### E.1 Introduction

All the parts required for the test rig was modelled in ProEngineer WildFire 3 and manufactured by the UCT Mechanical Engineering workshop or laser cut at Vulcan Steel. For the manufacturing all parts were represented in two dimensional drawings. This section includes various significant assembly drawing as well as drawings of single components. Section D.2 and D.3 gives a list of all the drawings included in this Appendix.

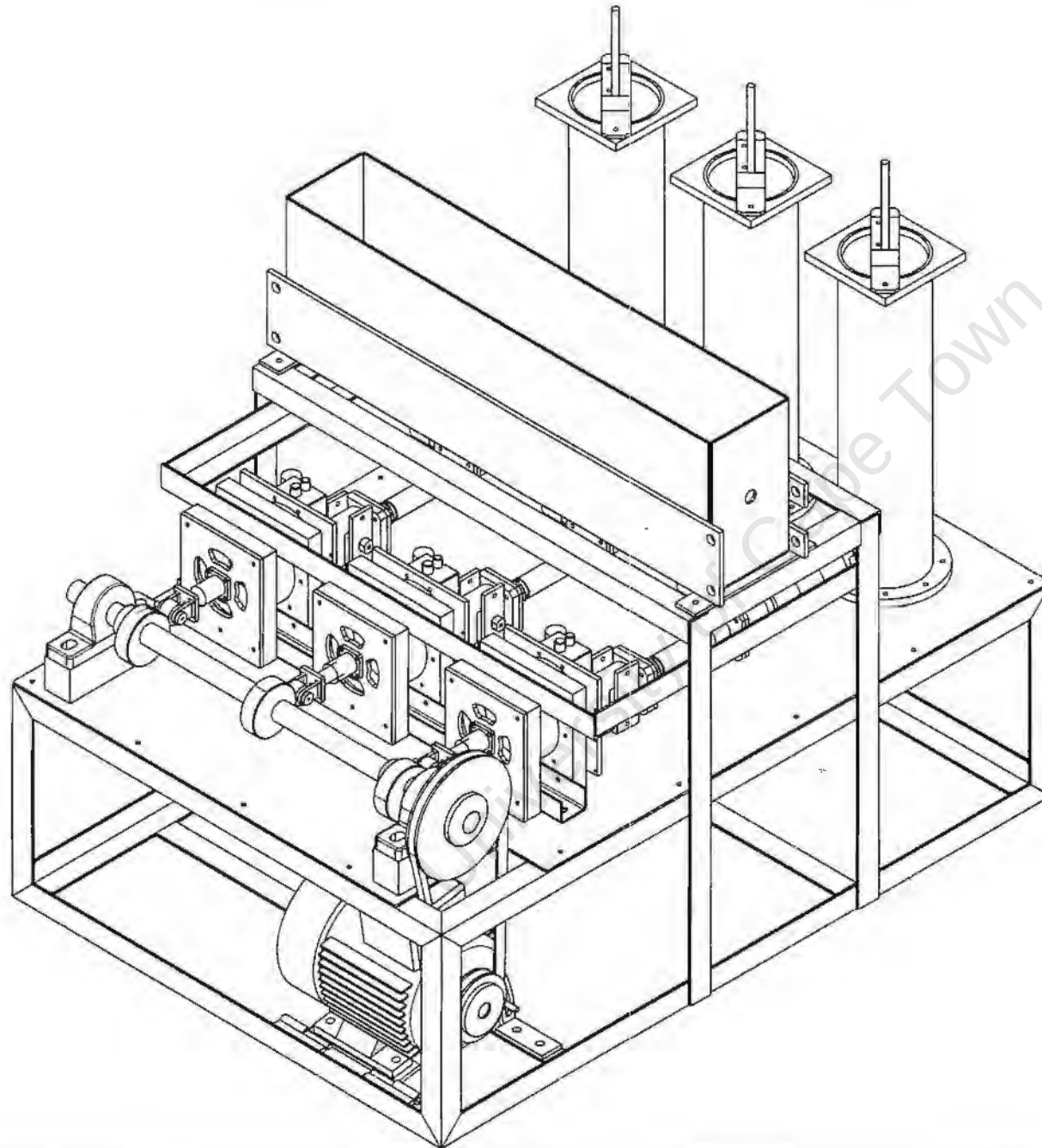
## E.2 List of assembly drawings

| Page | Drawing # | Name                       | Scale |
|------|-----------|----------------------------|-------|
| 1    | ASM_00_01 | Full Rig: Isometric        | 0.15  |
| 2    | ASM_00_02 | Full Rig: Front And Top    | 0.15  |
| 3    | ASM_01_01 | Frame Base                 | 0.15  |
| 4    | ASM_01_02 | Frame With Bracing         | 0.15  |
| 5    | ASM_02_01 | Testing Line               | 0.35  |
| 6    | ASM_02_02 | Piston To Follower         | 1     |
| 7    | ASM_02_03 | Heart And Piston Assembly  | 1     |
| 8    | ASM_02_04 | Flow Rectifier             | 1     |
| 9    | ASM_02_05 | Prox Transducer Mount      | 1     |
| 10   | ASM_02_06 | Tube Clamp (Flow Reg Plate | 1     |
| 11   | ASM_02_07 | Dist Transducer Mount      | 1     |
| 12   | ASM_02_08 | Compliance Chamber Explode | 0.35  |
| 13   | ASM_02_09 | Compliance Plunger         | 1     |
| 14   | ASM_02_10 | Ventricular Compliance     | 1     |
| 15   | ASM_03_01 | Driveshaft Spacing         | 0.4   |
| 16   | ASM_04_01 | Motor Hinge Mount          | 0.5   |
| 17   | ASM_04_02 | Motor Mount Spacing        | 0.3   |
| 18   | ASM_04_03 | Hinge Male                 | 1     |
| 19   | ASM_04_04 | Hinge Femal                | 1     |
| 20   | ASM_04_05 | Slot Left                  | 1     |
| 21   | ASM_04_06 | Slot Right                 | 1     |
| 22   | ASM_04_07 | Slot Pin                   | 1     |

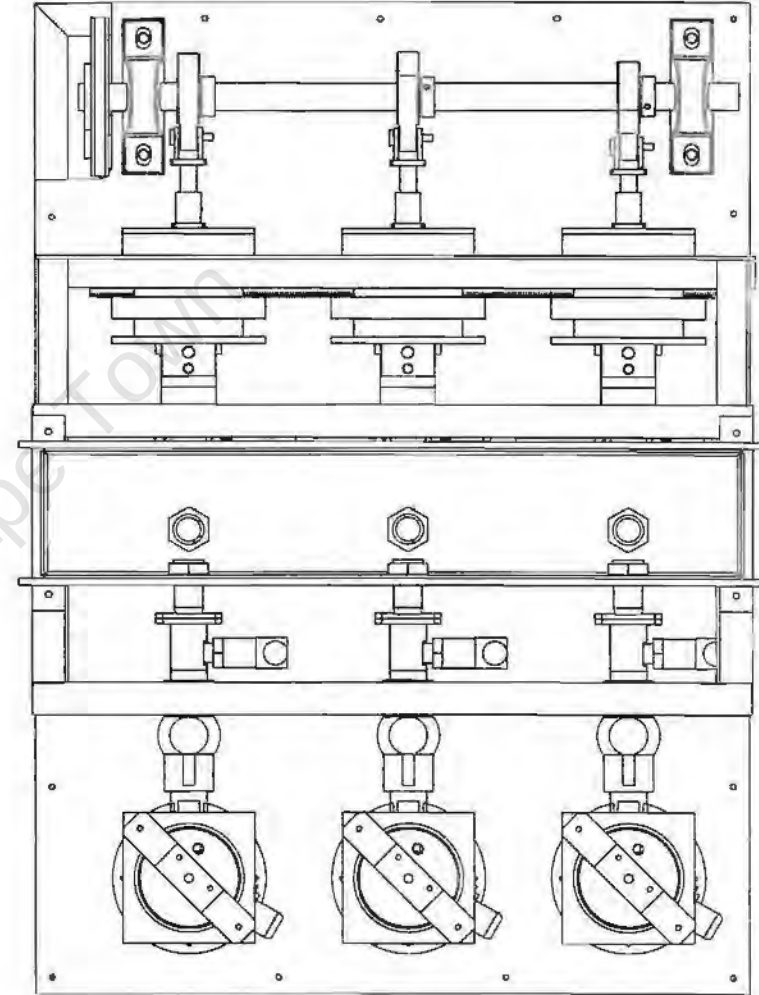
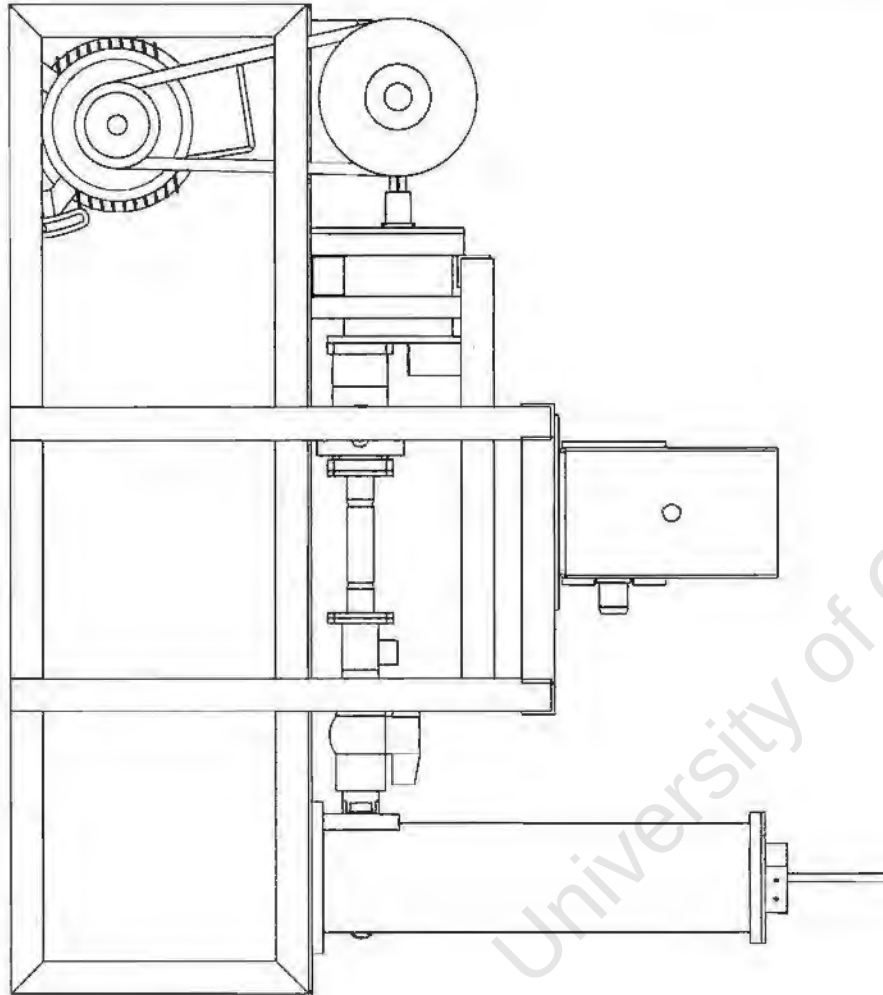
## E.3 List of part drawings

| Page | Drawing # | Name                    | Scale |
|------|-----------|-------------------------|-------|
| 23   | PRT_01    | Ventricle Front Flange  | 0.75  |
| 24   | PRT_02    | Ventricle Rear Flange   | 0.75  |
| 25   | PRT_03    | Ventricle Cylinder      | 1     |
| 26   | PRT_04    | Ventricle Sealing Plate | 0.5   |
| 27   | PRT_08    | Compliance Plunger Nut  | 1     |
| 28   | PRT_09    | Ball Valve Interface    | 1     |
| 29   | PRT_10    | Perspex Flange          | 1     |
| 30   | PRT_11    | Prox Flow Expansion     | 1     |
| 31   | PRT_12    | Dist Flow Contraction   | 1     |
| 32   | PRT_13    | Transducer Clamp        | 1     |
| 33   | PRT_15    | Optical Scope Port      | 1     |
| 34   | PRT_16    | Aluminium Flange 1      | 1     |
| 35   | PRT_18    | Compliance Cylinder     | 0.4   |
| 36   | PRT_19    | Compliance Base         | 0.75  |
| 37   | PRT_20    | Compliance Mount Ext 1  | 1     |
| 38   | PRT_21    | Compliance Top Flange   | 0.75  |

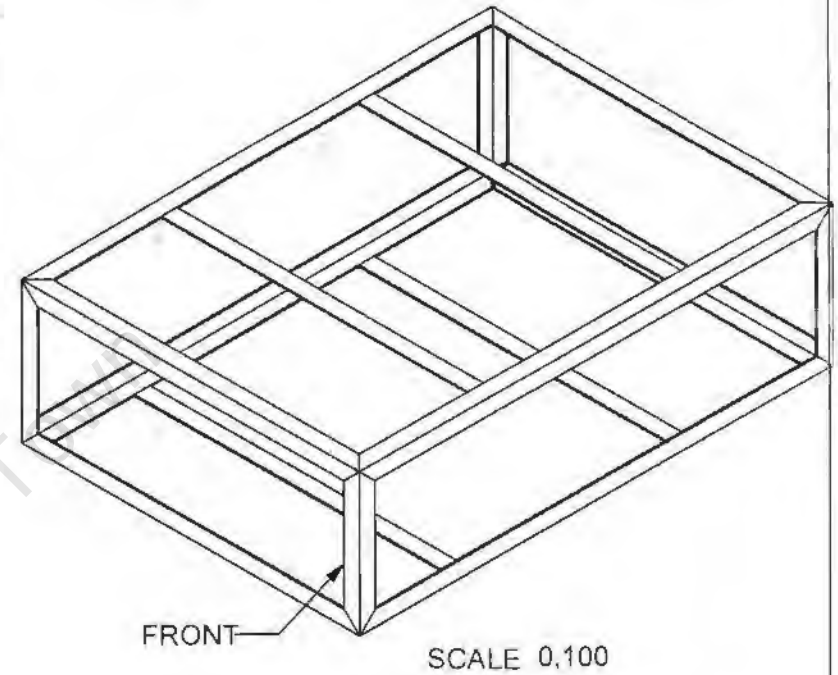
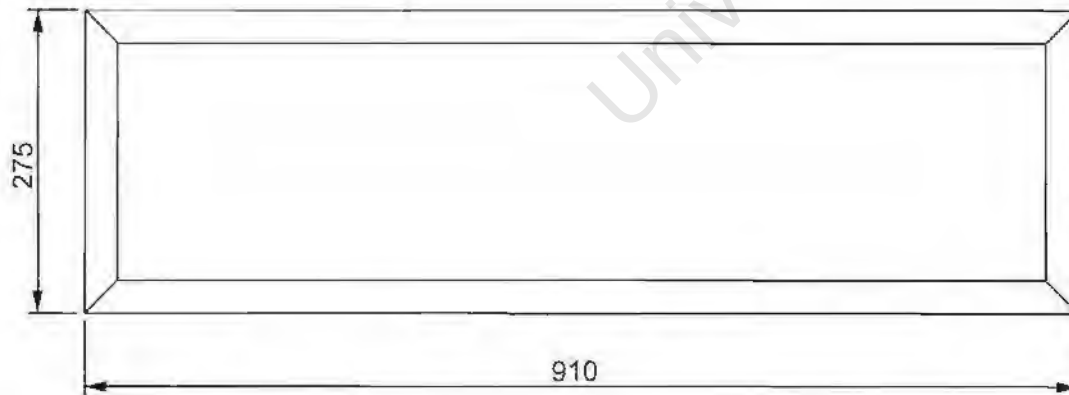
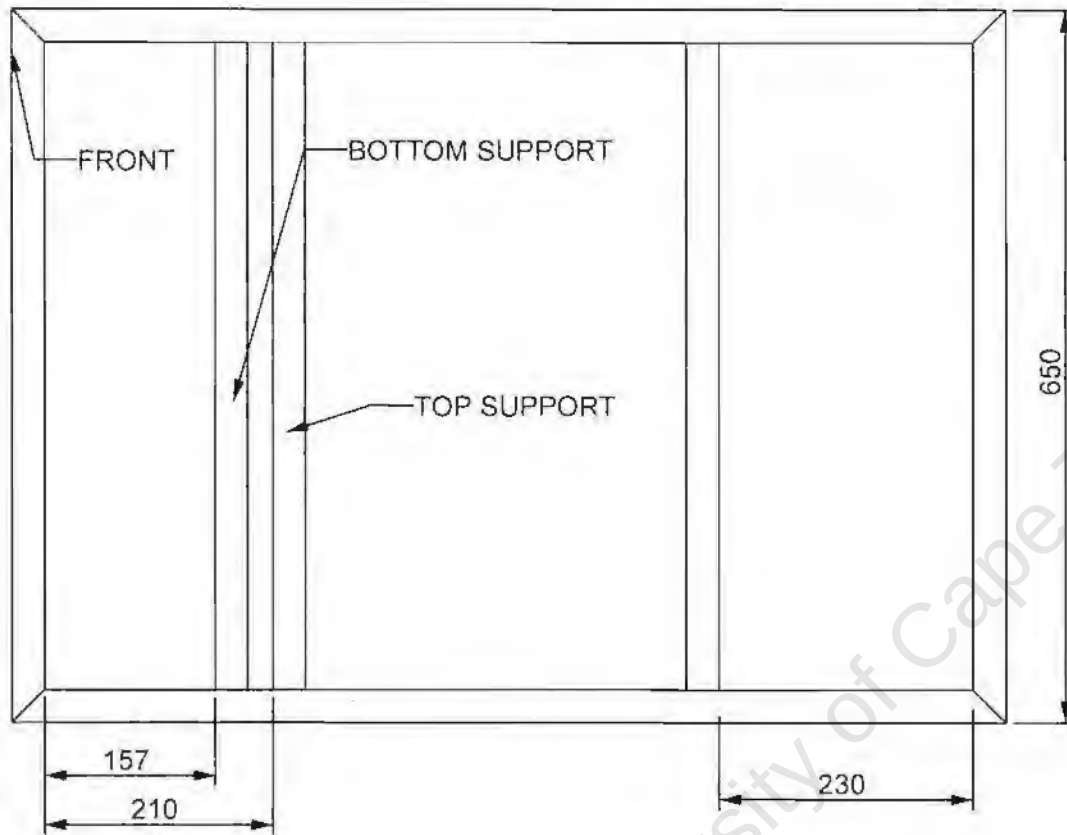
|    |           |                                |      |
|----|-----------|--------------------------------|------|
| 39 | PRT_22    | Compliance Plunger Plate       | 1.5  |
| 40 | PRT_23    | Plunger Locking Plate          | 1    |
| 41 | PRT_26    | Cam Follower Pin               | 2    |
| 42 | PRT_27    | Cam Follower Bracket           | 1    |
| 43 | PRT_29    | Linear Bearing Rod             | 1    |
| 44 | PRT_30    | Bearing Attatching Plate       | 0.75 |
| 45 | PRT_31    | Piston Head                    | 1.5  |
| 46 | PRT_33    | Motor Mount Plate              | 1    |
| 47 | PRT_34    | Driveshaft                     | 0.4  |
| 48 | PRT_36    | Motor Hinge Pin                | 1    |
| 49 | PRT_37    | Cam                            | 1    |
| 50 | PRT_38    | Motor Hinge Tube               | 1    |
| 51 | PRT_39_01 | Reservoir Folded               | 0.2  |
| 52 | PRT_39_02 | Reservoir Flat                 | 0.2  |
| 53 | PRT_41    | Testin Base Sheet              | 0.15 |
| 54 | PRT_49    | Motor Slot                     | 1    |
| 55 | PRT_50    | Ventricle Mounting Channel     | 0.3  |
| 56 | PRT_51    | Transducer Thread              | 2    |
| 57 | PRT_52    | Scope Seal Top                 | 3    |
| 58 | PRT_53    | Plumber Block Mount            | 0.5  |
| 59 | PRT_54    | Scope Seal Bottom              | 3    |
| 60 | PRT_55    | Aluminium Flange 2             | 1    |
| 61 | PRT_56    | Pipe Gland                     | 2    |
| 62 | PRT_60    | Mount Intern                   | 1    |
| 63 | PRT_61    | Mount Intern 2                 | 1    |
| 64 | PRT_62    | Mount Ext 2                    | 1    |
| 65 | PRT_63    | Motor Slot Pin                 | 1    |
| 66 | PRT_64    | Motor Mount Plate 2            | 1    |
| 67 | PRT_65    | Plunger Clamp                  | 1    |
| 68 | PRT_67    | Ballvalve Tank Connector       | 1    |
| 69 | PRT_68    | Tank Connector Nut             | 1    |
| 70 | PRT_69    | Tank Gland 1                   | 1    |
| 71 | PRT_70    | Tank Connector Nut             | 1    |
| 72 | PRT_72    | Tank Gland 2                   | 1    |
| 73 | PRT_73    | Mitral Pipe Gland              | 1    |
| 74 | PRT_74    | Aluminum Mitral Flange         | 1    |
| 75 | PRT_81    | Compliance Bleed Gland         | 2    |
| 76 | PRT_82    | Compliance Bleed Thread        | 2    |
| 77 | PRT_84    | Heater Clamping Plate          | 0.2  |
| 78 | PRT_85    | Heater Bolting Plate           | 0.2  |
| 79 | PRT_86    | Ventricular Compliance Block   | 1    |
| 80 | PRT_87    | Ventricular Compliance Gland 1 | 4    |
| 81 | PRT_88    | Ventricular Compliance Gland 2 | 4    |



| Item                                                                 | Material              | Qty                         | Remarks          |
|----------------------------------------------------------------------|-----------------------|-----------------------------|------------------|
| University of Cape Town<br>Department of Mechanical Engineering      |                       |                             |                  |
| <div> <div> </div> <div> Title<br/>FULL RIG: ISOMETRIC </div> </div> |                       |                             |                  |
| Dimensions in mm<br>Tolerance 1:0.5                                  | Scale<br>0.150        | Date<br>OCT 2008            | Sheet of<br>1 81 |
| 01                                                                   | Drawn By<br>H KRYNAUW | Drawing Number<br>ASM_00_01 |                  |

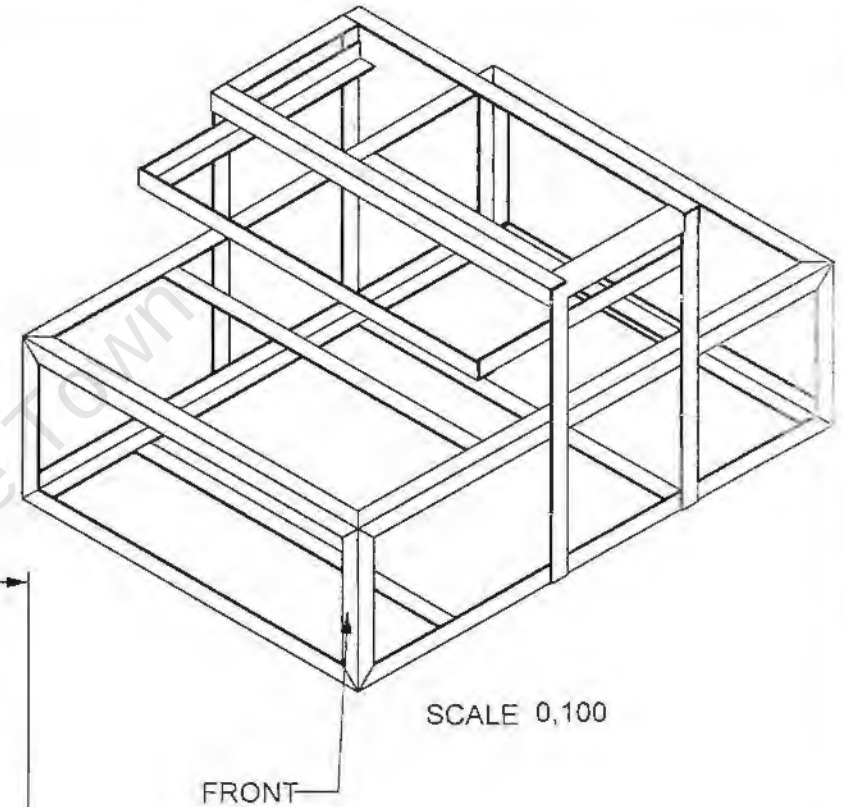
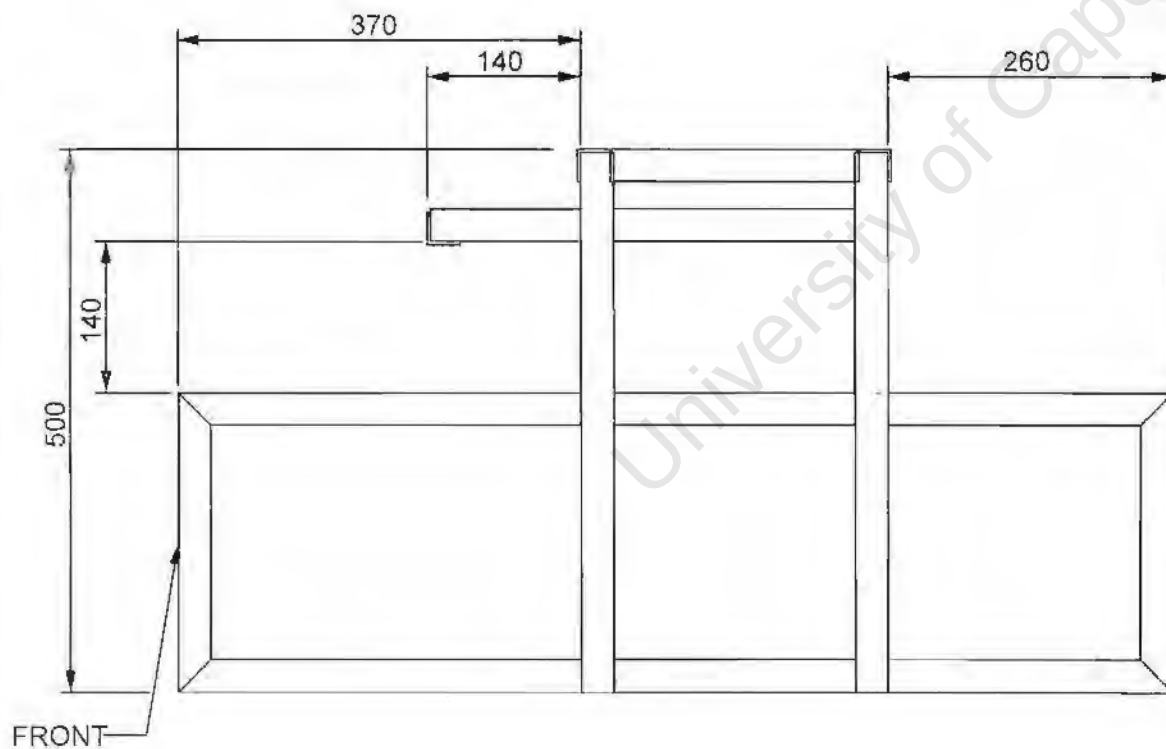


| Item                                                            | Material       | Qty                         | Remarks          |
|-----------------------------------------------------------------|----------------|-----------------------------|------------------|
| University of Cape Town<br>Department of Mechanical Engineering |                |                             |                  |
| Title<br>FULL RIG: FRONT AND TOP                                |                |                             |                  |
| Dimensions<br>in mm<br>Tolerance<br>u.o.s.                      | Scale<br>0,150 | Date<br>02/08/2008          | Sheet<br>2 of 31 |
| Drawn By<br>H KRYNAUW                                           |                | Drawing Number<br>ASM_00_02 |                  |



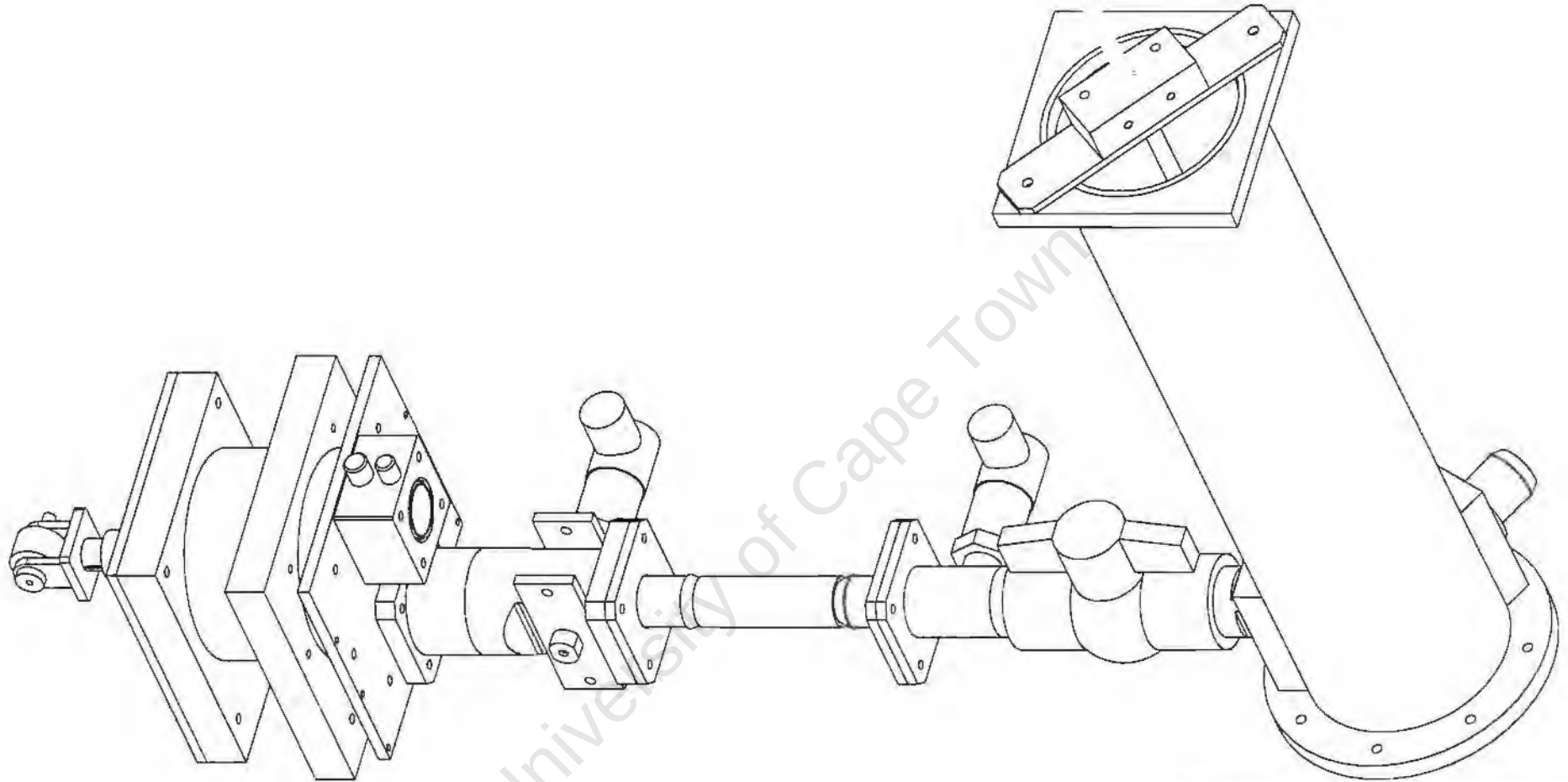
OUTSIDE FRAME: 30x3 CORNER  
FLAT SUPPORTS: 30x3 FLAT

|                                                                                       |                                                                 |          |           |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------|----------|-----------|
|                                                                                       | STEEL_ANGLE                                                     |          |           |
| Item                                                                                  | Material                                                        | Qty      | Remarks   |
|                                                                                       | University of Cape Town<br>Department of Mechanical Engineering |          |           |
|  | Title<br><br>FRAME BASE                                         |          |           |
| Dimensions<br>in mm<br>Tolerance<br>D.U.S.                                            | Scale                                                           | Date     | Sheet of  |
|                                                                                       | 0,150                                                           | OCT 2008 | 3 81      |
| 0,1                                                                                   | Drawing Number                                                  |          |           |
|                                                                                       | H KRYNAUM                                                       |          | ASM_01_01 |

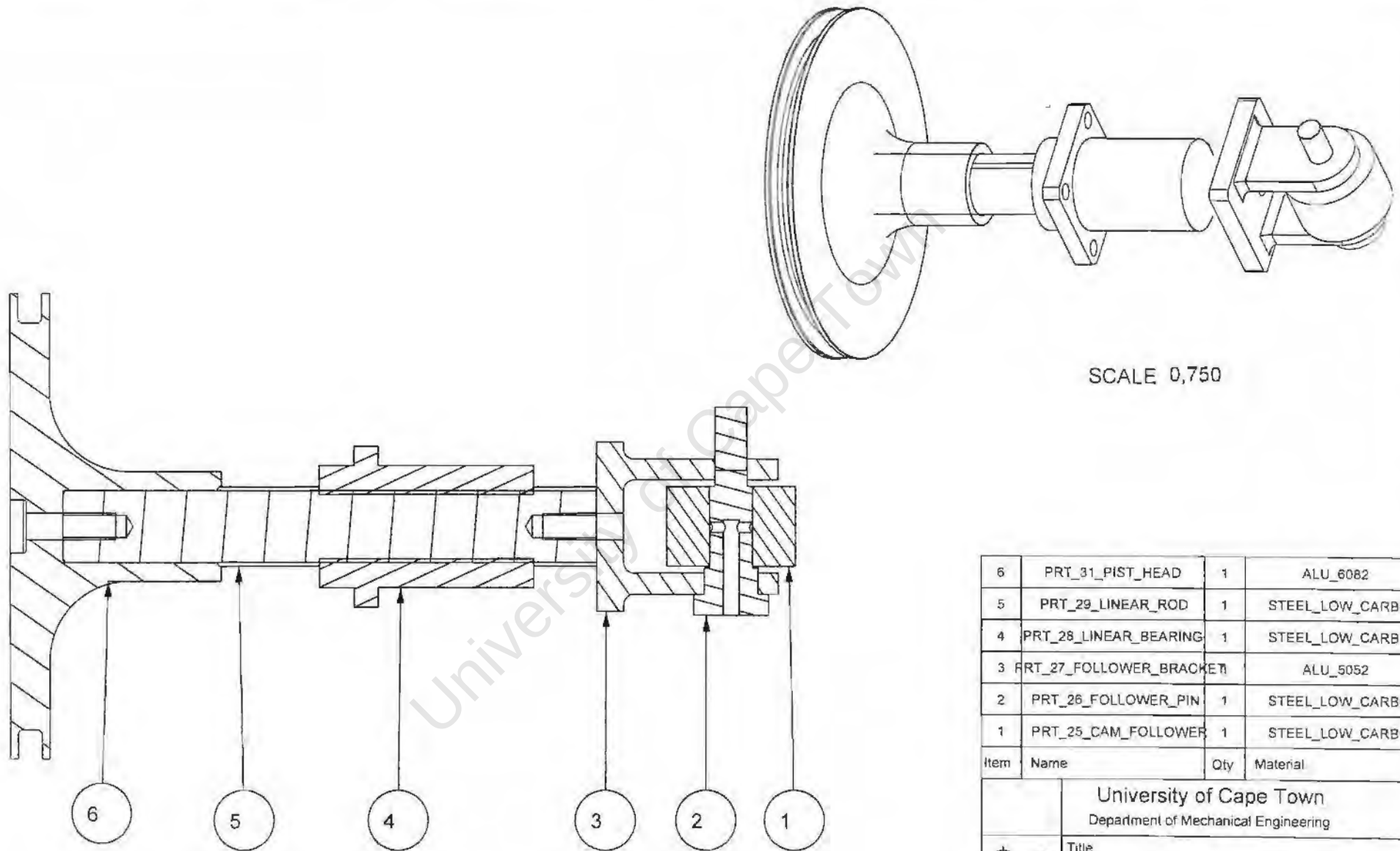


SCALE 0,100

|                                                                 |          |                    |          |
|-----------------------------------------------------------------|----------|--------------------|----------|
| STEEL_ANGLE                                                     |          |                    |          |
| Item                                                            | Material | Qty                | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |          |                    |          |
| Title                                                           |          | FRAME WITH BRACING |          |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale    | Date               | Sheet of |
| 0,150                                                           | 0,150    | 10/03/2008         | 4 of 81  |
| Drawn By                                                        |          | Drawing Number     |          |
| H KRYNAUW                                                       |          | ASM_01_02          |          |



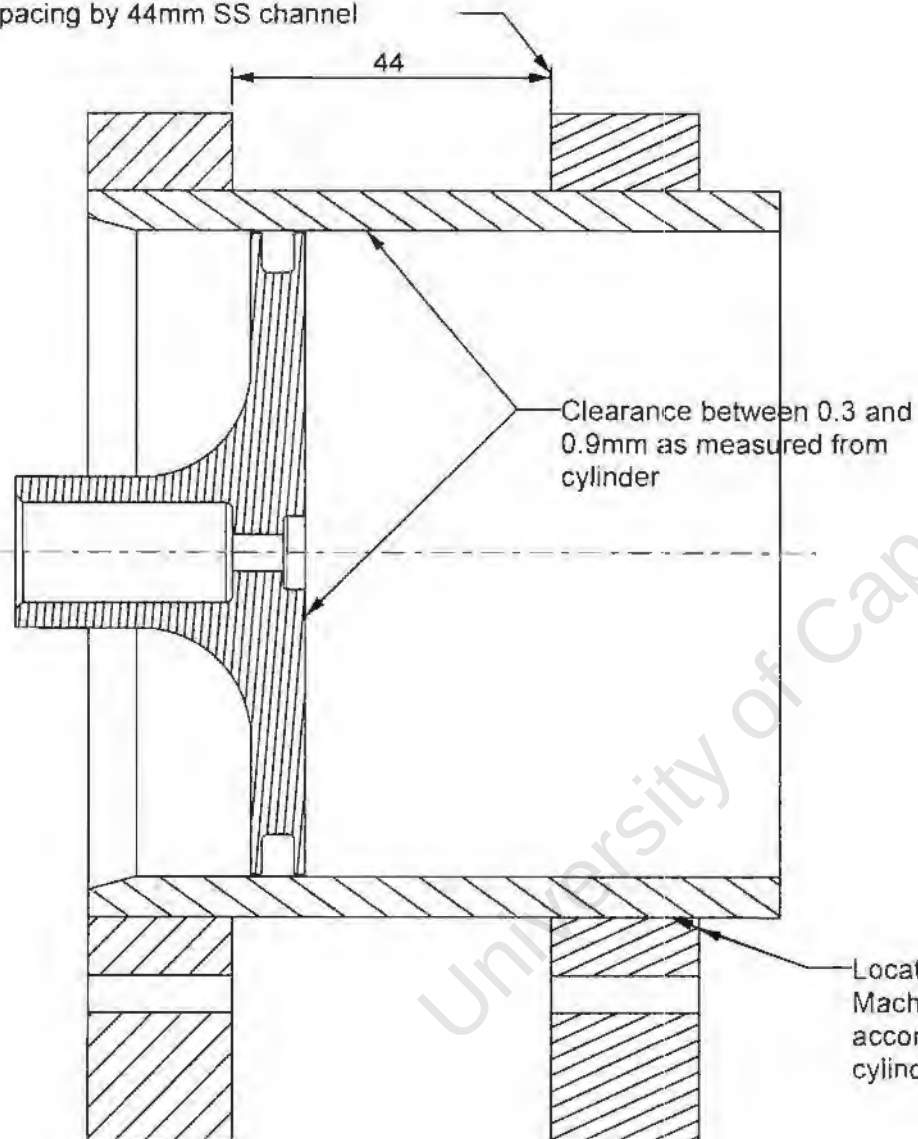
|                                                                                       |                    |                                                                 |                                 |              |
|---------------------------------------------------------------------------------------|--------------------|-----------------------------------------------------------------|---------------------------------|--------------|
| Item                                                                                  | Name               | Qty                                                             | Material                        |              |
|                                                                                       |                    | University of Cape Town<br>Department of Mechanical Engineering |                                 |              |
|  |                    | Title<br><br>TESTING LINE                                       |                                 |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>0,060 | Date<br><br>OCT 2008                                            | Sheet<br><br>5                  | of<br><br>81 |
| Drawn by<br><br>0.1                                                                   | H KRYNAUM          |                                                                 | Drawing Number<br><br>ASM_02_01 |              |



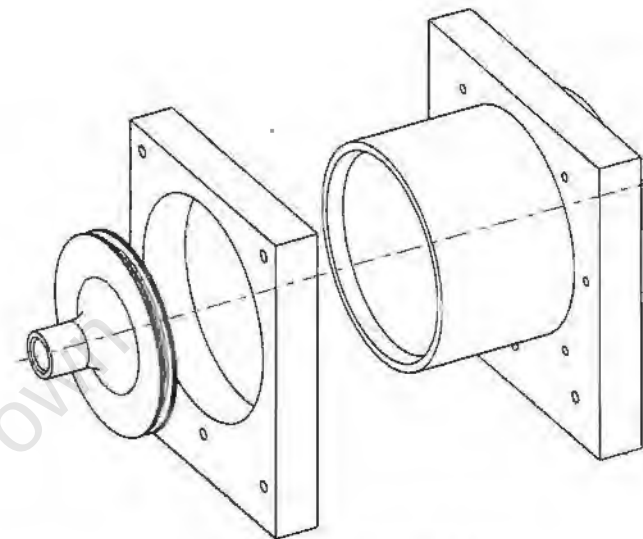
| 6    | PRT_31_PIST_HEAD        | 1   | ALU_6082         |
|------|-------------------------|-----|------------------|
| 5    | PRT_29_LINEAR_ROD       | 1   | STEEL_LOW_CARBON |
| 4    | PRT_28_LINEAR_BEARING   | 1   | STEEL_LOW_CARBON |
| 3    | PRT_27_FOLLOWER_BRACKET | 1   | ALU_5052         |
| 2    | PRT_26_FOLLOWER_PIN     | 1   | STEEL_LOW_CARBON |
| 1    | PRT_25_CAM_FOLLOWER     | 1   | STEEL_LOW_CARBON |
| Item | Name                    | Qty | Material         |

|                                                                 |                |                                 |                  |
|-----------------------------------------------------------------|----------------|---------------------------------|------------------|
| University of Cape Town<br>Department of Mechanical Engineering |                |                                 |                  |
| Title<br>PISTON TO CAM FOLLOWER                                 |                |                                 |                  |
| Dimensions<br>in mm<br>Tolerance<br>U.S.S.                      | Scale<br>1,000 | Date<br>2008                    | Sheet<br>5 of 81 |
| Drawn By<br>H KRYNAUW                                           |                | Drawing Number<br>IPR2024-00320 |                  |
| 01                                                              |                | ASM_02_C2                       |                  |

Spacing by 44mm SS channel



SECTION A-A



SCALE 0,330

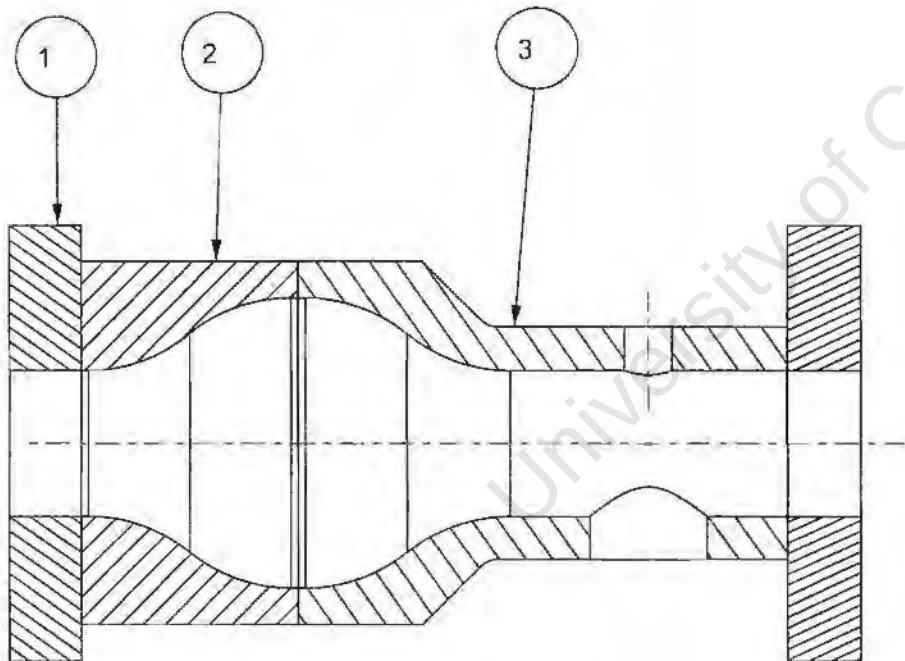
| 4                                                                                                                             | PRT_31_PIST_HEAD          | 1              | ALU_6082     |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------|--------------|
| 3                                                                                                                             | PRT_03_CYLINDER           | 1              | PERSPEX_CAST |
| 2                                                                                                                             | PRT_02_HEART_FLANGE_REAR  |                | PERSPEX_CAST |
| 1                                                                                                                             | PRT_01_HEART_FLANGE_FRONT |                | PERSPEX_CAST |
| Item                                                                                                                          | Name                      | Qty            | Material     |
| University of Cape Town<br>Department of Mechanical Engineering                                                               |                           |                |              |
| Title<br>VENTRICLE & PISTON ASSEMBLY                                                                                          |                           |                |              |
| <br>Dimensions in mm<br>Tolerance U.O.S. | Scale                     | Date           | Sheet of     |
|                                                                                                                               | 1,000                     | OCT 2008       | 7 81         |
| Drawn by                                                                                                                      |                           | Drawing Number |              |
| H KRYNAUM                                                                                                                     |                           | ASM_02_03      |              |

Penitioner's Exhibit 1015

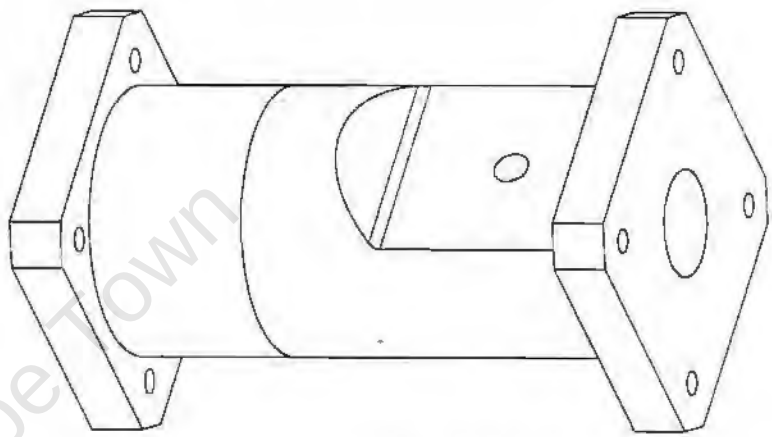
VIVITRO v. BDC

IPR2024-00320

ALL PARTS GLUED WITH TENSOL12  
AND CLAMPED OVERNIGHT



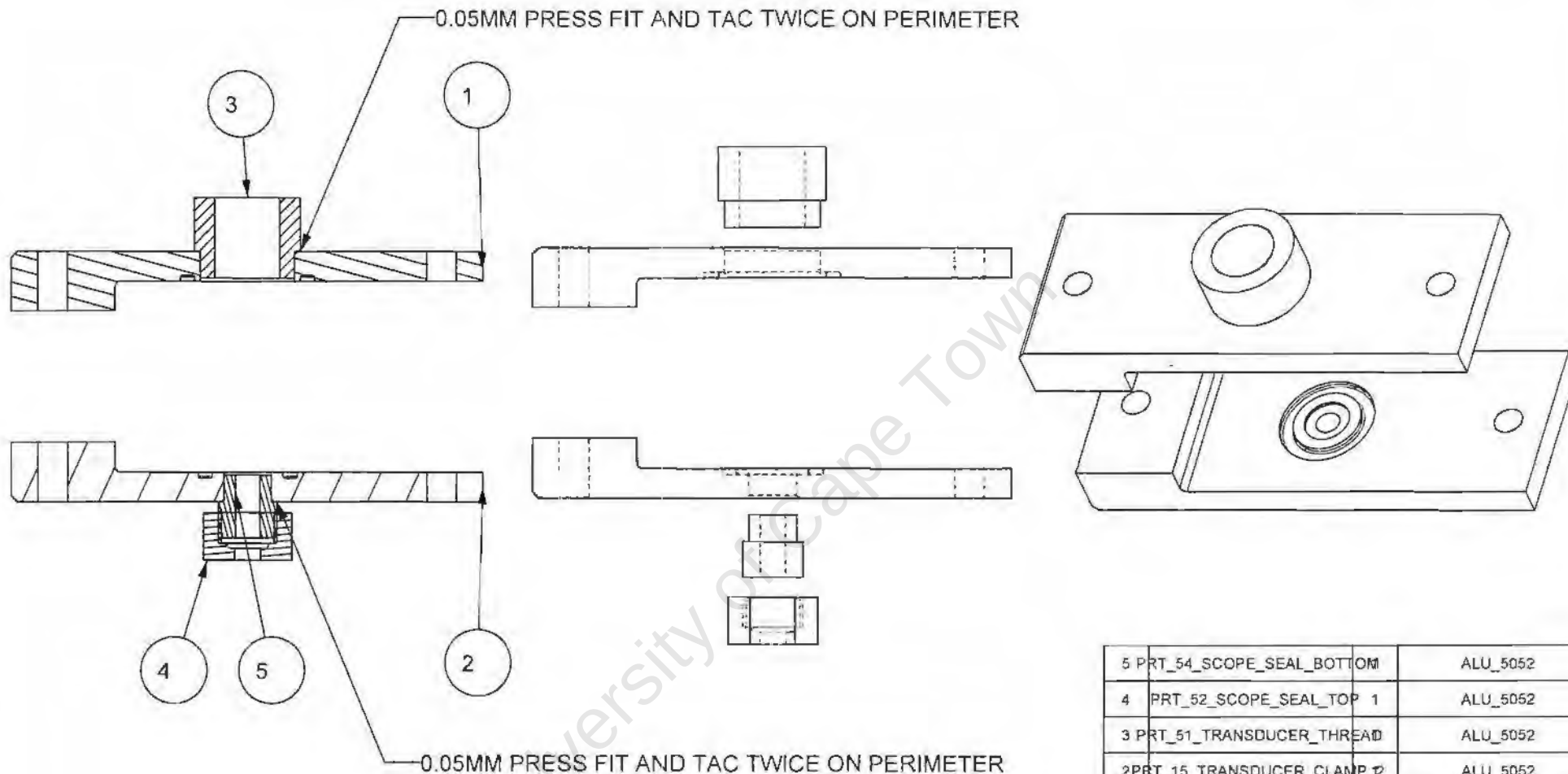
SECTION A-A



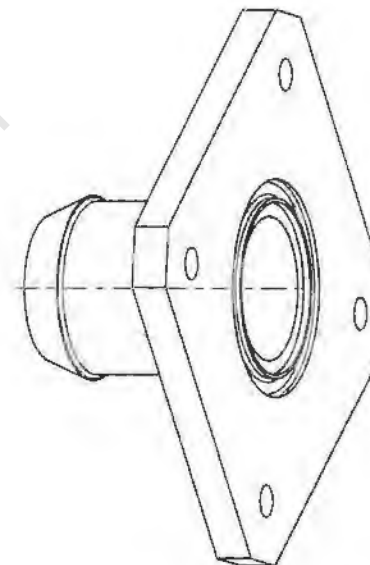
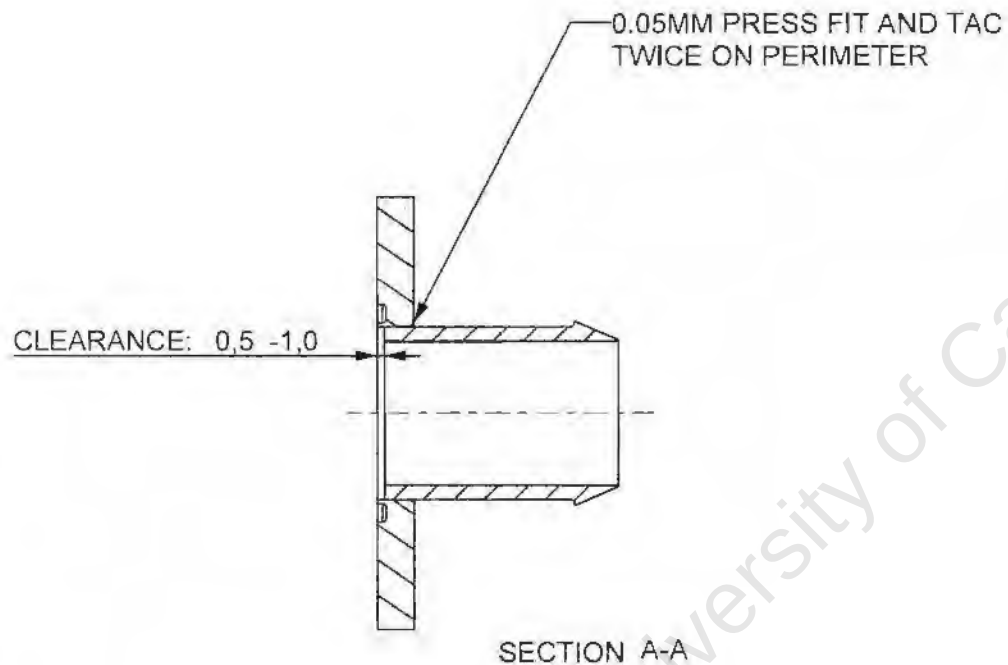
SCALE 0,750

| 3                                                                                           | PRT_12_FLOW_CONVERGENCE |                             | PERSPEX_CAST           |
|---------------------------------------------------------------------------------------------|-------------------------|-----------------------------|------------------------|
| 2                                                                                           | PRT_11_FLOW_EXPANS      | 1                           | PERSPEX_CAST           |
| 1                                                                                           | PRT_10_PX_FLANGE        | 2                           | PERSPEX_CAST           |
| Item                                                                                        | Name                    | Qty                         | Material               |
| University of Cape Town<br>Department of Mechanical Engineering                             |                         |                             |                        |
|  Title |                         | FLOW RECTIFIER              |                        |
| Dimensions<br>in mm<br>Tolerance<br>u.c.s                                                   | Scale<br>1:000          | Date<br>007/2008            | Sheet<br>8<br>of<br>81 |
| Drawn By<br>H KRYNAUW                                                                       |                         | Drawing Number<br>ASM_02_04 |                        |

Petitioner's Exhibit 1013  
VIVITRO V. BDC  
IPR2024-00320

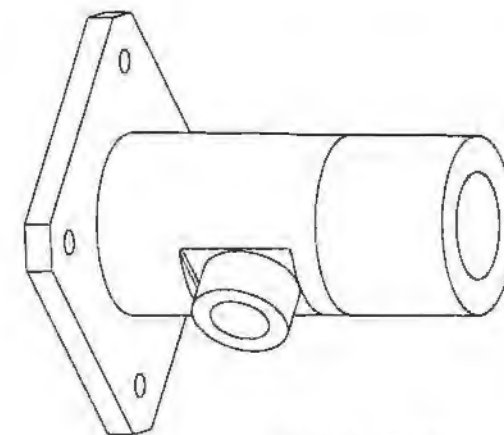
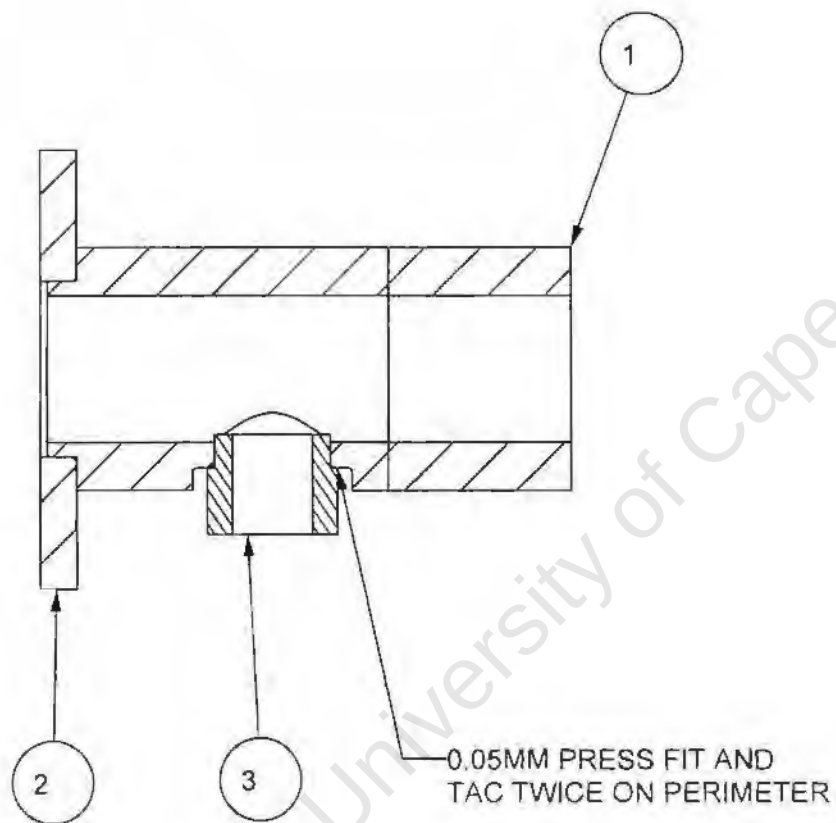


| 5                                                               | PRT_54_SCOPE_SEAL_BOTTOM  |                             | ALU_5052 |
|-----------------------------------------------------------------|---------------------------|-----------------------------|----------|
| 4                                                               | PRT_52_SCOPE_SEAL_TOP 1   |                             | ALU_5052 |
| 3                                                               | PRT_51_TRANSDUCER_THREAD  |                             | ALU_5052 |
| 2                                                               | PRT_15_TRANSDUCER_CLAMP_2 |                             | ALU_5052 |
| 1                                                               | PRT_13_TRANSDUCER_CLAMP   |                             | ALU_5052 |
| Item                                                            | Name                      | Qty                         | Material |
| University of Cape Town<br>Department of Mechanical Engineering |                           |                             |          |
| Title<br><b>PROX TRANSDUCER CLAMP</b>                           |                           |                             |          |
| Dimensions in mm<br>Tolerance U.O.S.<br>0.1                     | Scale                     | Date                        | Sheet of |
|                                                                 | 1:000                     | OCT 2008                    | 9 R1     |
| Drawn By<br>H KRYNAUW                                           |                           | Drawing Number<br>ASM_02_05 |          |



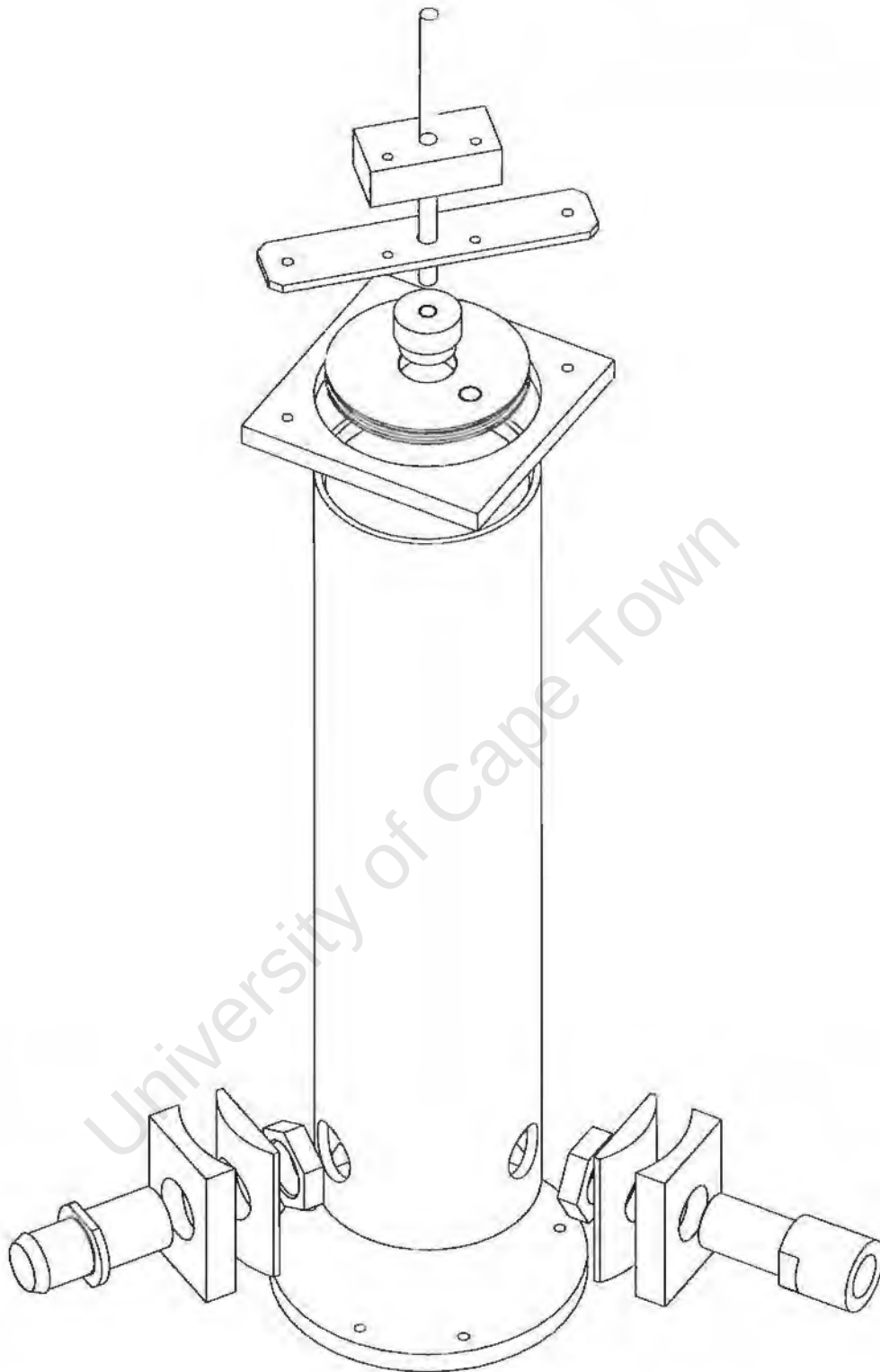
QUANTITY: 2

| PRT_56_FLOW_REG_PLATE_GLAND                                     |                       | ALU_5052                    |                   |
|-----------------------------------------------------------------|-----------------------|-----------------------------|-------------------|
| 1                                                               | PRT_55_FLOW_REG_PLATE | 1                           | ALU_5052          |
| Item                                                            | Name                  | Qty                         | Material          |
| University of Cape Town<br>Department of Mechanical Engineering |                       |                             |                   |
| Title                                                           |                       | TUBE GLAND                  |                   |
| Dimensions<br>in mm<br>Tolerance<br>U.D.S.                      | Scale<br>1,000        | Date<br>09-2-2008           | Sheet<br>10 of 31 |
| 0.1                                                             | Drawn By<br>H KRYNAUW | Drawing Number<br>ASM_02_06 |                   |



SCALE 0,750

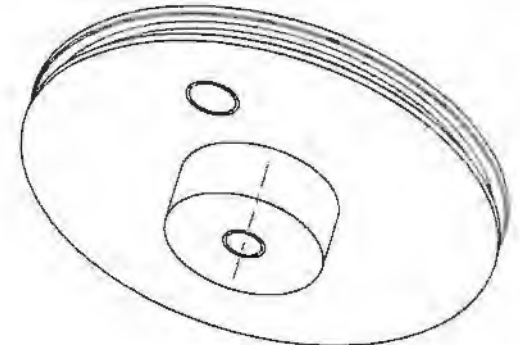
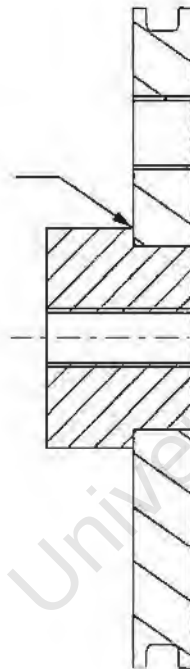
| 3                                                                                     | PRT_51_TRANSDUCER_THREAD   | ALU_5052             |
|---------------------------------------------------------------------------------------|----------------------------|----------------------|
| 2                                                                                     | PRT_16_FLOW_REG_PLATE_21   | ALU_5052             |
| 1                                                                                     | PRT_09_BALL_VALVE_FLANGE_3 | ALU_5052             |
| Item                                                                                  | Name                       | Qty                  |
| University of Cape Town<br>Department of Mechanical Engineering                       |                            |                      |
|  |                            |                      |
| Title<br>DIST TRANSDUCER MOUNT                                                        |                            |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>1,000             | Date<br>OCT 2008     |
| 0,1                                                                                   | H KRYNAUW                  | Sheet<br>11 of<br>A1 |
| Drawing Number<br>ASM_02_07                                                           |                            |                      |



|                                                                                     |                |                                                                 |             |          |
|-------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------|-------------|----------|
| Item                                                                                | Name           | Qty                                                             | Material    |          |
|                                                                                     |                | University of Cape Town<br>Department of Mechanical Engineering |             |          |
|  |                | Title<br>COMPLIANCE CHAMBER EXPLODE                             |             |          |
| Dimensions<br>in mm<br>Tolerance<br>U.S.                                            | Scale<br>0,350 | Date<br>OCT 2008                                                | Sheet<br>12 | of<br>81 |
| 01                                                                                  | H KRYNAN       | Drawing Number<br>ASM_02_08                                     |             |          |

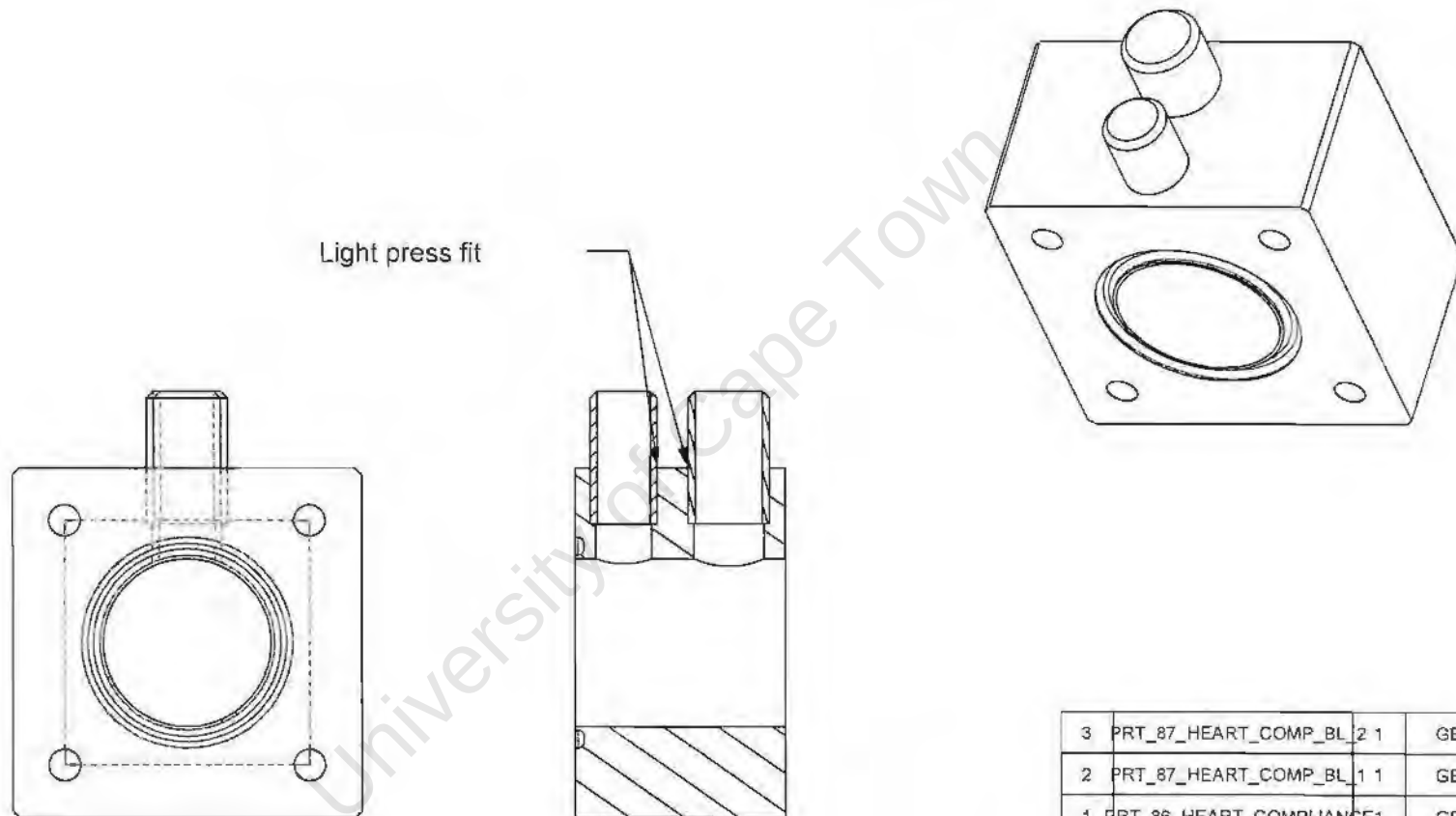
Petitioner's Exhibit 1015  
 VIVITRO v. BDC

PRESS FIT AND TAC

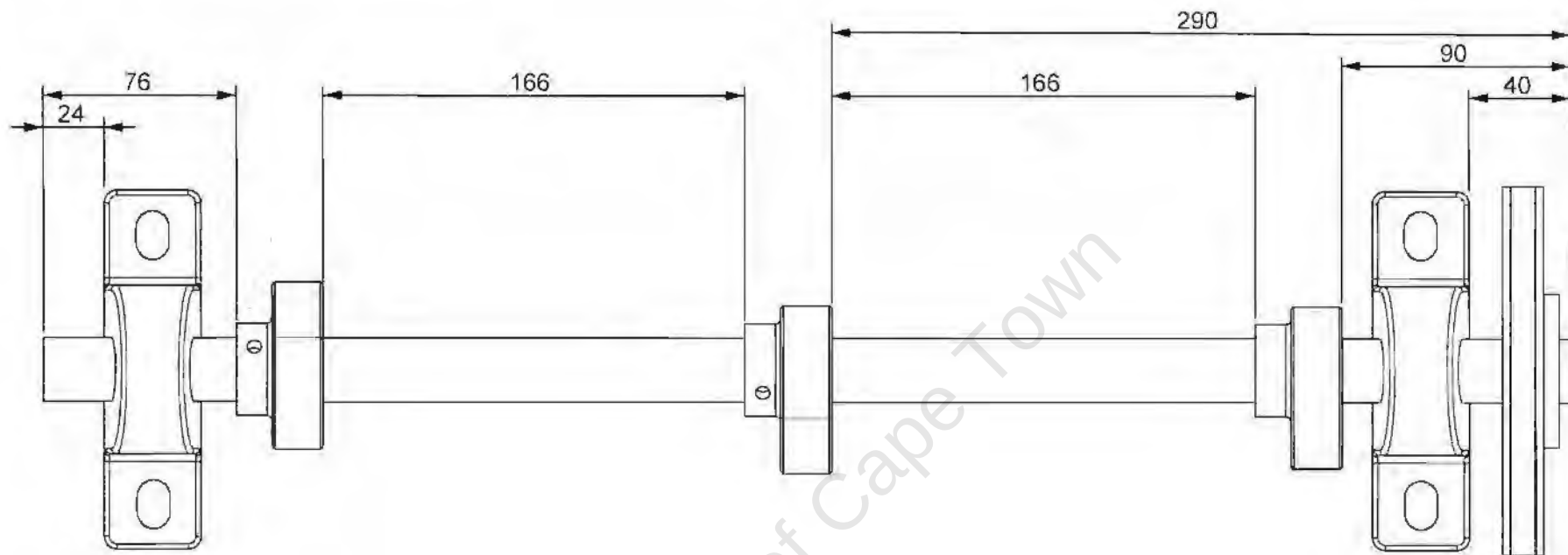


SCALE 0.750

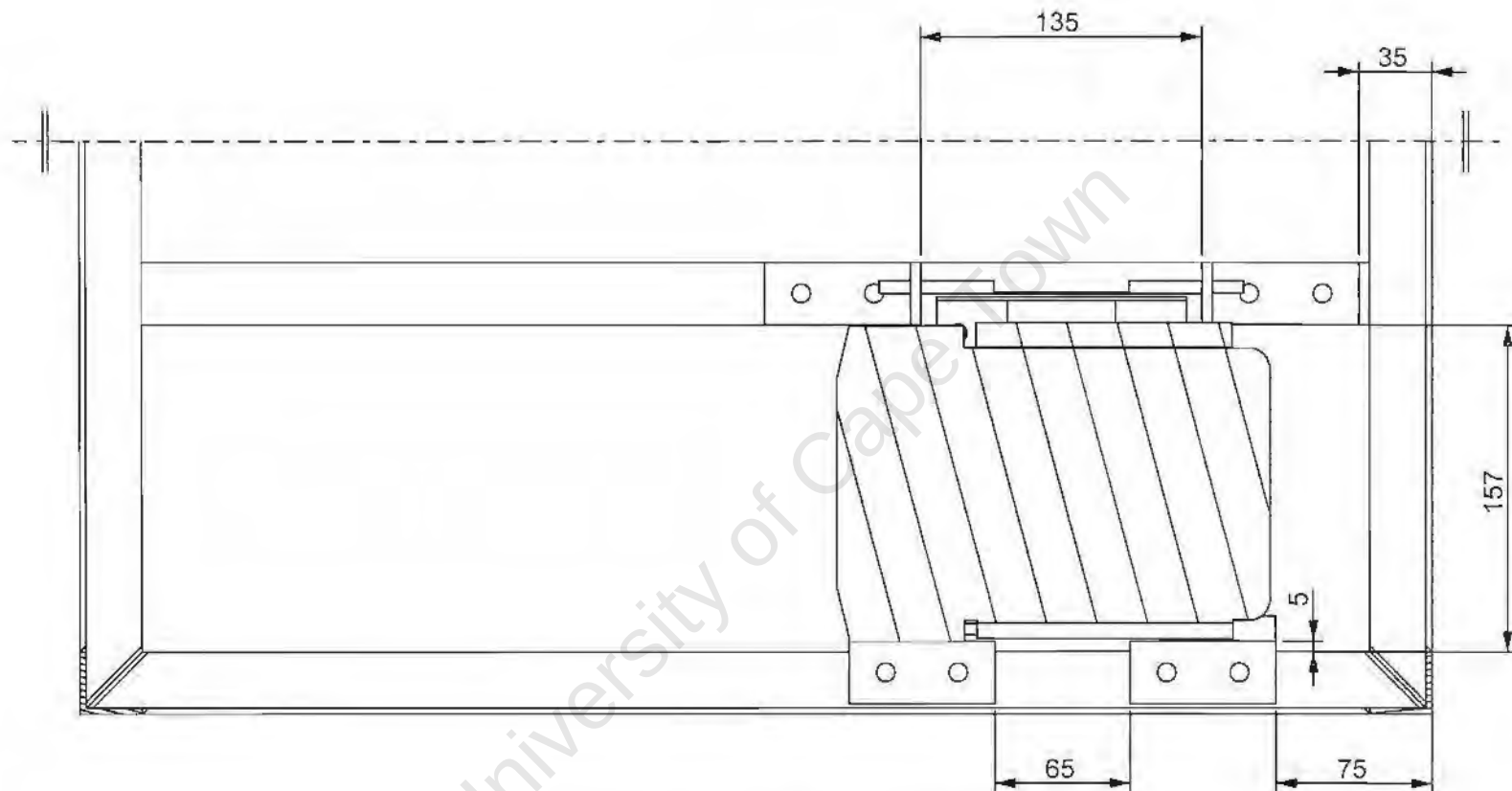
| 2                                                               | PRT_22_PLUNGER_PLATE  | 1                           | ALU_6082          |
|-----------------------------------------------------------------|-----------------------|-----------------------------|-------------------|
| 1                                                               | PRT_08_COMP_PIST_PRES | 1                           | ALU_5052          |
| Item                                                            | Name                  | Qty                         | Material          |
| University of Cape Town<br>Department of Mechanical Engineering |                       |                             |                   |
| Title                                                           |                       | COMPLIANCE PLUNGER          |                   |
| Dimensions in mm<br>Tolerance<br>U.O.S.                         | Scale<br>1:1000       | Date<br>OCT 2008            | Sheet of<br>13 R1 |
| 0.1                                                             | H KRYNADU             | Drawing Number<br>ASM_02_09 |                   |



| 3                                                               | PRT_87_HEART_COMP_BL_2   | 1                                            | GENERIC_ALUMINUM     |
|-----------------------------------------------------------------|--------------------------|----------------------------------------------|----------------------|
| 2                                                               | PRT_87_HEART_COMP_BL_1   | 1                                            | GENERIC_ALUMINUM     |
| 1                                                               | PRT_86_HEART_COMPLIANCE1 | 1                                            | GENERIC_ALUMINUM     |
| Item                                                            | Name                     | Qty                                          | Material             |
| University of Cape Town<br>Department of Mechanical Engineering |                          |                                              |                      |
| Title<br>VENTRICULAR COMPLIANCE                                 |                          |                                              |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale<br>1,000           | Date<br>17/07/2008                           | Sheet<br>14 of<br>81 |
| 01                                                              | Drawn By<br>H KRYNAUW    | Drawing Number<br>IPR2024-00320<br>ASM_02_10 |                      |

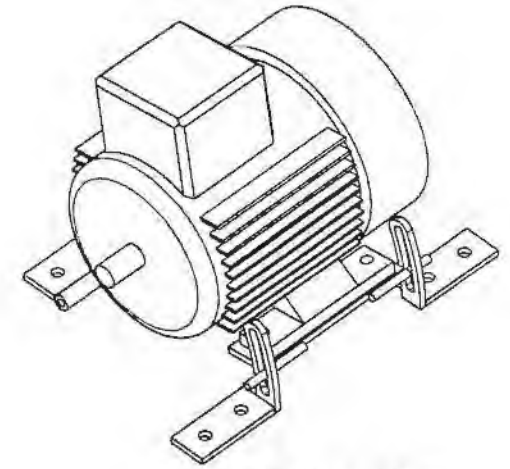
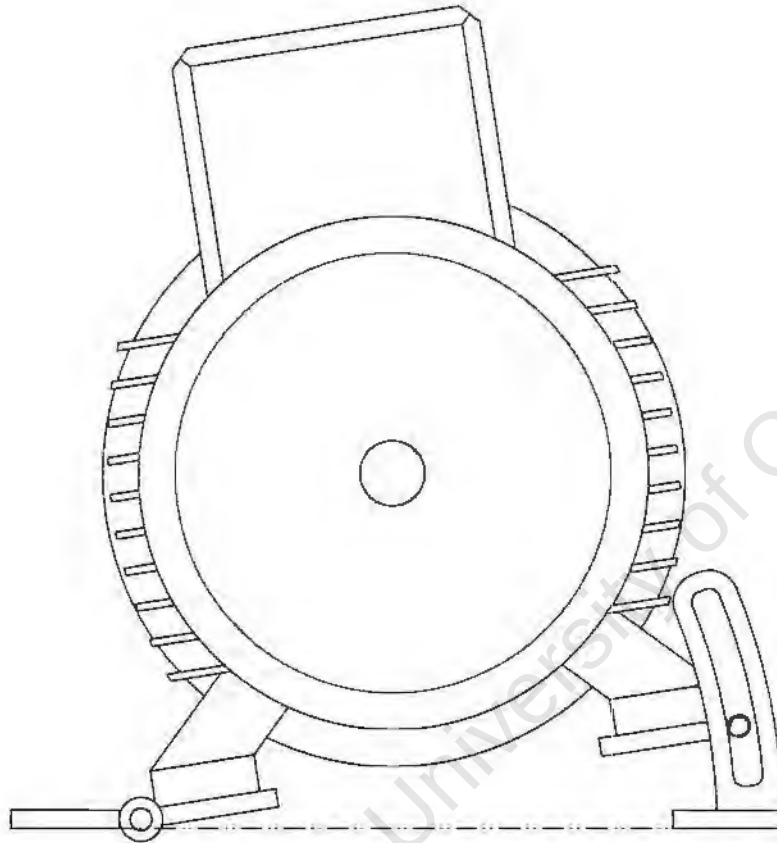


| Item                                                            | Material | Qty                | Remarks  |
|-----------------------------------------------------------------|----------|--------------------|----------|
| University of Cape Town<br>Department of Mechanical Engineering |          |                    |          |
| Title                                                           |          | DRIVESHAFT SPACING |          |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale    | Date               | Sheet of |
| 0.1                                                             | 0,400    | OCT 2008           | 15 81    |
| Drawing Number                                                  |          | ASM_03_01          |          |



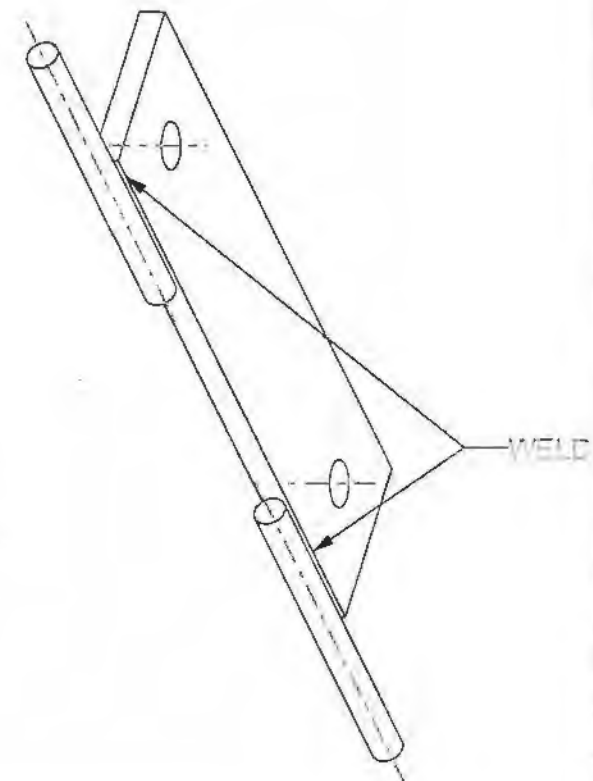
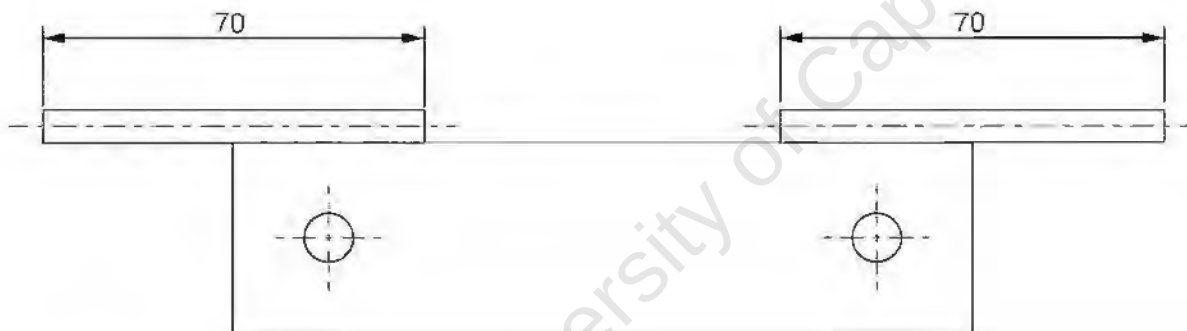
SECTIONAL VIEW THROUGH MOTOR

| Item                                                            | Material       | Qty  | Remarks  |
|-----------------------------------------------------------------|----------------|------|----------|
| University of Cape Town<br>Department of Mechanical Engineering |                |      |          |
| Title                                                           |                |      |          |
| MOTOR MOUNT SPACING                                             |                |      |          |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale          | Date | Sheet of |
| 0,300                                                           | 1:1            | 2008 | 17 of 51 |
| Drawn By                                                        | Drawing Number |      |          |
| H KRYNAUW                                                       | ASM_04_02      |      |          |

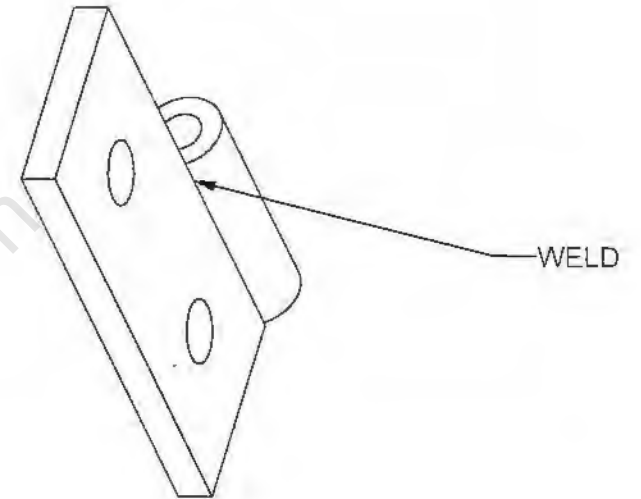
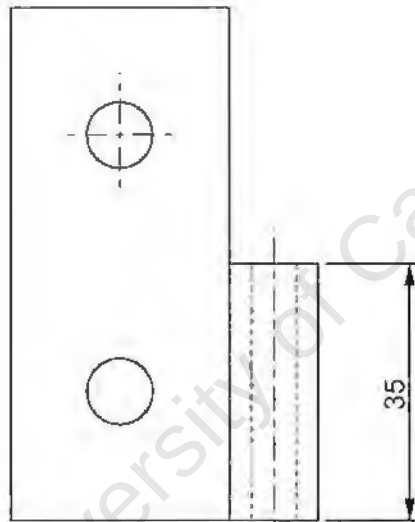


SCALE 0,200

| 6                                                               | PRT_32_MOTOR            | 1         |          |
|-----------------------------------------------------------------|-------------------------|-----------|----------|
| 5                                                               | ASM_18_MOTOR_SLOT_PIN   | 1         |          |
| 4                                                               | ASM_17_MOTOR_SLOT_B     | 1         |          |
| 3                                                               | ASM_17_MOTOR_SLOT       | 1         |          |
| 2                                                               | ASM_18_PIN_HINGE_FEMALE | 2         |          |
| Item                                                            | Name                    | Qty       | Material |
| University of Cape Town<br>Department of Mechanical Engineering |                         |           |          |
| Title<br>MOTOR HINGE MOUNT                                      |                         |           |          |
| <br>Dimensions in mm<br>Tolerances U.D.S.<br>0.1                | Scale                   | Date      | Sheet of |
|                                                                 | 0,500                   | OCT 2009  | 16 of 81 |
| Drawing Number                                                  |                         | ASM_04_01 |          |
| H KRYNAUM                                                       |                         |           |          |

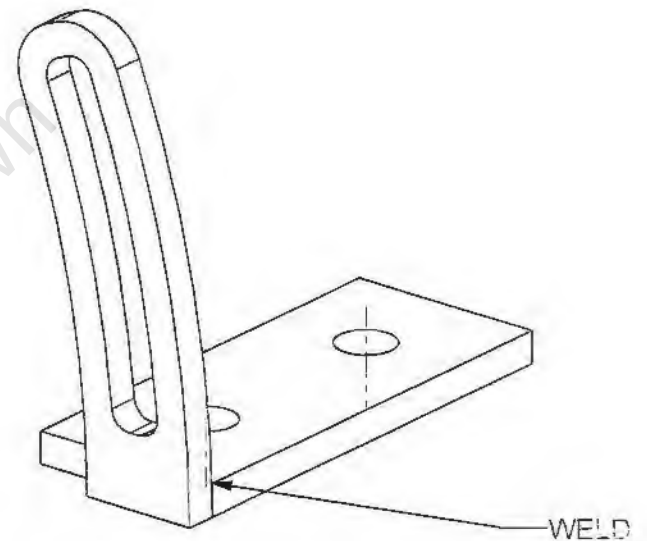
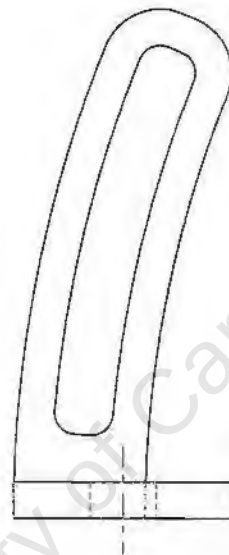
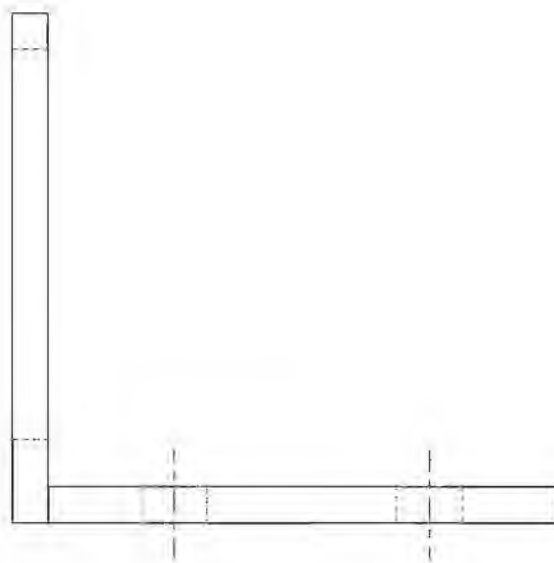


| PRT_64_MOTOR_MOUNT_PLATE1.2                                                                 |                       | ST_STEEL_304       |                             |
|---------------------------------------------------------------------------------------------|-----------------------|--------------------|-----------------------------|
| 1                                                                                           | PRT_36_PIN_HINGE_PIN  | 2                  | ST_STEEL_304                |
| Item                                                                                        | Name                  | Qty                | Material                    |
| University of Cape Town<br>Department of Mechanical Engineering                             |                       |                    |                             |
|  Title |                       | MOTOR HINGE MALE   |                             |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                                  | Scale<br>0,750        | Date<br>09/01/2008 | Sheet<br>18<br>of<br>81     |
| 0,1                                                                                         | Drawn By<br>H KRYNAUW | IPR2024-00320      | Drawing Number<br>ASM_04_03 |

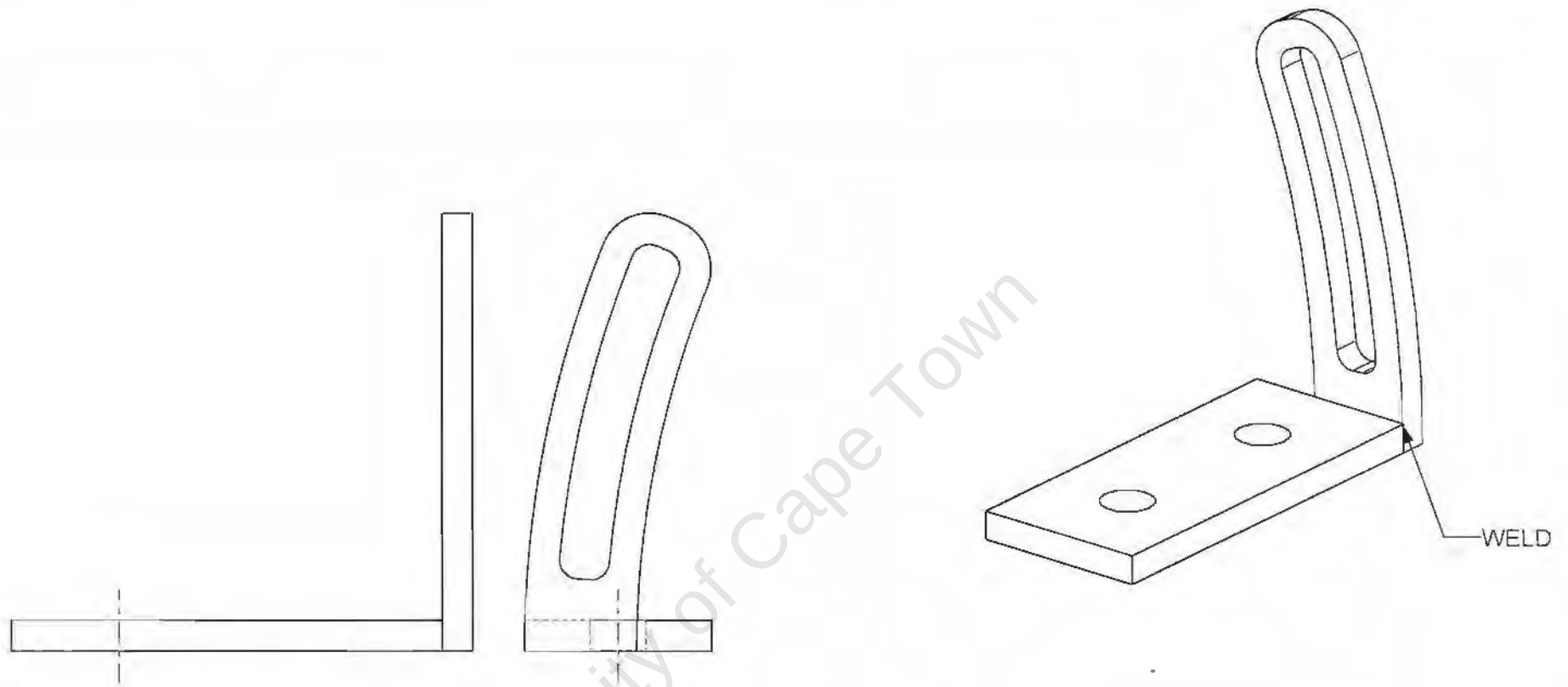


QUANTITY: 2

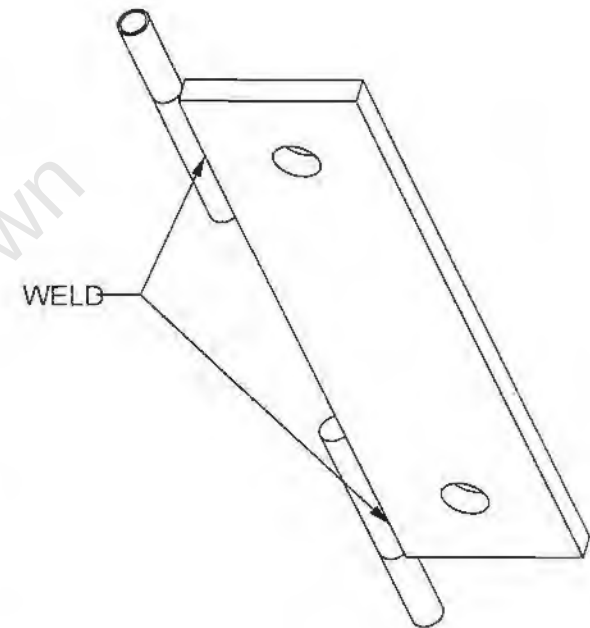
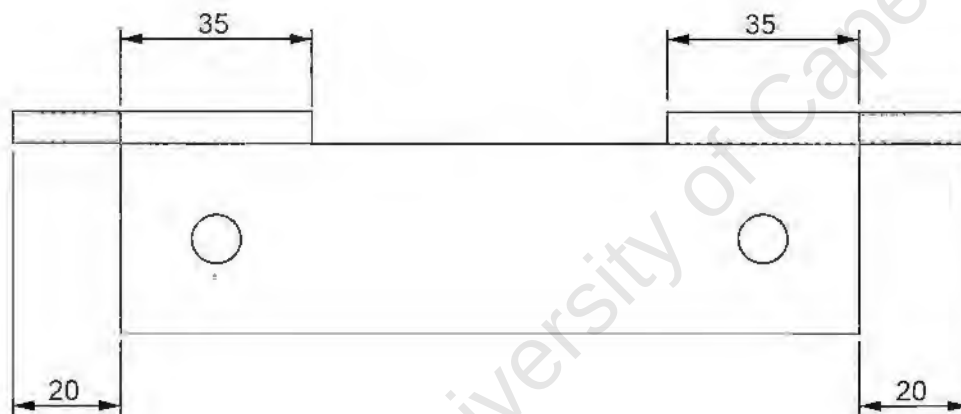
| 2                                                               | PRT_38_PIN_HINGE_TUBE    | 1                           | ST_STEEL_304            |
|-----------------------------------------------------------------|--------------------------|-----------------------------|-------------------------|
| 1                                                               | PRT_33_MOTOR_MOUNT_PLATE |                             | ST_STEEL_304            |
| Item                                                            | Name                     | Qty                         | Material                |
| University of Cape Town<br>Department of Mechanical Engineering |                          |                             |                         |
| Title                                                           |                          | MOTOR HING FEMALE           |                         |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale<br>1,000           | Date<br>OCT 2008            | Sheet<br>19<br>of<br>81 |
| 0.1                                                             | H KRYNAUM                | Drawing Number<br>ASM_04_04 |                         |



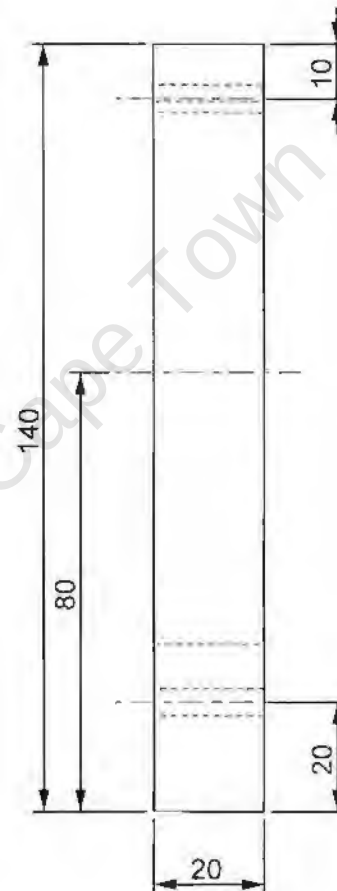
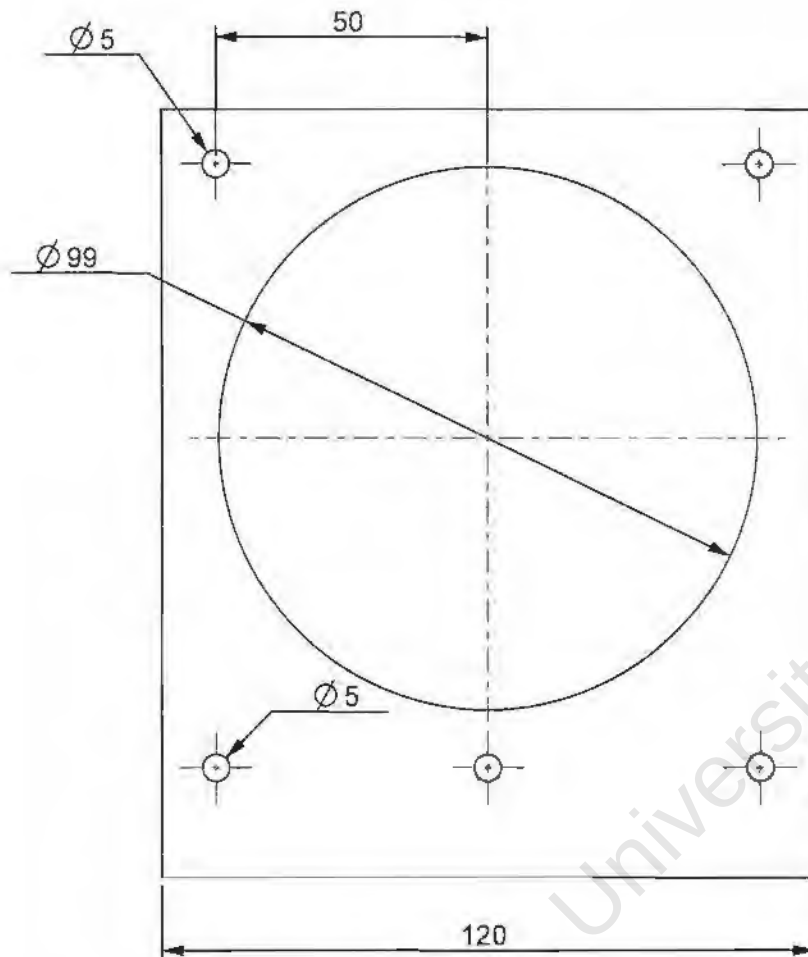
| 2                                                                                                                             | PRT_49_MOTOR_SLOT        | 1          | ST_STEEL_304 |
|-------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------|--------------|
| 1                                                                                                                             | PRT_33_MOTOR_MOUNT_PLATE |            | ST_STEEL_304 |
| Item                                                                                                                          | Name                     | Qty        | Material     |
| University of Cape Town<br>Department of Mechanical Engineering                                                               |                          |            |              |
| Title<br>MOTOR SLOT NDE                                                                                                       |                          |            |              |
| <br>Dimensions in mm<br>Tolerance U.O.S. | Scale                    | Date       | Sheet of     |
|                                                                                                                               | 1:1                      | 10/01/2018 | 20 of 81     |
| Drawn By H KRYNAUW                                                                                                            |                          |            |              |
| Drawing Number SM_04_05                                                                                                       |                          |            |              |



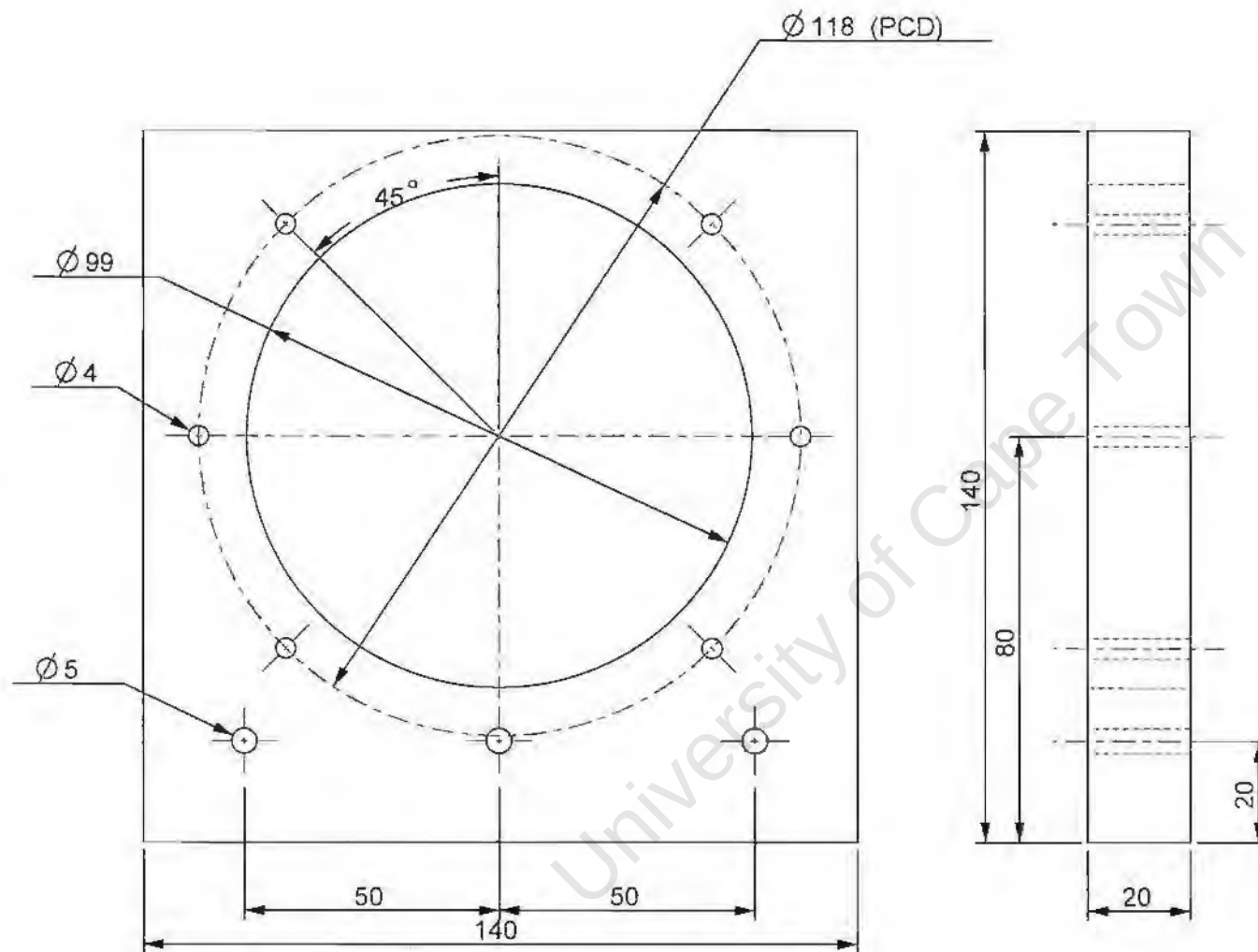
| 2                                                                                     | PRT_49_MOTOR_SLOT        | 1                             | ST_STEEL_304                |
|---------------------------------------------------------------------------------------|--------------------------|-------------------------------|-----------------------------|
| 1                                                                                     | PRT_33_MOTOR_MOUNT_PLATE |                               | ST_STEEL_304                |
| Item                                                                                  | Name                     | Qty                           | Material                    |
| University of Cape Town<br>Department of Mechanical Engineering                       |                          |                               |                             |
|  |                          | Title<br><b>MOTOR SLOT DE</b> |                             |
| Dimensions<br>in mm<br>Tolerance<br>U.D.S.                                            | Scale<br>1,000           | Date<br>OCT 2008              | Sheet<br>21<br>of<br>81     |
| 0.1                                                                                   | H KRYNAUW                | Drawn by<br>VIVITRO v. BDC    | Drawing Number<br>ASM_04_06 |



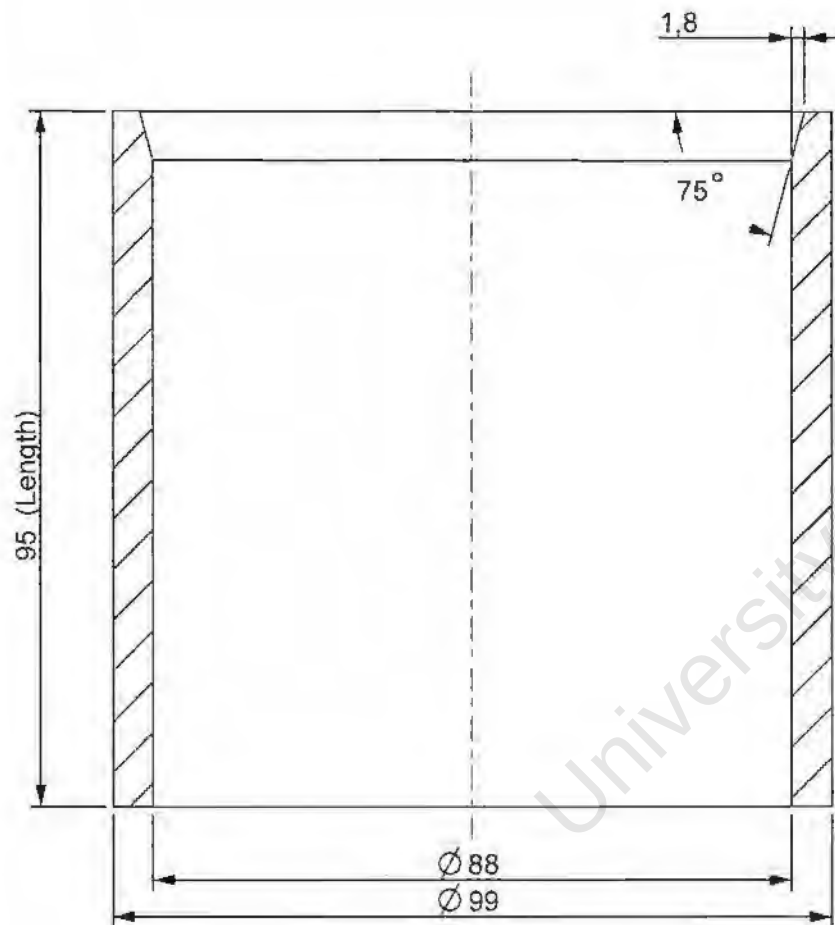
| PRT_64_MOTOR_MOUNT_PLATE1.2                                     |                 | ST_STEEL_304   |              |
|-----------------------------------------------------------------|-----------------|----------------|--------------|
| 1                                                               | PRT_63_SLOT_PIN | 2              | ST_STEEL_304 |
| Item                                                            | Name            | Qty            | Material     |
| University of Cape Town<br>Department of Mechanical Engineering |                 |                |              |
| Title                                                           |                 | MOTOR SLOT PIN |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale           | Date           | Sheet of     |
|                                                                 | 0.1             | 01/01/2015     | 22 of 31     |
| Drawn By                                                        |                 | Drawing Number |              |
| H KRYNAUW                                                       |                 | ISM_04_07      |              |



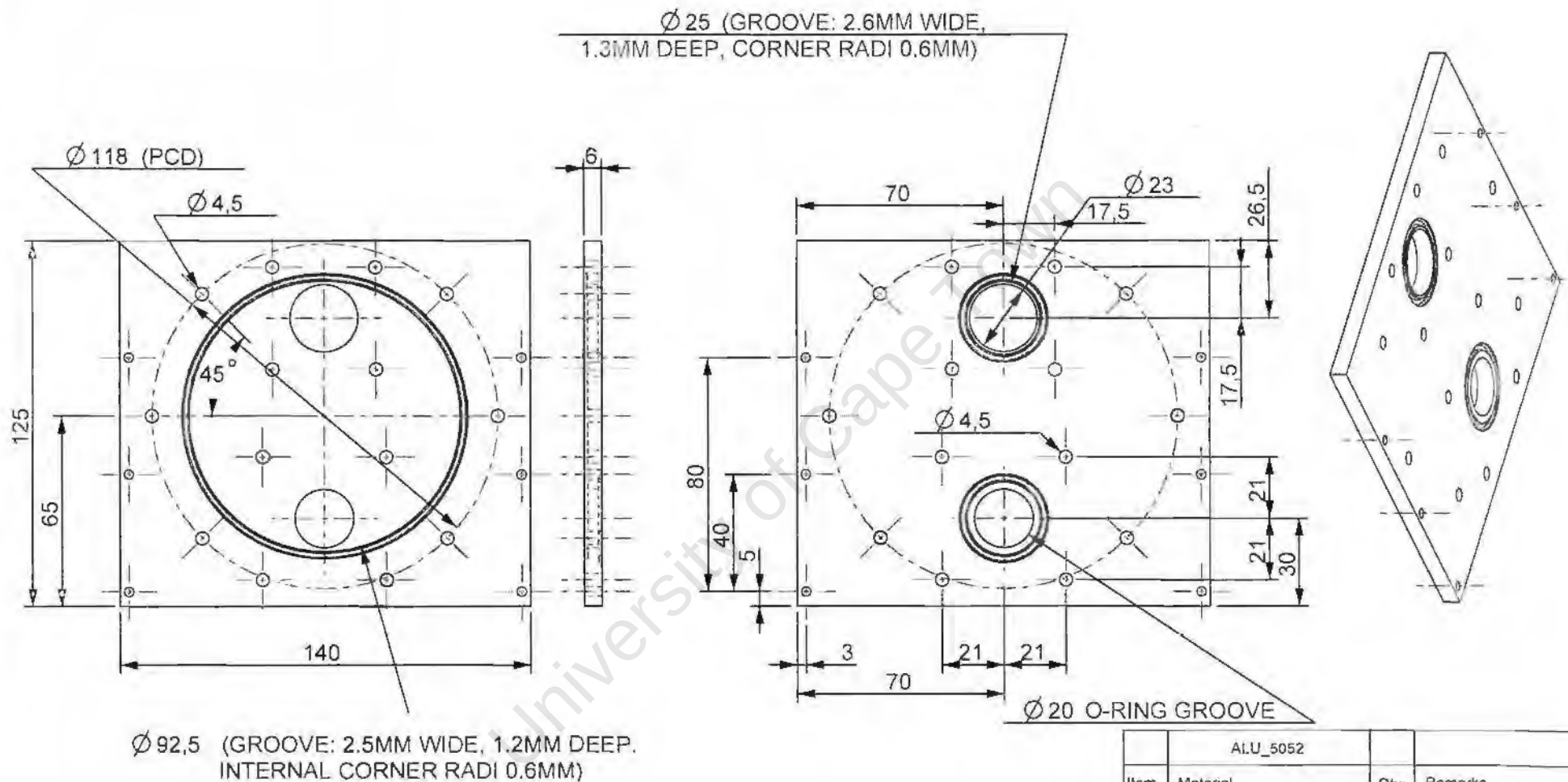
|                                                                                       | PERSPEX_CAST                   | 1                |                          |
|---------------------------------------------------------------------------------------|--------------------------------|------------------|--------------------------|
| Item                                                                                  | Material                       | Qty              | Remarks                  |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                |                  |                          |
|  | Title<br>VETRICLE FRONT FLANGE |                  |                          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>0,750                 | Date<br>OCT 2008 | Sheet<br>23<br>of<br>81  |
| 0.1                                                                                   | H KRYNAUM                      | VIVITRO v. BDC   | Drawing Number<br>PRT_01 |



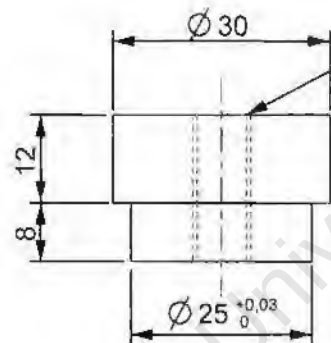
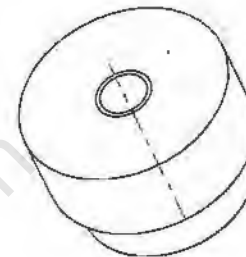
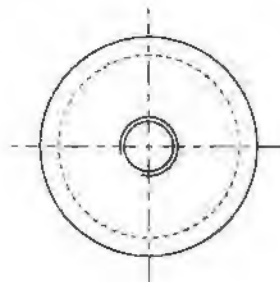
|                                                                                                                              |          |                |          |
|------------------------------------------------------------------------------------------------------------------------------|----------|----------------|----------|
| PERSPEX_CAST                                                                                                                 |          |                |          |
| Item                                                                                                                         | Material | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering                                                              |          |                |          |
| Title<br>VENTRICLE REAR FLANGE                                                                                               |          |                |          |
| <br>Dimensions in mm<br>Tolerance U.O.S | Scale    | Date           | Sheet of |
|                                                                                                                              | 0.1      | 01/01/2015     | 24 of 81 |
| Drawn By VIVITRO v. BDC                                                                                                      |          | Drawing Number |          |
| H KRYNAUW                                                                                                                    |          | IPT_02         |          |



|                                                                 | PERSPEX_CAST   | 1                        |                      |
|-----------------------------------------------------------------|----------------|--------------------------|----------------------|
| Item                                                            | Material       | Qty                      | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                |                          |                      |
| Title                                                           |                | VENTRICLE CILENDER       |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale<br>1,000 | Date<br>OCT 2008         | Sheet<br>25 of<br>81 |
| 0.1                                                             | H KRYNAUM      | Drawing Number<br>PRT_03 |                      |

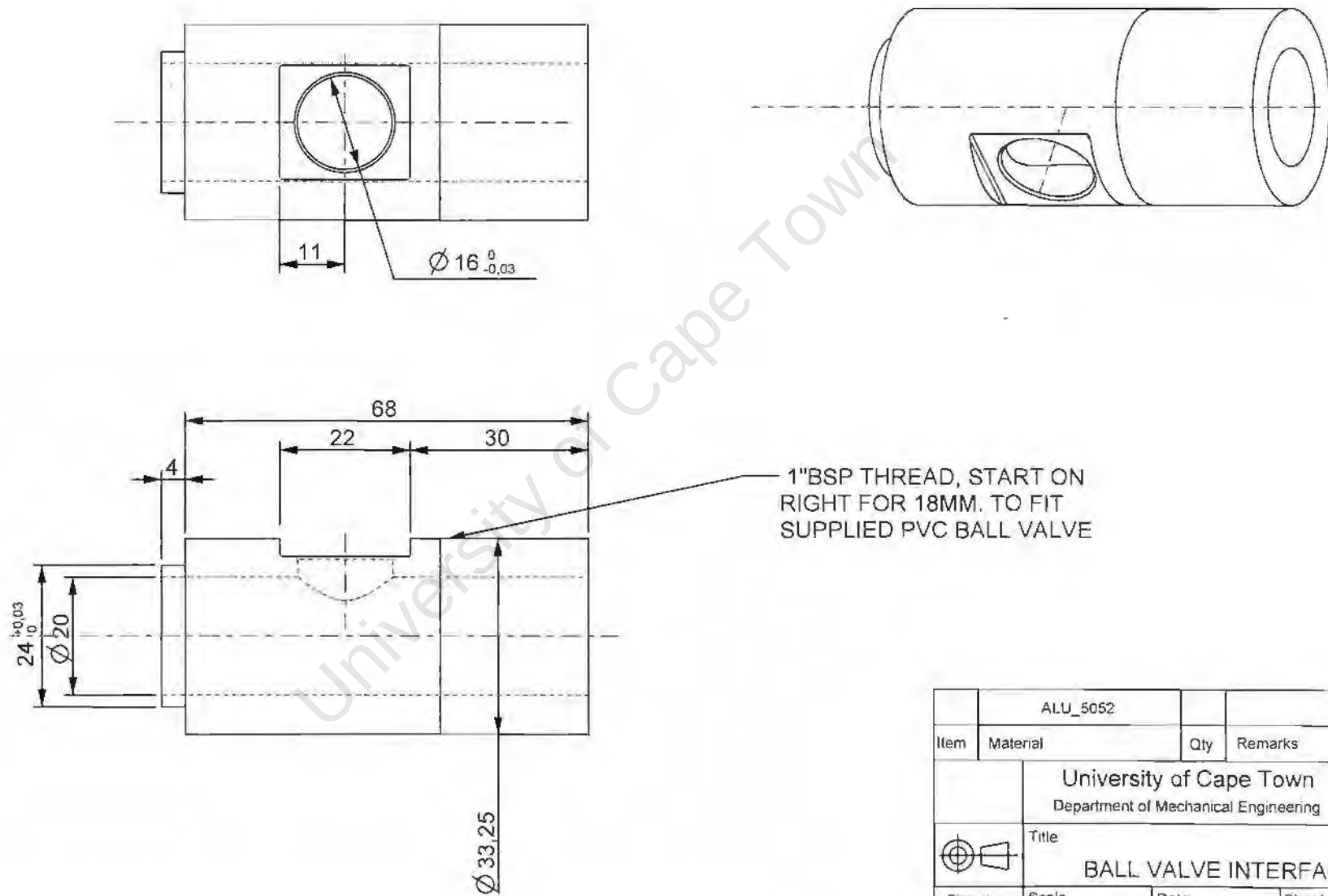


|                                                                 |          |                         |         |
|-----------------------------------------------------------------|----------|-------------------------|---------|
| Al.U_5052                                                       |          |                         |         |
| Item                                                            | Material | Qty                     | Remarks |
| University of Cape Town<br>Department of Mechanical Engineering |          |                         |         |
| Title                                                           |          | VENTRICLE SEALING PLATE |         |
| Dimensions<br>in mm<br>Tolerance<br>U.S.                        | Scale    | Date                    | Sheet   |
| 0.1                                                             | 0.5      | 0.5                     | 81      |
| Drawn By                                                        |          | Drawing Number          |         |
| H KRYNAUW                                                       |          | IPR2024-00320           |         |

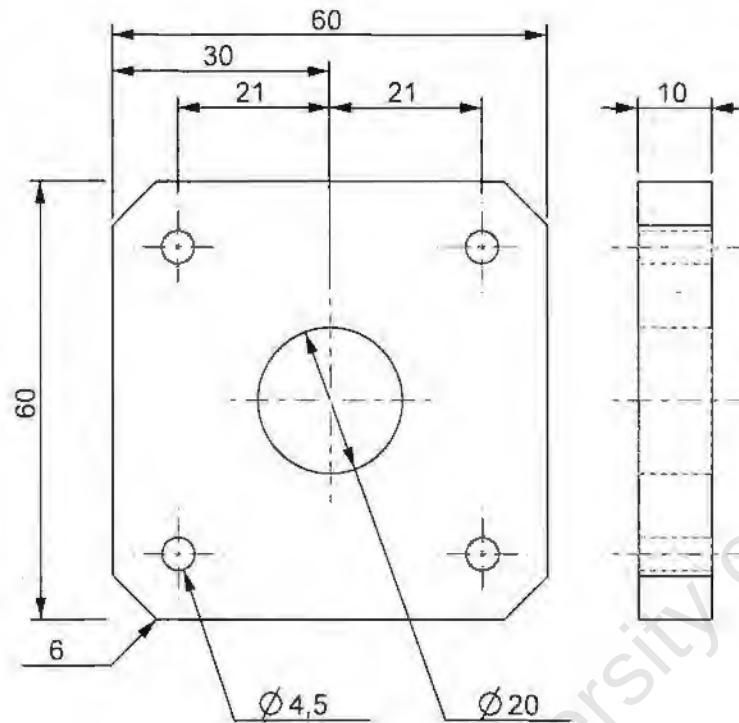


M8x1.25 ISO - H TAP  $\nabla$  21,000  
6.8 DRILL ( 6,800 ) THRU - ( 1 ) HOLE

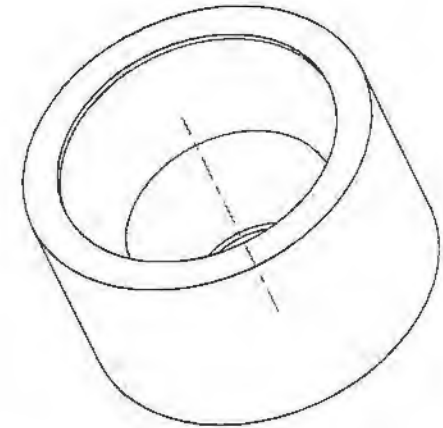
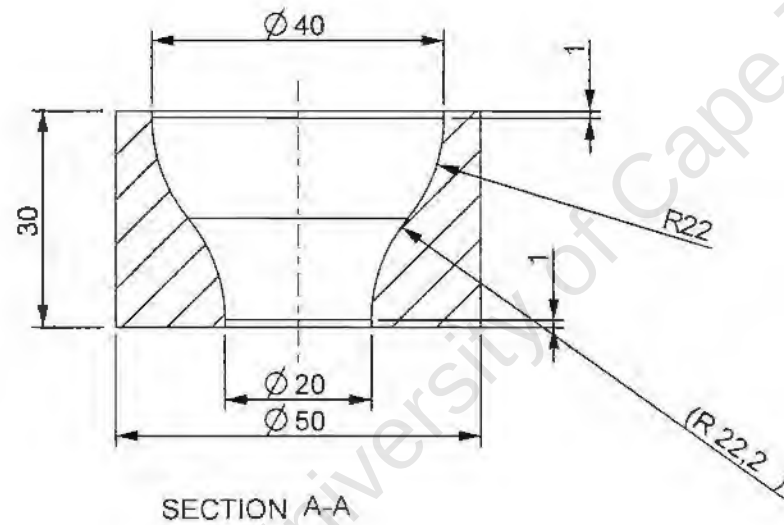
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|-----------------------------------------------------------------|--------------------------------|--------------------------|----------------------|
|                                                                 | ALU_5052                       |                          |                      |
| Item                                                            | Material                       | Qty                      | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                                |                          |                      |
|                                                                 | Title<br>PRT_08_COMP_PIST PRES |                          |                      |
| Dimensions<br>in mm:<br>Tolerance<br>U.O.S.                     | Scale<br>1,000                 | Date<br>OCT 2008         | Sheet<br>27 of<br>81 |
| 0.1                                                             | H KRYNALIN                     | Drawing Number<br>PRT_06 |                      |



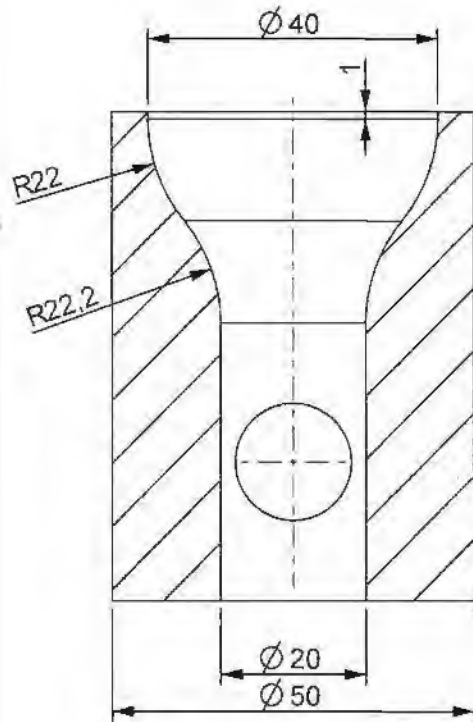
| ALU_5052                                                        |          |                      |          |
|-----------------------------------------------------------------|----------|----------------------|----------|
| Item                                                            | Material | Qty                  | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |          |                      |          |
| Title                                                           |          | BALL VALVE INTERFACE |          |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale    | Date                 | Sheet of |
| 0.1                                                             | 1:1      | 001/2008             | 28 of 81 |
| Drawn By                                                        |          | Drawing Number       |          |
| H KRYNAUW                                                       |          | IPR2024-00320        |          |
|                                                                 |          | ERT_09               |          |



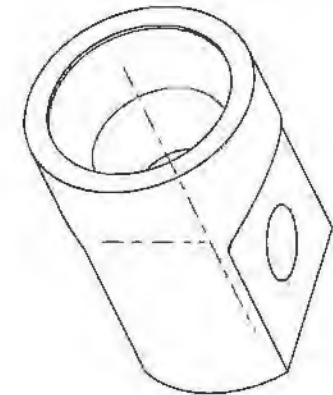
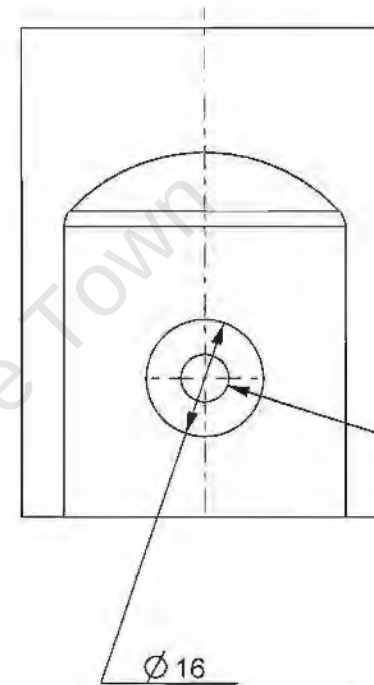
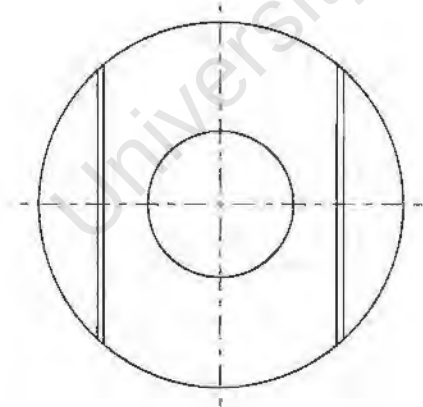
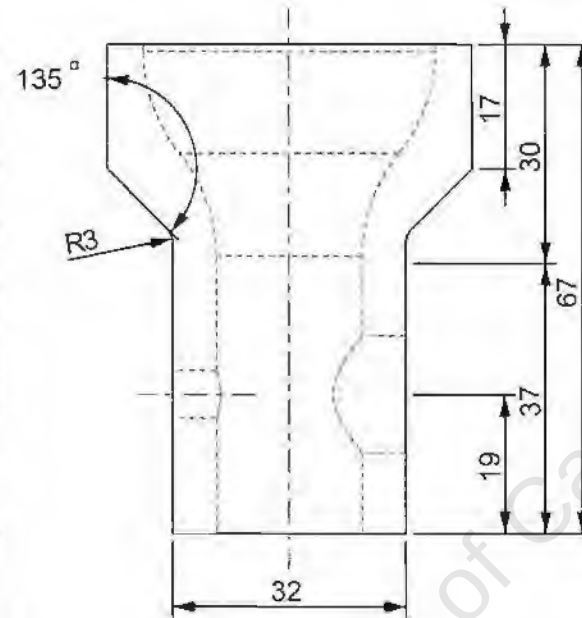
|                                                                                       |                             |                                                                 |                 |              |
|---------------------------------------------------------------------------------------|-----------------------------|-----------------------------------------------------------------|-----------------|--------------|
|                                                                                       | PERSPEX_CAST                |                                                                 |                 |              |
| Item                                                                                  | Material                    | Qty                                                             | Remarks         |              |
|                                                                                       |                             | University of Cape Town<br>Department of Mechanical Engineering |                 |              |
|  | Title<br><br>PERSPEX FLANGE |                                                                 |                 |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>1,000          | Date<br><br>OCT 2008                                            | Sheet<br><br>29 | of<br><br>81 |
| 0.1                                                                                   | Drawn By<br>H KRYNAUW       | Drawing Number<br>PRT_10                                        |                 |              |



|                                                                                       |                                                                 |      |                     |         |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------|------|---------------------|---------|
|                                                                                       | PERSPEX_CAST                                                    |      |                     |         |
| Item                                                                                  | Material                                                        |      | Qty                 | Remarks |
|                                                                                       | University of Cape Town<br>Department of Mechanical Engineering |      |                     |         |
|  | Title<br><br>FLOW EXPANSION                                     |      |                     |         |
| Dimensions in mm<br>Tolerance U.O.S.                                                  | Scale                                                           | Date | Sheet               | of      |
|                                                                                       | 1:1                                                             | 1:1  | 30                  | 81      |
|                                                                                       | Drawn By VIVITRO v. BDO                                         |      | Drawing Number      |         |
| 0.1                                                                                   | H KRYNAUW                                                       |      | IPR2024-00320 RT_11 |         |

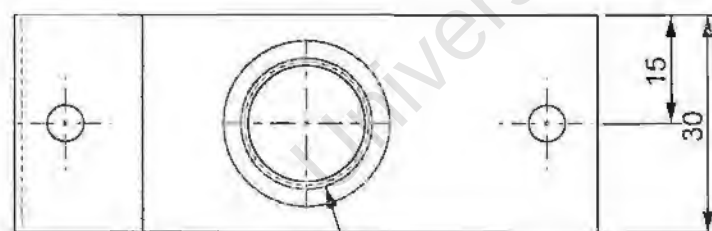
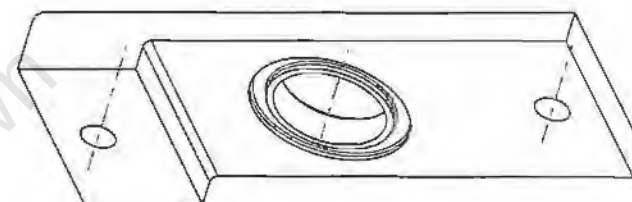
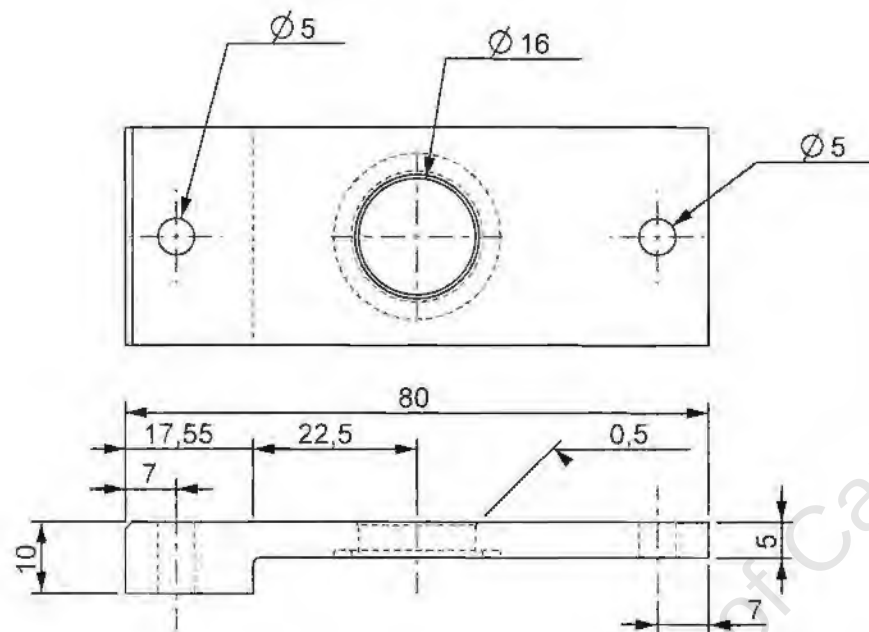


SECTION A-A



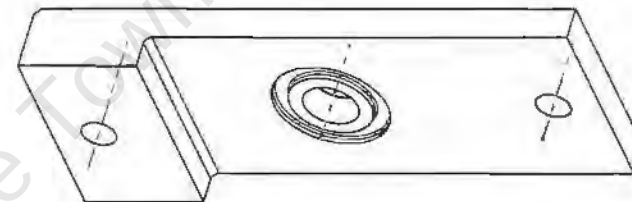
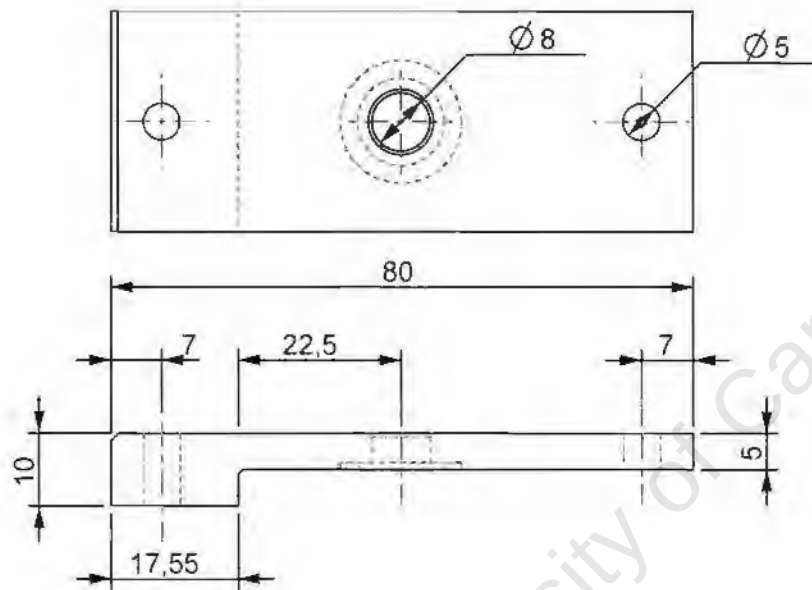
SCALE 0,660

|                                                                                       |                              |                                                                 |                 |              |
|---------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------------------------|-----------------|--------------|
|                                                                                       | PERSPEX_CAST                 |                                                                 |                 |              |
| Item                                                                                  | Material                     | Qty                                                             | Remarks         |              |
|                                                                                       |                              | University of Cape Town<br>Department of Mechanical Engineering |                 |              |
|  | Title<br><br>FLOW CONVERGION |                                                                 |                 |              |
| Dimensions<br>in mm<br>Tolerance<br>J.O.S.                                            | Scale<br><br>1,000           | Date<br><br>OCT 2008                                            | Sheet<br><br>31 | of<br><br>81 |
| Drawing No.                                                                           |                              | Drawing Number                                                  |                 |              |
| 0.1                                                                                   | H KRYNAUW                    |                                                                 | PRT_12          |              |



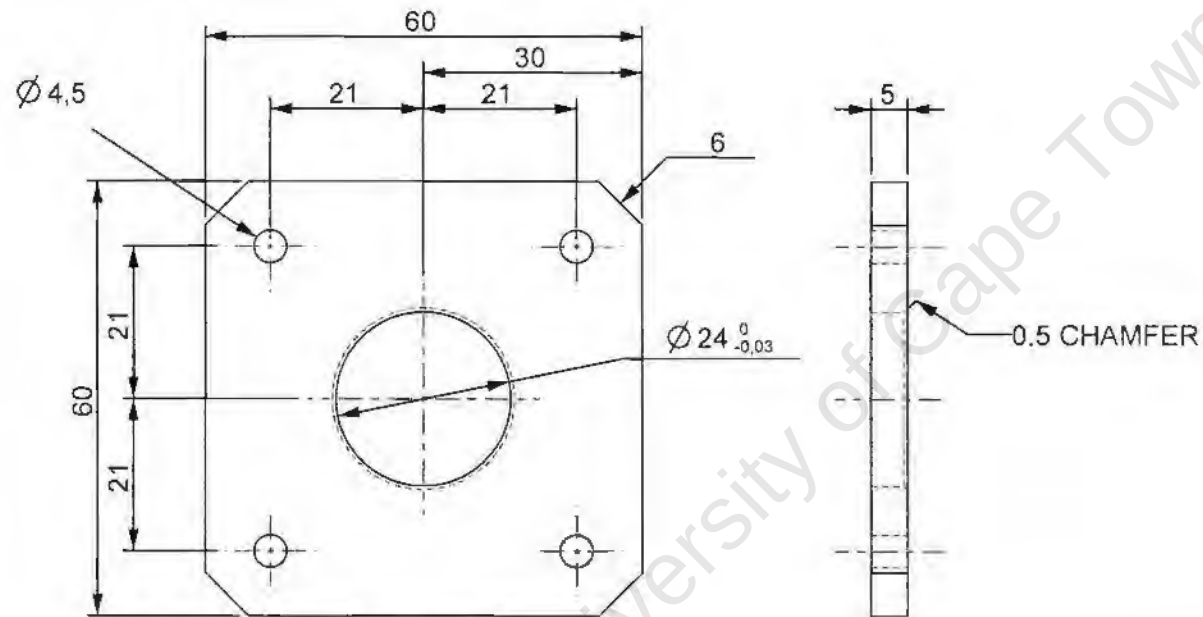
18 GROOVE, 2.4 WIDE, 1 DEEP

|                                                                                       |                               |                                             |                 |              |
|---------------------------------------------------------------------------------------|-------------------------------|---------------------------------------------|-----------------|--------------|
|                                                                                       | ALU_5052                      |                                             |                 |              |
| Item                                                                                  | Material                      | Qty                                         | Remarks         |              |
| University of Cape Town<br>Department of Mechanical Engineering                       |                               |                                             |                 |              |
|  | Title<br><br>TRANSDUCER CLAMP |                                             |                 |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>1:100            | Date<br><br>01/12/2008                      | Sheet<br><br>32 | of<br><br>81 |
| Drawn By<br><br>H KRYNAUW                                                             |                               | Drawing Number<br><br>IPR2024-00320 PART 13 |                 |              |

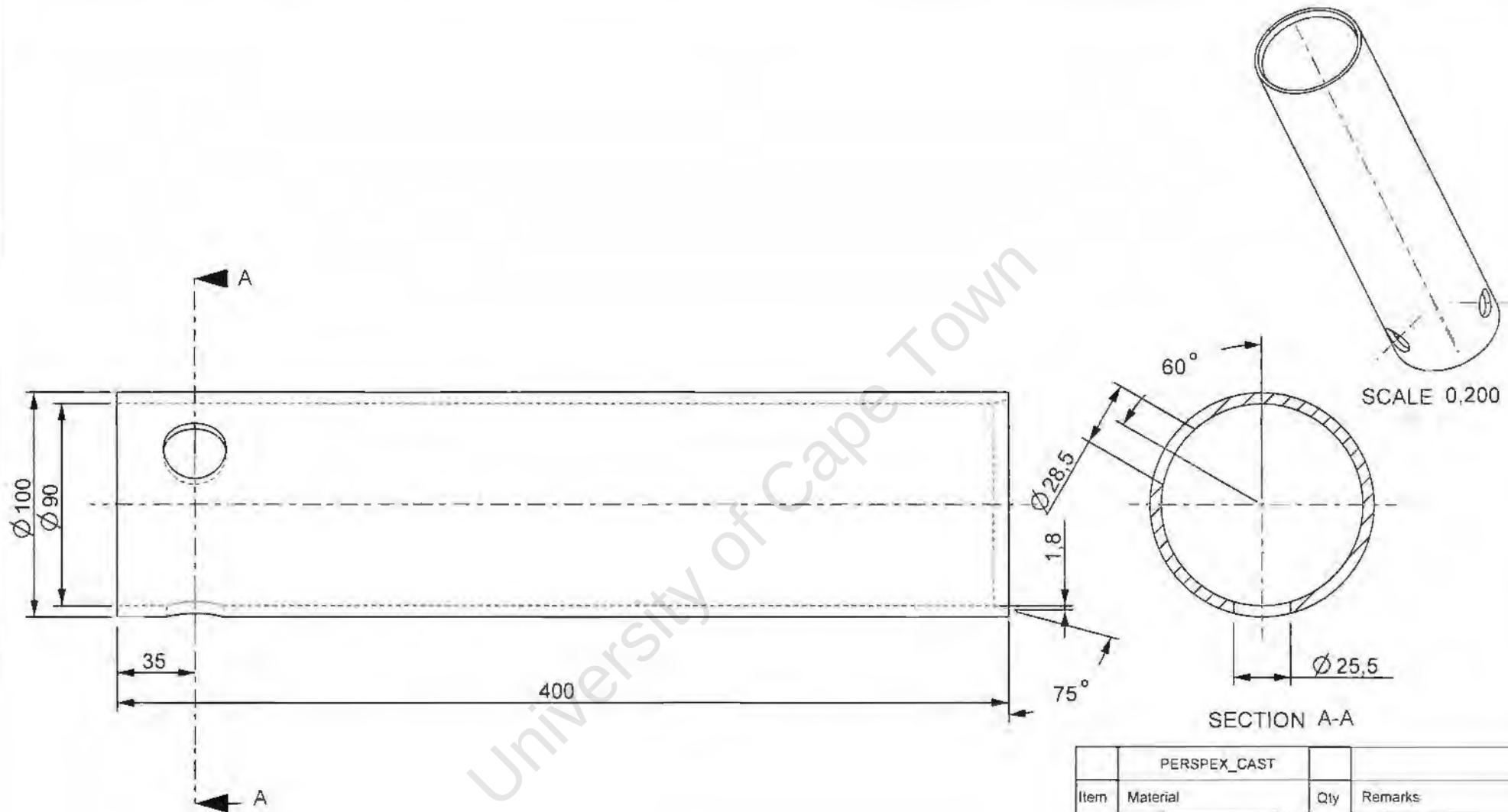


$\varnothing 12$  CROOVE, 2.1 WIDE, 1 DEEP

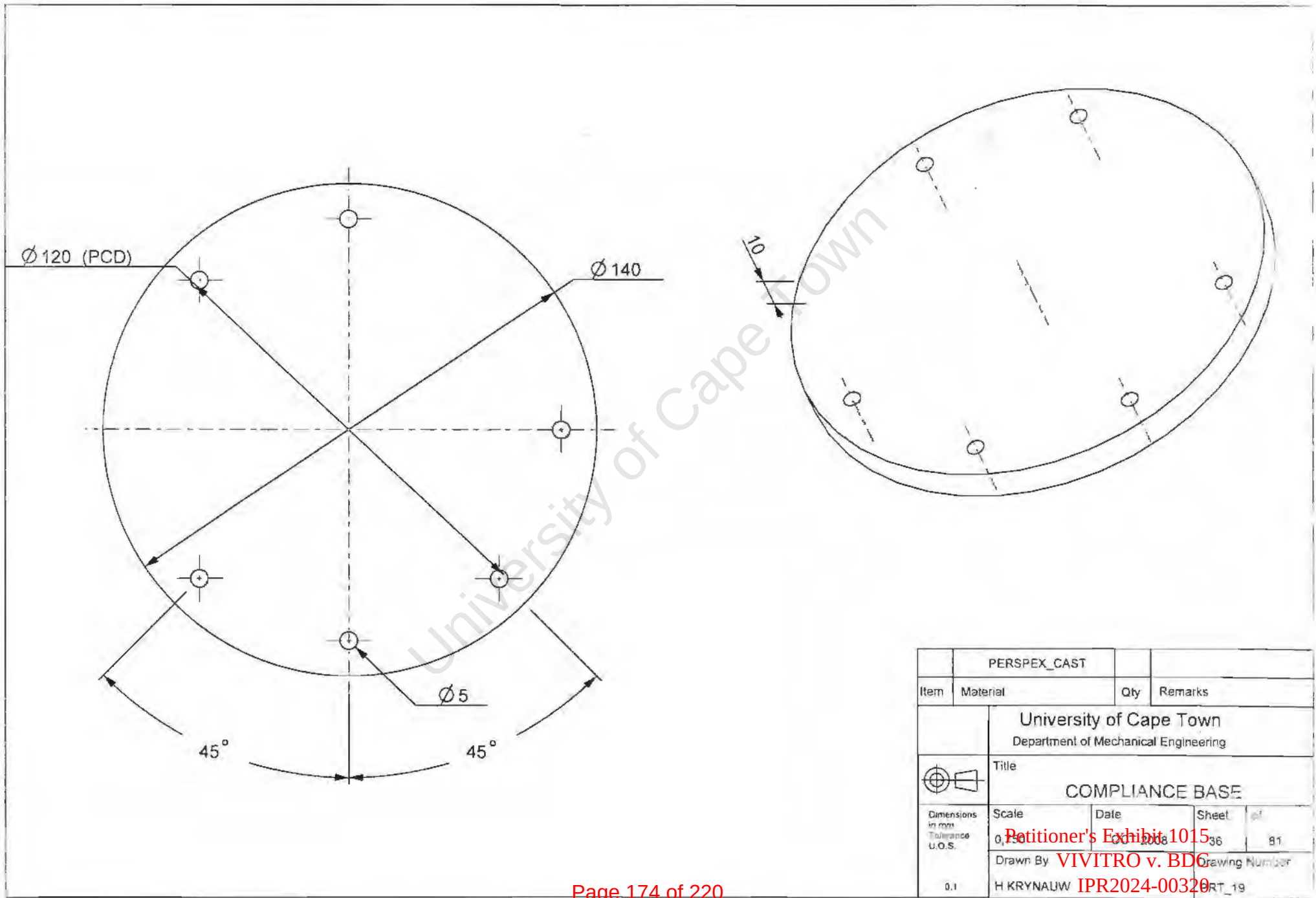
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|-----------------------------------------------------------------|--------------------|----------|----------|
| ALU_5052                                                        |                    |          |          |
| Item                                                            | Material           | Qty      | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |                    |          |          |
|                                                                 | Title              |          |          |
|                                                                 | OPTICAL SCOPE PORT |          |          |
| Dimensions in mm<br>Tolerance<br>u.o.s.                         | Scale              | Date     | Sheet of |
|                                                                 | 1,000              | OCT 2008 | 33 81    |
| Drawn by                                                        | Drawing Number     |          |          |
| H KRYNAUW                                                       | PRT_15_00          |          |          |



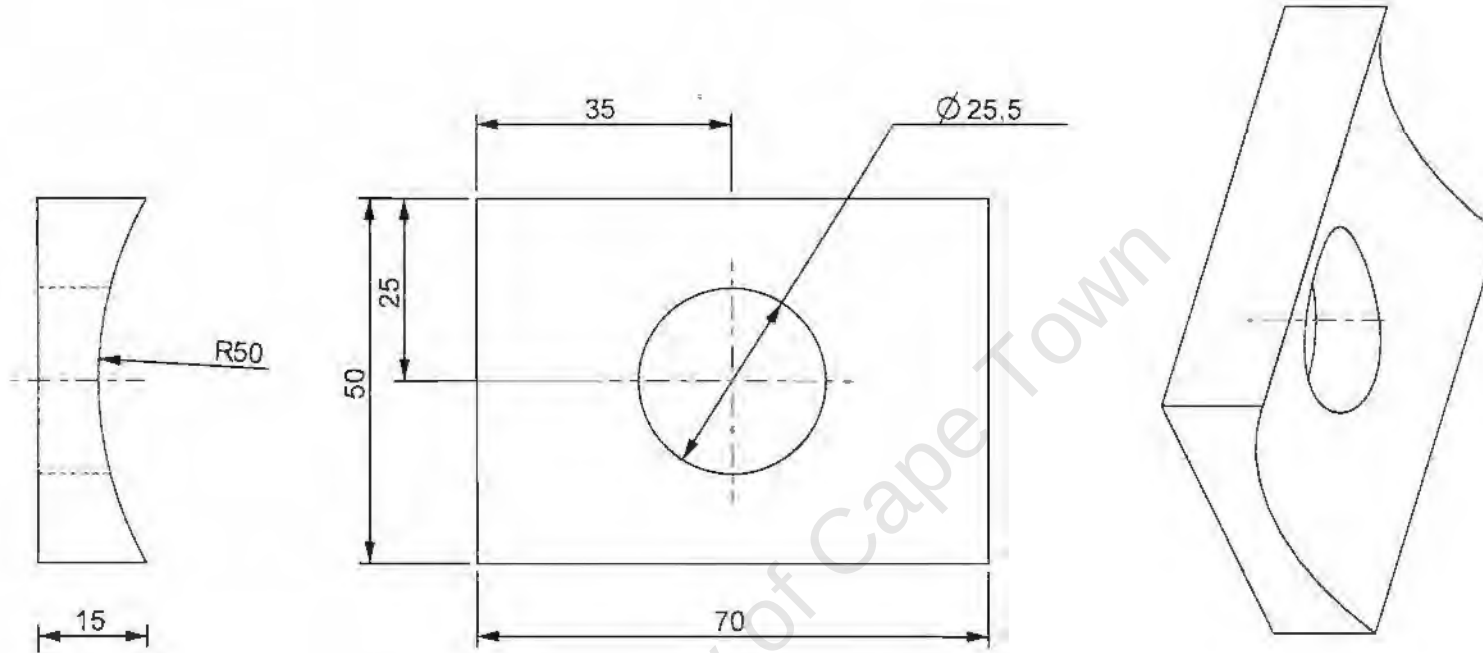
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|---------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------|----------------|---------|
|                                                                                       | ALU_5052                        |                                                                 |                |         |
| Item                                                                                  | Material                        |                                                                 | Qty            | Remarks |
|                                                                                       |                                 | University of Cape Town<br>Department of Mechanical Engineering |                |         |
|  | Title<br><br>ALUMINIUM FLANGE 1 |                                                                 |                |         |
| Dimensions in mm<br>Tolerance<br>U.O.S.                                               | Scale                           | Date                                                            | Sheet          | of      |
|                                                                                       | 1:1                             | 01/01/2008                                                      | 34             | 61      |
|                                                                                       | Drawn By                        |                                                                 | Drawing Number |         |
| 0.1                                                                                   | H KRYNAUW                       |                                                                 | PART_16        |         |



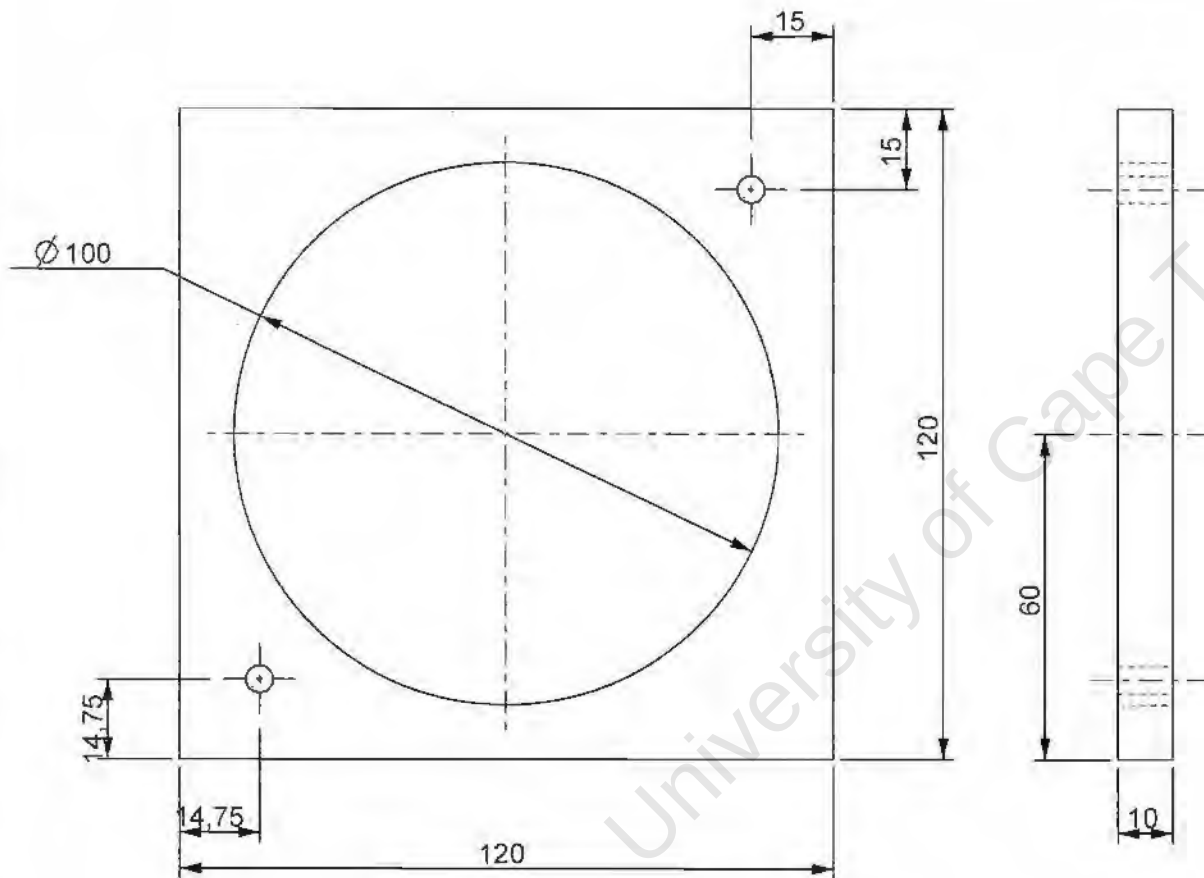
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|---------------------------------------------------------------------------------------|------------------------------|--------------------------|-------------|----------|
|                                                                                       | PERSPEX_CAST                 |                          |             |          |
| Item                                                                                  | Material                     | Qty                      | Remarks     |          |
| University of Cape Town<br>Department of Mechanical Engineering                       |                              |                          |             |          |
|  | Title<br>COMPLIANCE CYLINDER |                          |             |          |
| Dimensions in mm<br>Tolerance U.O.S.                                                  | Scale<br>0,400               | Date<br>OCT 2008         | Sheet<br>35 | of<br>81 |
| 0.1                                                                                   | H KRYNAUW                    | Drawing Number<br>PRT_18 |             |          |



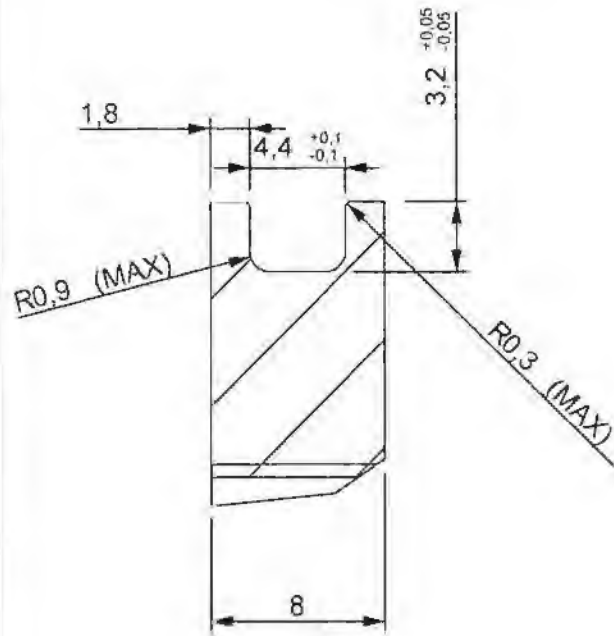
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|---------------------------------------------------------------------------------------|------------------------------|------------|--------------------------------------|----|
|                                                                                       | PERSPEX_CAST                 |            |                                      |    |
| Item                                                                                  | Material                     | Qty        | Remarks                              |    |
| University of Cape Town<br>Department of Mechanical Engineering                       |                              |            |                                      |    |
|  | Title<br><br>COMPLIANCE BASE |            |                                      |    |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale                        | Date       | Sheet                                | of |
| 0.1                                                                                   | 1:1                          | 01-01-2008 | 36                                   | 81 |
| 0.1                                                                                   | Drawn By H KRYNAUW           |            | Drawing Number IPR2024-00320 PART_19 |    |



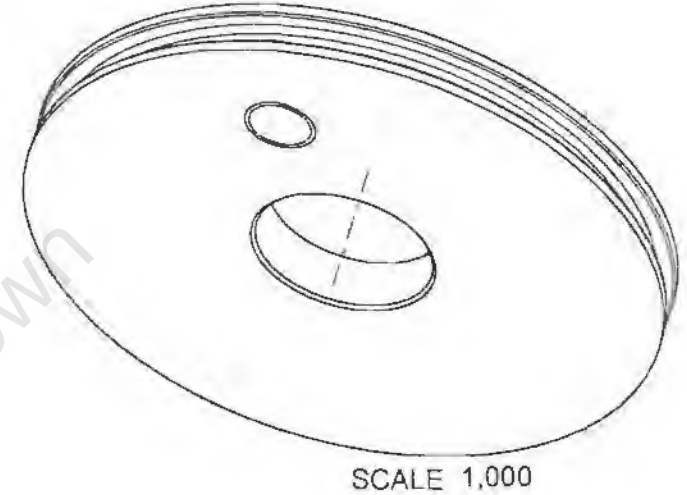
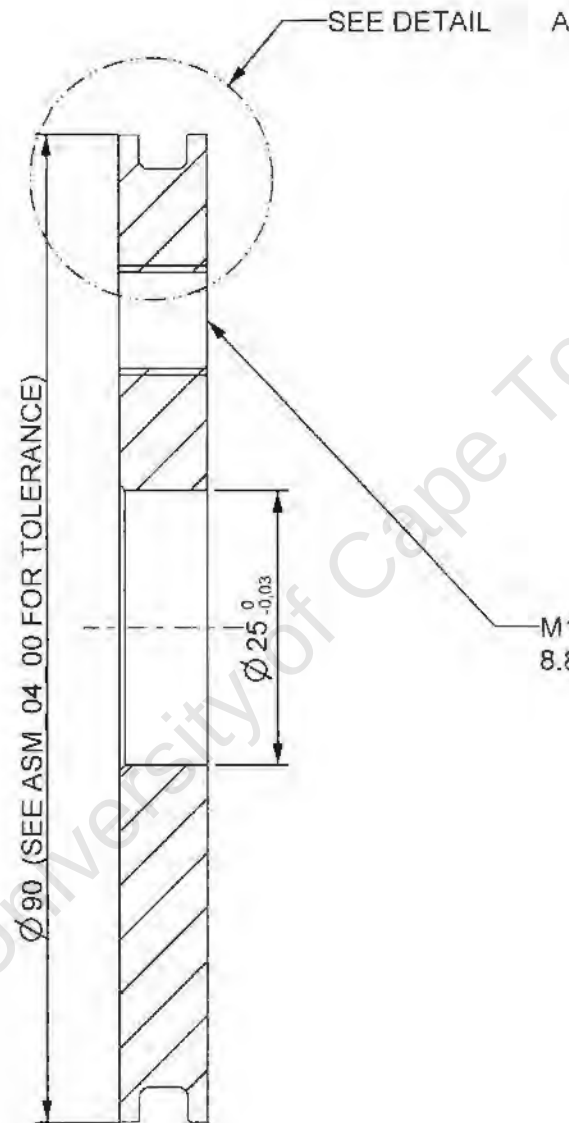
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|---------------------------------------------------------------------------------------|--------------------------------|------------------|--------------------------|----------|
|                                                                                       | PERSPEX_CAST                   |                  |                          |          |
| Item                                                                                  | Material                       | Qty              | Remarks                  |          |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                |                  |                          |          |
|  | Title<br>COMPLIANCE EXTERNAL 1 |                  |                          |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>1,000                 | Date<br>OCT 2008 | Sheet<br>37              | of<br>81 |
| 0.1                                                                                   | H KRYNAUW                      |                  | Drawing Number<br>PRT_20 |          |



|                                                                                       | PERSPEX_CAST                   | 1              |          |
|---------------------------------------------------------------------------------------|--------------------------------|----------------|----------|
| Item                                                                                  | Material                       | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                |                |          |
|  | Title<br>COMPLIANCE TOP FLANGE |                |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale                          | Date           | Sheet of |
| 0.1                                                                                   | 0.1                            | 01/02/2015     | 38 of 81 |
| Drawn By H KRYNAUW                                                                    |                                | Drawing Number |          |
| IPR2024-00320                                                                         |                                | PART_21        |          |

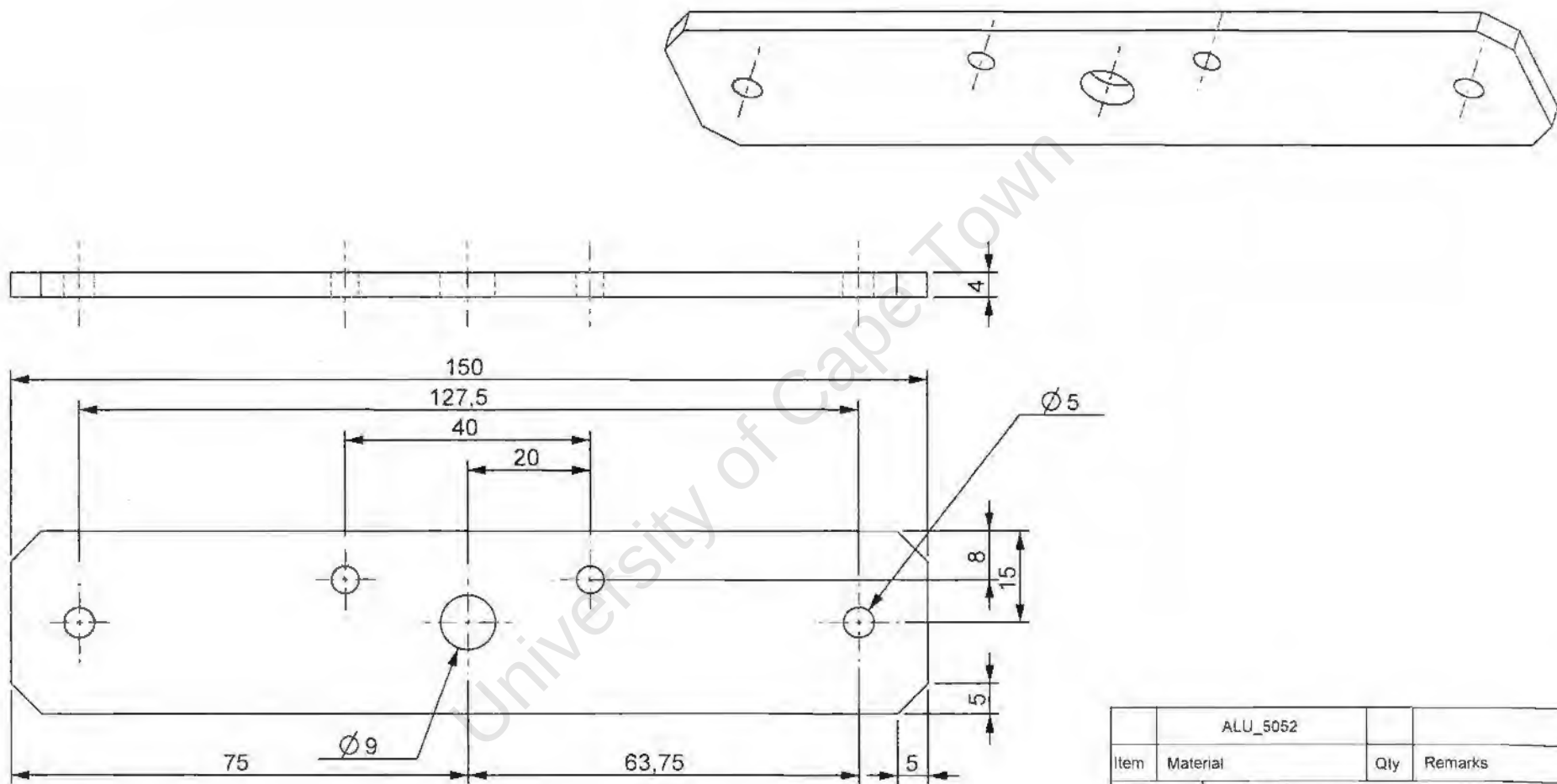


DETAIL A  
SCALE 3,000

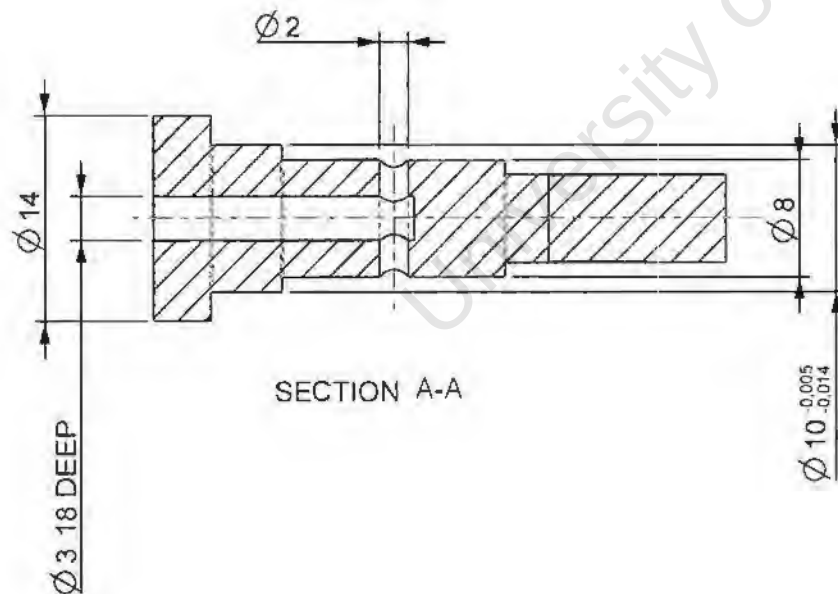
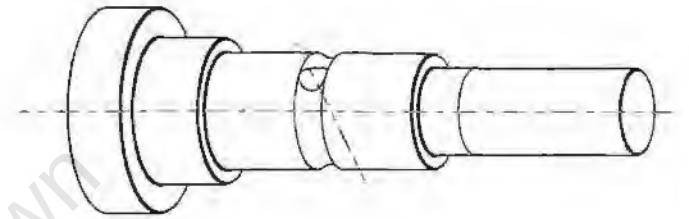
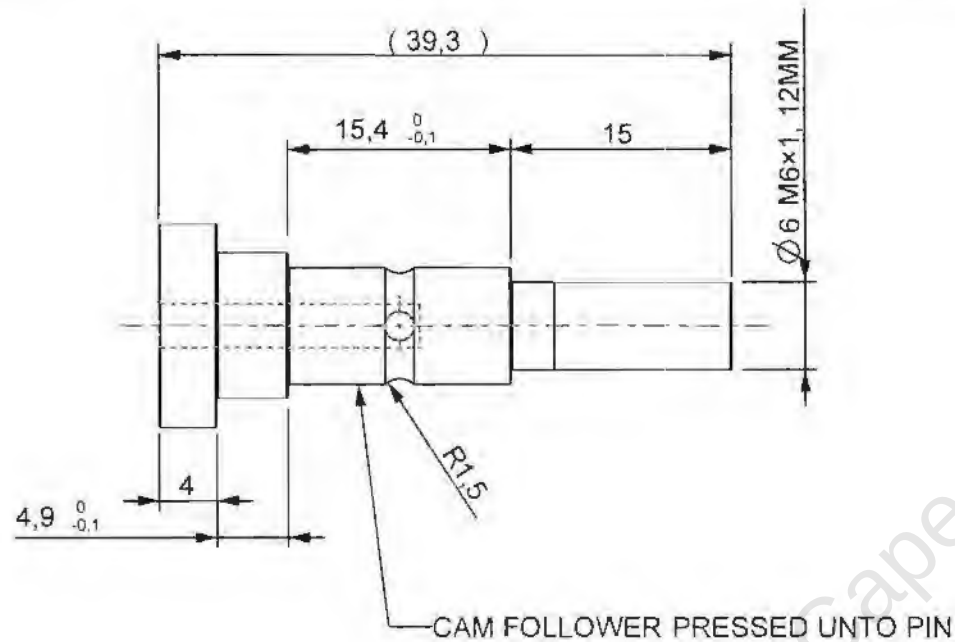


M10x1.25 ISO - H TAP  $\nabla$  8,000  
8.8 DRILL ( 8,800 ) THRU - ( 1 ) HOLE

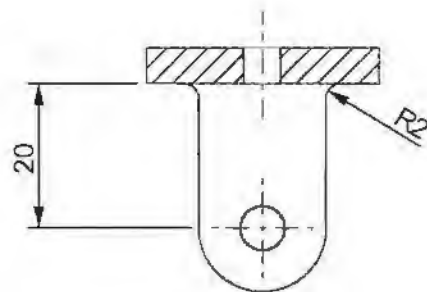
|                                                                 | ALU_6082  | 1                        |          |
|-----------------------------------------------------------------|-----------|--------------------------|----------|
| Item                                                            | Material  | Qty                      | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |           |                          |          |
| Title<br>COMPLIANCE PLUNGER PLATE                               |           |                          |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale     | Date                     | Sheet of |
|                                                                 | 1,500     | OCT 2008                 | 39 81    |
| 01                                                              | H KRYNAUW | Drawing Number<br>PRT_22 |          |



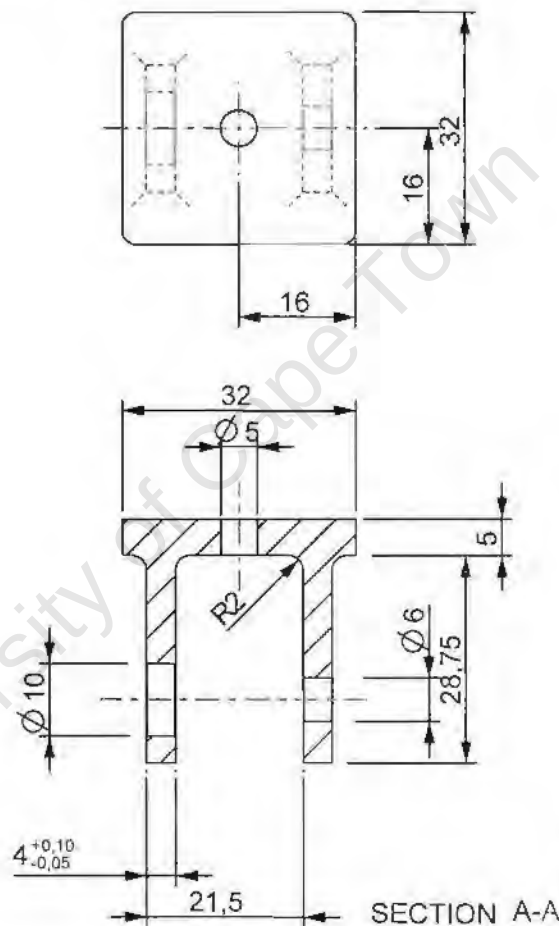
|                                                                 |          |                          |          |
|-----------------------------------------------------------------|----------|--------------------------|----------|
| ALU_5052                                                        |          |                          |          |
| Item                                                            | Material | Qty                      | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |          |                          |          |
| Title                                                           |          | COMPLIANCE LOCKING PLATE |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale    | Date                     | Sheet of |
| 0.1                                                             | 1:1      | 01/01/2018               | 40 of 81 |
| Drawn By                                                        |          | Drawing Number           |          |
| H KRYNAUW                                                       |          | IPR2024-00320            |          |
|                                                                 |          | RT_23                    |          |



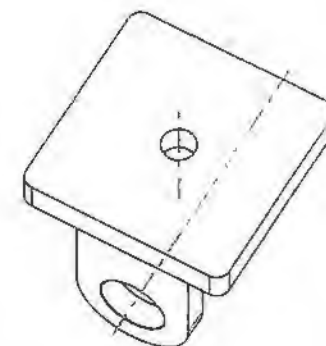
|                                           | M300                                                            |                          |                      |
|-------------------------------------------|-----------------------------------------------------------------|--------------------------|----------------------|
| Item                                      | Material                                                        | Qty                      | Remarks              |
|                                           | University of Cape Town<br>Department of Mechanical Engineering |                          |                      |
|                                           | Title<br>CAM FOLLOWER PIN                                       |                          |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S | Scale<br>2,000                                                  | Date<br>OCT 2008         | Sheet<br>41 of<br>81 |
| Drawn By<br>0.1                           | H KRYNALWA                                                      | Drawing Number<br>PRT_26 |                      |



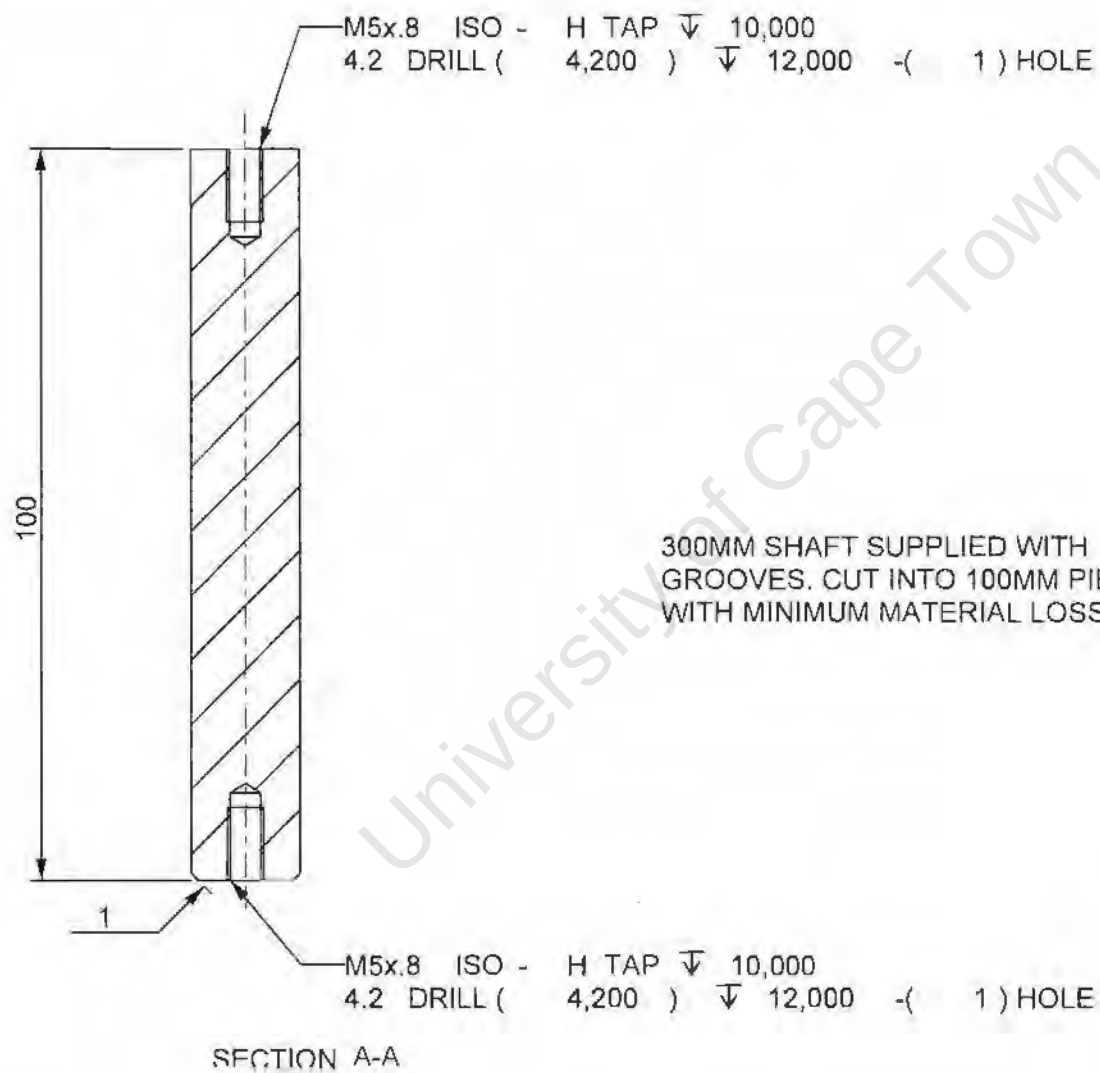
SECTION B-B



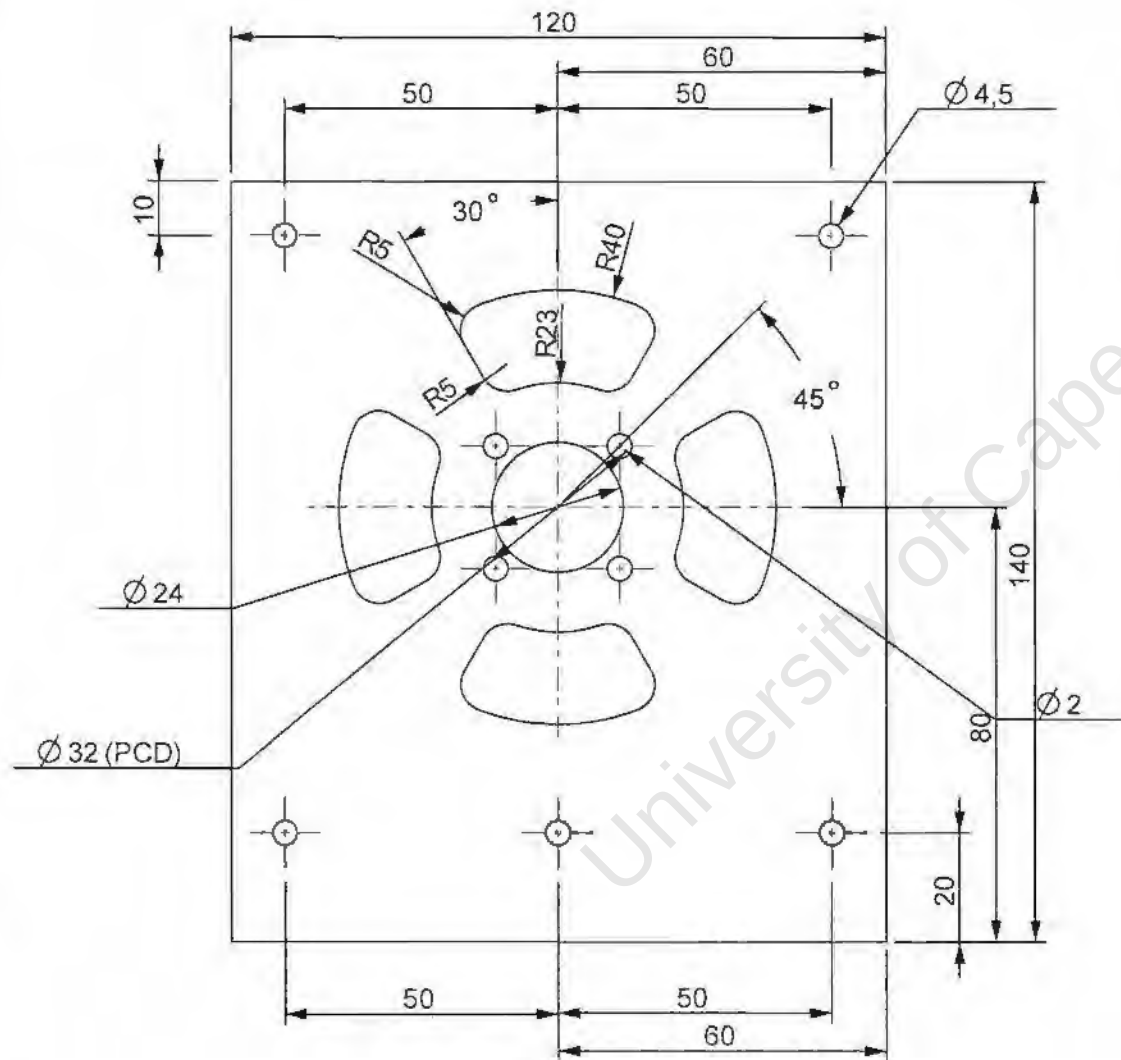
SECTION A-A



|                                                                 |                |                                 |                   |
|-----------------------------------------------------------------|----------------|---------------------------------|-------------------|
| ALU_5052                                                        |                |                                 |                   |
| Item                                                            | Material       | Qty                             | Remarks           |
| University of Cape Town<br>Department of Mechanical Engineering |                |                                 |                   |
| Title<br>CAM FOLLOWER BRACKET                                   |                |                                 |                   |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale<br>1:100 | Date<br>00/12/2008              | Sheet<br>42 of 81 |
| Drawn By<br>H KRYNAUW                                           |                | Drawing Number<br>IPR2024-00320 |                   |
| 0.1                                                             |                | ERT_27                          |                   |

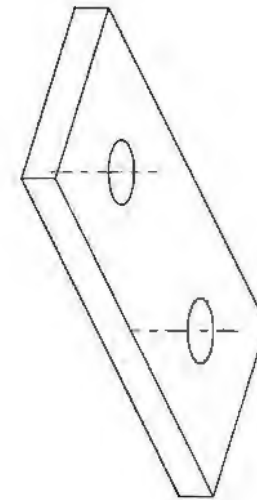
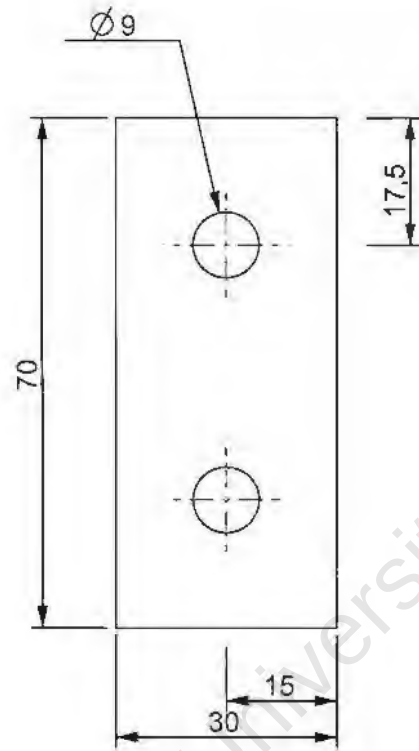


|                                                                 |                          |                    |                      |
|-----------------------------------------------------------------|--------------------------|--------------------|----------------------|
| STEEL_LC                                                        |                          |                    |                      |
| Item                                                            | Material                 | Qty                | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                          |                    |                      |
| Title                                                           |                          | LINEAR BEARING ROD |                      |
| Dimensions in mm<br>Tolerance UDS                               | Scale<br>1,000           | Date<br>OCT 2008   | Sheet<br>43 of<br>81 |
| Drawn by<br>H KRYNALW                                           | Drawing Number<br>PRT_29 |                    |                      |



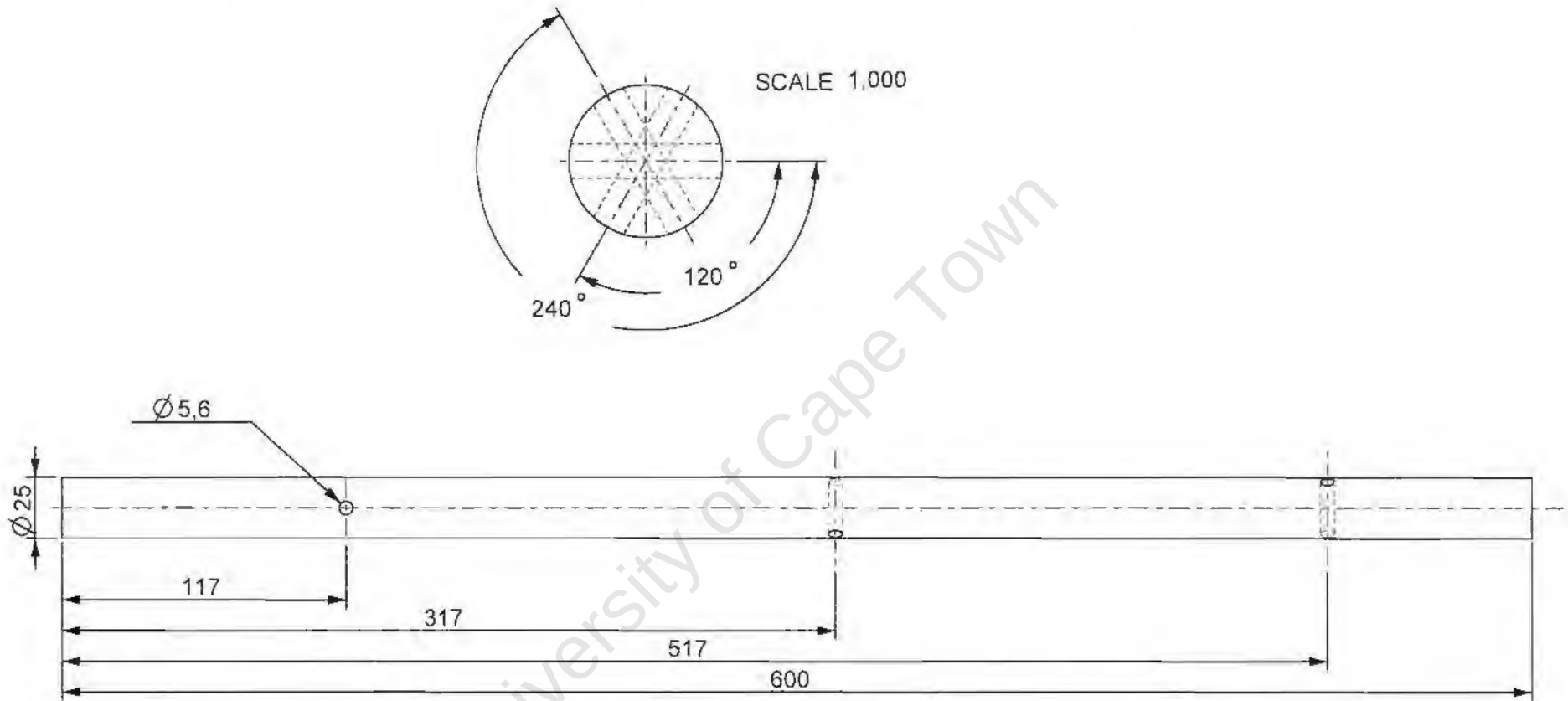
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|-----------------------------------------------------------------|----------|-------------------------|----------|
| ALU_5052                                                        |          |                         |          |
| Item                                                            | Material | Qty                     | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |          |                         |          |
| Title                                                           |          | BEARING ATTACHING PLATE |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale    | Date                    | Sheet of |
| 0.1                                                             | 1:1      | 2024/08/15              | 44 of 81 |
| Drawn By VIVITRO v. BDC                                         |          | Drawing Number          |          |
| H KRYNAUW                                                       |          | IPR2024-00320           |          |
| 0.1                                                             |          | PART_30                 |          |



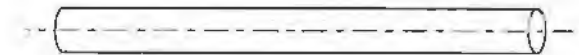
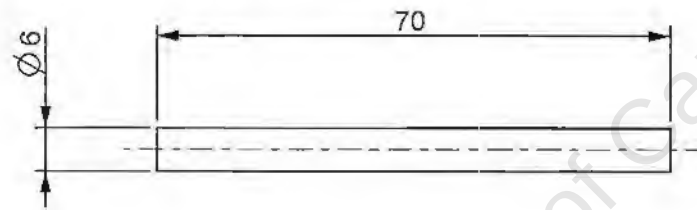


QUANTITY: 4

| ST_STEEL_304                                                                                                                  |          |                   |          |
|-------------------------------------------------------------------------------------------------------------------------------|----------|-------------------|----------|
| Item                                                                                                                          | Material | Qty               | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering                                                               |          |                   |          |
| Title                                                                                                                         |          | MOTOR MOUNT PLATE |          |
| <br>Dimensions in mm<br>Tolerance U.O.S. | Scale    | Date              | Sheet of |
|                                                                                                                               | 1:100    | OCT 2008          | 46 of 61 |
| Drawn By                                                                                                                      |          | Drawing Number    |          |
| H KRYNAUW                                                                                                                     |          | IPR2024-00320     |          |
| 01                                                                                                                            |          | PRT_33            |          |

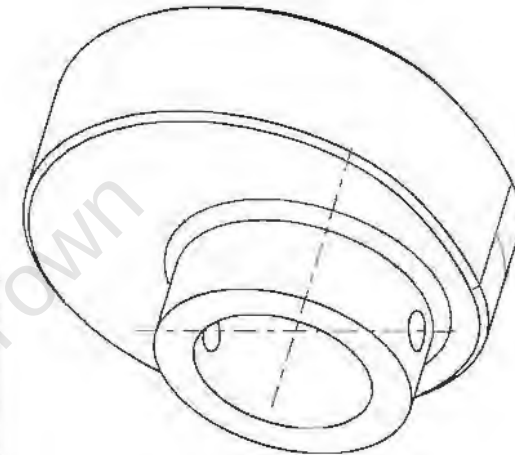
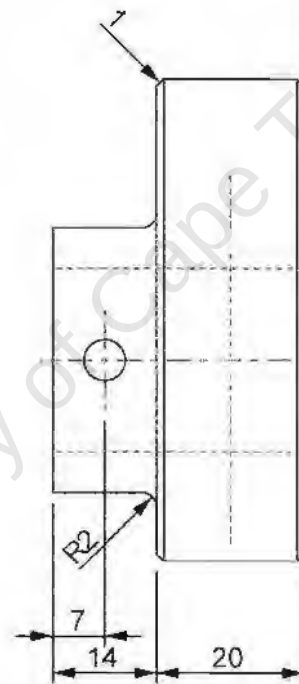
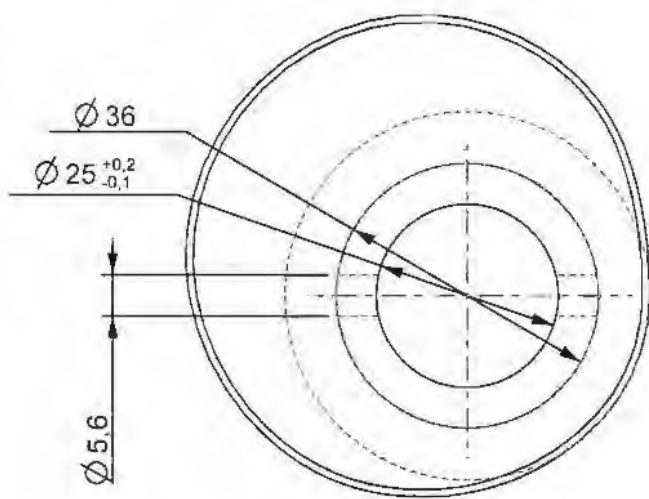


|                                                                                       |                         |          |                |    |
|---------------------------------------------------------------------------------------|-------------------------|----------|----------------|----|
|                                                                                       | SILVERSTEEL             |          |                |    |
| Item                                                                                  | Material                | Qty      | Remarks        |    |
| University of Cape Town<br>Department of Mechanical Engineering                       |                         |          |                |    |
|  | Title<br><br>DRIVESHAFT |          |                |    |
| Dimensions<br>in mm<br>Tolerance<br>U.G.S.                                            | Scale                   | Date     | Sheet          | of |
|                                                                                       | 0,400                   | OCT 2008 | 47             | 81 |
| Drawing Number                                                                        |                         |          | Drawing Number |    |
| 0.1                                                                                   | H KRYNALWA              |          | PRT_34         |    |

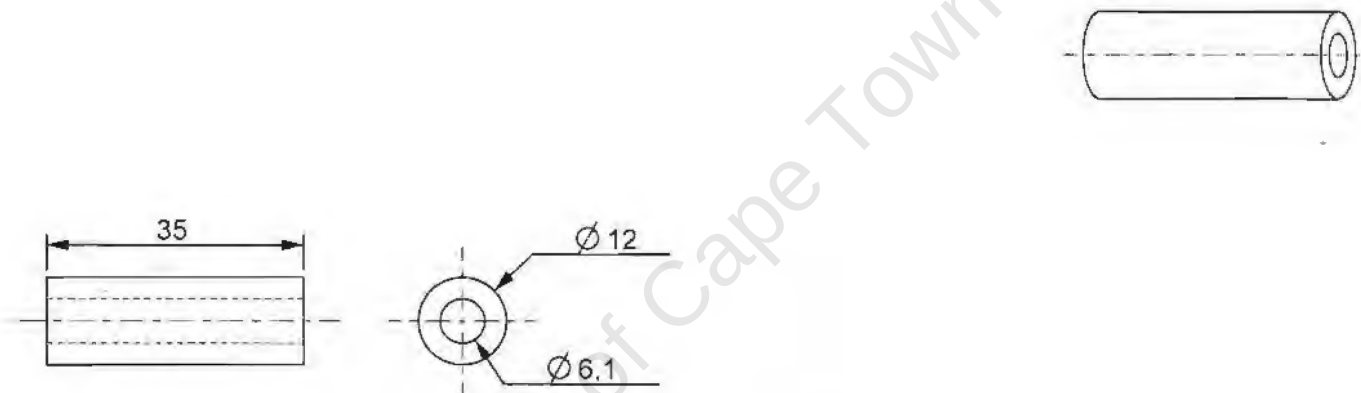


QUANTITY: 2

|                                                                                       |                              |                                                                 |             |          |
|---------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------------------------|-------------|----------|
|                                                                                       | ST_STEEL_304                 |                                                                 |             |          |
| Item                                                                                  | Material                     |                                                                 | Qty         | Remarks  |
|                                                                                       |                              | University of Cape Town<br>Department of Mechanical Engineering |             |          |
|  | Title<br><br>MOTOR HINGE PIN |                                                                 |             |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>1:500               | Date<br>Oct 2008                                                | Sheet<br>48 | of<br>81 |
|                                                                                       | Drawn By<br>H KRYNAUW        | Drawing Number<br>PRT_36                                        |             |          |

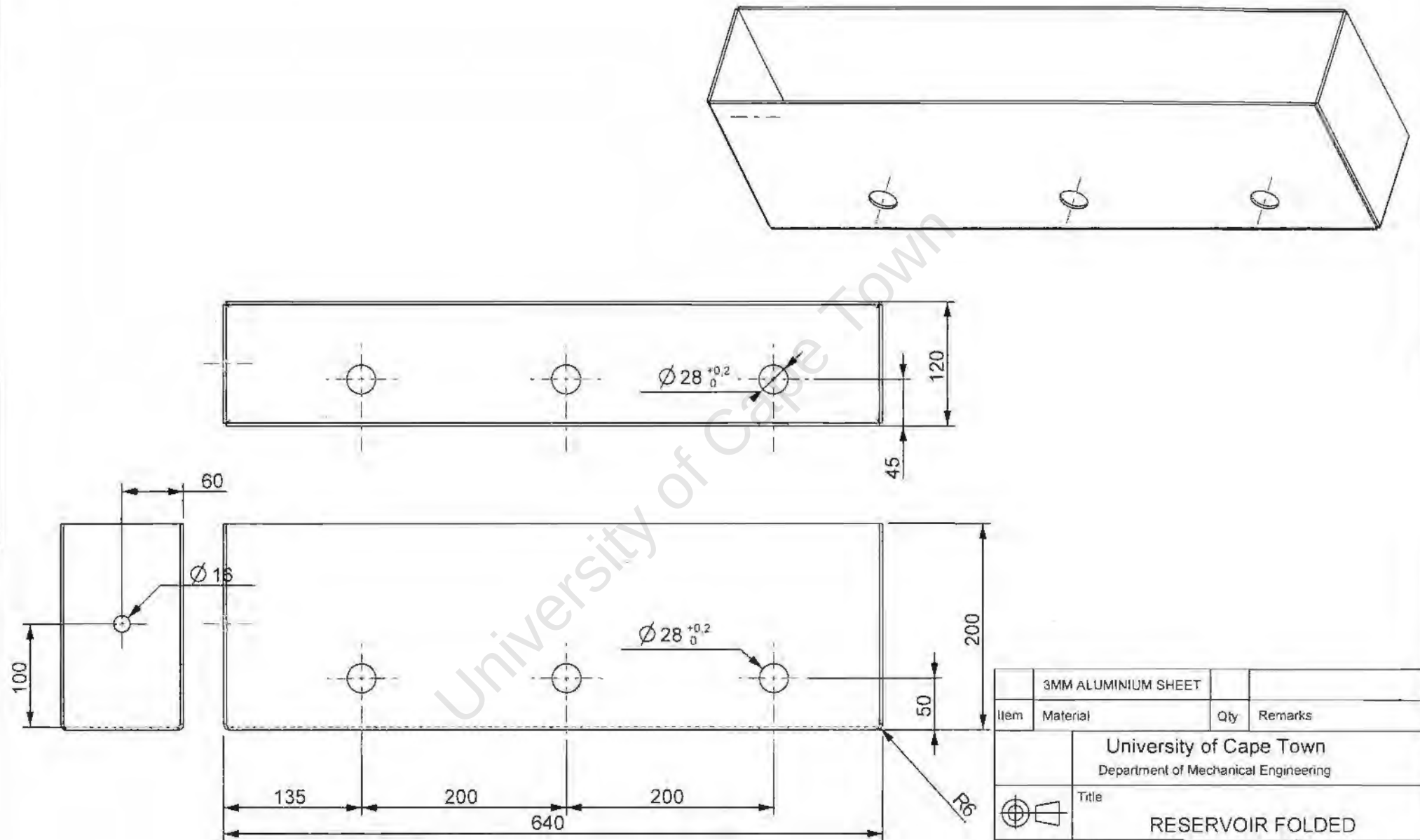


|                                                                                       |                                                                 |                          |                      |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------|----------------------|
|                                                                                       | M300                                                            |                          |                      |
| Item                                                                                  | Material                                                        | Qty                      | Remarks              |
|                                                                                       | University of Cape Town<br>Department of Mechanical Engineering |                          |                      |
|  | Title<br><br>CAM                                                |                          |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>1,000                                                  | Date<br>OCT 2008         | Sheet<br>49 of<br>81 |
| 0.1                                                                                   | H KRYNAUW                                                       | Drawing Number<br>PRT_37 |                      |



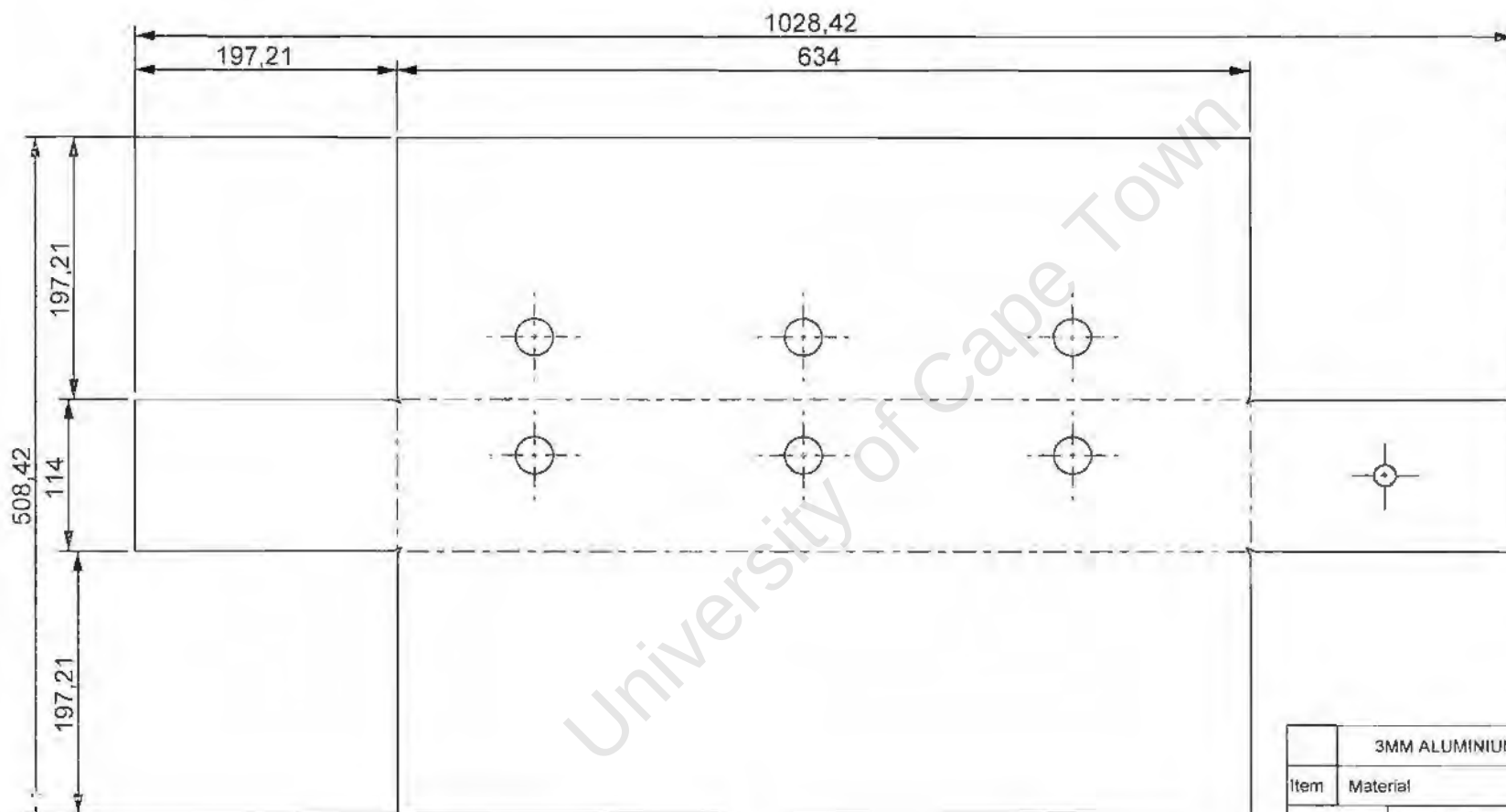
QUANTITY: 2

|                                                                                       |              |                                                                 |                |         |    |
|---------------------------------------------------------------------------------------|--------------|-----------------------------------------------------------------|----------------|---------|----|
|                                                                                       | ST_STEEL_304 |                                                                 |                |         |    |
| Item                                                                                  | Material     |                                                                 | Qty            | Remarks |    |
|                                                                                       |              | University of Cape Town<br>Department of Mechanical Engineering |                |         |    |
|  |              | Title<br><br>MOTOR HINGE TUBE                                   |                |         |    |
| Dimensions<br>in mm<br>Tolerance<br>U.D.S.                                            | Scale        | Date                                                            |                | Sheet   | of |
|                                                                                       | 1:100        | OCT 2008                                                        |                | 50      | 81 |
|                                                                                       | Drawn By     |                                                                 | Drawing Number |         |    |
| 0.1                                                                                   | H KRYNALW    |                                                                 | PRT 38         |         |    |

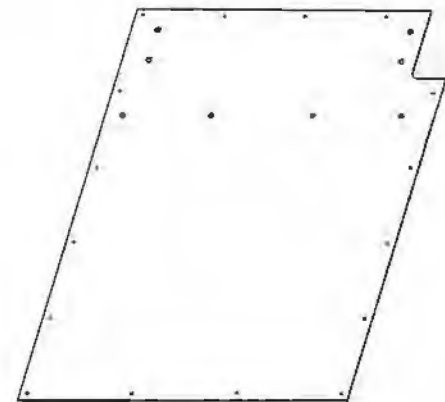
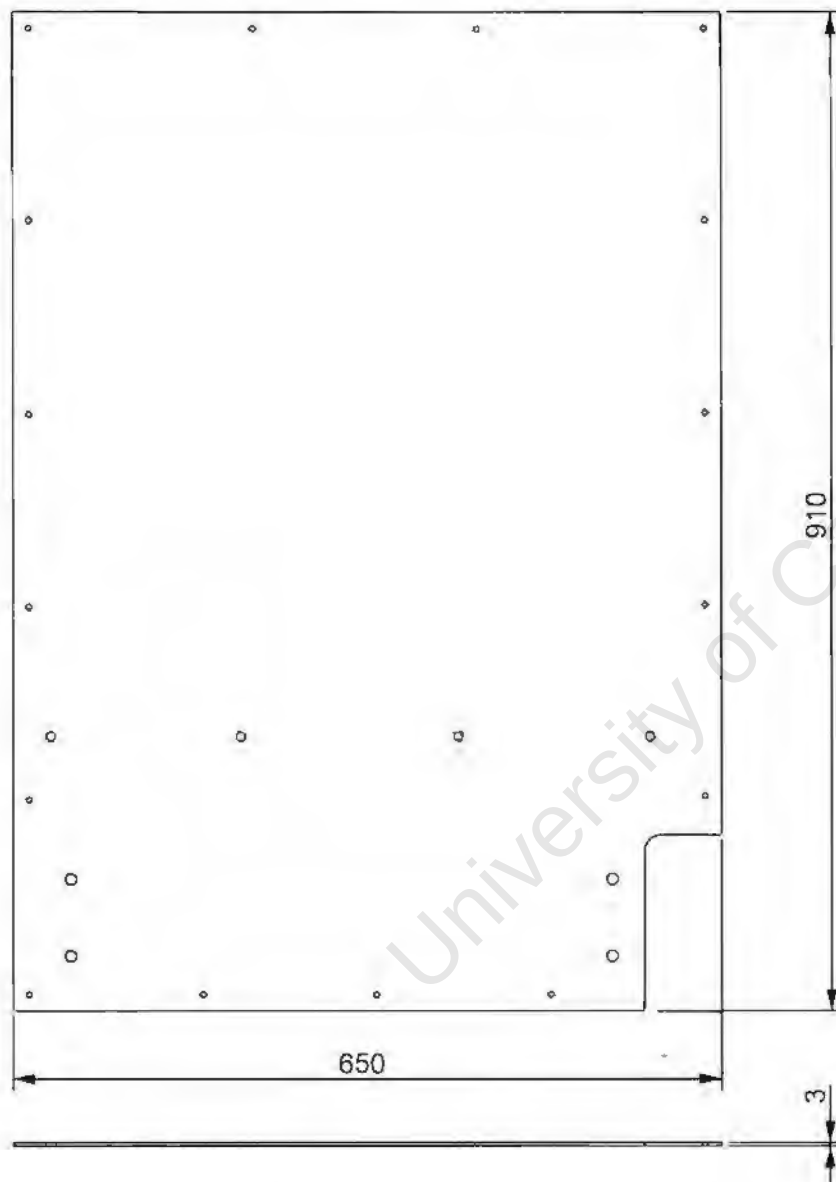


|                                                                 |                |                             |                      |
|-----------------------------------------------------------------|----------------|-----------------------------|----------------------|
| 3MM ALUMINIUM SHEET                                             |                |                             |                      |
| Item                                                            | Material       | Qty                         | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                |                             |                      |
| Title                                                           |                | RESERVOIR FOLDED            |                      |
| Dimensions in mm<br>Tolerance U.C.S.                            | Scale<br>0,200 | Date<br>OCT 2008            | Sheet<br>51 of<br>81 |
| Drawn By<br>01                                                  | H KRYNAUW      | Drawing Number<br>PRT_39_01 |                      |

Pertitioner's Exhibit 1015  
 VIVITRO v. BDC  
 IPR2024-00320

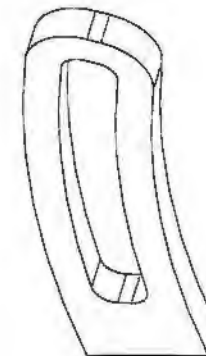
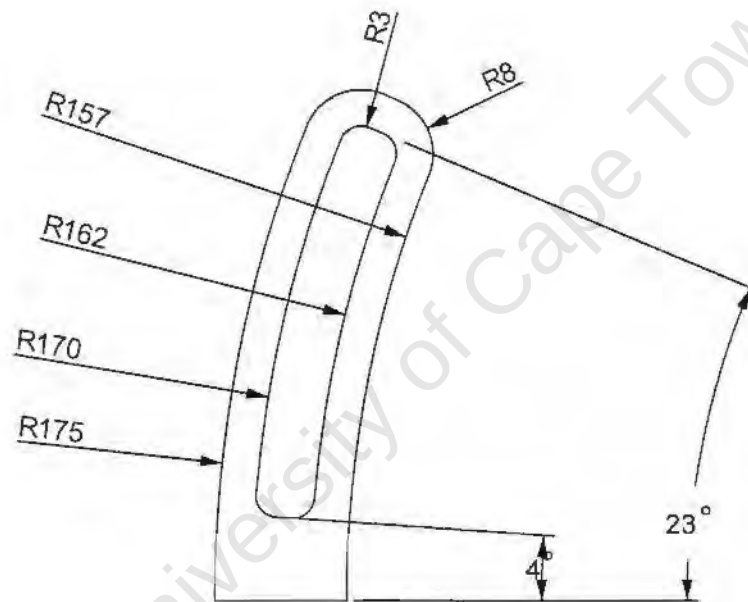
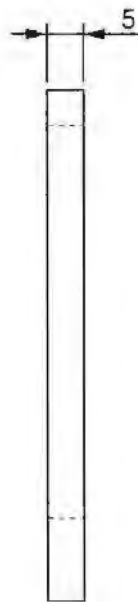


|                                                                                                                                      |          |                |          |
|--------------------------------------------------------------------------------------------------------------------------------------|----------|----------------|----------|
| 3MM ALUMINIUM SHEET                                                                                                                  |          |                |          |
| Item                                                                                                                                 | Material | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering                                                                      |          |                |          |
| Title<br>RESERVOIR FLAT                                                                                                              |          |                |          |
| <br>Dimensions in mm<br>Tolerance U.Q.S.<br>0.1 | Scale    | Date           | Sheet of |
|                                                                                                                                      | 0,200    | OCT 2008       | 52 81    |
| Drawn By                                                                                                                             |          | Drawing Number |          |
| H KRYNAUW                                                                                                                            |          | PRT_39_02      |          |



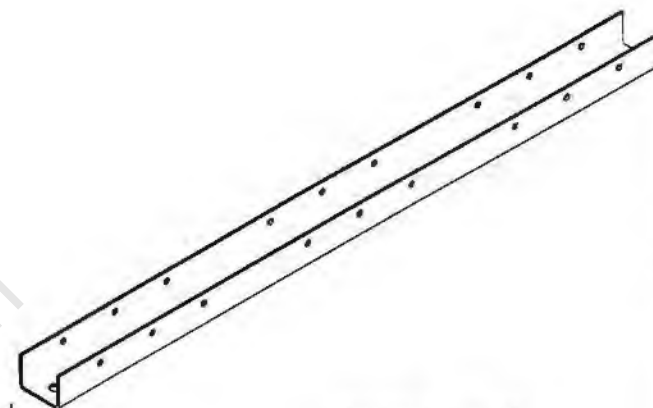
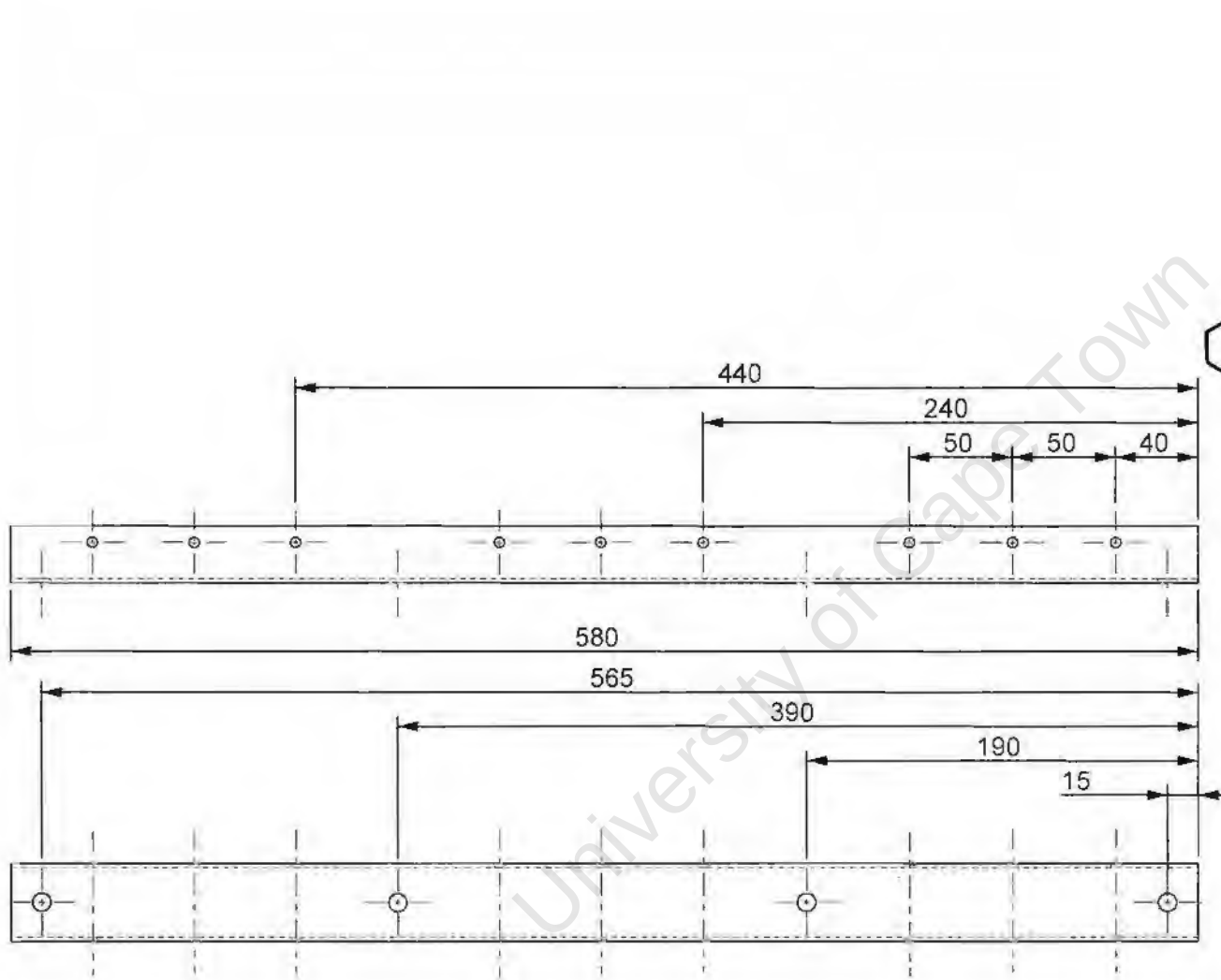
SCALE 0,075

|                                                                                       |                                 |                          |                 |              |
|---------------------------------------------------------------------------------------|---------------------------------|--------------------------|-----------------|--------------|
|                                                                                       | 3MM ALUMINIUM SHEET             |                          |                 |              |
| Item                                                                                  | Material                        | Qty                      | Remarks         |              |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                 |                          |                 |              |
|  | Title<br><br>TESTING BASE SHEET |                          |                 |              |
| Dimensions<br>in mm<br>Tolerances<br>U.D.S.                                           | Scale<br><br>0,150              | Date<br><br>OCT 2008     | Sheet<br><br>53 | of<br><br>81 |
| 0.1                                                                                   | H KRYNADU                       | Drawing Number<br>PRT_41 |                 |              |



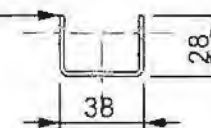
QUANTITY: 2

|                                                                 |                |                          |                      |
|-----------------------------------------------------------------|----------------|--------------------------|----------------------|
| ST_STEEL_304                                                    |                |                          |                      |
| Item                                                            | Material       | Qty                      | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                |                          |                      |
| Title                                                           |                | MOTOR SLOT               |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale<br>1:500 | Date<br>06-12-2008       | Sheet<br>54 of<br>81 |
| Drawn By<br>H KRYNAUW                                           |                | Drawing Number<br>PRT_49 |                      |

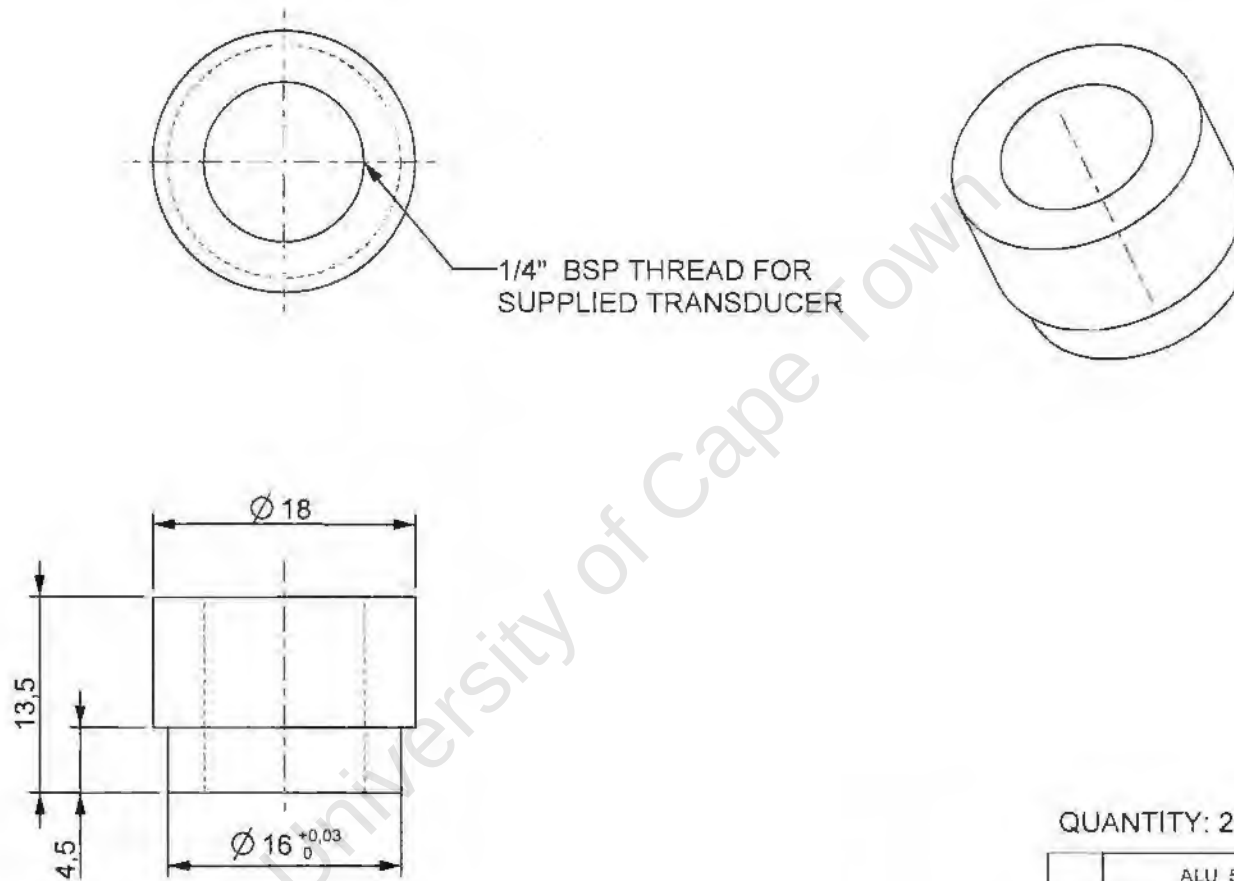


SCALE 0,200

2 THICK

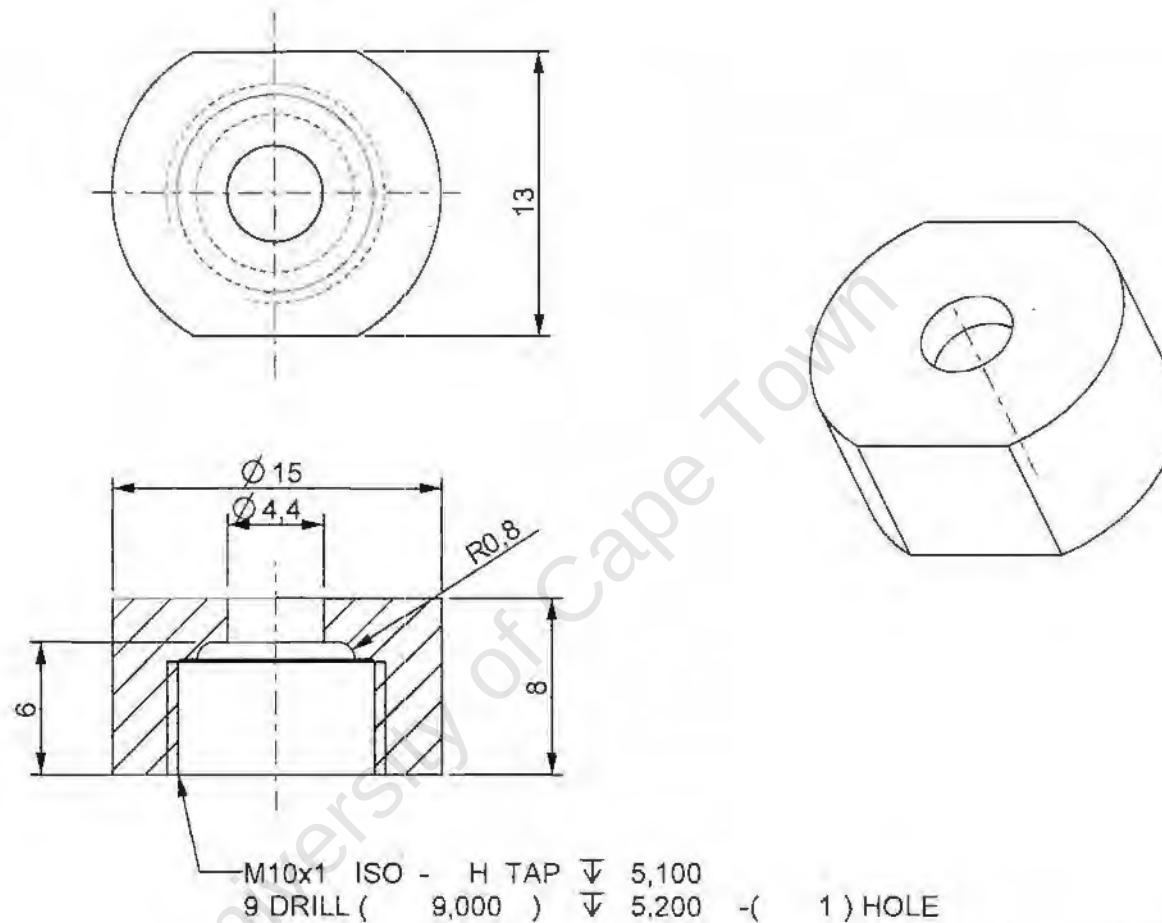


|                                                                 |                |                            |                          |
|-----------------------------------------------------------------|----------------|----------------------------|--------------------------|
| SS304                                                           |                |                            |                          |
| Item                                                            | Material       | Qty                        | Remarks                  |
| University of Cape Town<br>Department of Mechanical Engineering |                |                            |                          |
| Title<br>VENTRICLE MOUNTING CHANNEL                             |                |                            |                          |
| Dimensions<br>in mm<br>Tolerances<br>U.O.S.                     | Scale<br>0,300 | Date<br>OCT 2008           | Sheet<br>55 of<br>81     |
| 0.1                                                             | H KRYNAUW      | Drawn By<br>VIVITRO v. BDC | Drawing Number<br>PRT_50 |

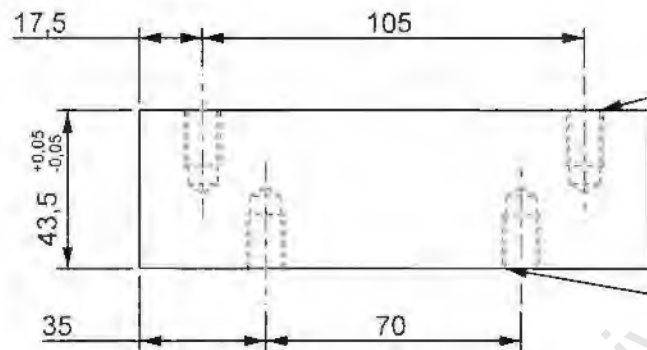
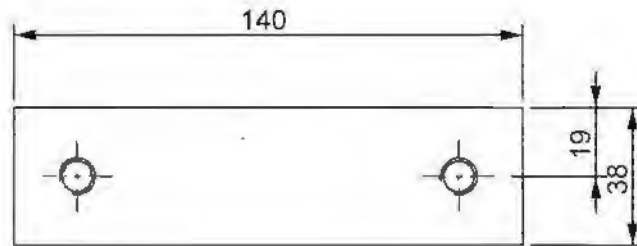


QUANTITY: 2

|                                                                                       | ALU_5052                                                        |                              |          |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------|------------------------------|----------|
| Item                                                                                  | Material                                                        | Qty                          | Remarks  |
|                                                                                       | University of Cape Town<br>Department of Mechanical Engineering |                              |          |
|  | Title<br>TRANSDUCER THREAD                                      |                              |          |
| Dimensions<br>in mm<br>Tolerance<br>U.S.S.                                            | Scale                                                           | Date                         | Sheet of |
| 0.1                                                                                   | 2:1                                                             | 01/01/2018                   | 56 of 81 |
| Drawn By H KRYNAUW                                                                    |                                                                 | Drawing Number IPR2024-00320 |          |

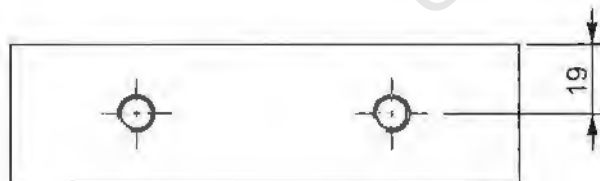


|                                                                 | ALU_5052   |                |          |
|-----------------------------------------------------------------|------------|----------------|----------|
| Item                                                            | Material   | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |            |                |          |
| Title<br>SCAOPE SEAL TOP                                        |            |                |          |
|                                                                 | Scale      | Date           | Sheet of |
|                                                                 | 3,000      | OCT 2008       | 57 71    |
| Dimensions in mm<br>Tolerance U.O.S.                            | Drawn By   | Drawing Number |          |
| 0.1                                                             | H KRYNALUW | PRT_52         |          |



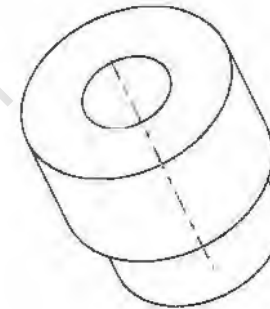
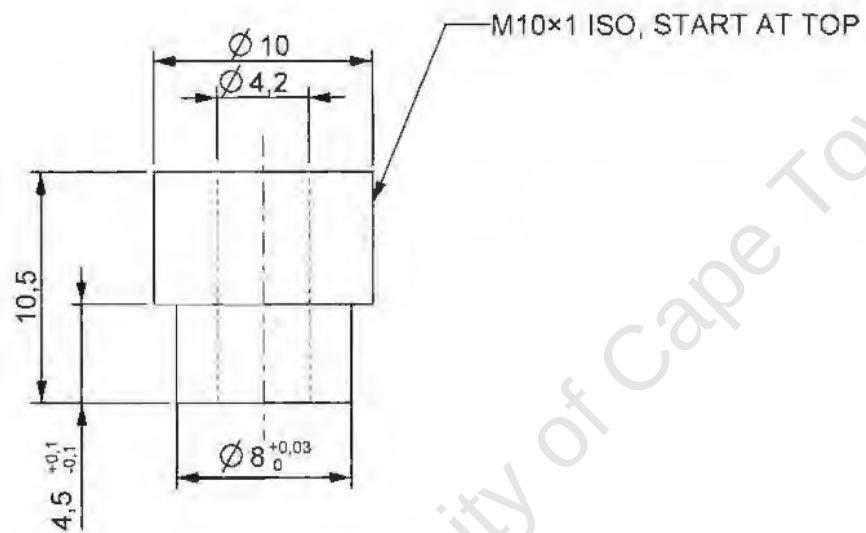
M10x1.5 ISO - H TAP  $\nabla$  15,000  
8.5 DRILL ( 8,500 )  $\nabla$  20,000 - ( 1 ) HOLE

M10x1.5 ISO - H TAP  $\nabla$  15,000  
8.5 DRILL ( 8,500 )  $\nabla$  20,000 - ( 1 ) HOLE

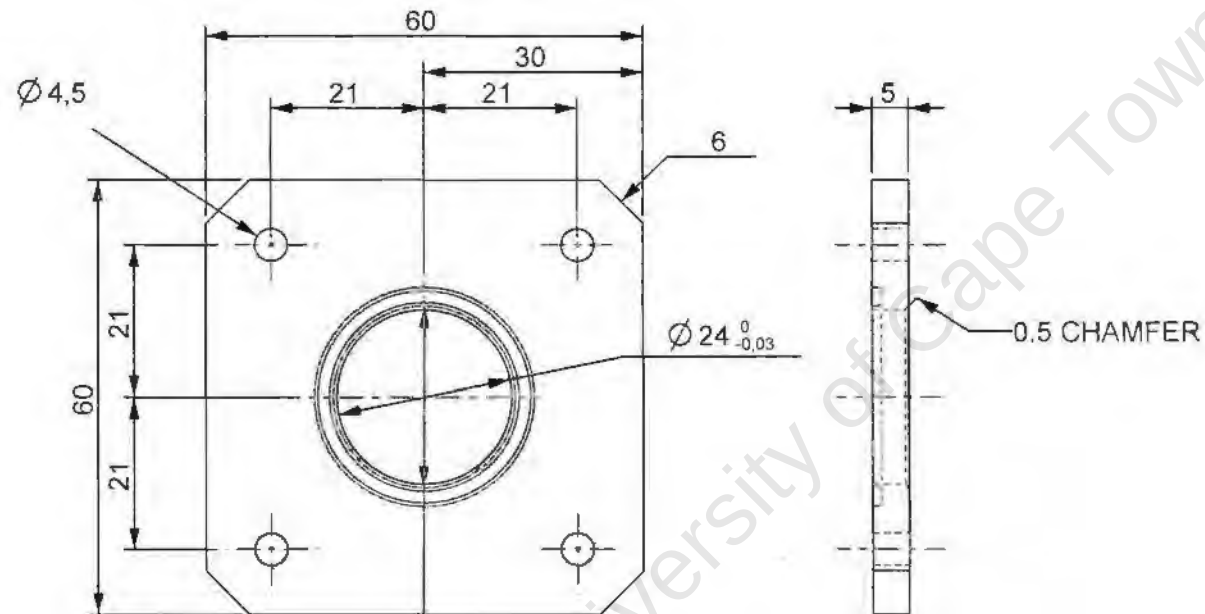


QUANTITY: 2

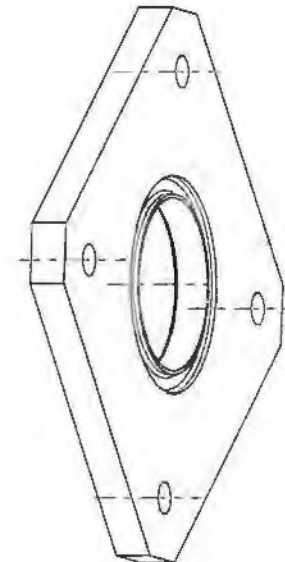
|                                                                 |                |                          |                      |
|-----------------------------------------------------------------|----------------|--------------------------|----------------------|
| STEEL_LOW CARBON                                                |                |                          |                      |
| Item                                                            | Material       | Qty                      | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                |                          |                      |
| Title<br>PLUMBERBLOCK MOUNT                                     |                |                          |                      |
| Dimensions<br>in mm<br>Tolerance<br>u.o.s.                      | Scale<br>0,500 | Date<br>01/2008          | Sheet<br>58 of<br>81 |
| Drawn By<br>H KRYNAUW                                           |                | Drawing Number<br>PRT_53 |                      |



|                                                                                       |                                |                      |                              |              |
|---------------------------------------------------------------------------------------|--------------------------------|----------------------|------------------------------|--------------|
|                                                                                       | ALU_5052                       |                      |                              |              |
| Item                                                                                  | Material                       | Qty                  | Remarks                      |              |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                |                      |                              |              |
|  | Title<br><br>SCOPE SEAL BOTTOM |                      |                              |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>3,000             | Date<br><br>OCT 2008 | Sheet<br><br>99              | of<br><br>51 |
| Drawn By<br><br>0.1                                                                   | H KRYNAUW                      |                      | Drawing Number<br><br>PRT_54 |              |

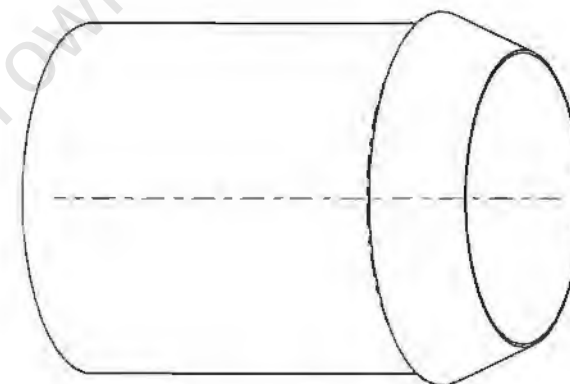
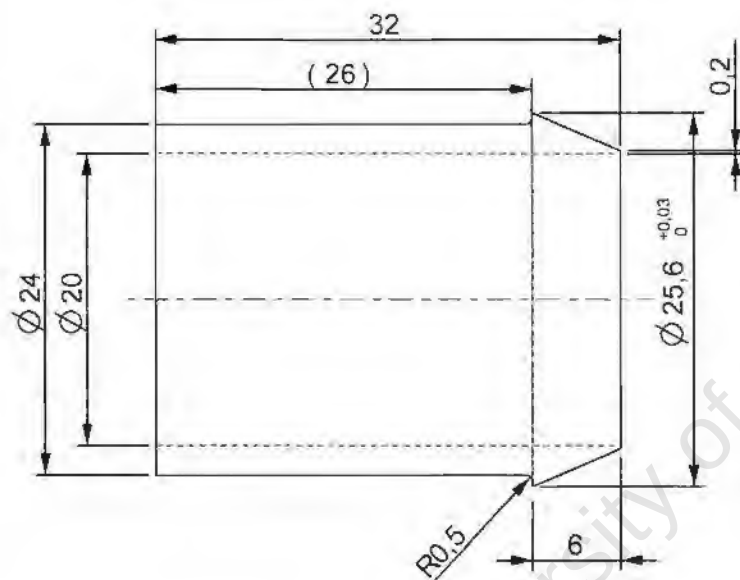


Ø 25 GROOVE: 2.6MM WIDE,  
1.2MM DEEP,  
0.5MM ROUNDS



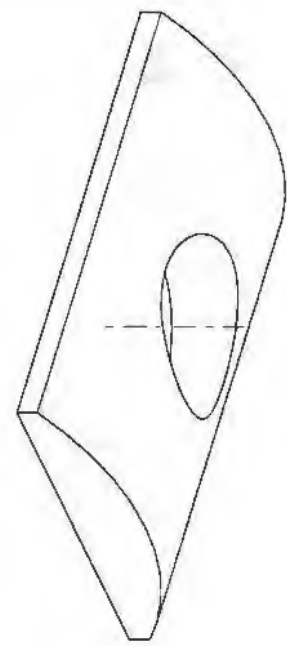
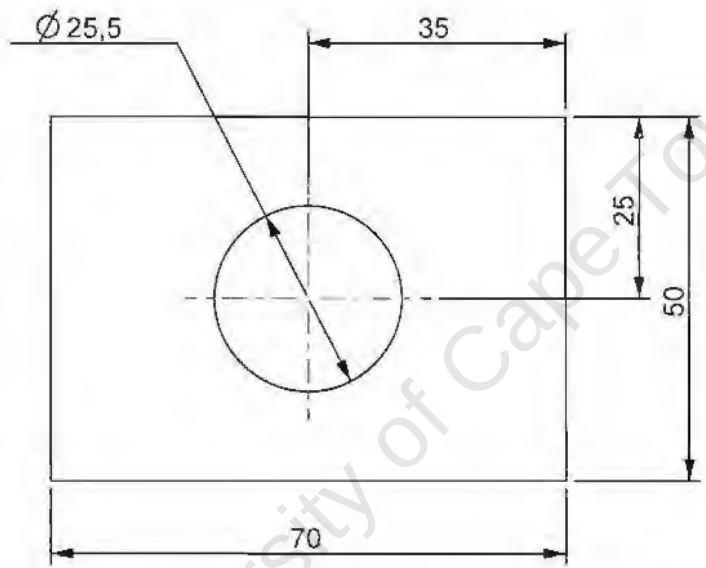
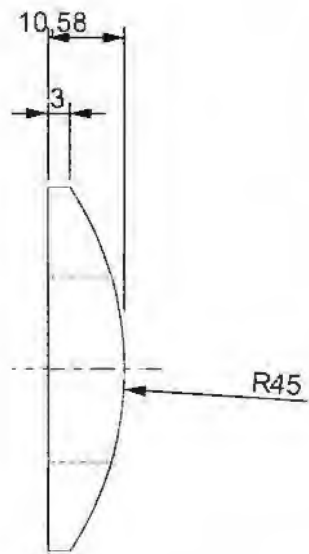
QUANTITY: 2

|                                           | ALU_5052                                                        |                                 | OR 6063              |
|-------------------------------------------|-----------------------------------------------------------------|---------------------------------|----------------------|
| Item                                      | Material                                                        | Qty                             | Remarks              |
|                                           | University of Cape Town<br>Department of Mechanical Engineering |                                 |                      |
|                                           | Title<br>ALUMINIUM FLANGE 2                                     |                                 |                      |
| Dimensions<br>in mm<br>Tolerance<br>u.d.s | Scale<br>1:100                                                  | Date<br>OCT 2008                | Sheet<br>60 of<br>61 |
| 0.1                                       | Drawn By<br>H KRYNAUW                                           | Drawing Number<br>IPR2024-00320 |                      |

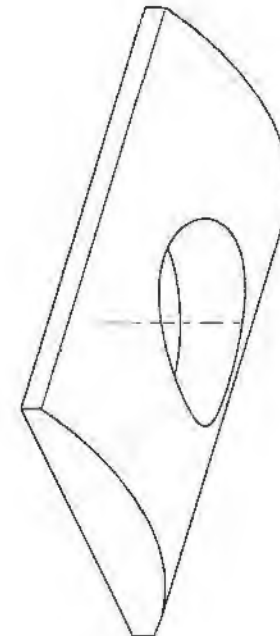
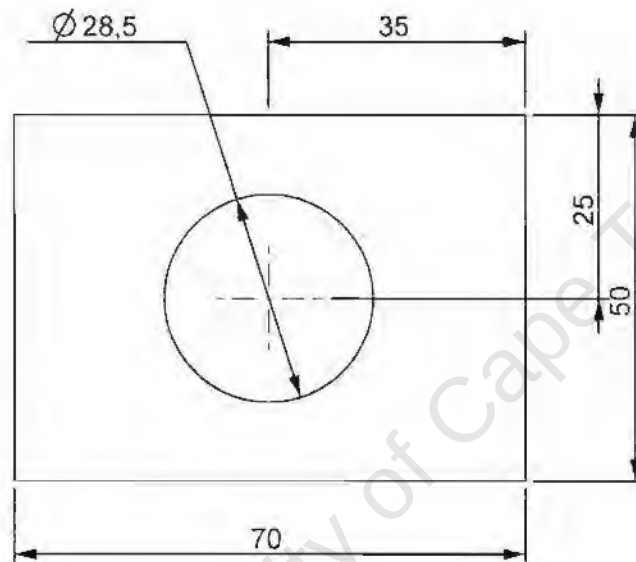
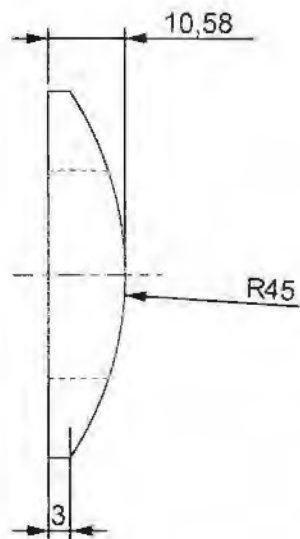


QUNATITY: 2

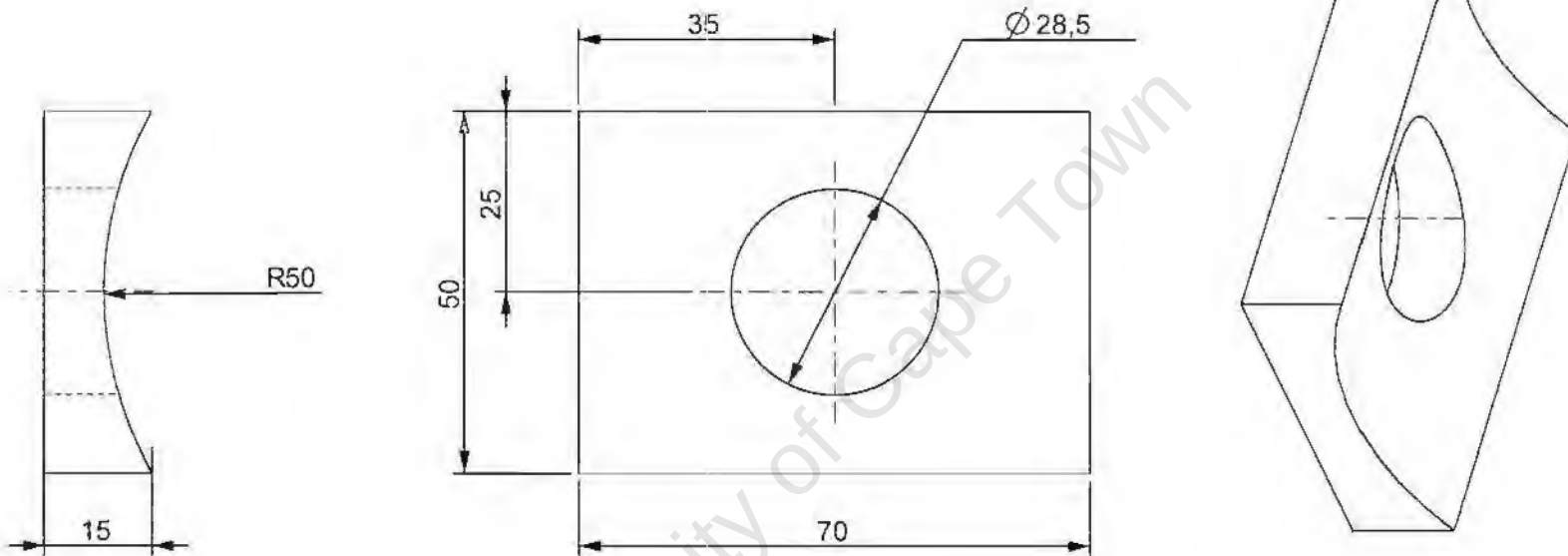
|                                                                                       |                           |                                             |                 |                              |
|---------------------------------------------------------------------------------------|---------------------------|---------------------------------------------|-----------------|------------------------------|
|                                                                                       | ALU_5052                  |                                             | OR 6063         |                              |
| Item                                                                                  | Material                  | Qty                                         | Remarks         |                              |
| University of Cape Town<br>Department of Mechanical Engineering                       |                           |                                             |                 |                              |
|  | Title<br><br>PIPE GLAND   |                                             |                 |                              |
| Dimensions<br>in mm<br>Tolerance<br>U.C.S.                                            | Scale<br><br>2 000        | Date<br><br>OCT 2008                        | Sheet<br><br>A1 | of<br><br>A1                 |
| 0.1                                                                                   | Drawn By<br><br>H KRYNAUM | Petitioner's Exhibit 1015<br>VIVITRO v. BDC |                 | Drawing Number<br><br>PRT_56 |



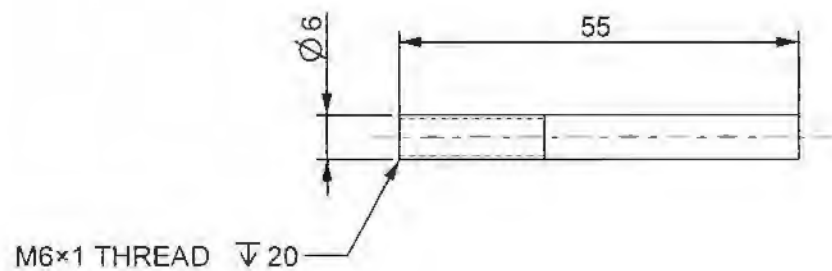
|                                                                 |                             |                |          |
|-----------------------------------------------------------------|-----------------------------|----------------|----------|
| PERSPEX_CAST                                                    |                             |                |          |
| Item                                                            | Material                    | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |                             |                |          |
|                                                                 | Title                       |                |          |
|                                                                 | COMPLIANCE MOUNT INTERNAL 1 |                |          |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale                       | Date           | Sheet of |
| 0.1                                                             | 1:500                       | OCT 2008       | 62 of 81 |
| Drawn By                                                        |                             | Drawing Number |          |
| H KRYNAUW                                                       |                             | PRT_60         |          |



|                                                                                       |                |                                                                 |             |          |
|---------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------|-------------|----------|
|                                                                                       | PERSPEX_CAST   |                                                                 |             |          |
| Item                                                                                  | Material       | Qty                                                             | Remarks     |          |
|                                                                                       |                | University of Cape Town<br>Department of Mechanical Engineering |             |          |
|  |                | Title<br>COMPLIANCE MOUNT INTERNAL 2                            |             |          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>1,000 | Date<br>OCT 2008                                                | Sheet<br>63 | of<br>81 |
| 0.1                                                                                   | H KRYNAUW      | Drawing Number<br>PRT_61_00                                     |             |          |

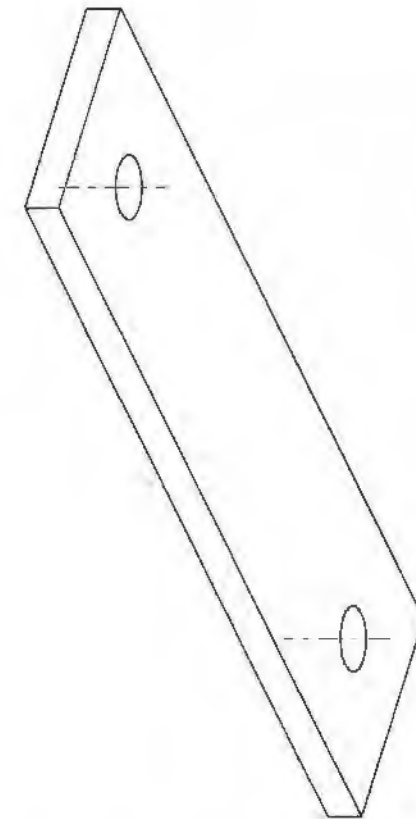
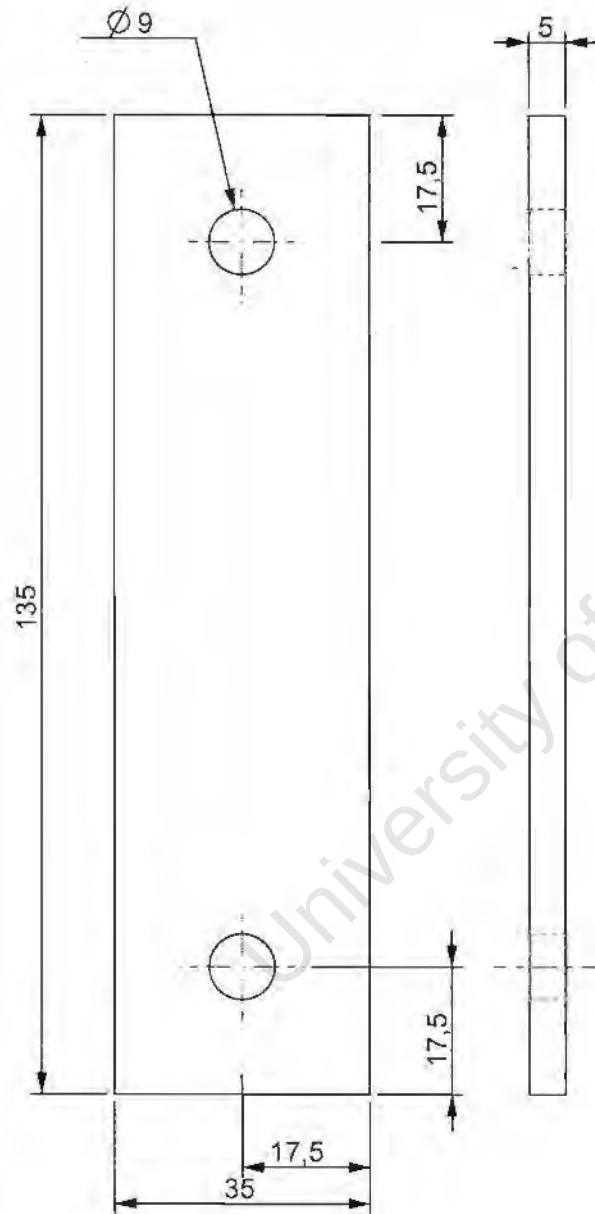


|                                                                                       |               |                                                                 |             |          |
|---------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------|-------------|----------|
|                                                                                       | PERSPEX_CAST  |                                                                 |             |          |
| Item                                                                                  | Material      |                                                                 | Qty         | Remarks  |
|                                                                                       |               | University of Cape Town<br>Department of Mechanical Engineering |             |          |
|  |               | Title<br><br>COMPLIANCE MOUNT EXT 2                             |             |          |
| Dimensions in mm<br>Tolerance<br>U.O.S.                                               | Scale<br>1:50 | Date<br>09/12/2008                                              | Sheet<br>64 | of<br>81 |
| Drawn By<br>H KRYNAUW                                                                 |               | Drawing Number<br>DRT_62                                        |             |          |
| 0.1                                                                                   | IPR2024-00320 |                                                                 |             |          |



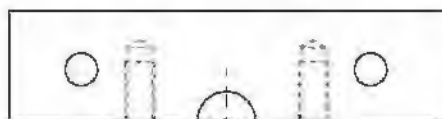
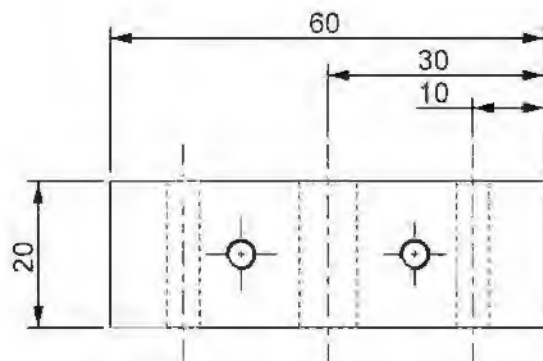
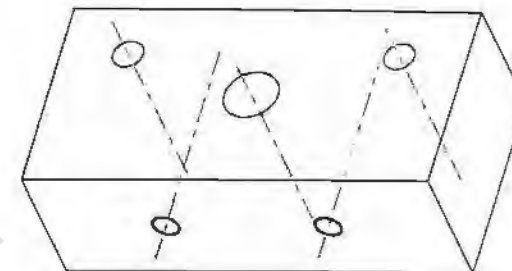
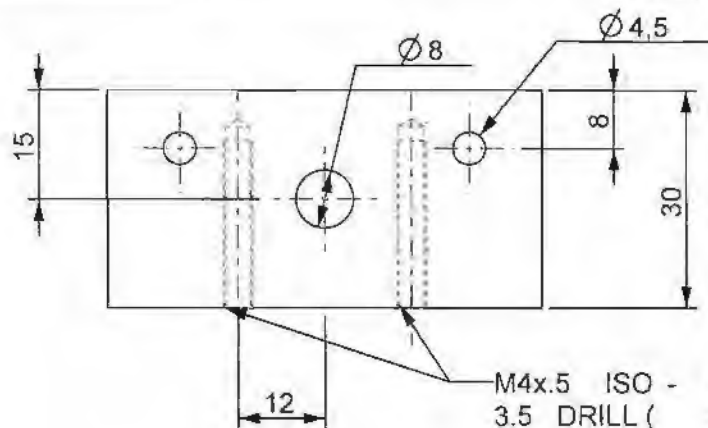
QUANTITY: 2

|                                                                                       |                             |                                                                 |        |         |    |
|---------------------------------------------------------------------------------------|-----------------------------|-----------------------------------------------------------------|--------|---------|----|
|                                                                                       | ST_STEEL_304                |                                                                 |        |         |    |
| Item                                                                                  | Material                    |                                                                 | Qty    | Remarks |    |
|                                                                                       |                             | University of Cape Town<br>Department of Mechanical Engineering |        |         |    |
|  | Title<br><br>MOTOR SLOT PIN |                                                                 |        |         |    |
| Dimensions in mm<br>Tolerance U.O.S.                                                  | Scale                       | Date                                                            |        | Sheet   | of |
| 0.1                                                                                   | 1:000                       | OCT 2000                                                        |        | 00      | 01 |
| Drawing Number                                                                        |                             |                                                                 | PRT 63 |         |    |



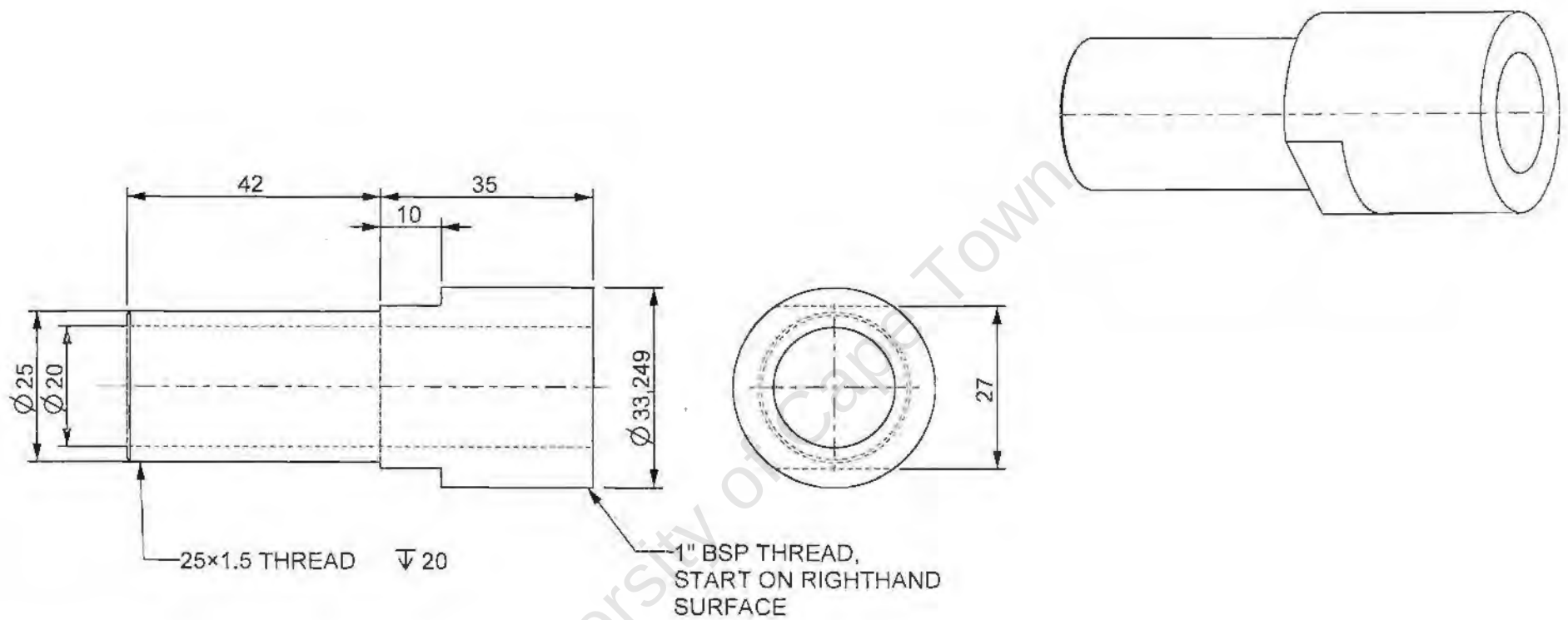
QUANTITY: 2

| ST_STEEL_304                                                                                                                  |          |                     |          |
|-------------------------------------------------------------------------------------------------------------------------------|----------|---------------------|----------|
| Item                                                                                                                          | Material | Qty                 | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering                                                               |          |                     |          |
| Title                                                                                                                         |          | MOTOR MOUNT PLATE 2 |          |
| <br>Dimensions in mm<br>Tolerance U.O.S. | Scale    | Date                | Sheet of |
|                                                                                                                               | 1:500    | OCT 2008            | 66 of 81 |
| Drawn By                                                                                                                      |          | Drawing Number      |          |
| H KRYNAUW                                                                                                                     |          | PRT_33              |          |

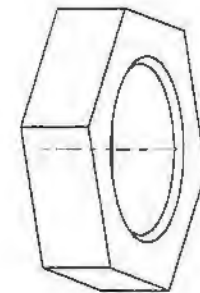
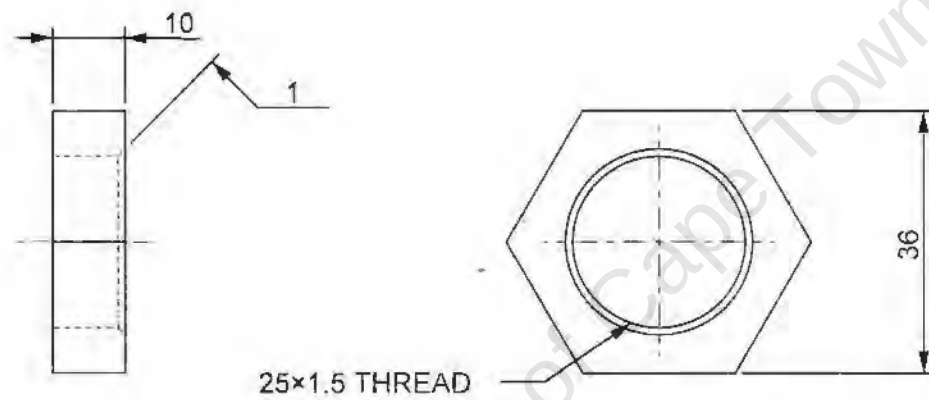


CUT BLOCK IN HALF AS  
INDICATED, WITH  
MINIMAL MATERIAL LOSS

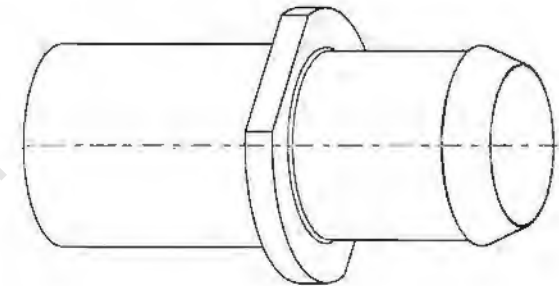
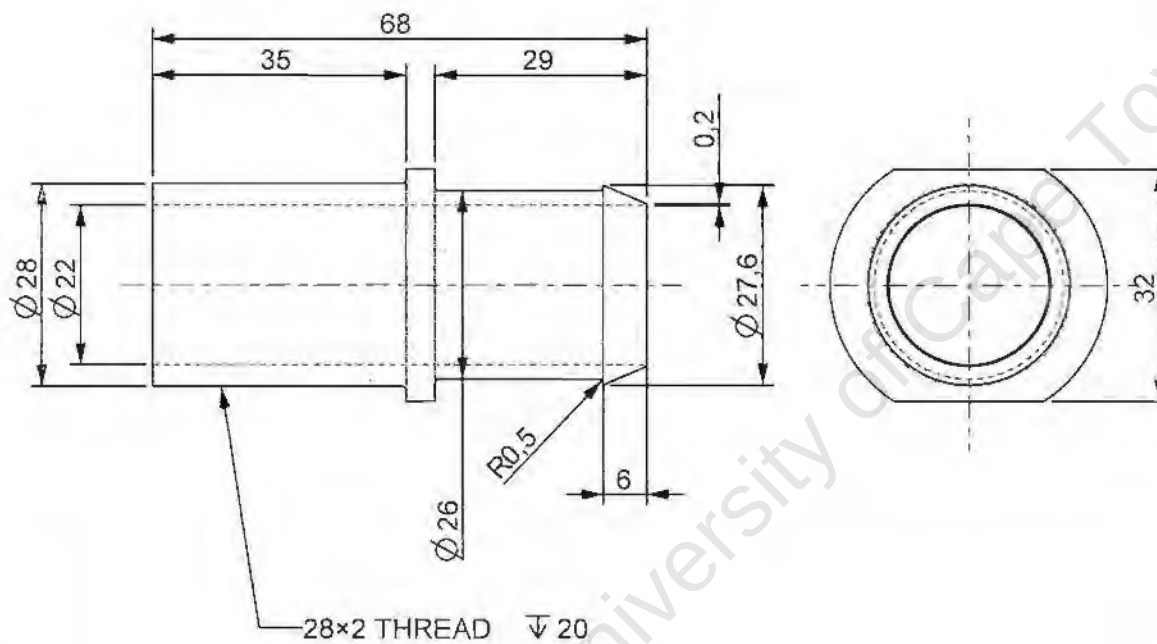
|                                            |                                                                 |                            |                          |
|--------------------------------------------|-----------------------------------------------------------------|----------------------------|--------------------------|
|                                            | ALU_5052                                                        |                            |                          |
| Item                                       | Material                                                        | Qty                        | Remarks                  |
|                                            | University of Cape Town<br>Department of Mechanical Engineering |                            |                          |
|                                            | Title<br>COMPLIANCE PLUNGER CLAMP                               |                            |                          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S. | Scale<br>1,000                                                  | Date<br>OCT 2008           | Sheet<br>67 of<br>81     |
| 0.1                                        | H KRYNAUW                                                       | Drawn By<br>VIVITRO v. BDC | Drawing Number<br>PRT_65 |



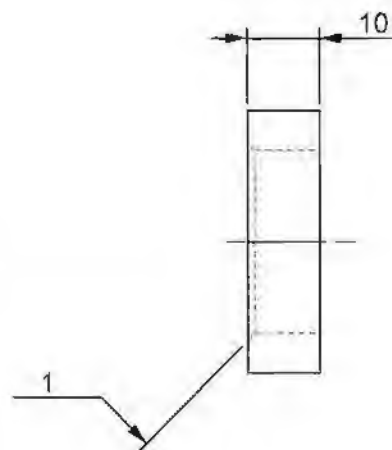
|                                                                                       |                                   |                      |                              |              |
|---------------------------------------------------------------------------------------|-----------------------------------|----------------------|------------------------------|--------------|
|                                                                                       | ALU_5052                          |                      |                              |              |
| Item                                                                                  | Material                          |                      | Qty                          | Remarks      |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                   |                      |                              |              |
|  | Title<br><br>BALL VALVE TANK CONN |                      |                              |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>1,000                | Date<br><br>OCT 2008 | Sheet<br><br>68              | of<br><br>81 |
|                                                                                       | Drawn By<br><br>H KRYNAUW         |                      | Drawing Number<br><br>PRT_67 |              |
| 0.1                                                                                   |                                   |                      |                              |              |



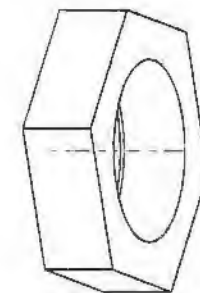
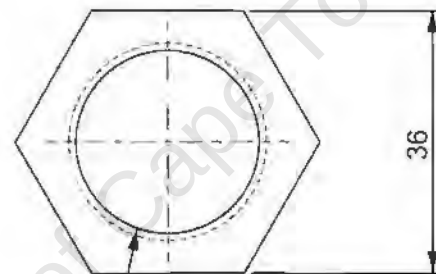
|                                                                                       |                            |                             |                 |              |
|---------------------------------------------------------------------------------------|----------------------------|-----------------------------|-----------------|--------------|
|                                                                                       | ALU_5052                   |                             |                 |              |
| Item                                                                                  | Material                   | Qty                         | Remarks         |              |
| University of Cape Town<br>Department of Mechanical Engineering                       |                            |                             |                 |              |
|  | Title<br><br>TANK CONN NUT |                             |                 |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>1:000         | Date<br><br>OCT 2008        | Sheet<br><br>69 | of<br><br>81 |
| 0.1                                                                                   | Drawn By<br>H KRYNAUM      | Drawing Number<br>PRT_68_00 |                 |              |



|                                                                 |          |                |          |
|-----------------------------------------------------------------|----------|----------------|----------|
|                                                                 | ALU_5052 |                |          |
| Item                                                            | Material | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |          |                |          |
| Title                                                           |          | TANK GLAND 1   |          |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale    | Date           | Sheet of |
| 0.1                                                             | 1:1      | 001/2008       | 70 of 61 |
| Drawn By                                                        |          | Drawing Number |          |
| H KRYNAUW                                                       |          | IPR2024-00320  |          |
|                                                                 |          | PART_69        |          |

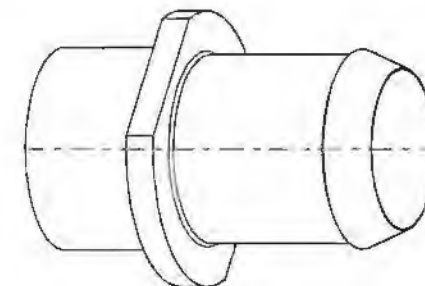
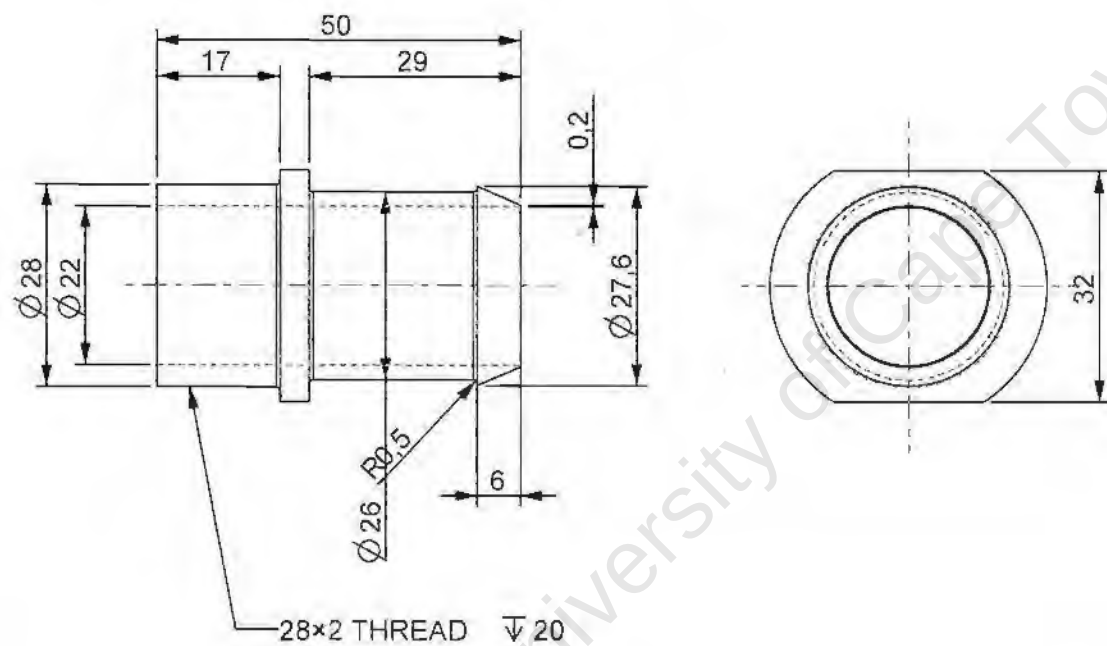


28×2 THREAD

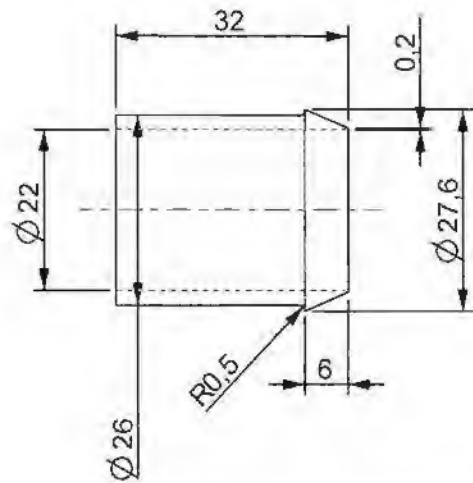


QUANTITY: 6

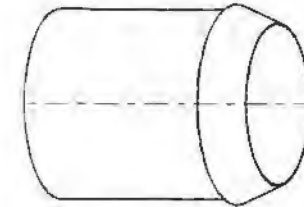
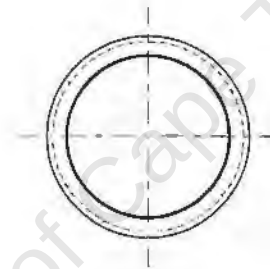
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|---------------------------------------------------------------------------------------|-------------------------------|------------------------------|------------------------------|
|                                                                                       | ALU_5052                      |                              |                              |
| Item                                                                                  | Material                      | Qty                          | Remarks                      |
| University of Cape Town<br>Department of Mechanical Engineering                       |                               |                              |                              |
|  | Title<br><br>TANK GLAND NUT 2 |                              |                              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br><br>1:100            | Date<br><br>OCT 2000         | Sheet<br><br>71 of<br><br>01 |
| 0,1                                                                                   | H KRYNAUW                     | Drawing Number<br><br>PRT_68 |                              |



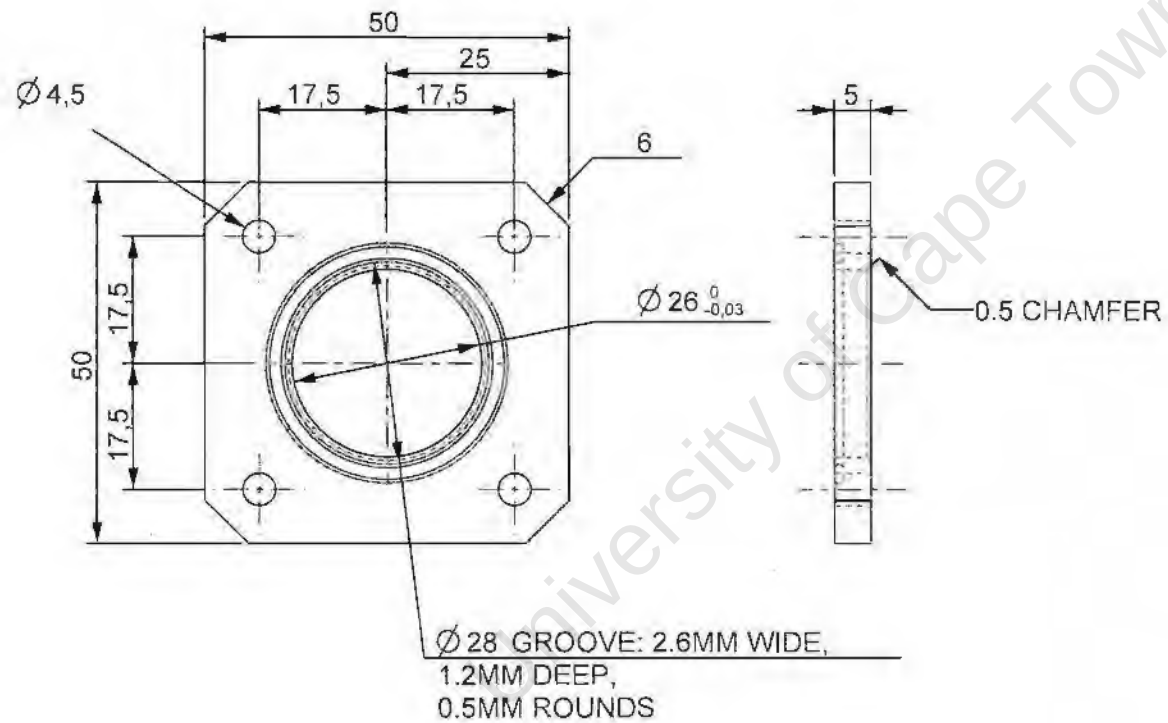
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|-----------------------------------------------------------------|--------------|----------------|----------|
| ALU_5052                                                        |              |                |          |
| Item                                                            | Material     | Qty            | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |              |                |          |
|                                                                 | Title        |                |          |
|                                                                 | TANK GLAND 2 |                |          |
| Dimensions in mm<br>Tolerance -<br>U.O.S.                       | Scale        | Date           | Sheet of |
| 0.1                                                             | 1:1          | 10/01/2015     | 72 of 81 |
| Drawn By H KRYNAUW                                              |              | VIVITRO v. BDC |          |
| IPR2024-00320                                                   |              | Crawling       |          |



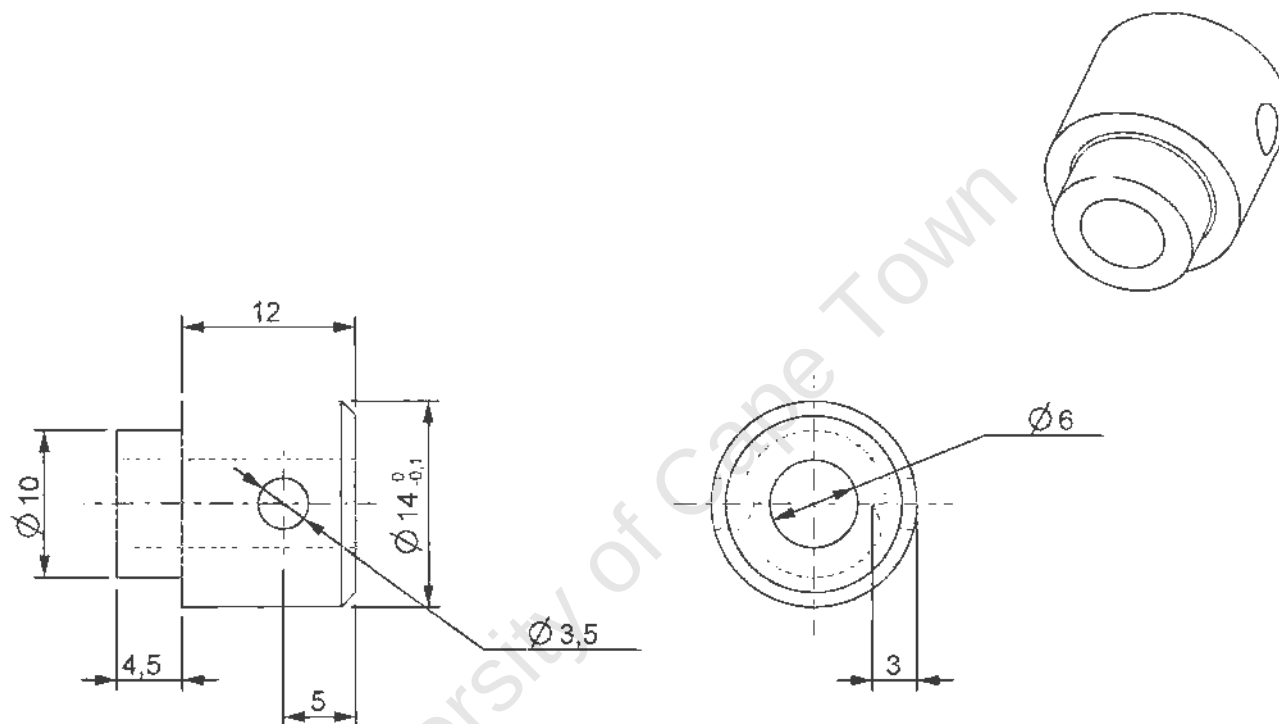
28x2 THREAD DOWN 15



|                                                                 |                            |                            |                          |
|-----------------------------------------------------------------|----------------------------|----------------------------|--------------------------|
|                                                                 | ALU_5052                   |                            |                          |
| Item                                                            | Material                   | Qty                        | Remarks                  |
| University of Cape Town<br>Department of Mechanical Engineering |                            |                            |                          |
|                                                                 | Title<br>MITRAL PIPE GLAND |                            |                          |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale<br>1:500             | Date<br>OCT 2008           | Sheet<br>73 of<br>81     |
| 0.1                                                             | H KRYNAUW                  | Drawn By<br>VIVITRO v. BDC | Drawing Number<br>PRT_73 |

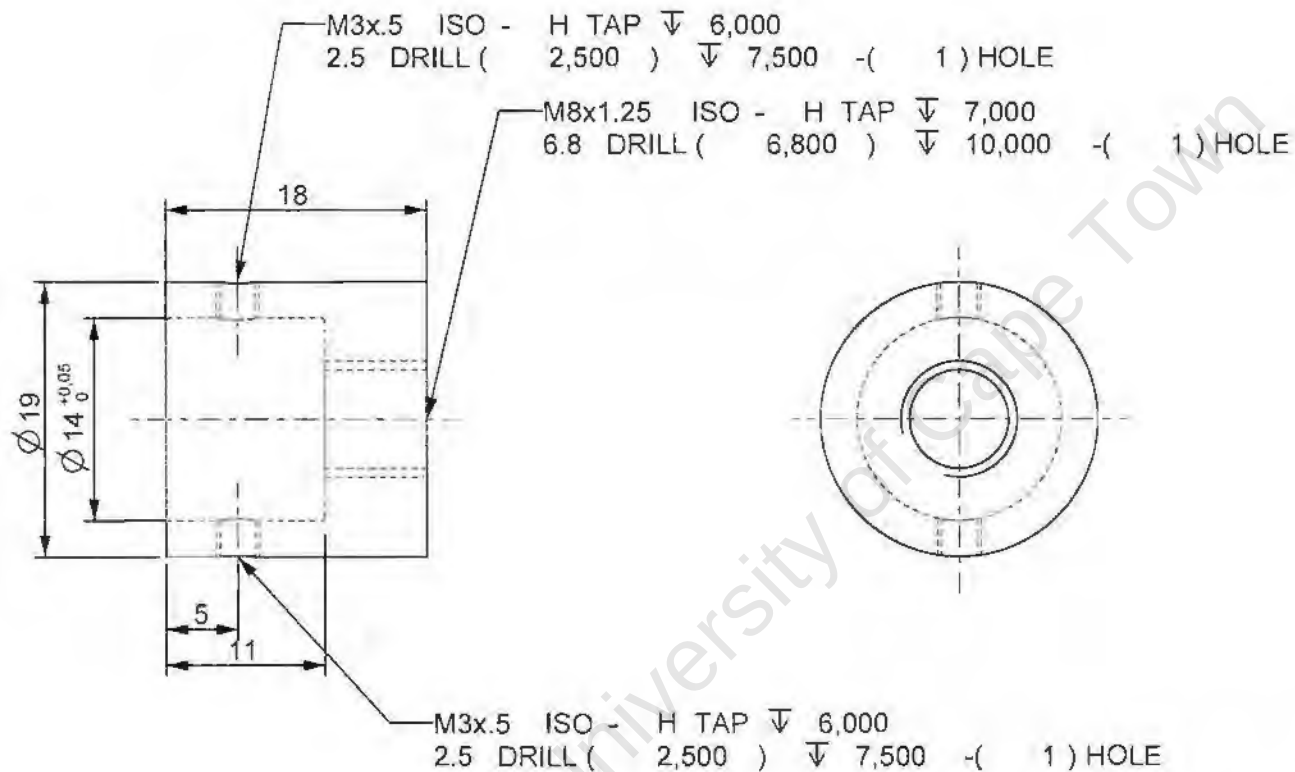


|                                                                 |          |          |          |
|-----------------------------------------------------------------|----------|----------|----------|
| ALU_5052                                                        |          | OR 6063  |          |
| Item                                                            | Material | Qty      | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering |          |          |          |
| Title<br>ALUMINIUM MITRAL FLANGE                                |          |          |          |
| Dimensions<br>in mm<br>Tolerance<br>U.C.S.                      | Scale    | Date     | Sheet of |
| 1:1                                                             | 1:1      | 09/11/18 | 74 of 81 |
| Drawn By<br>H KRYNAUW                                           |          |          |          |
| Drawing Number<br>IPR2024-00320                                 |          |          |          |
| Part Number<br>PART_55                                          |          |          |          |

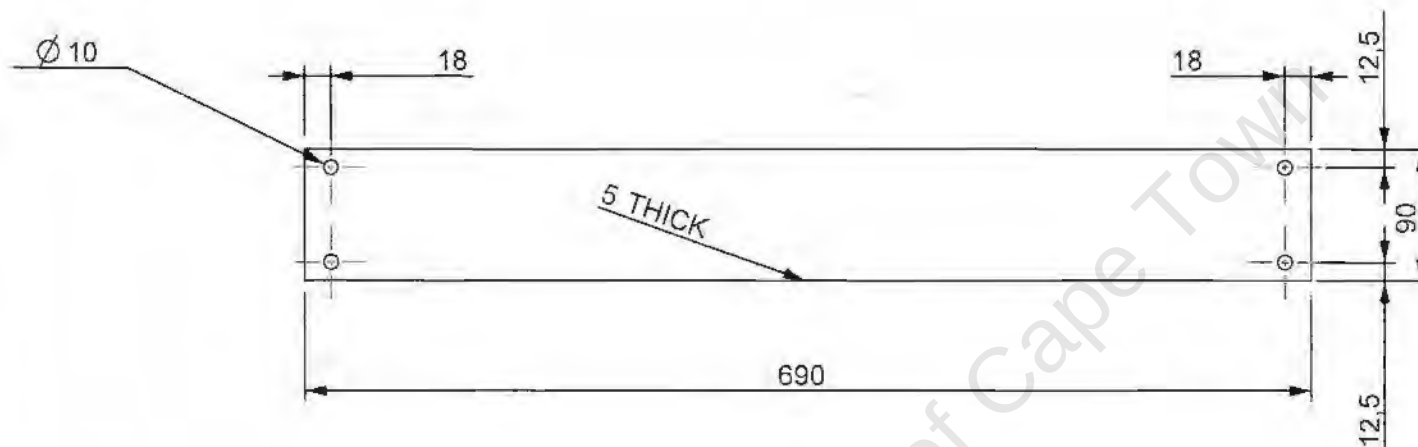


QUANTITY: 2

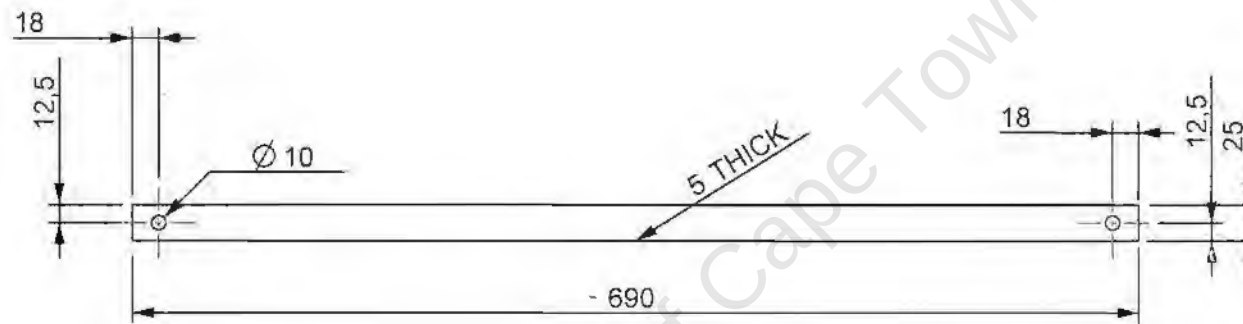
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|---------------------------------------------------------------------------------------|-----------|------------------------|----------------|----|
|                                                                                       | PERSPEX   |                        |                |    |
| Item                                                                                  | Material  | Qty                    | Remarks        |    |
| University of Cape Town<br>Department of Mechanical Engineering                       |           |                        |                |    |
|  |           | Title                  |                |    |
|                                                                                       |           | COMPLIANCE BLEED GLAND |                |    |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale     | Date                   | Sheet          | of |
|                                                                                       | 2,000     | OCT 2000               | 76             | 01 |
| 0.1                                                                                   | H KRYNAUW |                        | Drawing Number |    |
|                                                                                       | PRT_81    |                        |                |    |

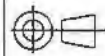


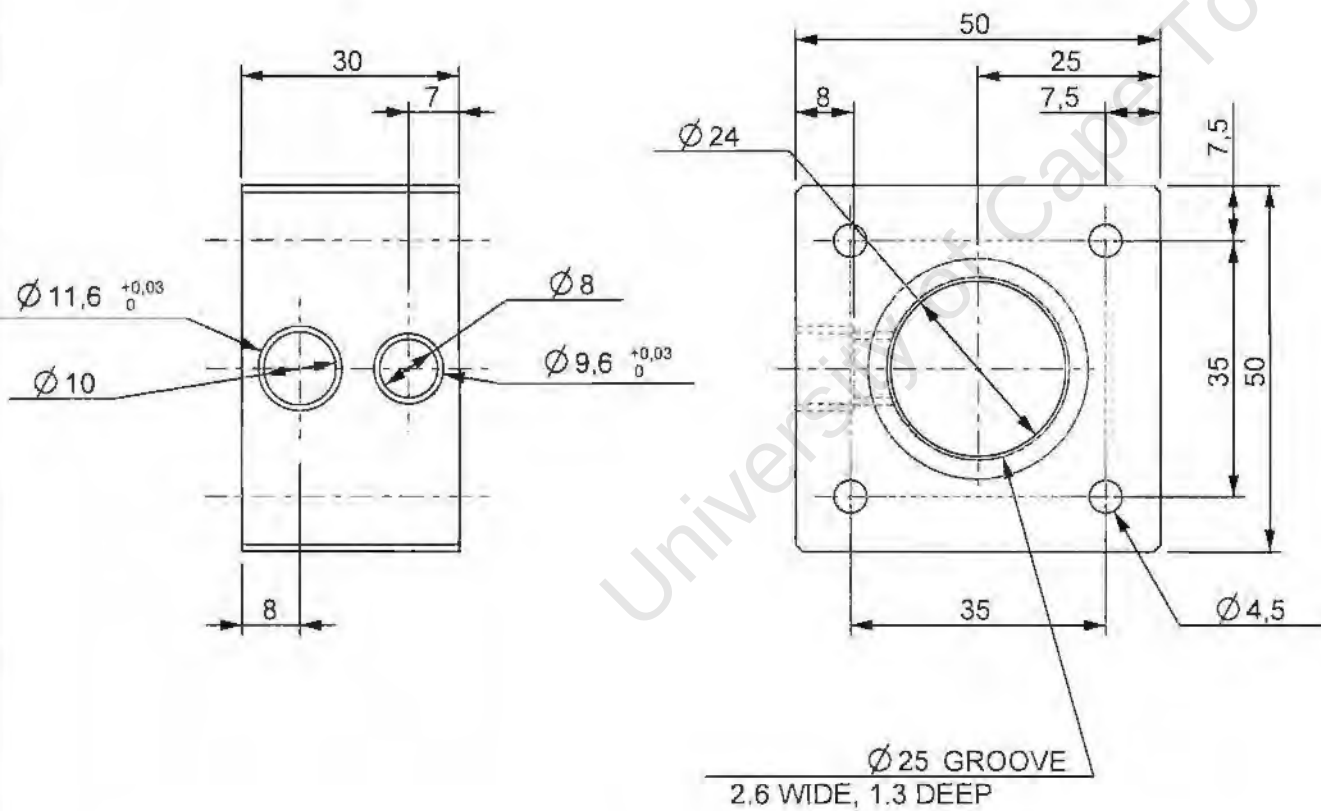
|                                                                 |                         |          |                |
|-----------------------------------------------------------------|-------------------------|----------|----------------|
| ALUMINIUM                                                       |                         |          |                |
| Item                                                            | Material                | Qty      | Remarks        |
| University of Cape Town<br>Department of Mechanical Engineering |                         |          |                |
|                                                                 | Title                   |          |                |
|                                                                 | COMPLIANCE BLEED THREAD |          |                |
| Dimensions in mm<br>Tolerance U.O.S.                            | Scale                   | Date     | Sheet of       |
|                                                                 | 2:1                     | 10/10/15 | 76 of 81       |
| 0.1                                                             | Drawn By                |          | Drawing Number |
|                                                                 | H KRYNAUW               |          | PR2_82         |



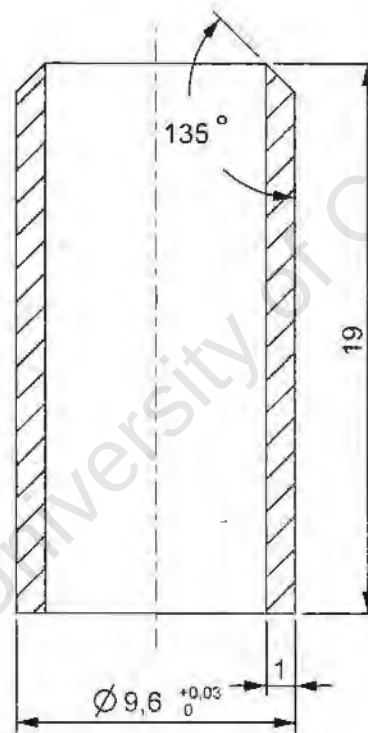
|                                                                                       | SS304                                                           |                          |                         |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------|-------------------------|
| Item                                                                                  | Material                                                        | Qty                      | Remarks                 |
|                                                                                       | University of Cape Town<br>Department of Mechanical Engineering |                          |                         |
|  | Title<br>HEATER CLAMPING PLATE                                  |                          |                         |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                                            | Scale<br>0,200                                                  | Date<br>OCT 2000         | Sheet<br>77<br>of<br>81 |
| 0,1                                                                                   | Drawn By<br>H KRYNAUW                                           | Drawing Number<br>PRT_84 |                         |



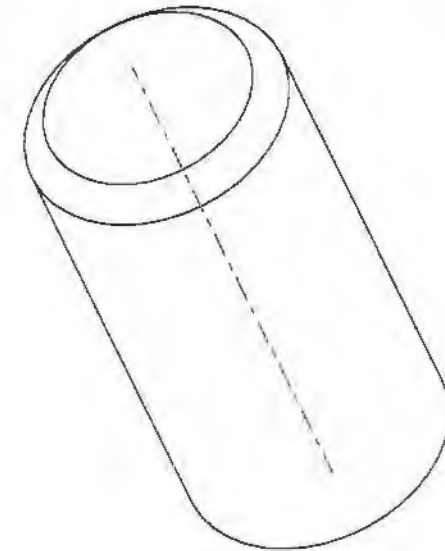
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|---------------------------------------------------------------------------------------|----------|---------------------------------|----------|
| SS304                                                                                 |          |                                 |          |
| Item                                                                                  | Material | Qty                             | Remarks  |
| University of Cape Town<br>Department of Mechanical Engineering                       |          |                                 |          |
|  |          | Title<br>HEATER BOLTING PLATE   |          |
| Dimensions in mm<br>Tolerance U.O.S.                                                  | Scale    | Date                            | Sheet of |
| 0.1                                                                                   | 0.1      | 0.1                             | 81       |
| Drawn By<br>H KRYNAUW                                                                 |          | Drawing Number<br>IPR2024-00320 |          |



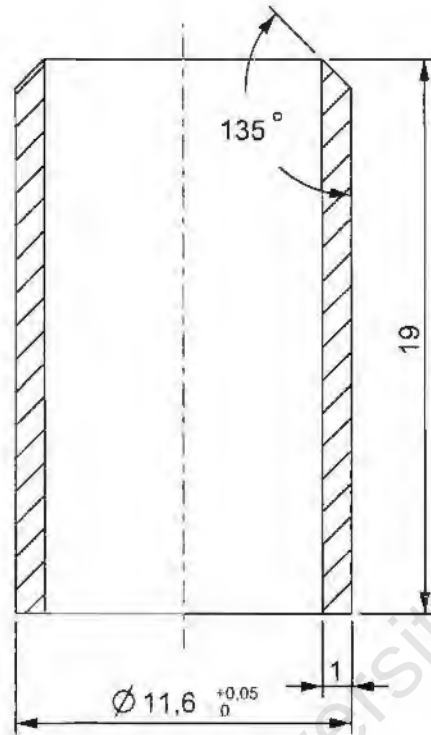
|                                            | ALUMINIUM                                                       |                            |                          |
|--------------------------------------------|-----------------------------------------------------------------|----------------------------|--------------------------|
| Item                                       | Material                                                        | Qty                        | Remarks                  |
|                                            | University of Cape Town<br>Department of Mechanical Engineering |                            |                          |
|                                            | Title<br>VENTRICLE COMPLIANCE                                   |                            |                          |
| Dimensions<br>in mm<br>Tolerance<br>U.D.S. | Scale<br>1,000                                                  | Date<br>OCT 2006           | Sheet<br>79 of<br>81     |
| 0.1                                        | H KRYNALL                                                       | Drawn by<br>VIVITRO v. BDC | Drawing Number<br>PRT_86 |



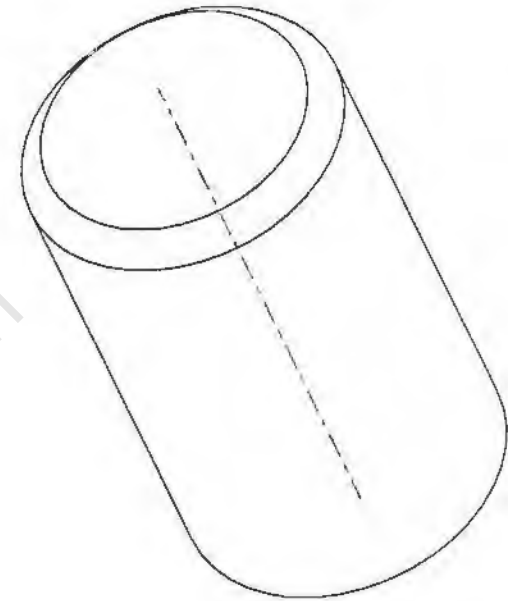
SECTION A-A



|                                                                 |                            |                                                                                |                      |
|-----------------------------------------------------------------|----------------------------|--------------------------------------------------------------------------------|----------------------|
|                                                                 | ALUMINIUM                  |                                                                                |                      |
| Item                                                            | Material                   | Qty                                                                            | Remarks              |
| University of Cape Town<br>Department of Mechanical Engineering |                            |                                                                                |                      |
|                                                                 | Title<br>VENT COMP GLAND 1 |                                                                                |                      |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S.                      | Scale<br>4:1               | Date<br>2018-08-10                                                             | Sheet<br>80 of<br>31 |
| 0.1                                                             | Drawn By<br>H KRYNAUW      | Petitioner's Exhibit 1015<br>VIVITRO v. BDC<br>Drawing Number<br>IPR2024-00320 |                      |
|                                                                 |                            | RT_87_00                                                                       |                      |



SECTION A-A



|                                                                                       |                                 |                      |                              |              |
|---------------------------------------------------------------------------------------|---------------------------------|----------------------|------------------------------|--------------|
|                                                                                       | GENERIC_ALUMINUM                |                      |                              |              |
| Item                                                                                  | Material                        | Qty                  | Remarks                      |              |
| University of Cape Town<br>Department of Mechanical Engineering                       |                                 |                      |                              |              |
|  | Title<br><br>VENT COMPL GLAND 2 |                      |                              |              |
| Dimensions<br>in mm<br>Tolerance<br>U.O.S                                             | Scale<br><br>4,000              | Date<br><br>OCT 2008 | Sheet<br><br>61              | of<br><br>81 |
| 0.1                                                                                   | H KRYNAUW                       |                      | Drawing Number<br><br>PRT_87 |              |

University of Cape Town