

## Abstract

Silicone breast prostheses are made from a two part silicone oils mixed at 1:1 ratio by weight. Upon mixing and cooking this mixture the molecules crosslink creating a non-flowable gel. This is necessary to prevent silicone from seeping into body tissue if the prosthetic membrane were to rupture. Currently these oils are measured, mixed, and injected by hand. This process is labor intensive and prone to human error which can result in expensive wasted material. This goal of this project was to create an automated device to improve mixing accuracy, reduce processing time, eliminate the need for skilled labor, and decrease material waste of the breast prosthesis manufacturing process.



Figure 1. Caption in Arial, 28 points, bold.

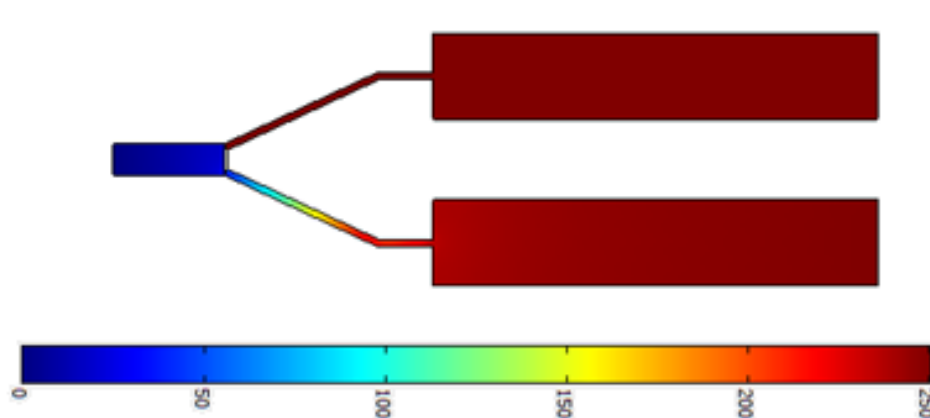
## Requirements

Due to medical device requirements, the device must be made from silicone compatible materials and sealed from environmental contact to reduce contamination.

### Design Requirements:

- Batch volume range: 100 to 400cc ± 5cc
- Mixing accuracy: 0.5%
- Output pressure requirement for injection through 16 gauge needle: 250psi
- Full automation with LabVIEW Software

$$\Delta p = \frac{128\rho v L_{needle} Q}{\pi D_{needle}^4} + \frac{128\rho v L_{mixer} Q}{\pi D_{mixer}^4} + \rho \sum K_L \frac{v^2_{mixer}}{2} + \frac{128\rho v L_{pipe} Q}{\pi D_{pipe}^4}$$



Mixing Accuracy defined as:  

$$\frac{abs(W_1 - W_2)}{\min(W_1, W_2)} * 100 < 0.5\%$$

Figure 2. Comsol model showing necessary pressure of ~250psi for injection through 16 gauge needle.

## Design Evolution

The device operates by filling two hydraulic cylinders sequentially with Part A and Part B silicone oils. Linear transducers meter the cylinder volumes while differential weight measurements taken throughout the process verify that the mixing accuracy is met. After verification, the actuator forces the silicone oils simultaneously through a static mixer.

After initially proving the ability to infer weight of the cylinder contents, we proved the feasibility of using a single load cell for both cylinders, while providing the necessary accuracies. This reduced cost, minimized error due to calibration, but forced the process to fill each cylinder sequentially increasing cycle time.

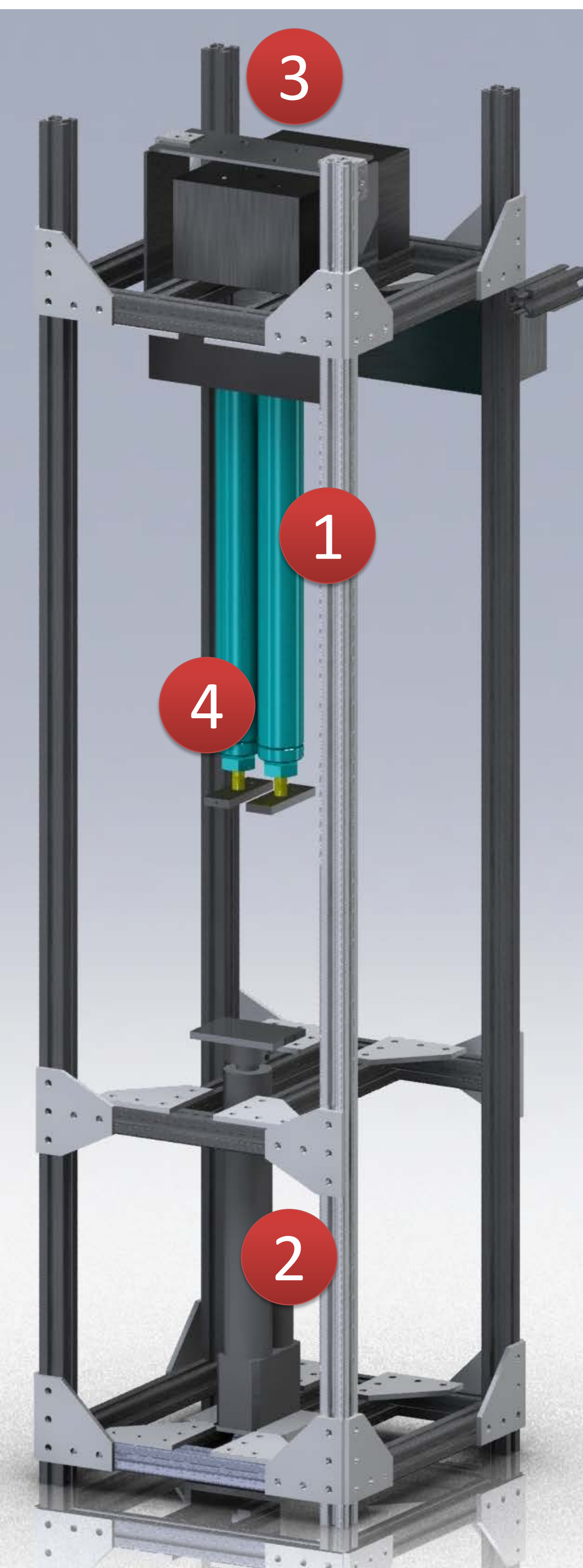


Figure 3. CAD Rendering of Prototype (1) Weighing Cylinders (2) Actuator (3) Load Cell (4) Linear Transducers

We then tested different cylinder configurations: hanging or standing on the load cell. Hanging the cylinders reduced the need for mechanical overload protection of the load cell, and enabled automatic purging air from the system due to the cylinder outlets being located at the top.

We tested metering the volume by using the actuator as a mechanical stop and through using linear transducers. The linear transducers were highly advantageous—both accuracy and repeatability were improved due to elimination of movement during weighing. Processing time was also reduced

## Testing Results

We performed extensive preliminary testing that proved the feasibility of weighing the contents of two cylinders with a single load cell, either standing or hanging. Preliminary tests showed that accurate metering was possible through using the actuator as a piston stop during filling. In the final prototype this method proved inconsistent and linear transducers were adopted for metering purposes. Figure 4 shows that the mixing ratio error was consistently below 0.5% over the range of 100 to 400cc. Final Volumes were within the requirement of ± 5cc.

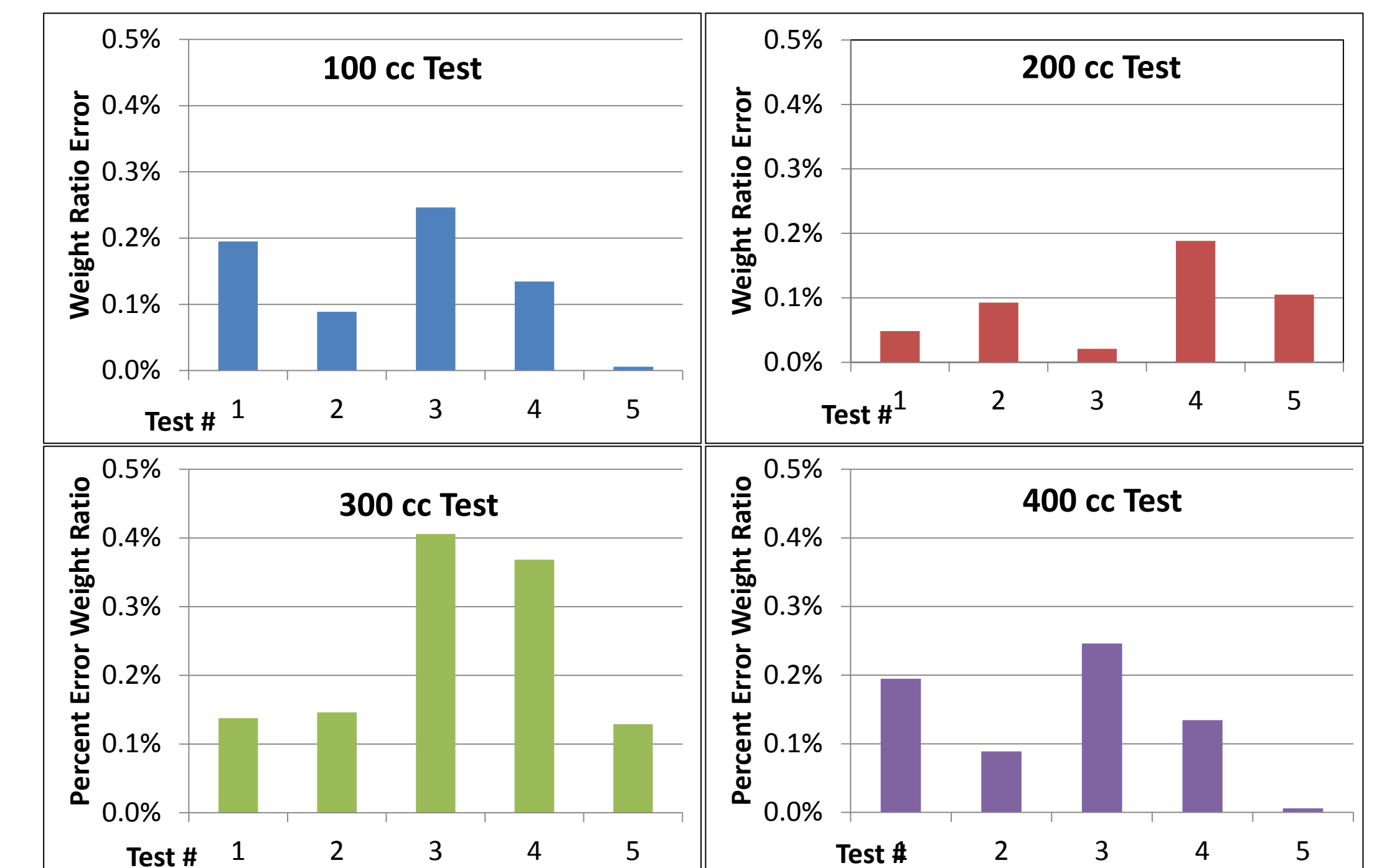


Figure 4. Caption in Arial, 28 points, bold.

The final prototype underwent a pressure test where the system was pressurized and we inspected for leaks, and monitored cylinder volumes which would change in presence of leaks. The results can be seen in Figure 5.

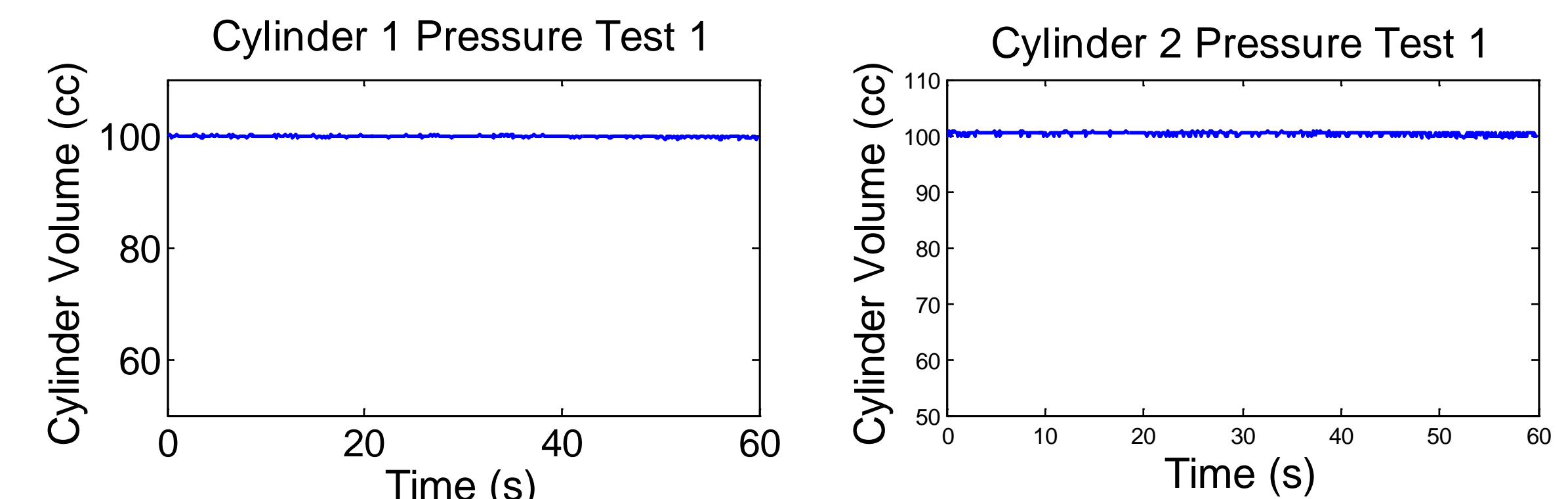


Figure 5. Cylinder volume during pressure test, indicating no leaks

### Acknowledgments

Applied Silicone, Alastair Winn, Stephen Laguette

### References

Munson, Bruce R., Donald F. Young, and Theodore H. Okiishi. "Fundamentals of Fluid Mechanics." Fifth Edition