

# The Dual-Piston Jet Injector and the Viability of Drug Delivery

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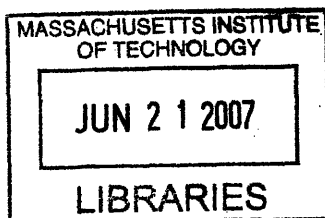
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Submitted to the Department of Mechanical Engineering on April 11, 2007  
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## **Abstract**

Drug delivery through jet-injection opens the doors to very rapid drug dispersion by eliminating the need for needle sterilization. With this comes the need for a continuous flow of fluids from a large reservoir, currently not available to the single-piston drug delivery systems. A two-piston system in a jet injector enables the use of a cyclic motion of pistons to drive the injected fluids, as opposed to the one-piston design that requires resetting the mechanism. This provides a way to dispense high-volume doses of medication without reloading. In order to test the feasibility of using a two-piston arrangement in jet-injected drug delivery, we have constructed a bench-top version to attempt to achieve the velocities and flow rates needed for jet injection. Using water as the injected fluid, we have found that driving the two pistons with 180° out-of-phase, 80% symmetric, saw-tooth waveforms and a frequency of 10 Hz is sufficient to inject 900  $\mu\text{L/s}$  of water through the jet and maintain a pressure of more than 2 MPa.

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# Table of Contents

Abstract.....	2
1. Introduction.....	4
2. Design .....	5
2.1. Mechanical Components.....	5
2.1.1. Jet Nozzle.....	5
2.1.2. The Fluid Pathways.....	6
2.1.3. Pistons.....	7
2.1.4. The Lorentz Force Actuators .....	8
2.2. Electrical Components.....	9
3. Theory.....	11
3.1. The Lorentz Force Actuator.....	11
3.2. The Fluidic System .....	12
4. Results.....	13
5. Conclusions.....	14
6. References.....	15

# 1. Introduction

Most automatic needle-free drug delivery systems currently in use are single-dosage dispensers, relying on springs or compressed air to actuate the delivery [1]. By eliminating the need for single-dosage containers through the use of multi-shot dispensers, the cost per dose could be reduced. We believe that using a two-piston driving system can provide the following benefits over a single piston system:

- Draw multiple doses from a single dosage source
- Eliminate the need for resetting the injection mechanism
- Provide more controllable injection waveforms through interlocking driving signal waveforms

A two-piston system could be used in a needle-assisted or a needle-free drug delivery system with very few modifications to the existing system. As long as the pressure supplied by the pistons is sufficiently high, the drugs could be delivered with or without needle assistance.

If used in a needle-free system, the multi-shot design would allow the rapid dispensing of vaccinations without the need of reloading the doses or sterilizing the injector. In a needle-assisted device, the multi-shot capacity would reduce the between-shot time by eliminating the single-dosage loading.

In order to test the validity of a continuous-drive drug delivery system, we show that a multi-piston system is able to provide a source of constant pressure high enough to inject a standard dosage within a reasonable amount of time.

## 2. Design

To test the feasibility of a multi-piston drug delivery system, we designed and built a bench-top model, utilizing a two-piston, upright, vertical injector. The designs for this system were developed through over a year of testing iterations.

### 2.1. Mechanical Components

The design of our drug injector has four main components: the jet nozzle, the fluid pathways, the pistons, and the solenoid drivers. Each component is modularly designed as separate systems, with the interactions between the being as minimal as possible.

#### 2.1.1. Jet Nozzle

For simplicity, our design adapts the commonly-used Injex™-brand injectors into our needle-assisted/needle-free drug delivery system. These “Ampules” provide a sterile injection

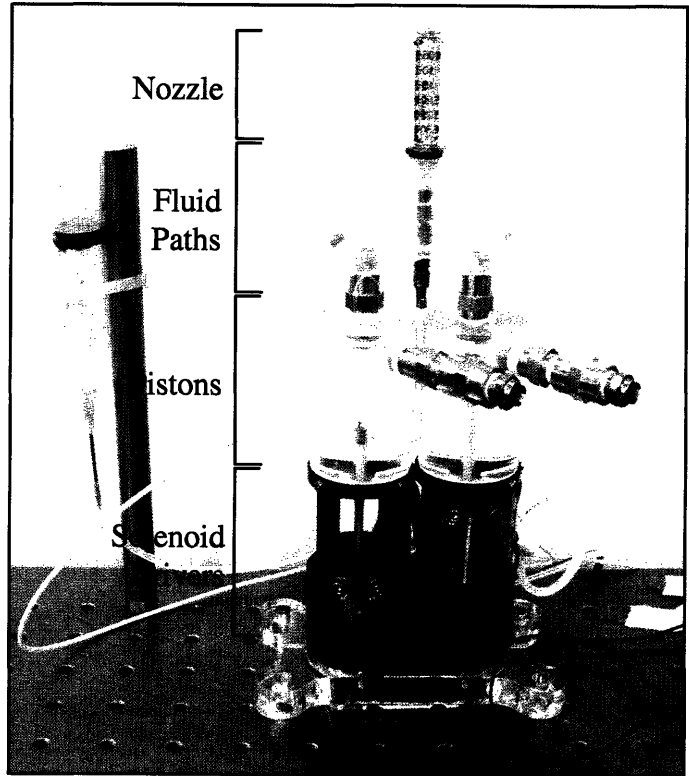


Figure 1 – The four main components are highlighted here, alongside the fluid reservoir and piping.

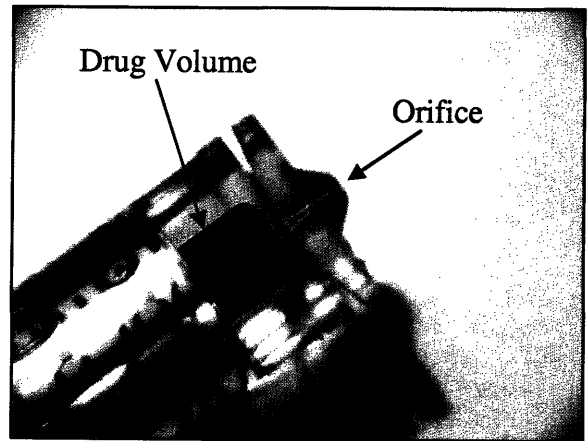


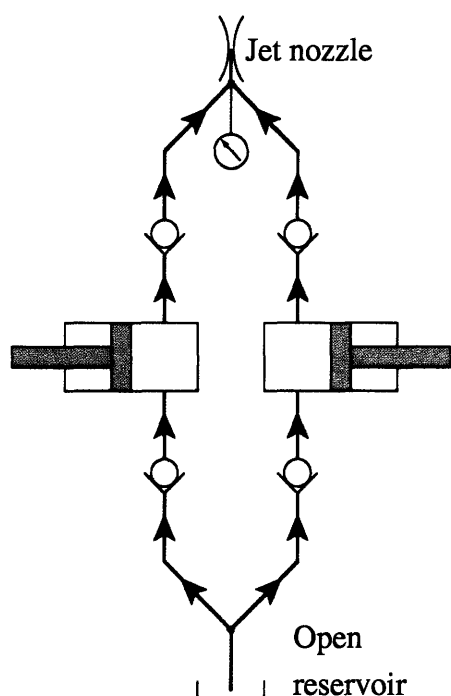
Figure 2 - The Injex™ needle tip jet orifice has a 160  $\mu\text{m}$  opening.

chamber, a precisely defined jet orifice, and are available in large quantities. These come as two components: a 0.3 mL chamber with a 160  $\mu\text{m}$  jet orifice (as shown in cross-section in Figure 2), and a piston with a rubber-seal head. The chamber/orifice has a threaded base that we use to mate with the top of the fluid pathway.

Removing the plastic and rubber piston, we add a rubber o-ring to the threads of the “Ampule”, under a bottom plate. We then add PTFE plumbers’ tape to the threads for added seal integrity. The “Ampule” is screwed into a receiving tap at the end of the fluid pathway.

### 2.1.2. The Fluid Pathways

The flow of the fluid through the system is much like that of a traditional pump; two check valves regulate the flow as the pistons pump the liquid in one direction. Broadly, our system is simply two dual action reciprocating pumps that draw from the same reservoir and also recombine in an upper chamber to flow out the same jet. The difference is that our pumps are rapid and the piston trajectories are highly controllable.



**Figure 3** – The hydraulic diagram of the fluid passages is much like a simple pump with two paths.

It took many iterations before we came up with this final design; initial tries had perpendicular fluid throughways, but bubble-collection became a problem. This was an issue because any build-up of compressible fluids within in the system acts as a pressure damper, and much of the motion of the pistons go into compressing the bubbles before it increases the pressure of the liquid.

We currently use an upright, side-by-side piston configuration (similar to that shown in Figure 3) where both pistons draw from the same reservoir, in this case a large oral syringe. To remove any residual air in the system, the plunger is inserted in the syringe and liquid is forced through the system until the pathways are sufficiently clear of air.

The check valves used in the system would ideally have low cracking pressure, and would allow no backflow before closing. Because of their small size, we initially tried Beswick Engineering's miniature metric check-valves (0.5 mm profile, less than 20 mm long, and about 3 kPa cracking pressure). We found that these used rubber nipples to regulate the flow, and in high-pressure situations this rubber flexed beyond what was acceptable (much like an additional compressible fluid in the line, this added damping). Looking slightly larger, we found more durable check valves that utilized a brass seat held with a small return spring. This provided us with a sensitive-enough check valve that did not increase the pressure damping of the system.

### 2.1.3. Pistons

Utilizing the Injex™ injector's supplied pistons with rubber-seal heads, we developed a piston chamber of the same dimensions of the original "Ampule" chamber. This allowed us to attach the original piston and rubber head to our solenoid coil and drive the fluids in a way very similar to that which Injex™ intended.

A smooth and clean surface finish is critical for a good seal between the piston orifice and the rubber head. Machining this 3.5 mm diameter hole was difficult, but after many manufacturing iterations we developed a consistent procedure. This included undersized drilling with only 2 mm-deep pecks, and chip clearance on each peck., which ensured a consistently clean surface for cutting. This process was then repeated using a 3.5 mm straight machining reamer.



**Figure 4** - The pistons shown here are taken from the original Injex™ needle and adapted for our use.

Interfacing the base of the needle piston with our solenoid coil was a simple matter of concentrically threading the end of the piston to mate with a tapped hole in the middle of the coil. Initially there were some concentricity issues due to threading the piston at an angle, which increased the mechanical resistance between the piston and the chamber walls. To solve this, a

tool was developed for a milling machine in order to hold the piston and threading dye concentric, ensuring a straight thread.

#### **2.1.4. The Lorentz Force Actuators**

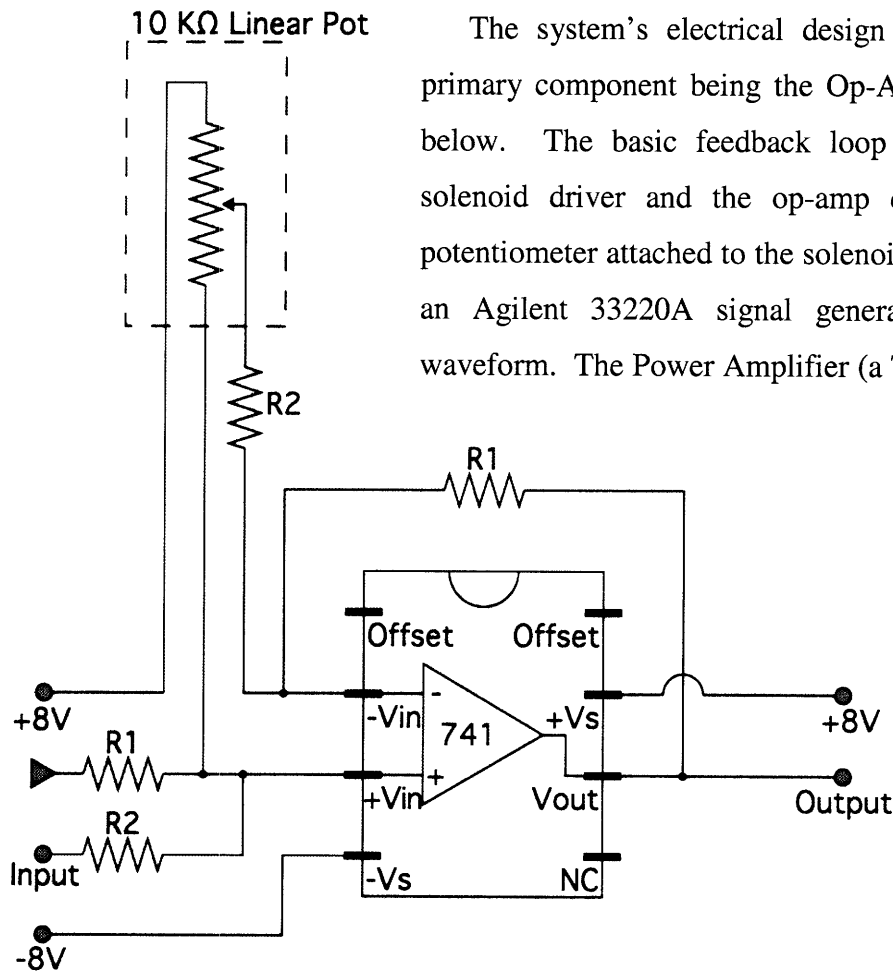
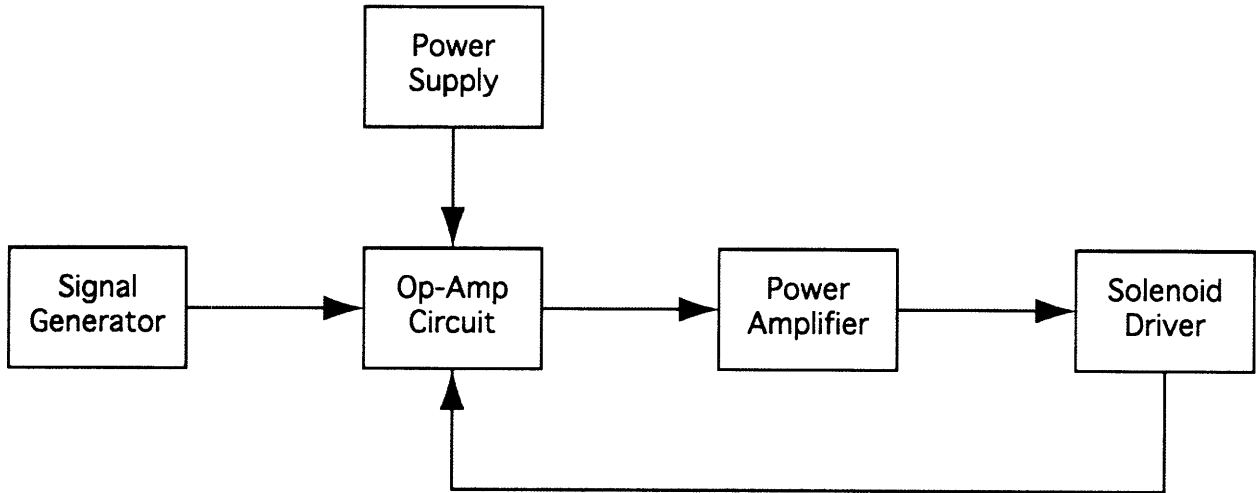
Extensive prior art exists on a type of linear actuator utilizing a Lorentz force driver. These have been used previously in various single-shot needle-less injectors created in MIT's BioInstrumentation Lab [2, 3].

The solenoid coils are wound with a machine we developed. Our primary coils consist of more than 600 wraps of 350  $\mu\text{m}$  (28 gauge) enamel-coated copper wire with a layer of adhesive, but a special application coil was developed that used 120 wraps of 500  $\mu\text{m}$  (20 gauge) enamel-coated wire. The adhesive on our current wire is activated after the coil is wound, to help prevent loop-jumps or breaks during operation. During normal use, these coils carry more than 100 A of current and so would normally get very hot, but the time that it carries this current is smaller than the time constant in heating the wires.

The magnets used within the coil to provide a strong, stable magnetic field are 0.4  $\text{MN}/\text{m}^2$  (50 MGOe) NdFeB magnets specially purchased for this application. They have an extremely strong magnetic field (approx 0.6 T at the coil location), and are made with a 6.35 mm (1/4") bore down the longitudinal axis. This allows us to run an alignment pin down the center of the magnet and into the housing, ensuring that the coil is perfectly concentric and is as close as possible to the strongest areas of the magnetic field.



## 2.2. Electrical Components



The system's electrical design is rather simple, with the primary component being the Op-Amp control circuit, detailed below. The basic feedback loop is completed between the solenoid driver and the op-amp circuit by a linear sliding potentiometer attached to the solenoid coil. The coil is driven by an Agilent 33220A signal generator providing the desired waveform. The Power Amplifier (a Techron 8803 Power Supply Amplifier) increases the amperage supplied to the solenoid coil.

The Op-Amp circuit we constructed uses a 741 Op Amp and a 10 kΩ Linear Potentiometer. We set up the 741 into a system that subtracts two

Figure 5 – The electrical diagram is a basic subtraction op-amp with a gain.

voltages, with a gain. The first voltage is the supplied input voltage from the signal generator; the second is the voltage coming from the linear potentiometer, driven by the location of the solenoid.

Resistances R1 and R2 were chosen to provide an ample gain (defined as  $\frac{R1}{R2}$ ) in order to provide sufficient power to the solenoid through the power amplifier.

By subtracting the current voltage (position) from the desired voltage (position) we determine the magnitude the solenoid needs to move to be at the goal location. The gain in the system is the proportionally-increased voltage that will be supplied to the solenoid coil, which will cause a force in the desired direction.

The internal pressure is measured by a Kistler 211B Miniature Pressure Sensor (with a pressure range of 0-7 MPa), which supplies a voltage proportional to the pressure detected by way of a standard voltage mode IEPE (Integral Electronic PiezoElectric) power supply/coupler. This pressure (as well as position voltage, signal waveform, etc) is recorded by Tektronics TDS 3012B digital oscilloscope.

### 3. Theory

The two major systems to model are the Lorentz Force actuator and the fluid dynamics within the system. The Lorentz Force actuator provides the link from the electronic signal to moving the fluid, and the dynamics dictate the fluid's response to the piston's motion, producing a velocity and flow rate, as well as the pressure behind the injection.

#### 3.1. *The Lorentz Force Actuator*

The common Lorentz Law states that a charged particle moving within a magnetic field creates a force perpendicular to both the field's and particle direction's vectors [4]. By inducing an electric current in a coil of wire around a static magnetic field, a force can be produced along the length of the core of the coil. This is the mechanism behind voice coils, commonly found in digital speakers.

We use this method to drive a coil with high current in a strong magnetic field, creating forces upward of 200 N. As mentioned before, our coils have more than 600 hand-wound turns of 350  $\mu\text{m}$ -diameter enamel-coated copper wire. Lorentz Law states that

$$F = \pi D n I \times B, \quad [1]$$

where  $F$  is the force in Newtons,  $I$  is the current in Amperes,  $n$  is the number of turns,  $D$  is the diameter of the coil, and  $B$  is the magnetic field at the coil. In the case of a coil of wire around a circular magnetic field, the cross product is equal to the simple product.

The force from the coil is transferred to the fluid through the piston, where the force is concentrated over the small area of the head to make pressures on the order of megapascals. From there, the energy in the system is dictated by fluid dynamics.

### **3.2. The Fluidic System**

Bernoulli's principle states that when there is an area of high pressure connected to an area of low pressure, there will be a fluid flow with velocity proportional to the square root of the pressure difference divided by the fluid density [5, 6]. In our case of incompressible, inviscid flow, Bernoulli equation simplifies to

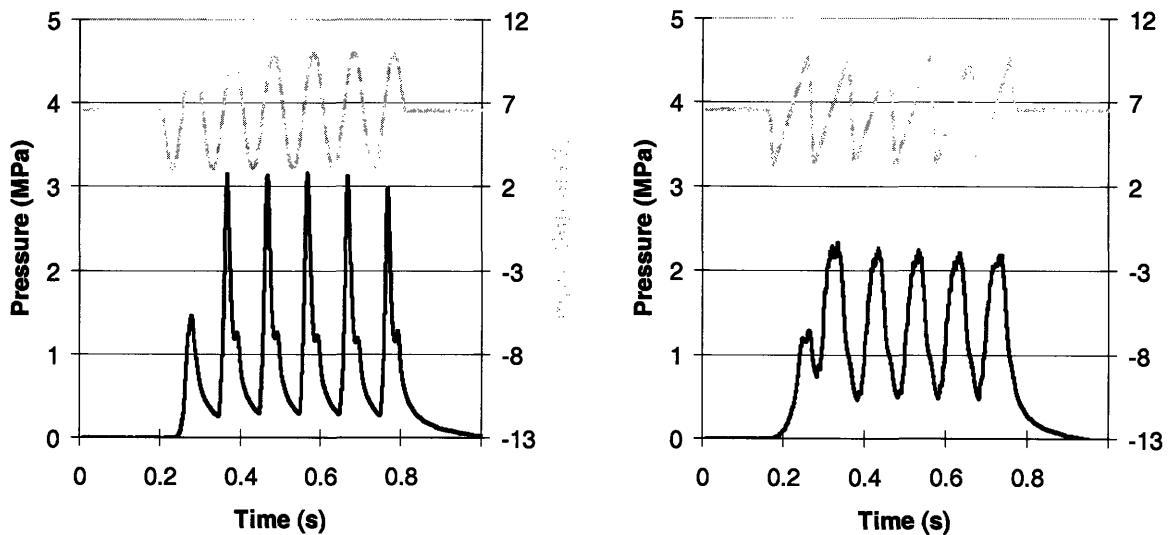
$$v = \sqrt{\frac{2P}{\rho}}, \quad [2]$$

where  $P$  is the gauge pressure and  $\rho$  is the fluid density. By controlling the pressure within the piston chamber, we can control the fluid velocity out of the jet injector, as long as we are dealing with fluids of known density.

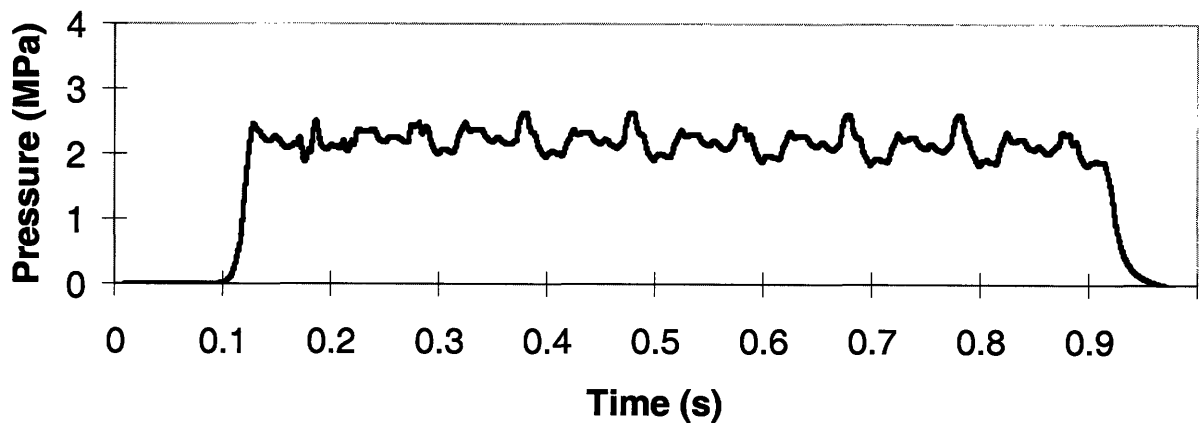
Also, because the opening diameter of the jet injector is known, the volumetric flow rate of the injector can be obtained by simply multiplying the area of the jet and the velocity of the fluid.

## 4. Results

Initially we tested the pistons separately, with good results. After eliminating any residual air in the system, with step input signals to the individual pistons we were able to get 2.5 MPa spikes of pressure, which was above the target constant pressure.



We initially tested 8-signal bursts of an 80% symmetric saw tooth wave at 10 Hz, triggering one piston with a signal 180° out of phase from the other. This successfully held a pressure at more than 2 MPa for as long as the bursts were sustained.



Later tests proved that as long as the waveforms were maintained, the pressure would average out to more than 2 MPa. Further, we found that higher frequencies generated higher pressure-spikes, but were more sporadic between those spikes, even dropping down below 1 MPa. Nevertheless, the pressure averaged over each period was greater than 2 MPa.

## **5. Conclusions**

A multi-piston injection system utilizing high-power Lorentz force actuators can sustain more than 2 MPa of pressure within the fluid chambers, creating volumetric flow rates out of the Injex™ 160  $\mu\text{m}$  jet orifice sufficient to providing standard doses in a reasonable amount of time. The possibility for hundreds of doses to be injected before dosage refilling is highly beneficial to applications involving large-scale or frequent injections. Further work would include miniaturizing our current system to allow for hand-held applications, as well as developing a way to better design the driving waveforms to facilitate more controllable needle-less injections.

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