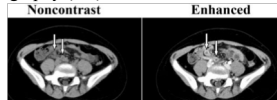




Clinical Need

- Contrast injectors deliver radiopaque contrast media into patients to improve the quality of images produced using computerized tomography (CT) scans



- Typical power injectors cost about \$22,000¹
- The high cost of power injectors limits their availability to low-resource areas, such as developing countries like Brazil, India, and China (BRIC)⁴
- Such facilities are forced to utilize manual injections which are inconsistent and less accurate

Market Analysis

- The global contrast injector market is poised to grow at a compound annual rate of around 6.1% over the next decade to reach approximately \$6.82 billion by 2025. However, BRIC countries are unable to support this sort of growth
- This project aims to target this niche market of emerging regions capable of supporting CT scans but unable to utilize current automated power injectors
- By developing a powered injection system at a fraction of the price (<\$100), Bayer will be able to reach a new market and increase the accessibility of power injectors across the globe for more enhanced CT images

Testing Procedure

- The design efficacy at reaching the desired flow rate will be measured during flow tests
- The average flow rate (in mL/s) will be measured timing the amount of time it takes the injector to empty a 100 mL syringe filled with water and a glycerin solution of a viscosity similar to that of contrast fluid

Needs Statement

- To design and develop a low cost contrast injector, that delivers fluid accurately and reliably, to increase the accessibility of higher quality soft tissue diagnostic imaging in developing countries
- Our design aims to function at the same clinical standards of 100 mL at a constant flow rate between 4 and 6 mL/second
- The injector design addresses concerns of safety, consistency, compatibility with existing catheters and CT suites, repeatability, and affordability

Description of Design

- Linear actuator model in which a stepper motor, stepper driver, arduino, threaded rod, and guide wire are used to provide linear motion to a collar lead screw
- The collar has been redesigned to have an extended top half, which will be used to apply pressure to the plunger of a filled syringe.
- As the collar progresses down the rod, the pressure provided by the top half will cause the plunger to compress and cause fluid delivery into an attached tube set and catheter, leading to injection

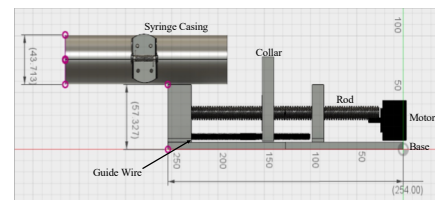


Figure 1: Model of Final Design (measurements in mm)

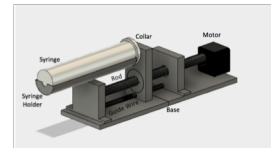


Figure 2: Isometric CAD Rendering of Final Prototype

Flow Rate Data

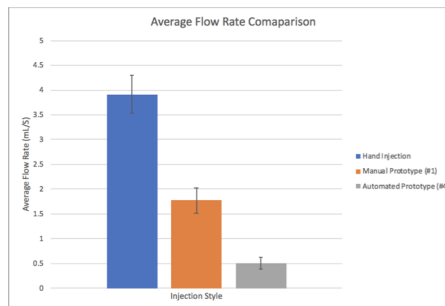


Figure 3: Flow Testing Data

- While unable to achieve the targeted flow rate, the automated prototype proved to have more consistent and precise measurements indicated by the lower standard deviation in Figure 3
- Comparatively, the automated prototype shows promise of being a more consistent and reliable alternative to manual injections once motor function and performance has been further developed

Novelty

- Current low cost injection methods are limited to manual injections, typically using a hand syringe or some sort of hand pump
- Our design offers a lost-cost automated solution, previously unavailable in any form

Estimation of Cost

Table 1: Price Per Unit Estimation

Part Description	Quantity	Unit	Unit Cost (\$)	Total Cost (\$)
Items Bought from Outside Supplier				
12 V 300 RPM Motor*	1	1	13.99	13.99
37 mm motor bracket	1	1	4.99	4.99
Set Screw Shaft Coupling	1	1	10.90	10.90
1018 Carbon Steel Precision ACME Lead Screw*	1	1	14.08	14.08
Aluminum Threaded Rod, 1/4"	1	1	0.91	0.91
20 Thread Size, 6" Long	1	1	0.05	0.05
6" guide wire	1	1	0.05	0.05
12V motor power controller	1	1	12.99	12.99
Items Produced In-House by Bayer				
3D Printed Injector board base	1	1	2.00	2.00
3D printed Rod Stabilizers	2	1	0.50	1.00
TOTAL COST PER UNIT				60.09

Table 2: Bulk Ordering Cost Estimation

Part Description	Minimum Bulk Quantity	Cost per Unit (\$)
12V DC Motor	1000 units	4.00
Aluminum Threaded Rod, 1/4"-20 Thread Size, 6" Long	2 tons	0.10
37 mm motor bracket	10 units	2.55
Set Screw Shaft Coupling	100 units	3.00
12V motor power dimmer	20 units	7.00

Regulatory Pathways

- This device will be marketed outside of the U.S. and should adhere to international regulatory processes such as ISO standards on Medical Devices (13485) and on Infusion Equipment for Medical Use (8536)
- Components bought must have a certification to prove these standards

Acknowledgements

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