Hand Powered Contrast Delivery System

by

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Abstract

The most common method of Medical Imaging, X-ray, often requires the injection of a contrast agent to improve the image. Because many of the tissues and organs of the body have similar x-ray absorption characteristics it often becomes difficult to distinguish one from the other on the x-ray film. To enhance the image in the area of interest a substance that x-rays cannot pass through, called contrast, is used. The contrast is injected into an artery or vein of the patient being examined. After the injection is made there is a delay before the image can be captured while the contrast makes its way through the vascular system to the area of interest. It therefore becomes desirable to inject the contrast at a higher flow rate to reduce the delay time and assure that an ample amount of contrast is present during the scan.

Current hand injections of contrast are limited by the amount of force that the technologist or doctor can apply to a syringe. Because the force required is quite high the individual performing the injection experiences a considerable amount of hand trauma. The Hand Powered Contrast Delivery System uses the mechanical advantage of a simple lever to increase the force applied to the syringe by a factor of 7.5. Since the force applied by the hand is greatly reduced the aforementioned hand trauma is virtually eliminated.

The increased force to the syringe that is available with the Hand Powered Contrast Delivery System can also provide increased flow rates in the two milliliter per second range.

Current hand injection procedures require the use of two hands to actuate the syringe. Because the Hand Powered Contrast Delivery System can be operated with only one hand, the second hand can feel the injection site helping to prevent patient injury.

The Hand Powered Contrast Delivery System provides enhanced comfort and improved safety for both the user and the patient.
Acknowledgements

Without the perpetual support of my beloved wife, Pam, my pursuit of a Bachelor degree would never have been initiated. For almost 30 years she has been the inspiration and motivation for all that I have accomplished. I could never express my gratitude and love for Pam in mere words, but I thank God for letting her be the most important part of my life.

I would be remiss if I didn’t mention the many talented people who assisted me with the completion of this prototype injector. My advisor, Amir Salehpour’s assistance with the development process and design intricacies was invaluable. Thanks, Amir, for treating me with respect while teaching me.

Dr. Muthar Al Ubaidi has been an inspiration to me throughout my years at CAS. His genuine concern for the students, the MET program and the college is sincere and very much appreciated by all. Thank you for being a friend and a mentor.

Thanks to my son, Chip, an EET CAS grad, for helping with the machining of parts, a task I helped him with for his senior project.

Without Jonathan Gibbs’ CNC instruction and Wendell Lambdin’s machinist expertise, the prototype couldn’t have been possible. Thanks guys.

The engineering and moral support that I have received from my manager, Frank Fago, has been more than could be expected. Thank you Frank, I owe you.

The support that I have received from all of my co-workers in the Mallinckrodt R&D Department has been phenomenal throughout the entire process. Special thanks to Elaine Borgemacke for the X-rays. Thanks to all of you.

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Introduction

What Is Contrast?

Medical Imaging is a valuable non-invasive tool for physicians to diagnose disease or injury that cannot be outwardly observed. The most common methods of Medical Imaging, X-ray and Magnetic Resonance (MR), are being continuously improved to assist physicians with these diagnoses. Because many of the tissues and organs of the body have similar x-ray absorption characteristics it often becomes difficult to distinguish one from the other on the x-ray film. One technique used to enhance the contrast of an image is to inject a liquid that is opaque to x-rays into the vascular system of the patient. [1] This radio-opaque liquid is known as contrast. [2]

Figure 1 (below) shows two x-rays of the abdominal cavity. In the image on the left the absence of the abdominal aorta seen in the image on the right is obvious. With liquid contrast present in the bloodstream, the arteries can be seen due to a contrast difference in the x-ray image. It becomes quite clear that contrast actually gets its name from its function.

![Abdominal X-ray comparing shots with and without contrast.](image)

Figure 1. Abdominal X-ray comparing shots with and without contrast.
The contrast medium of interest for many CT procedures is Mallinckrodt’s Optiray® 350. Optiray® 350 has a viscosity of 9 centipoise (cP) and a specific gravity of 1.405 at 37°C (normal body temperature). The recommended dosage or volume to be delivered is 50ml for body imaging.[3]

Why Is This Injector Important?

There are two methods currently used to introduce contrast into the patient’s system: oral ingestion or injection. Injection can be further divided into two categories: hand or power injection. Both methods of injection have a place in today’s imaging industry. The power injector is used in cases where a large volume is required at higher flow rates. Hand injections are performed in pediatric cases and situations that require smaller amounts of contrast. The hand injection method presents the problem addressed by the design of a new working prototype, the “Hand Powered Contrast Delivery System”.

Mallinckrodt Medical, a large international pharmaceutical company, is one of the largest suppliers of contrast media to the medical industry. For many years Mallinckrodt held the patent for contrast which gave them exclusive rights to the sale of contrast media. When the patent expired, the market was opened for competition from other pharmaceutical companies. It is this competition that keeps the interest high at Mallinckrodt in concepts such as the Hand Powered Contrast Delivery System. Items that enhance the sales of contrast, the main staple of the Mallinckrodt Imaging Division, are of great value.

Current hand injections of contrast are limited by the amount of force that the technologist or doctor can apply to the syringe. The Hand Powered Contrast Delivery System uses the mechanical advantage of a simple lever to increase the force applied to the syringe by a factor of five. Since the flow rate is directly related to the amount of force applied to the syringe, a substantial increase in the delivery of the contrast can be realized without the use of an outside power source.

Its compact size, simple setup and ease of use make the Hand Powered Contrast Delivery System ideal for applications that require flow rates in the two milliliter per second range. Current procedures where hand injections are prescribed may also benefit from the Hand Powered Contrast Delivery System due to the great reduction in hand trauma it affords.
Design Objectives

The primary objective of this prototype injector is to reduce the force exerted by hand to perform a contrast injection. This reduction in force results in the reduction or elimination of the hand trauma experienced using the syringe only method. A simple lever, as seen in Figure 2, is employed to gain a mechanical advantage allowing this force reduction.

Figure 2. A simple lever used to decrease force on the hand.

A secondary objective is to increase the flow rate of the injection by utilizing the amplified force applied to the plunger. This is achieved, once again, by employing the lever to increase the pressure applied by the hand, which will change the force on the plunger.

Thirdly, the injector is capable of being operated using only one hand. This frees the second hand to feel the injection site to detect any problems that might occur such as extravasation. Extravasation is the accidental injection of contrast into tissue instead of the vein. This can be very painful to the patient.

Because the development of this injector is sponsored by Mallinckrodt, a leading manufacturer of contrast, the use of Mallinckrodt 50mL pre-filled contrast syringes in the hand powered contrast delivery system is required. The injector is designed to accept this syringe.
Design Solution

In order to achieve the three design objectives of reduction of hand trauma, increased flow rate and one hand use, the concepts shown in Figures 3, 4 and 5 were considered and evaluated. These concepts were based on the goal of attaining sufficient pressures to obtain desirable flow rates. To that end, a test was performed to determine the highest force that can be introduced into a syringe using the current method of hand injection (see Test Report T0001, Appendix A). This test concluded that a force of 40 pounds exerted by the hand was the maximum force that is achievable by the current syringe only method.

Concern over the relatively low 40 pound force applied to the larger diameter (1.012 inches as opposed to the tested syringe diameter of .451 inches) of the desired Mallinckrodt syringe led to the investigation of an alternative method of applying force to the syringe. A test was performed to determine how much force could be applied by the foot as opposed to the hand (see Test Report T0002, Appendix A). This test concluded that a force of 90 pounds was the maximum force to be used for design purposes. Because of the size and complexity of the system required to transmit that force to the syringe this method of powering the syringe was not further investigated.

Alternative Designs

The objective of reducing the force input by the hand led to two designs that employed external power sources. The first (see Figure 3), utilized an external power source in the form of a clock spring. The spring would be wound prior to the insertion of the syringe. When the injection is initiated the trigger would release the lock on the spring gear transmitting the force to the syringe through a rack connected to the spring gear.

The second design (see Figure 4) involves a charged air tank that would actuate a cylinder that applied additional force to the force being applied by the hand. While these two alternatives were being considered, I decided to investigate just how much force could be exerted by the grip of the hand alone (see Test Report T0003, Appendix A). My results indicate that the need for an external assist is unnecessary due to the capability of the human hand to exert a minimum average force of 76.17 pounds. Consequently, these two designs were abandoned.

The 40 pound maximum force from Test Report T0001 was attained by one hand pushing against the other using the arms. The thought occurred that when lifting a heavy sheet of plywood or drywall vertically the sheet can only be carried if a great amount of force is exerted by the grip of the hand to induce enough friction force to keep the sheet from sliding out of the hand. I decided to find a way to test the force capability of the hand grip.
Figure 3. Spring Assist Design

Figure 4. Charged Air Assist Design
Physical therapists use a device called a hand dynamometer to determine the degree of improvement in hand strength of rehabilitating patients. The device has an adjustable grip width and a gage indicating pounds force. When the grip is squeezed the amount of force applied is registered on the gage. A test using this device (see Test Report T0003, Appendix A) indicates that at a span of 3.0 inches a force of 75 pounds is easily achievable by the average individual. With the mechanical advantage of the lever handle the force necessary for the injection is more than adequate while reducing the trauma to the hand. Because of this information and the simplicity of the lever mechanism the choice was made to begin the design process based on the design alternative shown in Figure 5.

Figure 5. Lever Mechanism Design Alternative
Injector System Pressure Calculator

Now that it has been determined that an equal amount of force can be applied to the syringe while reducing the amount of force input by the hand the question arises: What flow rate can be expected with this system? To answer this question the Injector System spread sheet was created (see Figure 6). [4] As can be seen by the diagram, a complete injection system that is typically used is represented. The syringe, fittings, coiled tubing and catheter are represented. Pressure losses for each element are calculated based on the friction factor for each component of the system and the input variables. The input variables are the desired flow rate, specific gravity and absolute viscosity of the contrast.

The compilation of this Injector System spread sheet is based on the following:

A. Fitting Losses

A loss of pressure occurs when the flow experiences a change in conduit diameter. This loss is caused by flow adjustments that generate turbulence and heat.

\[ h_f = K \left( \frac{v^2}{2g} \right) \]

\( h_f \) = fluid head loss in feet
\( \Delta p = 12 \rho h_f \)
\( \rho \) = fluid density (lb/ft\(^3\))

\( K \) = fitting coefficient
\( v \) = flow velocity at most restricted cross section (ft/sec)
\( g \) = acceleration due to gravity (32 ft/sec\(^2\))
Fitting Coefficients for the Injection System are:

\[
K_A = 0.02 \\
K_B = 0.02 \\
K_C = \frac{(v_{BC} - v_{CD})^2}{v_{BC}^2} \\
K_D = 0.05 \\
K_E = \frac{(v_{DE} - v_{EF})^2}{v_{DE}^2} \\
K_F = 0.02 \\
K_G = 1 \text{ for discharge into same fluid} \\
K_G = 0 \text{ for discharge into air}
\]

B. Flow Losses

Pressure losses occur due to friction between the fluid and tubing walls.

\[
h_f = f \left( \frac{L}{D} \right) \left( \frac{v^2}{2g} \right)
\]

\( f \) = friction factor
\( L \) = length of the tube (ft)
\( D \) = diameter of the tube (ft)

Friction Factor \((f)\)

\[
N_{RE} = \frac{Dv}{V_K}
\]

\( N_{RE} \) = Reynolds Number
\( V_K \) = kinematic viscosity

Use the Moody Diagram to estimate the friction factor when the Reynolds Number is greater than 4000. For Reynolds Numbers 2100 and lower use:

\[
f = \frac{64}{N_{RE}}
\]

For Reynolds Numbers between 2100 and 4000 this formula may be used but empirical data should be gathered for verification of values.

\( \epsilon \approx 0.000005 \) in. for most plastic tubes

All of the head losses are totaled to obtain the system pressure required for the input flow rate.
Flow "Q" (ml/s) = 2 = 7.06E-05 ft³/s
Fluid Specific Gravity = 1.405
Fluid Density "ρ" (g/cm³) = 1.405 = 87.71 lb/ft³
Absolute Viscosity "μ" (cP) = 9 = 0.09 g/cm·s
Kinematic Viscosity "ν" (cm²/s) = 0.06406 = 6.9E-05 ft²/s

<table>
<thead>
<tr>
<th>Length &quot;L&quot; (in)</th>
<th>0.4</th>
<th>0</th>
<th>0.315</th>
<th>60</th>
<th>0.4</th>
<th>1.25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter &quot;D&quot; (in)</td>
<td>0.08</td>
<td>0.1</td>
<td>0.156</td>
<td>0.06</td>
<td>0.164</td>
<td>0.031</td>
</tr>
<tr>
<td>Velocity &quot;V&quot; (ft/s)</td>
<td>2.023382</td>
<td>1.294964</td>
<td>0.532119</td>
<td>3.597123</td>
<td>0.481471</td>
<td>13.47517</td>
</tr>
</tbody>
</table>

Fitting Losses
- Fitting Coefficient (K): 0.2, 0.34702, 0.2, 0.77872, 0.2, 1
- Fitting Loss (head-feet): 0.012715, 0.001526, 0.040184, 0.002803, 0.563914, 2.81957
- Fitting Loss (psi): 0.063341, 0.000929, 0.024476, 0.001707, 0.343483, 1.717417

Flow Losses
- Reynolds Number "N_Re" (VD/ν): 195.6276, 156.5021, 100.3219, 260.8369, 95.42812, 504.8455
- Relative Roughness (є/D): 0.00075, 0.0006, 0.000385, 0.001, 0.000366, 0.001935
- Friction Factor "f": 0.327152, 0.40894, 0.637947, 0.245364, 0.670662, 0.034
- Flow Loss (head-feet): 0.103989, 0.000929, 0.005664, 49.29872, 0.005888, 3.865539
- Flow Loss (psi): 0.063341, 0.000929, 0.00345, 30.02815, 0.003586, 2.354524, 32.45306

Syringe Diameter "d" = 1.012
Req'd force on Plunger = 27.78971
Mechanical Advantage Req'd = 0.365654

Figure 6. Injection System Spread Sheet
In order to validate the Injection System spread sheet results a test was performed using a mock-up injector (see Test Report T0004, Appendix C). The results of the test can be seen in Figure 7 along with the graph of data taken from the Injection System spread sheet output forces for varying input flow rates.

The blue curve on the graph represents calculated data obtained using the Injection System spread sheet. The red curve indicates the test results from the mock up system. Examination of this graph indicates that the Injection System spread sheet does indeed coincide with actual injections. The variation in force that occurs as the flow rate increases can be accounted for by the fact that contrast has a higher viscosity than the water that was used in the test. Because contrast is very expensive, water is the most commonly used liquid for injector testing.
Figure 7. Injector System and Empirical Data Compared

Flow Rate vs Force on Plunger
Calculated vs Empirical

Flow Rate "Q" (ml/s)
0 0.5 1 1.5 2 2.5 3 3.5 4

Force (lb)
0 20 40 60 80 100 120

Calculated
Poly. (Empirical)
Optimization

To optimize the design in regards to force and the accompanying flow rate, an optimization chart was made (see Figure 8). This chart plots the lever arm length ratio against the output force from the lever on the left of the chart and the lever arm length ratio against the output displacement of the lever on the right of the chart. The output displacement correlates to the flow rate in that the plunger movement displaces a volume of fluid during the stroke. The point at which these curves intersect indicates the optimal lever length ratio to deliver the greatest force along with the greatest flow.
Figure 8. Force vs Flow Optimization

Force - Flow Optimization
(50lb Force on Handle; Displacement Potential Flow)
Balance

A syringe forward design constituted the initial design. While evaluating the ergonomic aspects of the injector a concern was raised about balance. When using the injector it is desirable to use only one hand. The push rod on the pre-filled syringe makes it necessary to place the filled syringe barrel far in front of the handle. With 50 mL of contrast pulling the nose of the injector system downward at a distance of approximately 10 inches from the handle, it becomes obvious that the center of gravity is not centered over the handle (see Figure 10).

In order to achieve greater balance and enable one hand operation, the syringe had to be moved to a position that is more central to the entire mechanism. To that end, a design referred to as the “over – under” was created (see Figure 11). The term over – under refers to the syringe being over the hand and the driving mechanism is under the syringe. This improved design solves the problem of balance but introduces another problem. The loading of the syringe is no longer directly in line with the pushing rod. This eccentricity in loading could induce a downward deflection or bending of the pushing rod causing binding and / or premature wear of the bearings. To determine the extent of the deflection the following calculations were done.

![Figure 9. Free Body Diagram of syringe actuator.](image)

As the free body diagram in Figure 9 indicates, the eccentric beam loading of $F = 650 \text{ lb}$ applies a couple at beam end of $M = 650 \times 1.302 = 846.3 \text{ in lb.}$
Figure 10. Syringe Forward Design
Figure 11. Over – Under Design
\[
\delta_{\text{MAX}} = \frac{MI^2}{2EI}
\]
\[
\delta_{\text{MAX}} = \frac{846.3(3.986)^2}{2(30E6)(4.6E-4)}
\]
\[
\delta_{\text{MAX}} = .4872
\]

where:

\( E = \) modulus of elasticity for steel = 30,000,000 psi
\( I = \) moment of inertia for beam circular cross section
\( d_{\text{MAX}} = \) maximum deflection at end of beam
\( l = \) length of beam

The deflection of .487 inches is obviously excessive and would probably cause binding as suspected, not to mention excessive bearing wear. To decrease the deflection, the moment of inertia \((I)\) must be increased. This can be done by changing the beam’s cross sectional shape or size or both. Because the circular shape is integral to the function of the mechanism, increasing the diameter is the only option. At the same time the weight increase is undesirable. To reduce the weight while increasing the diameter a cylindrical shaped is utilized.

\[
I = .049(D^4 - d^4)
\]
\[
I = .049(.50^4 - .25^4)
\]
\[
I = .0029
\]

\[
\delta_{\text{MAX}} = \frac{MI^2}{2EI}
\]
\[
\delta_{\text{MAX}} = \frac{846.3(3.986)^2}{2(30E6)(.0029)}
\]
\[
\delta_{\text{MAX}} = .0781
\]

The deflection is now in a manageable range. In order to further reduce the chance of binding spherical bearings are used to guide the rack (see drawing 227006 in Appendix B).

An area of concern, due to a sizeable load applied by the lever, is the pivot boss that is a part of the left and right handle halves. These bosses support the pivot pin and lever that actuates the rack. Figure 12 depicts an excel spreadsheet that is used to quickly calculate stress induced into the boss by the lever. The total stress includes torsional stress that would be present if the load was rigidly attached to the face of the boss. Because the loading is through a pin that is free to rotate, this torsional stress can be neglected leaving only the compressive and tensile stresses at points A1 and A respectively.
Another area of concern is the lever at the pivot pin connection. The possibility of failure is highest at this point due to the thin wall sections and high stress concentration at the pivot pin. The stress at the pin holes is 3840 psi. The similar stress at the boss and lever indicate the use of the same material for both the handle and the lever. This indication is further reinforced by the economic benefit of using the same material for injection molding for production parts. Plastic is generally less expensive per pound when purchased in larger quantities. Color matching of different parts of an assembly is also made much easier when using the same material. These two factors further justify the decision to use Delrin for the load bearing plastic parts.

Figure 12. Stress Calculation for Handle Lever Boss [5]
Fabrication and Assembly

Machining of Component Parts

All of the component parts, with the exception of springs and screws, are custom machined for the Hand Powered Contrast Delivery System prototype injector.

A Haas TM1 CNC Tool Room Mill was used to machine both handle halves and the lever for the prototype injector (see Appendix B, drawings 227001, 227014 and 227006). The material, Delrin, chosen for its strength characteristics proved to have excellent machining characteristics as well. Spindle speeds of up to 3800 rpm were used with no melting or distortion of the plastic. Feed rates exceeding 20 inches per minute were used with excellent finishing cut results.

All of the tool path programming was produced using Pro-NC software in conjunction with Parametric Technology Corporation’s (PTC) Pro-Engineer solid modeling software. Because all of the component parts of the prototype injector were designed using Pro-Engineer, the transition to Pro-NC was virtually seamless.

The CNC Tool Room Mill’s table motion is directed by a programming language called G-Code. To translate the Pro-NC tool paths into G-Code, a custom Post Processor was used.

The most challenging of all the parts to machine were the spherical bearings. The spherical outside diameter, which allows for misalignment, proved to be very difficult to turn on a lathe. The use of a good tool grinder, which was not available, will simplify the turning procedure guaranteeing easier fabrication for production.
Performance Testing

Test Plan

The test plan is designed to verify that the Hand Powered Contrast Delivery System prototype fulfills all of the design objectives. Two separate tests comprise the performance testing. The first test, of the current syringe only injection method, determines a baseline to compare to the second test results. The second test is of the prototype injector. Both test setups are identical to allow for comparison of the data. A detailed description of the test set-up can be found in Test Report T0006 in Appendix A.

To assure that the hand trauma is reduced, the force exerted by the hand is calculated from the maximum pressure measured in the syringe. The values are compared and the percent of reduction is calculated. The reduction of force on the hand is directly related to the amount of hand trauma incurred.

Flow rate values for both systems are calculated from captured average pressure data. The Injection System spread sheet is used to perform these calculations. Data values from both tests are compared and a percent difference is calculated.

All testing of the prototype injector is performed using only one hand to hold and actuate the injector.

The syringe used for all testing is the 50 milliliter Mallinckrodt syringe.
Test Results

The test results can be found in detail in Test Report T0006 (Appendix C). The overall results of the test are as follows.

Hand Trauma

Because the magnitude of the hand trauma caused by the syringe-only method is directly related to the amount of force placed on the hand, the maximum data values for system pressure were used in the following calculations.

The comparison test for hand injection, using the syringe only, resulted in a maximum pressure of 47.3 PSI measured in the injection system. This equates to a maximum force applied by the hand of 47.87 lbf. Using the same test set-up and placing the syringe into the Hand Powered Contrast Delivery System injector, a maximum pressure of 111.22 PSI was measured in the injection system. This pressure equates to a maximum force on the syringe of 89.46 lbf. Considering the 7.5:1 length ratio of the injector lever arm the force actually applied by the hand is 11.93 lbf. These figures represent a 75.08% reduction in force applied by the hand when using the Hand Powered Contrast Delivery System injector.

Flow Rate

Examination of individual data collected in the test reveals a cyclical pressure trend where pressure varies between a maximum value and a minimum throughout the duration of the injection. Due to the nature of the ratchet drive mechanism pushing and resetting for the next push, this is to be expected. Because the syringe-only method displays the same cyclical characteristics, although of a lesser amplitude, average values of pressure were used to determine the following flow rates.

The cumulative average pressure for the syringe only method was calculated to be 22.291 PSI. Likewise, the cumulative average pressure for the Hand Powered Contrast Delivery System injector was calculated to be 38.6 PSI.

The Injection System Pressure Calculator was then used to determine flow rate for each pressure (see Test Report T0006, Appendix A). A flow rate of 1.35 mL/s was calculated for the syringe only method. A flow rate of 2.2 mL/s was calculated for Hand Powered Contrast Delivery System injector. This result represents a 63% flow rate increase over the syringe-only method.
Conclusion

The performance test results clearly indicate a significant reduction of the force required of the hand to perform the injection with the Hand Powered Contrast Delivery System injector. This reduction in force virtually eliminated all hand trauma, which was the primary objective of this prototype.

The 63% increase in flow rate with the Hand Powered Contrast Delivery System injector that was achieved while applying less force clearly demonstrates an enhancement over the syringe only method. This improvement satisfies the second performance objective of increased flow rate.

The third performance objective was an injector that could be operated using only one hand. During the performance testing all cycles were performed using only one hand to actuate the Hand Powered Contrast Delivery System injector. Thus, the third objective has been met successfully.

Overall, this prototype performs to or exceeds all standards set in the original objectives statement. Therefore this successful prototype is ready for the next phase of development, refinement of the design for release to manufacturing.
Recommendations

Because this injector is only a prototype, further development is necessary before it can be released to production.

There is a definite need to make the design more aesthetically pleasing. Careful color consideration to fit the “Mallinckrodt Family of Injectors” marketing mandate is imperative. An Industrial Designer should be consulted to improve the overall shape of the injector.

Although one hand operation is possible, a smaller, lighter machine would be easier to control. Consideration should be given to any size and weight reduction opportunities.

To give this injector a more comfortable feel and reduce the occasion of hand fatigue, a dual injection molded handle and lever with a soft material such as Santoprene in the handle area should be considered. Previous experience with such a design has proven this to be not only a feel issue but an aesthetic one as well.

Overall this prototype proves to be a viable solution to common problems encountered daily in hospitals. It is therefore my recommendation that further development be pursued with a final goal of producing marketable units.
Appendix A

Test Reports
Liebel-Flarsheim Business

Engineering Test Report

<table>
<thead>
<tr>
<th>Product:</th>
<th>Hand Powered Injector</th>
</tr>
</thead>
<tbody>
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<td>Part No.:</td>
<td>NA</td>
</tr>
<tr>
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<td>Namic</td>
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Purpose of Test
To determine the amount of force that can be applied by hand to a syringe that is currently used in procedures where contrast media is injected.

Test Set Up
Attach Namic 12cc syringe to coil tubing. Attach coil tubing to pressure gage and reservoir setup.

Test Procedure:
1. Fill syringe with water by opening the blue valve and pulling the syringe plunger back.
2. Purge all air from syringe and tubing.
3. Close blue valve to prevent evacuation of the water.
4. Reset the red indicator on the pressure gage to 0.
5. Holding the syringe barrel tightly with one hand, depress the plunger with the palm of the other hand applying as much force as you can.
6. Observe the pressure gage and continue applying pressure until the gage needle ceases to rise.
7. Record the reading of the red needle on the gage.

**Results:**
Five cycles of the test were run by two different individuals for a total of 10 cycles. The maximum value achieved was 250 psi.

**Conclusion:**
Because all of the pressure values obtained in this test were at or very near to 250 psi. When an injection is being made and a high volume is desired, the physician will apply as much pressure as he can. These two points justify accepting the 250 psi as a maximum.

The inside diameter of the syringe barrel used in this test is .451 inches. The area of the plunger face is therefore .1598 in\(^2\). The maximum force applied by the hand is calculated to be

\[250 \times .1598 = 39.94 \text{ lb} \approx 40 \text{ lb}.\]
Purpose of Test
To determine the amount of force that can be applied by foot to a syringe that is currently used in procedures where contrast media is injected.

Test Set Up
Tanita Model 1631 Digital Bathroom Scale on a flat hard surface.
2-people of different stature: 1. Weight = 240 lbs
2. Weight = 140 lbs

Test Procedure:
8. Stand with the scale in front you.
9. Place one foot on the scale and apply constant pressure.
10. Record reading on scale.
11. Repeat steps 1 through 3 to obtain 5 total readings.
12. Repeat step 4 for both people.

Results:
Five cycles of the test were run by two different individuals.

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<tr>
<th>Weight (lbs)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Average Force (lbs)</th>
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<tbody>
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<td>148</td>
<td>149</td>
<td>152</td>
<td>151</td>
<td>150</td>
</tr>
</tbody>
</table>
Conclusion:
The average force of 90 pounds should be accepted as the maximum value for design purposes in order to render a product that is useable by the greatest range of individuals.

An interesting statistic arose from this test: the average force exerted by the foot is approximately 63% of the weight of the person performing the test.
Engineering Test Report

<table>
<thead>
<tr>
<th>Product:</th>
<th>Manually Powered Injector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part No.:</td>
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</tr>
<tr>
<td>Model No.:</td>
<td>NA</td>
</tr>
<tr>
<td>Description:</td>
<td>Force that can be applied by hand</td>
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<tr>
<td>Mfr. Name:</td>
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<td>Mfr. Part No.:</td>
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<tr>
<td>Tested by/Date:</td>
<td>Skip Boertlein  2/6/03</td>
</tr>
<tr>
<td>Approved by/Date:</td>
<td></td>
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</tbody>
</table>

**Purpose of Test**
To determine the amount of force that can be applied by hand to a hand grip.

**Test Set Up**
Jamar Hand Dynamometer Model 5030 J1 manufactured by J.A. Preston.

3-people of different stature:  
1. 6’4” Male  
2. 5’4” Female  
3. 5’9” Male

**Test Procedure:**
13. Set dynamometer span to 3.5 inches.  
14. Reset marker needle on gage to near zero.  
15. Squeeze dynamometer handle.  
16. Record reading of marker needle  
   (maximum pound reading).  
17. Repeat steps 3 through 4 to obtain 2 readings.  
18. Repeat steps 2 through 5 for 3, 2.5 & 2 inch spans.
Results:

<table>
<thead>
<tr>
<th>Span (inches)</th>
<th>6’4” Male</th>
<th>5’4” Female</th>
<th>5’9” Male</th>
<th>Average Force (lbs)</th>
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</thead>
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Conclusion:
The maximum force achievable seems to be affected by the span across which the hand must be extended. Even though the smaller male's hand was only ¼” shorter than the larger male (7 ¾” to 8”) the shorter span seemed to favor the smaller male.
### Engineering Test Report

<table>
<thead>
<tr>
<th>Product:</th>
<th>Manually Powered Injector</th>
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#### Purpose of Test
To determine the relationship between the amount of force applied and the flow rate of a water filled syringe.

#### Test Set Up
1. Ohaus Scout Digital Scale CCN# 2910 with plastic container to collect expelled water.
2. Digital Pressure Box with pressure transducer connected to tee fitting with standard tubing connectors.
3. Stop Watch.
4. Ratchet drive caulk gun modified to accept 50 ml syringe.
5. 50 ml Syringe connected to transducer tee.
6. 60 inch coiled extension tubing connected to transducer tee.
7. 20ga. Catheter connected to extension tubing and fixed to plastic container on scale.
**Test Procedure:**

19. Fill plastic container with water enough to cover needle during syringe fill.

20. Pull plunger back slowly to fill syringe.

21. Purge all air from syringe and tubing.

22. Remove remaining water from plastic container and zero scale.

23. Reset the Pressure Box peak reading to 0.

24. Engage the ratchet mechanism and squeeze the handle of the caulk gun repeatedly until water has been expelled from syringe. Time the duration of the injection.

25. Record the time, gram weight and peak pressure for the injection.

26. Repeat steps 1 through 7 for a total of 10 injections.
Engineering Test Report

<table>
<thead>
<tr>
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<th>Hand Powered Contrast Delivery System</th>
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<td>Tested by/Date:</td>
<td>Skip Boertlein 5/4/03</td>
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</table>

**Purpose of Test**
To determine the average pressure and the average flow rate of the Hand Powered Contrast Delivery System loaded with a water filled syringe.

**Test Set Up**
1. Pressure test system with Omega Engineering Pressure Transducer (A) model PX02C1-1KGV, 1-gallon reservoir (B) in a closed loop system, Omega Engineering Data Acquisition Device (C) model DP41-S-S2 and a serial connector cable.

2. Connect Data Acquisition Device to a computer serial port (computer must have HyperTerminal).

3. Hand Powered Contrast Delivery System (D).

4. Empty 50mL Mallinckrodt contrast syringe (E) connected to pressure test system tubing.
**Test Procedure:**

1. Fill syringe by pulling back on plunger rod.

2. Activate HyperTerminal and start text file acquisition.

3. Holding syringe as shown, expel a minimum of 30 mL while pushing the plunger rod as hard as possible.

4. Stop text file acquisition.

5. Repeat steps 1 through 4 creating five individual data text files.

6. Load the syringe into the Hand Powered Contrast Delivery System.

7. Fill syringe by pulling back on plunger rod.

8. Activate HyperTerminal and start text file acquisition.

9. Actuate the Hand Powered Contrast Delivery System by squeezing the lever as shown expelling a minimum of 30 mL.

10. Stop text file acquisition.

11. Repeat steps 7 through 10 creating five individual data text files.
### Results:

**Hand Injection**  
**Syringe Only**

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</table>

Max = 35.65
Max = 35.05
Max = 31.54
Max = 29.03
Max = 47.3

Avg = 21.15038
Avg = 23.23774
Avg = 23.04061
Avg = 21.24257
Avg = 22.78531

**Cumulative Test Results**

- Avg Pressure = 22.29132 PSI
- Avg Force on Plunger = 17.93027 lbf
- *Avg Flow Rate = 1.35 ml/s

*Based on injection system spreadsheet calculation.
Flow "Q" (ml/s) = 1.35 = 4.77E-05 ft³/s
Fluid Specific Gravity = 1.405
Fluid Density "ρ" (g/cm³) = 1.405 = 87.71128 lb/ft³
Absolute Viscosity "μ" (cP) = 0.09 = 0.09 g/cm·s = 0.006048 lb/ft·s
Kinematic Viscosity "ν" (cm²/s) = 0.06406 = 6.9E-05 ft²/s

<table>
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<tr>
<th>Length &quot;L&quot; (in)</th>
<th>Diameter &quot;D&quot; (in)</th>
<th>Velocity &quot;V&quot; (ft/s)</th>
<th>Fitting Coefficient (K)</th>
<th>Fitting Loss (head-feet)</th>
<th>Fitting Loss (psi)</th>
<th>Reynolds Number &quot;N_Re&quot; (VD/ν)</th>
<th>Relative Roughness (c/D)</th>
<th>Friction Factor &quot;f&quot;</th>
<th>Flow Loss (head-feet)</th>
<th>Flow Loss (psi)</th>
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</thead>
<tbody>
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Fitting Losses

Fitting Losses (head-feet) = 0.000695 + 0.018309 + 0.011152 + 0.01565 + 1.284667 = 1.299247
Fitting Loss (psi) = 0.000423 + 0.001277 + 0.000778 + 0.00421 + 0.782498 = 0.828627

Reynold’s Number “N_Re” (VD/ν) = 132.0487 + 105.6389 + 67.71726 + 176.0649 + 64.4139 = 340.7707
Relative Roughness (c/D) = 0.00075 + 0.0006 + 0.000385 + 0.001 + 0.000366 = 0.002506
Friction Factor “f” = 0.48467 + 0.605837 + 0.945106 + 0.363502 + 0.993573 = 2.28024

Flow Losses (head-feet) = 0.070193 + 0.003823 + 23.27664 + 0.003974 + 1.761236 = 22.34417
Flow Loss (psi) = 0.0042755 + 0.002329 + 0.002421 + 0.002421 + 0.002421 = 0.022329

Total required PSI into fluid = 22.34417
Hand Powered Contrast Delivery System

<table>
<thead>
<tr>
<th>Test #1</th>
<th>Test #2</th>
<th>Test #3</th>
<th>Test #4</th>
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Avg = 39.34733 Avg = 35.33229 Avg = 38.50125 Avg = 38.13571 Avg = 41.68214

Cumulative Test Results

Avg Pressure = 38.59975 PSI
Avg Force on Plunger = 31.04812 lbf
Avg Flow Rate = 2.2 ml/s

*Based on injection system spread sheet calculation.
Flow "Q" (ml/s) = 2.2 = 7.77E-05 ft³/s  
Fluid Specific Gravity = 1.405  
Fluid Density "ρ" (g/cm³) = 1.405 = 87.71128 lb/ft³  
Absolute Viscosity "μ" (cP) = 9 = 0.09 g/cm·s = 0.006048 lb/ft·s  
Kinematic Viscosity "ν" (cm²/s) = 0.06406 = 6.9E-05 ft²/s

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Fitting Losses
- Fitting Coefficient (K) = 0.2
- Fitting Loss (head-feet) = 0.015385
- Fitting Loss (psi) = 0.009371

Total length = 14.82269 ft

Reynold's Number "NRe" (VD/v) = 215.1904  
Relative Roughness (є/D) = 0.00075  
Friction Factor "f" = 0.297411

Flow Losses
- Flow Loss (head-feet) = 0.114388
- Flow Loss (psi) = 0.069675

Total required PSI into fluid = 38.49323

---

Moody Diag.

Total required PSI into fluid = 38.49323
**Conclusion:**

Comparison of the data from the syringe only hand injection and the Hand Powered Contrast Delivery System (HPCDS) injection clearly shows an increase in flow rate for the HPCDS. Average values for pressure were used because of the fluctuating nature of the HPCDS due to the impulse cycle of the lever actuation. The average values for both tests are considered to be the steady state pressure and are used to determine the flow rate of contrast in the prescribed Injection System.

An increase of .85mL/s is realized with the HPCDS over the hand injection. This represents a 63% increase in the flow rate.
# Bill of Materials

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Total: 77.00
Figure 13. Exploded Assembly
**BUSHING_RACK**

- **MATERIAL**: N/A
- **FINISH**: N/A
- **BREAK ALL EDGES**: TOLERANCE UNLESS OTHERWISE SPECIFIED
- **PRODUCT**: HAND POWERED INJECTOR
- **DRAWING/PART NO.**: 227006
- **DRAWN BY**: S. BOERTEIN
- **SCALE**: 2:1
- **WHERE USED QTY**: 2
- **DATE**

**SECTION A-A**

- **Φ .507**
- **.738 REF**
- **.826 REF**
- **.375**
NOTES:
1. ALL DIMENSIONS ARE REFERENCE.
2. THIS PART TO BE CREATED FROM PROVE SOLID MODEL "LEVER"
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2111 EAST GALBRAITH ROAD  CINCINNATI, OHIO 45237-1646 USA

WHERE USED: QTY

DRAWN BY:  S. BOETLEIN  227013

REV.

SCALE 10:000

45° X .01

Ø .091  Ø .123

.019

.020 REF

54
Appendix C

Research Patents
A hand-held instrument having a handle somewhat resembling a pistol grip depending from a horizontal frame having a slide on the forward end thereof to which a conventional hypodermic syringe is connected and including a tension spring connected to the rearward end of said slide for purposes of instantly injecting the needle of the syringe into flesh. The slide is held in its rearward, cocked position by a sear and the sear is released by means of the piston of a piston and cylinder unit, the piston being operated initially to release the sear from the syringe slide to effect injecting movement thereof. A flexible bulb is supported within the handle and a finger-engageable lever engages the bulb to force fluid against the piston to cause release of the sear and continued compression of the bulb operates a finger guided for movement against the outer end of the plunger of the syringe and forces the same in discharging direction immediately after the needle of the syringe has been injected into flesh.
MANUALLY DRIVEN SYRINGE

Inventors: Carlos A. Saez, Irvine; Robert P. Cooper, Yorba Linda, both of Calif.


Appl. No.: 227,557
Filed: Aug. 2, 1988

Related U.S. Application Data
Continuation-in-part of Ser. No. 141,989, Jan. 11, 1988, abandoned.

Int. Cl? A61M 5/00
U.S. Cl. 604/227; 604/218; 604/209; 222/386

Field of Search 604/187, 207-209, 604/218, 220, 227, 97-99; 222/386

References Cited
U.S. PATENT DOCUMENTS
201,443 3/1878 Parker 604/209
794,190 7/1905 Schneyder 604/227
1,325,699 12/1919 Oesterhaus 604/227
1,654,905 1/1928 Voos 604/227
2,420,102 5/1947 Shaford 604/227
2,632,445 3/1953 Kas 604/209
2,671,449 3/1954 Dunn 604/227
2,882,901 4/1959 DeVenezia 604/227

FOREIGN PATENT DOCUMENTS
6400092 11/1965 Netherlands 604/227

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Ralph Lewis
Attorneys, Agent, or Firm—Irell & Manella

ABSTRACT
A manually driven syringe for injecting fluids under high pressure is described that includes a barrel (12), a plunger (33) that is received within the barrel and extends rearwardly through an aperture (28) in the body (27) of a handle (14) which carries a pair of opposed finger grips (19, 22). The finger grips are located rearwardly of the barrel and laterally of the shaft (19) of the plunger, elongated so as to each accommodate two fingers, and angled rearwardly. This design minimizes the distance between (a) the inner edges of the grips and (b) the grips and the head of the extended plunger, thus making the syringe easier to grip in the palm of the hand and enabling the syringe to be gripped strongly between the fingers and the palm.

8 Claims, 2 Drawing Sheets
PORTABLE DRUG DELIVERY SYSTEM

Inventors: David C. Blakely, Mountain View, Calif.; Dale C. Harris, Fairfield, Ind.

Assignee: Eli Lilly and Company, Indianapolis, Ind.

Appl. No.: 695,495
 Filed: May 2, 1991

Int. Cl. .............................. A61M 8/00

U.S. Cl. .............................. 604/232, 604/235, 604/187, 604/208, 222/327, 222/386


References Cited

U.S. PATENT DOCUMENTS
Re. 32,214 7/1986 Schramm 604/232
1,685,984 10/1928 Courmand et al. 604/235
1,757,809 5/1930 Montouri 604/232
2,076,401 3/1937 Kauzl 604/232
2,118,221 5/1938 Montouri 604/235
2,625,338 1/1953 Moore et al. 604/233
2,748,767 6/1956 Wright 604/232 X
3,141,583 7/1964 Mapel et al. 604/234 X
3,469,750 9/1969 Vanderbeck 604/235
3,763,169 3/1974 Dill 604/236
3,997,085 12/1976 Lindquist 222/236
4,033,346 7/1977 Phillips et al. 83/140
4,255,946 3/1981 Chokoe et al. 83/140
4,275,628 6/1981 Greenhouse 83/167
4,315,446 2/1982 Ball 83/167
4,375,849 3/1983 Hansi 206/366
4,472,141 9/1984 Dragan 604/232 X
4,488,643 12/1984 Peiper 206/366
4,520,926 6/1985 Nelson 206/366
4,553,687 11/1985 Harkins et al. 225/93

ABSTRACT

An improved drug delivery system comprising a gun style injection device used for holding and administering a disposable pre-filled drug cartridge, a holster device for receiving and dispensing the cartridge, and a housing for the cartridge, and a housing for the drug in the cartridge. The cartridge design is improved in order to increase the performance of the gun style injection device and the holster universe mechanism.

8 Claims, 18 Drawing Sheets

FOR INVENTED PATENT DOCUMENTS

158,316 10/1969 France 603/223
8,705,945 4/1987 World Int. Prop. O. 604/218

Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Mark O. Polutta
Attorney, Agent, or Firm—Robert E. Lee, Leroy Whitaker
A surgical instrument for injecting/removing non-solid substances is disclosed. The instrument comprises a body formed from two legs (1, 2) pivotally articulated to each other at one of their ends, one of said legs (1) being provided with means (15, 17) for receiving and retaining a syringe or squirter (16) while the other of said legs (2) is provided with means (20, 22) for selectively retaining a plunger (19) which cooperates with said syringe or squirter, said legs being selectively pivotable between a first position wherein said plunger (19) is received within said syringe (16) and a plurality of positions wherein plunger (18) moves within syringe (16) in order to inject/remove a non-solid substance.

9 Claims, 3 Drawing Sheets
MULTI-DOSE SYRINGE DRIVER


Assignee: The General Hospital Corporation, Boston, Mass.

Filed: Aug. 14, 1996

Primary Examiner—Sam Rimell
Assistant Examiner—Luke Yeh
Attorney, Agent, or Firm—Nutter, McClennen & Fish, LLP

ABSTRACT

A syringe driver device is able to effect the controlled, parenteral infusion of a medical fluid using an available disposable syringe. The driver device includes a frame having a movable carriage, which houses a force applying element, mounted thereto. A disposable syringe mounts upon the frame and a lengthy microbore tubing attaches to the outlet tip of the syringe. As a force is applied to the syringe plunger, fluid is expelled from the syringe, but its flow rate is dependent upon the diameter of the microbore tubing. The driver device enables the delivery of multiple, sequential doses of fluid.

25 Claims, 10 Drawing Sheets
SYRINGE STROKE CONTROLLER WITH ELASTICALLY ENABLED SINGLE AXIS SLIDE ADJUSTMENT AND FINGER-MOLDED PISTOL GRIP

Inventor: James J. Sullivan, P.O. Box 1799, Ojai, Calif. 93024

Filed: Apr. 21, 1995

Abstract

A stroke length regulating apparatus for use with plunging dispensers such as syringes includes a device for compressing the plunging dispenser consisting of a pair of supports movable relative to one another, a device for arresting relative displacement of the pair of supports at a selected end point which includes a threaded metering rod fixed near one end thereof to one of the supports, an elastically deformable nut having internal threads threadably engageable with the threaded metering rod along the length thereof, and a device for permitting temporary elastic deformation of the elastic deformable nut so as to disengage the threads on the elastically deformable nut from threads on the metering rod, whereby to permit free movement of the pair of supports relative to one another for stroke length adjustment of the dispenser.
Appendix D

Customer Survey & QFD
Survey
Cardiac Catheterization Lab Physicians
Angiographic Procedures

Thank you for taking a few moments of your valuable time to participate in this survey. Your opinions, ideas and comments are very important to us. The input that you provide will be used to improve the Cardiac Cath Lab work environment making it easier for you to continue providing high quality healthcare.

This survey is intended for Physicians who conduct Angiographic Procedures. The following questions pertain to the injection of contrast media by hand without the use of a powered injector.

1. If a hand held instrument is accidentally dropped it must not break.
   □ 1 □ 2 □ 3 □ 4 □ 5
   Least Important Most Important

2. A hand injector should be able to withstand all of the force I can put into it.
   □ 1 □ 2 □ 3 □ 4 □ 5
   Least Important Most Important

3. When injecting a bolus under high pressure the syringe must be rigidly contained by the injector.
   □ 1 □ 2 □ 3 □ 4 □ 5
   Least Important Most Important

4. A hand held instrument must fit my hand comfortably.
   □ 1 □ 2 □ 3 □ 4 □ 5
   Least Important Most Important

5. Pre-procedure set-up must be completed quickly.
   □ 1 □ 2 □ 3 □ 4 □ 5
   Least Important Most Important
6. A hand powered injector should require very little exertion to actuate.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Least Important Most Important

7. A hand held instrument must be lightweight.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Least Important Most Important

8. An adjustable flow control on a hand injector is a valuable feature.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Least Important Most Important

9. Injection control via tactile feedback is desirable.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Least Important Most Important

10. A hand held injector should use a pre-filled syringe.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Least Important Most Important

11. Hand held instruments should be disposable.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Least Important Most Important

Thank you again for participating in this survey. Please return the completed survey in the enclosed self addressed, stamped envelope.
### QFD – House of Quality

#### Strength

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#### Absolute Importance

| Customer Importance | 11.04 | 0.88 | 9.40 | 1.68 | 12.26 | 2.20 | 13.08 | 2.34 | 13.49 | 2.41 | 17.85 | 3.20 | Absolute Importance | 11.04 | 0.88 | 9.40 | 1.68 | 12.26 | 2.20 | 13.08 | 2.34 | 13.49 | 2.41 | 17.85 | 3.20 | 17.90 |
| Importance Weight | | | | | | | | | | | | | 17.90 |

### Ratings

- **Strong Positive**: ★★★★
- **Positive**: ★★★
- **Negative**: ★★
- **Strong Negative**: ★★

9 = Strong
3 = Moderate
1 = Weak
Appendix E

Final Prototype Photographs
Internal Mechanism

- PLUNGER PLATE
- BRAKE
- RATCHET BAR
- LEVER PIVOT
- LEVER
- PUSHER
Injector In Use
References

1 Mallinckrodt, Inc. website: manufacturer of contrast & contrast delivery systems. [www.mallinckrodt.com](http://www.mallinckrodt.com) Provides information about contrast media, one of their products. Also technical data on the Illumena Contrast Media Injection System.


3 Mallinckrodt Optiray® 350 Package Information Sheet. Viscosity, Specific Gravity and dosage (volume) information for a variety of procedures are found here.

4 The recreation of the Injection System spread sheet is based on the work of Paul Diederlyn, an Engineer and former employee of Liebel Flarsheim (now Mallinckrodt, a Tyco Healthcare company)

5 Makrolon Polycarbonate Design Manual, Bayer Corporation, Pg. 28, 3.2.1 Bending and Torsional Stresses.