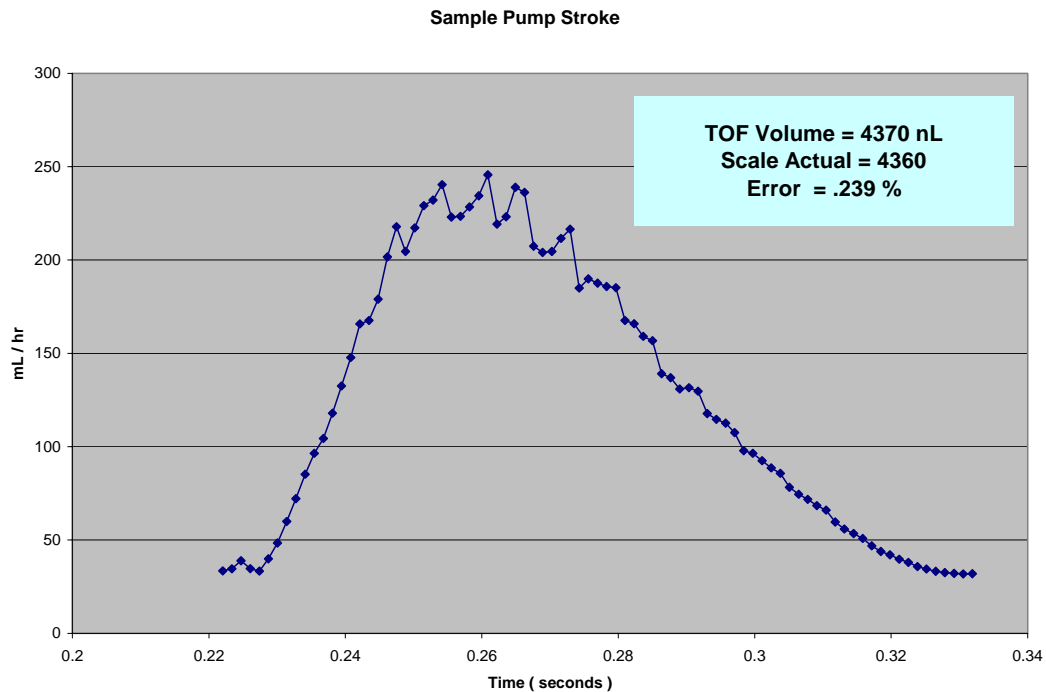


## Tech Brief TheraFuse Non-Contact Flow Sensor Technology Enables Next Generation Intravenous Fluid Delivery

March 2006

TheraFuse, Inc. is a start-up company founded in 2001 and located in Carlsbad, California. Over the past few years, TheraFuse has developed an optical flow sensor capable of measuring fluid flow with better than 3% accuracy. This technology uses a pair of miniature lasers to detect flow in a small tube. This tube may be removable from the durable sensor and integrated into a fluid delivery line as a disposable product. We believe there is broad application for this technology in next generation intravenous infusion products that require flow monitoring, measurement and control.

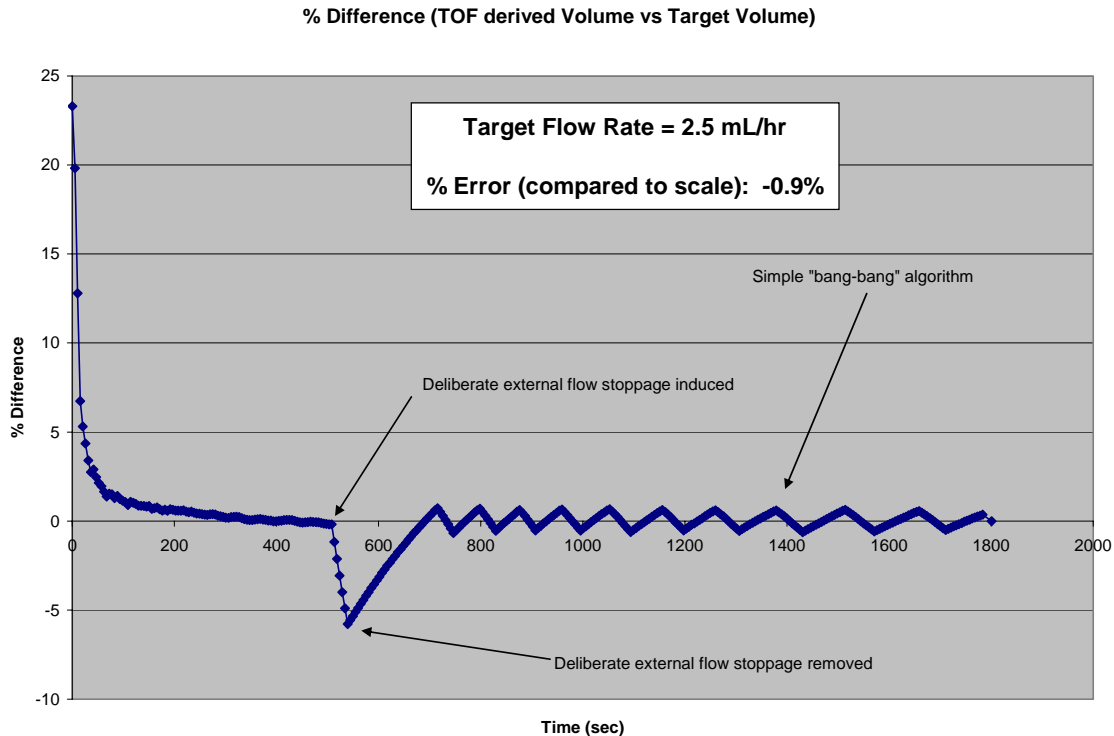
Our flow sensor is based on time of flight measured by creating an optical 'marker' in the fluid medium with a pulsed heat laser and then detecting the diffracted signal a few hundred microns downstream with a sense laser. By knowing the cross sectional area of the flow tube, volume is calculated. This data has been successfully used to provide feedback to a piezoelectric pump for precision flow control. Shown below is an actual trace of a single piezo pump stroke with flow measurements made every millisecond. Volume was calculated as the area under the curve and compared to the actual volume delivered as measured by a gravimetric scale.



Data shown in this Tech Brief was taken using commercially available piezoelectric pumps and electronic controllers purchased off-the-shelf.

## TheraFuse, Inc

Also shown below is the result of a first order control algorithm where a target flow rate has been set and the system drives flow errors to within a  $\pm 1\%$  error band. To demonstrate sensor response time, we introduced an external flow blockage by clamping the exit tube shut and then removing the blockage a short time later. Note the rapid recovery time and the immediate  $\pm 1\%$  feedback response.



Because this technology measures the velocity of a moving fluid, flow rate ranges are controlled simply by sizing the cross-sectional geometry of the flow tube. This data indicates we can cover over 2 logs of flow change with a simple, single channel sensor. The dynamic range can be extended with the addition of 1 or 2 additional sense laser channels. Flow rates from nano-liters per minute to milliliters per minute are possible with appropriate sizing of the flow tube. The technology works well in either a steady state flow regime or an on/off control system where either the pump stroke volume or frequency is controlled.

Additional benefits to be derived from this technology include:

- Built in air-in-line detection for all fluids via sense laser response
- Immediate detection of partial or full occlusions regardless of rate
- Closed loop feedback control of the pump output for unparalleled accuracy at all rates, fluids, head heights and operating backpressures
- Reduced cost of the durable 'pump' is enabled by closing the loop on inexpensive technologies like piezoelectric pumps
- Low cost disposables are maintained with a simple, injection molded flow tube integrated into the IV set
- Highest levels of safety are realized with IV solutions flowing into the body actually being measured, not estimated, providing verified patient infusion documentation.

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Because the flow sensing technology lends itself to current and future high volume manufacturing processes created in the photonics field, the durable sensor cost of goods for high volume production is projected to be in the \$30 to \$50 range. Physical sensor size would be approximately 2 square centimeters with control electronics mounted on the system circuit board assembly. The disposable flow tube is injection molded with a cost projected at 10 cents to 25 cents.

A testimonial to the TheraFuse technology was recently confirmed with a DOD SBIR Phase I research grant to develop a miniature, disposable, military IV pump with improved safety features and embedded software control. See our website [www.therfuse.com](http://www.therfuse.com) for more information or contact Michael Klimowicz directly at [m.klimowicz@therafuse.com](mailto:m.klimowicz@therafuse.com).