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SHAH AND OTHERS

MECHANICAL IV VOLUME REGULATOR FOR DEVELOPING WORLD

Maji: A New Tool to Prevent Overhydration of Children Receiving Intravenous Fluid Therapy in Low-Resource Settings

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Abstract.

We designed and evaluated the accuracy and usability of a device to regulate the volume of fluid dispensed during intravenous drip therapy. The mechanical system was developed in response to a pressing need articulated by clinicians in pediatric wards throughout sub-Saharan Africa, who require a tool to prevent overhydration in children receiving intravenous fluid in settings that lack burettes or electronic infusion pumps. The device is compatible with most intravenous bags and limits the volume dispensed to a preset amount that can be adjusted in 50 mL increments. Laboratory accuracy over a range of clinically relevant flow rates, initial bag volumes, and target volumes was within 12.0 mL of the target volume. The ease of use is “excellent,” with a mean system usability score of 84.4 out of 100. Use of the device limits the volume of fluid dispensed during intravenous therapy and could potentially reduce the morbidity and mortality associated with overhydration in children receiving intravenous therapy.

INTRODUCTION

Diarrhea-induced dehydration is the second leading cause of death in children under 5 years old. Each year, there are 1.7 billion cases of diarrheal illness, and 760,000 children die of diarrheal disease. Patients with diarrhea are at risk for dehydration.¹ Beyond gastroenteritis, there is a range of conditions that cause dehydration, including malaria and dengue fever.²⁻⁴ Combined, these conditions are responsible for the deaths of up to 1.4 million children under 5 years of age annually.^{1,5,6}

Severe cases of dehydration are treated with intravenous (IV) fluid therapy.¹ However, one risk of IV therapy in low-resource settings is overhydration, particularly for babies and young children who require low volumes of fluid. Overhydration can lead to tachypnea, edema, cardiac failure, and death.⁷ Because of the the risk of overhydration, the World Health Organization recommends that children who are severely dehydrated are given rapid IV therapy only with close monitoring.⁸

However, children who receive a bolus have a 3.3% point greater risk of death than those who do not receive a bolus.⁹ Possible reasons for this may include a lack of monitoring equipment,⁹ along with staff and equipment shortages. In the developing world, IV fluid is often delivered using gravity-fed IV infusion systems. However, it is difficult to ensure that patients

are constantly monitored to stop fluid administration at the appropriate time due to a limited availability of trained staff in such settings. On average, there are only 0.17 physicians and 0.90 nurses per thousand people, which are less than 10% of the per capita number of physicians and nurses in the United States.¹⁰ This situation is further complicated by the frequent lack of pediatric-sized IV bags (Molyneux EM, unpublished data). In many settings, only 1 L bags are available, but these bags are too large for small children who may need only a small portion of the fluid in the bag. Therefore, health-care providers in the developing world are often reluctant to start IV therapy for patients who require low volumes due of the risk of overhydration (Molyneux EM, unpublished data).

In developed countries, infusion or elastomeric pumps and burettes are commonly used to regulate delivery of IV therapy to pediatric patients; but these are too costly and not appropriate for many developing world health-care settings. Priced over 1,000 dollars, infusion pumps require routine maintenance, consumables that are not generally available in the developing world, and electrical power that may not be reliable. Although elastomeric pumps are accurate and come in fixed volumes, they too require costly consumables and are thus unsuitable for use in developing countries.¹¹ Burettes are similarly impractical in low-resource settings because they are single use.

In this report, we describe the design and evaluation of a low-cost, mechanical volume regulator to limit the volume of fluid dispensed during rehydration therapy. The device does not require any consumables, and results from nonclinical testing show that it is accurate across a wide range of flow rates and targeted volumes.

MATERIALS AND METHODS

Design criteria.

The design of Maji, Swahili for “water,” was guided by input from Malawian, Basotho, and Liberian clinicians who articulated a set of technical and usability specifications for the device as summarized in Table 1. Criteria regarding the user interface, portability, and ease of use ensure that the device may be integrated into the clinical workflow in developing world settings. Since these clinics may have intermittent access to electricity and weak supply chains, the device must be entirely mechanical, not require the use of consumables, and maximize compatibility with most IV bags and tubing. A set of clinical performance criteria was also established to ensure that the device is appropriate for safe use with dehydrated children.

Device design.

To meet these design criteria, we developed a mechanical, automatic IV volume regulator. Shown in Figure 1, the device consists of a metal frame, a clamping mechanism, and two horizontal lever arms that act as a modified two-pan balance from which the IV bag hangs on one side and a counterweight on the other. The position of the counterweight is adjusted along the lower, notched horizontal lever arm so that the linkage bar connecting the two traverses the horizontal axis when the desired amount of fluid is delivered, thereby triggering a clamping mechanism that stops flow. The lower lever arm is notched so that each notch corresponds to dispensing 50 mL of fluid. The theoretical device accuracy would thus be ± 25 mL.

The device is designed to be bolted to a wall to reduce the risk of bumping and premature activation. To keep the IV bag higher than the patient, the horizontal lever arms are connected by

a linkage bar. Detailed CAD drawings and a bill of materials may be obtained from the authors' website or in the files supplementing this publication.

A clamping mechanism was designed to induce a V-shaped kink in the IV tubing and stop fluid flow at the appropriate time. Two plastic tubing holders are positioned to hold the tubing taut during the course of IV therapy (Figure 2A and B). Each tubing holder consists of three cylindrical extrusions of varying diameters to ensure compatibility with most IV tubing. Although the left tubing holder is fixed, the right tubing holder moves horizontally along a track and is attached to the moving end of a compression spring housed in a plastic box. This moving tubing holder is also connected to a U-shaped plastic hook that integrates the clamping mechanism with the lever arm-counterweight system. A bolt that protrudes from the lower lever arm engages with this hook during IV therapy and disengages when the target volume has been delivered, causing the right tubing holder to move leftward and induce the V-shaped kink, thereby stopping fluid flow (Figure 2C and D).

Device usage.

Usage of the device consists of four steps. The user first hangs the IV bag on the device via the hook provided and equilibrates the counterweight by moving the weight and volume indicator to the rightmost notch for which the lever arm is horizontal (Figure 3A). The counterweight is then moved to the notch corresponding to the desired target volume indicated by a series of numbers along the lever arm (Figure 3B). The user then moves two blue knobs toward one another until a hook-and-pin engage to compress a spring in the clamping mechanism (Figure 3C). IV tubing is finally placed into two plastic tubing holders while ensuring that the tubing is taut and unoccluded (Figure 3D). IV therapy is then initiated.

Laboratory testing protocol.

Accuracy of the device was evaluated over a range of clinically relevant parameters with a 1,000 mL IV fluid bag (Baxter Healthcare Corporation, Deerfield, IL) and IV tubing with no catheter (TrueCare Biomedix TCBINF033, Doral, FL). The device was used to deliver water into a plastic beaker, and the dispensed volume was recorded with a digital scale with an accuracy of 0.05 g (Adam Equipment HCB-1502, Danbury, CT) every 0.25 seconds. The IV bag was placed approximately 4 feet above the beaker to simulate normal usage, and testing was performed at about 24°C and 70% relative humidity. Target volumes of 100–800 mL were tested in increments of 100 mL for initial bag volumes of 550 mL and 900 mL at a flow rate of approximately 4,000 mL/hr to simulate a bolus given with unobstructed IV tubing. These experiments were repeated for target volumes of 150–850 mL in increments of 100 mL for an initial bag volume of 1,000 mL, and for target volumes of 50, 100, and 150 mL for an initial bag volume of 200 mL. Since Maji is equilibrated in 50 mL increments, the device was further tested by delivering 150 mL at 4,000 mL/hr for an initial bag volume of 850–875 mL in increments of 5 mL. The device was then used to dispense 200 mL at flow rates of 20, 50, 100, 2,000, and 4,000 mL/hr to simulate long-term rehydration therapy or a short-term bolus at an initial bag volume of 550 mL. All tests were performed five times to assess reproducibility. A Wilcoxon signed-rank test was performed on each dataset to test whether the median residual was less than 25 mL.

Although reuse of IV tubing is not accepted medical practice due to the risk of disease transmission or infection, clinicians in the developing world sometimes reuse IV tubing for the

subsequent infusion for a given patient. The performance of Maji was tested under such conditions by delivering 250 mL at 4,000 mL/hr from an IV bag containing 550 mL with five sets of new, unopened IV tubing. This test was performed 10 times with each set of tubing or until the tubing became permanently occluded. A one-tailed, unpaired *t* test with equal variance was performed to determine whether the median residual varied with tubing reuse.

Field evaluation protocol.

Nonclinical usability testing was performed with health-care workers at Queen Elizabeth Central Hospital in Blantyre, Malawi. All participants were over the age of 18 and informed consent was provided. All procedures involving human subjects were approved by the Rice University Institutional Review Board (Protocol 13-072X) and the University of Malawi College of Medicine Research and Ethics Committee. Usage of the device was demonstrated to 33 nurses, medical students, and physicians in the pediatric ward. Each individual was asked to set up the device after they verbally indicated that they were comfortable and wished to proceed. The time required for each participant to be trained and to set up the device was recorded. Each individual was then asked to complete a modified system usability survey (SUS) that consisted of 14 questions in which alternate questions were reverse coded, as shown in Supplemental Figure 1. The first 10 questions of the SUS were used to quantify the usability of the device,¹² whereas the last 4 questions were used to inform potential future device improvements. The 5-point Likert scale typically used in SUS was made more culturally appropriate by reducing the dependence on grammatical qualifiers such as “strongly agree” that are not present in the participants’ native language of Chichewa.¹³ All data were anonymized. A Wilcoxon signed-rank test was performed to determine whether the median system usability score was greater than 70, or “good,”¹⁴ which is a widely accepted usability criterion for an acceptable product.¹³ Similarly, a Wilcoxon signed-rank test was performed to assess whether the median time to use the device was less than 2 minutes.

RESULTS

Figure 4 shows the mean, median, first and third quartiles, and range of the residuals for each combination of initial volume and target volume tested in the laboratory. For all parameters, the mean and median residuals were all within 25 mL of the target volume, and the maximum residual was 27.5 mL. For initial bag volumes of 1,000 mL (Figure 4A) or 900 mL (Figure 4B), the median residuals were on average 10.1 mL and 6.5 mL, respectively. Similarly, on average, the median residuals for initial bag volumes of 550 mL (Figure 4C) or 200 mL (Figure 4D) were 7.7 mL and 11.9 mL, respectively. A Wilcoxon signed-rank test confirmed that the median residuals were less than 25 mL for all groups at the 5% significance level for these tests.

Figure 5 shows the mean, median, first and third quartiles, and range of the residuals for a set of initial bag volumes from 850 mL to 875 mL in 5 mL increments. The mean residuals increased linearly with initial IV bag volume, with a slope and correlation coefficient of nearly one. The observed residuals were less than 25 mL for initial bag masses between 850 mL and 875 mL.

The mean, median, first and third quartiles, and range of the residuals are shown in Figure 6 for a target volume of 200 mL and initial bag volume of 900 mL for flow rates between 20 and 4,000 mL/hr. On average, the median residual was -3.4 mL and all residuals were less than 25 mL ($P = 0.031$ for each subgroup and $P < 0.00001$ overall).

On average, IV tubing could be used 7.8 ± 2.3 (mean \pm sample standard deviation) times before the tubing became permanently occluded. Reuse of tubing up to four times had no statistically significant impact on the median residual, which was, on average, 14.6 mL for the first four uses of IV tubing and 25.4 mL for the remainder of tests ($P = 0.03$).

Malawian clinicians reported a mean SUS score of 84.4 with a sample standard deviation of 11.1, which is significantly greater than the accepted threshold of 70 ($P < 0.0001$, $N = 28$). No statistically significant difference in SUS scores was recorded for participants with different levels of experience. SUS data from five participants were discarded due to incomplete survey responses. Clinicians set up the device within 79.5 ± 31.5 seconds, which is also significantly below 2 minutes ($P < 0.00001$). The average time to train each participant was 12.1 ± 3.07 minutes. The training time was significantly lower than 20 minutes ($P < 0.00001$).

These results demonstrate that Maji meets the performance criteria enumerated in Table 1. No statistically significant difference in performance was observed at the range of flow rates tested, and the device was found to be accurate within 12.0 mL of the target volume at the 5% significance level. The mean residual was 8.13 mL and was less than 25 mL for a 25 mL range of initial IV bag volumes, which corresponds to the theoretical performance hypothesized. In all 239 performed tests, the device did not visibly damage the IV tubing.

DISCUSSION

Young children in low-resource settings are especially susceptible to overhydration during IV therapy due to an inability to regulate the volume of fluid delivered during treatment. Devices used in the developed world are impractical in many low-resource settings due to the need for maintenance, consumables, and electricity.

Maji was designed to specifically address these concerns while remaining accurate and easy to use. The device consists of readily available aluminum, steel, and plastic parts that cost less than \$80 in materials for the current prototype. Maji is entirely mechanical and requires no consumables.

Our device has an average residual of 8.13 mL, which is slightly greater than the 3.97 mL and 3 mL average residual of infusion pumps and elastomeric pumps, respectively.^{11,15} The residuals of all performed tests were within 27.5 mL and comparable to the hypothesized theoretical accuracy of 25 mL. The average and median residuals were all within 25 mL, thereby potentially reducing the risk of overhydration in young children.

Maji can accurately deliver fluids throughout the clinical ranges of target volumes and flow rates for initial bag volumes between 200 and 1,000 mL (Figures 3 and 4), enabling clinicians to reuse an IV bag or infusion set with a given patient undergoing IV therapy. This reuse is consistent with accepted medical practices,¹⁶ and could potentially reduce the cost of treatment, which is especially beneficial to resource-limited hospitals.

IV bag reuse may cause Maji to be used with an IV bag that contains a fluid volume that is not a multiple of 50 mL, which could potentially reduce the accuracy of the device. However, in these circumstances, Maji maintains its accuracy, as shown in Figure 5, since the average residual varies from 0 to 25 mL for a range of IV bag volumes that extends from an equilibrium volume of 850–875 mL, or 25 mL beyond equilibrium, which corresponds to the theoretical maximum error. These data suggest that although each notch is optimized for bag volumes in multiples of 50 mL, differences of up to 25 mL in the initial bag volume will not significantly

impede the accuracy of the device because the counterweight will always be placed within half a notch of its true equilibrium.

One limitation of Maji is that the device controls only the volume of fluid delivered and not the rate of administration, unlike infusion pumps or elastomeric pumps. In low-resource settings, it is common practice for flow rate to be set using roller clamps that are included in IV tubing sets or by using catheter cannula of different gauges. When flow rates were set with a roller clamp, the device maintains accuracy across all tested flow rates from 20 to 4,000 mL/hr. Although no testing was performed with attached catheters, no difference in flow rate is expected as Maji does not impede the flow rate of delivery.

Typically, infusion pumps in the developed world are used to regulate the delivery of all types of IV fluids, including saline, glucose-containing solutions, and blood. The mechanical volume regulator is similarly versatile because the fluid volume delivered is based on the change in mass of the IV bag. The density of the fluid is thus inversely proportional to the volume of fluid delivered per notch. Although the device was optimized to dispense 50 mL of 0.9% sodium chloride or water per notch, it can also dispense 49 mL of 5% dextrose or 48 mL of blood per notch.

As reported in the results from the usability survey, 100% of participants agreed that the Maji device was easy to use and 93% believed that the device could help administer IV fluids to children. The mean SUS score of 84.4 is “excellent,”¹² and clinician responses were consistent with a standard deviation of 11.1 on the SUS scale. In the future, we plan to incorporate usability instructions onto the frame of the device, which would make device usage clear and easily accessible to trained and incoming physicians.

To further explore physician operation of the device, we plan to assess the accuracy of the device in the field before conducting a clinical trial with patients. Successful results will accelerate implementation of this mechanical volume regulator in the developing world; a step toward this goal would entail registering the device with the World Health Organization’s compendium of innovative health technologies for low-resource settings. By enabling clinicians to provide children with life-saving IV fluids safely, use of Maji may potentially prevent overhydration in resource-limited settings.

Received August 6, 2014.

Accepted for publication January 30, 2015.

Note: Supplemental figure appears at www.ajtmh.org.

Acknowledgments:

We appreciate the support of 3rd Stone Design for optimizing the device for manufacturability. We are especially grateful for the invaluable feedback throughout the design process provided by Malawian clinicians including Martha Mpunga and her colleagues at Queen Elizabeth Central Hospital.

Financial support: This program was supported in part by a grant to Rice University from the Howard Hughes Medical Institute through the Precollege and Undergraduate Science Education Program. Additional funding for this project was received from the National Collegiate Inventors and Innovators Alliance, Rice Center for Engineering Leadership, and the Oshman Engineering Design Kitchen.

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FIGURE 1. Schematic diagram (**A**) and photograph (**B**) of the Maji intravenous (IV) volume regulator. This figure appears in color at www.ajtmh.org.

FIGURE 2. Tubing is inserted when the spring is compressed (**A, B**). When the target volume of intravenous (IV) fluid is delivered, the spring is released, pinching the IV tubing shut (**C, D**). This figure appears in color at www.ajtmh.org.

FIGURE 3. Usage of the volume regulator consists of four steps: (**A**) Moving the adjustable counterweight and volume indicator to the notch that makes the lower horizontal lever arm level; (**B**) moving the adjustable counterweight leftward one notch for every 50 mL to dispense; (**C**) loading the spring by pushing together two blue knobs; and (**D**) placing the intravenous (IV) tubing in the designated holders. This figure appears in color at www.ajtmh.org.

FIGURE 4. The mean (diamonds) and median residuals are within ± 25 mL (dashed lines) for all target volumes ($N = 5$) for initial bag volumes of about: (**A**) 1,000 mL, (**B**) 900 mL, (**C**) 600 mL, (**D**) 200 mL ($P < 0.0001$ within each group). All residuals were within 30 mL of the target volume.

FIGURE 5. When the counterweight is stationary, the mean residuals (diamonds) are a linear function of the initial intravenous (IV) bag volume. The residual was between approximately 0 and 25 mL (dashed lines) for a 25 mL range of initial IV bag volumes from 850 to 875 mL.

FIGURE 6. For tested initial flow rates of 20, 50, 100, 2,000, and 4,000 mL/hr, the mean (diamonds) and median residuals are within ± 25 mL (dashed lines) for all target volumes ($N = 5$, $P = 0.031$ within each subgroup, $P < 0.00001$ overall). All tests were within 25 mL of the target volume.

TABLE 1

Intravenous volume regulator design criteria

Usability	Device specifications
Ease of use	Method of operation
Requires < 20 minutes to learn to use	Entirely mechanical
Requires < 2 minutes to set up	Automatically stops fluid flow
Requires minimal calculations	Requires no consumables
	Compatible with standard tubing sets and IV bags
Portability	Materials
Lightweight (< 5 lbs)	Cumulative cost of < \$100
Able to removably mount to wall	Withstands hot, humid environments
	Durable up to 5 years of use
User Interface	Clinical Performance
Requires < 3 lb _f to set up	Accurate within ± 25 mL of intended volume
Device is < 5 ft. above ground	Does not impede rate of fluid flow during treatment
	Accurate across range of clinically relevant target volumes (100–800 mL) and flow rates (20–4,000 mL/hr)

IV = intravenous.

SUPPLEMENTAL FIGURE 1. A standard SUS was modified to incorporate four additional questions to guide potential future improvements to the device.

Figure 1

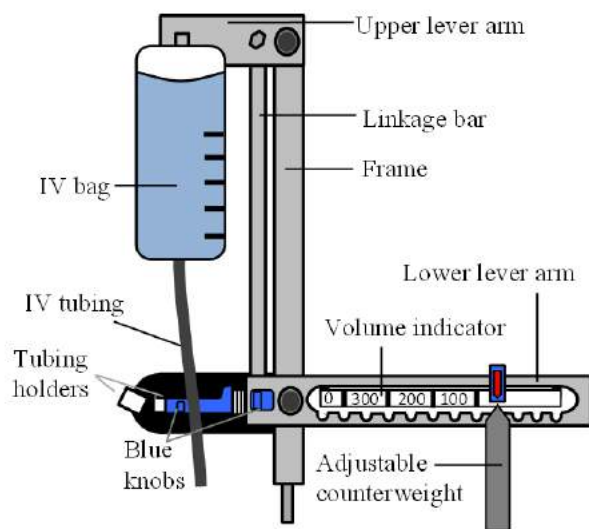
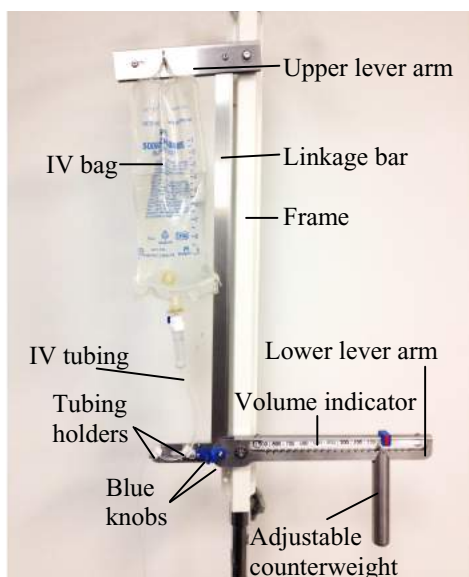


Figure 2

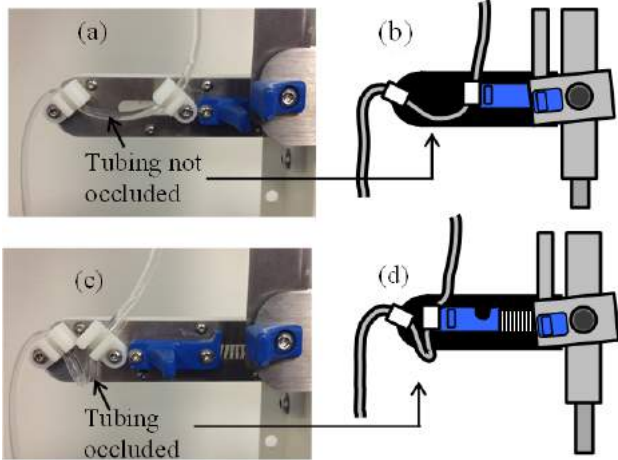


Figure 3

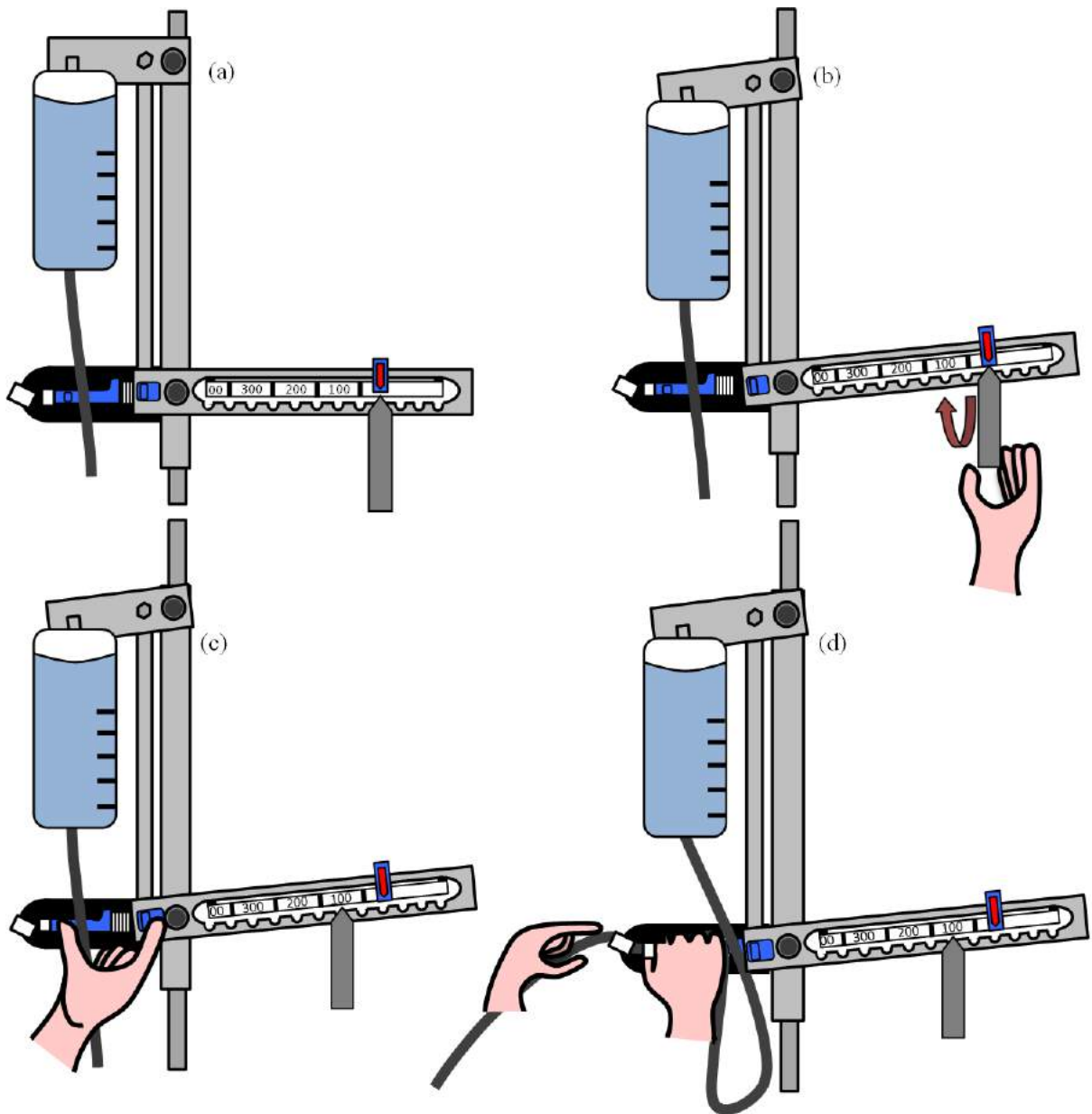


Figure 4

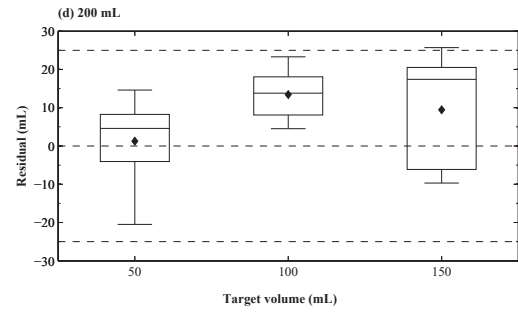
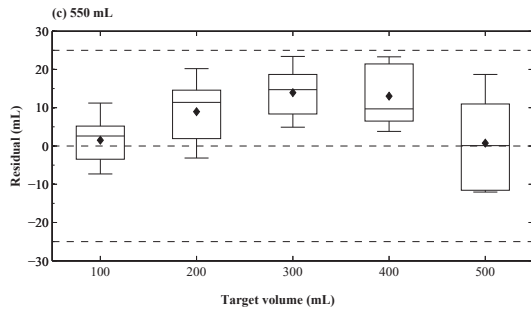
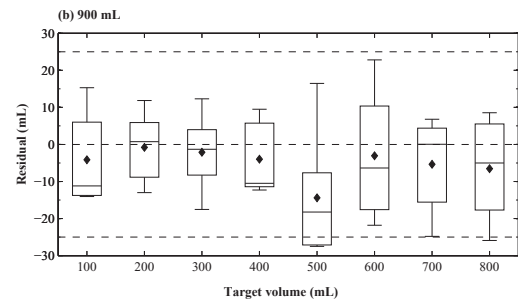
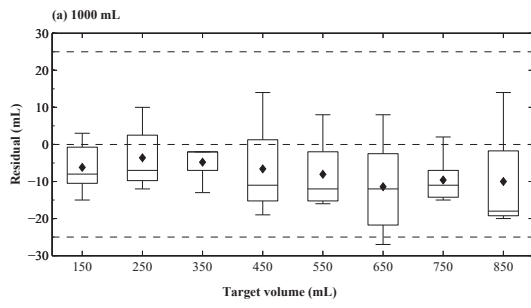


Figure 5

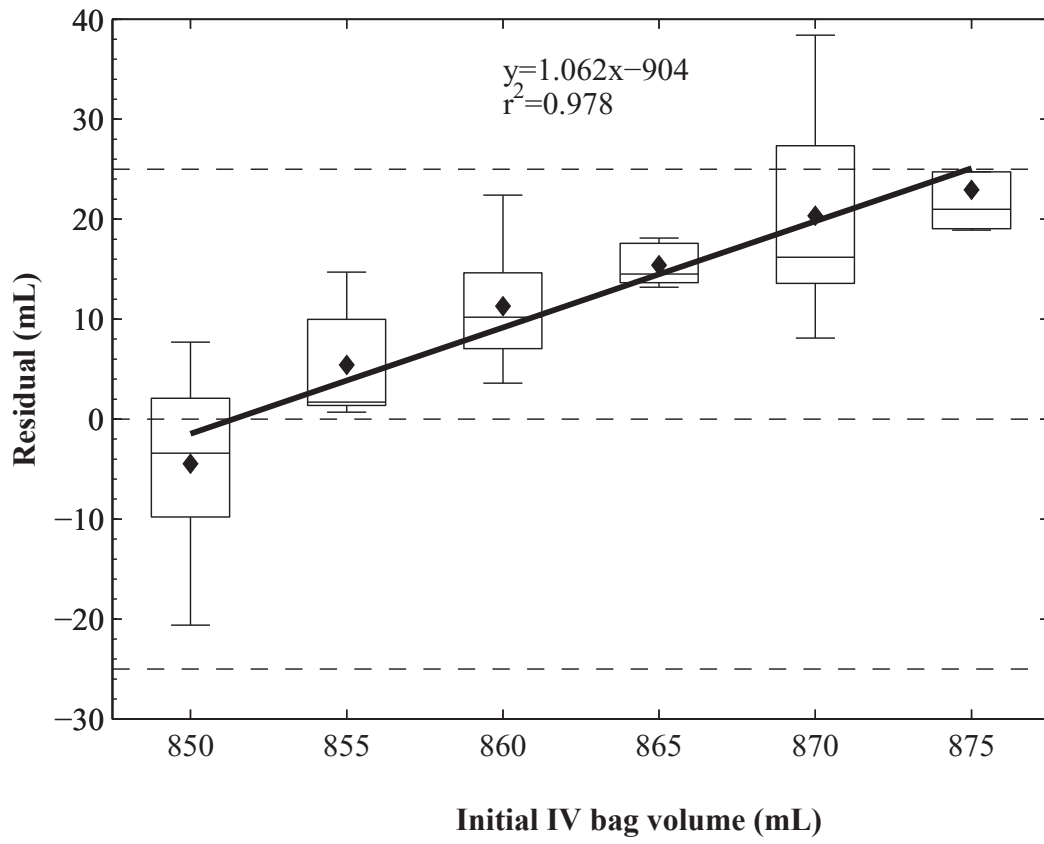


Figure 6

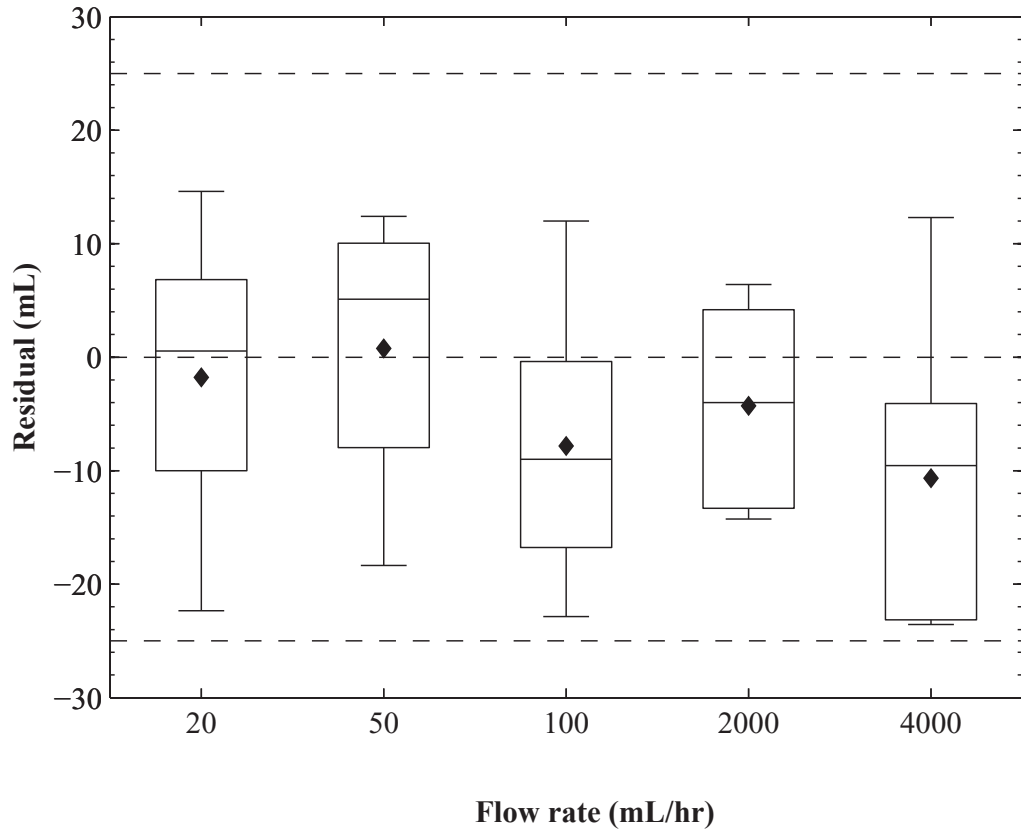
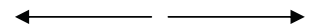


Figure S1

Please check the box that best reflects your thoughts on using IV DRIP.



	Certainly		Perhaps or Unsure		Uncertain
	Yes		Maybe		No
	1	2	3	4	5
1. I think that I would like to use this system frequently if I were administrating fluids to children					
2. I found the system unnecessarily complex.					
3. I thought the system was easy to use.					
4. I think that I would continuously need the support of a technical person to be able to use this device in the future.					
5. I thought the different parts of the device related well to each other.					
6. I thought that each part of the device did not work in the same way.					
7. I would imagine that most people would learn to use this system very quickly.					
8. I found the system very cumbersome to use.					
9. I felt very confident using the system.					
10. I would need to learn a lot of things before I could get going with this system.					
11. I think that I am ready to use this device independently.					
12. I think the device required too much force to set up.					
13. I think this device could help administer IV fluids to children.					
14. I think that I would not like to use this system when transfusing blood to patients.					