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Design of a Novel, Adjustable Flow Rate, Reusable, Electricity-Free, Low-Cost Syringe Infusion Pump

We present a proof-of-concept design and preliminary data to demonstrate a novel syringe infusion pump that is low cost, nonelectric, reusable, and adjustable. This device addresses the need for infusion therapy in low- and middle-income countries (LMIC), where intermittent electrical power precludes the use of conventional electronic infusion pumps and limited financial resources make high costs of disposable infusion pumps impractical. Our design uses a pneumatically pressurized, hydraulic (air over oil) drive piston coupled to a closed-circuit flow restriction to drive a syringe plunger at a constant velocity, thus providing a constant volumetric flow rate to the patient. The device requires no proprietary or precision consumables, significantly reducing treatment costs compared with other methods. The highly adjustable device provides constant flow rates across the range of 0.5–8 mL/h when used with a 30-mL syringe. The user interface is simple and intuitive; the hardware is robust and portable. This novel technology platform has broad applications in addressing priority health needs in LMIC.
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Introduction

Infusion pumps are used to safely administer fluids, such as medications or nutrients, intravenously to a patient. In high-resource countries, infusion pumps are common in both clinical and at-home settings and are used in broad therapeutic applications ranging from obstetric emergencies, to antibiotic therapy, to anesthesia and palliative care [1]. In these settings, electronic infusion pumps are ubiquitous in intensive medical care; these devices have broad flow rate adjustability, sophisticated software, and safety alarms [2]. However, conventional electronic infusion pumps require operator training and significant infrastructure, and they are susceptible to software or electrical failures such as shocks, sparks, and programming errors [3,4]. These attributes may make them unsuitable solutions for low-resource settings [5–7], as low-resource settings may have limited access to electricity, poor-quality electricity, or minimal technical resources to support and sustain operation of electronic infusion pumps [8].

Alternatives to electronic devices include continuous manual monitoring of an intravenous (IV) administration and nonelectric flow-restricting infusion pumps [9]. Manual monitoring is labor intensive and not always feasible. Existing nonelectric devices may have utility in low-resource settings, but they lack flow rate and dose adjustability and have expensive disposable components, resulting in high infusion therapy costs per patient [10]. Unlike programmable electronic pumps, these devices cannot modulate the flow rate once the infusion has begun. Commercially available nonelectric infusion pumps commonly employ a stretched elastomer, compressed spring, or gas generated from chemical reaction

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Table 1 Design requirements

	Design requirement	Rationale
1	Electricity-free operation.	Electricity is not always available or reliable in LMIC [3,4].
2	Flow rate accuracy of ±10% throughout infusion.	This matches the flow rate deviation of predicate devices [14].
3	Able to operate a minimum of 3 h for one infusion.	Typical infusion time for clinically relevant drugs in LMIC.
4	Flow rate range of at least 1–10 mL/h.	Common flow rates used for clinically relevant drugs in LMIC.
5	Simple user interface.	Device may be used by minimally trained staff.
6	Capable of flow rate modulation midinfusion.	Many infusion therapies require flow rate adjustment based on a clinical response.
7	Does not require proprietary single-use consumables.	Proprietary consumables are expensive and often unavailable in LMIC [10].
8	Field serviceable.	Repair services are often unavailable in LMIC [8].
9	Safety alarms.	Must indicate device failure or user error.
10	Able to operate over ambient range of 10 °C to 30 °C.	Often, ambient temperature is not controlled in LMIC; performance must be maintained.
11	Low cost relative to electronic systems.	LMIC health systems must be able to afford technology.

to pressurize the fluid [10]. These mechanisms characteristically result in significantly decreased flow rates as the mechanical force declines during delivery, which may be unacceptable for certain therapies.

Clinical field observations also identified an associated problem of inconsistent and understocked medical tubing and syringe supplies in low-resource settings [11,12]. These studies have noted insufficient sterilization of reused disposable precision components, whereby multiple patients received infusions from the same lines. Medical supply shortages can also lead to the use of improvised IV tubing without standard Luer fittings, creating mechanically unstable and inconsistent fluid delivery configurations [7]. This evidence suggests that infusion technology in austere settings should avoid proprietary consumables and accommodate most types of downstream IV tubing and supplies. In short, existing electronic and nonelectric infusion therapy pumps (ITPs) are not suitable for use in many low-resource settings. Ideally, devices must be designed to modulate the infusion flow rate, operate independent of electrical mains, accommodate a range of medical tubing and consumables, and have simple and intuitive user controls. This equipment gap highlights a pertinent clinical need in low- and middle-income countries (LMIC). A summary of the design requirements for this unmet need is presented in Table 1.

To address the equipment gap, we have developed a novel, syringe-based ITP that combines the functionality of electronic infusion pumps with the low cost and simplicity of nonelectric pump technology, and without the need for proprietary disposable consumables.

Methods

Experimental Apparatus. Our technology uses the same physical principles as many disposable infusion pumps, employing mechanical force to pressurize fluid passing through a narrow-bore tubing to achieve constant flow rates. We improved upon existing flow-restriction designs by enabling adjustable pressure and consequently, adjustable flow rates. Instead of using a fixed pressurizing force (e.g., compressed spring), our ITP uses compressed air with adjustable pressure regulation. Fluid flow in the system is governed by Poiseuille's law

$$Q = \Delta p \left(\frac{\pi d^4}{128 l \eta} \right) \tag{1}$$

In the laminar flow regime, this relationship defines flow rate (Q) of an incompressible fluid in a long cylinder as a function of pressure gradient (Δp), restriction cross section (d = diameter), restriction length (l), and fluid dynamic viscosity (η). The key implication from this relationship is that flow rate is directly proportional to the driving pressure of the circuit. This defines the core principle of our infusion pump. Furthermore, by regulating flow rate in a closed fluidic circuit, we eliminate the need for single-use, precision narrow-bore tubing consumables for each infusion. The drive pressure is supplied by regulated compressed air.

To demonstrate the concept in a controlled setup, we collected data on the experimental apparatus using compressed air from a central laboratory source with a precision air pressure regulator (0.1% accuracy, PRG200-60, OMEGA Engineering, Stamford, CT). This precision pneumatic system was used as a control for pressure fluctuations attributed to leaking air or imperfect regulation. As shown in Fig. 1, in operation, pressure-regulated compressed air (A) enters an air over oil double-acting drive piston (B), pushing on the syringe plunger. Oil passes through flow-restricting narrow-bore tubing (C), before passing into a reservoir (D). After infusion is complete, the device is reset by opening a push-button valve to direct flow through large-bore, low-resistance tubing (E) and retracting the piston rod to pull oil back into the air over oil drive piston.

The closed-circuit flow regulation fluid is ISO Grade 32 hydraulic mineral oil (2023K33, McMaster-Carr, Los Angeles,

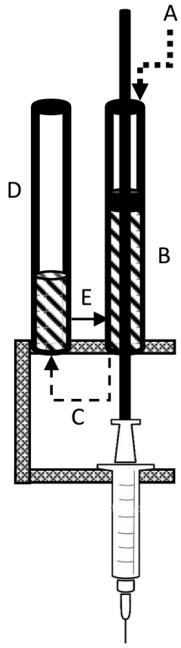

Fig. 1 Experimental apparatus consists of (A) central-source compressed air, (B) air over oil drive piston, (C) flow-restricting narrow-bore tubing (dashed arrow), (D) hydraulic oil reservoir, and (E) large-bore reset tubing. Hydraulic oil is denoted by a diagonal hatch. Aluminum frame is denoted by a crosshatch.

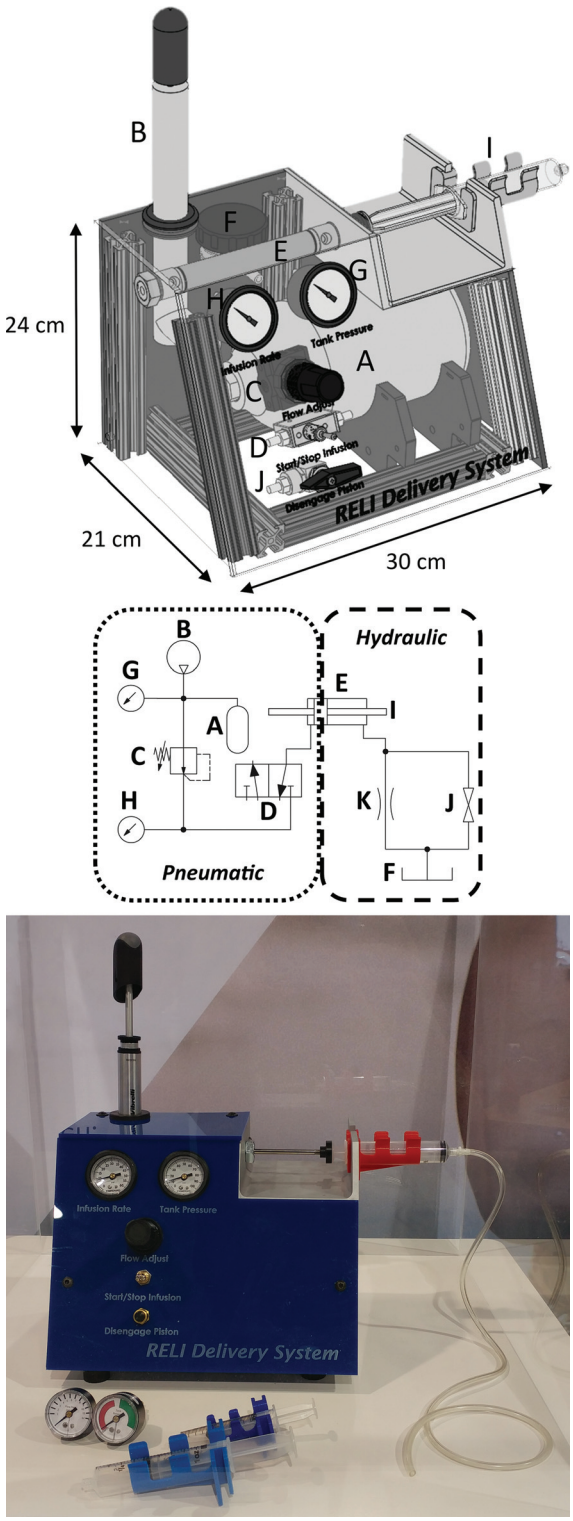

Fig. 2 Integrated device system. Panel (i) shows computer-aided design rendering of integrated device with side and front panels made transparent. Panel (ii) shows schematic hydraulic and pneumatic system components. The device consists of (A) a pneumatic vessel, (B) a hand pump, (C) a low-flow pressure regulator, (D) a shutoff valve, (E) a drive piston, (F) an oil reservoir, (G) vessel and (H) drive pressure gauges, (I) an infusion syringe and holder, (J) an on/off valve, and (K) flow-restricting tubing. Panel (iii) shows a photograph of the prototype. Fluid lines, including the flow-restricting tubing, were omitted from panel (i) for clarity.

CA). This oil is also food grade, implying minimal toxicity in the event of a malfunction. The longevity and cycles to failure of the mineral oil have not yet been evaluated. Flow-restricting narrow-bore tubing was used (24-cm length, 0.178-mm ID, 1.587-mm OD PEEK tubing, 51085K42, McMaster-Carr) with compression fittings (7473T201, McMaster-Carr) on both ends in the hydraulic oil circuit. A double-acting, double-ended air cylinder was used for the drive piston in an air over oil configuration (SR-044-DPY-OOMC, Bimba Manufacturing, University Park, IL). The low-pressure reset circuit was made from a 20-cm length of 3.2-mm inner-diameter polyurethane tubing (5108K43, McMaster-Carr) and a momentary push-button valve (6790T42, McMaster-Carr). The oil reservoir was a 60-mL syringe (309653, BD, Franklin Lakes, NJ) with the plunger removed to avoid pressure buildup from volume change. All components were mounted to a machined aluminum U-channel (5 in × 2.25 in (127 mm × 63.5 mm), 1630T35, McMaster-Carr). The support structure is made from 1 in × 1 in (25.4 mm × 25.4 mm) T-slotted aluminum extrusion (47065T101, McMaster-Carr).

Flow Rate. Flow rate was measured gravimetrically with a 1-mg resolution USB-output precision balance (HCB 123, Adam Equipment, Inc., Oxford, CT) with slight modifications to the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ID26:2004) methods [13]. Flow rate was calculated as the total volume delivered over a 3-h interval; measurements were performed in triplicate at each pressure setting. All measurements were done with new sterile 30-mL Luer-Lok™ syringes (302832, BD, Franklin Lakes, NJ) filled with de-ionized water and connected to a 3.2-mm inner-diameter, 50-cm long polyurethane tube connected to a #18 × 1.5 in (38 mm) needle simulating the infusion line to patient. The needle was suspended above a 100-mL collection vessel sealed with a thin film of polyvinyl chloride to prevent evaporation. No additional hydrostatic back pressure was used in any tests. Flow rate measurements of the integrated device began 10 min after setting the infusion rate; this delay accounted for the start-up pressure variation characteristics from the nonvented pressure regulator.

Controlled temperature tests were performed in an environmental test chamber (EPX-3H, Espec, Hudsonville, MI) and used a different precision balance (XS304, Mettler-Toledo, Columbus, OH). Test articles were conditioned at temperature (no humidity control) for at least 4 h before data collection was started. All scales, as well as test articles for nontemperature controlled tests, were maintained at ambient laboratory temperature (20–25 °C).

Evaporation rates from the system were measured as a mass differential over 7 days which averaged to be 8.6 mg/h. These effects were not incorporated into reported flow rates given the moisture retention of the scale apparatus and lack of environmental temperature and humidity control of the balance measurement location. The tip of the needle was suspended above the waterline at a height of 75 mm below the infusion syringe Luer-Lok™ fitting in the experimental apparatus. For the integrated device, the needle tip was submerged below the waterline at the same level as the infusion syringe to reduce the effect of inconsistent drips. Fluid mass was sampled in 1-min intervals and was divided by the density of water at 20 °C (0.998 g/mL) to convert to volume.

Rate deviation, expressed as percent difference from the mean flow rate, is presented as a rolling average (average calculated over a 10-min interval centered on the time point) to reduce aliasing from infrequent drips on the collection vessel.

Design of an Integrated Device

The integrated device (Fig. 2) is presented as a durable tabletop form-factor device designed to be used in clinical in-patient settings. This prototype was designed using the lessons from the experimental apparatus and operates with many of the same components and principles. Rather than using compressed air from a centralized laboratory source (as used in the experimental

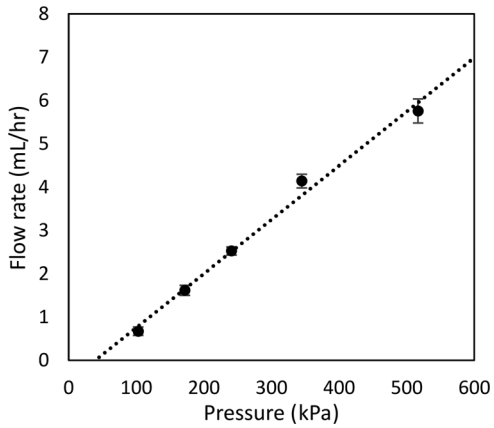

Fig. 3 Average flow rate measured for the first 3 h across five pneumatic pressure settings. One trial at 517 kPa stopped early and measured after 2.5 h. The error bars are standard deviation. *N* = 3 for all tests. Linear regression shown as dotted line.

Table 2 Mean flow rates, SD, and CV, accompanying Fig. 3

Pressure setting		Mean flow rate (mL/h)	SD	CV (%)
15 psi	103 kPa	0.67 mL/h	0.10	14.3
25 psi	172 kPa	1.62 mL/h	0.12	7.2
35 psi	241 kPa	2.52 mL/h	0.09	3.7
50 psi	345 kPa	4.14 mL/h	0.16	3.9
75 psi	517 kPa	5.76 mL/h	0.28	4.8

apparatus), this device is hand pressurized by the user, creating compressed air at the point-of-use. This design feature allows for decentralized use of the device in areas, where central compressed air or electricity is unavailable or unreliable. A unique feature of the device is that it offers both flow rate adjustability during an infusion to accommodate a patient's therapeutic response and adjustability between patients. The prototype integrated device is made of commercially available components and costs US$410. It consists of an M6L oxygen cylinder with the valve removed (A) (HF2POST6, Invacare, Elyria, OH), pressurized by a commercially available bicycle hand pump (B) (Vibrelli Mini Bike Pump, Amazon.com, Seattle, WA). Air flow from this reservoir is metered by a compact relieving 0–125-psi (0-862-kPa) pressure regulator (C) (6746K31, McMaster-Carr). A user-controlled shut-off valve (D) (6464K16, McMaster-Carr) directs compressed air from the regulator to an air over oil drive piston (E) upon starting infusion. The air over oil drive piston and flow-restricting narrow-bore tubing components are identical to the experimental apparatus; both of these components were replaced prior to temperature testing. Hydraulic oil passes through the flow-restricting tubing from the drive piston to the reservoir (F) (CaliBikerClub Universal Brake Reservoir Slim Style, Amazon.com). An on/off valve (J) (4118T62, McMaster-Carr) permits low-pressure return flow of oil from the reservoir to the drive piston. The valve is closed during infusion therapy to force flow through the flow-restricting tubing and is open to bypass the flow-restricting tubing when the device is being reset. Two pressure gauges (G and H) (3847K73, McMaster-Carr) indicate pneumatic vessel pressure (unregulated) and drive piston pressure (regulated). The infusion syringe (30 mL) snaps into a custom 3D-printed holder (I). After infusion, the piston plunger is retracted to transfer the oil back into the drive piston. Pressure gauges were modified with different scales, showing tank pressure as a qualitative "FULL/EMPTY" reading, and regulated pressure was recalibrated to show corresponding "FLOW RATE" in mL/h units. New scales were drawn with SOLIDWORKS 2015 software and printed on white paper.

Results

Experimental Apparatus. Using the experimental apparatus, flow rate was measured across five pneumatic pressure settings: 15 psi (103 kPa), 25 psi (172 kPa), 35 psi (241 kPa), 50 psi (345 kPa), and 75 psi (517 kPa) (Fig. 3). Measurement began

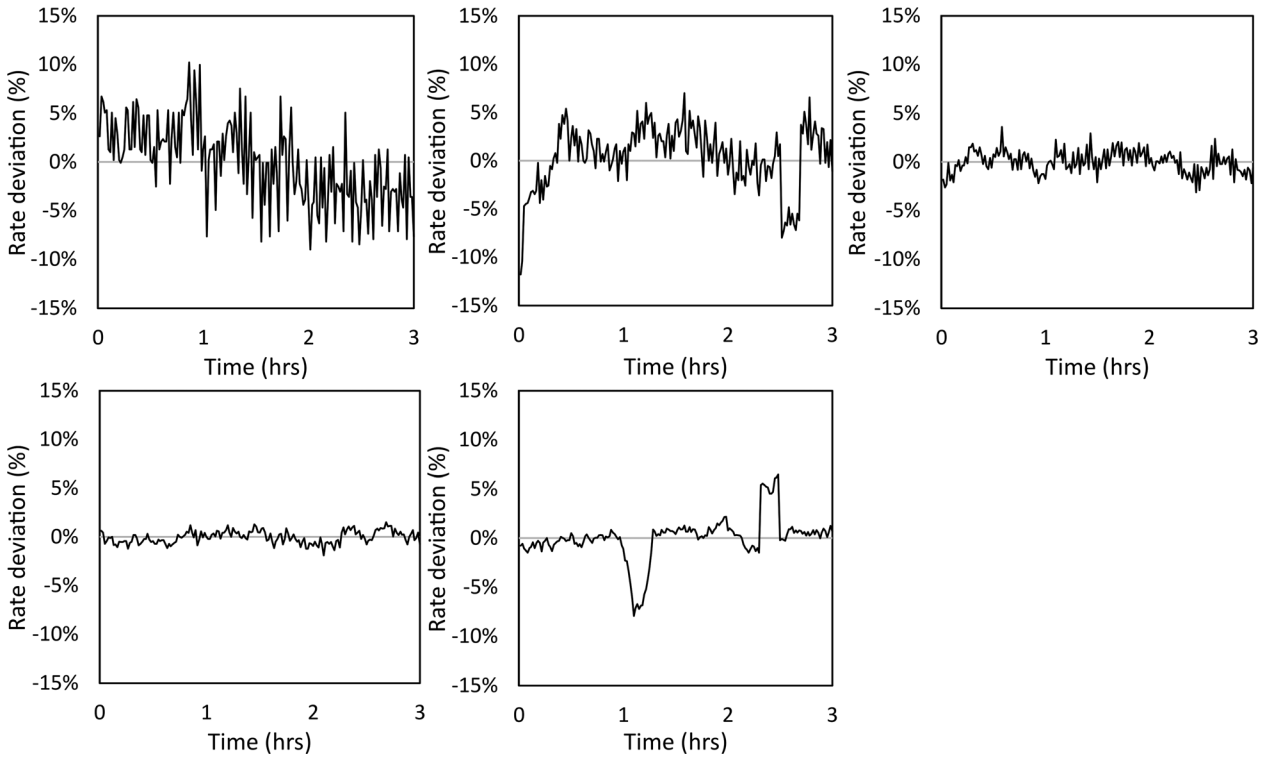

Fig. 4 Graphs show deviation (%) from mean flow rate over 3 h for each pressure setting (*N* = 3) on experimental apparatus. Profile A shows 15 psi (103 kPa) setting. Profile B shows 25 psi (172 kPa) setting. Profile C shows 35 psi (241 kPa) setting. Profile D shows 50 psi (345 kPa) setting. Profile E shows 75 psi (517 kPa) setting.

5 min after setting the infusion rate. Standard deviation (SD) and coefficients of variation (CV) are shown in Table 2.

Rate deviation profiles show percent difference from mean over 3 h runs for each pressure setting; all data are within ±10% deviation from the set point value (Fig. 4).

Integrated Device. The integrated device was tested across five pneumatic pressure settings: 15 psi (103 kPa), 25 psi (172 kPa), 35 psi (241 kPa), 50 psi (345 kPa), and 60 psi (414 kPa). 60 psi was tested instead of 75 psi due to pressure gauge limitations (Fig. 5). Standard deviation and coefficients of variation are shown in Table 3.

Temperature Testing. To evaluate the system performance variation with ambient temperature, the integrated device was tested in an environmental chamber at 10 °C, 20 °C, and 30 °C. Tests were run at 35 psi (241 kPa), as shown in Fig. 6. Table 4 shows the flow rate values along with their standard deviation and coefficient of variation.

Discussion

In ambient laboratory conditions, our device matches the performance of many disposable infusion therapy devices—operating mostly within a ±10% flow rate accuracy [14]. As predicted by Poiseuille flow (Eq. 1), flow rate shows strong linearity ($R^2 = 0.990$) with pressure gradient on both the experimental apparatus and integrated device. For the former, direct measurements show an infusion rate range of 0.67–5.76 mL/h over 15–75 psi (103–517 kPa). Extrapolation of this relationship between regulated pneumatic pressure and infusion flow rate shows a functional range of 0.5–8.0 mL/h over 11.6–98.8 psi (80–681 kPa). Error analysis over this range shows standard deviations of 0.09–0.28 mL/h (Table 2). This absolute error may have adverse implications for administrations at low flow rate settings, where CV of 14.3% (0.67 mL/h, 15 psi (103 kPa)) may pose clinical risk. However, at pressure settings greater than 15 psi (103 kPa), CV values were 3.7–7.2%, deemed acceptable for many therapies [15].

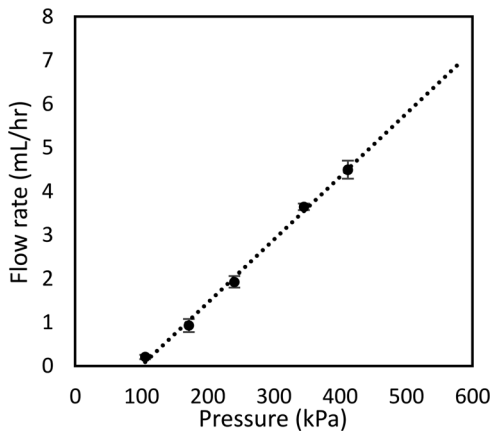

Fig. 5 Average flow rate measured for the first 3 h across five pneumatic pressure settings for the integrated device. The error bars are standard deviation. *N* = 3 for all tests. Linear regression shown as dotted line.

Table 3 Mean flow rates, SD, and CV for the integrated device, accompanying Fig. 5

Pressure setting		Mean flow rate (mL/h)	SD	CV (%)
15 psi	103 kPa	0.21	0.05	23.8
25 psi	172 kPa	0.93	0.15	16.0
35 psi	241 kPa	1.93	0.13	6.8
50 psi	345 kPa	3.65	0.08	2.1
60 psi	414 kPa	4.50	0.20	4.5

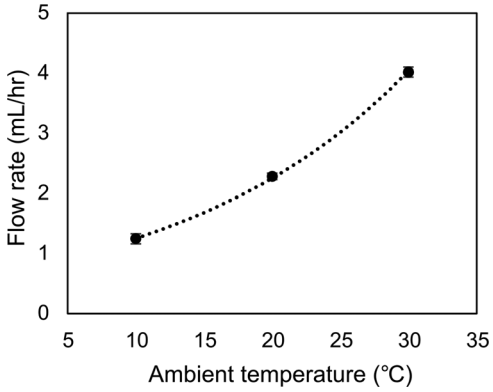

Fig. 6 Average flow rate for first 3 h across three temperature settings for the integrated device at 35 psi (241 kPa). The error bars are standard deviation. *N* = 3 for all tests. Exponential regression shown as dotted line.

Rate deviation across pressure settings shows improved flow accuracy with the increased pressure of higher flow rates (Fig. 4). This relationship could be attributed to the higher frequency of drips from the infusion line to the collection vessel for higher flow rates; this is an inherent methods limitation. On the lowest flow rate setting, drips were approximately 90 s apart, which led to coarser approximations of instantaneous flow rate. Other key sources of error include internal friction in the hydraulic pistons and back pressure from the syringe. These factors have a larger relative impact on low flow rates. Transient deviation events observed on the 172 and 517 kPa tests may have been caused by variable friction along the length of the syringe. We speculate that the internal friction may vary as a function of length, potentially causing the sharp deviation spikes in these runs.

The integrated device displayed an infusion rate range of 0.21–4.50 mL/h over 15–60 psi (103–414 kPa). While we expected the integrated device's infusion rate range to be identical to the experimental device, we measured lower flow rates and higher coefficients of variation. The higher coefficients of variation for flow rates in the integrated device are attributed to the lower-precision nonventing pressure regulator compared with the continuously venting precision regulator use in the experimental apparatus. Other potential sources of error are (1) residual air in the oil hydraulic lines due to incomplete bleeding of the system, (2) diametric variation in the flow control tubing, and (3) varying internal friction within moving components.

Controlled temperature testing of the integrated device at 10 °C, 20 °C, and 30 °C reveals a strong dependency of infusion flow rate on ambient operating temperature, with rates of 1.25 mL/h, 2.28 mL/h, and 4.02 mL/h, respectively, at a constant pressure. This variability is predicted in Poiseuille's law (Eq. (1)), as flow rate is inversely proportional to fluid viscosity (temperature dependent), thus, the device shows increased flow rate with ambient temperature increase.

Conclusions and Future Work

Our preliminary data show promising results for adjustability, flow rate accuracy, and infusion rate deviation. However, further

Table 4 Mean flow rates, SD, and CV for the integrated device temperature testing, accompanying Fig. 6

Temperature (°C)	Mean flow rate (mL/h)	SD	CV (%)
10	1.25	0.08	6.6
20	2.28	0.06	2.4
30	4.02	0.08	2.0

long-term cycle testing will be required to assess variation in flow rates over time. We also recognize that the current infusion pump prototype lacks (1) safety alarms for flow occlusion and excess rate deviation, (2) temperature compensation for ambient conditions, and (3) compensation for potential downstream pressure variability caused by patient physiology, intravenous line geometry, gravitational head, and syringe plunger frictional forces [16,17].

These constraints and limitations will be addressed in future designs including investigation of viscous fluids with increased temperature stability, such as silicone oil, or incorporate a temperature compensation feature to maintain constant flow rates across ambient temperatures. Water was considered as a working fluid to help with longevity and challenges around procurement of spare parts, but preliminary designs using water had issues with lubricity and corrosion of metal parts. We will also investigate alternative drive mechanisms to reduce error from friction. The addition of a filter in the oil circuit or using larger-bore flow-restriction tubing could help prevent blockage from contaminants. Additional testing will investigate factors affecting variability and explore flow rate dependency on vertical displacement of pump to patient [18]. While the existing prototype features a simple user interface, further design and testing can refine this concept to reach even better performance, affordability, and adjustability. We will continue to develop the device leveraging our public health expertise to conduct field studies of future prototypes. Future work will also characterize flow rates of syringes of different sizes (different cross-sectional areas) to expand the range of infusion flow rates. Future designs will incorporate human factors, such as ancillary safety functions and fundamental control logic, essential in critical care scenarios [19].

In summary, the prototype integrated device meets all of the design requirements (Table 1), with the exception of requirements 9 and 10. The design presented is electricity free (requirement 1), accurate within $\pm 10\%$ of the nominal flow rate (requirement 2), adjustable from 1 to 10 mL/h for 3 h (requirement 3 and 4), and simple to use (requirement 5). Additionally, it is capable of modulating flow rate midinfusion (requirement 6), and even at prototype scale, our device ($410) is much less expensive than current commercial electronic systems (ranging from $1200 to $15,000) (requirement 11) [2,7]. We have demonstrated performance within design requirements—entirely independent of batteries or electricity mains and free from proprietary consumables (requirement 7).The simplicity and utilization of commercially available pneumatic components makes this design amenable to field servicing with tools and resources commonly available in LMIC (requirement 8). However, the device lacks safety alarms (requirement 9) and temperature compensation (requirement 10) which will be addressed in future designs. This medical device innovation shows great promise in improving the performance of and access to infusion therapy in low-resource settings.

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