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# Human-centred and human-powered: an infusion device to offer a real alternative


## Abstract

*Despite the many brands and models of drug infusion delivery devices available there are only a few different basic types of device. Considering the breadth of therapeutic application, physical infusion volumes and the economic context, the healthcare provider has a diminished choice and the patient (often the user) has barely any.*

*A new infusion device innovation from Danby Medical offers choice and versatility suited to the transition from clinic to home, addressing the real-life human issues encountered on the way.*


## Drug and delivery choice

The primary selection of an effective drug treatment starts, not surprisingly, with the drug formulation itself. The formularies and pharmacopeia in most countries are there to guide prescribing staff through the proliferation of branded and generic drugs and various modalities and containers. Once the drug form and dose regime is determined, the next decision is often the delivery and device if one is needed.
Oral medicines and more recently transdermal patches are generally accepted as the most convenient forms, not only for consumption but for other factors including storage, dispensing, shelf-life and administration costs. However, not all drugs can be delivered in this form and so less convenient administrations such as injection and more complex infusion continue to be used widely.

## Why infuse?

Oral medicines do of course require the patient to be conscious, able to swallow and to have a working, and sometimes robust, digestive system. Injection provides an alternative. This delivers an immediate bolus of drug, which when required might be delivered into the bloodstream. For slower and regulated release injection can be provided subcutaneously or intramuscularly, but this is not necessarily controlled enough for most drugs or when greater volumes are needed. In such cases infusion can be the most effective treatment for various reasons, both bio-chemical and fluid-mechanical. Infused formulations can be custom-made for individual patients (such as parenteral and enteral preparations) and they can comprise freshly combined reagents for optimum efficacy, which might otherwise suffer short shelf-lives. They can be delivered intravenously, subcutaneously or to targeted tissue or organ locations and the profile of delivery can be set to the body's ability to transport or react to fast-acting drugs. The delivery profile can be varied and even controlled in a closed-loop system that monitors the patients. Collectively, these factors are why infusion remains an important delivery system despite its relatively complex management.

## Choice of infusion system

Its importance and the broad context of use is probably why there are so many categories of infusion and delivery methods available;-

- Gravity Drip
- Volumetric Pumps


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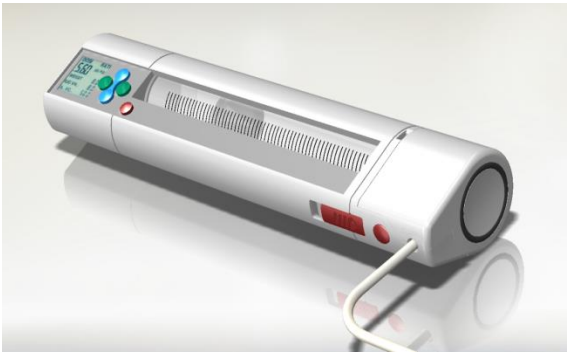
- Syringe Pumps
- Syringe Drivers
- Elastomerics

The main differences characterising each of these can be summarized as follows:







**Gravity Drip** is the traditional and familiar means of delivery from an IV bag, it is inexpensive and suits medium to large infusion volumes, especially parenteral nutrition. Based on droplet size and count, it is not particularly accurate and requires manual intervention and calculation to control, change and monitor safety. It confines a patient to bed, or to wheel along a cumbersome drip stand so limits patient mobility and might limit patient well-being and rehabilitation.

**Volumetric (IV) Pumps** assume control over the 'gravitational effect' above. In doing so they provide greater accuracy and sophisticated, programmable control of delivery. This can include delivery profiling,

and control of different lines and formulations and they feature fault detection and safety systems, compliance data-logging and connectivity. For the most part these are mains-operated bedside units, with battery backup for short transfers. Ambulatory models are also available but remain relatively large given the battery power, mechanical drive and control they need, and being ambulatory, there is of course a limit to the practical drug volume that can conveniently be carried around. Being sophisticated and fully-featured, IV Pumps are high capital cost items that cannot be justified for all medical applications, especially those where they might go astray when they accompany patients transferred or discharged from hospitals and clinics.

**Syringe Pumps** offer potentially accurate drug delivery of small to medium infusion volumes at which size syringes are economic and practical (above which they become more costly and hard to push). These pumps are generally mains-powered, offer the same sophisticated delivery control and safety features as the IV Pumps, but are also high capital cost items.

**Syringe Drivers** are the ambulatory equivalents of the Syringe Pumps, offering potentially accurate delivery of small to medium infusion volumes. As with the ambulatory IV pumps, they still need the batteries to power mechanical drive and control so remain large and heavy when compared to the actual syringe volumes. They also remain expensive capital items.

**Elastomerics** is the term given to a family of disposable devices intended for single use. A flexible drug container is expanded which then delivers the drug through a flow-controlling orifice as it contracts back to its original size. Being disposable, there is no capital cost associated with these devices so they suit patients transferred or discharged from hospitals and clinics. The penalty is that the disposable cost is higher than syringes and IV bags. Their flowrate is also less accurate so completion times for infusion are less predictable. This can increase the healthcare cost of attending to remove or replace such a device.

| | Infusion Volume | | | Cost | Context |
|---|---|---|---|---|---|
| | Small > | Medium > | Large | | |
| **Bedside** | Syringe Pump | Volumetric Pump | | High Capital | Hospital & Clinics |
| **Ambulatory** | Syringe Driver | Ambulatory Pump | | | Hospitals Home |
| | Elastomeric | | | High per use | Transition to home |

## Limited choice

The different types of systems, brands and models underscore the continued and widespread use of infusion as an effective delivery method. Collectively they create the impression that there is a wide choice of devices. However, the appropriate type of infusion system for any application depends on the infusion volume and rate, the location and mobility of the patient and the economics of the healthcare provision. Without the opportunity to influence these in specific use cases, they become constraints and the infusion system to use is probably already narrowed to one and so pre-determined.

This has happened before further consideration of other factors, many human, such as patient transfer and changes in the use of equipment with context and rehabilitation.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Healthcare providers don't want needless choice and understandably don't want to support more types and models of device than necessary which adds to their management burden in terms of stocking, maintenance, sterilisation and training.

## Healthcare context

The existing infusion device types are not ideal at bridging across the significant change in context of use and the type of user, for instance from hospital care managed by professionals, to rehabilitation at home and used by the carer or patient themselves. The pressure is on healthcare providers to make this transition reliably and at the soonest opportunity to reduce the cost of care.

Elastomeric devices are particularly suited to the transition itself, but are less widely used exclusively within hospitals because of their higher cost and are not well suited to patient use in the home environment either. IV and Syringe Pumps, which are used extensively in hospitals and clinics, are often too costly for some applications and simply too valuable for many healthcare providers to allow them to accompany discharged patients given the risk of loss, damage or failure to be recovered.

Devices such as Syringe Drivers appear to offer a reasonable compromise where they are controllable enough for hospital use, ambulatory enough for transfer and mobility and sometimes easy enough for carers and patients to use at home. They have moderate disposable costs but are still too high a value item for healthcare providers in many countries to risk losing.

| | Volumetrics | Elastomerics |
|---|---|---|
| **Advantages** | Accuracy<br>Control<br>Preditability | No Capital cost<br>Low risk of loss (disposable) |
| **Disadvantages** | High Capital cost<br>Maintenance costs<br>Risk of loss<br>Low disposable costs | Poorer accuracy<br>Inferior control<br>High disposable cost<br>Unpredictable end-times<br>High waste content |

## Danby Medical

Faced with the schism that exists between the accurate-capital devices and the costly-disposable devices, Danby Medical, a company founded to innovate medical devices comprising Danby Scientific and Product Innovation Consultancy 'PDD', tried to envision an affordable best-of-both world's delivery solution.

Firstly it needed to be human-centric in its conception, being simple and convenient in use by both professionals and patients themselves, undercutting many of the seldom-used bells and whistles of the fully featured hospital units. Yet it still needed safe, accurate and controllable delivery with predictable infusion


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times. It needed to be inexpensive in capital terms with low disposable and operating costs. Such benefits would suit patients, healthcare providers and reimbursing insurers alike.

The Danby m60 device is the result of extensive research with healthcare providers, physicians, nurses and patients suffering chronic conditions. Together this research provided the insights into the unmet needs of users, design solutions used in non-foreseen circumstances, redundant features and cost-inefficient care practices.

The Danby m60 retains the familiar, proven, adaptable and inexpensive format of the syringe, which spans the infusion volumes in hospital as well as those for practical ambulatory home use. The syringe type is dedicated to Danby with a removable stem which makes the device in use considerably smaller. The Danby m60 also retains the electronic control required for safe and accurate drug delivery.

Its distinguishing feature compared to most current devices is that it dispenses with the common motorised delivery, also removing the associated need for mechanical drive train, circuitry, large and powerful batteries and recharging circuit. The capital cost is reduced correspondingly as too are the operating, maintenance and calibration costs and the continual management of batteries.

Instead, the Danby m60 uses simply-stored human-power. The approach is a familiar one in many other devices and was long used to power our clocks and telephones and more recently our radios, torches and sometimes mobiles. In more analogous medical device terms, it has powered auto-injectors, insulin pens and of course the naked syringe for many years. The simple principle of the Danby m60 is to store the human effort that would be required to plunge the syringe and release it slowly over the infusion.

The patent archives show that stored-energy devices have been developed in the past but none has adequately addressed the mechanical risks and human fears of excess delivery should the 'hold-back' control fail. Danby recognised this from the outset and invented and developed several patented fail-safe mechanisms that act concurrently yet independently. Together these stop infusion as well as quickly alert the user in the unlikely event of a breakdown. They are akin to the type of systems that make the safety of underground trains, elevators and ski-lifts taken for granted.

## Accompanying this approach are several other human-centred advantages:

Without the motor, gear-train, and especially heavy batteries it is more compact and considerably lighter. Able to release stored mechanical energy instead of power a motor it is also much quieter and vibration free. These are ideal qualities for an ambulatory, highly mobile and wearable device.

Without batteries the device is also easier to live with. There is no need to stock and replace costly disposable batteries, charge and wait for batteries and worry about the state of charge and whether battery life will be sufficient. Without batteries, the device also has a long shelf-life and is always available which suits use as an emergency stand-by device.

The infusion delivery remains electronic for reasons of safety, accuracy, reliability and as well as simple user interaction and compliance data-logging. This means the device still qualifies for reimbursement in cases where mechanically-controlled devices don't. In conjunction with the precise mechanical release mechanism, the electronic control ensures very low constancy and rapid detection of occlusion.

As a low-cost and simply-used Syringe Driver, the Danby m60 is able to service many of the existing hospital to home and chronic applications more effectively and economically. Its qualities also extend its application to other arenas. Its low capital cost makes it affordable to some single patient regimes where it

can be considered disposable afterwards, avoiding sterilisation and maintenance costs. It also makes it viable for lower-value applications and especially within markets with constrained budgets or emerging market regions without the necessary infrastructure to manage, maintain and charge devices.

As a significant departure from the norm within the Syringe Driver category the Danby m60 might also be used in new contexts where existing equipment is not appropriate, such as disaster relief, defence emergencies and field hospitals and repatriation into all types of aircraft.

## Post-script

The Danby m60 device continues in development to market having been proven in early prototypes. Danby is seeking parties that can benefit from its advantages to participate in further phase development, licensing or marketing of the device.


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