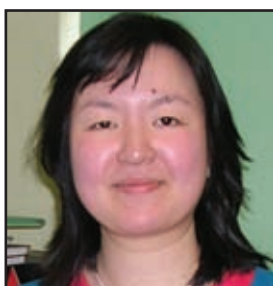


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AMBULATORY SYRINGE DRIVERS: A BUYER'S GUIDE

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The UK National Health Service (NHS) Purchasing and Supply Agency (PASA) Centre for Evidence-based Purchasing (CEP) has recently published a Buyers' Guide on Ambulatory Syringe Drivers [1]. It is a comparative report on the specification, technical performance and usability of electronic ambulatory syringe drivers to help inform purchasing decisions. Seven models of ambulatory electronic syringe drivers, produced by ZiMed, Eden Medical, Smiths Medical (formerly Graseby) and CME McKinley were reviewed. These products can be grouped according to the offered infusion delivery units; some syringe drivers require the delivery rate to be set in millimetres of plunger travel per hour ($\text{mm}\cdot\text{h}^{-1}$) or per day ($\text{mm}\cdot 24\text{ h}^{-1}$) and, for some syringe drivers, the delivery rate has to be set up in volumetric units ($\text{mL}\cdot\text{h}^{-1}$) (table 1).

This article is based on the Ambulatory Syringe Drivers buyers' guide [1]. Detailed information relating to the technical performance of ZiMed and CME McKinley syringe drivers is also available from the recently published CEP evaluation reports [2, 3]. Details of the Smiths Medical syringe drivers evaluation are available from the MHRA Pump Evaluation database [4]. A separate evaluation report of the Eden Medical Micrel MPml/h was also published earlier by the UK Medicines and Healthcare products Regulatory Agency (MHRA) [5].

APPLICATIONS OF AMBULATORY SYRINGE DRIVERS

The reliability, safety, small size and ease of use of some modern drug-administration devices allow many

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patients with chronic conditions to receive their treatment in the comfort of their own homes and, as the therapies can be received ambulatory, with minimum disruption to patients' daily lives. One of the key priorities of the Department of Health for England is to support people in managing their care and treatment at home, wherever possible [6]. In addition to enhancing the patient's quality of life and their independence, ambulatory infusion devices potentially help to reduce clinical staff time involved in administering treatment and in shorter hospital stays. The latter of which could help in limiting the risk of acquiring hospital-related infections [7].

The main application area of ambulatory syringe drivers is for continuous subcutaneous drug administration (infusion) (CSI). Typically, CSI is less expensive than intravenous infusion and is associated with a lower incidence of injection site complications [8]. Drugs given *via* CSI are usually rapidly absorbed and have high bioavailability (generally 100%) [9].

The main area of CSI application is seen to be in symptom management for cancer patients and palliative care. However, there is a variety of drugs that can be administered *via* CSI; this includes heparin, insulin, chemotherapy, cytotoxic drugs and bronchodilators [10].

Long-term CSI of terbutaline (CSIT) is one of the ways of treating adult patients with brittle asthma [11]. Continuous subcutaneous salbutamol has been used to treat infants with acute asthma [12] and a case study was reported on long-term use of CSIT in children with chronic severe asthma [13].

MAIN FEATURES OF AMBULATORY SYRINGE DRIVERS

Ambulatory syringe drivers (also known as syringe pumps) are small,

battery-powered medical infusion devices which allow continuous fluid delivery from a syringe at a programmed rate. They are designed to deliver the therapy with minimal disruption to a patient's daily life and activities and, therefore, are of small size and lightweight. Typical weight of a syringe driver with a battery is around 200–250 g (~470 g when used with a lock box). Most syringe drivers are designed to deliver infusions from any brand of syringe with a volume of 2–30 mL. However, some devices require the larger syringes (20–30 mL) to be under-filled to allow delivery, which is due to the limited length of the mechanism that drives the syringe plunger. A variety of carry cases, both disposable and reusable, are typically offered to facilitate the ambulatory applications.

Power supply

Ambulatory devices need to be battery powered to allow mobility during the therapy provision. There are syringe drivers offering use of either a disposable or a rechargeable battery. Only one syringe driver, currently offered by the market, offers the use of both. An option to run on mains power is offered by some syringe drivers as well, but this requires connection either to a docking station or to a special charger for a device running on an integral rechargeable battery.

Delivery patterns

Typically, fluid is not delivered smoothly by ambulatory syringe drivers but as a series of small boluses. This is common for most battery-operated ambulatory pumps and is a deliberate design to conserve battery power. Smooth and continuous delivery requires more battery power and reduces the overall battery life, thus resulting in frequent battery replacement. However, CSI does not require very smooth flow patterns. The overall hourly accuracy of delivery is more important than minute-to-minute

accuracy. Smooth delivery might be important for the administration of some *i.v.* drugs, particularly cardiovascular drugs, and ambulatory syringe drivers would not be suitable for this type of application.

Start up time of delivery

Start-up time is defined as the time required for an infusion device to start delivering at a set rate. All modern syringe pumps have a delayed start of infusion and this is also the case with ambulatory syringe drivers. The start up time is affected by the design of the device's driving mechanism and by procedures carried out prior to starting the infusion. For a syringe pump, automatic purging of a syringe reduces the start-up time, as this helps to eliminate the mechanical slack in the system. Most modern syringe drivers offer the purge function as an option. The purge volume can be set up when the pump is configured or it can be controlled by the user.

Safety








Alarms

Alarms alerting users to situations that could compromise therapy delivery, such as power interruption, a blocked line, a displaced syringe, tampering with the infusion and end of infusion, are expected from all modern infusion devices. Ambulatory syringe drivers complying with IEC 60601-2-24 [14] offer these safety alarms. An alarm typically involves an audible signal, sometimes accompanied by a visual message on a driver's display indicating the reason for alarm and providing instructions on how to resolve the problem.

Syringe recognition system

A syringe recognition system, offered by the syringe drivers complying with IEC 60601-2-24, performs two functions: it alerts ►

Table 1. Ambulatory syringe drivers

	ZiMed	Eden Medical	Smiths Medical	CME McKinley
$\text{mm}\cdot\text{h}^{-1}$		 MP-101	 MS16A	
$\text{mm}\cdot 24\text{ h}^{-1}$		 MPdaily	 MS26	
$\text{mL}\cdot\text{h}^{-1}$	 AD Syringe Driver	 MPml/h		 T34

a user that syringe displacement has occurred during delivery and helps to prevent delivery error from the use of an incorrect syringe. Syringe displacement can have serious consequences for a patient as this may result in the syringe emptying its content into the patient (if a driver is raised relative to infusion site) or syphoning, when a driver is lower than the infusion site. However, syphoning is considered to be a less important issue in a subcutaneous infusion than it is for an *i.v.* infusion. Confirming incorrect syringe may result in serious delivery error for devices delivering in $\text{mL}\cdot\text{h}^{-1}$ and, as an extra precaution, a syringe recognition system requires users to confirm the volume and brand of the syringe used.

Lock boxes

Lock boxes are offered for all ambulatory syringe drivers but one, which offers an integral syringe cover as a part of the device, providing excellent protection against syringe displacement. Prevention of accidental changes to an infusion delivery can also be achieved using a keypad lock. This feature is present on all modern syringe drivers.

Carry cases

A variety of carry bags and pouches are typically offered for a syringe driver to facilitate its ambulatory applications. The offered carry bags can be disposable or reusable (washable). Some carry bags can provide extra protection against fluid ingress and claim compliance with the IPX4 standard for waterproofness.

KEY PURCHASING FACTORS TO CONSIDER

Clinical applications

The selection criteria for a new ambulatory syringe driver are dependent on the clinical application(s). Compliance with IEC 60601-2-24 ensures that the driver meets the key requirements for delivering therapies *via* both subcutaneous and *i.v.* routes. This application diversity supports standardisation of infusion equipment on a relatively small number of devices. The option to set up a delivery in volume units ($\text{mL}\cdot\text{h}^{-1}$) allows consistency in training, as other infusion equipment are typically set up to deliver in the same way.

Technical features

Infusion delivery units

Infusion delivery units offered by the currently available ambulatory syringe drivers are different, with some drivers offering delivery in $\text{mm}\cdot\text{h}^{-1}$ or in $\text{mm}\cdot 24\text{ h}^{-1}$ with the others offering delivery in $\text{mL}\cdot\text{h}^{-1}$ (table 1). Using delivery in $\text{mm}\cdot\text{h}^{-1}$ (or $\text{mm}\cdot 24\text{ h}^{-1}$) is traditional and adapted in many practices. Syringe drivers compliant with the safety requirements set up in the IEC 60601-2-24 deliver in $\text{mL}\cdot\text{h}^{-1}$; the delivered volume in mL is recorded by the device and is available for viewing at any time during delivery from the display. Using dosing units of $\text{mL}\cdot\text{h}^{-1}$ also facilitates drawing up solutions and monitoring the delivery using the mL measurement scale on the side of the syringe.

Delivery options

Delivery options offered by a syringe driver can differ depending on the model. An option to set up infusion over a fixed period, *e.g.* 24 h, can be very convenient for some applications, *e.g.* for palliative care, as drug dosage is typically prescribed over 24 h. For devices offering a syringe recognition system, a user

would only need to check the parameters of the infusion and initiate the delivery if the time of infusion is fixed. With an automatic syringe volume recognition system, the rate is calculated by the pump. Other delivery options may be offered, such as setting up a different delivery rate or setting up the time of delivery. The choice of delivery options may be restricted by the manufacturer, at the purchaser's request, to minimise the risk of user error.

Bolus function

Bolus function is offered by some syringe drivers. This allows initiation of immediate delivery at maximum flow rate. A user can set up a limit for the bolus volume. Bolus function is typically configurable and can be disabled from configuration, if clinical practice does not advise using it.

Power supply

Power supply provision differs for different syringe drivers. Most of them use a standard disposable battery to run. There is one driver, however, which utilises an integral dedicated lithium-ion rechargeable battery, and another driver which can run on both: a disposable or a standard rechargeable battery. Disposable batteries allow greater flexibility for ambulatory applications as they typically run for longer compared with a rechargeable battery's single charge, they do not require regular recharging and can be purchased from most retail outlets. However, the use of rechargeable batteries can reduce wastage significantly, and is more cost-effective. For integral rechargeable batteries, management of the battery charger should be taken into account and provision made for its storage.

Safety

Pump appearance

Pumps offering delivery over different fixed time periods should

be clearly distinguishable from each other, to minimise the risk of setting up an incorrect delivery rate. Confusing a pump delivering in $\text{mm}\cdot\text{h}^{-1}$ with a pump delivering in $\text{mm}\cdot 24\text{ h}^{-1}$ can result in infusion rate 24-times higher than required, which can result in serious harm or even death to a patient.

Alarms

The ability of a pump to indicate a malfunction or a dangerous condition, which can compromise the therapy, is an important safety feature. Users should check that the alarm tone is sufficiently audible. Clear messages on the device's display to guide the user on the cause of alarm and actions for resolving the problem are helpful. Duration of standby alarm time is important: a long standby alarm time could result in delayed feedback from the pump, if infusion is not initiated immediately for any reason.

Syringe recognition system

Pumps offering a syringe recognition function require a user to confirm the volume and brand of the syringe used; this is an extra safety precaution which helps to prevent a delivery error from an incorrect syringe. Any permitted syringe brand and volume can be configured for use; the volume of the syringe content is estimated by the pump.

Lock box

Some clinical protocols may require drugs to be locked in the infusion devices in order to prevent tampering with syringe content. This would require the use of a lockable box during delivery. The total weight of a driver and its lockable box would need to be taken into account, and provision for carry accessories to accommodate the lockable box should be offered.

Limits on flow range

An option to restrict the flow rate to a specific range with an upper

and lower limit, or configuring the system for a single flow rate is a good safety feature, as this would prevent the user from setting rates outside the preset safety limits.

Monitoring

Visual indication of the battery status should be available to users. Visual and audible alerts to warn a user of low battery status are essential to ensure safe therapy delivery. Option to check the delivered volume, flow rate and time until the end of delivery allows intermediate monitoring of infusion. A running infusion indicator is another important safety feature which must be offered.

Event logging

Event logging allows the driver's operation or any unauthorised interference with its performance to be traced by storing the history of any key presses in the driver's memory. This could help in identifying the cause of performance issues.

Ease of carrying





The quality of the offered carry cases is important and should be checked. Carry cases should be washable if for multiple use, or disposable if for single use. Users should refer to the manufacturer's instructions regarding cleaning of washable cases; however, it is an advantage if reusable carry cases can be washed at 60°C [15]. Provision of carrying accessories to accommodate the lockable box should be checked as well.

Cost

Capital outlay

List prices for the ambulatory syringe drivers are similar, being £860–1000. Some level of service and on-site training is typically included in this price. ►

Table 2. Ambulatory syringe drivers: features

Pump	AD Syringe Driver	MPdaily / MP-101/ MPml/h	MS26 / MS16A	McKinley T34
				
List price (excl. VAT) £	960	875*	852.5	995
Manufacturer	ZiMed	Eden Medical	Smiths Medical	CME McKinley
Meets IEC 60601-2-24	✓			✓
Size (H × W × D) mm	230 × 87 × 43	165 × 40 × 23	166 × 53 × 23	169 × 53 × 23
Weight with battery g	470	200	185	260
Lock box weight g	Integral lockable cover	290	183	188
Water resistance	IPX1	IPX4	IPX1	IPX1
Power supply	Battery, mains	Battery	Battery	Battery, mains
Battery options	Rechargeable (integral)	Disposable	Disposable	Disposable or rechargeable (standard)
Battery life [#] days	3 [¶]	70	50	7 ⁺
Battery replacements per year	0 [§]	6	8	53 ⁺
Stated flow rate accuracy	±2%	±4%	±5%	±2%
Overall summary	New to the market. Complies with IEC 60601-2-24. Runs on an integrated rechargeable battery, requires an external charger. Accepts fully-filled 30 mL syringes. Offers limits for flow rate, good syringe protection by a lockable syringe cover. Does not require additional lock box. Infusion monitoring and syringe displacement protection were praised by users, as well as good manufacturer support.	Compact, lightweight and small size driver. Users found it easy to use and set up. Similar to the Smiths Medical MS drivers, but offers extra safety features: key press start and stop of infusion, limits for flow rate, low battery alarm, event log, brief instructions on the pump body.	Compact, lightweight and small size driver. Users found it robust, easy to use and set up, however the lack of essential safety features makes it vulnerable to user error. Good quality lock box is offered.	Complies with IEC 60601-2-24. Runs on both: a disposable or a standard rechargeable battery. 30-50 ml syringes should be significantly under-filled to fit the driver, and some 30 ml and 50 ml syringes do not fit into the lock box. Offers limits for flow rate, good font size, ease to maintain and repair. Logical menu and easy monitoring were praised by users, as well as good manufacture support.

[#]: for a typical 24-h infusion in palliative care; * MPml/h price list is £912; [¶]: battery needs to be recharged regularly, at least every 3 days, using a provided charger. Estimated battery life is 3 yrs; ⁺: for disposable battery; [§]: this driver uses an integrated rechargeable battery which, on average, needs to be changed once in three years. Initial cost of the battery is included into the driver's list price.

Manufacturers sometimes include accessories in the overall bundle of costs, but these can vary and it would be recommended to check which accessories are included.

Accessories usually include a carry bag, a user manual and training material. The lockbox is provided by some manufacturers free of charge with any new purchased pump, whilst others supply it as a cost option.

Although syringe drivers do not require use of dedicated infusion sets, some manufacturers offer proprietary infusion sets for their products.

Maintenance

The warranty period for a syringe driver is typically either 1 or 2 yrs, depending on the manufacturer, with the typical recommended servicing interval being 12 months. In the UK, most purchasers carry out their own servicing and maintenance of syringe drivers, with the hospital technical departments typically servicing local community devices as well. Some manufacturers may offer a preventative maintenance contract,

extended warranty or comprehensive warranty at extra cost.

Training

Manufacturers typically conduct initial training programmes for clinical and technical staff at no extra charge. Any further upgrade training would generally be the purchaser's responsibility. However, some manufacturers offer extra training if required over the life-time of the device, at no additional cost. ■

The NHS Purchasing and Supply Agency's Centre for Evidence-based Purchasing (CEP) provides independent, objective evidence-based information on medical technologies to underpin purchasing decisions and to drive the uptake of innovative devices by the NHS in England. All CEP reports published since 2002 are available to freely download from www.pasa.nhs.uk/cep. An email alert service is also available, by contacting cep@pasa.nhs.uk. Further details about CEP service are available from the organisation's website www.pasa.nhs.uk/cep.

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