

Rapid Response Report NPSA/2010/RRR019: Safer ambulatory syringe drivers

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Supporting Information



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This supporting information should be read in conjunction with Rapid Response Report NPSA/2010/RRR/019 *Safer ambulatory syringe drivers* available at www.nrls.npsa.nhs.uk/alerts

1. Background

Clinical uses of ambulatory syringe drivers

Ambulatory syringe drivers are widely used for palliative care and long term therapy in all clinical settings and at home. Some ambulatory syringe drivers have rate settings in millimetres (mm) of syringe plunger travel. The use of millimetres rather than millilitres (ml) as a basis for medication calculation is unique to ambulatory syringe drivers. This is not intuitive for many users and not easy to check. Errors include the wrong rate of infusion caused by inaccurate measurement of fluid length or miscalculation or incorrect rate setting of the device. Errors can also be made through confusion between models calibrated for mm per hour or mm per 24 hours. Syringes in some of these devices can become dislodged in use. Some have inadequate alarms and no internal memory (which makes establishing the reason for any over or under-infusion difficult). Because ambulatory syringe drivers are often used to deliver opioids and other palliative care medication, over-infusion can cause death through respiratory depression while under-infusion can cause pain and distress.

Current best practice

A harmonised European Standard, BS EN 60601-2-24 1998¹ identifies technical features for ambulatory syringe drivers that aim to reduce the risk of serious incidents in practice. It stipulates mechanisms that only allow the infusion to begin if the syringe is properly fitted and alarms that activate if the syringe is removed before the infusion is stopped. Many older ambulatory syringe drivers do not provide these features. More modern ambulatory syringe drivers with these safer design features and with rate settings in millilitres (ml) per hour are now available. In November 2007 the New Zealand Medicines and Medical Devices Safety Authority issued recommendations to discontinue the supply of mm-calibrated syringe drivers to the market. The target date for their removal from use in New Zealand was June 2010.²⁻⁴ These syringe drivers have also been taken off the market in Australia.⁵⁻⁷

Some leading cancer and palliative medicine centres in the UK have already replaced all their mm-calibrated ambulatory syringe drivers with devices incorporating safer design features, while other healthcare organisations are currently using both mm-calibrated and ml-calibrated designs.

Designs of ambulatory syringe drivers

All syringe drivers and pumps used in healthcare are calibrated in ml with the exception of some models of ambulatory syringe drivers which are calibrated in mm. Exposure to two different types of measurement (mm and ml) may increase the risk of human error. Even in community settings where ambulatory syringe drivers calibrated in mm were traditionally the only type in common use, exposure to ml per hour calibrated devices is becoming more common, which increases the risk of confusion. Devices calibrated in ml per hour may be used for a variety of conditions in the community (for example Parkinson's Disease) and terminally ill patients may be transferred home from hospital or hospice settings with ml per hour calibrated devices.

Ambulatory syringe drivers that are programmed in mm of plunger travel and in common use in UK settings include:

- MS16A (mm per hour) from Smith Medical (formerly from Graseby Medical)
- MS26 (mm per 24 hours) from Smith Medical (formerly from Graseby Medical)
- MP100 (mm per hour) from Micrel Medical Devices
- MP101 (mm per hour) from Micrel Medical Devices
- MPdaily (mm per 24 hours) from Micrel Medical Devices

Calculation issues with ambulatory syringe drivers

Ambulatory syringe drivers have traditionally been calibrated in mm of plunger travel to allow them to operate with syringes of any brand or volume that can physically fit in the driver. The rate setting therefore has to be calculated based on the dimensions of the syringe being used, and errors can be made in the syringe measurement and calculation process.

Some clinical users may not know how to undertake this calculation, but rely on a protocol based on filling a set size of syringe to a set amount. The assumption is that this will produce a set length of plunger travel (for example, always making up the prescription as 10 ml of medication in a 10 ml syringe then, without measurement, assuming this equates to 48mm of plunger travel per 24 hours). This method will not work for prescriptions requiring other volumes to be administered over 24 hours. This reliance on standard syringe sizes and volumes may mean that few clinical users double-check that the rate setting, in mm of plunger travel, is correct.

Many organisations have tried to reduce the risk of confusion between ambulatory syringe drivers calibrated as mm per hour and mm per 24 hours by rationalising their stock to only one kind. As a result staff are at risk of applying the wrong 'calculation by rote' if the other type of mm-calibrated syringe driver is encountered. Where the two devices are confused, a 24-fold overdose or underdose is possible. While many healthcare organisations try to further reduce the risk of a rate setting error (or undetected battery failure or dislodgement) through hourly checks of syringe driver travel, this may not be adequate to prevent a 24-fold dose error.

In addition, where ambulatory syringe drivers have their rate of administration set in mm of plunger travel, clinical users cannot easily estimate how long the remaining contents of the syringe will take to infuse (and therefore, for example, when the next community nurse visit will need to take place). This estimation is easier with a rate of administration calibrated in ml per hour as it is not necessary to measure the length of the remaining contents.

Where ambulatory syringe drivers are used without a lockable cover (which was not always supplied as standard in the past) they are not protected from unintended rate changes and the syringes fitted to them can become accidentally dislodged. Older designs of mm calibrated syringe drivers have few alarms and do not alert staff and carers when this happens.

The lack of an event log (an internal memory that can be read by engineers investigating an error or fault) in older designs of mm-calibrated ambulatory syringe drivers makes it almost impossible to identify when and how the events of a patient safety incident have occurred.

2. Review of evidence of harm

Evidence from National Reporting and Learning System (NRLS)

The National Patient Safety Agency (NPSA) carried out a range of keyword searches to identify incidents involving apparent over- or under-infusion with ambulatory syringe drivers that occurred between 1 January 2005 and 30 June 2010. Details of search strategies can be found in Appendix 3 (page 13). Key findings are shown in Table 1 below.

Table 1 Type of errors associated with patient safety incidents involving ambulatory syringe drivers

Type of error	Number of incidents
Incorrect rate setting	53
Unexplained fast infusion	42
Confusion between mm/hr and mm/24hrs	14
Syringe incorrectly inserted	11
Syringe dislodged	9
Unexplained slow infusion	8
Driver setup incorrectly	8
Tampering by patient	7
Confusion over mm and ml	7
Unexplained failure to deliver infusion	5
Other	11
Total	175

The review revealed eight deaths as resulting from over-infusion, with four of these occurring in 2009. While attributing death to the wrong rate settings is complex in situations where the patient was already within days or hours of death due to terminal illness, significant overdoses of opiates given through over-infusion are likely to have caused respiratory depression and/or respiratory arrest.

Free text descriptions of the fatal incidents:

- 1. The patient was expected to die at home within hours/days and a syringe driver was set up to administer prescribed analgesia at 2mm per hour over a 24 hour period. When the on call GP visited to certify the patient's death, it was discovered that the contents of the syringe driver had been discharged within a four hour period at a rate of 60mm per hour. The incident was investigated by the police who concluded that there was insufficient evidence to show how the rate was changed.*

2. Patient prescribed Diamorphine 10mg & Buscopan 60mg to be given subcutaneously via a syringe driver over 24 hours. The staff state the rate was set at 2mm per hour and medication drawn to 48mm. Therefore the medication would go over 24 hours. At 13.00 hours the same two staff went to turn the patient and check the syringe driver, the syringe driver was empty meaning the medication went in under 2 hours. The ward sister was informed who went and checked the pump. She found that the pump was set to between 89 or 99 mm (the first digit was between 8 & 9 and the second digit clearly 9).
3. Two District Nurses visited patient at approx 22:30. Patient was agitated and in pain, care plan checked. Decision to increase syringe driver in situ from diamorphine 10mg to 20mg over 24 hours. District nurses discussed what size syringe to use. Drew up diamorphine 20mg in to a 20ml syringe. Checking and re-siting procedure was interrupted by patient trying to get out of bed. Approx 1:20 one of the district nurses realised that this dose would go through too quickly. Contacted nurse on call who refused to visit patient to check. Stated that dosage was within the maximum dose. The patient died later that day.
4. Informed by Care manager that a patient had required attention from out of hours medical service last night and a syringe driver had been set up to control symptoms of distress. Carers also expressed concern that the driver appeared to be running low on medication, therefore I arranged to meet with them prior to commencing my morning visits and told them to contact the out of hours medical service to review the medication situation. On arrival at the care home, I checked the syringe driver and noted that indeed the fluid had all been administered and the rate had been set to 90mm. I checked this rate with the carer who accompanied me to the patient. The patient was totally unresponsive to any stimulus.
5. Syringe driver set at 22mm per hour instead of 2mm per hour. 20mg diamorphine, 10mg midazolam, 30 mg metoclopramide given in a 2 hour 40 min period instead of 24 hours. Patient died at approx 2200 hrs. Error discovered [next day] and GP informed on [following day]. Coroner informed and investigations commenced.
6. Patient discharged home from hospital with subcutaneous controlled drug in syringe driver prescribed amount morphine 10mg, hyoscine 1.2mg. The District Nurse (DN) subsequently visited to continue the regime and reload the syringe driver with prescribed medication which should have gone through over 24 hours. The DN reloaded the syringe driver the patient already had in-situ with the medication. A palliative care nurse from a hospice visited approximately 1 hour after administration and identified an error. The medication had gone through within 2 hours instead of 24.
7. Two Community Staff Nurses visited a terminally ill patient. They administered 5mgs of Diamorphine subcutaneously and commenced him on a syringe driver of Diamorphine 10mgs, Midazolam 10mgs and Cyclizine 150 mgs mixed with sterile water for injection. They left the patient home approximately 0100 hours. At 0600 hours, they were informed that the patient had passed away. A Healthcare Assistant had also attended to the patient and reported that the syringe driver was empty. The nurses who set up the syringe driver discovered that they had set the rate incorrectly which had resulted in the rapid administration of the prescribed medication.
8. While beginning last offices on patient at 0200 his syringe driver was found to be empty. There was no paper work for the checking or set up of this syringe driver in the notes. The prescription stated that the syringe driver was set up at 0845 meaning it was due to finish at 0845 the following morning. The syringe also has 0845 written on the label and the syringe driver was set for the correct dose.

Examples of incidents with non-fatal outcomes

Incorrect rate setting

The drugs in the syringe driver were diamorphine 5mg and midazolam 5mg in 1ml and 6ml of water for injection and this was checked by DNs. Unfortunately, the dial on the syringe driver was set for 20mm/hr instead of 0.2mm/hr. As a result, the drugs went quicker than estimated. The syringe driver started at 4.30pm and should have run for 24hrs

I visited the ward and noticed that a patient's Micrel syringe driver was not working and that the infusion rate was wrong. The rate was set at 0.02mm per hr, but it should have been set at 0.20mm per hour.

Subcutaneous syringe driver checked at 22:00 and was found to be running at the wrong rate. Nurses were trying to save diamorphine, which is in short supply, by altering the rate of infusion rather than changing the syringe. Rate was doubled instead of halving.

Unexplained fast infusion

On regular check of syringe driver (Graseby): Check time 22:00hrs. I noticed that syringe driver had finished after only infusing for 9 hours. Syringe should have infused over 24hrs changed at 15:00hrs.

Patient on subcutaneous syringe driver - morphine and cyclizine over 24 hours pump due to finish at 19.15 however when checked pump at 8.00am all the medication had been administered.

Driver set up incorrectly

Prescribed medication administered via syringe driver. Should be administered over 24 hours. Medication drawn up in 20ml syringe, but not diluted with water to total of 20mls. Total of 10mls in syringe. Therefore, administered over 12hrs instead of 24hrs.

Confusion between mm/hr and mm/24hrs

Assessing patient for uncontrolled pain. Nurses reported the subcutaneous syringe driver did not infuse any of the oxycodone analgesia overnight, so they changed the Graseby syringe driver. I checked the new one, a MS26, this still barely infused any drug set at 06mm over 24 hours. I measured the fluid length (in the syringe) and reset the rate to 30mm (the length of the current syringe content) and got a stat dose given to the patient who was in great pain around the oesophagus. The patient was due for transfer that day. I briefed the ward as to what had happened.

Syringe incorrectly inserted

I visited at approximately 22.00hr and on arrival found patient to be very nauseous. Patient had been discharged with a syringe driver containing cyclizine 150mg for nausea and diamorphine 20mg for pain. I checked the syringe driver and found that the syringe was not attached to the driver correctly and it had not been delivering the medication. I reattached the syringe to the driver and ensured that it was then running correctly.

Syringe became dislodged from the syringe driver

Call to out of hours services due to patient in pain and agitated. Syringe driver had come apart due to movement from patient in the bed. 23ml left in driver. Syringe reloaded into syringe driver. Patient lost approximately 5 hours medication

Unexplained slow infusion

Syringe driver for above patient commenced 14:20 hours. Called out on night service to administer stat doses, as patient agitated and pain expressed. Syringe driver checked, satisfactory no tissuing or inflammation - appeared to be running satisfactory. Approx 9mls in syringe, should have run through by half [by] twelve hours later to being set up, 15mls originally in syringe at a rate of 45 correct rate, (should be down to 7.5mls). Unable to re start as no Diamorphine available in home.

Tampering by patients

Patient received 12 hourly morphine pump in situ which was set up at 16:00hrs and due to be changed at 04:00hrs. At 23:30hrs, patient approached nurses to advise his morphine pump was completed and needed changing. When checked, the syringe was empty. Patient admitted pushing the remaining morphine in.

Confusion over mm and ml

The patient had a paediatric syringe driver set up as there were no adults pump available. It contains 150 mg in 15 ml to run over 24 hrs. The pump settings were calculated using mls / hr instead of mm / hr and consequently, the infusion went in 9 hours.

Unexplained failure to deliver infusion

I visited patient as arranged to replenish her syringe driver to find that 5mls was still in the syringe. The machine appeared to have stopped. I pressed the boost button and it restarted. The patient had taken Oramorph, but she was complaining of nausea so I gave her Metoclopramide 10mgs s/c, as prescribed. She was still in pain at 10.30am so I gave her Diamorphine 2.5 mg s/c as prescribed. This lady was admitted to a hospice later that day.

3. Alternative devices

Until recently, there have been few ambulatory syringe driver pumps with safer designs. Alternative devices are now available that have rate settings in ml per hour and additional safety features, including lock functions, additional alarms, and event logs.

Technical features recommended by IEC Standard 60601-2-24 1998¹ can be found in Appendix 4 (page 14). The Centre for Evidence based Purchasing (CEP) has also produced a purchasing guide for these devices⁸, which highlights many of the issues that should be considered before choosing designs of syringe drivers for purchase.

4. Cost implications

Cost implications for equipment replacement within individual organisations will depend on a number of factors including:

- the number of mm-calibrated and ml-calibrated syringe drivers that they have in use currently;
- the remaining life expectancy of older devices;
- the period over which the organisation plans to phase replacement.

Longer periods of transition (for example five years) will reduce cost, as devices would generally only be replaced at the end of their expected functional life. However, prolonging the use of both types of devices increases the risk of confusion and therefore error.

Training staff on the new ml-calibrated equipment will also involve additional costs, although some training may be delivered by manufacturers of purchased devices as part of the purchasing agreement. Training may be required both for those prescribing medication (who

may have adopted prescribing styles specific to mm-calibrated devices) and those responsible for administering the prescriptions.

The average cost difference between mm-calibrated ambulatory syringe drivers and ml-calibrated devices is currently estimated at around £90 to £125; depending on order volume and negotiation.⁸ Maintenance costs and battery costs also need to be considered, however these were found to be very similar between the different types of syringe drivers.⁸ The newer devices need to be correctly configured to a standard defined by the organisation. This requires some additional equipment and technical expertise for medical/clinical engineering departments. Software updates also need to be managed and may require additional consideration in local protocols and through negotiation with the device supplier.

Ambulatory syringe drivers have often been purchased by charitable funds and as memorials for patients who benefitted from palliative care. Any replacement of these devices will therefore need to be considered with sensitivity.

Special considerations

In the case of paediatric patients, the size of the driver is an important factor. The newer devices are larger than the older style drivers and this should be considered when a decision is made on which device to purchase.

5. Risk reduction during transition

Ambulatory syringe drivers calibrated in ml are already in use and because patients transfer between settings with their equipment attached, the risks of confusion between designs are already present. However, as healthcare organisations work through a period in which different designs are in use but the proportion of ml per hour devices increases, they need to consider all possible steps to reduce the risks during transition. Key issues to consider include:

- balancing the costs of a rapid transition with the risks of a prolonged one;
- collaborating with other local providers who may provide care at different stages of patients' terminal illness;
- considering phasing replacement e.g. per hospital site or community team;
- ensuring theoretical and practical training and appropriate competencies and expert support is in place before newer designs of equipment are introduced into clinical practice.

While mm calibrated ambulatory syringe drivers remain in use, all appropriate measures to reduce the risk should continue to be taken.

6. Summary and conclusion

Review of the NRLS database has revealed that incorrect operation of ambulatory syringe drivers can lead to patient harm and even death. The use of mm-calibrated syringe drivers and a lack of in-built safety design features on older models were shown to be important contributory factors to many of the incidents reported. The transition to ml per hour designs of syringe driver is therefore recommended and is already underway in many organisations. The NPSA also recommends that healthcare organisations providing NHS-funded care actively manage the transition between driver models by setting a target date for completion of transition. In the interim, risk should also be actively managed.

7. References

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Appendix 1: Summary of rationale for suggested actions

An executive director, nominated by the chief executive, working with the clinical users and procurement personnel should:

Action	Rationale
<p>1. Develop a purchasing for safety initiative that considers the following safety features before ambulatory syringe drivers are purchased:</p> <ul style="list-style-type: none"> a) rate settings in millilitres (ml) per hour; b) mechanisms to stop infusion if the syringe is not properly and securely fitted; c) alarms that activate if the syringe is removed before the infusion is stopped; d) lock-box covers and/or lock out controlled by password; e) Provision of internal log memory to record all pump events. 	<p>The problem of confusion when setting infusion rates in mm of plunger travel is demonstrated by the reports to the NRLS described above. Making use of standard ml per hour rates for infusion will reduce the complexity of calculations and avoid 'calculation by rote'.</p> <p>The additional functions and alarms ensure any problem can be identified and rectified at an early stage.</p> <p>Covers and lock-outs reduce the likelihood of accidental changes or tampering.</p> <p>An internal memory makes it possible to investigate error events.</p>
<p>2. Agree an end date to complete the transition between existing ambulatory syringe drivers and ambulatory syringe drivers with additional safety features (as soon as locally feasible, and within no more than five years)</p>	<p>Although there is a need to address the risks posed by older designs of syringe driver, there will be a need for careful budget and risk management planning. Realistic timescales are likely to vary between healthcare providers, dependant on how far they have already purchased newer designs and the number of devices needing replacement and numbers of staff who need training. As these devices have a life of about five to seven years, many of the current devices could be replaced through normal wastage within a five-year timeframe.</p>
<p>3. Take steps to reduce the risks of rate errors while older designs of ambulatory syringe drivers remain in use based on a locally developed risk reduction plan which may include: raising awareness, providing information to support users with rate setting, and using lock-boxes.</p>	<p>While mm-calibrated devices without a full range of alarm functions remain in use, healthcare organisations should continue to take all reasonable steps to reduce the risks of human error. Additional lock-boxes can be purchased separately from all manufacturers.</p>
<p>4. Take steps to reduce the risks during any transition period when both types of design are in use, including:</p> <ul style="list-style-type: none"> a) reviewing and updating policies and protocols to include the use of all designs of ambulatory syringe driver in local use; b) revising user training programmes to include the safe operation of all designs of ambulatory syringe driver in local use. 	<p>mm-calibrated devices have been dominant for over 25 years and the processes for setting up the newer designs of ml per hour devices are significantly different. Organisations need to plan the period of transition to ensure users are fully aware of these differences and competent in the use of all designs of syringe drivers they are likely to encounter.</p>

Appendix 2: Suggested compliance checklist

Action	Suggested Evidence of Compliance
<p>1. Develop a purchasing for safety initiative that considers the following safety features before ambulatory syringe drivers are purchased:</p> <ul style="list-style-type: none"> a) rate settings in milliliters (ml) per hour; b) mechanisms to stop infusion if the syringe is not properly and securely fitted; c) alarms that activate if the syringe is removed before the infusion is stopped; d) lock-box covers and/or lock out controlled by password; e) provision of internal log memory to record all pump events. 	<p>Agreed, documented strategy ratified by an NHS organisation's governance committee and senior professionals, such as clinical risk managers, purchasing managers and clinical engineering managers.</p>
<p>2. Agree an end date to complete the transition between existing ambulatory syringe drivers and ambulatory syringe drivers with additional safety features (as soon as locally feasible, and within no more than five years)</p>	<p>As above, with agreed end date to complete the transition; within no more than five years from the publication date of the RRR.</p>
<p>3. Take steps to reduce the risks of rate errors while older designs of ambulatory syringe drivers remain in use, based on a locally developed risk reduction plan which may include: raising awareness, providing information to support users with rate setting, and using lock-boxes.</p>	<p>Documented risk assessment and record of actions taken, for example, purchase of lock-boxes and calculation proformas issued to wards.</p>
<p>4. Take steps to reduce the risks of a transition period when both types of design are in use, including:</p> <ul style="list-style-type: none"> a) reviewing and updating policies and protocols to include the safe operation of all designs of ambulatory syringe driver in local use; b) revising user training programmes to include the safe operation of all designs of ambulatory syringe driver in local use. 	<p>Documentation (for example meeting notes or policy documents) to confirm that existing policies, procedures or protocols, (printed or electronic), referring to the use of syringe drivers in current use in the organisation have been reviewed and if necessary updated and approved. Documentation indicating clear lines of responsibility and timescales for any further amendments as new designs of equipment are purchased.</p> <p>Content of local training courses and/or competency assessments and printouts from a log or database that can be used to track the updated training for all existing users and that records training for all new users of these drivers.</p>

NOTE that this RRR can be recorded as 'action completed' on the Central Alerting System once all the actions above have been completed. There is no need to wait until the locally agreed date for finalising transition between device types.

Appendix 3: NRLS search strategy

All incidents reported between 1 Jan 2005 and 30 Jun 2010 and including any of the following in the free text fields:

Graseby MS26

Graseby MS16A

Graseby MS16 A

Graseby syringe infusion system

Graseby syringe pump

Graseby driver

Graseby

Subcutaneous syringe driver

micrel syringe driver

mp101

mp100

mpdaily

"syringe pump" or "syringe driver" in combination with the term "diamorphine"

Appendix 4: International recommendations (BS EN/IEC60601-2-24 Standard)

The current standard for syringe drivers is BS EN60601-2-24¹. It is related to the general standard on medical devices, BS EN60601-1 which covers many aspects of all medical devices and BS EN60601-1-2 the associated standard that deals with electromagnetic compatibility. The BS EN60601-2-24 standard is specific to “*Particular requirements for basic safety and essential performance of infusion pumps and controllers*”. Most of the standard relates to the various tests for ensuring that the basic requirements are met.

BS EN60601-2-24¹ identifies five separate types of infusion device:

- Type 1: continuous infusion flow only
- Type 2: non-continuous flow only
- Type 3: discrete delivery of a bolus
- Type 4: type 1 combined with type 3 and/or type 2 in the same equipment
- Type 5: profile pump (controlled infusion by means of a programmed sequence of rates).

Ambulatory syringe drivers fall into the ‘Type 4’ category.

BS EN60601-2-24¹ also defines a syringe pump as:

“Equipment intended for controlled infusion of liquids into the patient by means of one or more single action syringe(s) or similar container(s) [e.g. where the cartridge is emptied by pushing on its plunger] and in which the delivery rate is set by the operator and indicated by the equipment in volume per unit of time”.

An ‘infusion pump for ambulatory use’ is defined as “*Equipment intended for the controlled infusion of liquids into the patient and intended to be carried continuously by the patient.*”

Clause 54.101 deals with the fitting and removal of syringes and states that the device should not allow the infusion to begin if the syringe is not properly and securely fitted. The pump should also alarm if the syringe is removed before the infusion is stopped.