Design for patient safety

A guide to the design of infusion devices

Edition 1
2009
About this publication

This booklet is one of a series of design publications produced by the National Patient Safety Agency (NPSA). Other publications in the Design for patient safety series:

NPSA in collaboration with the Royal College of Art Helen Hamlyn Centre:
A guide to labelling and packaging of injectable medicines (2008)
Future ambulances (2007)
The design of infusion devices (in progress)

NPSA in collaboration with Lucid Design:
A guide to the design of dispensed medicines (2007)
A guide to the design of the dispensing environment (2007)

Research and Methodology

This publication is based on the results of a design research collaboration between the NPSA and the Royal College of Art Helen Hamlyn Centre (HHC), London.

The study was carried out over a one-year period by Sally Halls, a postgraduate specialist in medical design, working to a brief set out by the NPSA and the HHC. Existing design guidance was reviewed and consultations were undertaken with experts in graphic and information design, and design for patient safety. Technical support was provided throughout the project by David Cousins, Head of Safe Medication Practice, NPSA.

A wide range of stakeholders contributed to the research, including patients, healthcare professionals, NHS organisations, the Medicines and Healthcare products Regulatory Agency (MHRA) and industry personnel.

Observational research was undertaken in clinical environments, such as critical care areas, wards and pharmacies. The outcome was a design rationale to enhance patient safety and a fully illustrated set of design considerations with both good and bad examples.
Foreword

To be added later.
Introduction

Fifteen million infusions are performed in the NHS every year. The vast majority are delivered safely. However, at least 700 unsafe incidents are reported each year, of which 19 per cent are attributed to user error. In the 10 years between 1990 and 2000 there were 1495 incidents involving infusion pumps alone in the UK.

In 2004 the National Patient Safety Agency published a patient safety notice on infusion devices to reduce the risk of patient safety incidents involving infusion devices. The Safety Notice made recommendations concerning:

- how purchasing decisions on infusion pumps should be made in NHS organisations;
- the importance of evaluating the necessity for an infusion device before it is purchased;
- the need to reduce the range of infusion device types in use and, within each type, have agreed default configurations;
- the benefits of establishing a centralised equipment library.

The NPSA published a toolkit to help NHS organisations review their existing device management systems, as well as assess the potential for significant cost benefits and improved patient safety and an evaluation report on this safety initiative piloted in six hospitals.

Design for patient safety: infusion devices is the first guidance published that focuses on the safe design of infusion devices including infusion pumps and syringe drivers used in hospital and ambulatory care.

This publication illustrates how design can be used to change and make safer the use of infusion devices in practice. It is intended as a best practice guide to be used by infusion device developers in medical devices companies as well as a reference guide for those involved in the procurement of medicines in the NHS.

The Department of Health, Design Council report published in 2003, Design for Patient Safety, acknowledged that the use of design in other safety critical industries had produced significant improvements in safety, quality and efficiency. The report recommended that a similar approach be taken within healthcare.

Human beings usually make mistakes because the systems, tasks and products they work with are poorly designed. Effective design can deliver systems, products that are intuitive, simple to understand, simple to use and mistake-proofed.

Mistake-proofing is the use of process design to facilitate correct actions, make wrong actions more difficult, make it easier to discover errors that occur, and make it possible to reverse or undo incorrect actions. Mistake-proofing tends to be inexpensive, very effective, and based on simplicity and ingenuity.

Review of Infusion Device Technology and Evidence Based Purchasing

The Centre for Evidence-based Purchasing (CEP) is part of the Policy and Innovation Directorate of NHS PASA. CEP underpins purchasing decisions by providing objective evidence to support the uptake of useful, safe, innovative products and related procedures in health and social care.

CEP Buyer’s guides include one or more of the following elements:
- technology overview
- market information
- decision trees
- comparative specifications
- whole life costing
- cost/benefit analysis
- adoption guidance
- sustainable procurement
- reliability analysis.

CEP have published buyers guide reviews on some infusion devices and more are planned in the future:
- Evaluation report, Hospira Plum A+ volumetric infusion pump, CEP 07014, October 2007

Planned Publications:

The Medicines and Healthcare Product Regulatory Agency (MHRA) in collaboration with the Bath Institute of Medical Engineering publish evaluations of infusion devices.

The MHRA also publishes medical device alerts concerning infusion devices.
Advisory Panel

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Craig Davey | Centre Manager, BiME Evaluation Laboratory
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Shakira Watts | ITU Nurse Educator, Imperial College Healthcare NHS Trust
Background information

To be added later.
User Testing

Stakeholders are invited to provide details of user testing for infusion devices.
1

Hardware design
1.1 Physical dimensions

**Issues**
- Consideration is not given to the maneuverability of the pumps, leading to bulky and heavy equipment.
- The pump size/shape is not suitable for its application.
- Pump are awkward to hold and handle.
- Attaching devices to stands can be very cumbersome, particularly if there is more than one device already loaded onto the stands. Pole clamps may also be too small to fit around the stand.

**Recommendations**
- Products should be developed with users, to ensure that they are of an appropriate size, shape and weight.
- Different sizes and shapes may be more suited to different applications. For example, an ambulatory device needs to be small and portable, but may be too small for hospital use.
- Pumps should have handles positioned to aid lifting and transport.
- Design the device to be able to be attached to the dripstand as easily as possible. Consider the ergonomics and logistics of holding the device whilst operating attachment mechanisms.
- Consider the addition of mini fluid stands to aid transportation.
1.2 Durability

**Issues**
- Pumps are not designed for the rough treatment they receive in hospitals, where they are often dropped.
- Pump surfaces are not sealed against fluid ingress.

**Recommendations**
- Products should be tested for durability. A pump should be able to be dropped from bed height without significant damage occurring. Manufacturers should consider ways of alerting the user that the pump has previously been dropped and may malfunction.
- Surfaces should be sealed such that they are able to be wiped with a wet cloth without undue harm occurring to the pump.
1.3 Pump stand

Issues

• Pump stands are not designed to hold stands and can be unsteady and inclined to topple over.

• Consideration is not given to the manoeuvrability of the stands, and makes movement very awkward for patients.

• Base units can make pump stands heavy and cumbersome.

Recommendations

• Stands should consider the additional weight that pumps add to the stand, and be designed accordingly. They should also specify how many pumps can be safely mounted. Refer to the British Standards for guidelines on stability.12

• Manufacturers should consider ways of aiding the pump attachment process. Docking stations may be a suitable option.

• Consider the incorporation of power sockets to facilitate battery management.

• Add handles to the stands to aid patient movement. Larger wheels can also help navigate over uneven floor surfaces.

• Consideration should be given to the manoeuvrability of stands, particularly with regard to the needs of mobile patients.
1.4 Use of colour and labelling of pumps

Issues

• Colour is used as an identifier without additional visual indicators.

• Poor use of colour and design can increase the risk of miselection of infusion devices.

• The overuse of colour creates overwhelming interfaces.

• Colour application has not considered the needs of colour blind users.

Recommendations

• If colour is used as an identifier, there should be an additional differentiator such as text, to emphasise this difference.

• Use the colour yellow to denote spinal & epidural infusions. Text should be added to emphasise this difference.

• Colour should be used judiciously to highlight key information.

• Consider the requirements of colour blind users when applying colour.
1.5 Power

**Issues**

- It can be unclear whether a pump is plugged into the main supply.
- The level of battery charge is often ambiguous. This may lead to pumps cutting out mid-transfer, with the consequential delay to patient treatment.
- Power cords may be inadvertently pulled out when the pump is in use.

**Recommendations**

- Pumps should notify the user when they are not plugged into the mains supply. Depending upon the application of the pump, for example in ICU wards, it should require the user to confirm this state.
- Pumps should give a good indication of battery life. This should be expressed in hours and minutes.
- The battery indicator light should flash if the pump is running on the battery power.
- Consider how to prevent power cords being pulled out. Take care to provide for the needs of the patient as well as the user.
1.6a Loading and priming infusion pumps

**Issues**

- It can be unclear if an administration set has been correctly loaded into the pump.
- Lines may not be primed before beginning the infusion.
- Lineloading can be an awkward, complex process with very little signposting to aid the user. Horizontal feeds can be particularly confusing, as the line may go from right to left, or left to right.
- In-line cassettes can complicate lineloading processes.
- Fitting lines into multi-channel pumps may cause confusion, particularly as to where each line goes.
- Fluid may leak from the bags into the pump, causing the pump to fail.
- It can be ambiguous as to which way horizontally loading administrations sets should be loaded into the pump.

**Recommendations**

- Loading mechanisms should be designed such that incorrect installation is extremely difficult. It should be immediately apparent when a line has been misloaded, with a corresponding alarm message on screen.
- Clear instructions should be visible to the user for the lineloading process. The vertical loading of administration sets is more instinctive than horizontal loading. There should always be an indication as to the direction of the fluid flow to prevent confusion.
- Cassettes should be easy to install in the pump. Good design should indicate the orientation of the cassette, and aid its installation.
- Multi-channel pumps should clearly indicate which channel operates which medicine. Lineloading processes should be as simple that of single channel pumps.
- Pumps should be sealed to prevent fluid contamination and aid cleaning.
- Pumps should prompt the user to prime the line and provide functionality to aid this process.
1.6b Loading and priming syringe pumps

**Issues**

- Fitting the syringe into the pump can be a complex and unwieldy process.
- The syringe and plunger may not be secured into the pump, potentially allowing the entire contents of the container to freeflow into the patient.
- The syringe driver may not be calibrated for the make and size of syringe used.
- The syringe and giving set may not be adequately purged, with the consequential mechanical backlash delaying treatment.

**Recommendations**

- The syringe loading process should be simple and able to be performed by users with limited dexterity. Simultaneous actions should be avoided where possible.
- The pump should be designed to ensure that the syringe and plunger cannot disengage. It should also have corresponding alarms to alert the user to potential free flow.
- The driver should allow for easy calibration of the make and size of syringe. It should also be simple to change the settings if the auto-sensing detects the wrong syringe.
- The pump should prompt the user to prime the line and reduce any mechanical backlash.
1.7a Device controls - numeric keypads

Issues

- Infusion pumps use different layouts for numerical keypads, causing confusion amongst users.
- The keypad layout may be rearranged, placing the ‘0’ and ‘.’ in unexpected places.

Recommendations

- Tests found that staff are more familiar with the telephone layout, where the number ‘1’ is in the top left corner. This layout should be used on all devices.
- The numerical layout should not be altered. The ‘0’ and ‘.’ should always be positioned below the rest of the numbers.
1.7b Device controls - other buttons

Issues

- It can be unclear what function soft keys perform or what figures they correspond to.
- It can be ambiguous which figures arrow keys refer to.
- The start and stop functions may be provided by one button, which may cause ambiguity as to which operation is being invoked.
- Numerous keypresses may be required in order to reach a particular desired function.

Recommendations

- It should be clear what action controllers perform.
- Space controls intelligently and ensure that there is sufficient space between them.
- Start and stop should be two distinct buttons. Key buttons such as the bolus, start, stop and on/off buttons should be positioned away from the main group of buttons.
- Consider grouping buttons of similar functions together.
- Minimise the number of key presses required to perform any function.
1.8a Symbols - ISO standards

Manufacturers are increasingly replacing text with symbols on their device controls. This enables one product to be marketed to many countries and overcomes many of the different language requirements.

**Issue**

- The use of symbols introduces new risks as symbols may be poorly understood by users. Some symbols have been included in ISO 60878. However, the meaning of these symbols is not always intuitive or well known by healthcare users.

**Recommendation**

- It is recommended that manufacturers add text labels to symbols until the meaning of the symbols are universally recognised by users.
1.8b Symbols - manufacturer variations

Issue

- Manufacturers devise their own symbols for device controls in addition to using ISO standards symbols. Non standard symbols may be misunderstood by users.

Recommendations

- Symbols need to be tested with users in context. There is an ISO standard for developing and testing symbols with users.\(^\text{14,15}\)

- It is recommended that manufacturers add text labels to symbols until the meaning of the symbols are universally recognised by users.

- The on/off button should be the only button with 2 functions. In line with MDA requirements, turning off the pump should be a 2 step process requiring confirmation from the user.

- Use green as an additional indicator for the start button.

- Use red as an additional indicator for the stop button.

- Use 3 arrows to indicate the bolus function and avoid confusion with rewind/fast forward icons.

- Keep icons simple and minimalist. Remove any unnecessary graphics where possible.

- Where abstract icons are used, use labels to help identify the button.
1.9 Display screen

Issues
- Screens are too small to be able to display the key information properly.
- Screens cannot be seen when interacting with pumps due to the screen angle.
- Light reflections can impede legibility of information.
- Screens cannot be read in dark lighting conditions.

Recommendations
- Screens should be large enough to display the key information without causing user confusion.
- Consideration should be given to the visibility of screens when pumps are stacked. Tilt the screen towards the user where possible.
- Use non-reflective finishes to reduce reflections.
- Screens should have variable backlighting settings to maximise usability and patient comfort.
- Consider the use of screens with a black background and white numerics. These can be more visible in all lighting conditions than other types of screens.
1.10 Touchscreens

**Issues**

- Touchscreens are usually operated with a finger. Touchscreen controls may be too small to be easily selected and operated using a finger.
- Keying in many numbers or letters by finger pointing is tiring.
- Buttons are touched to provide information, provide options and initiate action. Unintended action may be initiated whilst reviewing information and selection options.

**Recommendations**

- Points of interaction should be clearly identifiable without the need to clarify these by activation.
- Points of interaction should be large enough to be pushed by a finger. The minimum size of vital buttons should be 2cm wide with 1mm spacing in between. Buttons should not be less than 12mm wide. \(^1\)\(^2\)
- Create invisible active areas around buttons in case the finger is not correctly positioned. Leave at least 1mm of inactive space between buttons.
- Group buttons of similar function together to streamline hand movement.
- Action buttons should be positioned at the bottom of the screen so that consequences are not obscured by the hand or arm.
- Some touchscreen technologies are less reliable at screen edges. Position buttons in from the edge or make them larger to compensate for this.
- The software should be error tolerant and allow the user to backtrack easily. Using a lift-off tapping strategy instead of a land-on strategy allows for greater accuracy.
- Use a list selection option where possible to avoid many button presses and user fatigue.
- Create tactile feedback for the user. Non-audible methods are preferred.

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**Downstream occlusion values**

<table>
<thead>
<tr>
<th>Flowrate ml/h</th>
<th>Minimum</th>
<th>Moderate</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;32</td>
<td>2</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>32-150</td>
<td>4</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>&gt;150</td>
<td>6</td>
<td>11</td>
<td>15</td>
</tr>
</tbody>
</table>

**Alarm sensitivity**

- **Low**
- **74**
- **High**

**Software**

- Error tolerant
- Backtrack easily
- Lift-off tapping strategy
- User fatigue avoidance
- Tactile feedback
- Non-audible methods preferred
1.11 Alarms

**Issues**

- It can be hard to identify which piece of equipment is alarming. Particularly in intensive care wards, where equipment may be stacked up.

- Patients in isolated rooms with alarming pumps may not be noticed by nursing staff.

- Abbreviated warning messages lead to confusion in how to rectify the situation.

- Alarms don’t indicate the urgency of the situation.

- It is possible to silence the alarm situation by pressing keys other than the alarm silence key.

**Recommendations**

- Alarms should be clearly visible as well as audible.

- Consider the possibility of alarms signalling to pagers or radio signals. This would allow for a quieter alarm at the patient’s bedside, and a louder alarm with the user.

- Alarm messages should be in clear simple English (or the language of the country).

- Differentiate between an alert and an alarm, through the use of different colours and audio rhythms.¹⁵

- When drug libraries are in use, consideration should be given to the different toxicity levels of drugs being dispensed so that a saline infusion receives a lower alarm status than a cytotoxic.

- Users should only be able to silence the alarm by pressing the alarm silence key and/or rectifying the cause of the alarm.
1.12 Cleaning

Issues

• Pumps are cleaned daily, but poorly designed pumps take longer to clean.

• Moisture may get into the pumps and contaminate the working mechanics.

• Sensors become dirty but poor device design prevents them from being cleaned.

• Incidence of super viruses are increasing in hospitals, leading to a higher risk of cross infection between patients.

• Pumps may have to be cleaned whilst in operation, but controls may be knocked accidentally.

Recommendations

• Pumps should be designed to have smooth surfaces, with filled corners and no crevices. IT connections should be recessed into the pump. Where grooves are necessary (for example with heat sinks) make these large enough to be easily cleaned.

• Pump surfaces should be impermeable to moisture and be fitted with watertight seals.

• Sensors should be designed to enable access for cleaning purposes.

• Consider the use of bacteria-resistant coatings.

• Incorporating keypad locks into devices can help prevent accidental knocks from occurring.
1.13 Maintenance

Issues

• Maintenance prompts are provided by stickers, which get worn away and lost in the visual clutter of the pump.

• Items that require regular access such as batteries, cannot be easily accessed by maintenance staff.

Recommendations

• When pumps are due for maintenance they should prompt the user with an onscreen warning. Pumps should not function when they require servicing.

• Pump designs should facilitate simple maintenance procedures such as changing batteries and cleaning sensors. Simple designs create simple maintenance procedures, and minimising part numbers can also make repairing easier.
1.14 Pump storage

Issues

• Pump storage is disorganised and chaotic, leading to device mismanagement.

• Pumps are left unplugged when not in use, leading to flat batteries.

Recommendations

• Hospital trusts should have central storage units implemented, where pumps are sent to be serviced, maintained and stored.

• Consider ways of ensuring devices are plugged in whilst in storage. Potential solutions may be alarms of docking stations.

• Consider ways of tracking devices throughout a trust. For example the incorporation of RFID technology can help to easily locate a device, and even prompt the pump to change its personality settings with location.
Software design
2.1 Layout - essential information

**Issues**
- Users cannot readily find the information they require as emphasis is given to less important data.
- It can be difficult to ascertain what a pump is doing.
- Screen layouts are cluttered with information clustered around the edges of screens.

**Recommendations**
- Highlight the information most readily required by the users of the pump. They need to be able to see:
  - Drug name and concentration (where applicable)
  - Flowrate
  - Device status (infusing/stopped/standby)
  - Time remaining/Volume to be infused
  - Volume infused / Total volume infused
  - Mode of delivery - continuous, PCA, KVO
  - Device status (Infusing, stopped, standby)
  - Power supply (mains/battery, battery life)
  - Occlusion pressure levels
- There should be a clear visual indicator of whether a pump is on and of what it is doing.
- Key information should be positioned in the centre of the screen.
2.2 Fonts and text

**Issues**
- Text is written in small font sizes that are hard to read.
- Text can be hard to read when written in capital letters.
- Similar words/drugnames may be confused with each other.
- Words may be abbreviated into unintelligible words.
- Terms are used that may be misunderstood or confused e.g. ‘proximal and distal’.

**Recommendations**
- Use clear legible anti-aliased fonts, in large font sizes. Numbers after a decimal point should be in a smaller font size.
- Use sentence case.
- Use tallman lettering to distinguish between drugs with similar names.
- Use clear, simple English that can be easily understood.
- Avoid using terms such as proximal and distal that may not be understood. Terms like downstream and upstream are better.

**NB**
Distortion occurs when high resolution graphics are displayed on a low resolution screen. Anti-aliasing is the technique of minimising this distortion and thereby maintaining legibility.
2.3 Pump configuration and personalities

Pump configuration or personalities enable default rate, volume, air and occlusion detection, drug settings and displays to be set for different patient types and clinical areas of use. Pumps may also be configured for continuous, patient control, intermittent and background infusion.

From time to time device manufacturers release new versions of device software to correct software faults and provide new functionality. These settings assist the safe and effective use of new versions of device software to correct

**Issues**

- It is often not clearly displayed which configuration, personality or software release is operating in the device.
- The default settings of each personality are not always displayed or understood by users.
- Infusion devices may move between clinical areas and be used for different patient groups. The configuration, personality and software version that helps to ensure safe use in one clinical area and group of patients, may increase risk in another area with different patients.
- Pumps are often moved to different patients and areas that require other personalities.

**Software versions, configuration and personality setups should be clearly displayed.**

- The default settings of the different personalities should be made clear to the user.
- Hospital trusts should give great consideration to the way that pump personalities are managed. If pumps are frequently moving between different care areas they may want to consider not using personalities and having one standard setting. Alternatively, a trust may wish to allow authorised users as well as clinical engineering staff to be able to change the personality settings. Manufacturers should discuss the different options with the trusts to best provide for their varying requirements.
- In future these configurations may be controlled by wireless signals. For example, a pump would automatically configure to its paediatric settings when brought into a paediatric area. Or a critical care configuration would change to a general ward area set-up if the device is moved from the critical care environment. This will help to ensure that the pump is always operating with the correct personality, and help to minimise risk to the patient.

**Recommendations**

### Table 2.3: Pump configurations and personalities

<table>
<thead>
<tr>
<th>Clinical Area</th>
<th>Flowrate (ml/h)</th>
<th>Total Volume to be infused (ml)</th>
<th>Volume infused (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General ward</td>
<td>4</td>
<td>500</td>
<td>21.3</td>
</tr>
<tr>
<td>Critical care</td>
<td>4</td>
<td>500</td>
<td>21.3</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>4.1</td>
<td>500</td>
<td>21.3</td>
</tr>
</tbody>
</table>

**General ward**

- Flowrate: 4 ml/h
- Total volume to be infused: 500 ml
- Volume infused: 21.3 ml

**Critical care**

- Flowrate: 4 ml/h
- Total volume to be infused: 500 ml
- Volume infused: 21.3 ml

**Paediatrics**

- Flowrate: 4.1 ml/h
- Total volume to be infused: 500 ml
- Volume infused: 21.3 ml

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4.1 ml/h

**Flowrate**

- Total volume to be infused: 1.3 ml
- Volume infused: 10 ml

**Flowrate**

- Total volume to be infused: 1.3 ml
- Volume infused: 10 ml

**Flowrate**

- Total volume to be infused: 1.3 ml
- Volume infused: 10 ml
2.4 Setting up an infusion

**Issues**
- Instructions can be unclear or hidden.
- Programming may be a lengthy and unwieldy process, with very little information conveyed to the user as to the end of the process.
- Prompts and roadmaps are absent, leaving the user lost and confused.
- The user may become overwhelmed by too many options being displayed.
- It can be unclear what mode a pump is operating in, which may have completely different settings assigned to it. Modes can also be very difficult to exit or change.

**Recommendations**
- **Order of basic information entry** -
  1. Select mode (where appropriate)
  2. Select drug (label AND dosage checking)
  3. Enter volume
  4. Enter rate of administration, ml/h, or time to be delivered, hr:min.
- Instructions should be clearly highlighted on screen, particularly those requiring the user to press start or stop.
- The number of steps required should be kept to a minimum. Indicate to users how many steps there are, and how far through the programming process they are.
- Use prompts and menus to cue the user about important steps.
- Show only the minimum options necessary.
- There should be clear indicators as to what mode the pump is operating in. It should be very clear how to exit or change the mode.
2.5 Feedback and communication

Issues

- Ambiguous displays may lead users to believe that the pump is performing an action that it's not.
- Users may become confused about whether an action has been carried out by the pump.
- It may be unclear as to whether a button press has been registered by the pump.

Recommendations

- Users should be given continual feedback as to what the pump is doing.
- Users want to know that a command is being carried out. If it can't be carried out then they should be informed why.
- Buttons should give tactile feedback to the user, to confirm that the button action has taken place.

**OCCLUSION ALARM**
- HIGH
- MEDIUM
- LOW

Choosing reverts to main screen. No indication of alarm level selected.

Main screen

Alarm response:
- Slow
- Normal
- Fast

Normal alarm response time selected.

Main screen
2.6 Error recovery

**Issues**

- Users may not be able to exit from an error message, resulting in them turning the pump off and on again.
- Users cannot rectify a mistaken keypress.
- Users cannot exit back to the main screen without changing settings.
- Data can be easily deleted in error.

**Recommendations**

- There should be clear instructions on screen as to how to rectify an error.
- It should be clear to users how to rectify any mistaken keypresses and return to previous screens.
- There should be a way of returning to the main screen without changing any settings. This will encourage users to explore the system and understand the system. If any settings have been changed the user should be clearly notified.
- Where an action has potentially dangerous consequences, such as deleting data like the patient history, the default action should be the cancelling option.
2.7 Shortcuts & multi-function buttons

**Issues**
- Shortcuts may create confusion amongst users who are not familiar with them. It also discourages users from exploring the pump features, for fear of causing undesirable consequences.
- Hidden shortcuts may be inadvertently activated without the user’s knowledge and cause changes to the infusion.
- Buttons that are labelled with two symbols can be confusing and hard to identify.

**Recommendations**
- Shortcuts should be avoided where possible.
- Where shortcuts must be used, the function should be confirmed by the user before operating. It should also be clear how to perform an action through the longer route.
- Buttons should have one function only and be clearly marked and identifiable.

```
[Diagram showing user interface]
```

e.g. F + [Symbol] = Bolus function

```
[Diagram showing user interface]`
2.8 Interface consistency

Issues

- The pump may behave differently in different areas of the software.

- Pumps from one manufacturer may have differing interfaces, requiring two different interfaces to be learnt by the user. This may cause confusion and error in operation and may also lead to additional time being spent training users.

Recommendations

- There should be the same user interface and operation in all areas of the software. This means that the same set of actions should produce the same response from the pump throughout the software.

- By applying consistent interfaces across a range of products, users are able to transfer a set of skills from one pump to another.
2.9 Medicine labels

**Issues**

- There is risk of pump mis-selection in a multiple device infusion system.

- Sometimes paper labels are attached to devices to identify individual infusions, but these paper labels must be removed at the end of each infusion treatment and are not always easily read.

**Recommendations**

- Medicine labels software (sometimes confusingly called drug library software) enables medicine names to be clearly displayed on the infusion device screens to help minimise device mis-selection.

- It is important for users to be made aware of the difference between medicine label software and dose error reduction software (see next page).
2.10 Dose Error Reduction Software (DERS)

DERS software alerts the user if they try to over or under infuse a specified infusion. The user will be alerted to potential over or under infusion and will have the opportunity to select a safer rate of administration for the patient.

Issues

- Users may think that the pump is using dose error reduction software when it is displaying a medicine label.
- Devices with DERS software usually have default configurations with the DERS software switched off. Consequently the DERS may not be used on these pumps in practice.
- Users are presented with traditional rate and volume of infusion screens at start-up and have to take separate actions to switch DERS on.
- Programming and configuring DERS can be a time consuming and tedious process.

Recommendations

- The pump should clearly indicate whether it is using DERS or a medicine label.
- The default configuration for infusion devices with DERS should be for the software to be on. When the device starts up, the user should be presented with the DERS medicine selection screen. Users should have to turn DERS off to obtain the traditional rate and volume to be infused screens.
- The device should have comprehensive log-analysis software, where it monitors the number of occasions where DERS alerts have been activated, and what percentage of these have resulted in a revised rate of administration. It should also monitor the percentage of infusions where DERS is switched on and off.
- It should be possible to develop and edit drug libraries and DERS on a spreadsheet based system and transfer this information to the device.
2.11 Data logging

Data logging records individual key presses and other operating events of the infusion device. Review of this data is helpful in the event of a patient safety incident to determine how the pump was operated up to and beyond the incident.

**Issues**
- Pumps may store insufficient amounts of data.
- Data may be inadvertently lost by pressing the wrong button.
- Data can be hard to access and awkward to view.
- Keypress data is not separated from DERS logging data.

**Recommendations**
- The recent ECRI report requested a minimum data log of 1000 actions, and praised pumps that could store 10,000.19
- When data is being deleted a confirmation message should come up to confirm the deleting action.
- Data should be easily downloaded to a computer and be easy to read and access.
- There should be a dedicated DERS log, which can store a minimum of 256 entries of alerts/alarms.
2.12 Future technology

**Issue**
- Infusions may be prepared in ward areas or supplied ready to administer. Users have to correctly select and connect the correct medicine, infusion device and administration set to the correct patient and programme the device accurately.

**Recommendations**
- Use of bar code technology in the future will enable infusion pumps to check and record the correct selection of the medicine, administration set and patient, and consequently set-up the appropriate dose error prevention software.
- Pumps should be enabled for wireless connectivity in order to facilitate data downloads and automatic personality profile activation. Bi-directional connectivity will be expected in the near future to enable smart software upgrades.
3
Administration sets
3.1 Administration sets

Issues

- Infusion systems may be very complex in practice. It is often difficult to identify the infusion container and infusion line with the corresponding infusion catheter.
- It can be easy to confuse administration sets. This can be especially problematic where the sets are for different routes of administration.

Recommendations

- Consider the development of different coloured lines for different routes of administration. Spinal/epidural infusions should use the colour yellow, and arterial lines should use red. Manufacturers should consider the use of different connectors on their epidural administration sets.
- Manufacturers may wish to consider the inclusion of labels with the administrations sets to promote good practice.
3.2 Anti-freeflow systems

**Issues**
- There can be a risk of uncontrolled ‘free flow’ of infusions in infusion devices.
- Administration sets can be easily removed from infusion pumps.
- Syringe plungers are not retained or may become disengaged in syringe drivers, leading to the occurrence of free flow.

**Recommendations**
- Anti-freeflow technology should be employed in infusion devices.
- Volumetric pumps should automatically engage a valve or clamp when the administration set is removed from the pump.
- Syringe drivers should ensure that the pump does not operate when the syringe driver is disengaged from the retaining clips.
Specialist pumps
4.1 Patient controlled analgesia devices

Issues
- Setting up an infusion can be a long and complex procedure.
- It may be unclear as to what mode the pump is operating in.

Recommendations
- Setting up an infusion should be a clear and simple procedure. Manufacturers should consider the provision of a default setup for PCA pumps.
- The pump should clearly indicate whether it is operating in a ‘continuous’, ‘PCA’ or ‘continuous&PCA’ mode.

An example of a PCA setup process
4.2 Devices for epidural use

**Issues**

- Users are easily confused between pumps that are being used for epidural infusions and those that are being used for intravenous infusions.

- Identical, unlabelled infusion administration sets may be used for both epidural and intravenous administration, and can be connected to the wrong route and the wrong infusion container.

**Recommendations**

- The label, colour and design of epidural infusion pumps, syringe drivers, and the infusion systems they are attached to, should clearly identify them as for epidural use only.

- The administration sets for epidural infusions should be clearly identifiable through the use of labels or colour. Manufacturers should consider the use of different connectors on their epidural administration sets.
4.3 Devices for ambulatory care

Issues

- Pumps may be large and cumbersome, making them awkward and embarrassing for patients to carry around.
- Outpatients require discrete pumps, but flashing lights may cause distress by attracting attention.\(^\text{20}\)
- It may be complicated to set up an infusion and be awkward to load the administration set.

- Some pumps are programmed in mm of syringe plunger travel per hour or per 24 hours. This can cause confusion and is prone to changes in the infusion rate.
- It can be hard to determine battery life and know when the battery will run out.

Recommendations

- Ambulatory pumps should be small and light for maximum patient comfort. This may mean that the pump is too small for on-ward use.
- Flashing lights should be concealed where possible. Consider vibratory alerts to alert the user to potential problems.
- It should be easy to set up an infusion and load the administration set.

- All infusions should be calculated and programmed in ml/hr.
- Pumps should give an indication of battery life and alert the user to waning battery power.
- Consideration should be given to the incorporation of a keylock into the pump.
Information and training for users

Stakeholders are invited to identify issues concerning the use of user manuals in practice and possible design solutions to improve safer use of these devices.
References


12. Stability in normal use, Section 24 BRITISH STANDARD BS EN 60601-1:11990, BS 5724-1: 1989


14. ISO7239 Development and principles for application of public information symbols

15. ISO/DIS 9186 Procedures for the development and testing of public information symbols


Further reading

Stakeholders are invited to recommend further reading to provide further understanding and background on this topic.