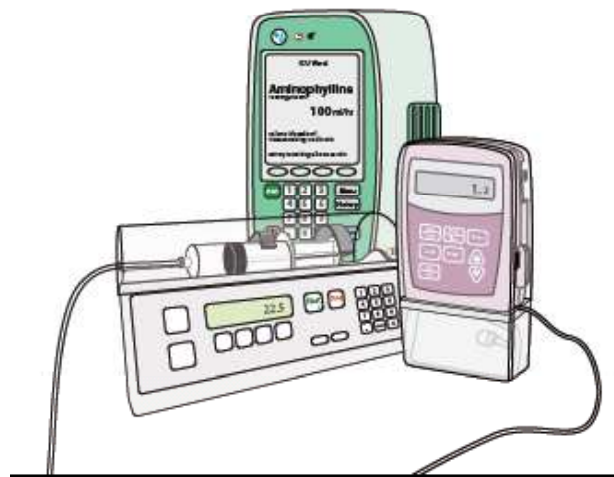


Safe Design Of Infusion Devices And Materials



Professor David Cousins

Head of Safe Medication Practice
and Medical Devices

NPSA - London



National Patient Safety Agency

National Reporting and Learning Service

The image shows the cover of a report titled 'Design for Patient Safety'. The cover is red with white text. At the top left is the Design Council logo. The main title is 'DESIGN FOR PATIENT SAFETY'. Below it, in a white box, is the subtitle 'A SYSTEM-WIDE DESIGN-LED APPROACH TO TACKLING PATIENT SAFETY IN THE NHS'. The main text describes the report as being based on a scoping study by a research team from the Universities of Cambridge and Surrey and the Royal College of Art, aimed at identifying previously unrecognised opportunities for improved patient safety in the NHS. At the bottom right is the Department of Health logo.



DESIGN FOR PATIENT SAFETY

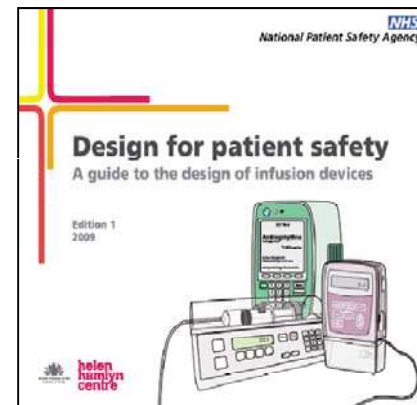
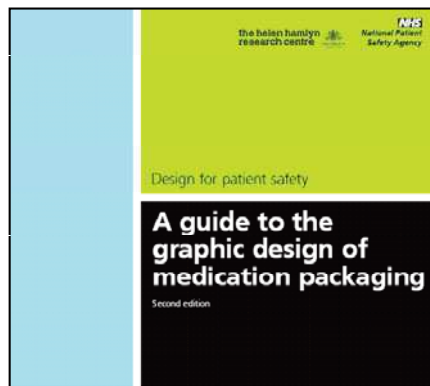
A SYSTEM-WIDE DESIGN-LED APPROACH TO TACKLING PATIENT SAFETY IN THE NHS

This report sets out a perspective from the world of design – based on a scoping study carried out by a research team from the Universities of Cambridge and Surrey and the Royal College of Art – to identify previously unrecognised opportunities for improved patient safety in the NHS.

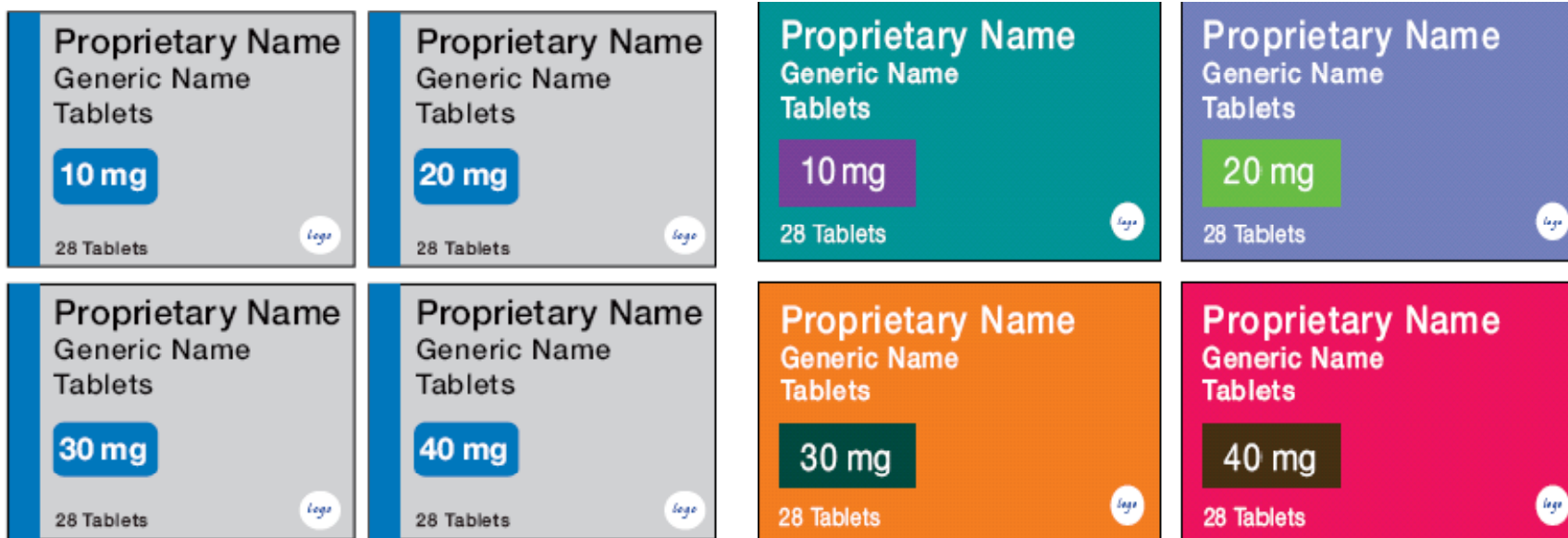




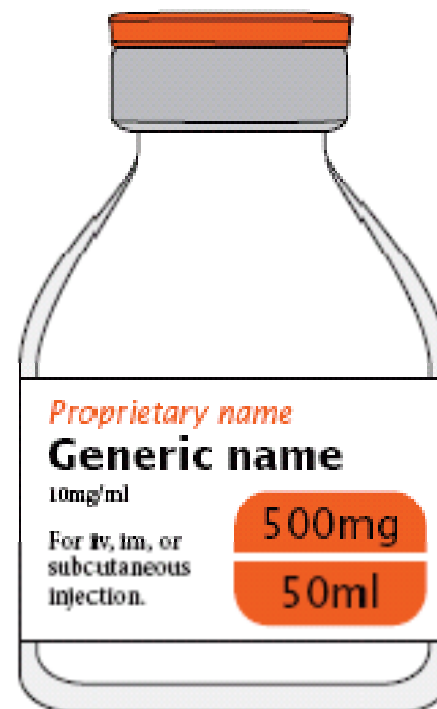
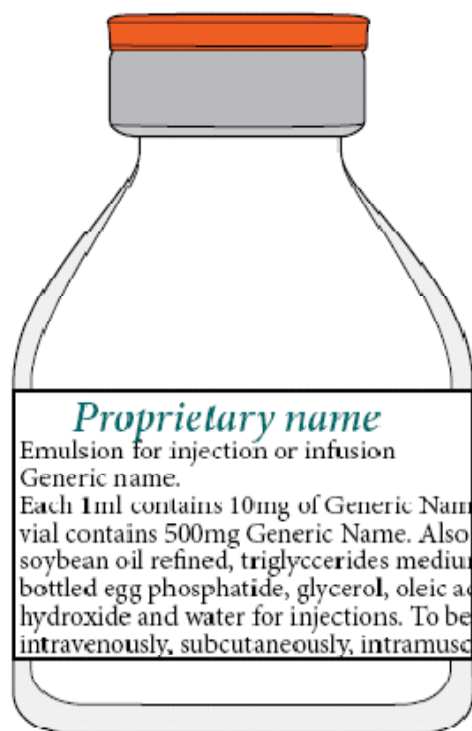
Design For Patient Safety Series



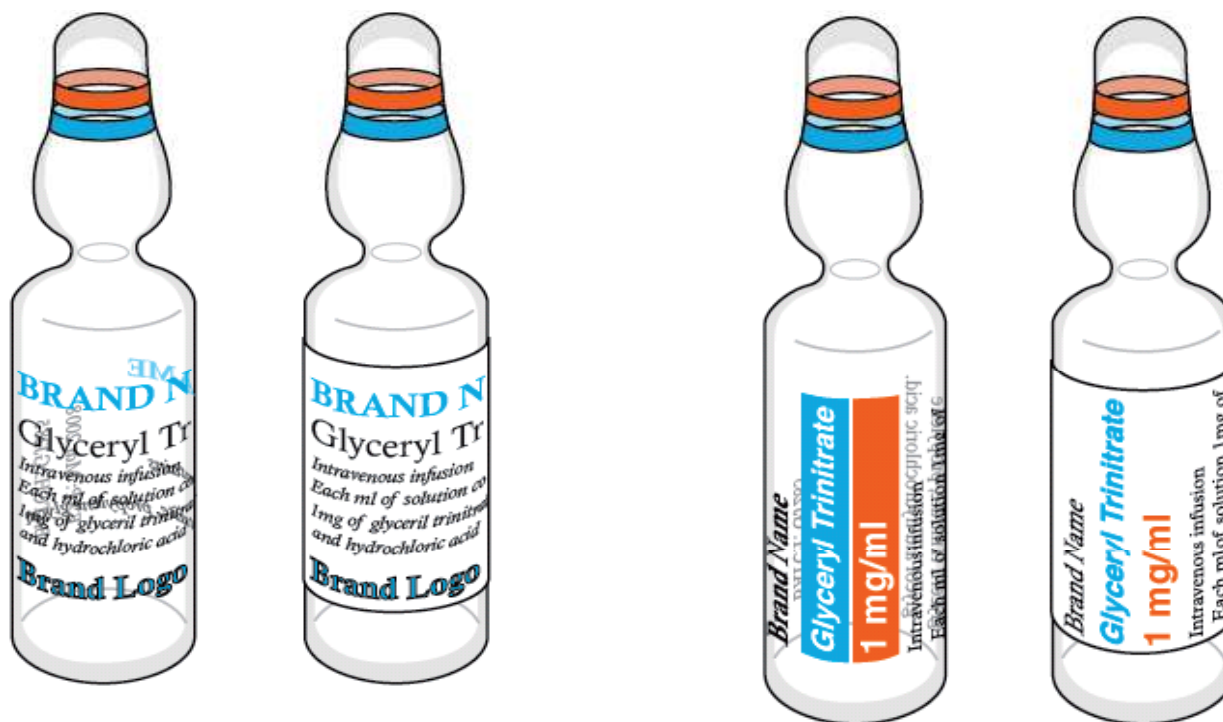
Use Colours To Differentiation to Highlight Information



Injection vial design

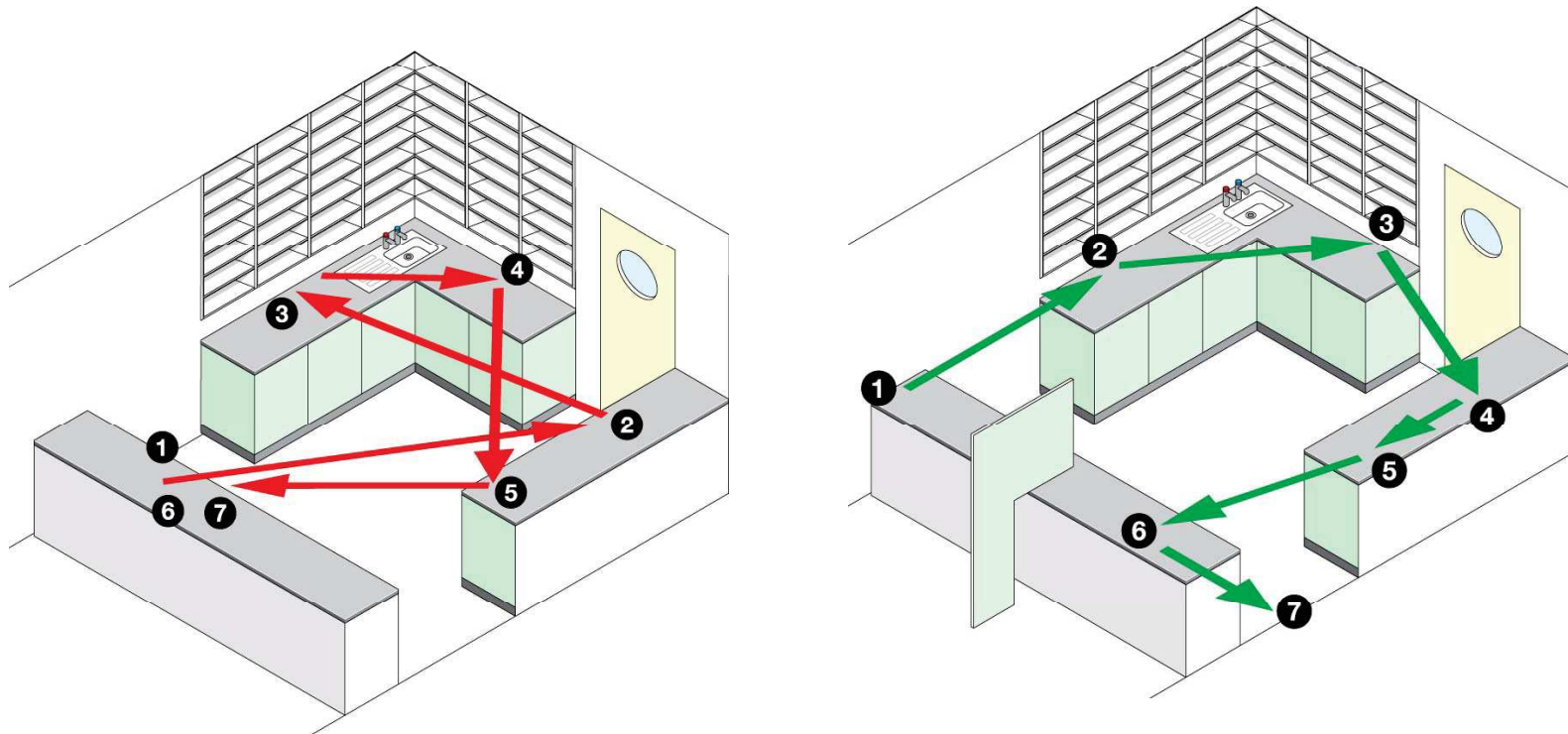


Injection vial design

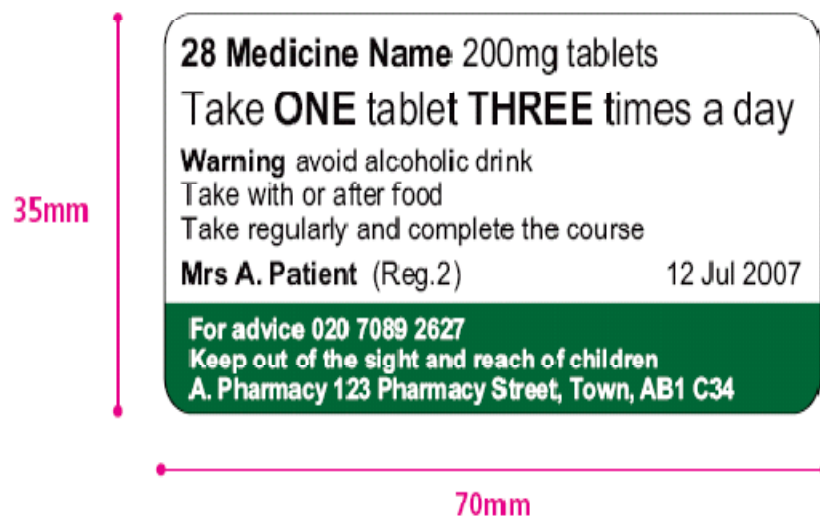




Design of dispensing environment



Size of Dispensing Label and Font

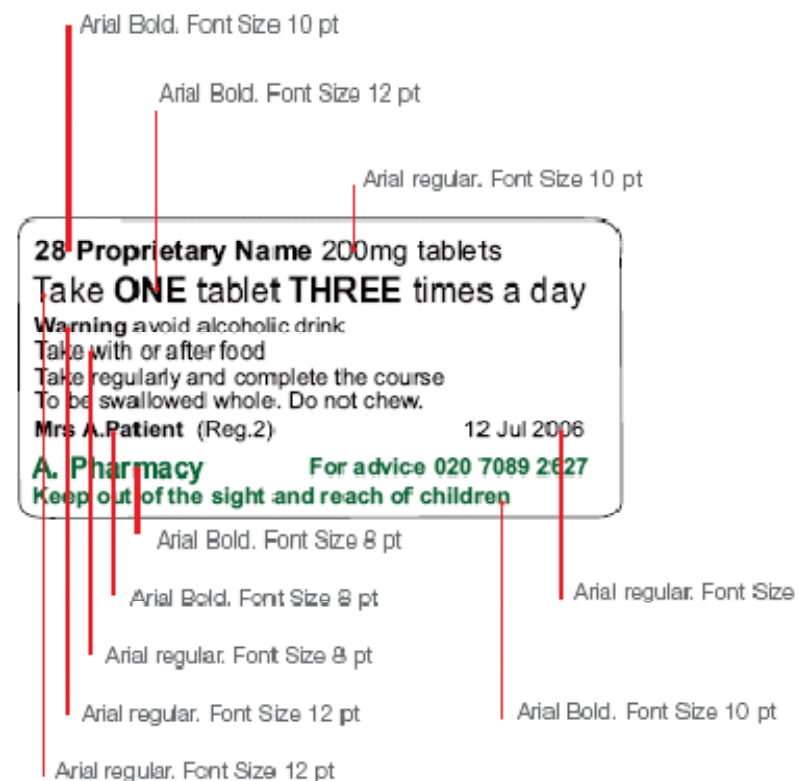


35mm

70mm

28 Medicine Name 200mg tablets
 Take **ONE** tablet **THREE** times a day
Warning avoid alcoholic drink
 Take with or after food
 Take regularly and complete the course
Mrs A. Patient (Reg.2) 12 Jul 2007

For advice 020 7089 2627
Keep out of the sight and reach of children
A. Pharmacy 123 Pharmacy Street, Town, AB1 C34



Arial Bold. Font Size 10 pt

Arial Bold. Font Size 12 pt

Arial regular. Font Size 10 pt

28 Proprietary Name 200mg tablets
 Take **ONE** tablet **THREE** times a day
Warning avoid alcoholic drink
 Take with or after food
 Take regularly and complete the course
 To be swallowed whole. Do not chew.
Mrs A. Patient (Reg.2) 12 Jul 2006

A. Pharmacy **For advice 020 7089 2627**
Keep out of the sight and reach of children

Arial Bold. Font Size 8 pt

Arial Bold. Font Size 8 pt

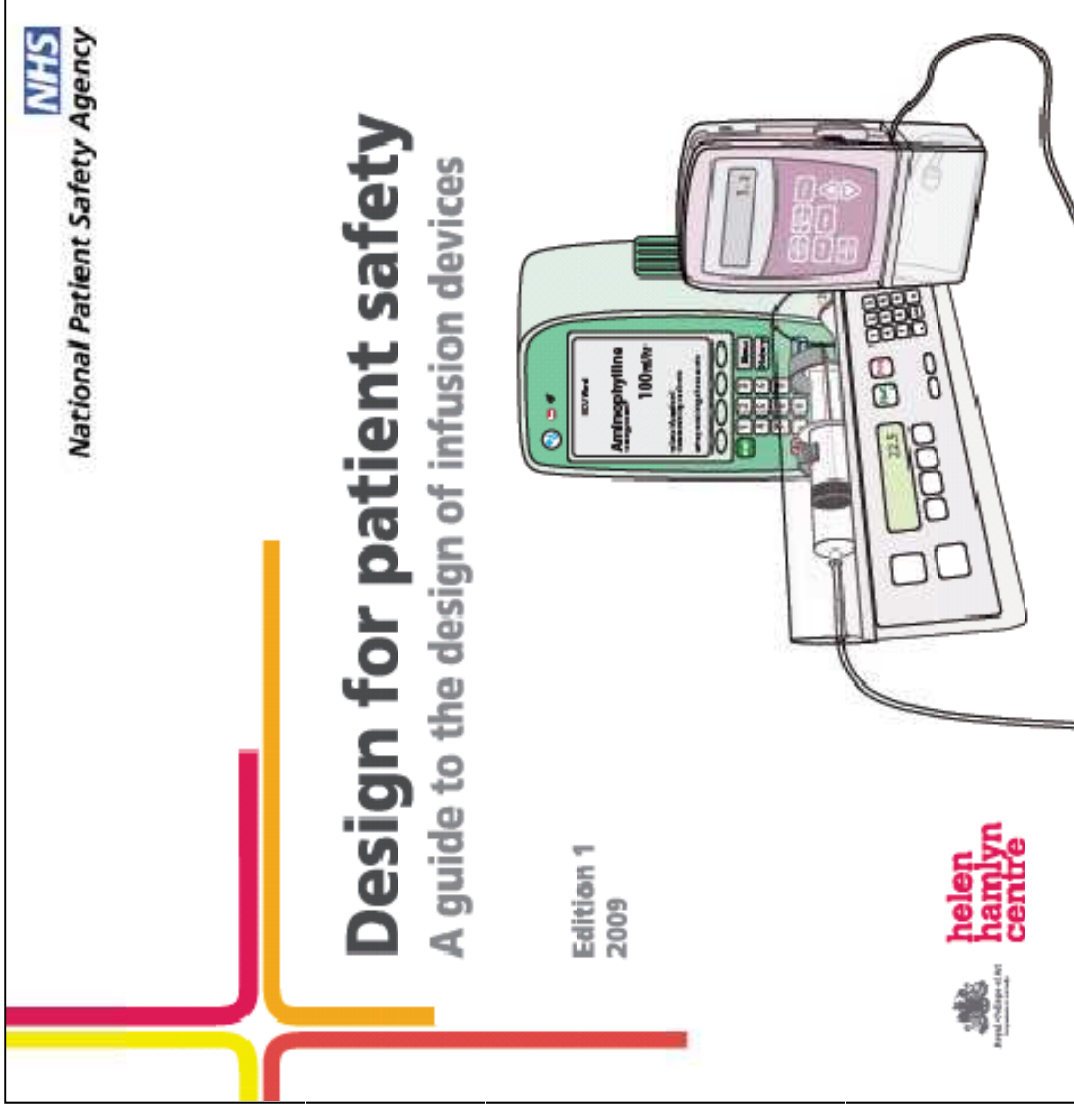
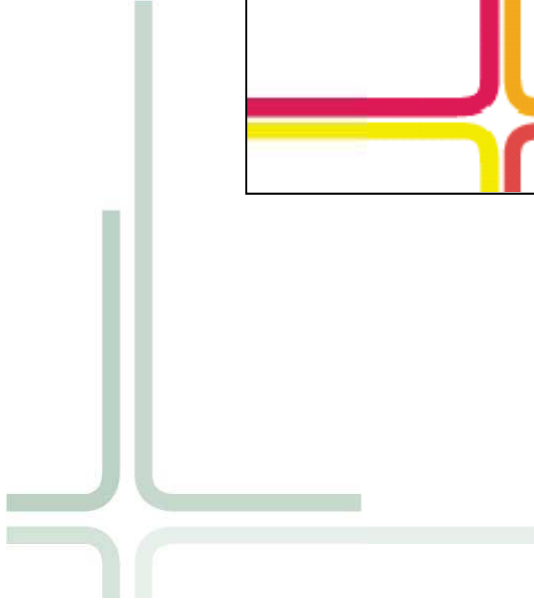
Arial regular. Font Size 8 pt

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Arial regular. Font Size 12 pt

Arial regular. Font Size

Arial Bold. Font Size 10 pt





Patient Safety Incidents Involving medical devices April – August 2009 (5 months)

- Each Month:
2469 – 3641
- Closer working and data sharing with MHRA



Patient Safety Incidents Involving Medical Devices April – August 2009 Reported Outcomes

Death	26
Severe	89
Moderate	789
Low	2548
No Harm	11278
Total	14730

Types of device incidents

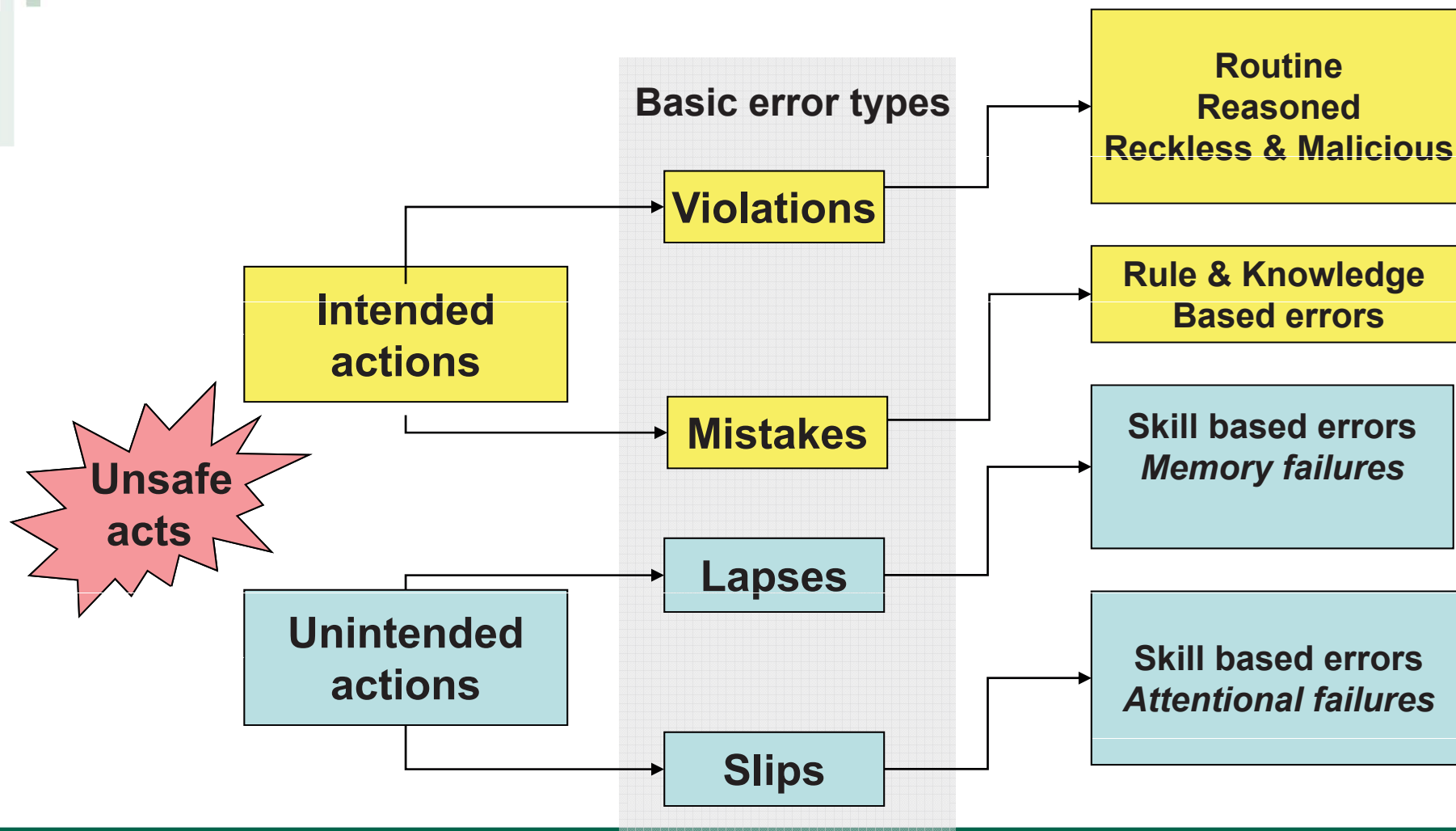
Surgical instruments	1,452
Beds and mattresses	1,358
Infusion pumps, syringe drivers	1,202
Intravenous catheters and cannulae	338
Ventilators	338
Administration and giving sets	311
Patient monitoring equipment	302
Monitors and electrodes	294
Endoscopes and accessories	283
X-ray equipment, systems and accessories	278
Anaesthetic machines and monitors	270
Patient hoists	264



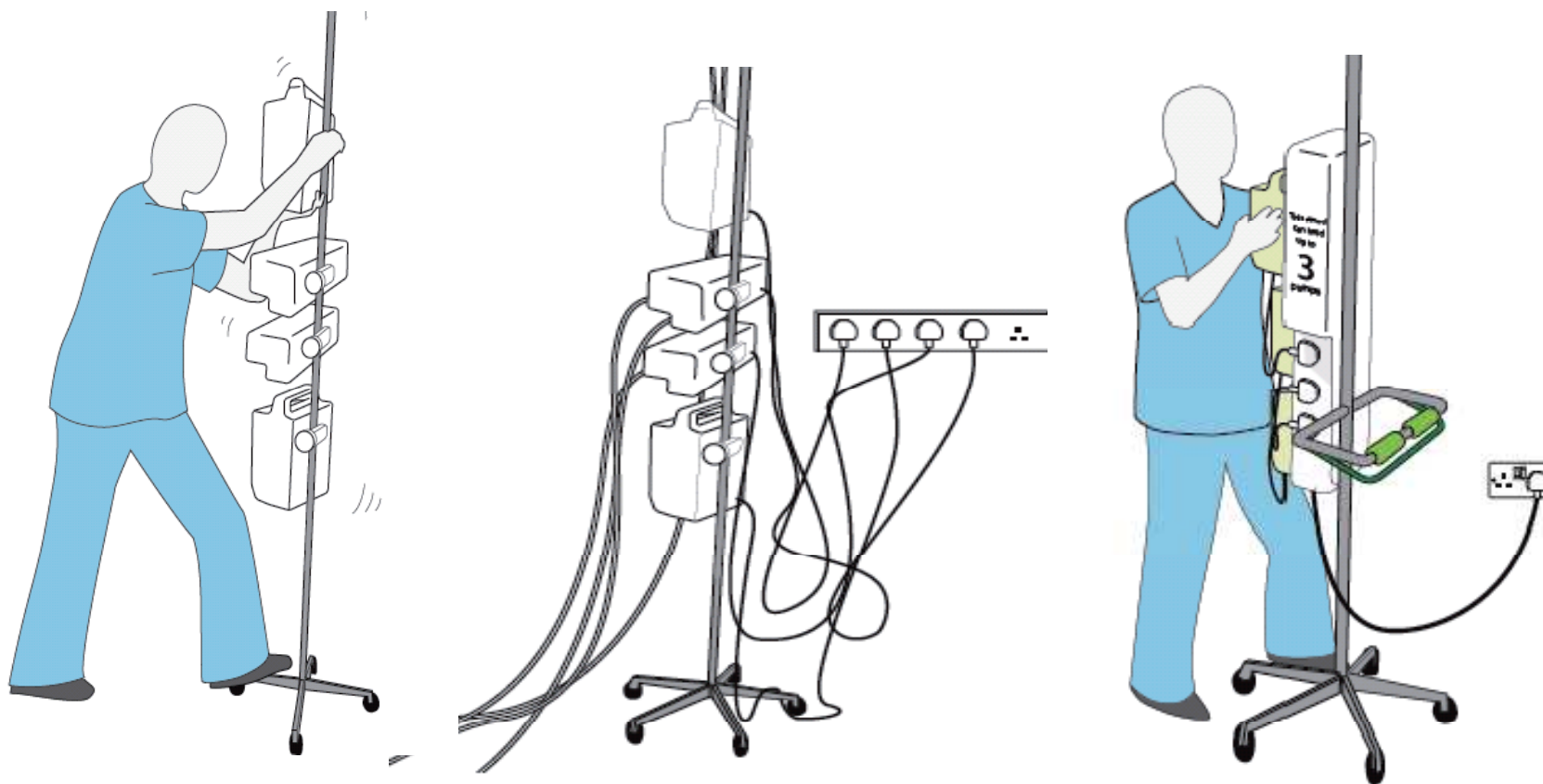
Reported cause of incident

Failure of device / equipment	6,026	41%
Lack / unavailability of device / equipment	5,080	34%
Other	2,002	14%
User error	1,306	9%
Wrong device / equipment used	290	2%
No information	26	0
Total	14730	100

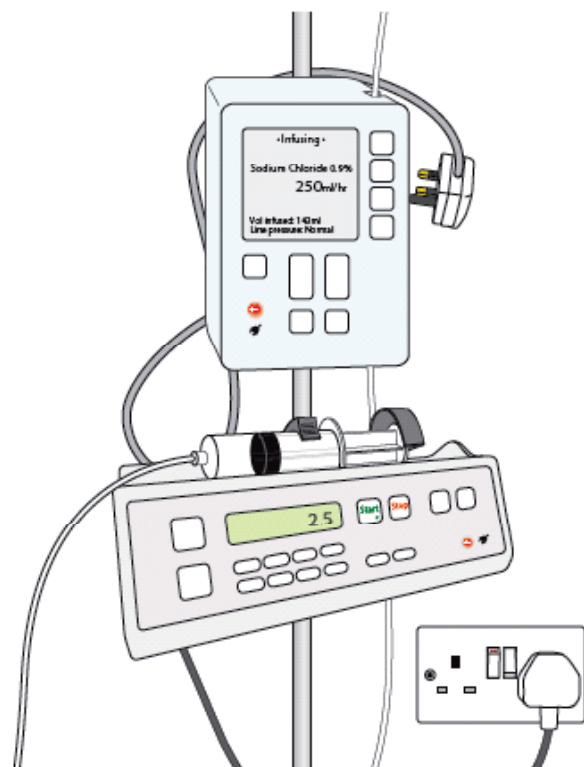
Human Factors – Error Types



Gravity infusion vs device stand

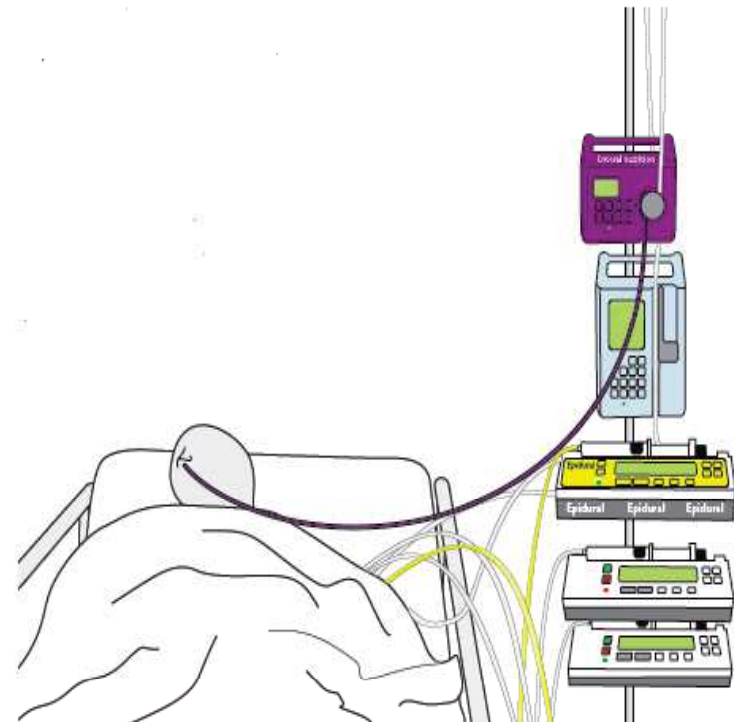
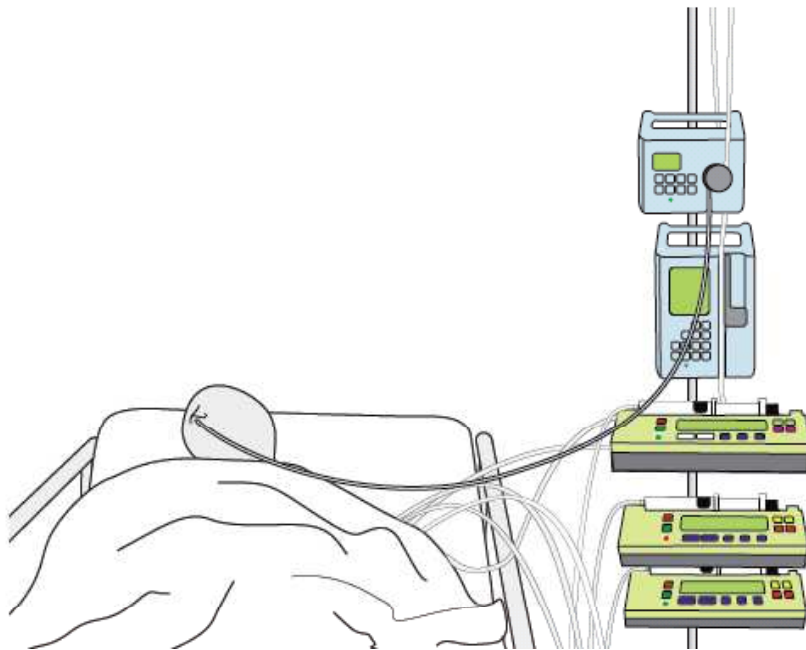


Mains Power

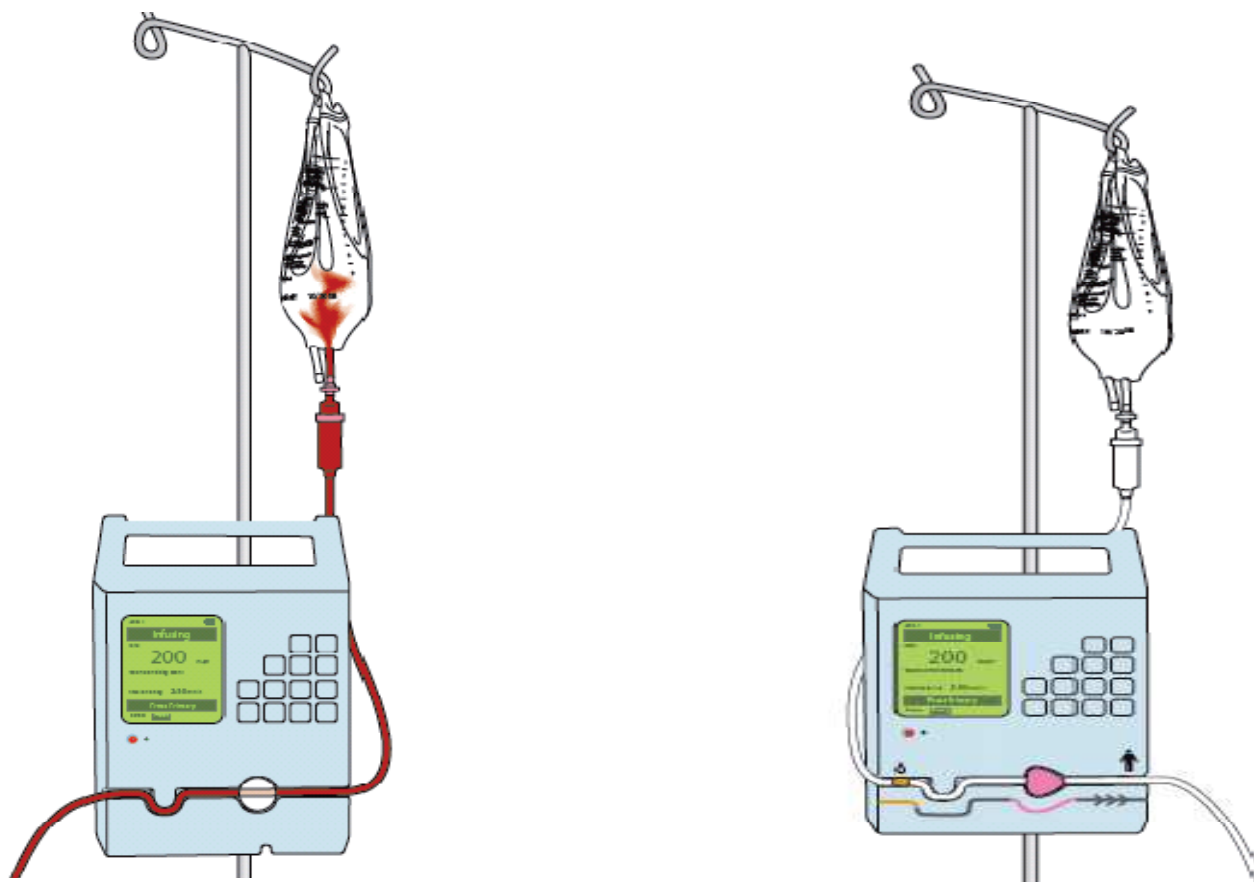




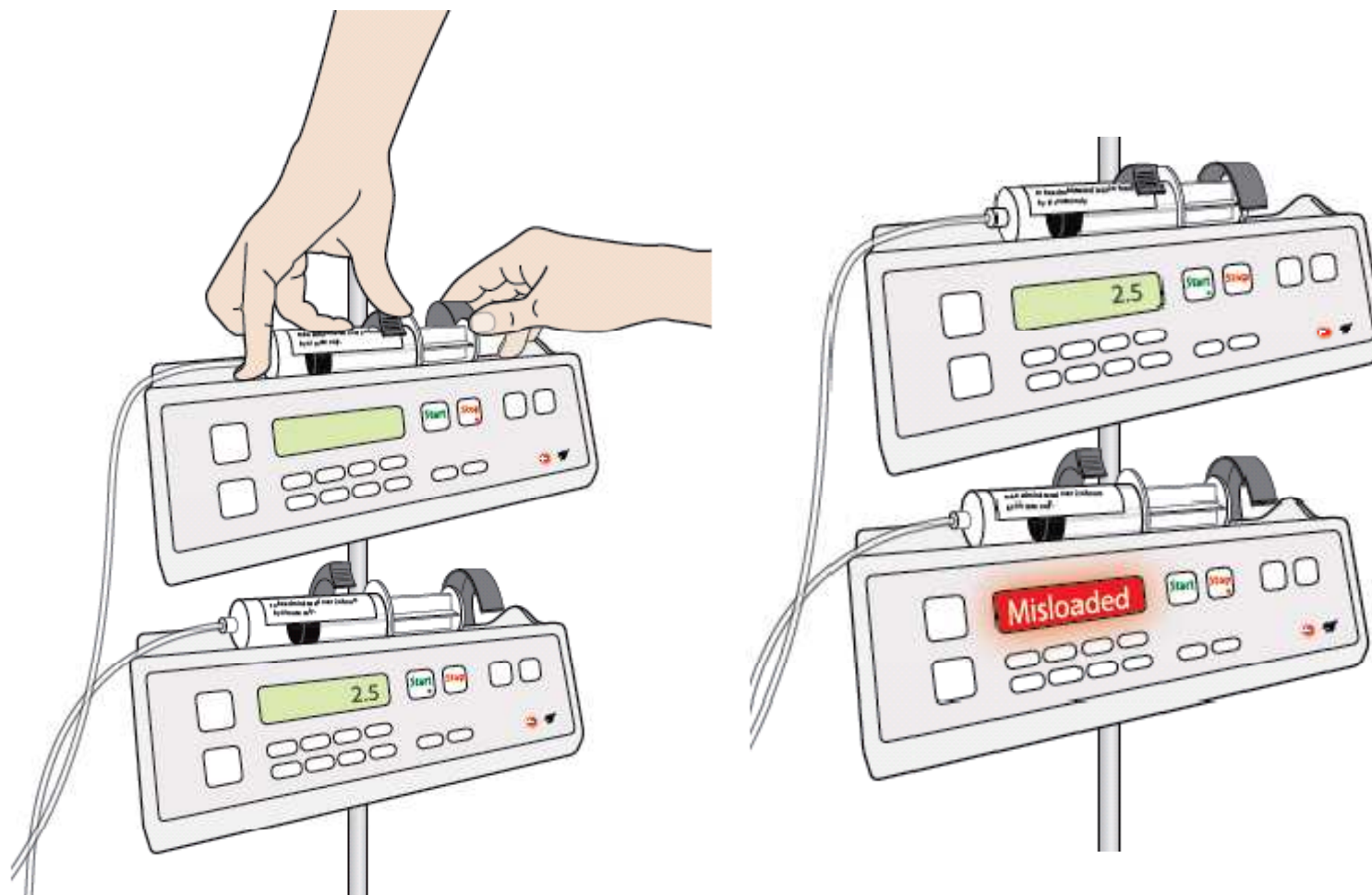
Use of colour and design



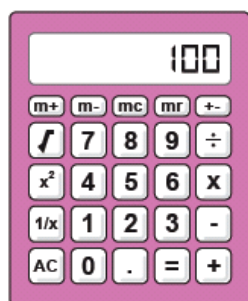
Loading administration sets



Loading Syringe Drivers

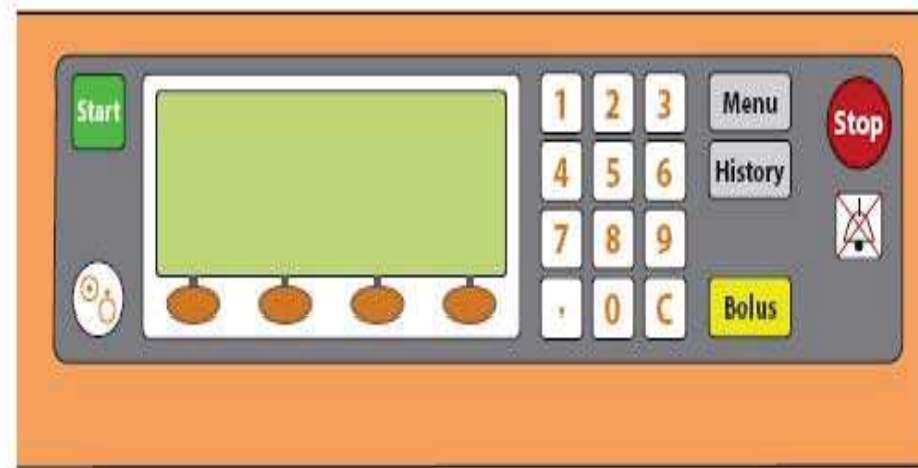
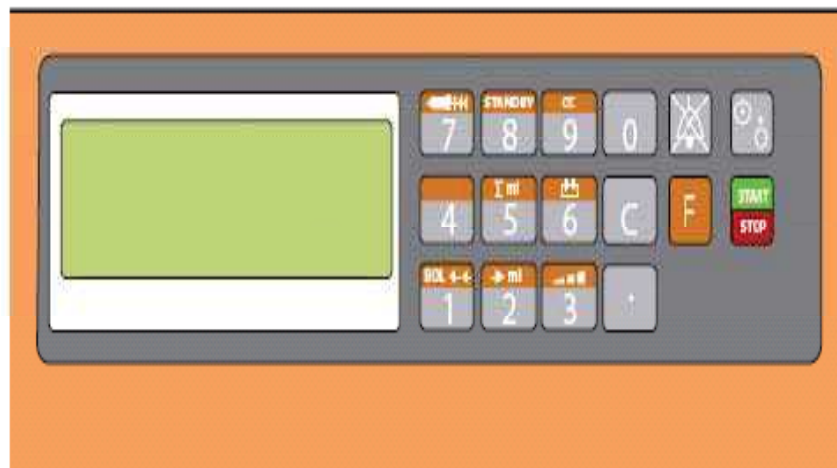


Keyboard Layout

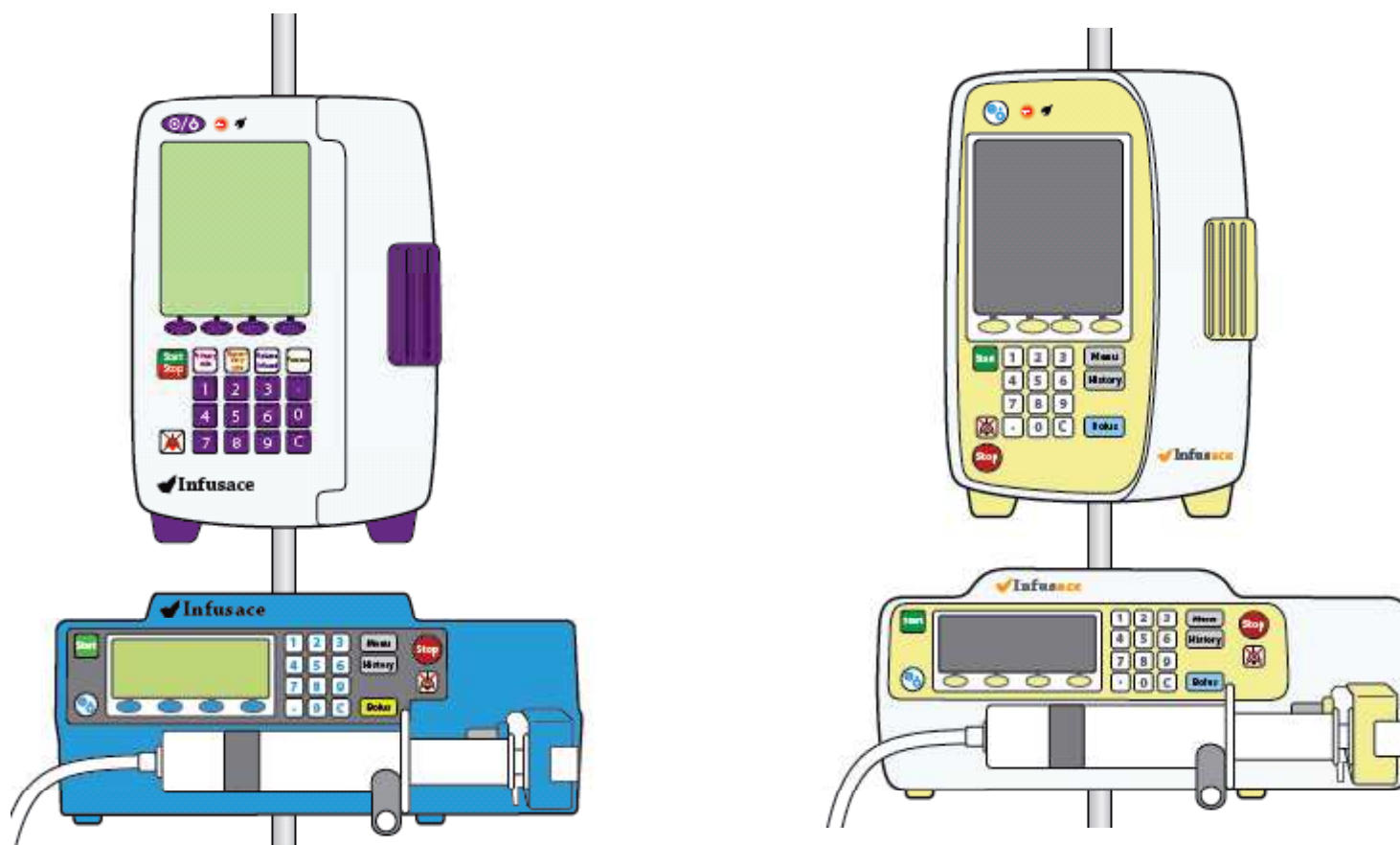


Multifunction buttons




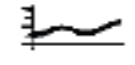










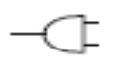











e.g.  +  = Bolus function



Interface consistency



Use of ISO Symbols

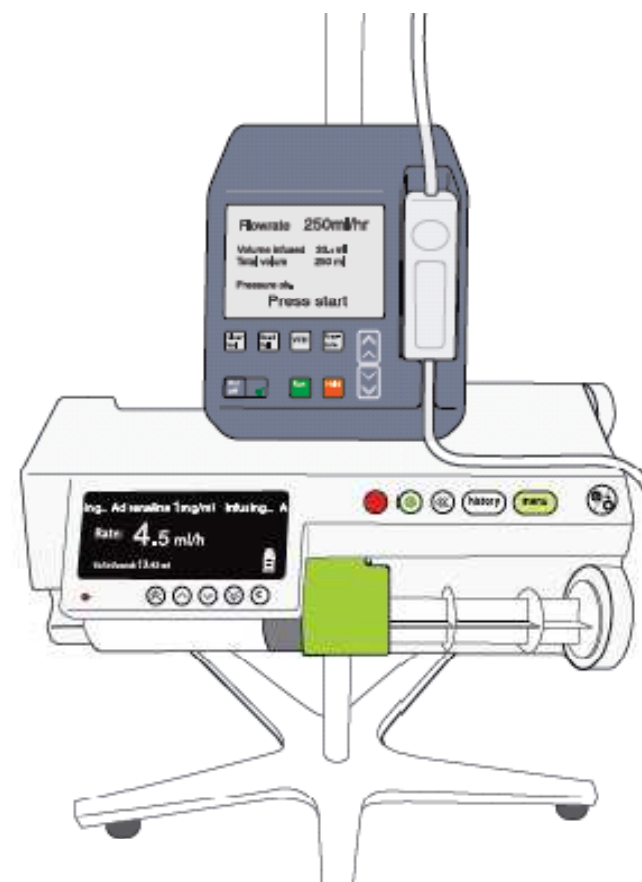
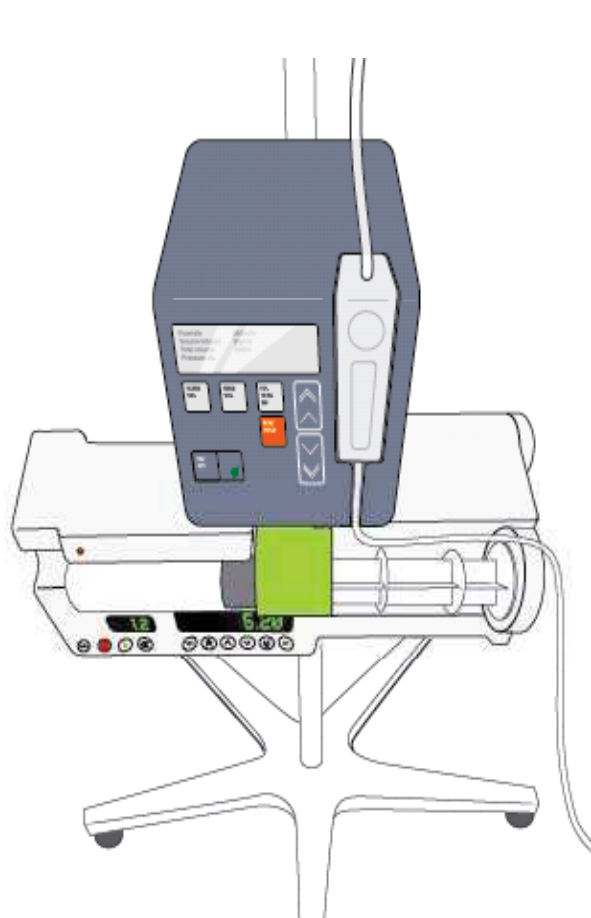
						
			Infusion status	Injection syringe	Infusion bottle	Trend information
						
			Manual control	Handheld switch	Variability	Variability in steps
						
			Patient	Nurse	Lighting	Do not reuse
						
			Battery check	Power plug	Bell cancel	Sound muting
						
			On	Off	Start	Stop



Use of Manufacturers Symbols



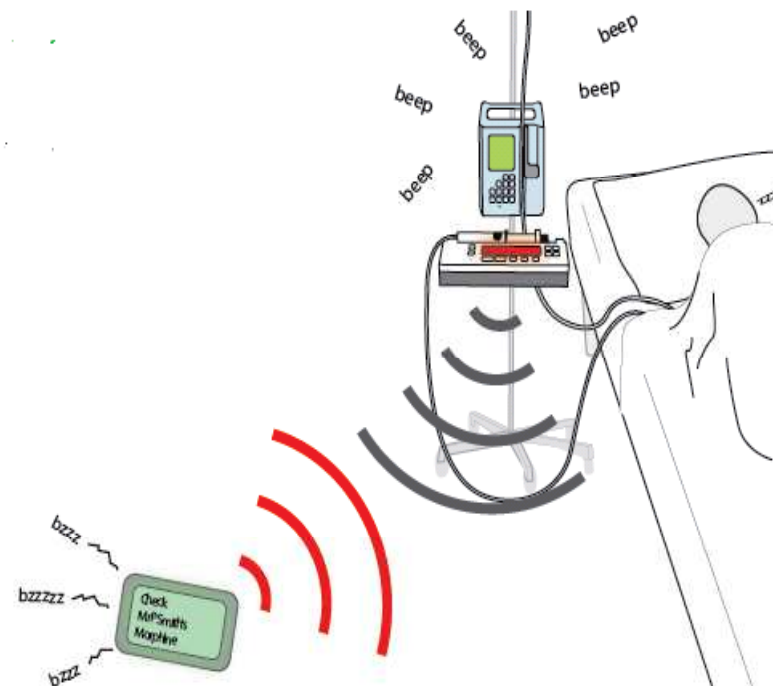
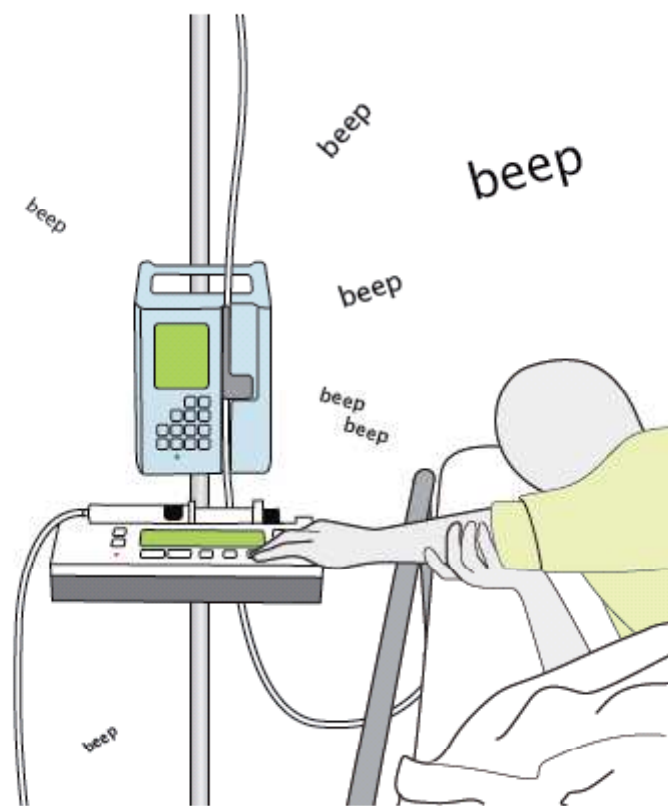
Screen display



Alarms

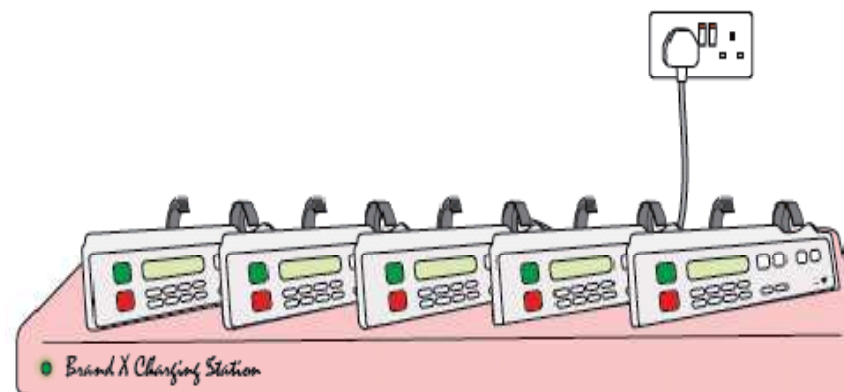
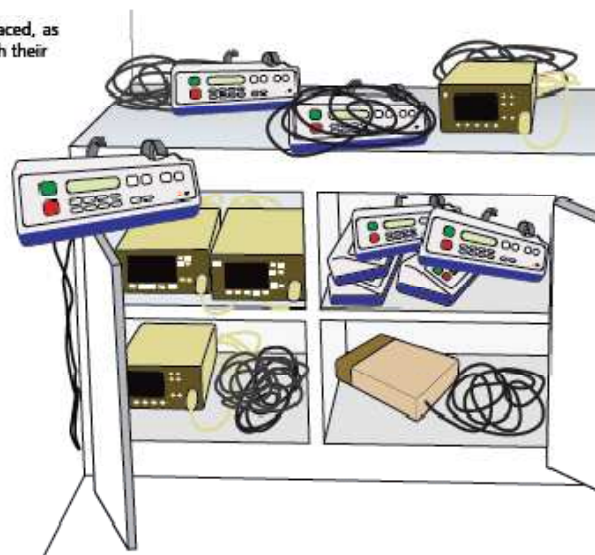


Alarms



Device storage

misplaced, as
s with their

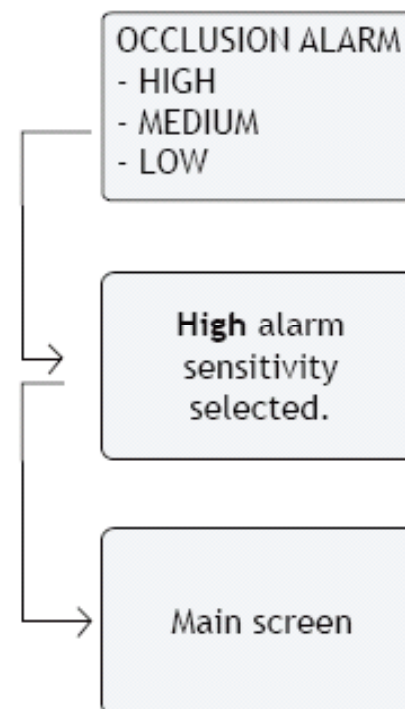
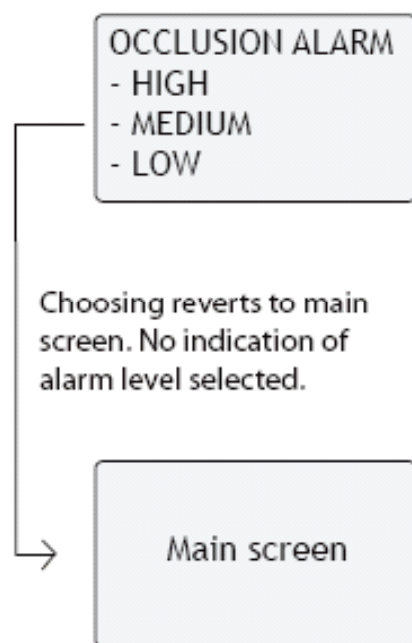


Screen layout / font size

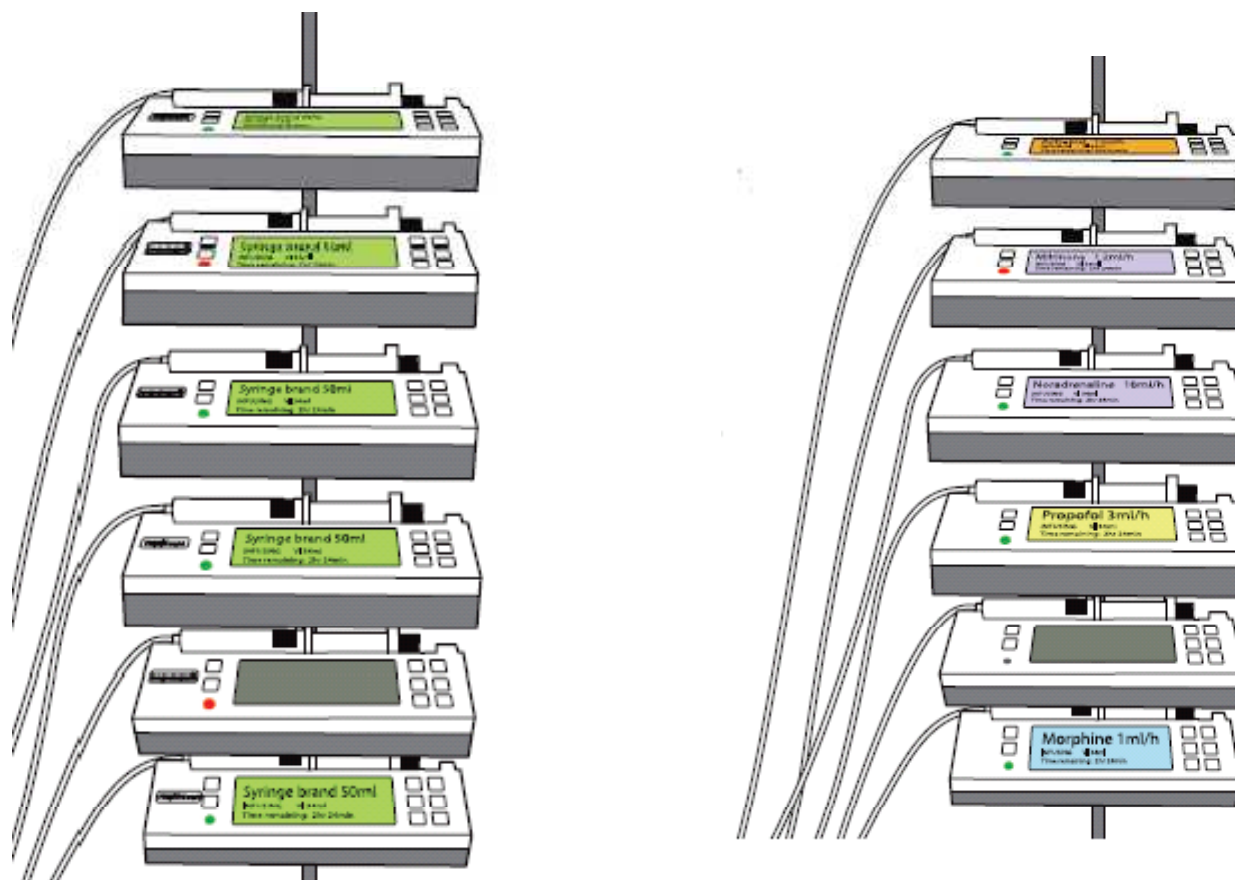


- Drug name and concentration
- Flow rate
- Device status
(infusing/stopped/standby)
- Time remaining / Volume to be infused
- Volume infused / Total volume infused
- Mode of delivery - continuous, PCA, KVO
- Power supply (mains/battery, battery life)
 - Occlusion pressure levels

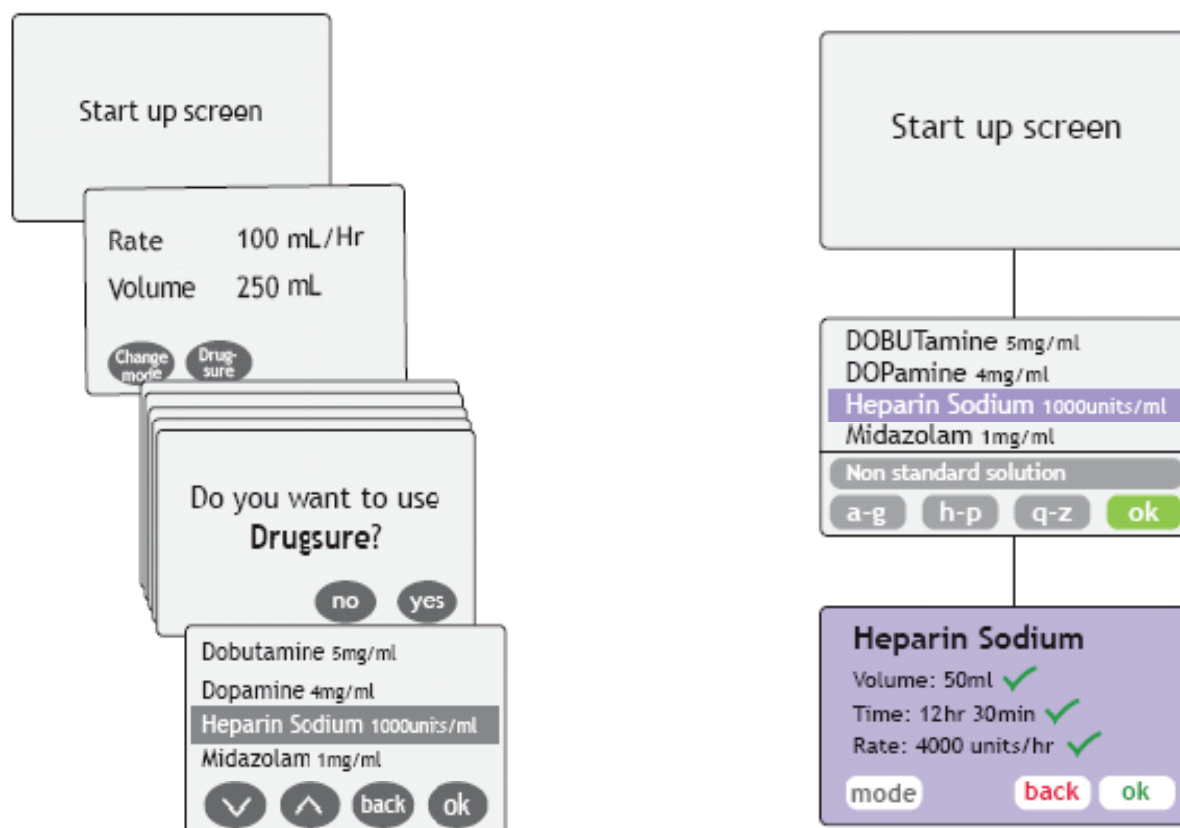
Confirmation of new settings



Drug Libraries / Medicine Labels



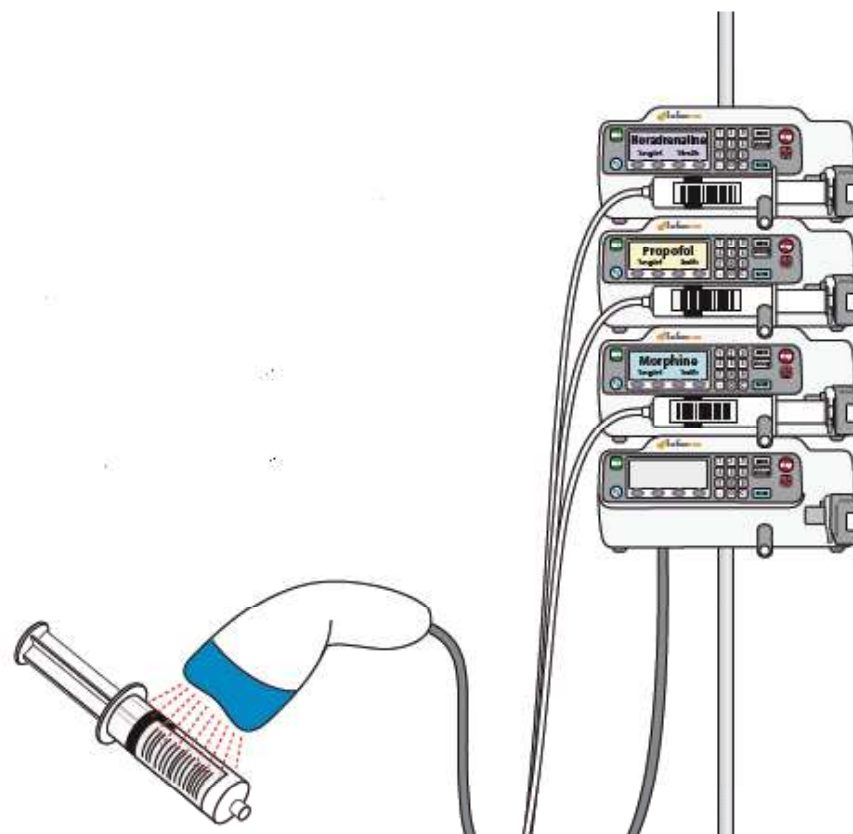
Dose error reduction software



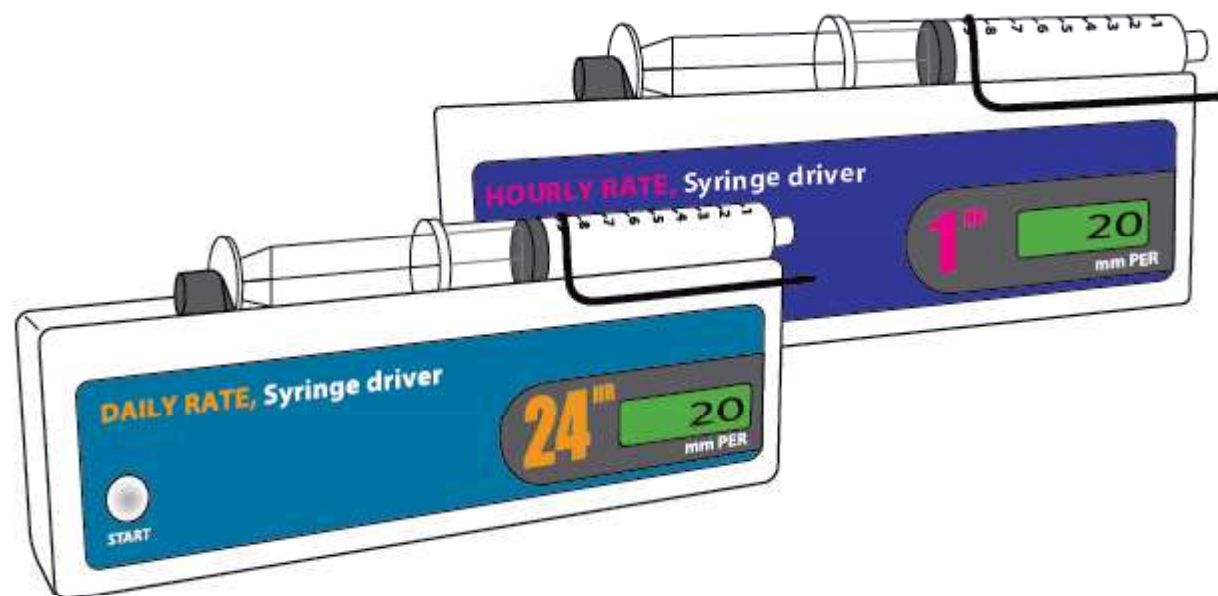
Data logging



Identification of the medicine



Rates of infusion

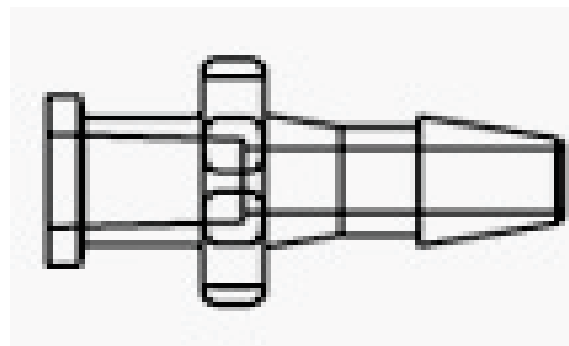
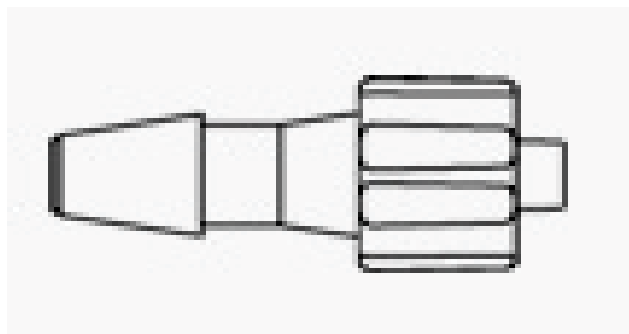


The 'Universal' Connector

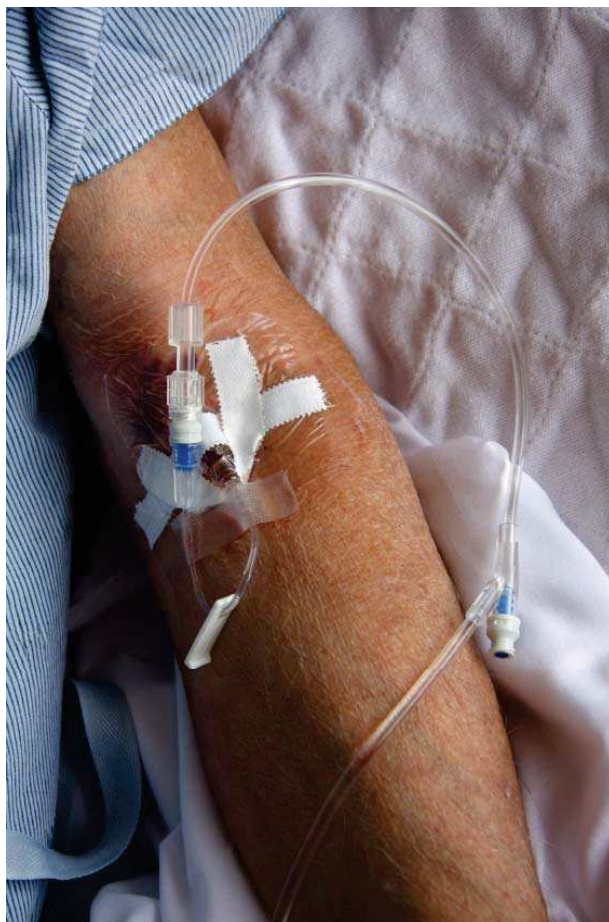


'Luer' – The Universal Connector

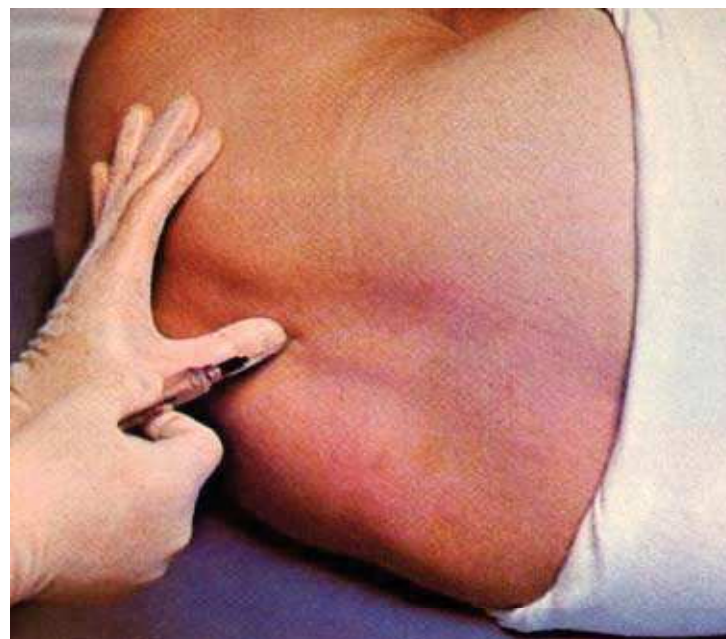
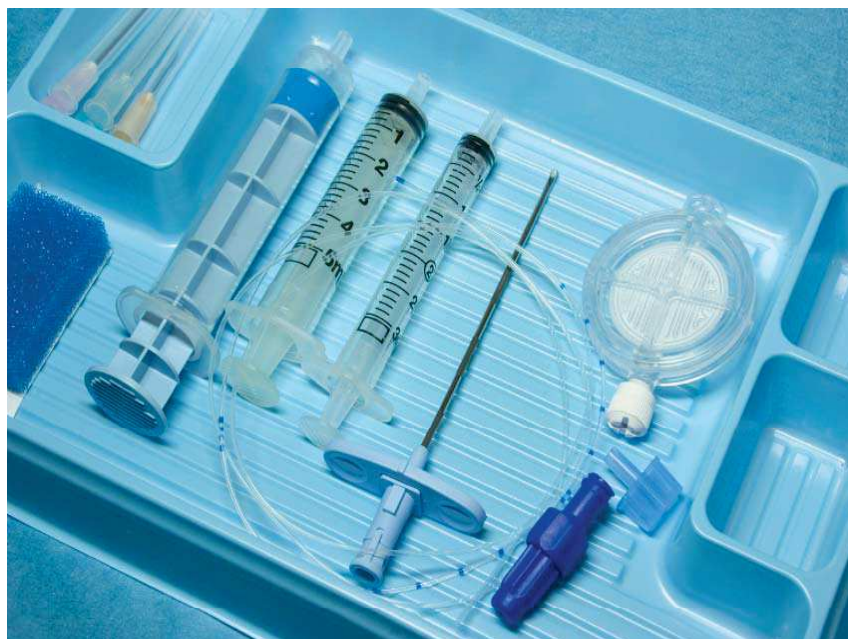
- Designed for IV and hypodermic use.
- Also used for neuraxial, respiratory, blood pressure monitoring devices etc.

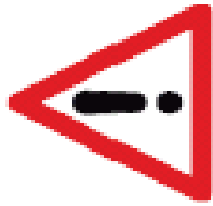


Luer connector and infusion spike



Spinal (intrathecal), epidural and regional administration of medicines





Patient Safety Alert

NPSA/2009/PSA003A

12 November 2009

Alert



**National Patient
Safety Agency**

**National Reporting
and Learning Service**

Safer spinal (intrathecal), epidural and regional devices – **Part A**

From 1 April 2011 all spinal (intrathecal) bolus doses and lumbar puncture samples must only be performed using syringes, needles and other devices with connectors that **will not** also connect with intravenous equipment.

**Action by all
organisations
in the NHS and
independent sector**

An executive director,
nominated by the chief
executive, working with clinical
and procurement staff should
implement a purchasing for
safety initiative to ensure that:
by 1 April 2011



Patient Safety Alert

NPSA/2009/PSA003B

12 November 2009

Alert



National Patient
Safety Agency

National Reporting
and Learning Service

Safer spinal (intrathecal), epidural and regional devices – Part B

From 1 April 2013 all epidural, spinal (intrathecal) and regional anaesthesia infusions and bolus doses must be performed with devices with connectors that **will not** also connect with intravenous equipment.

Action by all
organisations
in the NHS and
independent sector

An executive director,
nominated by the chief
executive, working with clinical
and procurement staff should
implement a purchasing for
safety initiative to ensure that:

by 1 April 2013

Incidents

- The NPSA issued Patient Safety Alert 21, *Safer Use of Epidural Medicines in March 2007, with an implementation date of December 2008⁵*.
- A further 18 low or no harm reports of wrong route errors involving epidural devices and four involving regional devices have been reported between 1 January 2008 and 31 July 2009. There have been no further reports of intravenous vinca alkaloids being administered by the spinal (intrathecal) route in the UK, but additional deaths have occurred in other countries.

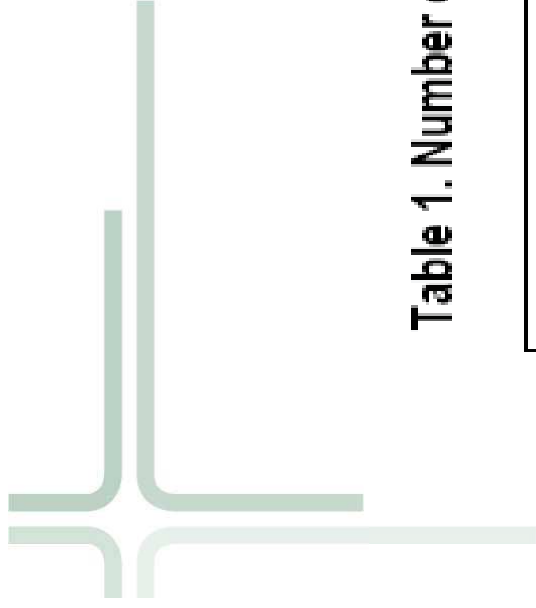
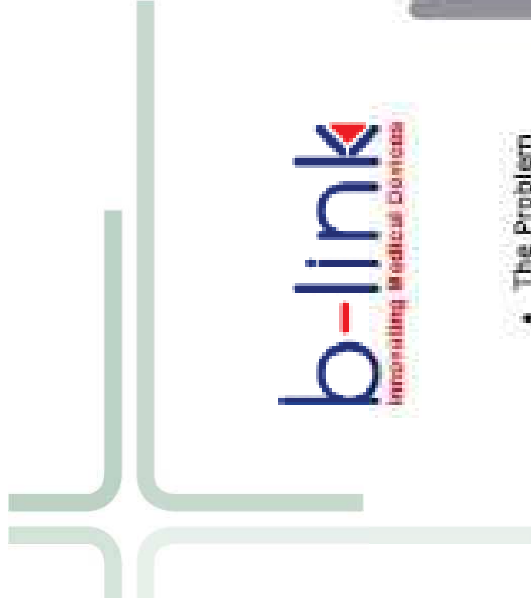


Table 1. Number of patient safety incidents by wrong route incident type

Wrong route incident type	Number of incidents
Epidural medicine administered by the intravenous route	9
Intravenous medicine administered by the epidural route	9
Intravenous medicine administered by the regional anaesthetic route	3
Regional medicine administered by the intravenous route	1



Home

neurax

- The Problem

- The Solution

- Connectors

- Products

- Why Choose Neurax

- About Us

- Contact Us

The Neurax is designed to prevent misconnections

The Neurax is a specialised small-core connector system, moulded from hard plastic, which is either permanently-fitted or moulded onto specific small-diameter tubular medical devices, typically needles, syringes, microbial filters, drug containers and flexible fluid-conducting tubes.

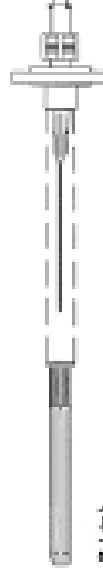
TECHNOLOGY DEVELOPMENT
via the NHS Supply Chain or direct from B-Link (UK) Ltd

Latest News

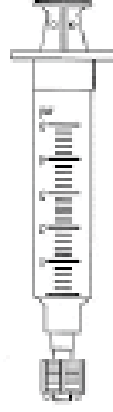
Page 1 of 2 > >>

Independent Clinical Tests give 'thumbs-up' to Neurax - July 2010

[more>](#)



B-Link Neurax 0.2 micron filter with 19G x 38mm needle ATP636



B-Link Neurax 5ml Syringe ATP600

Neurax® Devices

B-Link are planning to supply the following devices from September 2010:

- non-luer syringes 1,3,5,10, 20 and 50ml . The syringes can be used either in 'slip' or 'lock' mode, by optional use of a slide-able collar;
- non-luer loss of resistance, lock and slip,7ml syringe;
- 22G-27G Quincke & 'Pencil Point' spinal needles & introducers, in various lengths plus accessories to aid diagnostic & chemotherapeutic procedures;
- 16G -18G Tuohy epidural needles, with detachable wings, together with accessories to enable infusions of local anaesthetic (e.g., catheters, filters, lines).



Publications available on the NPSA website

- Search terms NPSA and Design for Patient Safety

Surety® System for Spinal, Epidural and Regional Anaesthesia - Available from November 2010

Welcome to the Surety® website.

(S) Surety®

Surety® is a neuraxial system designed by award-winning UK syringe manufacturer, InterVene Limited in response to the MPSA's 'purchasing for safety' initiative for neuraxial (spinal and epidural) medical devices with safer connectors to further minimise wrong route errors.

We recognise that to achieve a quick and substantial uptake from healthcare professionals it is important to collaborate with other manufacturers. With this in mind, Surety® is available to industry partners without exception and at low cost.

Home

The Issue

Surety® Syringes

Surety® Design

Surety® Range

Contact Us

About Us



Surety® Devices

InterVene are planning to supply the following devices from November 2010:

- Non-luer slip and lock syringes
1,3,5,10ml and 20ml, 60ml lock syringes;
- Non-luer loss of resistance, lock and slip, 10ml syringe;
- Non-luer three way tap, drawing up filter straws and needles and a introducer needle.

REGANESTH® Spinal Needles Pencil-Point and Quincke

Safer Spinal Devices with Non Luer (S) Surety Connectors



NPSA Compliant Products for Spinal Anaesthesia

- Facilitate safer practice and minimise risks to patients
- Do not connect with intravenous equipment
- Spinal needles with pencil-point tip and Quincke bevel
- REGANESTH® spinal needles pencil-point with non-glare and non-reflecting liquor chamber
- Quick detection of the liquor reflux due to the transparent needle hub

TRANSMED
Product Range



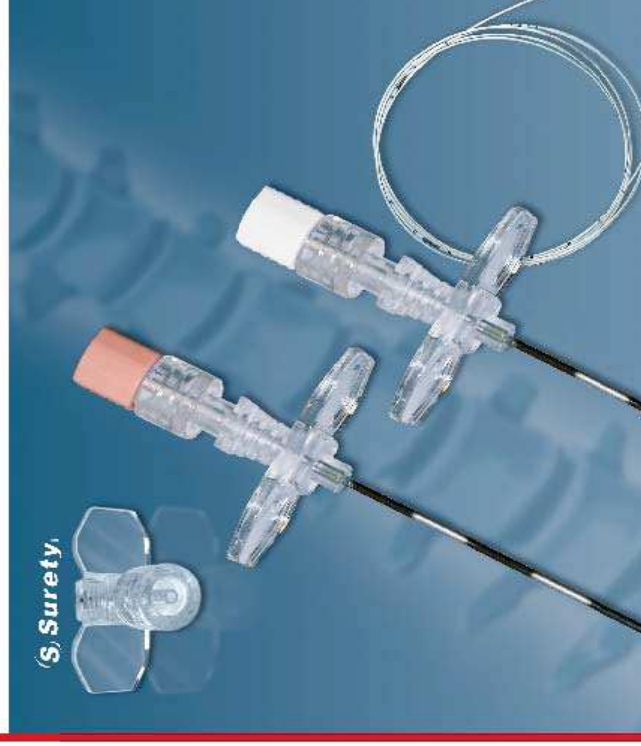
SARSTEDT

SA_SpinalSURETY_Non_Luer_Connector_08_0910.indd 1

14.03.10 14:13

Epidural Anaesthesia

Safer Epidural Devices with Non Luer (S) Surety Connectors



NPSA Compliant Products for Epidural Anaesthesia

- Facilitate safer practice and minimise risks to patients
- Do not connect with intravenous equipment
- Epidural needles with Tuohy bevel in different lengths
- For long-term anaesthesia and analgesia

TRANSMED
Product Range



SARSTEDT

NE_EpiduralSURETY_Non_Luer_Connector_08_0910.indd 1

14.03.10 14:13

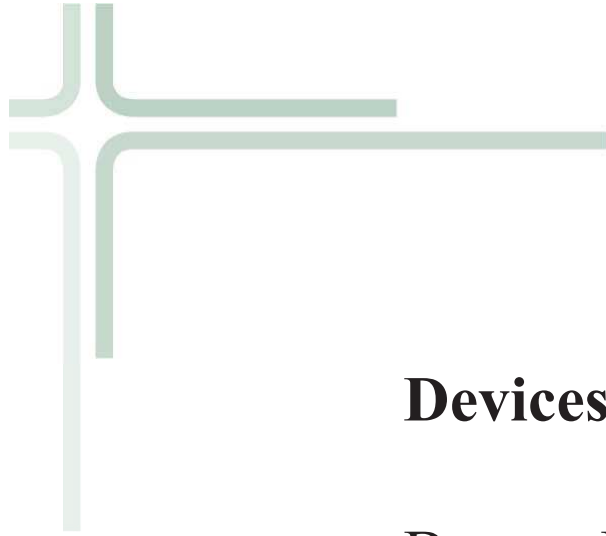
Needles and device manufacturers planning to incorporate Surety® connectors

Blue Box Medical,
Pajunk UK,
Rocket
Saesedt
Medical
Vygon.

SafeConnect Devices

B Braun Medical are planning to supply new devices from February 2011:

- a wide range of spinal needle sizes 18G to 27G, 40mm to 120mm;
- Quincke and Pencil Point bevels;
- a full range of required accessories including 5ml slip and lock syringes, drawing up devices and protective caps for prefilled syringes;
- Ready-to-use safety packs and single items;
- Single packed items will be introduced step by step after the market launch of the packs.



Devices from Becton Dickinson

Becton Dickinson (BD) are planning to supply the following devices before April 2011:

- A wide range of spinal needles with Whitacre or Quincke tip types, various gauge sizes from 18 to 27G, and lengths of 38 to 127mm;
- Syringes and blunt fill needles

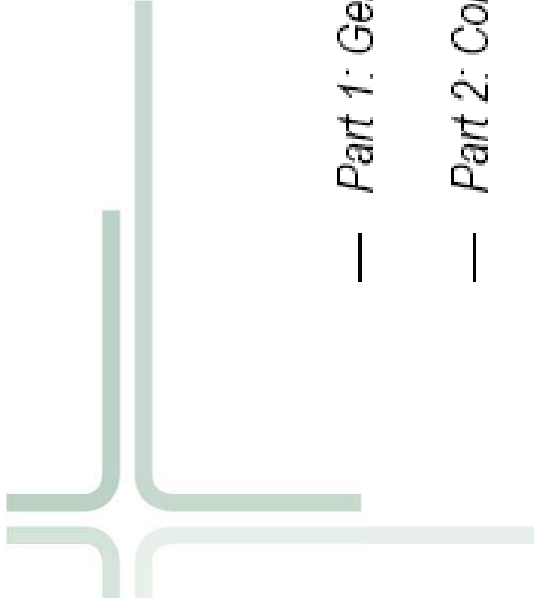
CorrectInject® *Devices*

Smiths Medical are planning to supply the following devices:

- epidural catheters, including a catheter connector, syringe, filter, filter straw and infusion adapters, by the end of 2010;
- CorrectInject® safety system technology will be developed into CADD® epidural infusion systems, including yellow CADD® medication cassette reservoirs, extension sets and administration sets with bag spikes. The project schedule for the CADD® CorrectInject® System is still being determined but is targeted for the middle of 2011;
- Devices for spinal procedures are also being developed. Again the project schedule is still being determined but is targeted for early 2011.

ISO TC 210

Small-bore connectors for liquids and gases in healthcare applications — Part 1: General Requirements

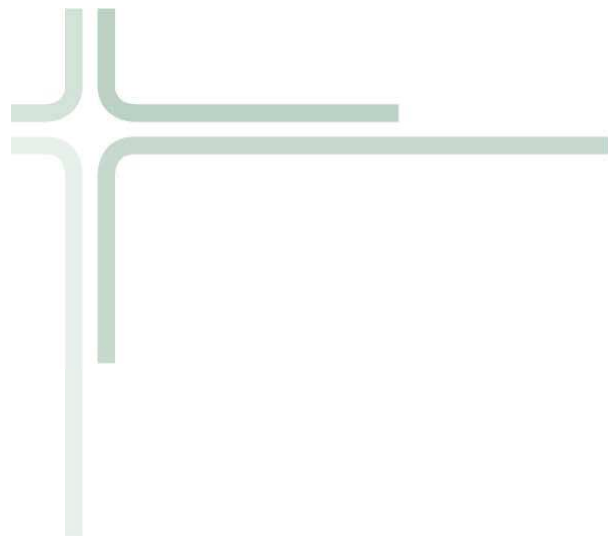


- *Part 1: General Requirements*
- *Part 2: Connectors for breathing systems and driving gases applications*
- *Part 3: Connectors for enteral applications*
- *Part 4: Connectors for urethral and urinary applications*
- *Part 5: Connectors for cuff inflation applications*
- *Part 6: Connectors for neuraxial applications*

ISO TC210 Meeting in Seattle

14th – 17th October 201

- Review committee draft of part 6 standards proposal B-link design
- Receive presentation for potential part 6 standards proposal Surety
- Nothing on the table from Smith Medical or Becton Dickinson



National Patient Safety Agency

National Reporting and Learning Service

WWW.NPSA.NHS.UK