## AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM D14-27299

National recommendations for user-applied labelling of injectable medicines, fluids and lines

Evaluation of pre-printed medicine and fluid labels on the perioperative sterile field (Report 2)



**24 November 2014** 

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This paper is available on the Commission web site at www.safetyandquality.gov.au.

National recommendations for user-applied labelling of injectable medicines, fluids and lines

# Evaluation of pre-printed medicine and fluid labels on the perioperative sterile field (Report 2)

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#### 1. Background

The high incidence of error and serious patient harm from injectable medicines is a national patient safety issue. Developing and implementing consistent user-applied labelling of injectable medicines and fluids, and the devices used to deliver them, has been identified as a national patient safety priority.

In 2010, Australian Health Ministers endorsed National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines (the labelling recommendations) <sup>1</sup> for use in Australian health services. The labelling recommendations require identification of injectable medicines and fluids removed from the original container. Moreover, the labelling recommendations apply to all non-injectable solutions, chemicals and reagents used in perioperative areas when these are removed from their original containers in a practice area where injectable medicines are used.

The Australian Commission on Safety and Quality in Health Care (the Commission) developed and maintains the labelling recommendations. The Commission also identifies and reduces national barriers to implementation of the labelling recommendations.

The Commission convenes a specialist advisory group, the Labelling Recommendations Reference Group (LRRG), to advise it on maintenance and implementation. Resulting changes to the labelling recommendations are reflected in the *Labelling recommendations issues register*. <sup>2</sup>

The Labelling recommendations issues register (issues register 11) provides advice on suitability of and specifications for pre-printed labels used to identify medicines and fluids on the perioperative sterile field.

The requirement to label all medicines and fluids on the perioperative sterile field removed from the original manufacturer's packaging is a change in practice for some facilities. Userapplied labels are required to be practical, durable and sterile in the operating room. These requirements have resulted in a number of stepwise evaluations of user-applied labels to elucidate a standardised and consistent method of medicine and fluid identification (see Section 2, Introduction). This report describes the development, use and evaluation of label sheets that differentiate non-injectable and injectable medicines and fluids.

#### 2. Introduction

User-applied labelling requirements for the perioperative sterile field are as follows<sup>1</sup>:

- Label all medicine containers, including jugs, basins and syringes, according to the labelling recommendations.
- Pack and sterilise container/conduit labels for use on the sterile field.
- Make sterile markers available for use on the sterile field.
- Discard any medicine or fluid remaining in the container (e.g. syringe) at the end of a procedure.
- Discard labelled disposable containers.
- Thoroughly remove labels from reusable containers before their cleansing and resterilisation.

The perioperative area operating room is a closed practice environment where patient and user identities are not required on the container label as these details are recorded elsewhere in the operating room records. Abbreviated container labels may be used (see Figure 1 below) to identify all medicines and fluids on the sterile field in the perioperative area. The active ingredient medicine name should be used. Concentration is optional.

## Figure 1: Abbreviated container label for closed practice environments e.g. perioperative sterile field

Medicine	
Conc (units/mL)	

Pre-printed labels are a suitable alternative for routine operations where the same medicines are frequently used and have the following advantages:

- A sterile marker is not required.
- There is ready availability.
- It takes less time to select and apply.

Health services may choose to order: a) label sheets individually packaged to be used across an entire operating suite; or b) labels within a procedure pack for a routine operation, e.g. arthroscopy.

A series of evaluations has been undertaken to assist health services to design labels and to address issues raised during implementation. These are described here.

## 2.1 Evaluation of pre-printed labels for identification of medicines and fluids on the perioperative sterile field (Report 1)

Evaluation of pre-printed label sheets in the perioperative sterile field at Calvary Wakefield Hospital in 2012 <sup>3</sup> found pre-printed labels were easy to use provided they were manufactured with materials that were durable and fit for purpose.

## 2.2 Evaluation of label adherence to hollowware containers in operating rooms (Reports 1 and 2)

Adhesive strength is dependent on whether disposable or reusable containers are used in the operating room. Stronger adhesive is appropriate for disposable containers because there is no requirement to remove labels. Reusable containers, e.g. stainless steel, will require labels to adhere for the duration of the procedure and then be removed entirely for the container to be cleaned and sterilised for reuse. Label stock and adhesives suitable for reusable hollowware containers have been evaluated in two bench top trials. <sup>4, 5</sup>

## 2.3 Evaluation of standardised medicine syringe labels in interventional cardiac catheter and radiology laboratories

Evaluation of pre-printed labels was conducted within interventional cardiology laboratories. These specialist medical intervention areas differ from operating rooms in two main respects:

- The interventionist manages the majority of medicine administrations at the same time as performing a clinical procedure.
- Both tasks are often required to be undertaken in low-light conditions allowing for simultaneous review of angiography or other radiology procedures.

Pre-printed medicine line labels were well accepted in interventional cardiology and radiology laboratories and a series of recommendations were made for user-applied labelling based on trial outcomes. A full list is detailed within the trial report <sup>6</sup> and, after consultation with the LRRG, the following approach to colour coding was adopted across all medicine labels.

The colour of sterile pre-printed medicine labels should be consistent with colour coding in the anaesthetic labelling standard (ISO 26825:2008)<sup>7</sup> with the following exceptions:

- Antiplatelet agents/anticoagulants are labelled with teal green (PMS 3255).
- Heparin are labelled with teal green with a black border.
- Protamine are labelled with teal green with a black diagonal stripe border.
- Heparinised saline are labelled with white with a teal green border (PMS 3255).
- Contrast media are labelled with white with a brown border (PMS 471).

Pre-printed labels were well accepted in these trials. However, the LRRG acknowledged that injectable and non-injectable medicines and fluids could be more clearly differentiated within the same practice area. Ideally, as described in best practice guidelines from the Australian and New Zealand College of Anaesthetists (ANZCA) <sup>8</sup>, user-applied labelling of non-injectable fluids should take place before the patient enters the operating room or procedure area. However, it still may be necessary to differentiate injectable and non-injectable medicines and fluids in the operating or procedure room. The following methods were proposed:

- Use a red St Andrew's Cross applied as a watermark across the labels of noninjectable medicines and fluids.
- Segregate the two medicine and fluid types within the one label sheet.

In November 2013, the Commission engaged Princess Alexandra Hospital (PAH) and Redcliffe Hospital to evaluate pre-printed sterile container labels on the perioperative sterile field. These hospitals had previously implemented the labelling recommendations within the operating room and were establishing the next iteration of their label sheets based on the recommendations in the current labelling recommendations issues register.

Label sheets were prepared, including medicines and fluids most frequently used in routine procedures (Appendices 8.1 and 8.2) where non-injectable medicine and fluid labels were printed with a red St Andrew's Cross and positioned together in a separate section on the label sheet. The sheets were individually packaged, sterilised and evaluated in relation to identification and label quality.

This report details the evaluation of pre-printed labels for the intra-operative sterile field in the perioperative area and physical differentiation between labels for injectable and non-injectable medicines and fluids.

#### 3. Aims and objectives

The aim of the study was to evaluate standardised pre-printed medicine container labels, with separation of labels for injectable and non-injectable medicines and fluids, for use on perioperative sterile field in the perioperative area.

The objective of the study was to develop advice on implementing the labelling recommendations for health services and health professionals in relation to the intra-operative sterile fields.

The labelling recommendations require identification of all medicines and fluids on the sterile field in the perioperative area.

The Commission engaged PAH and Redcliffe hospitals to:

- prepare a label sheet including medicines most frequently used in routine procedures;
- procure individually packaged sterile sheets; and
- evaluate them in terms of identification and label quality. Label quality must be such that labels are fit for purpose, progress through sterilisation intact and retain integrity throughout the procedure.

The trial aimed to determine the following for pre-printed labels on the sterile field:

- The pre-printed label set is suitable for identification of all medicines and fluids on the sterile field.
- Any colour used on pre-printed labels for the perioperative sterile field is consistent with anaesthetic standard ISO 26825:2008 as described in the labelling recommendations issues register.
- The distinction between non-injectable and injectable medicines and fluids is facilitated by segregation into 2 areas on the sterile label sheet and marking labels for non-injectable fluids with a red St Andrews Cross.

The following assumptions from previously reported trials <sup>3,4,5,6</sup> were made:

- Containers are handled many times in one procedure. Exposure to fluids may be repeated and label integrity is retained during this time.
- The surface of the label remains intact to avoid transfer to the patient.
- Labels adhere throughout the procedure.
- Labels can be removed from any equipment required to be cleaned and resterilised for reuse.
- Packaging size is kept to a minimum to minimise waste and facilitate handling.

#### 4. Methodology

#### 4.1 Test hospitals

Redcliffe Hospital in Queensland is a tertiary base hospital with six operating rooms specialising in orthopaedics, obstetrics, urology, vascular and general surgery.

Redcliffe began implementing the labelling recommendations <sup>1</sup> in July 2013 with implementation in the perioperative area in July 2013.

Princess Alexandra Hospital (PAH) in Queensland is a tertiary public hospital with 21 operating rooms within its perioperative suite covering all operative specialities except paediatrics, obstetrics and gynaecology.

PAH began implementing the labelling recommendations in July 2013 with implementation in the perioperative area in August 2013.

#### 4.2 Label development

The PAH developed a draft label sheet consistent with the *Labelling recommendations* 2<sup>nd</sup> edition and the labelling recommendations issues register. They established if label stock and presentation of the individually packaged label sheets would meet the requirements of the intra-operative area and engaged Defries Industries to produce the labels.

The LRRG proposed differentiation of non-injectable and injectable medicines and fluids in September 2013. PAH agreed to evaluate the label set devised at PAH with application of the St Andrew's Cross to labels of non-injectable medicines and segregation of the two groups within the label sheet.

Label sheet artwork had previously been prepared by Defries Industries and the Commission engaged Defries Industries to revise artwork and produce labels according to the new specifications.

The Commission and the LRRG reviewed the label sets. Approved label sheets were produced and individually packaged and sterilised (see Appendix 2a: Pre-Printed Labels). Defries Industries contracted Steritech to undertake gamma sterilisation of the label sheets.

Sufficient labels sheets were produced to cover a trial period of four weeks at PAH and Redcliffe Hospital.

#### 4.3 Label size and content

The specifications for individual labels within the labels sheets were:

- Label size: Large 55 mm x 20 mm; small 40 mm x 10 mm.
- Full generic medicines names with no abbreviations and no brand names.
- No labels with medicine class names with the exception of contrast media.
- Text in plain sans serif font, as large as possible ranging from 15 point to 20 point.
- Lower case letters with initial letter uppercase (i.e. Title case) and application of National Tall Man Lettering as appropriate.

- Colour coding of labels according to the Anaesthetic labelling standard (ISO26825:2008) and extensions to this standard as described in the labelling recommendations issues register.
- Route labels were consistent with the labelling recommendations.

Label sheets were prepared by Defries Industries with properties described in Appendix 9.3.

#### 4.4 Testing and evaluation

The evaluation took place between June and July 2013:

- Education was provided for all intra-operative staff in each test hospital.
- Label sets were trialled for four weeks.
- An evaluation survey was completed for each morning and afternoon operating list (see Appendix 9.4).
- The survey had a selection of open and closed questions including some using the Likert psychometric scale to grade responses.
- Test hospitals collated their evaluation forms and provided these to the Commission with an overview of the test period and outcomes.

#### 5. Evaluation

The two trial centres submitted a total of 57 completed evaluation surveys (Appendix 9.4). One survey was completed for each list (either morning or afternoon) by the respondent who had participated in the majority of cases during that session.

#### **Princess Alexandra Hospital**

**Evaluation started June 2014** 

**Duration** 30 days

Pre-printed label set Appendices 9.1 and 9.2

Total audits completed 42

A total of 625 label sheets were used during the 30 day period in orthopaedic, vascular, cardiology, urology and general surgery lists.

#### **Redcliffe Hospital**

Evaluaiton started June 2014

**Duration** 30 days

Pre-printed label set Appendix 9.1

**Total audits completed** 15

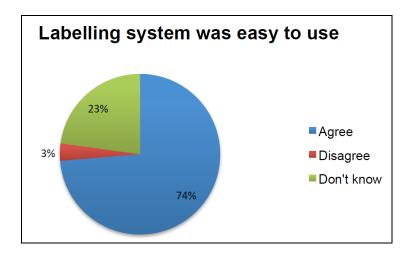
A total of 160 label sheets were used during the 30 day period.

#### 6. Summary and observations

#### 6.1 Acceptability

The majority of respondents (74%) found the labelling system easy to use.

Figure 2: Labelling system ease of use (n=57)



#### 6.2 Label size

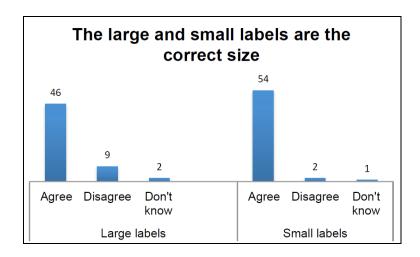
Two label sizes were used; a larger label for large volume fluids (55 mm x 20 mm) and a smaller label for other medicines and fluids (40 mm x 10 mm).

Figure 3: Examples of large and small medicine/fluid labels



The size of the large and small medicine/fluid labels was assessed as fit for purpose.

Figure 4: Medicine/fluid label size



#### 6.3 Font

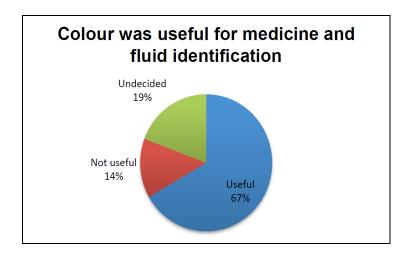
The typeface was sans serif and font size was proportionate to the label sizes ranging from 15 point (small container labels) to 20 points (large container labels).

The size of font used on all labels was found to be legible and appropriate for the intended purpose with 56 and 54 respondents confirming the font sizes were suitable for large and small labels respectively.

#### 6.4 Colour

Label colour assisted medicine and fluid identification. 67% of responding staff stated that label colours were useful for identification, 19% were undecided and 14% felt colour was not useful (see Figure 5). There was no feedback to indicate that colour was detrimental to identification.

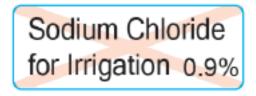
Figure 5: Utility of label colour



#### 6.5 Use of St Andrew's Cross

The pale red St Andrew's Cross water mark was used to differentiate solutions that are toxic if injected (see Figure 6). It was applied to labels for non-injectable medicines and fluids.

Figure 6: Non-injectable medicine/fluid label



The meaning of the red St Andrew's Cross watermark was clear for the majority of staff (46) (see Figure 7) and 83% of staff agreed the red St Andrew's Cross was helpful for label selection (see Figure 8).

Figure 7: The meaning of the red St Andrew's Cross

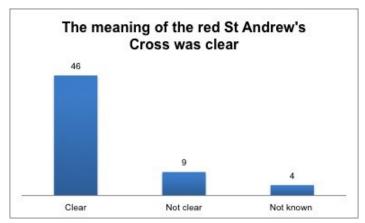
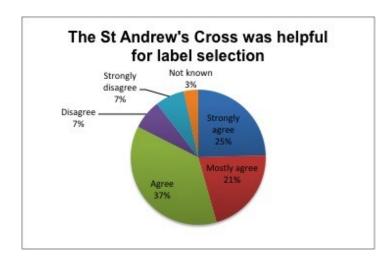


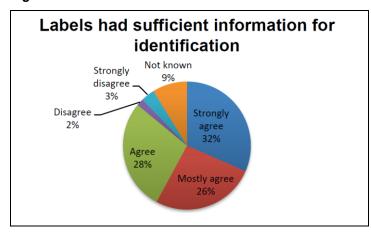
Figure 8: Utility of red St Andrew's Cross for label selection



#### 6.6 Information

The labels had sufficient information to allow for accurate identification of each medicine or fluid on the sterile field.

Figure 9: Level of information detail



#### 6.7 Abbreviated container label

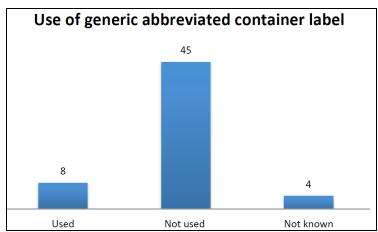
An abbreviated container label or generic label was included (two labels per sheet) to be completed with a sterile marker pen for medicines and fluids not already included on the label sheet.

Figure 10: Abbreviated container label



The abbreviated container label was required in 8 of the 57 surveyed lists.

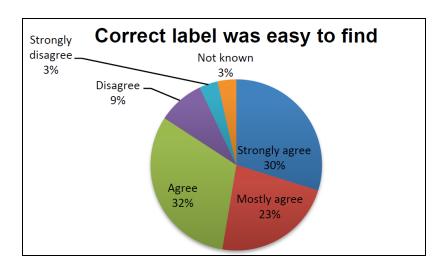
Figure 11: Use of generic abbreviated container label



#### 6.8 Layout of label sheet

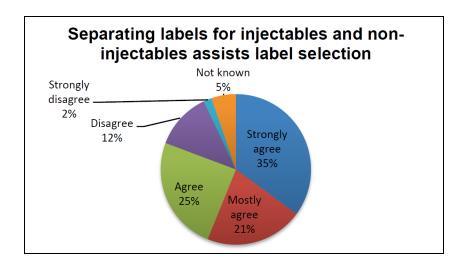
The layout of the label sheet was well accepted. 85% of staff agreed that the correct label was easy to find.

Figure 12: Label selection was relatively easy



Separating labels for injectable and non-injectable medicines assisted label selection for 81% of users.

Figure 13: Separating labels for injectable and non-injectable medicines and label selection

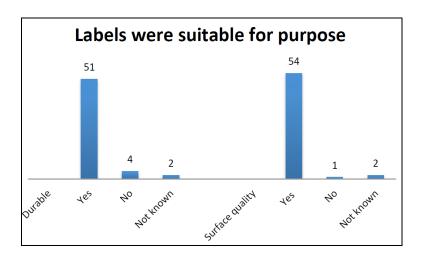


#### 6.9 Suitability for purpose

The labels were durable in 51 of 57 lists.

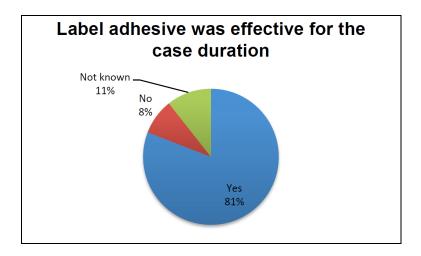
The labels maintained their surface quality in 54 of 57 lists.

Figure 14: Label durability and surface quality



Label adhesiveness was effective and the label remained attached to the syringe or container in 81% of lists. However, label adhesion was compromised in wet conditions (see Section 6.10).

Figure 15: Label adhesion



#### 6.10 Additional comments

#### Acceptability and ease of use

Many of the labels are still not applicable to most of the fluids used – many cases only use one fluid on the field – usually saline – I still don't feel that it should be necessary to use labels for these cases.

Time to find labels due to unfamiliar with layout. Will improve with more use.

Some were still grouped strangely, e.g. Betadines – alcoholic + non alcoholic.

These are great. Suitable for intended use.

More than adequate for endoscopic urology.

Just find the sheet 'too busy'.

The sheet is just 'too busy'. Takes time to find what you want.

#### Label size

They should all be the same size.

Some of the large stickers don't fit on the paper provided on the jugs.

Smaller size preferred – not so much room needed.

Small – application to other size items is better.

Smaller labels are preferable over less larger labels.

#### Use of colour

Black on solid different colours would be good, different coloured writing or 'crosses' makes the label too difficult to read.

Colour blind staff (green). White preferred.

#### Other labels required

Not enough local labels.

Tranaxemic acid

Ringers's solution

Hartmann's solution

Urokinase

Adrenaline 1:1200000

Local anaesthetic

Can we please have more heparin and sodium chloride labels or can we have heparinised saline labels made?

Would like to see more sodium chloride labels - at least 5.

#### Use of abbreviated container label

When there are not enough labels to identify certain medications. E.g. Heparin always runs out.

Have needed this label in other cases.

Did not use because using the pen makes the ink run when wet.

But our sterile pen is water soluble + ineffective.

Sterile marker pens are not waterproof & run if wet (for marking blank labels).

When all printed options are used get extra sheet & use appropriate label rather than abbreviated container label.

#### Label quality

Preparation solutions, heparinised saline and water all removed labels from plastic and they were found on and in the set-up.

Sometimes labels came off.

Surface wasn't compromised. However, adhesive was insufficient when wet.

Would sometimes get caught on another surface and peel away.

They come off if the container became submerged or if a lot of fluid washed over it.

If wet, fluid stickers came off.

The pack used to sterilise the labels does not have a gamma sterilisation indicator. Instead depicts that the pack is designed for other forms of sterilisation as per chemical indicators on package edges.

#### 7. Conclusion

In summary, the results of this trial were positive. The labels presented in this way were easy to use and in most cases the labels were durable and fit for purpose.

The staff were positive about the additional differentiation provided for injectable and non-injectable medicines and fluids. The red St Andrew's Cross water mark and the separation of labels into two distinct areas on the labels sheet were well accepted.

At a local level, the label sheet will require minor adaptation to include fluids used for which there was no label. The abbreviated container label was not used in the majority of lists. However, this generic label was required for some lists where a pre-printed label was not available implying the abbreviated container label should be included on pre-printed label sheets and a sterile marker pen be made available.

Redcliffe Hospitals only use disposable containers and are likely to use labels with a stronger adhesive because there is no requirement to remove labels. There are some reusable metal fluid containers at the PAH, which mean that strategies will be needed for labelling and reuse.

#### 8. References

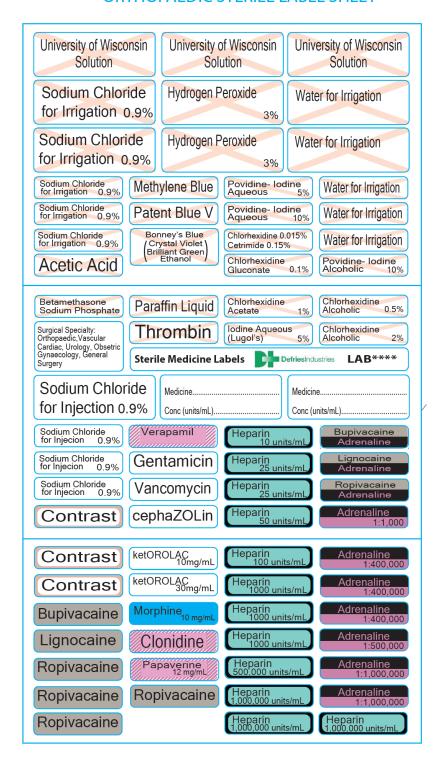
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#### 9. Appendices

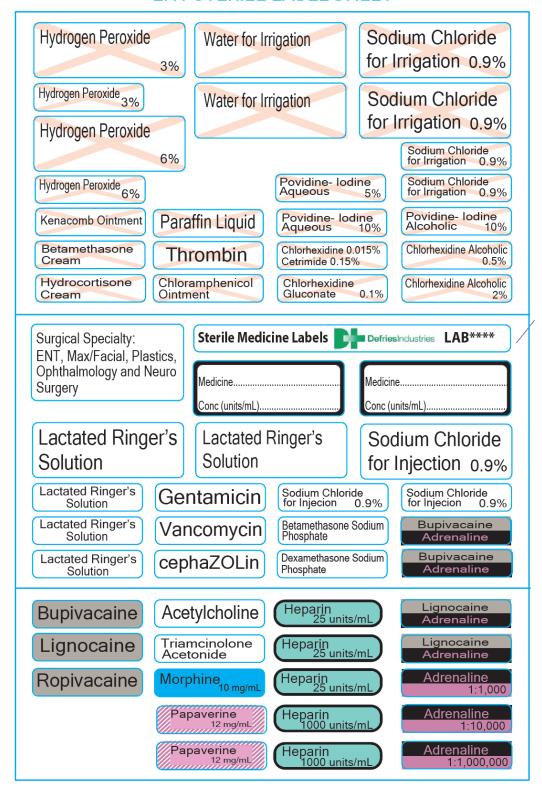
#### Appendix 9.1 Pre-Printed Label Sheet – Orthopaedic (used at PAH and Redcliffe)

#### ORTHOPAEDIC STERILE LABEL SHEET



#### Appendix 9.2 Pre-Printed Label Sheet - ENT (used at PAH)

#### ENT STERILE LABEL SHEET



#### Appendix 9.3 Pre-printed label sheet specifications

Print carrier	Physical Properties
Facestock	
White, one side cast coated, gloss finished, woodfree, printing paper	
Weight	85 g/m²
Thickness	0.085 mm
Liner	
supercalendered glassine paper	
Weight	62 g/m²
Thickness	0.055 mm
Adhesive	
General purpose, permanent, acrylic, latex free	
Peel adhesion 90° FTM 2	100N/m
Tack° FTM1	160N/m
Sterilisation	
Gamma irradiation	

### Perioperative Sterile Labelling Trial Evaluation

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Labelling Trial Evaluation				1	ON SAFEI I	AND QC	JALII 1	IN MEA	ALIH C	ARE
We	eek:		1	Date						
Th	eatre:		:	Scru	b Nurse:					
•	User-a	applied pre-printe	d labels will be asse	essed	over a trial pe	riod of u	up to 4 v	weeks to	)	
	evalua	ite if the <b>Labellin</b>	g System meets th	e nee	ds of the perio	perative	e sterile	fields		
•	Labels	were designed	to ensure easy and	effect	ive use and yo	u can a	ctively	oarticipa	ate in th	iis
	proces	ss by completing	one evaluation per	list wh	ere you are th	e scrub	nurse.			
•	Please	e evaluate the pro	ogram using the follo	owing	statements as	guidar	nce, circ	ling the	item th	at
	best in	idicates your leve	el of agreement							
	1=	Strongly Agree	2=Mostly Agree	3=Ag	ree 4=Disag	ree 5=	Stron	gly Disa	agree	
1.	The	labelling syster	n was easy to use	<b>)</b> .		1	2	3	4	5
La	ıbel siz	ze								
2.	Was	the large label	size suitable for th	he sp	ecified purpo	se?			Yes	/ No
3.	If no	, please indicat	e the preferred lab	oel siz	ze and why.					
4.	For t	he large labels	, please indicate if	f the f	ont size is:					
	a)	too small	b)	abou	t right			<b>c</b> ) 1	too lar	ge
5.	Was	the small label	size suitable for the	he sp	ecified purpo	se?			Yes	s / No
6.	If no	, please indicat	e the preferred lab	oel siz	ze and why.					
7.	For t	he small labels	, please indicate it	f the f	ont size is:					
	a)	too small	b)	abou	t right			<b>c</b> ) †	too lar	ge
Us	se of c	olour								
8.	Whe	re colour has b	een used was it u	seful	for identificat	ion?				
	a)	yes	b)	no				c)	unded	ided
9.	For ea	ach label not su	itable indicate pre	eferre	d colour (incli	uding b	lack or	n white	) and v	vhy.

	The red St Andrew's Cross denotes solutions that are to	oxic if	injecte	d.		
	Chlorhexidine Gluconate 0.1%					
Was	s the meaning of the red cross watermark clear?				Yes	/ No
11.	The red cross was helpful for label selection?	1	2	3	4	5
Info	ormation					
12.	The labels had sufficient information to allow for					
	accurate identification of each medicine or fluid on the sterile field.	1	2	3	4	5
13.	For each medicine or fluid with insufficient information, I required?	ist add	itional	informa	ation	
14.	Did you require the "Abbreviated Container Label" durin	g the c	ase?			
	Medicine					
	Construits (mt.)					
	Yes / No					
15.	If yes, please specify the container and contents that realiabel.	quired	identifi	cation	with th	is
Lov						
	out out					
	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label selection?	1	2	3	4	5
16.	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label	1	2	3	4	5
16. 17.	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label selection?				<u>-</u>	
16.	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label selection?  The labels were easy to find				4	
16. 17. Fitr 18.	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label selection?  The labels were easy to find  ness for purpose	1			4 Yes	5
16. 17. Fitr 18. 19.	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label selection?  The labels were easy to find  ness for purpose  The labels were durable throughout each case.  The labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels are supported by the labels of the labels o	ase.	2 at occi	3 urred a	4 Yes Yes	5 / No / No
16. 17. Fitr 18. 19.	Placing injectable medicines and non-injectable medicines and fluids into separate areas assists label selection?  The labels were easy to find  ness for purpose The labels were durable throughout each case.  The labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained their surface quality throughout countries of the labels maintained	ase.	2 at occi	3 urred a	4 Yes Yes	5 / No / No

- 23. Do you have any other comments?