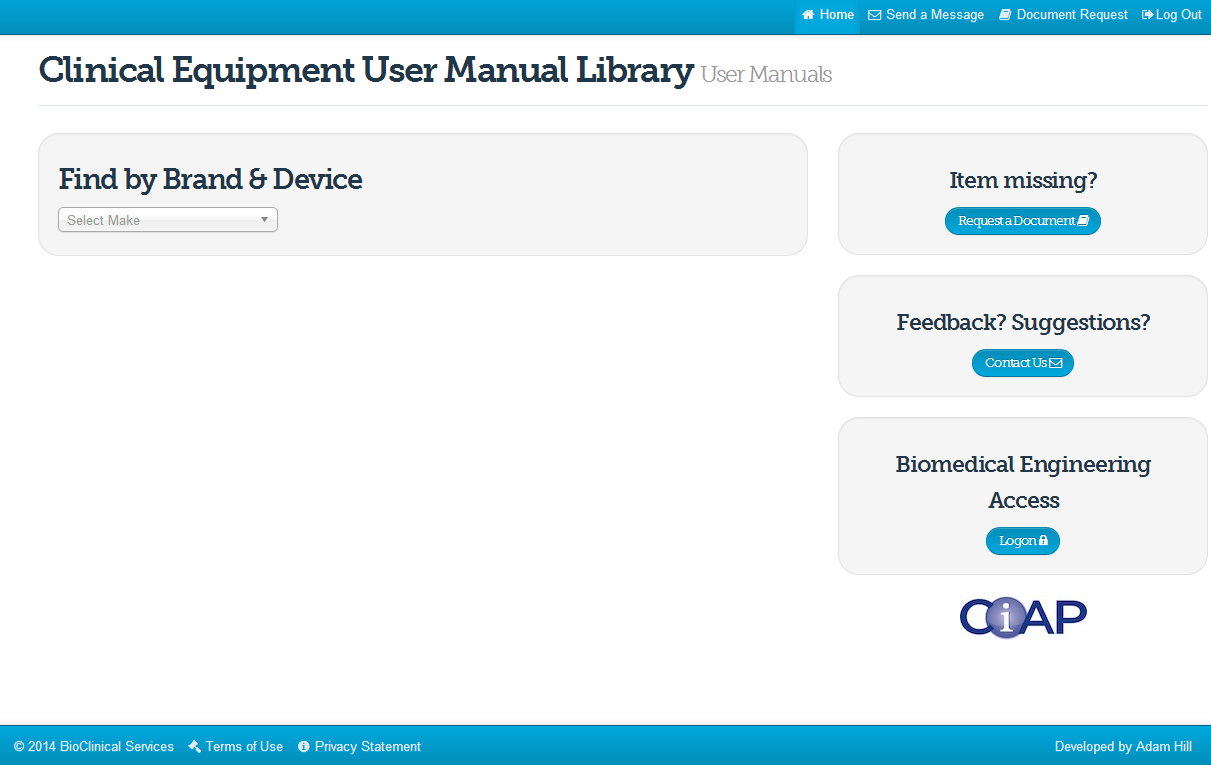
PAGE 2



**Accreditation has been a significant contributor to driving and inspiring continuous quality improvements within healthcare.**

Standardization has a proven track record within large complex systems and Healthcare is no exception

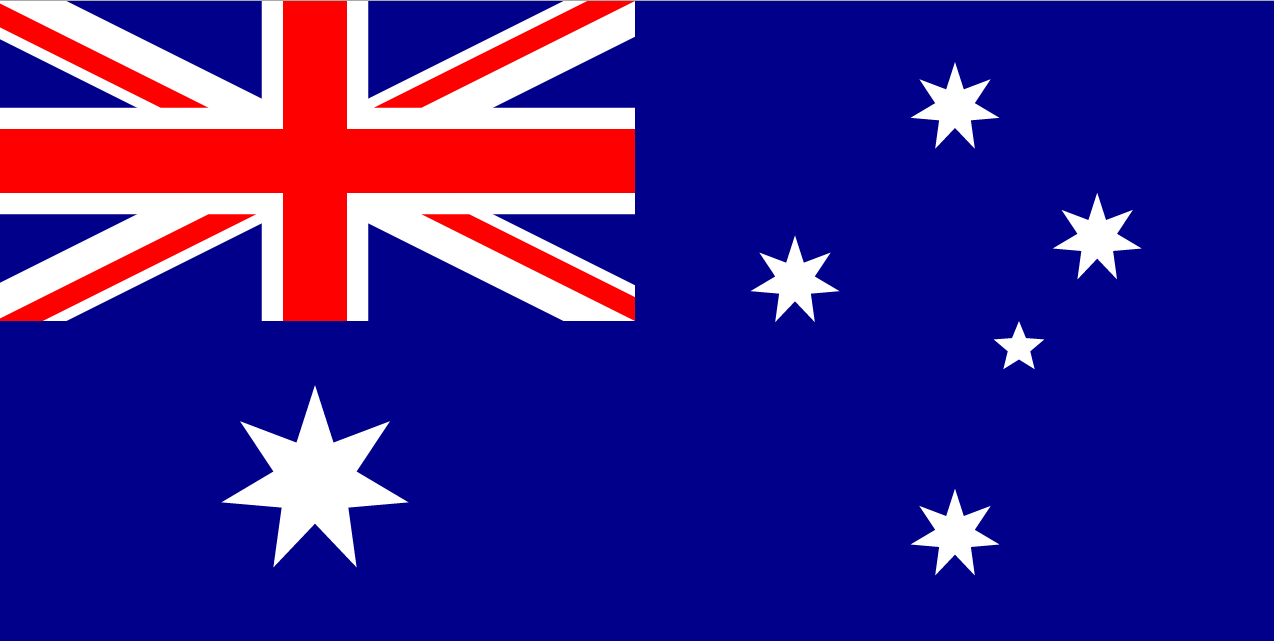
One of the benefits of the new National Safety and Quality Health Services Standards is that it will continue to drive proven and tested strategies which inevitably become standards

The Clinical Equipment User Manual Library ( CEUML ) has entered into its 5th year as the single access point for all New South Wales hospitals to access the medical equipment instruction manuals

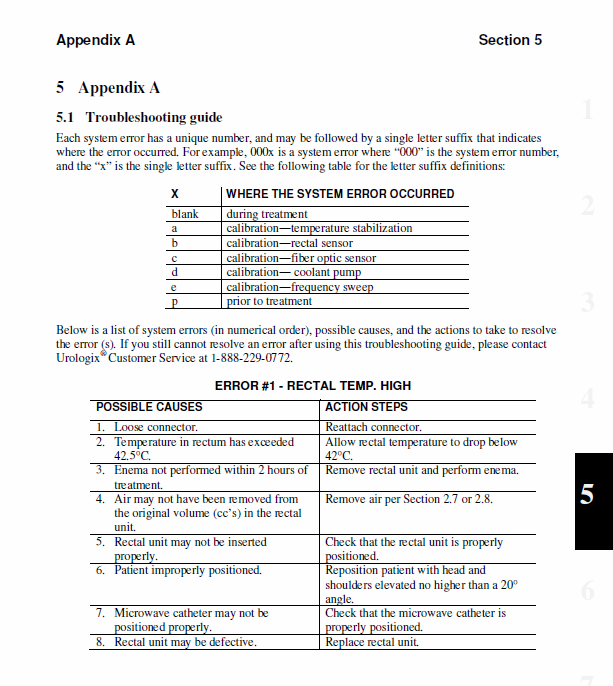
**We have standardized access to over 220 Australian and UK Hospitals, and we would like your support to roll this out to all Australian Hospitals**

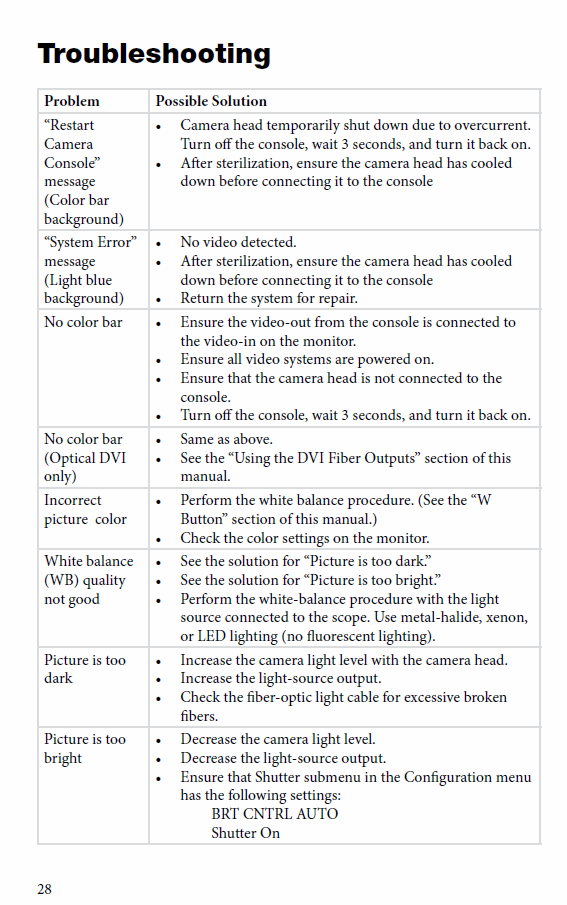
Nursing Staff , Clinicians and other professional Medical Equipment Users should be able to walk up to any PC in any hospital in Australia and get the Manufacturer’s Reference Documentation ( Instructions for Use , Set-up Guides , User Manuals ) within a few clicks ……….

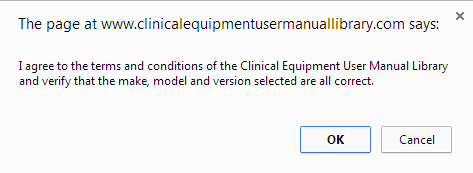
Just like they do with Chemicals and their MSDS

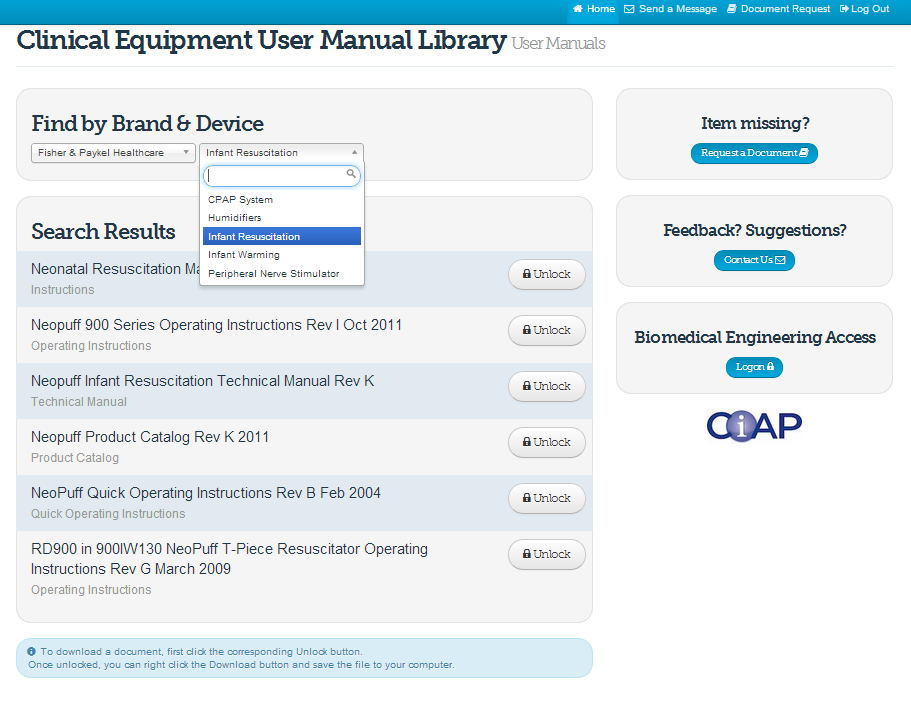


Made by Australians , Employing Australians , Supporting Australian Healthcare











PAGE 1

**Every Hospital in Australia and New Zealand has a legal and compliance obligation to make sure all Clinical Staff can access the Manufacturer’s Instructions for Use for equipment they use every day**

National Safety and Quality Health Service (NSQHS) Standards

ACHS EQuIPNational Guidelines – **Guideline 15 Corporate Systems and Safety**

**National Safety and Quality Health Service Standard 3**

**3.16** Reprocessing reusable medical equipment, instruments and devices in accordance with relevant national or international standards and manufacturers’ instructions.

**National Safety and Quality Health Service Standard 8**

8.4.1 Key task : Outputs of improvement processes may include :

procedures, protocols and guidelines for the use of and access to equipment

**Criterion 15.15.1**

“ ……..An organisation should have documented management strategies for all medical devices used within its facilities including:

• medical devices owned, leased or rented by the organisation etc …….

AS/NZS 3551:2004 *Technical management programs for medical devices*67

details for the organisation’s Board, executives and managers the minimum

requirements of an effective strategy for the management of medical devices …..”

AS/NZS 3551:2012

S E C T I O N 2 M E D I C A L D E V I C E

M A N A G E M E N T P R O G R A M

2.4.3 2.4.3 Supporting documentation

Documents such as standards, user guides, technical manuals and other supporting publications shall be identified, stored, issued and updated in a controlled manner.

AS/NZS 3551:2004

S E C T I O N 2 M E D I C A L D E V I C E

M A N A G E M E N T P R O G R A M

2.3.4.4 Device-specific documents

*Documents such as technical and user manuals shall be identified and their location recorded in the database.*

**PAGE 3**

**No Body Reads the User Manual , so now what !**

I don’t ,and in all likelihood neither do you.

We don’t think it was ever meant to be read – it’s a Reference Manual and professionals in healthcare have been using Reference Manuals for many years.

**So how can these Reference Documents make a difference?**

We believe that by focusing on one aspect of the Manufacturers’ Instruction Manual: The User Troubleshooting Guide

Largely driven by the culture of litigation in the USA most manufacturers have developed robust data and error logging systems this has allowed them to create very useful failure indicators, when used in conjunction with the **USER Troubleshooting Guide in the Manufacturers Reference Document aka User Manual, allows staff to:**

* Accurately identify the problems
* Establish the possible cause – User or Technical Issue
* Offer suggested solutions which can be actioned at the point-of-care

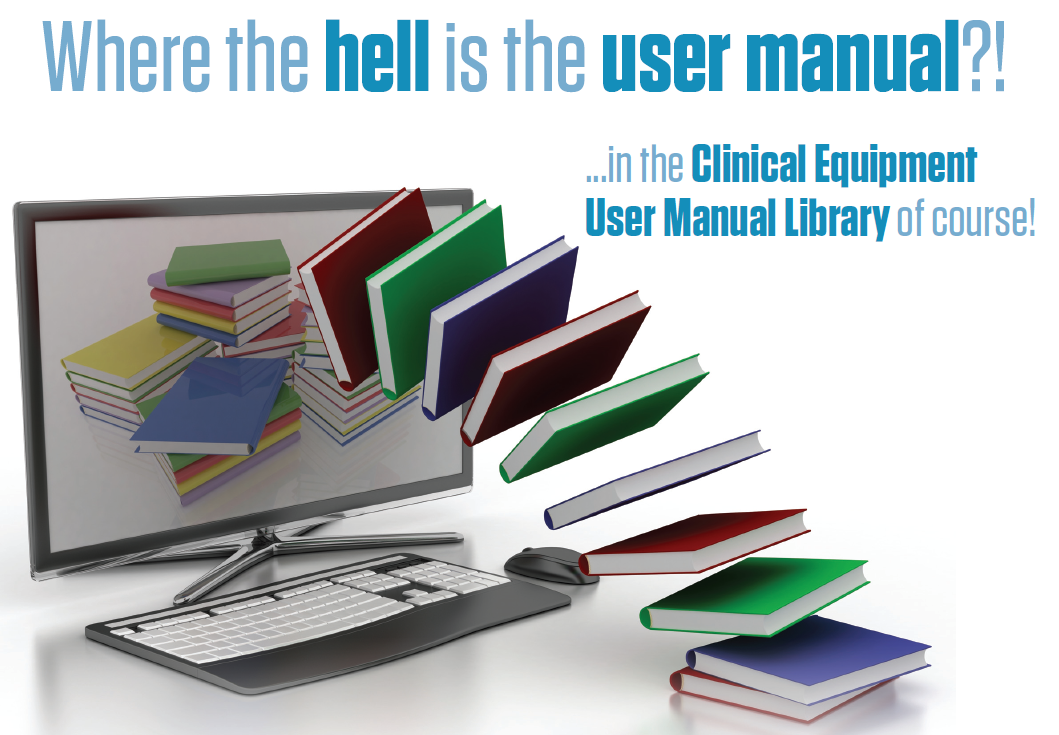
**Our experience has been that most USE issues are the same problems repeated over and over**  , in many cases irrespective of the make or model of the device . User troubleshooting is a skill which can be taught and transferred and this allows medical and nursing staff to gain confidence and real experience .

Searchable pdf User Manuals allowsstaff to find the information they need within seconds and universal access to these manuals throughout the organisation allows management , educators and suppliers to grow these skills

**Immediate Benefits to Using the User Manual Library**

* **Standardised Access**
* to all your hospitals Medical Equipment User Manuals throughout the various Departments, Buildings and Trusts.
* **24hrs e-mail support** via the Document Request Tab to any logged in member of staff – they will get feedback regarding their request!
* **Simple Set-up**  as quick as you can get the IT Department to place a link on your hospital Intranet.
* **No Administrative Burden** or increase in staff work load to keep it up-to-date. We do all the work.
* **One of the most valuable components of the Manufacturers’ Reference Manual is the *User Troubleshooting Guide***
* This is part of the process of getting Make and Model experience – working through and “fixing” user issues helping Clinicians in their understanding of the devices they use everyday

“No Fault Found” is an objective outcome of a device reported as been faulty and sent for repairs with no technical issue established without focusing on an individual ability or competence



**ACHS Clinical Indicator User Manual 2012 Intensive Care version 4**

7.2.16 Library facilities – an appropriate range of bench manuals , textbooks , journals and access to electronic medical information should be available 24 hours a day within the unit complex.

8.3 Protocols and in-service training for medical and nursing staff need to be available for the use of all equipment , including steps to be taken in event of a malfunction

**AORN : RECOMMENDED PRACTICES**

RP for Electrosurgery 2.8 March 2012

Read and attach the manufacturer’s manual to the unit or cart on which the ESU sits (pg 375)

During the use of AEC ( Argon enhanced coagulation technology) , all manufacturers written instructions should be followed in addition to all safety measures for monopolar surgery .

**Australian and New Zealand College of Anaesthetists (ANZCA)**

PS31BP 2012 Guidelines on Checking Anaesthesia Delivery Systems

It is the responsibility of each facility to ensure that specific checklists are available in accordance with manufacturers’ guidelines, for each item of equipment relevant to anaesthesia delivery systems.

**AS/NZS 4173:2004 Guide to the safe use of lasers in health care**

SECTION 9 SAFE PRACTICES

9.2 (j) The laser safety rules and equipment instructions are required to be made available at the site of use .

**Australian / New Zealand Resuscitation Council :Guideline 11.4 Dec 2010**

Electrical Therapy for adult advanced life support

Care should be taken to ensure that the pads or electrodes are applied in accordance with the manufacturer’s instructions …..

|  |
| --- |
| **STATE CORONER VICTORIA** |

Coroner’s “Investigation Standard”: Fall-related deaths in hospital

Relevant Equipment or work practice ( pages 2 )

b) If a particular product was involved, were the manufacturer's instructions available and followed? (If not why not?).