GUIDELINE

Reusable Medical Devices: Reprocessing, Tracking and Traceability

Scope (Staff):	Nursing and Medical Staff
Scope (Area):	NICU KEMH, NICU PCH, NETS WA

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this disclaimer

Aim

To outline the expected standard for the reprocessing (cleaning, disinfecting and/or sterilisation) of reusable medical devices (RMDs) prior to, and between patient use and the requirements for traceability of RMD's in Neonatology.

Risk

Patient safety may be compromised if a standardised protocol is not followed.

Reusable Medical Devices (RMDs)

- All RMDs will be reprocessed according to their intended use, refer to Medical Devices: Single Use, Single Patient Use and Reusable (see Appendix 1: Spaulding Classification System) and manufacturer's advice.
- All semi-critical and critical medical devices will be reprocessed as required to ensure compliance with AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.
    - At KEMH: Refer to the CSSD Protocol: Reprocessing of reusable medical devices.
    - At PCH: Refer to the CAHS IPC Policy: Medical Devices: Single use, Single Patient Use and Reusable.
- Traceability of RMD's is required to comply with the traceability requirements of AS 5369:2023.

- Censitrac electronic tracking and data management system for RMDs is used. Please see CAHS IPC Policy: Medical Devices: Single use, Single Patient Use and Reusable.

Note: Infant feeding equipment is not considered to be a medical device and is therefore out of scope for this guideline. Please see Guideline: Management of Infant Feeding Equipment in Western Australian Healthcare Facilities

Tracking and Traceability of Reusable Medical Devices at Point of Care

- At KEMH - remove the Meditrax label from the outer wrapping of the reusable instrument pack and place in the patient progress notes MR420. This label identifies the date of sterilisation, cycle number and contents for tracking and traceability compliance with AS 5369:2023. This is the responsibility of the staff member who removes the outer wrapping of the reusable device and it is verbally confirmed to the operator.
- At PCH – Refer to Appendix 1 Work Instruction: Capture and Track RMD's to Infants using Censitrac™. This is the responsibility of the staff member who removes the outer wrapping of the reusable device and it is verbally confirmed to the operator.
- NETS – Contact NETS CNC/CNM for NETS processes.

Critical and Semi-Critical Medical Devices that must be reprocessed by HSSD/CSSD	
NICU KEMH	3B PCH / NETS
Universal Tray	CMAC blades
Eye Speculum	Magill forceps
IA Kits	
ENT tray	
Suture tray	
Video laryngoscope blades	

Semi-Critical Reusable Medical Devices that are reprocessed within the Neonatal Unit	
NICU KEMH	3B PCH & NETS
RetCam Lens	RetCam Lens

There are other reusable medical devices (non-critical) that require sterilisation by CSSD but do not require tracking or traceability processes as they are not categorised as semi-critical or critical (i.e non-critical are items that only come into contact with intact skin (and not mucous membranes).

Non-critical Medical Devices that are reprocessed by HSSD/CSSD	
NICU KEMH	3B PCH NETS
Manual Resuscitation bag with peep valve	Nitric injector module
Fabian exhalation valve and membrane holder	Fabian exhalation valve and membrane holder
MRI exhalation valve and green diaphragms	Draeger VN500 expiratory valve and flow sensor
Draeger Babylog ventilator expiratory block	MRI exhalation valve and green diaphragms
Test Lungs	Test Lungs

For further information on Tracking and Traceability of Reusable Medical Devices refer to the following Policies:

- PCH Tracking and Traceability of Reusable Medical Devices
- KEMH Reusable Medical Devices

Related CAHS internal policies, procedures and guidelines
CAHS Medical Devices: Single use, single patient use and reusable policy
WNHS Reprocessing of reusable medical devices policy
PCH CSSD Tracking and Traceability of Reusable Medical Devices
Retinopathy of Prematurity (ROP) Guideline
CAHS IPC Policy: Medical Devices: Single use, Single Patient Use and Reusable

References and related external legislation, policies, and guidelines
Guideline: Management of Infant Feeding Equipment in Western Australian Healthcare Facilities
AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities

This document can be made available in alternative formats on request.

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Appendix 1: 3B Capture/Track RMDs to Infants using Censitrac™

To instruct staff on the correct procedure on tracking critical and non-critical RMDs including ventilator blocks, flow sensors and lungs to infants using Censitrac™

Equipment

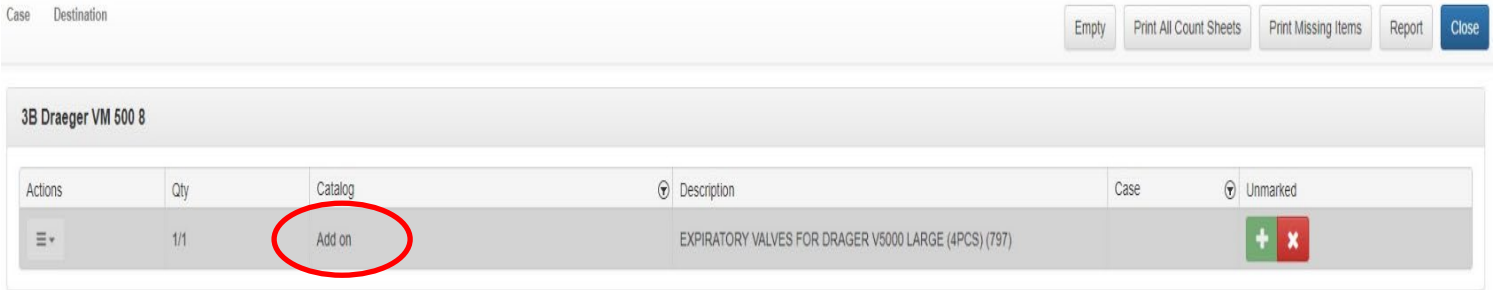
- Censitrac™
- Honeywell Scanner
- Ventilator (VN500) and associated RMDs, C Mac blades, reusable Magill forceps

Instructions

Assembling the Ventilator

Log onto Censitrac™ and from the main menu select Workflow (1) and then Case Cart Assembly (2)

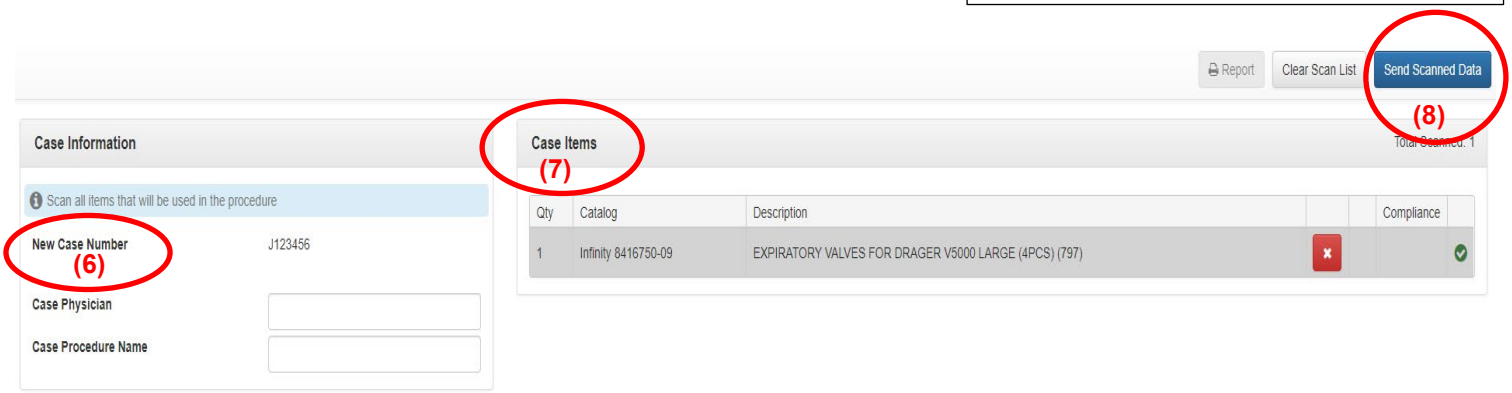
Scan the Censitrac Barcode on the Ventilator (3) and then scan each RMD used on the ventilator (4) Once all the RMDs are scanned, click on "Add on" in the grey bar pictured below, then exit.



Tracking to patient

Ventilator: Once the patient is admitted, track the RMDs on the ventilator to the patient via the case tracking function (5)

In case Tracking, scan the patients barcode or enter the patients UMRN into the case number field (6) Then scan the CMAC or magill forcep bar code **OR** ventilator barcode (3) and the RMDs attached to the ventilator will be visible in the case items list (7) Ensure 'Send Scanned Data' button is pressed to complete the capture of RMDs to patient (8) Once this is pressed a Case Tracking Report will display on the screen for your reference. You can close this.



Changing RMDs on the Ventilator

If the RMDs on the ventilator require changing, e.g. when setting up a new circuit, scan the ventilator barcode (3) The ventilator contents should appear on the screen. If putting an entire new circuit on the ventilator first click Empty (9) and then scan the new RMDs.

If an individual item is replaced on the circuit. Click the (X) Icon next to the RMD being replaced and then scan the new RMD to the ventilator. If the ventilator is still being used by the patient, the new RMDs will need to be tracked to the patient via the method above.