SA Health

Guideline

Asset Management: Biomedical Technology Lifecycle Part 2: Acceptance to Disposal

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Government of South Australia
SA Health

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Asset Management: Biomedical Technology Lifecycle Part 2: Acceptance to Disposal

2. Relationship to parent policy

The Asset Management Policy is the parent policy to this Asset Management: Biomedical Technology Lifecycle Part 2: Acceptance to Disposal Guideline

3. Guideline statement

SA Health applies consistent asset management principles over the asset lifecycle (planning, acquiring, managing, maintenance and disposal) for delivery of health services and ensure assets are appropriate, available, safe, used effectively, functioning correctly, and compliant with relevant laws, regulations, and standards.

These work practices for biomedical technology support the Asset Management Policy and the Australian Standard for Technical Management Programs for Medical Devices (AS3551) by providing minimum expectations.

The guideline applies to biomedical technology assets regardless of where in SA Health it is used or located, and for all acquisition processes: developed, purchased, leased, borrowed, rented, donated, on loan (short- or long-term) to hospital or patient, or within a consumable or fluid contract.

4. Applicability

This guideline applies to all employees and contractors of SA Health; that is all employees and contractors of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

5. Guideline details

5.1 Asset Registration

5.1.1 Registration in BAMS

- The Biomedical Asset Management System (BAMS) is the approved computerised equipment database for SA Health that enables management of biomedical technology and provides evidence of adequate and effective operation of the biomedical technology at all stages of its life in accordance with AS3551.
- The SA BME Asset number (using BAMS unique identification number) affixed to biomedical technology should be used to identify the asset and its records in BAMS over its lifetime and beyond until records can be disposed (refer Asset Management Policy).
- Instructions should be followed for asset registration. Refer to Appendix 1: Instructions for Asset Registration - Registration in BAMS.

5.1.2 Special Cases for Asset Registration

- Refer to Appendix 1: Instructions for Asset Registration – Special Cases for Asset Registration:
    - Generic asset number – special cases.
    - Replacement assets - insurance, recall, warranty, etc.
    - Homecare use.
    - Lease, hire or rent.
    - Medical gas systems.

- Systems of biomedical technology.
- Temporary use - Loan from supplier, evaluation, or Trial.
- Test equipment - Testers.

5.1.3 Fixed Asset Register and Annual Stocktake

- While it is the responsibility of the equipment owner to submit Fixed Asset Addition Forms for new capital assets (including donated, bequeathed or gifted) to the Fixed Asset Register, SA BME should facilitate this after BAMS registration.
  - Refer Property, Plant and Equipment Accounting Policy and associated Fixed Asset Fact sheets.
- Appendix 1: Instructions for Asset Registration– Fixed Asset Register and Annual Stocktake should be followed:
  - Asset registration agreement - Fixed Asset and SA BME.
  - Monthly report from SA BME to Fixed Asset Team.
  - Annual asset stocktake.

5.2 Acceptance and Commissioning

- Before first use, all biomedical technology entering a SA Health facility or being used on its clients should undergo an appropriate level of pre-operational testing such that BME LHN/ State-wide Clinical Support Services (SCSS) is satisfied it is safe, functioning correctly, and compliant with relevant laws, regulations and standards.
- This should apply whether:
  - fixed or mobile,
  - newly acquired or donated,
  - temporary or permanent
  - on loan
  - lease or hire
  - for the LHN or patient (short term or long term), or
  - being supplied as part of a clinical trial.

5.2.1 Delivery Checks

- All biomedical technology should be delivered to BME if possible, for acceptance and commissioning before first use and remedied if performance is unsatisfactory.
  - Follow Appendix 2: Instructions for Acceptance and Commissioning – Delivery checks.

5.2.2 Use and Pre-use Training

- Coordination should occur prior to acceptance between supplier, clinical users, clinical education and training provider (where offered internally), quality control and supply/stores to ensure adequate installation/implementation time frames are provided for education and training.
  - Follow Appendix 2: Instructions for Acceptance and Commissioning– Use and Pre-use Training.

5.2.3 Maintenance planning

- In addition to the requirements in section 5 of the AMBT Maintenance Planning Policy, the following should be considered in relation to maintenance planning:
  - Follow Appendix 2: Instructions for Acceptance and Commissioning- Maintenance planning.
- Performance Verification (PV) checklist should be developed for the pre-use test with consideration of special cases:
  - Configurable biomedical technology.

- Homecare use.
- Systems of biomedical technology.
- Non-biomedical technology within the patient environment.
- Temporary use (Clinical Trial).
- ICT-connected.

5.2.4 Pre-use Test and Documentation

> Should undertake performance verification using PV checklist and document in BAMS.
    - Refer AS/NZS 3551 Section 5 Acceptance, 5.3 Acceptance Check and Inspection, 5.3.2 General Acceptance Inspection.
> Appendix 2: Instructions for Acceptance and Commissioning - Pre-Use Test and Documentation should be followed.

5.2.5 Label Equipment

> Labels should be applied to the biomedical technology before delivering for clinical use.
> Appendix 2: Instructions for Acceptance and Commissioning - Labelling should be followed.

5.3 Lifetime Maintenance

5.3.1 Safety of Technical Staff including Cleaning of Assets

> Staff undertaking repairs should be employed based on qualifications and skills, qualified to undertake the work and should be expected to gain knowledge of risks documented in service manuals and from device-specific training.
> Refer to Appendix 3: Instructions for Lifetime Maintenance – Instructions for Safety of Technical Staff:
    - Contaminated equipment cleaning.
    - Electrical safety.
    - Mechanical workshop.
    - Chemical safety.
    - Working in Isolation.
    - Infectious patient areas.
    - Immunisations.
    - Travel.

5.3.2 Lifetime Service History

> All maintenance interventions on biomedical technology should be documented in the BAMS linked to the SA BME asset number.
    - Acceptance: pre-use testing, commissioning, configurations and purchase details
    - Configuration and approval.
    - Corrective, ad hoc, or breakdown maintenance including after-hours repair.
    - Scheduled maintenance: performance verification and/or preventive maintenance, checklists and test equipment.
    - Parts replaced.
    - Modifications and upgrades.
    - Hazards, recalls, safety issues and incidents with corrective actions.
    - Identification of personnel doing the work.

- Date of removal from service and reason for removal.
- Obsolescence: end of life supplier support, removal for legislative or safety reasons.

5.3.3 Asset Repair or Upgrade

> The most effective corrective maintenance (speed, cost and quality) should be performed by in-house or on-site BME with few devices under service contract or repaired by external service providers.

> Appendix 3: Instructions for Lifetime Maintenance - Instruction for asset repair (or upgrade) should be followed:

- Work request
- Repair action, prioritisation and safety
- Service history
- External repair costs
- Homecare use
- BME Loan Library
- ICT and computer-connected
- Biomedical technology - consumable and accessory storage and supply

5.3.4 After Repair or Upgrade - Performance Verification

> Before returning to use, performance should be verified using the PM checklist with consideration for:

- Fault preventable with PM
- No fault found
- Configurable biomedical technology
- Test equipment

> Appendix 4: Instruction for Asset Repair (or Upgrade) - Performance verification should be followed.

5.3.5 Modification of Biomedical Technology

> SA BME is the SA Health authority to determine if biomedical technology should be modified, arrange approval, documentation, and testing before use.

> Appendix 5: Instruction for Modification of Biomedical Technology - Instruction for Modification of biomedical technology should be followed.

5.3.6 After Hours Repair (on-call or pre-approved overtime)

> BME (LHN) may provide a 24-hour, 7 day on-call service for urgent disruptions to service delivery.

> Appendix 6: Instruction for After-Hours Repair (on-call or pre-approved overtime) should be followed.

5.3.7 Scheduled Maintenance

> Scheduled maintenance should be performed as planned during acceptance to ensure that biomedical technology, over its lifetime, remains available, safe, functioning correctly and compliant with relevant laws, regulations, and standards.

> Appendix 7: Instructions for Scheduled Maintenance should be followed:

- Notify users of devices due for scheduled maintenance.
- Prioritisation of scheduled maintenance.

- Label and return after scheduled maintenance.
- Overdue for scheduled maintenance.
- Lost/missing biomedical technology.
- Scheduled maintenance service history.
- Scheduled maintenance fail.
- Test equipment PV.

5.3.8 Shutdown and Outage Management

- If maintenance or a repair will adversely impact patients or health service delivery, or during a severe or catastrophic disaster with essential services outages, shutdown management may be necessary.
- BME LHN managers should facilitate the identification and assessment of key risks with biomedical technology, and collaborate with:
  - Clinical users - Follow an agreed Business Impact Assessment (BIA) and communication plan (usually identified in the LHN Business Continuity Plan, BCP).
  - Facility Asset Management Services - where there will be an impact on supply of mains power, mains water, medical gases, or other infrastructure, such as during installation or removal of large, hard-wired biomedical technology (eg medical imaging).
  - Medical departments - ensure equipment users are aware of, and can mitigate, the risks of outages.

5.3.9 Legislative Changes and Compliance

- Where biomedical technology or its use is impacted by changes to legislation or relevant Australian Standards, BME should be participants in the consultation process, aware of the impact, and collaborate with LHN on actions to be taken for compliance.
- Appendix 7: Instructions for Scheduled Maintenance - Legislative Changes and Compliance should be followed.
  - LHN BME managers.
  - Manager BME and SA BME Operations Manager.

5.3.10 Biomedical Technology Incident Investigation

- Where biomedical technology has been involved in a patient incident and is believed to have contributed to an adverse event, eg in the Safety Learning System (SLS), the investigation should be the responsibility of the medical department manager with engagement of SA BME as required.
- BME (LHN) should participate in the reporting, investigation and risk management of biomedical technology related incidents registered in the SLS, uploading BME investigation reports and recording actions and reports against the asset in the BAMS Incident Module.
- Appendix 8: Instruction for Biomedical Technology Incident Investigation should be followed:
  - Notification from SLS.
  - Investigation.
  - BME reviewer.
  - BAMS Documentation.
  - Review by SA BME Leadership Committee.

5.3.11 Hazard and Recall Alerts

- Hazard and recall alerts for biomedical technology should be monitored by BME LHN and actioned in a timely manner.

- Appendix 9: Instruction for Hazard and Recall Alerts should be followed:
    - Sources of alerts.
    - Actions.
    - Update BAMS asset history.

5.3.12 BME Service Review and Escalation

- SA BME has a range of surveys available for feedback to be provided on the service provided by BME, clinical training for users and clinical performance of biomedical technology.
- Appendix 10: Instruction for BME Service Review and Escalation should be followed.
- If BME service activities are not performed appropriately, issues may be raised to the BME LHN area manager. Further escalation should be to their LHN manager or manager BME to table at SA BME Oversight Committee for wider discussion.

5.3.13 Contract Management

- Where a service agreement exists to support a piece of biomedical technology, the services of the supplier, manufacturer or a third-party maintenance provider should be managed by BME.
- Appendix 11: Instruction for Contract Management for BME should be followed:
    - Acquire contract.
    - Purchase contract.
    - Register contract.
    - Manage contract.

5.3.14 Management of External Contractors

- SA Health has a responsibility for the safety of external contractors working within its organisation and on its biomedical technology.
    - External contractors include suppliers, installers and service providers.
- Appendix 11:5 Instruction for Management of External Contractors should be followed:

5.3.15 Asset Data Update

Fixed Asset Register

- While it is the responsibility of the equipment owner to submit Fixed Asset Update Forms to change the Fixed Asset Register, SA BME should facilitate this after changes of biomedical technology ownership, location or status within BAMS:
    - Monthly reports from BAMS identify biomedical technology additions, deletions and transfers of capital assets (for items and systems greater than $10,000), ‘BAMS Asset Additions, Deletions and Transfers YYYYMM’.
    - BME LHN assure correctness of report.
    - SA BME Capital Programs Manager sends corrected report to Fixed Asset Team.
    - Refer Property, Plant and Equipment Accounting Policy.

Data Integrity BAMS

- The BME LHN should validate BAMS for data integrity at their sites by:
    - Requesting clinical units and businesses report back to BME inconsistencies observed during stocktakes.
    - Requesting ward staff report back to BME inconsistencies observed during their normal daily work.

- BME Technical Teams performing periodical data cleansing tasks and review the data for consistency, eg make and model.
- Following procedures from SA BME BAMS Guidebook and Business Rules to promote consistency in data entry.
- Participating in BAMS User Group to monitor procedures and standardisation to ensure state-wide data consistency and provide communication between BAMS users.
- The SA BME Operations Manager arranging education and training sessions on data entry in BAMS:
  - New staff members (during induction).
  - Ongoing training sessions - focus education sessions for all staff.

5.4 Asset Removal – Reallocation, Trade-in, Sale or Disposal,

- SA Health requires maximising the use of all biomedical technology within SA Health before achieving value for money through trade-in, sale, donation, salvage, recycling, or disposal.
- Appendix 12: Instructions for Asset Removal – Reallocation, Trade-in, Sale or Disposal should be followed.

6. Supporting information

- Australian and International Standards (access latest release though SA Health Library Service):
  - *AS/NZS 2243 Series relevant Standards – Safety in Laboratories*
  - *AS/NZS 2500 Guide to the safe use of electricity in patient care*
  - *AS2896 Medical gas systems - Installation and testing of non-flammable medical gas pipeline systems*
  - *AS3551 AS/NZS 3551 Management programs for medical equipment*
  - *AS/NZS 3760 In-service safety inspections and testing of electrical equipment*
  - *IEC 60601 Relevant Standards pertaining to Medical Technology*
  - *IEC 80001-1 Application of risk management for IT-networks incorporating medical devices, Part 1: Roles, responsibilities and activities*
- Addressing Vaccine Preventable Disease: Occupational Assessment, Screening and Vaccination Policy
- Asset Management: Biomedical Technology Maintenance Planning Policy
- Asset Management Policy
- Asset Management: Biomedical Technology Lifecycle Guideline Part 1: Planning and Acquisition
- Capital Projects Accounting Framework Policy
- Remote or Isolated Work (WHS) Guideline
- Contractor Safety Management (WHS) Policy
- Medical Gas System Policy
- *National Association of Testing Authorities* (NATA) guidelines
- *Office of the Gene Technology Regulator* (OGTR) guidelines
- Procurement and Contract Management System (PCMS) Policy
- Procurement Policy
- *Procurement Services SA*

- Property, Plant and Equipment Accounting Policy
- *Radiation Protection and Control Act 1982*
- Risk Management Policy
- SA BME BAMS Performance Assessment Report
- SA BME BAMS User Guide and Business Rules
- SA BME Definition of Biomedical Technology
- Safe Driving Policy
- Disposal Policy
- *South Australian Cyber Security Framework*
- *Therapeutic Goods Act 1989* and associated Regulations
- *Treasurer's Instruction 2 Financial Management*
- *Work Health, and Safety Act 2012*

7. Definitions

- **Accessory** means user-replaceable items attached to biomedical technology that aren't consumables and can be changed without a tool. These additional parts are used in order to achieve the intended purpose of the biomedical technology; adapt it to some special use; facilitate its use; enhance its performance; or enable its functions to be integrated with those of other equipment.
- **Biomedical Asset Management System (BAMS)** means an electronic database comprising a record for each item of biomedical technology to provide evidence of adequate and effective operation of the biomedical technology management program in accordance with AS3551[1].
- **Biomedical technology management group** means organisations and people that provide biomedical technology management and maintenance services to SA Health and participate in SA BME Committees (Oversight, Leadership and Operations) and Community of Practice.
- **Biomedical technology** means any electronic, electro-mechanical, mechanical, optical or pneumatic instrument, device, equipment, apparatus, or appliance, (whether used alone or in combination, and including the software necessary for its proper application) intended, by the assigned SA Health manager, to be used either in-vitro or in-vivo for human beings for the purpose of, or research into, one or more of the following:
    - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
    - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
    - investigation, replacement or modification of the anatomy or of a physiological process, or pathological process, or
    - control or support of conception, and
    - that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which that may be assisted in its function by such means, or
    - an accessory to such an instrument, device, equipment, apparatus, appliance, or devices intended for disinfecting another medical device.

  Any device, instrument, apparatus, accessory or consumable attached to the item of biomedical technology whether by direct or indirect (eg wireless connection) means is to be considered part of the biomedical technology.

[1] AS/NZS 3551 Section 2 Medical Equipment Management Program, 2.5 Equipment Database, 2.5.1 General

The Manager BME should maintain a list of biomedical technology that is either exempt from this policy or included where such inclusion was either considered to be ambiguous or subject to a specific determination.

- **Consumable** means part of the biomedical technology that is replaced after patient use.
- **Performance Verification (PV)** means testing the essential performance parameters of the biomedical technology. This will require a range of physical, functional and electrical tests to confirm it can perform safely and as intended by the manufacturer.
- **Preventive Maintenance (PM)** means maintenance carried out at predetermined intervals, or according to prescribed criteria, and intended to reduce the probability of failure or the degradation of the functioning of an item.
- **South Australia Biomedical Engineering (SA BME)** means a state-wide Community of Practice that sets the standard for managing SA Health's biomedical technology and facilitates state-wide SA Health meetings at three levels: Oversight, Leadership and Operations. This also includes representation by BME LHN's/SCSS, the South Australian Ambulance Service (SAAS), and Medical Physics (RAH and LMH).
- **SA Health and Medical Department Managers** means SA Health staff with the responsibility of using biomedical technology within their clinical departments.

8. Document ownership

Guideline owner: Domain Custodian for the Infrastructure and Asset Management Policy Domain

Title: Asset Management: Biomedical Technology Lifecycle Part 2: Acceptance to Disposal Guideline.

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9. Document history

Version	Date approved	Approved by	Amendment notes
1.0	03/12/2023	Chief Executive, DHW	New guideline. Changed from the Biomedical Technology Policy Directive into two separate guidelines aligned with the new Asset Management Policy. Re-templated to align with the Policy Framework. Includes gap analysis of AS3551.

10. Appendices

1 Instructions for Asset Registration

2 Instructions for Acceptance and Commissioning

3 Instructions for Lifetime Maintenance

4 Instruction for Asset Repair (or Upgrade)

5 Instruction for Modification of Biomedical Technology

6 Instruction for After-Hours Repair (on-call or pre-approved overtime)

7 Instructions for Scheduled Maintenance

8 Instruction for Biomedical Technology Incident Investigation

9 Instruction for Hazard and Recall Alerts

10 Instruction for BME Service Review and Escalation

11 Instructions for Contract Management

12 Instructions for Asset Removal – Reallocation, Trade-in, Sale or Disposal

Appendix 1: Instructions for Asset Registration

Registration in BAMS

- Registration of biomedical technology on BAMS should follow instructions in the SA BME BAMS User Guide and Business Rules and include details to identify asset, ownership, location, and work history over its lifetime.
    - Refer AS/NZS 3551 Section 2 Medical Equipment Management Program, 2.5 Equipment Database, 2.5.3 History.

Table 1: BAMS Asset Register - details

Register type	Register detail
Asset register	BAMS unique identifying number (SA BME Asset Number) Oracle Fixed Asset Number if capital asset (Capital Projects Accounting Framework Policy 3.4 Capitalisation of Projects (or Property, Plant and Equipment Accounting Policy) Parent and child linkage for systems Nomenclature code identifier (typically UMDNS or GMDN) Description and condition Manufacturer, Model number and Serial number Software version (where applicable) Support contact details Owner: Organisation, Site, Clinical Directorate and Medical department Supplier, Purchase date and cost, Warranty date and details (AS/NZS 3551 Section 2 Medical Equipment Management Program, 2.5 Equipment Database, 2.5.2 Medical Equipment Details) Funding source, Project number, Procurement process Asset management details • Asset support family - Responsible asset manager (BME or other group) • BME (or equivalent service group) • Contract details for external service agreements • Maintenance responsibilities if not BME • Temporary assets – length of period approved for use, agreement roles and responsibilities

Table 2: BAMS Asset Register – special requirements

Register type	Register detail
Generic asset number – special cases	Exclusions from using a unique identifying number: • Generic devices: low value AND low risk AND no Planned Maintenance AND small • Lease, hire, or rent • Temporary repeat use (eg with special OT procedures)

Register type	Register detail
Homecare use	LHN approved patient identification and location
Lease, hire, rent	Externally supported (monitored by BME), may have generic asset with attached documents: • Supplier details. • Process for requesting maintenance. • Contract terms and conditions, contract summary, responsibilities for maintenance. • Fair market value field (not purchase price which is $0).
Medical gas systems	Tested to AS2896 with supporting documentation, register as not medical device. • Asset support group: NBT-NS (or NBT-EBS or NBT-PPP). No records of testing and commissioning to AS2896, register as a medical device with BME responsibility: Asset support group: BT-BME.
Replacement assets	Change of serial number needs a new asset number (e.g., insurance, recall, warranty)
Systems of biomedical technology	Register individual devices linking to show parent (system) and child (each of constituent parts) relationship with same Oracle Asset number for all, and costs total to value.
Temporary use	Loan from supplier, evaluation, or trial, register as a temporary asset with: • Expected end-use date or removal date. • PM schedule and who is responsible (supplier or BME). • Service provider.
Test equipment	Tester with Asset support group: BT-BME (ensure it requires scheduled maintenance)

Special Cases for Asset Registration

Generic Asset Number – special cases

> Replacing a unique number with a generic asset number may be appropriate in specific circumstances:

- Generic devices
  Where they are low value AND low risk AND require no scheduled maintenance AND are too small to hold a registration sticker, e.g., flow meters, tympanic thermometers, glucometers.
- Lease, hire or rent
  Where it is managed (and labelled) by the supplier under conditions approved by SA BME and identified in the asset register (Asset support family –BT-BME) eg rented compression mattresses.

Replacement Assets: insurance, recall, warranty, etc

- New unique asset numbers should be generated where replacement of biomedical technology results in a new serial number, such as insurance claim, recall, or warranty service replacement (and equipment decommissioned as in Asset Removal – Reallocation, Trade-in, Sale or Disposal).
    - If there is a change of serial number a new asset number should be generated for the replacement asset.
    - The new asset number should record the value of the replacement asset (not the cost originally paid for the asset) in accordance with fixed asset requirements.
    - The replaced asset should be retired in:
        - BAMS - retirement date and type.
        - Fixed Asset Register.

Homecare Use

- When biomedical technology is provided from SA Health to a patient for use outside SA Health sites the BAMS asset registration can include limited patient details. Note: BAMS is not an approved database for medical records.
- Approval should be sought from LHN Record Management for patient details to be placed in BAMS:
    - Location of the biomedical technology.
    - Patient name, Date of birth, Patient record number (UR#).

Lease, Hire or Rent

- Externally supported biomedical technology should be identified in BAMS to ensure BME technical staff understand who has maintenance responsibilities and don't repair in-house.
- At a minimum, a generic asset explaining the external support with attached documents should be registered:
    - Supplier details.
    - Process for requesting maintenance.
    - Contract terms and conditions, contract summary, responsibilities for maintenance.
    - Fair market value field (not purchase price which is $0).
        - Refer AS/NZS 3551 Section 8 Medical Devices on Loan Lease or Hire, 8.2 Hire or Loan to the Responsible Organisation.

Medical Gas Systems

- Medical gas systems are medical devices until they are tested and commissioned after which they should be the responsibility of LHN Engineering and Building Services.
    - Refer Medical Gas System Policy.
- The BME LHN service group should:
    - Participate as a healthcare representative to witness and ensure testing and commissioning of medical gas systems to AS2896.
    - Assure an appropriate LHN clinician (user of the medical gases) participates in the testing and commissioning and understands what they are witnessing.
    - Register the gas system as an asset on BAMS with all testing and commissioning documentation which verify that once the gas system is tested to AS2896 it is no longer a medical device.
        - Asset support group: NBT-NS (or NBT-EBS or NBT-PPP).

- If there are no records of testing and commissioning to AS2896, the medical gas system should be on BAMS as a medical device with BME responsibility:
  - Asset support group: BT-BME.

Systems of Biomedical Technology

- Systems should be created when two or more devices, at least one of which is a biomedical technology are interconnected electrically or functionally. Some devices within a system may not be biomedical technology (eg printer).
  - A system can be created using a multiple socket-outlet.
- Individual devices of the system should be registered in BAMS linking to show parent (system) and child (each of constituent parts) relationship:
  - The Oracle Fixed Asset number may be the same for all parts of the system.
  - Purchase costs may be a total against parent, or split among individual items, provided the total value for the Oracle Fixed Asset number is correct.
  - Individual BME Asset numbers enable tracking repair and replacement history of components, as well as recording test results of the system.

Temporary Use (Loan from supplier, evaluation, or trial)

- Management requirements should be the same as procured biomedical technology, including recording of maintenance, recalls and incidents during its temporary use.
- A temporary asset should be registered in BAMS, indicating:
  - Expected end-use date or removal date.
  - PM schedule and who is responsible (supplier or BME).
  - Service provider.
- Should label as temporary use with the expected end-use date.
- When returned, should update the asset register with the end of use date (SA BME BAMS User Guide and Business Rules).

Test Equipment (Testers)

- Equipment used in the management of biomedical technology should be tested to be identifiable, calibrated at suitable intervals and have calibration traceable to appropriate reference standards.
  - Refer AS/NZS 3551 Section 2 Medical Equipment Management Program, 2.3 Test Equipment, 2.3.1 General
- Test equipment should be uniquely registered in BAMS to monitor status, ensure scheduled maintenance and service history tracking and identify as Tester with Asset support group: BT-BME to identify it requires scheduled maintenance.

Fixed Asset Register and Annual Stocktake

- While it is the responsibility of the equipment owner to submit Fixed Asset Addition Forms for new capital assets (including donated, bequeathed or gifted) to the Fixed Asset Register, SA BME should facilitate this after BAMS registration.
- Property, Plant and Equipment Accounting Policy and associated Fixed Asset Fact sheets

Asset Registration Agreement - Fixed Asset and SA BME

- The Fixed Asset Team should recognise BAMS asset registration as a matching and validating tool to the Fixed Asset Register. There is agreement that:
  - Biomedical technology should be labelled preferentially with the SA BME asset number rather than the Oracle number (silver on red sticker) due to delay in provision until long after the equipment is in use.

- BAMS and Fixed Asset Register should record both SA BME and Oracle asset numbers.
- The purchase value for capital should be determined by the Fixed Asset Team.

Monthly Report from SA BME to Fixed Asset Team

- BAMS Report: Asset Additions, Deletions and Transfers YYYYMM (monthly) should identify biomedical technology additions, deletions and transfers of capital assets (for items and systems greater than $10,000) with details:
  - SA BME asset number; Description of asset, Asset installation date.
  - Supplier name, Purchase price, Manufacturer; Model, and Serial number.
  - Owner LHN, site, Responsible manager (Clinical Directorate/Medical Department), Responsibility index (RI account number), and Location of asset (to room).
  - Project ID, PO number and invoice numbers (where possible) to assist matching the asset clearing account.
- Reports should be validated by LHN/SCSS BME and SA BME Capital Manager before sending to the Fixed Asset Team by the SA BME Capital Manager.
- The Fixed Asset Team should generate an Oracle Asset number:
  - Add to the Fixed Asset Register once reconciled with invoices and the general ledger.
  - Advise SA BME BAMS Manager to upload Oracle Asset Number in BAMS.

Annual Assets Stocktake

- Biomedical technology information from BAMS should be made available to assist owners in completing physical requirements of annual stocktake**Error! Bookmark not defined.**.
- SA BME BAMS manager should update details from BAMS to the stocktake spreadsheet provided from Fixed Asset Register (in March) and share with LHN BME area managers to distribute according to LHN procedure:
  - Date last seen by BME.
  - BME status: Active/Lost/Missing/Retired etc.
  - Owner details (medical department).
  - Location (LHN, site, room).
  - Removal or retirement date and retirement type.
  - Current WO status (eg if sent out for repair).

Appendix 2: Instructions for Acceptance and Commissioning

Delivery Checks

- All biomedical technology should be delivered to BME, if possible, for acceptance and commissioning before first use.
    - If delivery to a site with no BME, staff on site should notify BME when the devise are delivered. The responsible BME facilitate an inspection and functional testing by an appropriate person (user, supplier, or third party) at the site.
    - The details should be recorded as partial acceptance until full acceptance by BME.
- A Work Order should be initiated: ACCEPT/COMMISSION/INSTALLATION.
- Check delivery should be complete against the purchase order deliverables (Goods Purchase Agreement).
    - For any damage record the nature and extent and arrange remediation with supplier (eg warranty or insurance).
    - Refer AS/NZS 3551 Section 5 Acceptance, 5.3 Acceptance Check and Inspection, 5.3.2 General Acceptance Inspection.
- Supplied documents should be checked and upload to BAMS:
    - Evidence of compliance (eg ARTG, ACMA EMC, declaration of conformity)
    - Calibration and performance certificates.
    - Configuration defaults.
    - Operator and Service manuals – attach to Model record (not individual asset).
    - Enable user access to Operator's manual through the user (web) portal.
- Pre-use tests should be performed to assure it can be safely and effectively used:
    - Meets specifications as specified by the manufacturer.
    - Meets compliance with relevant regulations and standards.
    - Refer AS/NZS 3551 Section 5 Acceptance, 5.2 General.
- Once delivery checked, performance should be verified, maintenance plan scheduled, labelled, and biomedical technology ready for use:
    - The item should be receipted against the Oracle purchase order.

Unsatisfactory Performance

- For serious shortcomings on delivery that would have caused an incident if not tested, should:
    - Record incident near miss on SLS.
    - Manage as per Legislative Changes and Compliance
    - Where biomedical technology or its use is impacted by changes to legislation or relevant Australian Standards, BME should be participants in the consultation process, aware of the impact, and collaborate with LHN on actions to be taken for compliance.
- Appendix 7: Instructions for Scheduled Maintenance - Legislative Changes and Compliance should be followed.
- LHN BME managers.
- Manager BME and SA BME Operations Manager.
    - Biomedical Technology Incident Investigation.
- Arrangement of remediation (repair or replacement) should occur:
    - Delay payment until acceptance completed satisfactorily.

- Receipt in Purchase Order system once resolved.

Table 3 Acceptance Process and Documentation before first use

Before first use	Acceptance detail	Document in BAMS
Initiate acceptance	Work order: ACCEPT/ COMMISSION/ INSTALLATION	WO actions
Delivery to BME	Check for damage – physical inspection - according to PO and procurement documents - all components, parts, accessories, and attachments as ordered - operator and service manuals	Operator, enable user access Service manual
Delivery remote from BME	BME facilitate appropriate on-site person to assure delivery and functional test until full acceptance performed.	Partial acceptance, tests and person Update with full acceptance checklist when completed at a later date
Maintenance plan	Use existing or create a new one: - PV Checklist with essential performance parameters	Maintenance plan: Checklist, Frequency, Service provider
Pre-use test	Test against PV checklist Electrical safety test	Test results: PV Checklist, Electrical safety, Test equipment used, Person doing tests, Date of test Calibration or performance certificates supplied with equipment
Label equipment	SA BME Asset number Scheduled maintenance label (one of): - Next Test - Run-to-Review - Supplier (if lease/rent/hire) Detachable power supply cords: re-test date, service group and compliance.	
Installation	Biomedical technology: - suitably and correctly installed - safe to use - security of equipment - check accessories and attachments	

Before first use	Acceptance detail	Document in BAMS
Use and pre-use training	Check completed to schedule in procurement or facilitate schedule with supplier if needed	
Unsatisfactory performance	Record in SLS as near miss - manage as incident (5.2.6 Biomedical technology incident investigation) - arrange remedy (repair or replacement) - delay payment.	Incident
Delivery and performance acceptable	Receipt against Oracle Purchase Order	

Use and Pre-use Training

- It should be checked that training is completed to schedule detailed in the purchase agreement:
  - Installation training:
    - Up-date and follow up training.
    - Train the trainer for super users to continue training new users.
  - Instruction and demonstration of the equipment:
    - Effective operation of the equipment.
    - Daily and/or periodical operator maintenance and care of the equipment.
    - Daily and/or periodical operator testing procedures.
    - Simple fault recognition and operator troubleshooting procedures.
  - Technical training: Front line, planned maintenance, modular replacement, factory-equivalent.

2.3 Maintenance Planning

- A maintenance strategy should be developed and document in the maintenance plan with PV checklist ready for pre-use tests.
- May refer to Asset Management: Biomedical Technology Maintenance Planning Policy.
- PV checklist consideration for special cases is detailed below, and in Table 4 Special Requirements for Pre-use Tests and Documentation:
  - Configurable biomedical technology.
  - Homecare use.
  - Systems of biomedical technology.
  - Non-biomedical technology within the patient environment.
  - Temporary use (Clinical Trial).
  - ICT-connected.

Table 4 Special Requirements for Pre-use Tests and Documentation

Special use	Acceptance detail	Document in BAMS
Configurable	Check configuration with each type of clinical user to ensure it is as required for the intended clinical application.	Approved configurations Label device if new or after maintenance or upgrade for user to check configuration
Homecare use	Maintenance plan considers increased risks in home environment	Medical department assurance of device class, house-wiring compliance, facilitation of service and loans.
ICT-connected	Pre-use test (and maintenance plan) includes: - Applications, operating system patching and antivirus deployment and updates. - Biomedical server and application monitoring. - ICT configuration information currency in BAMS. - ICT issues with biomedical technology and liaise with eHealth as required to resolve the issue.	ICT configuration: - ICT technical fields - Information Asset Classifications - Security impact assessments - System integration diagrams Support documentation: - Work instruction - Disaster recovery - Back up - Test and implementation
Non-biomedical items	Non-biomedical components of system to meet electrical requirements (touch)	Test results of components
Systems of biomedical technology	Electrical tests for the whole system and as individual devices. Non-biomedical components of system to meet electrical requirements (touch)	Test results: - System (against parent) - Components (against children)
Temporary use – Clinical trial	Pre-use tests and Maintenance Plan as for owned devices Technical Manager expertise for non-ARTG approved device	

Configurable Biomedical Technology

> Sometimes functionality of the biomedical technology or a system can be configured for a clinical application. Software is a type of configuration that can be amended or updated during the working life of the biomedical technology to improve functionality, correct product deficiencies, or add enhancements to its clinical use, and are not always visible to the user.

> Configuration options (includes software versions):

- Checked and approved by clinical users to ensure it is as required for the intended clinical application (eg infusion pumps for adult or paediatric).
- Include configuration checks (and software version) in PV Checklist.
- Record configuration in BAMS whether default settings or changes:
  - For each clinical application or medical department against the make-model.
  - Approved by a clinical delegate (person with authority to sign off clinical configurations).
  - Refer AS/NZS 3551 Section 5 Acceptance 5.3 Acceptance Check and Inspection, 5.3.4 Medical Equipment Configuration, and Section 6 Performance Verification and Maintenance, 6.6 Configurable Medical Equipment, 6.6.3 Documentation.
- Changes to software versions should be treated in the same way as other configurations.

Homecare Use

- When biomedical technology is provided to a patient for use outside the electrically protected patient areas of SA Health sites, its safety and function should be assured in the same manner as at SA Health sites using a risk-based approach (refer Asset Management: Biomedical Technology Maintenance Planning Policy*).*
  - Refer AS/NZS 3551 Section 8 Medical Devices on Loan, Lease or Hire, Section 8.3 Hire or Loan from the Responsible Organisation.
- Maintenance plan (PM and PV) should consider:
  - Ensuring integrity and safety of biomedical technology used in a home environment is not compromised.
  - Location of use: Local circumstances and variable environment.
  - Increased exposure to wear and tear and abuse (from children, pets etc) often in excess of that in a clinical setting.
  - Users may not be trained health care professionals.
  - Limited access to technical support or advice, and loan equipment.
- Biomedical technology preferably Class II or battery operated, or if Class 1, should be protected by:
  - Short term – inline 10mA Type 1 RCD.
  - Long term – area that complies with AS3003.
- The medical department should manage the process for maintenance:
  - All patient communication.
  - Arrangements for equipment service, repairs or recalls.
  - Process for facilitating return of assets for scheduled maintenance and arranging loan equipment if needed.
  - Assurance that house wiring complies with AS/NZS 3003 Section 5 Special Patient Areas, 5.2 Homecare Installations.

ICT-connected

- BME LHNs should manage and support biomedical technology that requires connection to, and or integration with computer systems and information computer technology (ICT) in accordance with the SA BME Medical ICT Systems Life Cycle Management Framework.
- SA BME responsibilities for this type of equipment should include:
  - Ensuring personal information privacy and security is maintained in accordance with the States Information Security Management Framework.

- Implementation and transition to operational services in accordance with SA BME Implementing Biomedical Devices/System with ICT Functionality Procedure.
- Connection to the network in accordance with SA BME Connection Biomedical Devices to the Network Procedure.
- ICT configuration information to be captured and recorded in BAMS:
  - ICT technical fields
  - Information Asset Classifications
  - Security impact assessments
  - System integration diagrams
  - Refer AS 3551Section 2 Medical Equipment Management Program, 2.4 Documentation Requirements.
- Support documentation should be captured and recorded in BAMS
  - Work instruction
  - Disaster recovery
  - Back up
  - Test and implementation
  - Refer AS 3551 and ISO 20000 support documentation.

Non-Biomedical Technology within the Patient Environment

> Should test all non-biomedical equipment that will be either a) within the patient environment, or b) outside the patient environment but functionally connected to a system.

Systems of Biomedical Technology

> If a biomedical technology system is created or a biomedical technology is part of a biomedical technology system, it should be tested as per AS/NZS3551 Section 7 Medical Electrical Systems: test the whole system, as well as individual devices, and record all results in BAMS.

> ICT-connected equipment (includes Bluetooth, ethernet, USB etc) which is integral to the medical equipment should be considered as part of the biomedical technology system for testing.

> Multiple socket-outlet and isolating transformers are components of the system and should be included in maintenance plans and tested as part of the system.

> Multiple outlet sockets and their connections require tool to access, and should be marked to indicate:
  - Equipment that can be connected.
  - The maximum allowed current draw from the biomedical technology.
  - That rearranging connections shall only be carried out by BME.

> Non-medical equipment that is functionally connected should be part of the biomedical technology system (eg remote monitoring of ICU). If, after final assembly of the system, it is not possible to access all the connected equipment (eg due to remoteness or lack of ready access) the system should be tested in accordance with (AS/ANZS3551 Clause 7.3.2) with all its external connections intact.

Temporary Use (Clinical Trial)

> Biomedical technology in a formal clinical trial with Principal Investigator, Ethics approval, and Clinical Trial Notification to TGA, may not be registered on ARTG.

> Management should be the same as procured biomedical technology, including recording of maintenance, recalls and incidents during its temporary use.

- Full compliance with AS3551 may not be possible. Professional judgement from a Technical Manager should be exercised in accepting the biomedical technology for temporary use in the LHN, and at the same time ensuring its use does not compromise user or patient safety.

Pre-Use Test and Documentation

- A supplier's representative may be present to either perform or observe the pre-use test.
- Performance verifications using PV Checklist should occur:
    - Eg electrical testing and non-electrical testing, physical inspection, calibration, functional testing as per AS/NZS 3551, and manufacturers recommendation.
    - Refer AS/NZS 3551 Section 5 Acceptance, 5.3 Acceptance Check and Inspection, 5.3.2 General Acceptance Inspection.
- The following should be documented in BAMS:
    - Numerical test result values.
    - Identification of the person completing the tests.
    - Date of test.
    - Calibration or performance certificates supplied with the equipment.
    - Test equipment used in performing checks.
    - Refer AS/NZS 3551 Section 5 Acceptance, 5.5 Documentation of Results.
- Accessories and attachments should be checked to ensure that biomedical technology is suitably and correctly installed, safe to use and ensure equipment security.
    - Refer AS/NZS 3551 Section 5 Acceptance 5.3 Acceptance Check and Inspection, 5.3.5 Permanently Installed Medical Equipment.

Labelling

- Labels should be applied to the biomedical technology before delivering for clinical use:
    - SA BME Asset number (BAMS unique identification number).
    - Scheduled maintenance, one of:
        - Next Test: Re-test due date; Service team; Compliance to AS/NZS 3551 or AS 3760.
        - Run to review (previously Run-to-Failure, or No scheduled maintenance required).
        - Supplier service (i.e., not owned by SA Health, under lease/rent/hire or temporary use agreements) with maintenance details (name, contact phone).
        - Refer AS/NZS 3551 Section 6 Performance Verification and Maintenance, 6.7 Review and Recording Results, 6.7.1 Medical Equipment Labelling.
    - Detachable power supply cords: re-test date, service group and compliance to AS/NZS 3551 or AS 3760.

Appendix 3: Instructions for Lifetime Maintenance

3.1 Instructions for Safety of Technical Staff

Table 5 Actions to mitigate known safety risks for technical staff

Safety risk	BME action
Contaminated equipment cleaning	All technology to be appropriately cleaned and decontaminated by the requesting department before being delivered to BME for maintenance. - When the equipment cannot be cleaned without it being damaged the requesting department: - Requesting department identify as contaminated and enclose in protective bag. - Technical staff use appropriate precautions (e.g PPE) as recommended by clinical users or infection control experts.
Electrical safety	Follow the Electrical Safety Guideline (WHS): - All electrical work is undertaken with protection of electrical safety switches (Residual Current Devices, RCD), may be portable. - Uncovered biomedical technology to be disconnected from mains power, where possible, when work is carried out. - When work is performed on live equipment away from the workshop, worker supervision to be present. - Hardwired equipment requires electrician presence and locking out of mains power switches.
Mechanical workshop	Follow the Plant and Equipment Safety Guideline and Personal Protective Equipment (PPE) Selection Guideline: - PPE to be used as required e.g eye protection, ear plugs, gloves, footwear, dustcoats, and facemask. - Staff to only use workshop equipment that they have sufficient training and experience with, unless undertaking training with a qualified trainer.
Chemical safety	Follow the Chemical Safety in the Workplace Guideline. Each biomedical technology service site to have: - A database accessible to all staff identifying all the chemicals in their department. - Material Safety Data Sheets located at a suitable and identifiable location within the department or allow online access to them. - Relevant chemical safety equipment and spill kits available for use. - All staff to use personal protective equipment when and as required.
Working in isolation	Follow the Remote or Isolated Work Health and Safety (WHS) Guideline: - Includes after hours work and work conducted outside the BME workshop, eg. on call and regional work. - Seek approval from manager before starting. - Arrange check-ins by manager, supervisor, or security at pre-determined times to monitor safety.

Safety risk	BME action
Infectious patient areas	Preferably use clinical staff to fault find or replace equipment rather than enter room. Follow SA Health procedures on working in infectious patient areas eg. PPE as directed by signage, wash hands in accordance with Infection Control Policy etc. - Enter only when necessary and under clinical staff supervision. - Confirm with clinical staff correct PPE use and removal process. - Use Personal Protective Equipment (PPE) Selection Guideline and Preventing and Responding to Work Related Exposure to Infectious Disease Guideline. Clean equipment appropriately before moving it to BME workshop.
Immunisations	All technical staff working within SA Health on biomedical technology need appropriate immunisations. Refer Addressing vaccine preventable disease: Occupational assessment, screening, and vaccination policy.
Travel	Follow the South Australian Government Financing Authority (SAFA), Safe Driving Policy. - Driving breaks: Staff are personally responsible to pull over and rest if they feel tired, unwell or in any way unable to drive safely. - Medical kits and fire extinguishers are to be checked by the driver before travel. - Driver training is available through Fleet SA. - First aid training is available (arrange through LHN). On bushfire safety and catastrophic fire danger rated days: - Maintain personal and passenger safety including hydration in accordance with the SA Health Catastrophic Fire Danger Rating Day Policy Guideline - Check bushfire safety kit in car. Use communication systems during remote and isolated travel work (Remote or Isolated Work (WHS) Guideline).

Appendix 4: Instruction for Asset Repair (or Upgrade)

Work Request

- The user should report the biomedical technology fault or failure to the BME service group as soon as possible providing a description of the fault and when it is next needed for clinical use.
    - Contacts the BME service staff directly (for urgent repairs).
    - Completes a Work Request Form, attaches to the equipment, and arranges delivery to the BME service group.
    - Submits an online request using BAMS web portal.
- The technology user should take the device out of service, attaches the Work Request Form:
    - If portable, arranges for its transport to BME.
    - If large, contacts BME to arrange for on-site service.
    - If no Work Request Forms, label equipment as “Not working – awaiting BME repair”.
    - Refer AS/NZS 3551 Section 6 Performance Verification and Maintenance, 6.5 Management of Medical Equipment Failure or Faults.

Repair Action, Prioritisation, and Safety

- Repairs should be timely with device (or a replacement loan) returned to users preferably within 1 day (or for regional, within 7 days).
- Prioritisation and allocation to technical staff should be controlled by the BME Site/Technical Manager considering:
    - Available resources and competing demands.
    - Spare device availability.
    - Ability to use external service providers, suppliers and manufacturers.
- Repairs should be done by an appropriately trained person:
    - In-house BME Technical or Professional Officer, or
    - External service provider.
- The person doing the repair should be responsible for identifying work risks before starting and using safe work practices.

Service History

- All maintenance interventions should be recorded in BAMS in accordance with AS3551, with the following information linked to the asset:
    - A description of the problem needing corrective action.
    - Details of the work performed.
    - Post repair performance verification results.
    - Labour and travel hours.
    - Identification of personnel performing work and date completed.
    - Details and costs of parts.
    - Date equipment removed and returned to service.
- Accurate failure category should be recoded to ensure critical failure data is used in review and adjustment of maintenance plans.
- Any deviation from the manufacturer specifications should be identified:
    - Include possible cause if identified: operating environment, level of use, user skill, extent of biomedical technology backup, local service facilities.
- Where critical items are replaced with non-OEM spare parts, should:
    - Use risk management techniques as for original design and manufacturing process (eg systems like Failure Modes and Effects Analysis, FMEA, or Risk Priority Numbers, RPN).
    - Document use of non-OEM part in BAMS.

- Where an external service provider is used, this information should be recorded in the BAMS External action with an uploaded service report.
- Work on biomedical technology should be recorded as in SA BME BAMS User Guide and Business Rules.

External Repair Costs

- Replacement parts and/or ad hoc use of external service provider for repairs should be requisitioned through Oracle with the asset and work request identified including:
    - Cost.
    - Quotation (attached).
    - Labour and travel hours.
    - Insurance claims: Insurance can be claimed for repair costs after accidents where failure is not due to normal “wear and tear”.
    - Use natural account 74819 Breakdown maintenance _BME.

BME Loan Library

- A range of loan and spare equipment may be available to Medical Departments for urgent, short-term replacement of biomedical technology, when equipment is not usable due to maintenance.
- The need for BME to hold loans or spares should be determined with the user:
    - During procurement.
    - When failures affect clinical business.
    - When old equipment is replaced, but still functional, and the old fleet is still in use.
- Loan and spares should be managed in the same way as biomedical technology in normal routine use, including registration in BAMS.
- Spare equipment owned by LHN:
    - Location should be either BME or the Medical Department as determined with clinical user during procurement process.
    - Device status should be “Spare parts” or “Temporarily out of Service”.
- Loan equipment temporarily provided by supplier:
    - The temporary location should be recorded against the asset record
    - Device Status should be LOAN UNIT.

ICT and Computer-Connected

- On-going management and support should include:
    - Applications, operating system patching and antivirus deployment and updates.
    - Biomedical server and application monitoring.
    - ICT configuration information currency in BAMS.
    - ICT issues with biomedical technology and liaise with eHealth as required to resolve the issue.

Consumable and Accessory Storage and Supply

- Storage and supply of limited consumables and accessory items may be available in consultation with the LHN/SCSS and are typically charged to the medical department on purchase or use.
    - Support technology that requires minimum down-time with in-house service provision.
    - Support technology that requires maintenance beyond guaranteed supplier upkeep.
    - Include selected retired technology still viable as a service spare device or still valuable as a source of spare parts.
    - Contain appropriate consumables, spare parts, and accessories of an acceptable quality.
    - Provide an auditable list of stock on request.
- Spare parts and replacement of broken accessories should be purchased through Oracle by the site RI under the Use natural account 74819 Breakdown maintenance _BME.

- Other consumables and additional accessories should be funded by the end-user medical department.

Homecare Use

- The medical department should manage the process for maintenance:
  - All patient communication.
  - Arrangements for equipment service, repairs or recalls.
  - Process for facilitating return of assets for scheduled maintenance and arranging loan equipment if needed.
  - Assurance that house wiring complies with AS/NZS 3003 Section 5 Special Patient Areas, 5.2 Homecare Installations.

Performance Verification

- Before returning to use, should verify performance using PM Checklist:
  - Ensure all performance requirements are met, all safety features are operational, and all configurations are restored as recorded in BAMS for user requirements.
  - Follow the manufacturers test process.
  - If configurations have not been restored to users' requirements, or users need to test, a label is to be attached across the controls.
  - Document the PV test results in BAMS.

Fault Preventable with PM

- Where a fault could have been prevented by PM and is likely to be preventable, should:
  - Select BAMS WO cause: "Insufficient or lack of PM".
- Should not use for overdue PM, or where it is expected user to notice fault before use.
- This should flag review of scheduled maintenance in BAMS report: Repair Analysis.

No Fault Found

- Where no fault can be found, should assess why:
  - Lack of user training – within the BAMS WO select "User Training Advised" within the Corrective action and liaise with medical department for supplier training. If supplier training not available, determine if expert clinical user available in-house, or if BME has expertise to support in-house clinical expert.
  - Clinical useability - Poor design, not meeting clinical need. Record in BAMS clinical performance for raising priority in Replacement Plan.

Configurable Biomedical Technology

- After repair or upgrade, to prevent a misconfiguration or inadvertent change (eg to default settings) that could result in harm to the technology user or patient, then should:
  - Check configuration as part of performance verification.
  - Return with a temporary label indicating a check of control settings is required before clinical use if a configuration change was possible during service. Suggested wording should be "Warning: Control settings may have been altered.
  - Ensure that control settings are reviewed appropriately before clinical use".

Test Equipment

- Test equipment used in the management of biomedical technology should be identifiable, calibrated at suitable intervals and have calibration traceable to appropriate reference standards.

- Refer AS/NZS 3551 Section 2 Medical Equipment Management Program, 2.3 Test Equipment, 2.3.1 General.

> Should keep test equipment safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

> When test equipment is used in the maintenance of biomedical technology, then should:
  - Record the work, includes identification of test equipment used.
  - Ensure the person using the test equipment ensures the calibration is valid.

> If the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, should document for both test equipment and affected devices back to the last correct calibration:
  - Document the change in calibration, its magnitude and actions needed.
  - Identify affected biomedical technology.
  - Re-test biomedical technology to assure safety and functionality.

> An easily removed label should be prominently affixed over the primary controls of the returned biomedical technology that includes a warning to the effect that controls, and settings may have been altered and should be checked before use.

Appendix 5: Instruction for Modification of Biomedical Technology

- SA BME is the SA Health authority to determine if biomedical technology should be modified and is to be carried out in accordance with AS3551 as per the Asset Management Policy.
- Where the modifications of the biomedical technology are to a medical device (as defined by the TGA) and change the manufacturer's intended purpose, the body performing the modification should become the manufacturer of the device.
    - Refer Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulations 2002.
- Any modification to biomedical technology should not reduce the safety of that device or its accessories to the patient, user, or environment.
    - Refer AS/NZS 3551 Section 9 Modification of Medical Equipment.
- A modification to biomedical technology should include:
    - A repair to a medical device using non-OEM sourced parts.
    - Installing software/firmware or patch not supplied and approved by the manufacturer.
    - Manufacture approved upgrade/safety modification or other modification that changes the use of the device.
    - Changing how the device is used, connected or communicated with, away from the manufacturers intended use.
    - Deviation from the manufacturer's specifications
    - Changing the design or structure.

Approval

- Formal approval to perform the modifications from the CE or CEO should be requested (by BME Manager, DHW or BME LHN Manager). This approval should be recorded in BAMS against the asset.
- Advice on modification works should be sought from the SA BME State-wide Research and Development team.
- The modification work should be done in in accordance with Part 1 of this Guideline (Section 5.2.1 Acquisition: Development).
- Deviation from manufacturer's specifications should be supported by a rigorous and documented risk management process (AS3551 Appendix A12): operating environment, level of use, user skill, extent of biomedical technology backup, and local service facilities.

Change in the Intended Purpose

- On completion of the modification:
    - The equipment should be tested, and all design changes and test results documented against the asset record.
    - The service manual should be updated with documentation of any testing and re-calibrations.
    - If the safety function or operation of the medical equipment has been changed, a label should be permanently secured to the devices, in a place clearly visible to the user, indicating that the medical equipment has been modified and the date of modification. The label should also outline the modifications and/or indicate where a description of the effect of the modification can be found.
- All modification works to an existing asset should be recorded in BAMS
    - Work order type TASK: PROJECT linked to the asset
    - The new intended purpose should be documented in the Intended Use Statement.docx and attached as a document to the asset.
    - TGA device classification and regulatory requirements should be assessed and recorded.
- Required TGA documentation should be generated and kept in accordance with the TGA regulations, these to include:

- Statement of the new intended use.
- Rationale, design specification, design documentation, testing and validation plan and evaluation of the modification.
- Risk assessment of the modified device and deviation from manufacturer's specification.
- Where the device is for 'Custom Use' (as defined by the TGA), the biomedical technology user should sign documentation stating the custom use and the specific patient or group of patients that they will use the device on 26,27.

> The device should be checked and registered in accordance with this Guideline before putting into use.

Appendix 6: Instruction for After-Hours Repair (on-call or pre-approved overtime)

- If a BME staff member is on site, they should be used before an on-call person travels to the site.
  - The BME Manager is responsible for the on-call roster.
  - The afterhours contact process is on each BME (LHN) website.
  - Not all calls will result in attendance on the site.
  - If the call is not urgent, it can be dealt with at the start of the next business day.
  - Work done during a call back to be recorded in BAMS:
    - WO Type: Corrective Maintenance and
    - WO Status: CALL BACK.
  - Staff eligible for call back payment should submit their HR21 claim form in the next pay period, including the work order number for the call back.
- SA BME (LHN) can also provide maintenance after hours (usually TOIL, or overtime where available) where health service delivery cannot be interrupted. This should be pre-approved by BME (LHN) area manager.
  - Approved afterhours work is recorded in BAMS:
    - WO Type: Corrective or Task or Checklist
    - WO Status: OVERTIME-APPROVED.
- Additional risks to technician safety (working in isolation, with electricity, and alone) should be the technician's responsibility:
  - Assess risks and implement safe work practices for each job
  - Refer Appendix 3: Lifetime Maintenance - Safety of Technical Staff including Cleaning of Assets
  - Check with supervisor if working in isolation or working with electricity.

Appendix 7: Instructions for Scheduled Maintenance

Notify users of devices due for scheduled maintenance

- BAMS Report: Due for Scheduled Maintenance:
  - Should generate report at start of each month and send to medical department manager.
  - Report should include items scheduled for maintenance in the coming month, or overdue, in order of priority and due date.

Prioritisation of scheduled maintenance

- Higher priority for scheduled maintenance should be allocated to biomedical technology:
  - Higher inherent risk (16 or 9) with increased impact on patient safety.
  - Longest overdue.
  - PM that prevents failure.
  - PV needed for legislation or assurance of function.
  - Where equipment has high usage, should collaborate with users to identify convenient time.
  - To schedule outside normal business hours, managers approval should be required and note if Overtime approved in BAMS (not needed if TOIL).

Label and return after scheduled maintenance

- Should affix warning label that is easily removed:
  - “Controls and settings may have been altered and should be checked before use.”
  - Place prominently over the primary controls.
- Biomedical technology should be returned to use after testing in a timely manner.

Overdue for scheduled maintenance

- Devices may not always be available for scheduled maintenance on or near their due date, eg high clinical use, missing or lost, out for repair.
- BAMS Report: Overdue Scheduled Maintenance YYYYMM (monthly) should:
  - Identifies equipment that is overdue by more than two months with the responsible SA BME Technical Department, listed in order of risk.
  - BME Technical Managers review the report, confirm the reason for its unavailability and collaboratively plan access to the device with the equipment users.
  - If equipment has moved to a new location, should update BAMS with the new Medical Department (if formally transferred with documentation) or the new location.

Lost/missing biomedical technology

- Lost equipment that is unable to be located should have its status updated in BAMS:
  - Device Status LOST/MISSING.
  - Devices subsequently found can be reactivated in BAMS.
- BAMS Report: Lost/Missing Devices YYYYMM (quarterly) should:
  - Be generated by BME LHN and sent to all medical department managers.
  - Request device be located for scheduled maintenance.
- If missing for greater than 12 months, should:
  - Update BAMS - Device Status UNKNOWN IF STILL IN SERVICE.
  - Reports lost devices to LHN Executive, and the Fixed Asset Team where it impacts clinical business continuity or asset value >$10k.
  - Consider retiring if device unlikely to be found (it can be un-retired if lucky).
  - Removal from the asset register should be subject to annual review and at the discretion of the BME LHN Manager in collaboration with the medical department manager.

- Update BAMS - Device Status RETIRED/CONDEMNED

Scheduled maintenance service history

- Record of all scheduled maintenance in BAMS (AS3551) should occur, following instructions in the SA BME BAMS User Guide and Business Rules:
  - Performance verification tests undertaken.
  - Preventive maintenance activities undertaken.
  - Identification of personnel performing work.
  - Details and costs of parts used or replaced.
  - Identification of test equipment used.

Scheduled maintenance fail

- Any deviation from the manufacturer's specifications should be identified:
  - Include possible cause if identified: operating environment, level of use, user skill, extent of biomedical technology backup, local service facilities.
- If an asset fails PM and/or PV, should:
  - Withdraw the biomedical technology from service
  - Label with a warning and create a new linked corrective maintenance WO in BAMS.
  - Repair as required.

Test equipment PV

- Test equipment used in the management of biomedical technology should be identifiable, calibrated at suitable intervals and have calibration traceable to appropriate reference standards.
  - Refer AS/NZS 3551 Section 2 Medical Equipment Management Program, 2.3 Test Equipment, 2.3.1 General.
- Test equipment should be kept safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
- If test equipment fails performance verification and is found to be unfit for its intended purpose, then should:
  - Assess if validity of previous measurement results is adversely affected.
  - Identify affected devices back to the last correct calibration.
  - Document as incident in BAMS: change in calibration, its magnitude and actions needed.
  - Locate affected biomedical technology that needs re-testing.
  - Re-test biomedical technology to assure safety and functionality.
  - Update BAMS service history.

Instructions for Legislative changes and compliance

- LHN BME Managers should:
  - Be involved in national consultation that may impact legislative changes:
    - *Subscribe to TGA lists*
      (eg Updates, consultations, guidelines, medical devices safety information)
    - Register as member of *Standards Australia*
    - Monitor committees associated with standards review and *nominate organisational representatives* from SA BME.
    - Monitor standards under review, in draft, and provide feedback in public consultation phase.
    - Share with Technical Managers and specialist technical staff.

- Gain access to a legislation monitoring system.
  - ComplyOnline (DHW subscription) or LHN equivalent.
  - Request notices on Medical Device topics.
- Monitor all TGA legislative changes (actions identified in ComplyOnline):
  - Therapeutic Goods Act (eg medical devices).
  - Radiation Protection and Control Act and Regulations (eg ionising radiation).
  - Work Health and Safety Act and Regulations (eg, Remote or Isolated work).
- Monitor Australian Standards for non-legislated, but improved practice:
  - AS 2896 Medical Gas Systems.
  - AS/NZS 3012 Electrical Installations.
  - AS/NZS 4187 Reprocessing of reusable medical devices in health service organisations.
- Determine actions to meet compliance obligations for LHN.
  - May include removal of non-compliant biomedical technology and prioritisation for replacement.

> Manager BME and SA BME Operations Manager should:

- Identify compliance obligations, issues and actions with state-wide impact.
- Identify TGA consultations for future changes.
- Share with SA BME Community of Practice by tabling actions and issues at SA BME Oversight, Leadership and Operations Committees.

Appendix 8: Instruction for Biomedical Technology Incident Investigation

Notification from SLS

- BME LHN Area, Site and Technical Managers should:
    - Register as reviewers on the SLS for medical device related incidents at their sites, in addition to LHN BME staff incidents.
    - Monitor SLS for all medical device incidents at their sites and respond accordingly.
    - Urgently attend any notifiable (SAC 1 or 2) incidents involving medical devices to:
        - Ensure equipment is quarantined with all accessories, consumables (and their packaging from bins if needed), and
        - Prevent alteration of medical device settings or programmable features.
        - Refer AS/NZS 3551 Section 6 Performance Verification and Maintenance, 6.10 Medical Equipment Adverse Event or Failure 6.10.1 Investigations.
- SA BME Manager and SA BME Operations Manager should:
    - Monitor all medical device incidents
    - If state-wide implications, forward to SA BME leadership and/or table at SA BME Committees.
    - Forward to appropriate acting or new LHN BME managers if they are not receiving notifications (eg temporary acting vice, on long service or sick leave or undergoing recruitment process).

Investigation

- Should quarantine biomedical technology from clinical and technical staff until independent investigator assigned. Include accessories and consumables, packaging from rubbish (if possible) to identify batch numbers, and isolation to prevent tampering of any settings or programmable features.
- BME LHN area manager should appoint an investigator depending on seriousness of incident to complete a root-cause analysis:
    - Add a technical specialist as a reviewer in the SLS if needed.
    - Allocated investigator to not be a staff member who last repaired the device, nor the usual repairer of the device.
    - Appoint an independent investigator if device failure or maintenance may have been a factor to a serious incident (SAC 1 or 2).
    - Take a team approach for assessment and investigation of the event, enlisting clinical staff, biomedical support services staff and other experts.
- Details should be forwarded to the sponsor and/or manufacturer as soon as practical where appropriate. Do not let the supplier investigate or have access to the device until formally agreed with medical department manager, and any internal investigation has been completed.
- TGA Medical Device Incident Report should be initiated where it is considered that the medical equipment did, or may have, contributed to an adverse event (in accordance with AS3551).
    - TGA documentation should be recorded in the BAMS (SA BME BAMS User Guide and Business Rules).
- Any SLS's that have potential to create a risk at other SA Health sites should be sent to the SA BME Operations Manager for distribution.

BME Reviewer

- BME reviewer should prepare a response to the SLS in collaboration with their area manager.
    - For longer investigations, update the SLS weekly with investigation status.

- If a separate report is created, attach PDF to SLS weekly to track progress.
- Attach final report (PDF) with outcomes to the SLS.
- Record as a new incident in BAMS or link to an already related TGA incident.

> Outcomes may include:

- Report to TGA for possible enforcement or corrective action.
- Equipment permanently or temporarily removed from use, eg specific device, or all make-model in site or LHN.
- Assessment of all similar make-model or category.
- Review and change to maintenance plan (frequency or checklist) for make-model or category.
- Need for user training, preferably provided by supplier.
- Return to supplier of newly acquired equipment that does not meet clinical safety requirements:
  - Refer to procurement terms and conditions, consult with the supplier and consider delaying payment until an acceptable solution is met.
  - Consult with TGA as needed.

BAMS Documentation

> SLS incidents caused by biomedical technology should be added to BAMS Incident module:

- Incidents that affect specific devices – link to the Asset.
- Incidents that affect all make-models – link to all assets with make-model.
- Follow SA BME BAMS User Guide and Business Rules, Incidents.

> Documents should include:

- All aspects of root-cause analysis: recording of biomedical technology settings, clinical circumstances and environmental conditions leading up to, at the time of, and after the event, error logs, configurations, software version, operating system, and anti-virus updates.
- Actions and tests that confirm finding.
- Outcomes.

Review by SA BME Leadership Committee

> SLS incidents that are of wider interest than to a specific site should be tabled at the SA BME Leadership Committee by the SA BME Operations Manager for noting and discussion.

Appendix 9: Instruction for Hazard and Recall Alerts

Sources of Alerts

- The primary and legislated (TGA) notification source is the hazard or recall notices directly from the supplier addressed to the LHN CEO or DHW CE.
- The SA Health Safety and Quality Unit (S&Q), DHW should also distribute TGA hazard and recall notices to the specific impacted LHN using the SA Health Safety Alert Broadcast System (SABS):
    - BME (LHN) – should confirm awareness of responsibility and need for action.
    - Manager BME (DHW) and Operations Manager SA BME should check distribution to BME LHN is correct. If SA BME Operations Manager is not available, Manager BME should ensure these are distributed appropriately.
    - Email notifications may require receipt confirmation to be replied.
- ECRI Hazards are used for informational purposes only and monitoring international trends. SA BME has a subscription enabling access to all international ECRI hazard reports (refer to SA BME Operations Manager).

Actions

- The LHN BME Technical Manager should identify biomedical technology affected and take the necessary action for the LHN.
- SA BME Operations Manager and SA BME Operations Committee should facilitate actions relating to state-wide notices, recording hazards or recalls on BAMS and monitor state-wide SA BME response where multiple sites are affected.
- SA BME Operations Manager should:
    - Receives SABS via a mailing list.
    - Distributes SABS to Area and Site Managers as confirmed by asset locations in BAMS.
    - Saves a copy of the Hazard Alert or Recall Notice in SA BME Shared drive:
    - Records in BAMS Incident Module where multiple sites have affected assets to ensure work orders are generated and notification reported consistently.
- Collaborate with Safety and Quality where issues are wider than the BME response (eg may need state-wide clinical response).

Update BAMS Asset History

- All hazards and recalls for biomedical technology that require checking or a corrective action should be recorded in BAMS Incident Module.
    - Notification details.
    - Linked to affected devices (all of make-model).
    - Further actions.
    - Amendments or modifications to devices.
    - Linked corrective maintenance work order where a corrective action is required.
    - Identification of personnel performing work.
    - Details and costs of parts used.
    - Dates of removal and return to service.
- For BAMS, instructions in the SA BME BAMS User Guide and Business Rules, Incidents should be followed.

Appendix 10: Instruction for BME Service Review and Escalation

- Service reviews can be conducted using feedback forms set up on the Inside Health SA Biomedical Engineering Feedback.
- LHN BME should determine:
  - Type of survey from Table 6 BME Customer Service Review (online survey)
  - Audience: eg equipment or Clinical Managers, Heads of Clinical Directorate or Medical Department, clinical users.
  - Distribution method: eg direct email (using BAMS equipment owner or contact fields), link in LHN newsletter.
  - Frequency: no more than annual is recommended.
- If maintenance activities for biomedical technology are not performed appropriately:
  - Issues should be raised to the BME LHN Area Manager.
  - Further escalation should be to their LHN Manager or Manager BME to table at SA BME Oversight Committee for wider discussion.

Table 6 BME Customer Service Review (online survey)

Feedback type	Purpose and audience
Feedback Form	Can be completed by anyone with feedback (praise or complaint) they wish to make SA BME aware of by a formal process
Complaint Handling Satisfaction Survey	After complaint has been lodged
Satisfaction with SA BME	Significant users of SA BME services may be asked to complete this Satisfaction Survey annually for the previous 12-month period
Satisfaction with External Contracts	Complete the External Contract Satisfaction Survey annually if you have external service contracts
Clinical training needs	A key control to reducing lifetime risk of biomedical technology not being used effectively by assuring ongoing training needs identified. This may be achieved outside BME by clinical speciality or medical department.
Clinical useability or performance inadequate (Pending)	Enable feedback to BME where biomedical technology is no longer appropriate for clinical need, either due to useability or performance. Information to be fed into BAMS and BME LHN replacement program recommendation. This may be achieved outside BME, e.g during annual stocktake process. Refer AS/NZS 3551 Appendix A Application of risk management principles in medical equipment management.

Appendix 11: Instructions for Contract Management

- Where a service agreement exists to support a piece of biomedical technology, the services of the supplier, manufacturer or a third-party maintenance provider should be arranged and monitored by BME.
    - Follow the Management of Biomedical Technology Service Contracts Procedure.
    - BME LHN should manage, document, and procure all service contracts.

Acquire Contract

- Approval should be gained for procuring service agreement in PCMS, particularly for multi-year and/or multi-site contracts.
- Financial approval should be gained where required by Treasurer's Instruction 8 (TI 8).
- Should draft and arrange for execution of service agreement/contract.
- Contract should be registered in PCMS.
    - Register contract expiry dates in PCMS and set up notification for contract expiry (use generic BME email address at site rather than individual email address).
- Contracts should be disclosed on government website as required PC027 "Disclosure of Government Contracts" (form within PCMS process).

Purchase Contract

- Purchase through Oracle BME shop with attachments: service agreement, financial approval (where applicable) and PCMS approval (screen capture).
    - Identify PCMS number in note to supplier.
    - Funding to be coded to BME RI for LHN/site/SCSS.
    - Use natural account 74825 R&M Preventive Maintenance _BME.
    - Separate line for each contract billing period.
- Receipt service agreement in Oracle annually.

Register Contract

- Contract should be recorded in BAMS
    - Link to devices.
    - Create PM schedule as agreed by service provider.

Manage Contract

- Service reports should be attached to asset in BAMS and close off completed scheduled visits.
- Perform Contract Management according to PCMS contract:
    - Liaise with clinical users to confirm contract KPIs met.
    - Begin contract review in sufficient time to enable renewal before contract expiry.
- Unless otherwise agreed by SA BME, the first point of contact by the service requester should be to SA BME who arranges contractor attendance if appropriate.

Instruction for Management of External Contractors

- LHN BME should follow the Contractor Safety Management (WHS) Policy to ensure external contractors:
    - Are inducted onsite where there is an appropriate administration office at the facility.
    - Are aware they need to:
        - Comply with all criminal and relevant screening and assessment requirements of legislation and SA Health polices to enter and work in an SA Health site. Proof of this compliance to be sighted and recorded at induction.

- Have licences/knowledge to meet all relevant standards and comply with all relevant regulatory requirements to carry out the task at the SA Health which is sighted and recorded at induction. And know of their legal responsibility to ensure that this is always up to date.
- Have insurance to cover them while at SA Health sites which is to be sighted and recorded at induction. And know of their legal responsibility to ensure that this is always up to date.

- Know of their responsibility to ensure they are currently inducted to perform service onsite, to sign in and out, and to send an electronic service report for record into the BAMS.
- Ensure personal information privacy and security is maintained in accordance with the States Information Security Management Framework.
- Ensure media handling and security is in accordance with the State information Security Management Framework when storage devices containing sensitive information (patient data) is removed from SA Health facilities.

Appendix 12: Instructions for Asset Removal – Reallocation, Trade-in, Sale or Disposal

Assess options

- Refer to Disposal Policy.
- Refer to Table 8 Test internal and external market for value.
- Options should be assessed to maximise value for SA Health:
    - Is the device to be traded in?
      May be agreed as part of a new purchase arrangement within quotation.
    - Is the device of value to the original LHN, Site or Technical Department?
      Hold as spare parts or temporary loan to support remaining fleet.
    - Does the device have possible value for other SA Health LHN?
    - Does the device have possible value for sale or donation?
        - Sale of goods can be made to external organisations and specialist equipment dealers.
        - Donations of medical equipment are best facilitated with Rotary Donations-In-Kind (DIK) who are confirm with requirements to successfully meet community needs, both national and international.
    - If “No” to all questions above, should recycle/dispose safely and appropriately.

Table 7 Assess options for reuse after removal of equipment from use

Process	BME action	Documentation
Ensure safe for reuse	Identify associated manuals and spare parts to go with the device if transfer/sold/donate	Attach Biomedical Technology Status Label
Reuse: Trade-in	Coordinate vendor pick-up - Goods are purchased at the buyer’s own risk - No warranty is to be provided as to the condition of the assets to be sold - Agreement for the Sale and Purchase of Goods, or Tailored disposal contract should be agreed	BAMS Retirement type: Trade-in
Reuse: within LHN	Continued value to LHN owner: as spare parts, spare fleet, or holding for relocation - Keep safely stored and labelled - Review annually - Recommission when needed	BAMS Retirement type: Spare parts or temporarily out of Service
Reuse: Test market	Options (see Table 3): - Transfer within SA Health - External buyer or donation Both new owner and old owner sign approval of transfer in current condition and for maintenance responsibility to shift. Transfer cost usually responsibility of the new owner.	BAMS Retirement Type: Available for Transfer, Sale or Donation

Process	BME action	Documentation
No re-use: recycle or disposal	All items that are deemed of no value or have not been acquired by another party are to be recycled or disposed. Make safe for disposal - Check decontaminated - Remove chemicals - Disable electrically & mechanically Remove SA Health labels Recycle/Dispose appropriately	BAMS Retirement Type: Recycle, or Dispose

Table 8 Test internal and external market for value

Process	BME action	Documentation
Test market 1 - transfer to another LHN within SA Health	Test market for value to other LHN: - Choose BAMS Retirement Type: - Available for Transfer - Keep appropriately stored for possible transfer up to 2 months. Publish in monthly report to LHN's/SCSS	Communicate with BME Technical Department (TD) retiring the asset and agree to transfer the Asset. The new BME TD to update BAMS on new MD, replenish original Asset number and coordinate transfer at cost to new owner.
Test market 2 - for external use: Sale or Donation	Test market for External buyer or Donation: - Choose BAMS Retirement Type: - Available for Sale, or - Donation - Keep appropriately stored for possible sale for 2 months. Publish in monthly report "Available for Sale" or "Donation" and TD send to list of possible customers.	Buyers contact ME TD to agree on a price to cover BME costs and any residual value. BME TD to arrange pickup and payment by customer

BME Actions

- BME should:
  - Oversee the removal through to disposal process:
    - Provide the point of contact for other stakeholders (eg Fixed Assets, PSCM, Clinical Managers).
    - Assure that the correct and complete processes are followed.
  - Gather associated manuals and spares to go with the device.

- Undertake proper research and risk management before transfer/disposal.
- Make device safe for reuse or disposal considering:
    - Hazardous materials.
    - Possibility of inflicting injury in the hands of untrained individual (eg defibrillators, lasers, diathermy generators).
    - Decontamination.
    - Electrical and mechanical safety or permanent disablement.
    - Compliance with jurisdictional requirements (environmental safety, hazardous waste, controlled substances etc).
- Sensitive data to be erased from systems containing clinical / patient information (media handling and security is in accordance *South Australian Cyber Security Framework)*.
- If not for SA Health reuse, remove asset number and other SA Health labels

> BAMS should be updated with new status and details:

- Device status change to: Removed, Relocated or Disposed.
- New owner details if transferred: LHN, Medical Department, Clinical Directorate, Building and room location, cost centre, BME Technical Group.
- Attach approved Form and Disposal Plan against all related assets and parent asset if a system.
- Replaced by Asset number (if applicable, i.e., funded from Capital replacement Program).
- Retirement date and type.

> Fixed Assets Team should be advised of the change in status by the monthly report from BAMS (Additions, Transfers and Removals) after endorsement by Area Managers.

> Device should be labelled:

SA BME Biomedical Device Status

☐Hold for spares ☐Temporary out of service
☐Available for Transfer ☐ Available for Sale
☐Donation ☐ Disposal/Recycle

Device is safe and decontaminated	Y	N
AssetPlus has been updated	Y	N
Description:		

Asset or Serial No:	

Name:		**Date:**	

Figure 1 SA BME Biomedical technology status label

Documentation

> For key decisions, data and discussions during the disposal process, BME should accurately record the detail and file the documentation to enable subsequent reviews and audits, including Asset Removal/Transfer/Disposal Form and Disposal Plan.

Disposal Plan

- A Disposal Plan should be completed where:
    - Residual value (current or written down) is close to, or over $10,000, and not part of the BME Capital Replacement Program, or
    - Removal for Standards not met, or Work Health & Safety reasons.
- Include: value estimate; risk assessment; decommission documentation / certification; disposal method; approvals.

Asset Removal/Transfer/Disposal Form

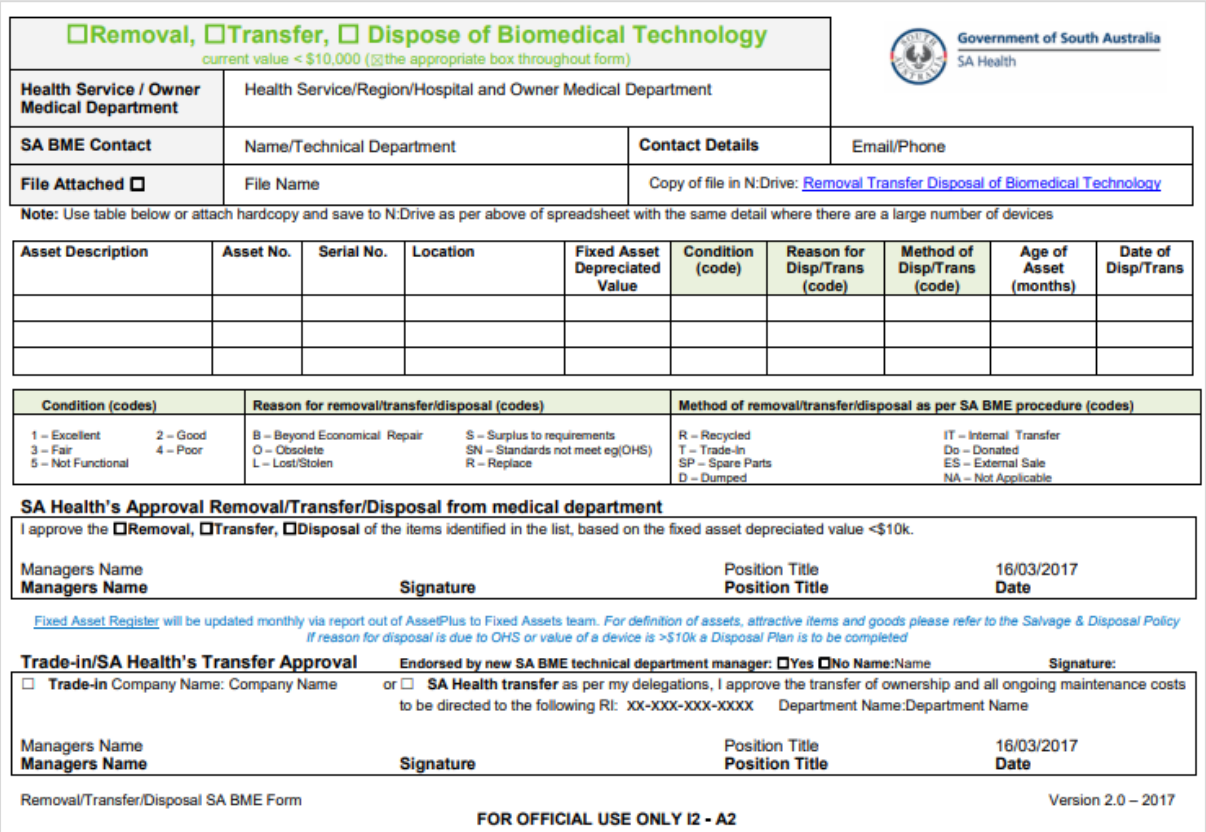
- The Asset Removal/Transfer/Disposal Form (Figure 2 Biomedical technology removal-transfer-disposal form) should be completed.
- Reason for removal should be identified:

  B – Beyond Economical Repair; O – Obsolete

  S – Surplus to requirements; R – Replaced; L – Lost/Stolen

  SN – Standards not met (If WHS, a Disposal Plan is required).

- Approval should be sought:
    - Where old asset number is identified in the BME Capital Replacement Program, approval for the annual program was given by LHN CEO (this includes equipment being removed).
    - Not a capital asset (purchase <$10,000) – LHN financial approval is needed, except where BME has the authority to retire the asset with supporting documentation:
        - Beyond its “Life Expectancy” date.
        - Beyond economical repair.
        - Unsafe for purpose.
        - Missing/lost for >2yrs.
    - If residual value (current or written down) is close to, or over $10,000, and not part of the BME Capital Replacement Program:
        - The residual value to be confirmed by the Fixed Asset Register; they may seek independent assessment.
        - Seek endorsement by medical department owner.
        - Proceeds from the asset disposal may be put back against DHW funds, however it is to be clearly identified that the original purchase was funded from the same location and the allocation of the proceeds is to be approved as part of the financial approval.
        - Approval needs financial delegation for disposals (refer to LHN Delegation Register).



☐Removal, ☐Transfer, ☐ Dispose of Biomedical Technology

current value < $10,000 (☒the appropriate box throughout form)

Government of South Australia
SA Health

Health Service / Owner Medical Department	Health Service/Region/Hospital and Owner Medical Department		
SA BME Contact	Name/Technical Department	**Contact Details**	Email/Phone
File Attached ☐	File Name	Copy of file in N:Drive: Removal Transfer Disposal of Biomedical Technology	

Note: Use table below or attach hardcopy and save to N:Drive as per above of spreadsheet with the same detail where there are a large number of devices

Asset Description	Asset No.	Serial No.	Location	Fixed Asset Depreciated Value	Condition (code)	Reason for Disp/Trans (code)	Method of Disp/Trans (code)	Age of Asset (months)	Date of Disp/Trans

Condition (codes)		Reason for removal/transfer/disposal (codes)		Method of removal/transfer/disposal as per SA BME procedure (codes)	
1 – Excellent	2 – Good	B – Beyond Economical Repair	S – Surplus to requirements	R – Recycled	IT – Internal Transfer
3 – Fair	4 – Poor	O – Obsolete	SN – Standards not meet eg(OHS)	T – Trade-In	Do – Donated
5 – Not Functional		L – Lost/Stolen	R – Replace	SP – Spare Parts	ES – External Sale
				D – Dumped	NA – Not Applicable

SA Health's Approval Removal/Transfer/Disposal from medical department

I approve the ☐**Removal,** ☐**Transfer,** ☐**Disposal** of the items identified in the list, based on the fixed asset depreciated value <$10k.

Managers Name — **Managers Name** | **Signature** | Position Title — **Position Title** | 16/03/2017 — **Date**

Fixed Asset Register will be updated monthly via report out of AssetPlus to Fixed Assets team. *For definition of assets, attractive items and goods please refer to the Salvage & Disposal Policy*
If reason for disposal is due to OHS or value of a device is >$10k a Disposal Plan is to be completed

Trade-in/SA Health's Transfer Approval **Endorsed by new SA BME technical department manager:** ☐**Yes** ☐**No Name:**Name **Signature:**

☐ **Trade-in** Company Name: Company Name or ☐ **SA Health transfer** as per my delegations, I approve the transfer of ownership and all ongoing maintenance costs to be directed to the following RI: XX-XXX-XXX-XXXX Department Name:Department Name

Managers Name — **Managers Name** | **Signature** | Position Title — **Position Title** | 16/03/2017 — **Date**

Removal/Transfer/Disposal SA BME Form Version 2.0 – 2017

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Figure 2 Biomedical technology removal-transfer-disposal form