HUNTER NEW ENGLAND CLINICAL TECHNOLOGY (HNECT)
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Medical Equipment – Acceptance and Commissioning Internal Procedure

This internal procedure relates to HNELHD PCP:	Medical Equipment – Corrective Maintenance PD2018_013:PCP 18
Subject	HNECT Internal Procedure for Medical Equipment – Acceptance and Commissioning Internal Procedure
Keywords	Acceptance ,Commissioning
Replaces existing Procedure?	No

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Issue date	22/10/2021
Review date	21/10/2024

1. **PURPOSE AND SCOPE**

- To establish the procedure for managing acceptance and commissioning of medical devices in Hunter New England LHD
- To clearly define the activities for HNECT staff in managing safety notices and recalls applicable to medical equipment within HNE LHD.
- This procedure excludes Medical Imaging equipment except for point of care (POC) imaging devices

2. **RESPONSIBILITIES**

All HNECT staff

3. **DEFINITIONS**

Medical Equipment:

A medical equipment is

a. Any instrument, apparatus or appliance, including software, whether used alone or in combination, which makes physical or electrical contact with the patient, or transfers energy from or to the patient, or detects such energy transfer to or from the patient, and is intended to diagnose, treat or monitor the patient.

b. an accessory to such an instrument, apparatus, appliance, material or other article.

Acceptance Testing:

A set of processes, which are performed before a newly acquired medical device may be released for clinical use. Acceptance Testing usually consists of an electrical safety and full functional test of the device. For equipment owned by HNE Health or on long term rental / loan (> 1 year), this also includes issuing a Medical Asset number to the device and entering it into the HNECT asset database.

Corrective Maintenance

Maintenance carried out on a medical device, accessory or a system after fault recognition and intended to restore the device, accessory or a system into a state in which it can safely perform its function specified by the manufacturer.

Preventative Maintenance: This comprises of the scheduled maintenance work including but not limited to replacing components of a device susceptible to wear, fatigue and depletion, performing calibrations and verification of functions prior to failure.

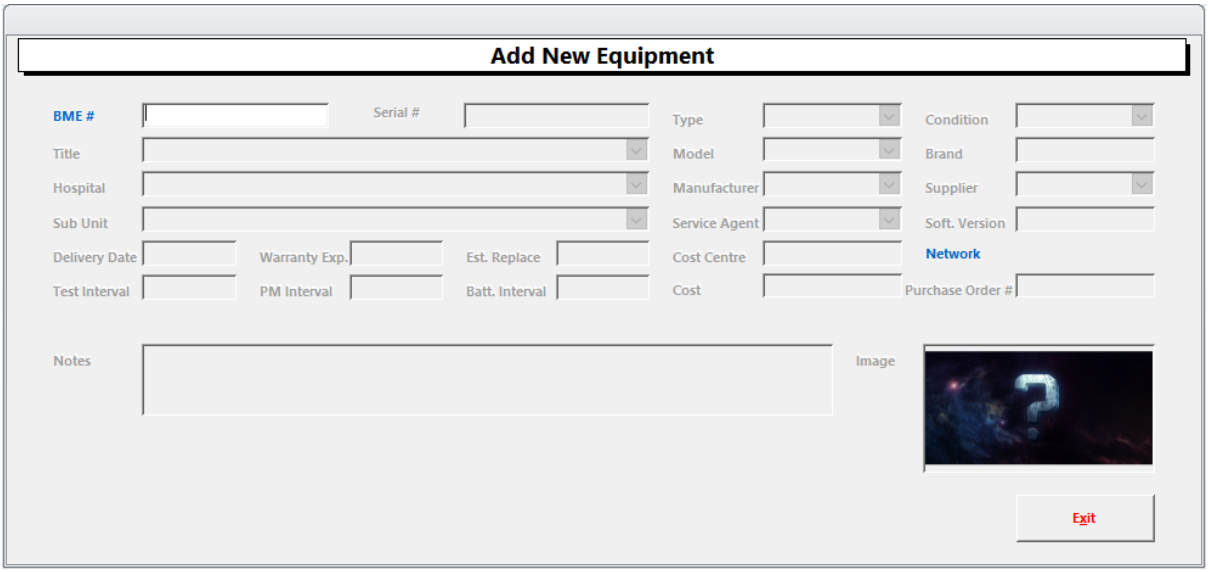
4. PROCEDURE

4.1 Acceptance Testing

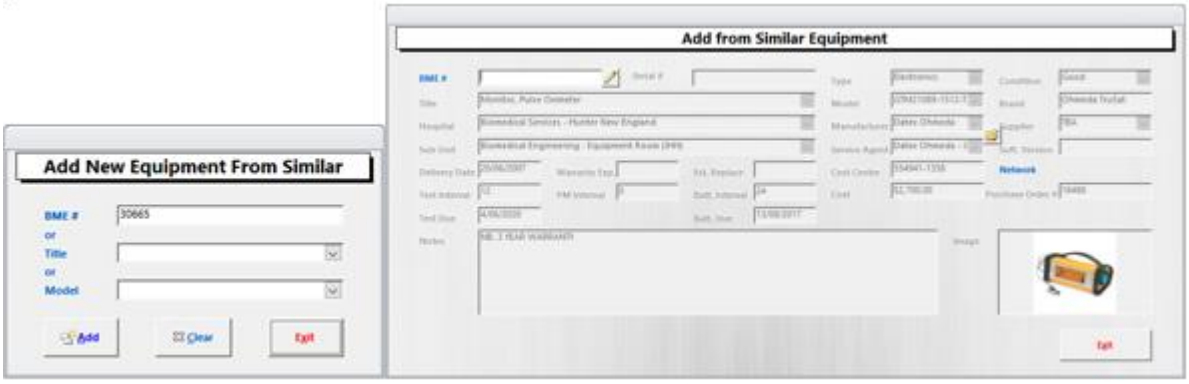
- Review Purchase order (PO) to ensure received goods (equipment , accessories and consumables) are complete and as per order
- Perform physical inspection of all received equipment and accessories to assess physical condition and identify any manufacturing discrepancies or damages during transportation
- Check specifications (Physical, Electrical, Network,) to ensure alignment with the purchase order
- Conduct electrical safety test (EST) according to AS3551-2021 and record results in EMS
- Conduct performance checks as per manufacturer's recommendations or HNECT test methods where available-Record results/report in EMS and scan folders
- Report discrepancies in above checks to HNECT management and/or supplier/manufacturer of the devices as soon as possible
- If discrepancies/defects are deemed high risk, DO NOT accept the equipment
- For equipment fulfilling the acceptance Criteria, affix an Asset number (BME#) tag ,EST tag and PM Tag to the equipment and accessories where applicable(e.g. Ultrasound Probes)

4.2. Updating Asset Register

- Update EMS by completing ALL fields in the "Add New Equipment" page. DO NOT proceed without updating information on this page



- If equipment already exists that is the same or similar, use existing details to make this process more efficient



- DO NOT forget to update new asset specific information including PO number, Cost and Network Information
- If new equipment is received that requires a new test Method , inform your supervisor/team leader of the same
- Supply additional useful information in the notes section, if required. This can be a special instruction, parent-child relationship with another asset or replacement note

4.2. Vendor supplied test reports

- Vendor supplied test reports will be accepted if
    - Tests were conducted on-site by vendors/manufacturers qualified representative
    - Tests were conducted in-country by vendors/manufacturers qualified representative and within a reasonable time (Three months prior to installation)
    - Test reports from overseas /factory will only be accepted after HNECT management's risk assessment
- Upon receiving the satisfactory test reports, HNECT staff will Asset number (BME#) tag , EST tag and PM Tag to the equipment and accessories(where applicable)
- Update asset details in EMS
- Update test results in EMS and scan folders

5. CMMISSIONING

- Upon completion of installation, equipment will be handed over to clinical users
- For existing general and non-critical equipment, commissioning will be complete upon handing over for clinical use(examples: Thermometers, SCD, Infusion pumps, stand-alone patient monitors)
- For specialised high risk and critical equipment commissioning will be complete upon user acceptance testing (examples: Anaesthetic machines, Ventilators, Networked patient monitoring networks, Diagnostic ultrasound)

6. Record keeping

- All records pertaining to acceptance and commissioning shall be recorded in EMS
- The numerical results of the safety and functional tests will be retained in the EMS

7. Compliance, Implementation and Monitoring

Compliance to the policy shall be monitored against the key performance indicators (completeness of EMS information) stipulated above.

8. Feedback

Any feedback on this document should be sent to the Procedure Contact Officer listed on page 1.

9. REFERENCES

- Australian Standard AS/NZS 3551.2012: Technical Management Programs for Medical Devices
- PD2018_013_PCP_18_Medical_Equipment_-_Corrective_Maintenance