

Medical Devices Policy Practice Guidance Note		
Sale, external transfer of ownership and disposal of used medical devices – external; transfer of ownership (i.e. to a body or organisation outside Cumbria Northumberland, Tyne and Wear NHS Foundation Trust (the Trust)) of a used medical device – V05		
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1 OUTLINE

- 1.1 Transfer of Ownership by sale or donation must be done in an approved and accountable route with Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (the Trust).
- 1.2 The Professional User who instigates the sale or donation must complete Appendix 3 of MD- PGN-12 and receive the appropriate managerial authorisation. A record of this authority must be included on the Disposal form.
- 1.3 The supplies department will coordinate the sale or donation of medical devices.
- 1.4 Statutory requirements must be followed when selling or donating used medical devices – failure to do so could lead to prosecution or liability for damages.
- 1.5 On selling or donating used medical devices the vendor should provide all the information needed to verify whether the medical device can operate correctly and

safely, plus details of the nature and frequency of maintenance and calibration needed to ensure that the device operates properly and safely at all times.

- 1.6 On selling or donating used medical devices a clear statement that the ownership is being transferred should be obtained and what liabilities are also being transferred.

2 SECURITY OF INFORMATION

- 2.1 Where appropriate information should be removed and archived.
- 2.2 Before any transfer takes place, any patient identifiable information must be removed/destroyed in such a way that it could never be retrieved (note a 'normal' computer delete file action is not considered adequate as these files can often be easily retrieved). Consult the IT department to delete any patient identifiable information.

3 DECONTAMINATION

- 3.1 The device should be fully decontaminated according to the manufacturer's instructions.
- 3.2 A certificate of decontamination should be attached to the equipment.
- 3.3 Any information, updates, notices or addendum's relating to the decontamination of the medical device, which is not already included in the manuals, should be provided.
- 3.4 If the device cannot be decontaminated it should not be transferred (for maintenance, repair or change of ownership), sold or donated unless special clearly documented arrangements have been made, which meet all legal, statutory and Health and Safety requirements.
- 3.5 Do not send contaminated devices through the post as it is illegal.

4 MANUALS AND TRAINING REQUIREMENTS

- 4.1 The original user operator/maintenance etc. manuals should be provided.
- 4.2 Any updates, notices or addenda to the manuals should be provided.
- 4.3 Any training requirements, recommendations, updates or notices not included in the manual(s) should be provided.
- 4.4 Any notices issued by the Medical Device Alerts (MDA)(Safety, Hazards or others) relating to the medical device should be provided.

5 DEVICE USAGE AND SERVICE HISTORY

- 5.1 Before sale or transfer of ownership of a medical device, both parties should have the opportunity to thoroughly investigate the legal liability aspect of the service history and consult their respective legal advisors if necessary.

5.2 The service history should be transferred.

6 RECORDS

6.1 The managing professional instigating the transfer should inform all other parties involved in the management of the equipment of the change of ownership, including service contractors and bodies external to the Trust.

6.2 All records should be updated to reflect the change in ownership including the Medical Device Inventory and the Capital Finance Asset Register (The Capital Finance Asset Register is managed by the Finance department, and can be accessed by contacting the Finance Department).