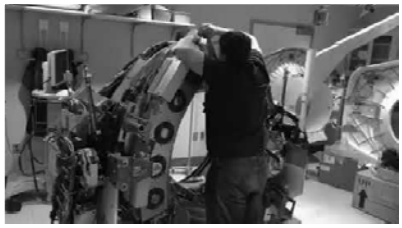
Specifications of Medical Imaging in Equipment

Slavik Tabakov



Acquisition and selection of devices 1

<u>Factors to consider before acquisition</u>

Choosing the correct device

- Correct assessment and selection
- Suitability for intended purpose/application
- The procedure for accepting new devices

Rationalising the range of models versus diversity: <u>CLINICAL NEEDS</u>

Ease of use. Consider user experience feedback from the clinical environment.

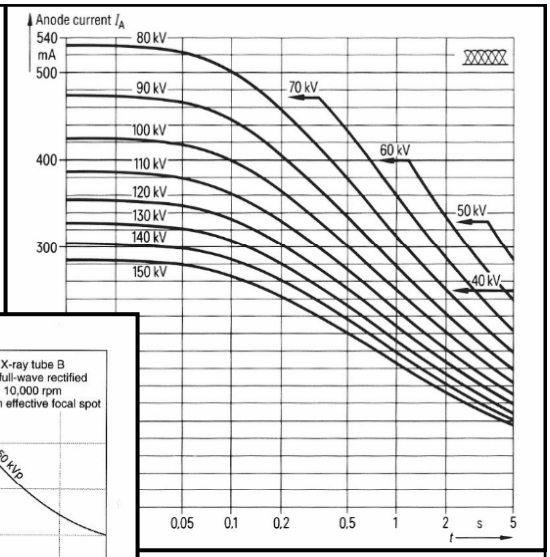
Max. power of the tube:

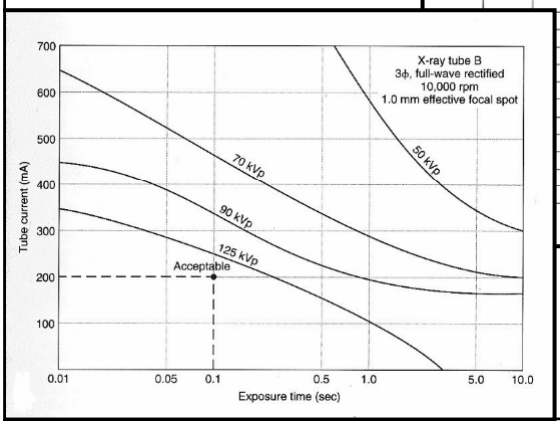
P=kV.mA (100x300=30kW)

Max anode heat capacity

HU=kV.mAs (100x1000=100kHU)

1HU=1.4 Joules

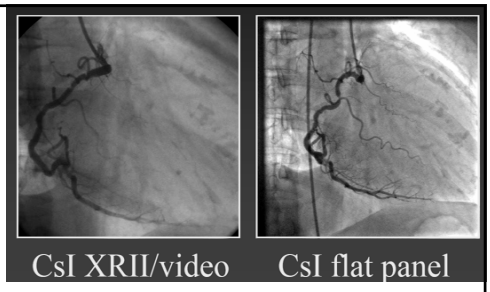


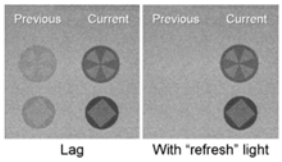


X-ray Tube characteristics: Using of single exp. chart

FPD Digital Flouroscopy

High cost, but more compact with better uniformity and without geometric distortion. Improved high-dose examinations as cine mode (at lower dose). Not enough strong signal at low dose examinations (II better). FPD with indirect technology still have insufficient temporal resolution (lag), but direct FPD are better.





Feature comparison of II/TV and FPD systems

Feature	Digital flat panel	Conventional II/TV
Dynamic range	Wide, about 5,000:1	Limited by TV, about 500:1
Geometric distortion	None	Pin-cushion and 'S–distortion
Detector size (bulk)	Thin profile	Bulky, significant with large FOV
Image area FOV	41×41 cm	40 cm diameter (25% less area)
Image quality	Better at high dose	Better at low dose

Acquisition and selection of devices 2

Factors to consider before acquisition

Rationalising the range of models versus diversity

Documentation and monitoring

- Evaluate the readability of manufacturer's instructions – Language!
- For which users are the Guides physicists, radiographers, etc)
- Are diagrams and technical guides included
- Timing of update and monitoring

Installation support services

- Is the installation to be carried out by manufacturer/supplier?
- What building and utility services are required?
- Is special calibration or other associated equipment needed?
- Does the device meet the required IT communication protocols
- Does the manufacturer endorse the installation of additional software
- How the equipment will link with you're HIS/PACS

Acquisition and selection of devices 3

Factors to consider before acquisition

- Agree the requirements for the intended medical procedure(s)
- Agree the needs of the user (Department, Hospital, Region, etc)
- Suitability for intended purpose by reviewing the manufacturer's description
- Software compatibility with archive systems, patient records etc.
- Software Updates – for how long and until when it will be free
- Electronic medical devices which process data needs to be secure;
- Safety issues and any limitations on use.

E	Extreme Risk, Immediate action required
H	High risk, action planned immediately, applied within one month
M	Moderate risk, action planned within one month, applied within three
L	Low risk, action planned within three months, applied within 1 year

Medical Equipment Risk Level

	Minor	Moderate	Serious	Major	Catastrophic
Certain					
Expected					
Likely					
Unlikely					
Rare					

- Check all necessary National and Local regulations
- Take advise from external experts (electrical, mechanical, building, other)
- All advice to be signed

Acquisition and selection of devices 4

Factors to consider before acquisition

- Availability, type and scope of training
  - In the manufacturer's premises
  - At the place of installation
  - In another hospital
  - e-Training over internet (time to be available)
  - Training update with new software or other
- Advice and help. What advice services does the supplier offer
- Ensuring the operating/environmental conditions of the place of device usage
- Decontamination and disposal procedures

Acquisition and selection of devices 5

Factors to consider before acquisition

- Pre-use set up, testing requirements, installation requirements, commissioning
  - Test objects and measuring devices to be included in the price
  - Specific test object and/or software
  - Attendance at installation and manufacturer's tests
  - Time for Commissioning (as per what protocol)
  - Actions in case of failed tests/commissioning

- The projected service life of the product and warranty details.
  - If manufacturer's tests are made – how (distance, on site, frequency)
  - If third party – what are their Contracts with Manufacturer
  - If in the hospital (own tests) – how these will be verified before action
  - Overall warranty (is there warranty for the software updates)
  - Periodic performance checks by the manufacturer
  - Spare parts (time of availability, standard price
  - Activities for replacement with new model

Acquisition and selection of devices 6

Maintenance support

- Can the desired service provider maintain the device?
- How will the proposed contract or service level agreement deal with continuity of care? For example: on site repair, if needed.
- Are alternative devices available to cover when device is repaired
- Are response times appropriate and guaranteed?
- What are the proposed servicing/callibration intervals?
- Are spares readily available, and for how long?
- Is service support guaranteed, and for how long?
- What information is available from the manufacturer, e.g. circuits, manuals, trouble-shooting, repair procedures, parts list, etc.

Final reliability and costs

- Reliability and previous performance.
- Whole life costs: acquisition and operational, maintenance and consumable, training, risk, renewal and disposal costs.

Acquisition and selection of devices 7

Second-hand medical devices

• record of any reconditioning work carried out, including replacement parts record
• copy of all maintenance and servicing that have been carried out, including the name of the maintenance/servicing organisation
• record, type and frequency of usage over its working life
• fault log
• date of installation
• tube usage (for X-ray devices) or helium level (for MRI)…
• Check WHO Guides on Second hand equipment

DO NOT FORGET

• Agree the specification with your Boss (Department & Hospital)
• Ask the agreed Specification to be signed by your Boss
• In case of Tender work together with Finance/Legal support

The lecture is based on the UK Guidance

Main Content of the Guidance:

Systems of management
Acquisition and selection of devices
Clinical investigations
Receiving a new device
Training
Instructions for use
Maintenance and repair
Decontamination
Decommissioning
Legislation

Also additional activities - more detail:

Need and Specification
Tendering
Acceptance testing
Quality Assurance