WEBINAR

Procurement process for medical equipment and service delivery

Wednesday, July 12

2pm UTC  10am NY

Register for free: https://tinyurl.com/GCEA-procurement
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globalcea.org
Medical Devices – Specification and Evaluation

Andrew Gammie
DPhil CEng MIET CSci MIPEM
Clinical Engineer, Fishtail Consulting Ltd, UK
Specification and evaluation of bids – part of the whole
• Good procurement brings:
  • safe, quality healthcare services
  • the best deal for the organization’s needs
  • timely delivery and handover
  • satisfactory delivery, installation, commissioning and training
  • effective payment and warranty
  • satisfactory after-sales service
  • greater interest in submitting offers in the future
  • transparent and trustworthy systems

• The right product of the right quality at the right price of the right quantity at the right place and time (Bailey, 1994)
Garbage in, garbage out

Computer software.....

....and procurement

“To obtain the right product or service
....... a clear specification is required.”

WHO Procurement Process
Resource Guide 2011
Poor procurement - examples

- Pulse oximeter with disposable probes
- User manuals in German
- 120V mains supply
Specifications - goals

- Get what you want
- Sufficient quality
- Good value
Get what you want

- Get what you want
- Sufficient quality
- Good value

Describe function

- What does it do? (Not “how?”)
- Check with users
Get what you want

- Describe function
- Describe clearly
  - Standard names
  - ‘Must / shall’ not ‘should’
  - One item at a time
  - Use testable words
    - E.g. not ‘modern’, ‘fast’
Get what you want

- Describe function
- Describe clearly
- Describe fully
  - Use template to remember:
    - spares, accessories, power, environment, training, manuals, standards

- Get what you want
- Sufficient quality
- Good value
Get what you want

- Describe function
- Describe clearly
- Describe fully

Write to evaluate
  - Will I know when I have the right device?
Specifications - goals

- Get what you want
- Sufficient quality
- Good value
Sufficient quality

- Set limits and ranges
  - What is actually needed?
Sufficient quality

- Set limits and ranges
- Get help
  - Use but don’t copy:
    - Other specifications
    - Manufacturer specifications
    - ECRI
Electrosurgical Units; Argon-Enhanced Coagulation

Scope of this Product Comparison

This Product Comparison covers electrosurgical units (ESUs) that are used in most hospital operating rooms (ORs); low-power and special-purpose ESUs that perform one function exclusively (e.g., cutting, coagulating); ESUs that administer argon-enhanced coagulation; and stand-alone gas-delivery units that can provide argon-enhanced coagulation when used with certain ESUs. This report excludes accessories such as active and return electrodes, which are frequently purchased from sources other than ESU manufacturers.

Purpose

ESUs are used for surgical cutting and for controlling bleeding by causing coagulation (hemostasis) at the surgical site. They deliver high-frequency electrical current through an active electrode tip, causing desiccation, vaporization, or charring by resistive heating in the target tissue.
# Chart A: Electrosurgical Units

<table>
<thead>
<tr>
<th>MODEL</th>
<th>ECRI INSTITUTE’S RECOMMENDED SPECIFICATIONS</th>
<th>AARON/BOVIE A1250</th>
<th>AARON/BOVIE A2250</th>
<th>AARON/BOVIE A800E/U: A900</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHERE MARKETED</td>
<td>Worldwide</td>
<td>Worldwide</td>
<td>Worldwide</td>
<td>Worldwide</td>
</tr>
<tr>
<td>FDA CLEARANCE</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CE MARK (MDD)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>GENERATOR TYPE</td>
<td>Solid-state</td>
<td>Solid-state</td>
<td>Solid-state</td>
<td>Solid-state</td>
</tr>
<tr>
<td>FREQUENCY, kHz</td>
<td>Typical: 500-1,000</td>
<td>500</td>
<td>800</td>
<td>550</td>
</tr>
<tr>
<td>OUTPUTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monopolar</td>
<td>Isolated</td>
<td>Isolated</td>
<td>Isolated</td>
<td>Ground referenced</td>
</tr>
<tr>
<td>Handswitch</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Footswitch</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Bipolar</td>
<td>Preferred</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>MODES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monopolar</td>
<td>Pure, blend, coagulate, fulgurate</td>
<td>Pure, blend, pinpoint, spray</td>
<td>Coagulate, desiccate, fulgurate</td>
<td></td>
</tr>
<tr>
<td>Cut</td>
<td>Maximum watts at (rated Ω) 300</td>
<td>120 (500)</td>
<td>200 (300)</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Maximum voltage, Vpp 2,000</td>
<td>2,500</td>
<td>2,500</td>
<td>NA</td>
</tr>
<tr>
<td>Coagulate</td>
<td>Maximum watts at (rated Ω) 120</td>
<td>80 (1,000)</td>
<td>120 (500)</td>
<td>30 (1,000)</td>
</tr>
<tr>
<td></td>
<td>Maximum voltage, Vpp 6,000</td>
<td>4,500, 6,500</td>
<td>3,500</td>
<td>10,000</td>
</tr>
<tr>
<td>Bipolar</td>
<td>Coagulate</td>
<td>Coagulate</td>
<td>Coagulate</td>
<td></td>
</tr>
<tr>
<td>Cut</td>
<td>Maximum watts at (rated Ω)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Maximum voltage, Vpp</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Coagulate</td>
<td>Maximum watts at (rated Ω) 50</td>
<td>30 (200)</td>
<td>80 (150)</td>
<td>30 (200)</td>
</tr>
</tbody>
</table>
 Specification libraries available

- ECRI www.ecri.org
  - US-based
  - Subscription service
  - Comparisons and guidelines
- UNICEF https://supply.unicef.org/
  - Fixed catalogue
  - Specifications therefore limited
- CENETEC http://www.cenetec.salud.gob.mx/contenidos/biomedica/cet.html
  - Useful spread of devices
  - Spanish language
- AFIB https://afib.asso.fr/
  - French language
- India: https://nhsricindia.org/technical-resource
- WHO – 74 items
  - https://www.who.int/publications/m/item/who-technical-specifications-for-61-medical-devices
<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDICAL DEVICE SPECIFICATION (including information on the following where relevant/appropriate, but not limited to)</td>
<td></td>
</tr>
<tr>
<td>NAME, CATEGORY AND CODING</td>
<td></td>
</tr>
<tr>
<td>PURPOSE OF USE</td>
<td></td>
</tr>
<tr>
<td>TECHNICAL CHARACTERISTICS</td>
<td></td>
</tr>
<tr>
<td>PHYSICAL/CHEMICAL CHARACTERISTICS</td>
<td></td>
</tr>
<tr>
<td>UTILITY REQUIREMENTS</td>
<td></td>
</tr>
<tr>
<td>ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS</td>
<td></td>
</tr>
<tr>
<td>PACKAGING</td>
<td></td>
</tr>
<tr>
<td>ENVIRONMENTAL REQUIREMENTS</td>
<td></td>
</tr>
<tr>
<td>TRAINING, INSTALLATION AND UTILISATION</td>
<td></td>
</tr>
<tr>
<td>WARRANTY AND MAINTENANCE</td>
<td></td>
</tr>
<tr>
<td>DOCUMENTATION</td>
<td></td>
</tr>
<tr>
<td>DECOMMISSIONING</td>
<td></td>
</tr>
<tr>
<td>SAFETY AND STANDARDS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic name</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------</td>
</tr>
<tr>
<td>3</td>
<td>Specific type or variations</td>
</tr>
<tr>
<td>4</td>
<td>GMDN name</td>
</tr>
<tr>
<td>5</td>
<td>GMDN code(s)</td>
</tr>
<tr>
<td>6</td>
<td>GMDN category</td>
</tr>
<tr>
<td>7</td>
<td>UMDNS name</td>
</tr>
<tr>
<td>8</td>
<td>UMDNS code</td>
</tr>
</tbody>
</table>

**TECHNICAL CHARACTERISTICS**

<table>
<thead>
<tr>
<th></th>
<th>Detailed requirements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td></td>
<td>1. Maximum speed to be at least 10,000 revolutions per minute (rpm).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. User operated timer to allow up to at least 60 min. operation before automatic stop.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Tachometer display of rpm required, with accuracy of better than 10%.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Supplied with both fixed-angle and horizontal (swinging bucket) rotor fittings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. At least six samples to be contained at one time.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. A single size of sample tube is acceptable, which must be within the range 5 ml to 15 ml.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. Electric braking feature incorporated.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. Lid interlock required, locking lid while motor is running.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>9. Power on button to be mounted on front panel.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10. Brushless motors are preferred.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11. Refrigeration is not required.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12. Closed lid security system during operation.</td>
</tr>
<tr>
<td>19</td>
<td>Display parameters</td>
<td>1. Alert indicators are required for imbalance, lid open and cycle complete.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Timer display required, showing cycle time remaining.</td>
</tr>
</tbody>
</table>
Sufficient quality

- Set limits and ranges
- Get help
- Decide what matters
  - Leave out unnecessary
Specifications - goals

- Get what you want
- Sufficient quality
- Good value
Good value

- Allow competition
  - No brand names, no precise values
Good value

- Allow competition
  - Know what’s out there
    - ECRI
    - Internet search
    - Pre-bid meeting
Review before sending

- Get what you want
- Sufficient quality
- Good value

- Check it makes sense
- External review
- Aim for evaluation
Completing the picture
## Good Specifications

### Get what you want
- Describe function
  - What does it do? (Not “how?”)
  - Check with users
- Describe clearly
  - Standard names
  - ‘Must / shall’ not ‘should’
  - One item at a time
  - Use testable words, e.g. not ‘modern’, ‘fast’

### Sufficient quality
- Describe fully
  - Use template to remember
- Write to evaluate
  - Will I know when I have the right device?
- Set limits and ranges
  - What is actually needed?
- Get help
  - Use others but don’t copy
- Decide what matters
  - Leave out unnecessary

### Good value
- Allow competition
  - No brand names, no precise values
- Know what’s out there
  - ECRI, Internet search, Pre-bid meeting
Evaluation – checking the bid submissions

• Develop a good recording system
  • Step by step through specification and bid response
  • Who said what, when

• Ensure evaluator does not see prices

• Check certificates
  • e.g. BSIF Is-it-Genuine-2023.pdf
  • Use notified bodies web services

• Ask for clarifications
  • e.g. “Please state if the spares pack includes batteries”

• Make clear final recommendation:
  • Acceptable / Not acceptable
Procurement Process for Service Delivery

Adrian Richards

Board Member, College of BME, Engineers Australia
Member, National Committee on Clinical Engineering, Engineers Australia
Collaborator IFMBE, Clinical Engineering Division
The Australian Context

• Tertiary Healthcare is largely public, being funded and run by the government

• Treatment is free of charge

• The majority of Clinical Engineers are government employees

• A private healthcare system runs in parallel for those who choose to take out private insurance
Selecting CE Service Providers - Scenarios

1. A full CE service
   - Most common in the private system, small hospitals or chains

2. Some elements of an established in-house service
   - Very common in the public system
Full CE service

• Small hospitals in which setting up a comprehensive service is not viable
• Bring strengths of a large provider in terms of skill set and systems/processes
• In principle strategy – contracting of support services
• Political agenda
Elements of an Existing Service

- Support of complex technologies
- Reducing cost for limited installed base
- Managing staffing resource
- Lack of training/software accessibility (right to repair)
- Mitigating financial risk or uncertainty
- Reliable access to upgrades
- Making best use of existing skill set
Whole Service – Key issues

• Clearly specify scope of service via a formal process
  • Technologies that are included and excluded – process to vary this
• Organisational expectations beyond HTM – e.g. committee roles, R and D support
• Service levels including performance and hours
• Number and level of staff – relationship to meeting KPIs
• Review process including client satisfaction
• Duration of contract and right of renewal
• Dispute resolution
Elements of an Existing Service

• Greater focus on operational and performance elements
• Response times and up-time guarantees – capacity to handle work
• Personnel undertaking work – qualifications and experience
• Reporting arrangements
• Dispute resolution
• Contract vs fee for service
• Reference clients – how to assess
Elements of an Existing Service

Note

• In this scenario you may not be getting a CE service by the true definition, but rather a repair and maintenance service
• Support under a vendor contract is a good example of this

• Nothing wrong with this, but you need to be aware of the difference
Key Take Home Messages

• Be very clear on your expectations and gain evidence that a provider can fulfil them competently
• Ensure a provider has capacity to fulfil their obligations appropriately
• Assess past performance at other sites
  • Speak to many clients not just selected ones
  • Use your networks
• Get a “feel” for the service provider and your ability to work with them
Thank You

Questions or Discussion
akrichards78@gmail.com
A list of additional topics and dates for next webinars will be soon announced through email campaign and on our website www.GlobalCEA.org

THANK YOU for your participation