PART C – CLINICAL PRODUCT SPECIALIST REVIEW FORM

To be completed by Biomedical or Engineering/Infection Control/OS&H / Manual Handling Specialists

PRODUCT INFORMATION

[See Part B for further information]

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Model Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BIOMETICAL OR ENGINEERING REVIEW

<table>
<thead>
<tr>
<th>Not Applicable ☐</th>
</tr>
</thead>
</table>

Is the purchase of this equipment in line with the Organisation’s equipment standardisation?

- ☐ Yes
- ☐ No

Provide details / explanation if you answer “no” to the above

Are accessories necessary?

- ☐ Yes
- ☐ No

Are there alternate sources of accessories?

- ☐ Yes
- ☐ No

Are dedicated consumables necessary?

- ☐ Yes
- ☐ NO

Comments on accessories / consumables:

Has evidence been provided to confirm compliance to the following?

- Regulatory Compliance?
  - ☐ Yes
  - ☐ No

- Quality Certification [ISO 9000]?
  - ☐ Yes
  - ☐ No

- Legible manufacturer / brand name on equipment?
  - ☐ Yes
  - ☐ No

- Date of manufacture stamp on equipment?
  - ☐ Yes
  - ☐ No

- Country of manufacture stamp on equipment?
  - ☐ Yes
  - ☐ No

- Labels including S.W.L are permanently attached & legible?
  - ☐ Yes
  - ☐ No
  - ☐ N/A

Estimated routine maintenance cost $ Per annum

Model and Serial Numbers of Reviewed Equipment:

Requirements/Considerations:

Acceptance testing as per AS3551 [Refer Part B Clinical Product Presentation Form]

Health acknowledges the use of concepts and wording (with permission) of the NSW Peak Purchasing Council.
Revised: Feb 11 Endorsed by Peak PESC: Mar 11
PART C – CLINICAL PRODUCT SPECIALIST REVIEW FORM

Trial No. _________________________________

To be completed by Biomedical or Engineering/Infection Control/OS&H / Manual Handling Specialists

---

- Is there an “Acceptance Test” done by supplier? □ Yes □ No
  - Is the supplier provided “Acceptance” Test acceptable? □ Yes □ No
  - Is the documentation acceptable? □ Yes □ No
  - Is the date of testing acceptable? □ Yes □ No

If answered NO to any of the above, Biomedical testing is required.

- Has acceptance testing been carried out? □ Yes □ No
- Document attached? □ Yes □ No

Comments & recommendations

---

Maintenance issues eg can preventative maintenance be carried out in-house? Special tool(s) required?

---

Known problems or hazards with this equipment

---

Comment on expected clinical effectiveness

---

DOCUMENTATION EVALUATION REVIEW [Refer Part B Clinical Product Presentation Form]

- Availability of service manual □ Paper □ CD □ Internet site
- Technical manual including drawings mechanical & electrical □ Acceptable □ Not acceptable
- Full service information □ Acceptable □ Not acceptable
- Description of circuits □ Acceptable □ Not acceptable
- Spare parts list and description □ Acceptable □ Not acceptable
- Operators manual □ Acceptable □ Not acceptable
- All necessary clinical information required to evaluate □ Acceptable □ Not acceptable
- Manufacturers details phone/fax etc □ Acceptable □ Not acceptable
- Technical specifications list, including S.W.L. for beds and hoists □ Acceptable □ Not acceptable

Comments & recommendations

---

Market assessment – should other suppliers be assessed? □ Yes □ No

Evaluating Officer – Biomedical Engineering □ or Engineering □

Name ____________________________ Position ____________________________

Signature ____________________________ Date ____/ ____/ ______
**LASER/RADIATION SAFETY REVIEW**

Is review required by the Laser Safety Officer/Radiation Safety Officer?   □ Yes  □ No  □ N/A

**Evaluating Officer – Laser/Radiation Safety**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature ___________________________________    Date ____/ ____/ ______

**INFECTION CONTROL REVIEW**

[Refer Part B Clinical Product Presentation Form]

<table>
<thead>
<tr>
<th>Is the equipment easy to clean?</th>
<th>□ Yes  □ No  □ N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the item require disinfection or sterilisation?</td>
<td>□ Yes  □ No  □ N/A</td>
</tr>
<tr>
<td>Manufacturer’s instructions for cleaning, disinfection/sterilisation acceptable?</td>
<td>□ Yes  □ No  □ N/A</td>
</tr>
<tr>
<td>If no, Infection control cleaning recommendations made?</td>
<td>□ Yes  □ No  □ N/A</td>
</tr>
</tbody>
</table>

Specify:

Cleaning protocol to be developed? □ Yes  □ No  □ N/A

Implementation of cleaning protocol to be undertaken by unit requesting purchase? □ Yes  □ No  □ N/A

**Evaluating Officer – Infection Control**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature ___________________________________    Date ____/ ____/ ______

**OCCUPATIONAL SAFETY & HEALTH REVIEW**

[Refer Part B Clinical Product Presentation Form]

<table>
<thead>
<tr>
<th>Contain hazardous substances?</th>
<th>□ Yes  □ No  □ N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual Handling issues?</td>
<td>□ Yes  □ No  □ N/A</td>
</tr>
</tbody>
</table>

Comments & recommendations:

Health acknowledges the use of concepts and wording (with permission) of the NSW Peak Purchasing Council.
Revised: Feb 11 Endorsed by Peak PESC: Mar 11
Evaluating Officer – Occupational Safety & Health

Name  Position

Signature _________________________________________ _______   Date  ____/ ____/ ______

MANUAL HANDLING REVIEW
[Refer Clinical Equipment/Consumables Presentation Document]

Evaluating Officer – Manual Handling

Name  Position

Signature _________________________________________ _______   Date  ____/ ____/ ______

Please forward completed forms to the following:
South Metropolitan Area Health Service (excluding RPH)  FHHS PESC  fh.pesc@health.wa.gov.au
RPH  RPH PESC  rph.pesc@health.wa.gov.au
SCGH  SCGH PESC  scgh.pesc@health.wa.gov.au
KEMH  KEMH PESC  kemh.pesc@health.wa.gov.au
PMH  PMH PESC  PMH.PESCmembers@health.wa.gov.au

OR the administering Hospital PESC if not covered by the above.

Health acknowledges the use of concepts and wording (with permission) of the NSW Peak Purchasing Council.
Revised: Feb 11 Endorsed by Peak PESC: Mar 11