### Name of device / project:

<table>
<thead>
<tr>
<th>Name of device / project:</th>
<th></th>
</tr>
</thead>
</table>

### 1. Aims and Benefits

- **What is the purpose of the device / equipment?**
- **What are the benefits?**

### 2. Effectiveness and Outcomes

- **How will it improve patient care?**
- **What evidence is there that the device / equipment is effective?**

### 3. Clinical Requirements

- **Does the device supplement/enhance existing clinical practices?**
- **Does it introduce new procedures and techniques?**
  - **If so are they approved and safe?**
- **Is the equipment a replacement of equipment already in use by the service or a request for equipment that has never been used by the service before (i.e. a service development)?**
- **Approximately how many patients will the equipment be used for annually?**

### 4. Risks

- **What are the risks to the Trust of not doing it?**
- **Is this issue on the Trust risk register?**

### 5. Safety

- **Have you obtained a pre purchase questionnaire for this equipment/device?** – Please liaise with the purchasing department
- **Have you consulted telematic and biomedical services (Althea, prev TBS GB) about this equipment/device?** – Please liaise with the purchasing department
- **Can the equipment be decontaminated in line with Trust policies?** – Please liaise with infection control

### 6. Resources

- **Are additional staff required to operate or carry out this service?**
- **Is additional staff training required?**
- **Could the use of the equipment reduce clinical time and or increase service efficiencies?**
- **Life expectancy of the device / equipment**
- **How long will the manufacturer maintain the equipment and are spare parts readily available?**
- **How will the equipment be disposed of and will there be additional costs associated with this?**
- **What are the costs of maintaining the equipment?**

### 7. Finance

- **Indicative one off costs (including accessories)**
- **Indicative ongoing costs (including costs of consumables)**
- **Indicative savings**
- **Potential funding source**
Guidelines on how to complete the bid request for medical devices or equipment

Definition of medical devices and equipment

Medical devices

The European Commission defines medical devices as:

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means.

Examples of medical devices could include electrocardiographs or electronic blood pressure monitoring equipment.

Medical equipment

The World Health Organisation defines medical equipment as:

Equipment that is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

Examples of medical equipment could include X ray machines, microscopes, operating tables, refrigerators and defibrillators.

Completing the bid template

Please complete all sections of the bid form before submission. An example of a completed bid form is outlined below to assist you in completing the form.

Pre Purchase Questionnaires (PPQ) and information about how to contact telematic and biomedical services can be found by contacting the Purchasing Department with the details of the equipment proposed. They will then obtain a PPQ from the supplier & ensure this is checked with the Trust’s Medical Devices Maintenance Contractor (Althea, previously
TBSGB Ltd). A copy of the PPQ & acceptance will then be returned to you so you can attach this to your bid. The Purchasing Department can be contacted at:

**Submitting a bid request**

Bid request forms should be e-mailed to [Carin.Day@nhs.net](mailto:Carin.Day@nhs.net). The bid will be considered by the capital accountant and procurement, then by the Medical Equipment Sub Group, who will consider the clinical need for the bid. If the group approves the bid on clinical grounds, the bid will progress to the Capital Group, who will agree if the bid will be approved on financial grounds. Please note the Medical Equipment Sub Group meets quarterly.

**Service developments**

Please note that if the bid is for new equipment that has not been used by the service before (rather than for replacement of existing equipment in use); this suggests the bid is a service development. All service development bids should be submitted to Senior Management Team as an operational business case and included within existing budget (rather than being submitted to the Medical Equipment Group).

**Example of a completed bid form for medical devices / equipment:**

<table>
<thead>
<tr>
<th>Name of device / project:</th>
<th>10 replacement defibrillators for adult inpatient mental health services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Aims and Benefits</strong></td>
<td>This equipment enables inpatient mental health teams to be able to provide defibrillation to those experiencing cardiac arrest while in inpatient services</td>
</tr>
<tr>
<td>What is the purpose of the device / equipment?</td>
<td>• There are currently approximately 14 cardiac arrests per year in SEPT inpatient mental health facilities where defibrillators are used</td>
</tr>
<tr>
<td>What are the benefits?</td>
<td>• It is proposed that the 10 defibrillators in use by the inpatient mental health teams be replaced by 10 new defibrillators. The existing defibrillators will have reached the end of their useful life (7 years old) and their contract for maintenance will expire at the end of January 2016</td>
</tr>
<tr>
<td></td>
<td>• The benefits is to enable continuation of the current service provision, whereby inpatients experiencing cardiac arrest while in inpatient mental health services can be treated with a defibrillator (where appropriate)</td>
</tr>
<tr>
<td></td>
<td>• This is of benefit to patients as defibrillation is an effective treatment for those experiencing cardiac arrest and improves survival outcomes (see information on effectiveness below)</td>
</tr>
</tbody>
</table>
### 2. Effectiveness and Outcomes

**How will it improve patient care?**
- The proposed defibrillators capture additional diagnostic information that is not currently captured by the existing equipment. This additional information will be used by clinicians to help improve patient care.
- There would also be improvements for staff as the new defibrillators are lighter to carry than the previous model.

**What evidence is there that the device / equipment is effective?**
- NICE guidance on cardiac arrest (advanced adult life support) recommends use of defibrillators in stated circumstances for those experiencing cardiac arrest.
- One review has concluded that early defibrillation is the most important intervention associated with survival following cardiac arrest.

### 3. Clinical Requirements

**Does the device supplement/ enhance existing clinical practises?**
- The defibrillators are replacements and therefore are to enable continuation of existing services. The inclusion of additional diagnostic information on the new defibrillators will help to enhance existing clinical practice (by providing additional information).

**Does it introduce new procedures and techniques? If so are they approved and safe?**
- This equipment does not introduce new procedures. Defibrillation is one of the methods that may be appropriate in managing cardiac arrest, as stated in NICE guidelines on cardiac arrest (advanced adult life support).

**Is the equipment a replacement of equipment already in use by the service or a request for equipment that has never been used by the service before (i.e. a service development)?**
- A replacement existing defibrillators that are reaching the end of their maintenance period.

**Approximately how many patients will the equipment be used for annually?**
- Approximately 5 patients per year may have an event where use of a defibrillator is appropriate.

### 4. Risks

**What are the risks to the Trust of not doing it?**
- The current defibrillators will no longer be maintained after January 2016. This could result in equipment becoming broken or unusable. There are reputational risks to the Trust if usable defibrillation equipment is not available in Trust inpatient services.

**Is this issue on the Trust risk register?**
- Yes

### 5. Safety

**Have you obtained a pre purchase questionnaire (PPQ) for this equipment/device? – Please liaise with the purchasing department**
- Yes – I have attached this with the bid.
### 6. Resources

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you consulted telematic and biomedical services (Althea, prev TBS GB) about this equipment/device? – Please liaise with the purchasing department</td>
<td>Yes - I have attached a record of these emails with the bid.</td>
</tr>
<tr>
<td>Can the equipment be decontaminated in line with Trust policies? – Please liaise with the infection control team</td>
<td>Yes</td>
</tr>
<tr>
<td>Are additional staff required to operate or carry out this service?</td>
<td>No, as this is a replacement of current equipment.</td>
</tr>
<tr>
<td>Is additional staff training required?</td>
<td>A one off two hour training session is delivered by the provider to relevant staff on purchase of the equipment.</td>
</tr>
<tr>
<td>Could the use of the equipment reduce clinical time and or increase service efficiencies?</td>
<td>Possibly as the equipment is lighter than previous models (quicker to be transported to the location) and additional diagnostic information available may reduce time taken by clinicians to collect this information.</td>
</tr>
<tr>
<td>Life expectancy of the device/equipment</td>
<td>10 years</td>
</tr>
<tr>
<td>How long will the manufacturer maintain the equipment and are spare parts readily available?</td>
<td>The equipment is maintained for 7 years, during which time spare parts are provided if required.</td>
</tr>
<tr>
<td>How will the equipment be disposed of and will there be additional costs associated with this?</td>
<td>Disposal through the manufacturer at no additional cost.</td>
</tr>
<tr>
<td>What are the costs of maintaining the equipment?</td>
<td>There are no additional maintenance costs other than those stated above.</td>
</tr>
</tbody>
</table>

### 7. Finance

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicative one off costs (including accessories)</td>
<td>£4,000 per defibrillator (including VAT), total for 10 defibrillators of £40,000</td>
</tr>
</tbody>
</table>
| Indicative ongoing costs (including costs of consumables)                  | • The above quote includes maintenance for 8 years which includes all consumables outlined below:  
  • Replacement of batteries every 4 years during the maintenance period  
  • 5 replacement defibrillation pads per defibrillator (additional pads required will need to be purchased at a cost of £55 per pair including VAT)  
  • Carry case for each defibrillator |
| Indicative savings                                                          | None identified                                                       |
| Potential funding source                                                    | To be identified by the capital projects programme group             |

### 8. Sponsors

<table>
<thead>
<tr>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bid submitted by and date:</td>
<td>XX</td>
</tr>
<tr>
<td>Executive sponsor:</td>
<td>XX</td>
</tr>
</tbody>
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1 Improving Survival From Sudden Cardiac Arrest, The Role of the Automated External Defibrillator, John P. Marenco, MD; Paul J. Wang, MD; Mark S. Link, MD; Munther K. Homoud, MD; N. A. Mark Estes III, MD, JAMA. 2001;285(9):1193-1200. doi:10.1001/jama.285.9.1193.