

Intraoperative Gamma Probe Procurement Tender Specification Questionnaire

Report October
2004



Science & Technology
Facilities Council

(Version 1)

**Prepared by the UK Gamma Probe Working Group
(see appendix 1 for authorship)**

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General Introduction

The aim of this document is to provide a standardised questionnaire as part of the gamma probe procurement process. It can be used to enable matching of the system features and allows the user requirements to be objectively assessed. It will also help those purchasers who have had no experience in the purchase of gamma probes.

See also the document “Guidelines on User Evaluation and Selection of Intraoperative Gamma Probes” (UK Probe Working Group).

1. Abbreviations

BS	British Standard
FWHM	Full width at half maximum
MBq	MegaBecquerel

2. Notes for responders:

For a gamma probe to be considered for purchase, attention must be given to full completion of each of the following sections.

The right hand column in each tabular section contains boxes for the supplier’s answers to each question. For many questions the response may be a simply Yes (Y) or No (N). If you wish to refer the prospective purchaser to supplementary information, an 'S' response should be used in addition to 'Y' or 'N'. Such supplementary information should keep to the numbering system in this document and be attached at the end of the document. If none of the responses are appropriate, please write 'NA'.

Numerical values should be given where specifically indicated

If a feature is available, but is an extra cost option, the response must include the term 'ECO' to make this clear.

Answers should only be given against items or functions which are currently available with the system. Any features which are in development should be clearly marked as such, with an estimate of when the features will be available.

Adequate supporting information should be included where appropriate. Such supporting information should be cross-referenced to the section in the response.

Statement of need

1. Overall statement of need: The purchaser requires [1,2,3...] Intra-operative Gamma probes, suitable for surgical use and fully able to meet the clinical need as specified here. If any stated requirement in this document is unclear it is the responsibility of the supplier to seek further information in order to complete this document. The system(s) must be reliable over a lifetime of at least 5 years, easy to operate, fully supported for maintenance and repair to cope with the pattern of use.

2. The main user is the..... department at:

..... hospital working in conjunction with
....., other users
are.....

3. The person responsible for preparing the technical specification, and to whom any technical queries should be addressed is:
.....
4. The gamma probe is primarily for *sentinel node/other
 - 4.1 For sentinel node work the main carcinoma is *melanoma/breast/other
 - a. The main radionuclide will be ^{99m}Tc / other, and the system must also be able to be used with $^{111}\text{-In}$ / $^{131}\text{-I}$ / $^{18}\text{-F}$
5. The routine injected activity (MBq) for the main radionuclide is.....
6. The surgery will normally be performed *same day/next day (as the injection)
7. The expected work load is:

Sentinel node: Breast	<i>n1</i>
Melanoma	<i>n2</i>
Parathyroid	<i>n3</i>
Other:	<i>n4</i>
Other:	<i>n5</i>
8. Shortlist to be prepared by: *date*
9. Date for purchase *date*

*delete as appropriate, if other specify details

**SUPPLIER OR
MANUFACTURER'S
RESPONSE**

Please respond to each numbered question or specification. Your replies must use the same headings and numbering as the question or specification.

Variation from the required specification in each section may be considered, provided that a full explanation of the variation is submitted at the time of the bid.

Supplier's Details

Company Name	
Company Address:	
Company Telephone number:	
Company Contact person:	
Department of Health GMP No.	

If the supplier is not the manufacturer, please complete the following section:

Manufacturers name:	
Manufacturers address:	
List any relevant company standards/ accreditations:	
For how long have you been supplying equipment from this manufacturer?	

Compliance with UK Standards

Failure to comply with any of section 4 shall be a breach of contract.

1. The equipment shall comply with all relevant standards. The supplier is asked to provide a list of all directives and standards complied with, and to provide copies of all compliance certificates. These are expected to include the following standards:
 - 1.1 IEC 60601-1 requirements for the safety of electro-medical equipment, and its later amendments.
 - 1.2 Ionising Radiation Regulations (1999) and the Approved Code of Practice for the Protection of Persons against Ionising Radiation Arising from any work activity, and the associated code of practice and guidelines.
 - 1.3 The Ionising Radiation (Medical Exposures) Regulations 2000 (IRMER)
2. The equipment supplied shall be compatible with the British electrical distribution system.

Gamma Probes

3. The equipment shall be CE marked appropriately.

1. Model Information

1.1	Model name/number:	
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2. Performance

NOTE: all performance measurements should follow NEMA document NU-3 (2004). If measurements follow another protocol then this must be noted and the full measurement protocol must be included with this response.

For each probe available with the system specify:

2.1	The detector type [eg caesium iodide, cadmium telluride etc] and dimensions (eg “5 mm diameter crystal, 4 mm thick”)	
2.2	The probe handle shape [straight or angled]	
2.3	The probe outer diameter at the tip – both with and without any removable collimator(s) as supplied	
2.4	The probe length – both with and without any removable collimator(s) as supplied	
2.5	The probe weight, both with and without any removable collimation as supplied	
2.6	Sensitivity (counts/s/MBq at a distance of 30 mm in water from a small source to the probe tip) <ul style="list-style-type: none"> a. ^{99m}Tc b. main isotope quoted in section 2.5 (if different from ^{99m}Tc) 	
2.7	Spatial resolution as FWHM of the point spread function (point source at 30 mm in water from the probe tip) for.... <ul style="list-style-type: none"> a. ^{99m}Tc b. the main isotope quoted in section 2.5 (if different from ^{99m}Tc) 	

2.8	Energy resolution of the system expressed as the FWHM of the photopeak for..... a. ^{99m}Tc b. for main isotope quoted in section 2.5 (if different from ^{99m}Tc)	
2.9	20% loss count rate capability (incident count rate at which 20% of counts are lost)	

2.10	The breakthrough through the side of the probe (Should be < 0.1% of the counting sensitivity for a source in front of the probe)	
2.11	Specify the type of collimation	
2.12	Is the collimation a. Removable? b. Adjustable?	
2.13	Can the probe be sterilised?	
2.14	If the probe is sterilisable, state the sterilisation technique(eg ethylene oxide)	
2.15	Are covering sheaths available - specify cost per unit, and supplier?	
2.16	Is the probe robust (state the height from which the probe may be dropped onto a hard surface without damage)?	
2.17	How many probes and collimators are included in the purchase price (a separate schedule of the equipment offered must be attached)?	
2.18	Specify cost of additional probes, cables, collimators and all other parts or supplies required for routine use (a separate schedule of all such items and costs must be attached)	

3. Quality Control

3.1	Is there a recommended quality control procedure?	
3.2	If yes, what source is needed (state radionuclide and activity range)?	

3.3	Is the source supplied with the probe?	
3.4	If yes, does it comply with the criteria required for exemption from registration under the UK Radioactive Substances Act?	
3.5	Give details of the QC procedure as an attachment	

Data display and settings

1.	Specify the dimensions of the display unit	
2.	Specify the weight of the display unit (kg)	
3.	Specify the type of display (LCD, LED, analogue swing needle)	
4.	If the display is LCD, is this backlit? It must be clearly visible in bright theatre lighting.	
5.	List the standard isotope settings	
6.	Specify the standard energy window (lower keV and upper keV) a. 99mTc b. Any other preset radionuclides	
7.	Can the energy window be set by the operator (state lower to upper range in keV)?	
8.	What counting modes are available? a. Timed (state duration available) b. Continuous (state time constant, and all time constants available for user selection)	
9.	Does the system auto-range?	
10.	Can the auto range be switched off?	
11.	Does the system give an audible signal?	
12.	Does the system auto-range on the audible signal?	

13.	Is there a choice of type of audible signal a. variable frequency proportional to count b. 'clicks' proportional to count rate	
14.	Is there a threshold setting below which no audible signal is given?	
15.	If there is a threshold setting, describe its operation	
16.	Is there a 'warm-up time' at start-up, before which the system cannot be used? If so, how long in duration is this, and can it be overridden?	
17.	Is there a "sleep mode" when no counts are detected	
18.	If yes how long before the sleep mode comes into operation	
19.	Is anything displayed along with the count/count rate?	
20.	If yes what else is displayed?	
21.	Can the system be connected to an external computer?	
22.	If the system can be connected to an external computer running Windows, state the connection protocol (eg serial USB connector) and state what data can be downloaded? What software is required for the PC?	

General

1. Casing

1.1.	Is a robust carrying case supplied?	
1.2.	What are the dimensions of the case	
1.3.	What is the weight of the case when fully loaded with the probe?	

2. Accessories

2.1.	Is there a remote a. foot switch ? b. external remote display repeater capability ?	
2.2.	List all of the available accessories and their cost ?	

3. Power

3.1.	Is the system powered by a. mains ? b. battery (specify Voltage)?	
3.2.	If battery powered, is the battery rechargeable?	
3.3.	If battery powered, specify the operating time for a single charge (when detecting counts and giving an audible signal)	
3.4.	How long does it take for a completed recharge?	
3.5.	What is the expected lifetime of the battery assuming recharged weekly?	
3.6.	Is the battery charger part of the probe unit?	
3.7.	If yes, is there an automatic switch off when the battery charger is connected?	
3.8.	If the battery charger is separate, is it included in the cost?	
3.9.	How many batteries are supplied with the unit?	
3.10.	Is there an audible signal for low battery?	
3.11.	If yes, how much life is left in the battery when it starts?	

4. Maintenance and Support

4.1.	Is on-site service and repair available?	
4.2.	How many trained engineers are there in the UK?	

4.3.	State the delay between reporting a serious fault and an engineer or replacement system arriving on site [next day repair/replacement service required]	
4.4.	If service is off site, is there a loan system during the repair period?	
4.5.	Is the loan system free of charge at the time of the loan?	
4.6.	Where is repair carried out?	
4.7.	Is carriage of the system for repair arranged by the service organisation?	
4.8.	Specify the service cost (call hour rate, hourly rate etc)	
4.9.	Specify the cost of replacement of major parts (probes, cables, chargers, battery)	

5. Quality Management

5.1.	Is your company accredited under BS EN ISO 9000 (formerly BS 5750)?	
5.2.	If yes, give certificate number and date achieved	

6. Supporting documentation

Does the Manual include...

6.1.	A simple one page summary/flowchart for simple 'default' setup.	
6.2.	A basic description of system operation?	
6.3.	Comprehensive block and circuit diagrams?	
6.4.	Fault-finding procedures?	
6.5.	Preventative maintenance procedures and schedules?	
6.6.	List of spares, with part numbers?	
6.7.	Calibration and adjustment procedures?	

7. Supplementary questions from the users:

Appendix 1: The UK Gamma Probe Working Group

The UK Gamma Probe Working Group is a group of Medical Physicists established in April 2004 to provide support to the application of Gamma Probe technology in Nuclear Medicine and Surgery.

The group is working with the knowledge and the approval of the British Nuclear Medicine Society (BNMS) and the Radionuclide Special Interest Group of the Institute of Physics and Engineering in Medicine (IPEM), but is not an official group of either body.

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