

User Evaluation and Selection of Interoperative Gamma Probes

Report October
2004



Prepared by the UK Gamma Probe Working Group

Introduction

This is intended as a guide to users who are purchasing intraoperative gamma probe systems, aimed mainly at institutions having little or no previous experience in the evaluation, purchase and use of such systems. Publication of this document by the UK Gamma Probe Group has been prompted by the planned national introduction of the sentinel node biopsy procedure into the management of Breast Cancer within the UK (1). This document is intended to provide some assistance in this process, outlining key criteria against which the user may evaluate systems marketed for this application and make an appropriate selection from their findings. A technical specification questionnaire document is also available for use in the purchase process (2). The authorship of these documents is outlined in Appendix 1.

Criteria for User Selection and Evaluation

For an intraoperative gamma probe system to be suitable for purpose it must meet a number of disparate requirements. Those considered by this document to be of critical importance fall into the following categories and are addressed in turn within this section. In summary, the probe system must :

- Possess good physical performance as a radiation detector.
- Be appropriately and ergonomically designed for intra-operative use.
- Be straightforward to use with a clear, well-designed control panel and easily interpretable display and audio signal.
- Meet all relevant electro-medical safety standards.
- Have CE certification and be well constructed and reliable in use.
- Have adequate applications and service support provided by the manufacturer or agent.
- Have a reasonable whole-life purchase cost.

System Specifications

A companion standard specification questionnaire document prepared by the UK Gamma Probe Group (2) addresses in extensive detail the design and performance specifications for commercially available probe systems, and

the user is strongly advised to consult this data for each probe system under consideration, as completed by the manufacturer.

A further document published by the Group (3) defines an evaluation protocol comprising a set of functional measurements devised to permit the performance of a probe system to be objectively characterised. This is itself based upon the protocol devised by the US-based manufacturer's standards body, NEMA (4). For each probe system under consideration, the user is actively encouraged either to conduct this set of performance measurements according to protocol within their own institution, or to access a set of data obtained by the manufacturer, the UK Gamma Probe Group or other experienced users.

The user should also inform their choice of system more fully by supplementing this assessment of the two documents above with direct experience gained in the use of the probe systems under consideration. If at all possible, the user should aim to become familiar with the performance of each system by conducting practice trials using focal ^{99m}Tc or ^{57}Co sources of the correct radioactivity within a representative scattering medium (e.g. water, perspex, gel or fat) and a suitable source-probe geometry. The user should ideally gain familiarity with all major settings and configurations offered by the control unit, and after identifying and selecting their preferred configuration they should assess critically the usability and performance of the probe in this setup.

Experience of using the probe system in the operating theatre is also invaluable.

Key Design Features and Ergonomic Factors

The total probe system must be designed and constructed to be suitable for intraoperative use. The detector itself should be designed for ease of manipulation in a surgical environment, and constructed to be suitable for sterilisation if this is planned. Optimal, successful use of the probe system is aided by good ergonomics, and the importance of the following elements of good probe design should be considered in respect of your application and personal preferences.

Probe design falls into a fundamental choice between a straight-bodied or angled probe; straight-bodied probes having a direction of response aligned parallel to the body of the probe itself, whereas the axis of response for angled devices is aligned parallel to the orientation of the angled front section only. The direction of response is thus easier to identify and track with a straight probe design, and this feature assists the user in adopting the 'line of sight' strategy to incrementally access the radioactive sentinel node through the surgical opening. When implementing this technique, the user identifies the orientation of the probe's axis of response at which the count-rate response to the radioactive sentinel node is maximal, and uses this as the guide by which to cut deeper along the continuation of this axis, checking with the probe frequently to ensure that, by repeating this procedure, the site of activity is progressively approached. Many users do, however, find an angled probe easier to manipulate within a small incision and therefore ergonomically more suited for conducting these progressive, systematic surveys of the near field once the incision has been made. In addition to its basic design, the weight of the probe, its shape and external dimensions, and the location of its centre of gravity all affect the ease of its handling. The user should aim to evaluate the handling characteristics of a number of probes in identifying their personal preference.

The probe detector should be constructed to offer a high level of radiation shielding within the side wall of the front section. This provides protection against 'shine through' or the penetration of gamma rays arising from sources of radioactivity lying close to the side face of the probe, principally the radiopharmaceutical activity retained at the injection site(s). The thickness of lead or tungsten actually incorporated within the probe itself should be at least sufficient to offer a factor of 1000 shielding against ^{99m}Tc , and this can be achieved by a 3mm thickness of these dense metals. The facility to add extra, removable tungsten side-shielding may however be helpful for those incidences when the probe must be used adjacent to very high activity sources.

Working against a reduction in overall probe dimensions, the inherent sensitivity of the probe is primarily dependent upon the diameter of the detection crystal set into the front face of the assembly and lying within the incorporated side-shielding. Thus it is necessary for the manufacturer to strike a fundamental compromise between physical size (i.e. compactness)

and this cornerstone of detector performance. It is essential that intraoperative radiation detectors possess acceptable detector sensitivity for the clinical application planned, and for probes used for the sentinel node technique this necessitates that they are sensitive enough to detect the weakest sentinel lymph nodes encountered, both transcutaneously when performing a systematic survey of the lymphatic basin(s) under investigation to identify the sentinel node(s) lying within, and then after node detection and initial incision, within the surgical cavity, as this is progressively exposed. As implied, the first of these two tasks is the most demanding test of performance, requiring the sensitivity of the detector be sufficient to identify a small, sometimes weak focal source of radioactivity whose emitted gamma rays may be attenuated by up to 5cm soft tissue. As a guide, sentinel nodes typically take up between 0.1% and 3% of the injected radiolabelled colloid and retain this for at least 24 hrs following administration. (5).

More challengingly, extraneous adjacent sources of higher radioactivity will hamper the accurate localisation of the more weakly radioactive sentinel node under investigation, such as encountered when a sentinel node lies close to the site of the tracer injection. Good probe collimation is required to allow the user to be able to discriminate between radioactivity originating from within the sentinel node and that arising from these neighbouring sites of high activity concentration. Use of a collimator designed as a detachable tungsten collar to be fitted around the front-face of the probe allows the user to significantly restrict the probe's spatial field of response to radioactivity sited within a narrow field centred along the forward-facing direction only, thereby increasing the lateral discrimination, or resolution, of the probe. This is however achieved at the inevitable cost of a notable loss in sensitivity, and so it is preferable that the major component of this be supplied to the probe in the form of a detachable collimator of suitable construction. By fitting this radiation shielding accompaniment to the probe only as and when it is required and dispensing with it otherwise, optimum performance is obtained for the range of situations encountered clinically. This retains the probe inherent compactness, maximizes its intrinsic sensitivity when most required and thereby improves ease of use. The practical means of removing or adding such additional collimation to a sheathed probe during the operation needs to be investigated to ensure that this is feasible. Some operators achieve this by leaving the plastic sheath relatively loose and with the detachable

collimator free in this sheath space until it is needed, when it is then manipulated into place within the sheath. If the uncollimated probe scan is only carried out with the uncollimated probe before the field is sterile, then these difficulties do not arise. Probes with significant collimation permanently incorporated into the construction of the detector head will suffer from a fixed, lower detector sensitivity and will lose flexibility in use as a result.

When extraneous adjacent sources of higher radioactivity are present, a combination of probe collimation, together with the adoption by the user of a 'line of approach' that tries at all times to place these high level sources away from the collimated response field of the probe will enhance detectability of the sentinel node.

A well-designed and easily operated control unit will greatly assist the user. The unit must have a clear visual count/count-rate display, and one that does not suffer indistinct brightness and/or reflected glare when subjected to typical operating theatre lighting conditions. The size of display must also be sufficient to allow its numerical display to be easily read at a distance of 2-3 metres. Although some users may find the instantaneous count-rate data presented by an analogue needle display easier to assimilate in real-time when the probe is being used to survey the operative field, most users generally find the data presented by a numerical count display at least adequately informative. A numerical display also allows the probe to be used to collect 'timed counts' i.e. to acquire count-rate information at a fixed location of interest or significance for a specified, user-selected time period (typically five or ten seconds) to obtain a statistically more reliable indication of the local count-rate. This is particularly useful when count-rates are low and yet must be interpreted reliably, and is also used for other clinical applications when the ratio of count-rates recorded over normal and suspicious tissue regions require to be logged and formally compared.

It is absolutely essential that the probe system also has a clear audio signal to provide the user with an indication of the instantaneous detected count-rate. Two main signal types exist; the variable frequency output, where the frequency of a continuous audio signal is made to be directly proportional to the count-rate detected, and the variable 'chirp' signal, where the repetition rate of a short, staccato-like pulsed signal is made to vary in the frequency of its repetition according to the count-rate. Feedback obtained from this varying audio signal allows the surgeon to perform an uninterrupted survey of the

region of interest (e.g. lymph node basin) without the requirement to follow the visual cue of a varying visual count-rate display. It is vital then that the user finds the audio signal easily interpretable. Most users find the variable frequency signal easier to assimilate, although the potential user should always establish their informed personal preference. The tone quality of the signal itself, its working frequency range and the full range of volume settings are also all critical to optimal use through ease of signal interpretation.

In clinical use the intraoperative probe is required to survey a very wide range of radioactivity levels, resulting in an equally wide range of detected count-rates. This can make the auditory identification of subtle differences in count-rates difficult and so the probe system's signal processing circuitry must subject the raw audio signal to some form of count-rate range control to enhance signal discrimination. This requires that the full range of detected count-rates allocated to the minimum and maximum available frequency or 'chirp-rate' is reset by the circuitry to be allocated to a more restricted count-rate range, chosen either manually by the user, or automatically by the control unit. The use of an auto-ranging facility may be preferred if this is available, where the audio signal frequency or chirp-rate is automatically 're-scaled' by the control unit to accommodate an increasing or decreasing count-rate range when this is encountered. Users however, may find the spontaneously varying re-scaled output signal from this facility more difficult to assimilate than that obtained by sweeping through the full range of manual settings. Manual selection by the user of the most appropriate range setting from within a logical set does unfortunately require in practice that a second staff member not in the sterile field be available to manipulate these controls promptly as required, and such a person may not be readily available to assist all users in this manner. Modification of the probe assembly to incorporate a simple set of probe-mounted controls for ranging, and for initiating timed counts has not, to the authors' knowledge yet been developed to allow the surgeon to take direct control of the device, but some systems include a footswitch to manage at least some of these functions autonomously.

System Operation

The detector probe is fragile and can easily be terminally damaged if it is dropped or hit against a hard surface. A means by which it can be stored safely should be provided with the system (e.g. within a padded bag or box), and the probe should always be secured within this case when not actually in use. Detector probes are expensive to manufacture, typically costing at least £5,000 each to replace. The user should clarify whether the probe itself may be sterilised, either by use of ethylene oxide or another process, and what guidance exists regarding appropriate cleaning protocols for the probe between investigations. The user should also determine whether the manufacturer recommends, or supplies, an appropriate design of sterile drape for intraoperative use should they not wish to use the probe as a sterilised device (the most typical situation). The length of the probe cable is important, in that it must extend sufficiently to allow the detector probe to be manipulated within the sterile field whilst the control unit is placed on a suitable surface (e.g. surgical trolley) in a convenient location on the opposite side of the patient to the surgeon. Systems have been placed on the market with cables of insufficient length to facilitate this.

The choice of a battery-powered probe system, or one powered directly from the 240 V AC mains power supply dictates the need, or otherwise, for the system to be maintained and kept charged ready for use. Battery-powered systems using rechargeable batteries will need to have these fully discharged and recharged periodically to prevent the cells suffering a memory effect; compromising their ability to take a full charge. Systems using non-rechargeable batteries will require the user to maintain stocks of the correct battery specification and both types will require the control unit to be fitted with a suitable low battery warning alarm. This must be designed to activate before the residual battery capacity falls too low to prevent an intraoperative procedure from being successfully completed, and must be easily detectable by the user once triggered. As outlined above, mains-powered systems must also possess a mains power cable of sufficient length to facilitate safe and convenient use in the operating theatre.

Regulatory Compliance

It is a requirement that all medical devices placed onto the market within the EC must comply with the EC Medical Devices Directive 93/42/EEC and must possess CE Certification (the 'CE Mark'). It should also be noted that the above definition also includes those systems placed on loan for evaluation, offered as a gift or in exchange, and loaned by other institutions. As the gamma detecting probe clearly falls under the definition of a medical device, then all systems evaluated should be checked to ensure that they are CE certified.

Electro-Medical Safety Issues

The gamma detecting probe is an intraoperative device, and must be used within the exposed body cavity of the surgical patient. The potential for a direct electrical connection to the heart exists, particularly if the electrical insulation offered by its sterile cover fails. Leakage currents greater than 50 μ A routed directly into the myocardium can induce ventricular fibrillation. All probe systems should pass IEC 60601 (1988) - General Requirements for Safety (Medical Electrical Equipment) and its later additions and amendments (6).

Manufacturer's Sales, Applications and Service Support

It is clearly important to determine the level of support that the manufacturer is able to offer. Support will be required in respect of sales advice at procurement and may also be required for ongoing user applications training. Manufacturers should be able to offer sales support through an agent in the UK. Purchase of systems without the services of a UK agent may require the customer to organise for the shipment and importation of their system independently. The absence of UK-based applications support may also present some difficulties when user support or technical advice is required.

More critically, service support will be required by the customer beyond the newly purchased system's period of warranty, and it is essential to evaluate critically the terms and conditions for the level of service support offered by the manufacturer. Again, manufacturers not able to offer service support through an agent in the UK should be considered adversely. Service support is perhaps most sensibly facilitated through timely access to an exchange system and/or individual detector probes made available by the manufacturer

or their agent. These should be shipped to the user's site within a stated time period following notification of a fault with the user system and such an arrangement has many advantages. This minimises the system's period of unavailability when an intraoperative procedure has already been scheduled and the exchange system can then continue to be used while repair or replacement of the customer's own system is in train. Service cover delivered by an authorised agent within the UK may also act to minimise the downtime suffered by a user's system providing such support is of the standard required to achieve this goal, both in terms of engineer training and expertise and in the ready availability of replacement parts from the manufacturer to the service engineer. Service agreements offering only the return shipment of a user's system to the manufacturer (especially if sited abroad) without an undertaking to repair or offer an exchange system within a stated time period should be considered adversely. As above, the absence of an agent's support within the UK may also require the customer to organise for the shipment and exportation/importation of their faulty system independently, with considerable consequent inconvenience and extra delay. The user should always obtain written confirmation of the time period after purchase for which the manufacturer undertakes to ensure service support and the availability of parts, and should appraise the acceptability of this declared period, which should be viewed as an indication of the actual expected working life for the system purchased.

System Cost

It is always prudent to determine the total operating cost of a system, when considered over the duration of its full expected working life. In identifying this figure, the user should take into account either the cost of a comprehensive service contact spanning the expected lifetime of the unit; or alternatively the unit cost for replacement of the detector probe used, and the level of cost and inconvenience involved in shipping the full system for repair should a fault develop in the main unit. As discussed above, the financial cost and likely duration of any requirement to ship the system abroad for repair is likely to prove especially difficult to accommodate.

Purchasing

It is now a requirement of the DoH Controls Assurance Control Standard 11 (Medical Devices Management) that all devices are procured and maintained in an appropriate manner. Equipment purchased within the NHS requires that the manufacturer complete a PPQ (Pre-Purchase Questionnaire) form issued by PASA (the NHS Purchasing and Supplies Authority). This addresses many of the issues discussed here, and more; particularly consideration of full life financial costing including service support, appropriate evaluation, user training, arrangements for maintenance and confirmation of regulatory compliance. A purchase specification and questionnaire document is available for use (2).

References

1. Clinical Protocol for the Application of the Sentinel Node Technique to Breast Cancer. UK Steering Group for Sentinel Node in Breast Cancer.
2. Intraoperative Gamma Probe Procurement Document – Standard Specification Questionnaire. UK Gamma Probe Working Group. April 2004.
3. Intraoperative Gamma Probe Procurement Document – Performance Evaluation Protocol. UK Gamma Probe Working Group. 2004.
4. NEMA Standards Publication NU 3-2004. Performance Measurements and Quality Control Guidelines for Non-Imaging Intraoperative Gamma Probes. National Electrical Manufacturers Association, Rosslyn, VA 22209, USA (www.nema.org).
5. Waddington WA, Keshtgar MR, Taylor I, Lakhani SR, Short MD, Eil PJ. Radiation safety of the sentinel lymph node technique in breast cancer. *Eur.J.Nucl.Med.* 2000;27(4):377-91.
6. International Electrotechnical Commission. Medical Electrical Equipment - Part I: General Requirements for Safety. IEC 60601-1 (1988-12), 1988. IEC, Geneva.

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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