Protocol

Technical evaluation of X-ray tomographic image-guided radiotherapy devices

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Contents

Introduction

In the UK, over 50% of cancer patients will have radiotherapy as part of their treatment [1]. In delivering radiotherapy it is important to maximise the dose to the tumour, whilst minimising the irradiation of surrounding tissues. Image-guided radiotherapy (IGRT) uses images to improve the accuracy of delivery of radiotherapy to the desired target. It involves the measurement, and subsequent correction of the target anatomy position, at the point of treatment delivery using imaging techniques. This will allow more accurate definition of the treatment volume, and a reduction of the dose to surrounding tissues with an associated reduction in complications and side effects caused by irradiation of normal tissues. It might also allow an increased dose to be delivered to the target tissues thereby increasing local control of the disease.

The term IGRT is ill-defined and may have a variety of meanings in different contexts. Here IGRT refers to the ability to visualise the anatomical target in 3D, to assess changes in position, shape and size of target anatomy relative to that planned, and to target the therapeutic beam accurately.

This technology is being rapidly deployed throughout the world and while there is, as yet, little clinical evidence to demonstrate its effectiveness there is no doubt in the clinical and scientific community that it has great potential to improve radiotherapy delivery for a significant proportion of patients treated in the UK.

IGRT can involve almost any imaging modality, but some form of on-board imaging closely allied to the radiation delivery, is the most common. A common implementation is to have a CT scanner closely integrated with the linear accelerator. For the purposes of this project, these systems have been termed 'X-ray tomographic IGRT systems'.

Scope

This protocol specifies methods for the evaluation of the functionality, accuracy and usability of X-ray tomographic IGRT systems. It is designed to allow comparison of the different systems and to allow individual trusts taking up IGRT to undertake their own local evaluations where necessary. The protocol includes detailed guidance on the technical testing of X-ray tomographic IGRT systems, including IGRT cone-beam systems and integrated CT-IGRT systems.

The protocol provides principles and a framework that are applicable to all approaches to IGRT, including non-CT based imaging systems. A detailed protocol for the technical evaluation of non-CT based approaches is not provided.

Protocol design

There are no previously published guidelines for the evaluation of IGRT. The protocol described here was developed as part of a multi-centre technical of X-ray tomographic radiotherapy devices sponsored by the Department of Health to support capital investment in IGRT within the NHS. It was developed in consultation with equipment suppliers, users, professional bodies, and recognised experts in the field.

Technical evaluation

The objective of the technical evaluation is to test the IGRT system to demonstrate that it is able to deliver accurate image guidance, and to do so in a standardised way so that comparison between different systems is possible.

Three aspects of performance are assessed:

- image alignment
- image dose
- image quality.

Image alignment

For image guidance, geometrical accuracy of the image is just as important as the ability to see an object in the image. For these systems, geometrical accuracy can be divided into a number of components:

- initial spatial registration of the image data to the treatment delivery system
- spatial integrity of the data within the image volume
- image registration of IGRT image to pre-treatment planning scan
- the correction of any patient misalignment.

The initial spatial registration identifies the position of the image volume with respect to the position of the isocentre of the mega-voltage beam delivery system; often this is in a different plane with a defined offset. Thus this measures the radiation isocentre which is a better representation of the delivered treatment centre and is quicker than measurement of the physical isocentre. For CT based imaging a kV-MV coincidence test has been devised [2]. For an integrated CT-treatment machine the imaging and treatment beams are one and the same and are therefore assumed to be registered.

Once the imaged volume has been registered to the isocentre of the treatment delivery systems it is also necessary to know that all points within an imaged volume are in the correct position relative to each other and that there are no rotations of the volume. The structures in an image quality test phantom enable image scaling, rotation and skew to be measured. While these do not demonstrate spatial integrity of the data over the whole imaged volume, they do at least demonstrate the integrity of a sample of points. Since image reconstruction relies on correct knowledge of the projection data geometry, identification of these few points goes some way to demonstrating the integrity of the whole volume.

Image registration of the IGRT image to the pre-treatment planning scan will be performed manually using visualisation tools in this protocol. Although automatic image registration algorithms are provided on some IGRT systems and have the potential to reduce time spent on image registration and reduce intra-observer variability, the performance of these is not easily measured and is the subject of current research [3]. It is not therefore within the scope of this protocol to evaluate the performance of the automatic image registration algorithms. In any case, it is good practice that automatic image registration is evaluated by an operator and adjusted manually where necessary.

To demonstrate the ability to measure and correct for the misalignment of a patient, an 'image-shift-verify' test has been employed using a geometric phantom. Although easy to implement, the results of such a test are likely to under-estimate the image registration component of error as the geometric shapes are easily imaged and unambiguous. However, the aim of this test is to demonstrate that the overall accuracy of the image guided system meets a minimum requirement.

The ability to correct the patient position is usually restricted to three orthogonal axes of translation (one axis of rotation for some systems) and these are evaluated. However, it is acknowledged that this test does not demonstrate that the treatment dose is delivered to the correct target. The test only verifies corrections performed by a translation or rotation shift of the phantom using the patient support system and does not verify corrections made by adjusting treatment delivery parameters.

Image dose
The X-ray dose produced by the imaging equipment, which affects normal tissue as well as tumour, is an important parameter which affects the usability of these systems, as in some circumstances, a high image dose may prohibit the repeated use of such systems for daily online image guidance.

Image quality
As an indicator of a systems ability to image soft tissue, the image quality must be sufficiently good to resolve contrast between muscle and fat. It is accepted that the

inter-dependence of contrast, resolution and dose is a complex relationship which limits the size of an object that can be seen at the same level of contrast. This is further complicated by the ability to change the reconstruction filters on some systems which can have large effects on this relationship. It is beyond the scope of this protocol to perform tests that comprehensively characterise the imaging system. Instead, basic image quality measures of contrast, noise and resolution are measured on each system using a selection of clinically relevant imaging protocols. The additional imaging of an anthropomorphic phantom has also been included to enable the image quality of a clinically realistic object to be visually assessed and allow subjective comparison between different systems.

Validation

The protocol has been validated via a multi-centre trial involving ten NHS trusts [4]

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Requirements for participating suppliers

Suppliers are required to:

- confirm that the IGRT systems to be evaluated are appropriately CE marked

- confirm that they have read and accept the provisions of the protocol

- facilitate access to their IGRT systems as necessary

- provide a normal level of training and customer support during the evaluation

- provide operator manuals and relevant supporting documentation, including details of validation studies where relevant

- provide cost information, including the cost of maintenance and service agreements, and alternative purchasing options.

Requirements for participating users

Users are required to:

- confirm that they have read and accept the provisions of the protocol

- facilitate access to their IGRT systems as necessary

- provide a trained operator of the system

- provide a description of physical attributes and functionality of the tomographic IGRT system being evaluated. This will incorporate information from manufacturers and other literature.

Test 1: Registration of image volume to treatment isocentre

This test is intended to check the centre of the imaging volume is registered to the treatment isocentre to within ± 1mm in all directions. This is particularly critical if the system is to be used as guidance for intra-cranial stereotactic treatments or for stereotactic body radiation. A greater tolerance of 2mm may be acceptable for other clinical sites [5].

The test relies on a phantom that can be imaged with both the imaging device and the treatment device. The imaging with the treatment device can be performed using portal imaging using the MV X-rays [6]. If the treatment device cannot provide direct imaging, then the laser alignment cross-hairs should be used. The alignment between the laser alignment beam and the isocentre of the treatment beams will have previously been established in initial equipment calibration and commissioning. For this test the phantom will have to be suitable for imaging with the imaging method, and have suitable markings that enable positioning with laser alignment cross-hairs.

For Cone-beam CT IGRT systems, and integrated CT/treatment systems, the MODUS Penta-Guide Quasar Phantom [2, 7] should be used. This is designed for quality assuring the alignment of kV imaging, both for planar and cone-beam CT with the mega-voltage treatment isocentre. Its design is such that the mega-voltage treatment isocentre is inferred from an anterior-posterior and lateral portal image. Note that this method does not measure the MV treatment beam isocentre sufficiently accurately to determine if the IGRT system is suitable for treatments which require high levels of accuracy and precision, *eg* stereotactic cranial irradiation.

Once the images have been obtained analysis software is used to confirm the alignment.

Materials
1. Modus QUASAR Penta-Guide phantom (Modus Medical Inc, Ontario, Canada) [7]
2. Analysis software [2]. For further details contact the authors.

Method
1. The Pentaguide phantom should be scanned at high resolution on a CT scanner with high resolution and slice thickness of 1mm or less.
2. A simple plan should be created on a treatment planning system using the CT images acquired in 1). A single isocentre should be defined at the geometric centre of the central air-cavity in the images of the Penta-Guide phantom.

3. The above images and plans may be acquired on a remote machine as part of a preparation phase. Prepared data may also be available from the authors of the report.
4. Eight 12cm x 12cm square[1] beams should be created at gantry angles of 0°, 90°, 180° and 270°, two at each gantry angle with opposing head angles (e.g. 90° and 270°). At least 10 cGy should be set for each beam to provide sufficient quality MV images for automated image analysis.
5. The DICOM images, DICOM-RT structure and plan data should be sent to the IGRT system(s) under evaluation.
6. The DICOM images, DICOM-RT structure set and plan data should be imported into the IGRT system(s) under evaluation and the plan data into the corresponding treatment delivery system(s). It may be necessary to import the DICOM data through a record and verify system. If a remote IGRT system does not allow import of the structure and plan data, then 2 & 3 above may need to be performed locally.
7. The phantom should be aligned to the room lasers of the IGRT system ensuring the phantom is level.
8. Eight images at MV energy should be acquired for the beams defined in the treatment plan.
9. The phantom should be scanned using the CBCT system with a standard field of view.
10. Use the analysis software to determine the shift of the centre of the Pentaguide phantom with the MV isocentre.
11. The IGRT system should be used to determine the shift required to align the central air-cavity in the CBCT image of the Pentaguide phantom with the air-cavity in the CT images of the treatment plan.
12. Calculate the vector (lateral, longitudinal and vertical) difference between the phantom centre measured with the MV imaging system with that of the kV-imaging system.

Test 2: Image-shift-verify test

This test is intended to demonstrate the ability of an IGRT system to perform a basic correction of patient misalignment to within ±2 mm.

The basis of the 'image-shift-verify' test is to image a misaligned object, perform an image registration to determine the misalignment, and correct the misalignment. Verification of the correction is achieved by a further image and image registration procedure. The test should preferably be carried out with a geometric phantom with

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[1] A 12cm x 12cm beam is suitable for MLC designs with 4mm, 5mm and 10mm leaf widths such as the Elekta Beam Modulator and Standard MLC as well as the Varian Millenium MLC.

unique orientation. The phantom should be capable of being imaged by both the CT planning system and the imager in the IGRT. For CT based IGRT systems the Pentaguide phantom used in test 1 is suitable.

Materials
1. Modus QUASAR Penta-Guide phantom (Modus Medical Inc, Ontario, Canada) [7].

Method
This test is suitable only for systems with X-ray tomographic imaging.

Preparation
1. The Phantom should be scanned at high resolution on a CT scanner (slice thickness and pixels size less than 1mm).
2. A basic plan should be created on the CT scan with the treatment isocentre at the centre of the phantom.
3. The DICOM images, DICOM-RT structure and plan data should be imported into the IGRT system at the evaluation site DICOM images should be imported into the local treatment planning system.

Testing
4. Using the external lasers on the IGRT system, the phantom should be aligned to a set of offset markers on the surface of the phantom.
5. Acquire an IGRT image using typical clinical image acquisition settings for prostate IGRT.
6. Perform image registration (automatic and/or manual) using all information available and the registration features of the IGRT equipment such as the checkerboard display. Record registration shifts and rotations as displayed by the IGRT system.
7. Correct the phantom position as far as possible by movement of the patient support system, using automated methods if available and manual movement where not available.
8. Observe alignment of external lasers with central cross-hairs on the Pentaguide phantom.
9. Re-image the phantom.
10. Perform image registration again and record registration shifts and rotations.

Test 3: Image dose

For IGRT systems that do not use ionising radiation for the imaging, eg ultrasound, MR, optical, record that no ionising radiation is used. In these cases, the field parameters relevant to the imaging modality should be recorded as follows:

a. Ultrasound: Record the ultrasound frequency and compliance with BS EN 60601-2-37:2008 [8]
b. MRI: Record the Field strength and compliance with BS60601-2-33: 2002+A2:2008 [9].

For X-ray tomographic systems use the protocol described below. This test is intended to measure the dose in air and the dose (to water) in two CTDI phantoms, using a standard method for a range of clinical protocols and scanner settings.

Currently no standards exist for the measurement of concomitant dose associated with IGRT procedures and there is no consensus as to what measurements should be made or what information should be reported. For standard diagnostic CT scanning procedures, a 10cm long CTDI chamber is used, which due to the elongated sensitive volume, enables all scatter contribution to be collected during the imaging of a single slice. Measurements are made both at the centre and at the periphery of a CTDI phantom. Resultant doses are then expressed as a weighted $CTDI_w$ (1/3 x central measurement + 2/3 x peripheral measurement). However, CBCT systems do not have narrow beam geometry thus it is no longer instructive to measure over 10cm. The situation is further complicated by the fact that for larger field of views, there is an offset between the tube and the panel thus resulting in a complex dose profile in the transverse plane. Consequently, in this evaluation protocol, dose should be sampled at a single point within the field using a Farmer chamber and measurements should be acquired at an intermediate position in a CTDI phantom (~7cm from the centre) in addition to the standard central and peripheral positions.

Materials
1. Two computed tomography dose index (CTDI) phantoms (head and body, 16cm and 32cm diameters) (ImPACT, London, UK) [10] to measure image dose in X-ray tomographic-based IGRT systems only.
2. A Farmer chamber with calibration traceable to NPL standard at the appropriate beam quality obtained by measuring the half-value thickness. Local measurements on the beam quality are usually available to calibrate the Farmer chamber, if not then contact the authors of this report for assistance.
3. Calibrated electrometer.

Method (X-ray tomographic systems)

This protocol closely follows the methods employed by Song et al [11]
1. Place the Ion chamber at isocentre ensuring the chamber is suspended over the end of the couch.
2. Measure the dose in air for CBCT scans with fields of view from 25cm to 50cm diameter and between 10 and 25cm in length depending on the equipment, recording the exact image parameters.

3. Place the two 16cm diameter CTDI phantoms (head phantoms) back to back on the couch with the ion chamber positioned longitudinally offset by approximately 1.5cm to ensure that measurements are not affected by the join between the phantoms. Align the phantoms such that their midline coincides with the imaging isocentre.
4. Record the details of the couch type as this may affect the dose measured.
5. Measure the dose at isocentre and at the periphery within the head phantoms for each small FOV clinical CBCT scan recording imaging parameters (kV, mA, ms, collimator setting, and filters used).
6. Place the two 32cm diameter CTDI phantoms back to back on the couch with the ion chamber again offset longitudinally and align the midline with the imaging isocentre. Measure dose at isocentre, periphery and mid-periphery within the body phantoms for each large FOV clinical CBCT scan.

Test 4: Clinical image quality

This test is intended to assess image quality using an anthropomorphic phantom which has realistic soft-tissue organs in order to simulate a clinical scenario as closely as possible.

Materials

1. General IGRT systems: A soft tissue equivalent phantom capable of being imaged both by the imager in the IGRT system.
2. X-ray tomographic imaging: Virtually Human Male Pelvis Phantom, CIRS (Norfolk, Virginia) [12]).

Method

1. Align the anthropomorphic phantom centrally to the isocentre.
2. Acquire an image of the phantom using typical image acquisition settings for prostate IGRT.
3. Display the images in the sagittal, coronal and transverse planes and visually inspect them for the presence of image artefacts.

Test 5: Image quality parameters

This test is intended to measure various indicators of image quality for 3D images measured for a selection of acquisition and reconstruction settings representative of clinical practice on each of the kV-CBCT systems. As there are no standard ways of measuring image quality over the whole volume the method measures image quality at specific points in the FOV.

The test uses a standard image quality phantom, such as those used for the evaluation of diagnostic CT scanners [13]. The image quality indicators measured should include:

a) contrast noise ratio

b) CT number accuracy

c) uniformity

d) axial plane resolution (lp/cm) & modulation transfer function (MTF)

e) spatial integrity.

f) slice sensitivity

g) low contrast visibility.

The method given below is for CT based imaging systems.

Materials
1. Catphan 504 (The Phantom Laboratory, Salem,NY,USA) [14].
2. CATphan annuli
3. Image analysis capability either on the system under test, or a separate Dicom viewer such as Image J [15]. Alternatively, specific image analysis software can be used such as *IQ works* [16].

Method

Preparation
1. Position the phantom to the isocentre of the imaging volume. On the upper surface of the Catphan there are five alignment markers to indicate the position of the centre of each module.
    a. The 2nd marker (CTP528) of the Catphan should be aligned to the isocentre using the room lasers. Care should be taken to ensure the Catphan is aligned laterally and vertically with the room lasers and to avoid any tilt of the phantom.
    b. For very small fields of view and cone angles such as the M2 and L2 collimators on the Elekta Synergy system a separate scan should be performed for the CTP404, CTP528 and CTP486 modules.

Testing
2. Scan the phantom at the required field of view. Acquisitions can be performed in either a clockwise or counter-clockwise direction.
3. If is recommended but not essential that further scans are taken at other fields of view available on the system such as the half fan and full fan on the Varian system. It is also recommended to scan the phantom at a range of available image acquisition exposures to enable image quality parameters to be assessed as a function of dose.
4. If available, scan the phantom with the annuli surrounding the phantom for each of the required image acquisition exposures to enable the variation in image quality parameters with phantom diameter to be assessed.

5. Image quality analysis is based on images exported by the system which are assumed to be the same as those viewed. The reconstruction kernel and filtration should be set to maximise contrast to noise ratio for large objects.

Analysis

1. *Contrast to noise ratio (CNR):* Contrast to noise ratio gives an indication of the ability of a system to distinguish the difference between two materials in the presence of image noise. It is given by the ratio of the difference in mean grey level between two objects (contrast) by the standard deviation of the noise. Using the image analysis function, record the mean and standard deviation of the mean pixel values occurring within square ROIs (approx 7mm x 7mm) placed on each of the 8 contrast inserts of the CTP404 module. CNR ratios should then be calculated for each insert relative to polystyrene using the equation below, where 'mat' indicates the material of the ROI, '$\bar{x}$' is the mean of the pixels in the ROI and 's' is the standard deviation of the pixel values in the ROI.

$$CNR_{mat} = \frac{\left(\bar{x}_{mat} - \bar{x}_{polystyrene} \right)}{\sqrt{\left(s_{mat}^2 + s_{polystyrene}^2 \right)}}$$

2. *Hounsfield number accuracy:* The mean pixel values found during the analysis above are related to the Hounsfield numbers for each of the inserts. To convert the raw image data into actual Hounsfield numbers, it is necessary to apply a scaling factor, 'Rescale slope' and an offset equal to the 'Rescale intercept'. Using the Dicom header files, these factors can be determined and applied to the data thus enabling the Hounsfield numbers to be calculated. Through comparison with the actual values specified by the phantom supplier, the Hounsfield number accuracy can then be determined by taking the difference between the two.

3. *Uniformity:* Uniformity is a measure of a systems ability to produce a uniform image across the field of view of an object with uniform density. To calculate uniformity, an image slice from within the large uniform region of the CTP468 module should be selected. A central ROI of size 10mm x 10mm, should be chosen with four other identical ROIs placed 45 mm above, below, left and right of the central ROI. Calculate the overall uniformity as defined below, where 'max' and 'min' refer to the maximum and minimum pixel value averaged over each ROI respectively, 'Ave(peripheral)' is the average pixel value within all peripheral ROIs and 'Centre' relates to the mean pixel value occurring within all central ROIs.

$$U1 = \frac{(Max - Min)}{(Max + Min)/2} \qquad U2 = \frac{Ave(peripheral) - Centre}{Centre}$$

4. *Axial plane resolution:* The ability of the system to resolve two lines of high contrast placed close together should be quantified by recording the greatest number of line pairs within the CTP528 module that are fully resolved. Additionally if time permits the MTF should be calculated from the image of the two 0.28mm ball bearings (this can be performed using the image analysis software, *IQ works* [16]).

5. *Spatial Integrity:* To assess the systems ability to accurately represent the object imaged without scaling, rotation or distortion, the four rods spaced at the corners of a 50mm square within the CTP404 module of the CATphan should be used. Linearity should also be quantified by recording the side length with the greatest deviation from 50mm and similarly the aspect ratio should be recorded as the maximum ratio of perpendicular side to length.

6. *Slice sensitivity:* Slice sensitivity is a measure of slice width. This should be assessed by measuring the full width at half maximum (FWHM) across the wire ramps present in the CTP404 module of the CATphan. This can be performed using the image analysis software *IQ works* [16]. If time permits an 8° angled foil phantom may be used to measure the slice sensitivity (this will be more accurate than the 45° angled wire provided in the CATphan).

7. *Low contrast visibility:* Within the central region of the CTP404 module of the CATphan, there are acrylic spheres with diameters ranging between 2mm and 10mm. To assess low contrast visibility, assess the images to see if any of the spheres are visible.

8. Inspect the images for the presence of image artefacts not picked up by the above tests and record as appropriate.

9. When reporting the results ensure the imaging protocols, acquisition settings and software revision numbers are recorded.

Reporting and publication

It is likely that the results of an evaluation will need to be published, either locally or externally. An example of an appropriate report is CEP10071 [4]. The content of the report should be agreed at the start of the project, and might include:

1. details of the equipment under test, including manufacturer, make, model number, and software revision number

2. a description of the functionality of the IGRT system

3. a summary statement on the suitability of the IGRT system for its purpose

4. results of the technical evaluation, covering image geometry, image dose and image quality.

1. Report to Ministers from National Radiotherapy Advisory Group, *Radiotherapy: developing a world class service for England*, 26 February 2007, http://www.cancerimprovement.nhs.uk/%5Cdocuments%5Cradiotherapy%5CNRAG_0507.pdf [viewed 090908]

2. Sykes J. R. et al. Measurement of cone beam CT coincidence with megavoltage isocentre and image sharpness using the QUASAR™ Penta-Guide phantom. *Phys.Med.Biol,* 2008, *53(19), p. 5275-5294*

3. Sykes J. R. et al Investigation of uncertainties in image registration of cone beam CT to CT on an image guided radiotherapy system. *Phys.Med.Biol, 2009, 54, p.7263-7283*

4. CEP Report CEP08049 :Evaluation Report : X-ray tomographic image guided radiotherapy

5. AAPM Task Group 142 Report: Quality assurance of medical accelerators, 2009

6. Sharpe, M.B., et al., The stability of mechanical calibration for a kV cone beam computed tomography system integrated with linear accelerator. Medical Physics, 2006. 33(1): p. 136-144

7. QUASAR™ Penta-Guide phantom, Modusmed, http://www.modusmed.com/igrt.htm, [viewed 090908]

8. BS EN 60601-2-37:2008 Medical electrical equipment. Particular requirements for the safety of ultrasonic diagnostic and monitoring equipment

9. BS EN 60601-2-33: 2002+A2:2008 Medical electrical equipment –Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

10. ImPACT, Bence Jones Offices,St. George's Healthcare NHS Trust, Tooting, London SW17 OQT http://www.impactscan.org/

11. Song, W.Y., et al., *A dose comparison study between XVI and OBI CBCT systems.* Medical Physics, 2008. 35(2): p. 480-486

12. Virtually Human Male Pelvis Phantom, CIRS Inc http://www.cirsinc.com/801_pf_rad.html. [viewed 090908]

13. Maria Lewis and Nicholas Keat, Wide bore CT scanner comparison report version 14. 2006, NHS Purchasing and Supplies Agency Centre for Evidence Based Purchasing.

14. CATPhan®, The Phantom Laboratories, http://www.phantomlab.com/catphan.html [viewed 090908]

15. ImageJ Dicom Viewer http://rsbweb.nih.gov/ij [viewed 090908]

16. IQ works automated image analysis software for use with DICOM test images. http://twiki.iqworks.org/cgi-bin/view/Main/WebHome) [viewed 090908]

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