

The EOS 2D/3D imaging system

Diagnostics guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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1 Recommendations

- 1.1 The EOS 2D/3D imaging system is an emerging technology with potentially important clinical benefits. Current evidence shows there are some patient benefits for people with spinal deformities in terms of radiation dose reduction and increased throughput. However, those benefits alone are insufficient to justify the cost of the system. No clinical evidence was available to quantify the extent of patient benefits from the EOS system's imaging features including 3D reconstruction, weight-bearing whole-body imaging, and simultaneous posteroanterior (PA) and lateral imaging. Therefore, the EOS 2D/3D imaging system is not currently recommended for routine use in the NHS.
- 1.2 NICE encourages use of the EOS 2D/3D imaging system in specialist research settings to collect evidence about potentially important clinical benefits associated with 3D reconstruction, single image weight-bearing whole-body imaging and simultaneous PA and lateral imaging.

2 The technology

- 2.1 The EOS 2D/3D imaging system (EOS Imaging – formerly Biospace Med) is a novel device that produces 2D images similar to those derived by conventional means as well as 3D reconstructions for some bony body parts. It differs from conventional film, computed, and digital radiography systems in several respects. First, it uses slot-scan technology (that is, scanning a line at a time rather than taking the entire image at the same instant) to vertically scan all or part of the body in a weight-bearing position. Second, it takes simultaneous images in two planes (PA and lateral). Third, by using computer models, it can construct 3D surface images from the simultaneous two-plane images. Additional details are provided in section 4.

3 Clinical need and practice

The conditions

- 3.1 The EOS 2D/3D imaging system can be used for many types of radiological examinations, but is likely to offer particular benefits for weight-bearing imaging, full-body imaging, simultaneous PA and lateral imaging, and 3D reconstruction, or where a reduced radiation dose is important.
- 3.2 The experts agreed that the most important applications of this technology for inclusion in the scope were the management of spinal deformities and lower limb problems such as leg length discrepancy, leg alignment and conditions that affect the hip and knee (notably hip and knee replacement planning).
- 3.3 The indications included in the scope can be divided into those affecting children and adolescents, and those affecting adults. Indications in children and adolescents included:
- spinal deformity, principally scoliosis but also including other conditions such as Scheuermann's disease
 - leg length discrepancy and alignment.
- Indications in adults included:
- spinal deformity, including degenerative scoliosis, progressive kyphosis and osteoporotic fractures
 - loss of sagittal and coronal balance, including issues relating to the hips and knees for which full-body or full leg length images are currently requested.
- 3.4 The management of scoliosis and other spinal deformities involves repeated imaging, which leads to increased radiation exposure, a particular concern for children and adolescents. Leg length discrepancy and leg alignment problems in children and adolescents are often assessed and monitored with multiple images that may require 'stitching' together (that is, aligning and combining).
- 3.5 For adults, the principal spinal deformities are those associated with

degenerative diseases that lead to arthritic changes, kyphosis or scoliosis. In some cases, problems resulting from adolescent scoliosis may appear with other symptoms in adulthood. Full leg and hip or full-body radiographs may be used to diagnose and manage degenerative conditions of the hips and knees, and may also be used to plan joint replacement.

- 3.6 During the initial phase of this assessment, the External Assessment Group (EAG) identified no evidence meeting the inclusion criteria for the review for some of the conditions that were initially included in the scope and, therefore, did not include these conditions in the diagnostics assessment report (see appendix C). These conditions included lordosis, acquired kyphosis, neurofibromatosis, osteoporotic fracture and issues relating to hip and knee replacement for which full-body or full leg length images are currently requested. In some cases these conditions can be sufficiently severe to cause significant disability. According to clinical experts, lordosis is very rare on its own and is almost always associated with scoliosis. Therefore the inclusion of scoliosis should encompass patients with lordosis secondary to scoliosis. Acquired kyphosis and neurofibromatosis were excluded because of high variability in patient groups and the relatively small numbers of patients needing surgery. Osteoporotic fracture was not considered because clinical experts advised that it is only rarely associated with spinal deformity.
- 3.7 In addition to the conditions included in the scope, the EOS system is capable of providing most images that are currently done with conventional radiography, the comparator.

The diagnostic and care pathways

- 3.8 The management of spinal deformity primarily involves monitoring at intervals to assess disease progression and guide treatment decisions. Progression is measured in terms of the degree of spinal curvature, which is typically monitored using serial X-rays in the upright weight-bearing position. The frequency of monitoring depends on the age of the patient, their rate of growth and the nature of the curvature. The frequency of monitoring for kyphosis and other deforming dorsopathies is broadly similar to that for scoliosis, which tends to range from every 4 months to almost 2 years. Patients are also monitored using X-rays in the weight-bearing position before surgery, for up to 2 years after surgery or up to the age of 20 years. Patients with congenital deformities

of the lower limbs, hips or spine are likely to undergo surgery at a younger age than patients with scoliosis, kyphosis or other deforming dorsopathies. Therefore, X-ray monitoring for congenital deformities usually continues for a shorter period.

- 3.9 Imaging in the weight-bearing position is important for evaluating deformities of the spine because of the effect of gravity. The American College of Radiology Practice Guideline for the Performance of Radiography for Scoliosis in Children recommends PA and lateral radiography of the spine in an upright position for initial examination or for screening. Imaging in a non-weight-bearing position can lead to misinterpretation of images and misdiagnosis. Full-body images also provide information about the position of the pelvis and legs, and so help to avoid misinterpretation of the degree of spinal curvature.
- 3.10 Erect weight-bearing PA and lateral images of the spine and lower limbs are also used in adults to evaluate sagittal balance and spinal deformity (lordosis and kyphosis) as well as coronal plane deformity (scoliosis). According to NHS Hospital Episode Statistics, admissions for instrumental correction of deformity of the spine (code V41) have nearly doubled to 2643 over the 5-year period ending 2009–2010.

4 The diagnostic tests

The referred technology: EOS 2D/3D imaging system

- 4.1 The EOS 2D/3D imaging system is a biplane system that uses slot-scanning technology to produce images of comparable or better quality with less irradiation than standard imaging techniques as well as 3D images of osseous structures. The EOS system allows imaging in an upright weight-bearing (or seated or squatting) position, and can image the full length of the body (up to 175 cm), removing the need for 'stitching' of multiple images. The system takes approximately 20 seconds for an adult full-body scan and 4–6 seconds to scan just the spine, depending on the patient's height. As for all spine radiographs, the patient is asked to remain still, with their arms folded at 45°, and to hold their breath during the scan.
- 4.2 The EOS system takes PA and lateral images simultaneously, using a c-shaped imaging device. The digital image is available immediately on a 2D workstation. A 3D image can be reconstructed on the separate sterEOS workstation using the PA and lateral images and a statistical 3D spine model, generated from data from multiple patients. The reconstruction of a 3D image takes 5–10 minutes for each part of the skeleton (for example, the spine or femur). The EOS system takes up a similar amount of space and uses a similar amount of power as other computed or digital X-ray suites.
- 4.3 The acquisition cost of the EOS system in the UK is approximately £400,000, with a current annual maintenance cost of approximately £32,000. The maintenance contract covers all parts except X-ray tubes, which require replacement every 3–5 years at a cost of approximately £25,000 (including fitting). In addition to the cost of purchasing and maintaining the equipment, there may be some building costs if existing rooms complying with radiation legislation requirements are not available. The EOS system requires the same room planning and shielding as a general X-ray room and the same radiation protection protocols apply. The EOS system is not currently in general use in the NHS, although it has been used in research settings.

The comparator: conventional radiography

- 4.4 Currently available imaging technologies that can be used in an upright weight-bearing position include X-ray film, computed radiography and digital radiography, although X-ray film has been replaced by computed radiography and digital radiography in standard UK practice. X-ray film, computed radiography and digital radiography can only take images from one angle at a time; simultaneous PA and lateral images, and 3D reconstruction are not possible. When a full-body image is required, these conventional X-ray imaging technologies need adjustment for distortion or stitching of multiple images.
- 4.5 The acquisition cost of a computed radiography system is approximately £95,000, with an annual maintenance cost of approximately £10,000. Cassettes for computed radiography need replacing every 3–5 years at a cost of £150–200. The acquisition cost of a digital radiography system is between approximately £105,000 and £230,000, with an annual maintenance cost of approximately £18,000. Upgrading software to improve the functionality and performance of digital radiography costs approximately £2000 and was assumed to occur every 4 years.

5 Outcomes

The Diagnostics Advisory Committee (appendix B) considered a review of the evidence by the External Assessment Group (EAG, appendix C).

How outcomes were assessed

- 5.1 The assessment consisted of a systematic review of clinical effectiveness data for the EOS system for the conditions described in the scope, followed by modelling to assess final patient outcomes and cost effectiveness when evidence was found. No studies followed patients to final outcomes, and therefore modelling was necessary to assess clinical effectiveness as well as cost effectiveness. Descriptions of the assessment process are contained in chapter 4 of the diagnostics assessment report. The only relevant data uncovered dealt with image quality and radiation dose reduction.
- 5.2 Three studies of image quality were found – two comparing the EOS system with X-ray film (Kalifa et al. 1998; Le Bras et al. unpublished data) and one comparing it with computed radiography (Deschênes et al. 2010). All found images from the EOS system to be comparable with or better than the comparator in most cases.
- 5.3 These three studies also reported radiation dose reductions with ratios of means ranging from 2.9 to 18.8, depending on the study and body part imaged. No direct comparisons with digital radiography were found, but similar dose reductions were assumed in the base-case models. A separate scenario assuming that digital radiography used two-thirds the radiation dose of computed radiography was also modelled.
- 5.4 Additional reviews were conducted to establish the impact of radiation dose reduction. Two different approaches to modelling cancer risk, identified in these reviews, were included in the assessment. These included data from a personal communication from the Health Protection Agency and data from the BIER VII phase 2 report.

Test accuracy: intermediate outcomes

- 5.5 No data meeting the inclusion criteria for the review were found to specifically compare the diagnostic accuracy of the EOS system with that of conventional radiological examinations beyond the three studies (described above), which showed comparable or better images. No evidence for sensitivity and specificity of the EOS system for any specific condition was uncovered.

Clinical outcomes

- 5.6 The only clinical outcomes assessed came from modelling, and were focused on the impact of radiation dose reduction in people with spinal deformities. Although direct evidence was available showing significant radiation dose reductions with the EOS system, modelling was needed to link dose reduction to reduced cancer occurrence. The base-case analysis used computed radiography as the comparator. Modelling of digital radiography was also performed as part of sensitivity analyses. Extensive modelling of the impact of radiation dose on future cancer was performed. The basic structure of the model is shown in appendix A. The modelling explored only the most prevalent forms of cancer, namely breast, lung, colorectal and prostate. In the base case, incremental quality-adjusted life years (QALYs) from cancer reduction as a result of radiation dose reduction varied by indication from about 0.0001 to 0.0009.
- 5.7 The original scope included spinal deformities (most of which were included in the model) and lower limb problems (which were excluded from the model because of a lack of evidence meeting inclusion criteria). In addition, the EOS system could be used for other conditions in which conventional radiography would usually be used. People with these other conditions might benefit from a reduced radiation dose as well. The EOS system also offers imaging enhancement for spinal conditions and lower limb problems, but the benefit associated with this enhancement could not be estimated from the existing evidence.

Cost and cost effectiveness

- 5.8 The EOS system costs 3–4 times as much as computed radiography machines and 2–3 times as much as digital radiography machines.

- 5.9 The cost-effectiveness analysis was performed using cancer reduction as the primary measure of benefit. The impact of throughput on cost effectiveness was modelled using three different assumptions about the throughput of the EOS system. The base-case throughput assumption (TA1) was based on using a single machine for the entire country and limiting use to only the number of cases of the studied conditions that actually exist in the country, with no other use of the machine. Additional throughput assumptions were based on full use of the machine for the indicated uses at the same throughput as computed radiography, namely 30 cases per day (TA2), or at a higher throughput, specifically, 48 cases per day (TA3). Because there are not enough cases of the indicated conditions to make full use of the machine, these last two assumptions were used to explore the impact on cost effectiveness of full use of the machine. If a machine that was fully used imaging the indicated conditions was found to be cost effective, then further analysis would have been needed to determine whether a machine partially used for the indicated conditions and also used for other conditions could still be cost effective. Thirty cases per day was the assumed rate of utilisation of the comparator. One reason the higher throughput of 48 cases per day may be justified is that the EOS system can take simultaneous PA and lateral images.
- 5.10 The base-case analysis showed the incremental cost-effectiveness ratio (ICER) to range from approximately £148,000 to over £15,000,000 per QALY gained, depending on the indicated use. The width of this range is primarily because the base case limits the use of the machine to the estimated number of cases of the studied conditions. For the throughput assumptions that are not limited by number of cases, the ICERs range from about £97,000 to £700,000 per QALY gained (TA2) and from £47,000 to £351,000 per QALY gained (TA3).
- 5.11 Additional scenarios modelled included:
- earlier age for cancer diagnosis (55 years versus the average age of diagnosis in the population for the cancers modelled)
 - reduced discount rate for both costs and benefits (0% versus 3.5%)
 - further reductions in radiation dose (3 times the reduction of base case)
 - probabilistic modelling of QALYs gained from cancer reduction

- increased cancer risk from radiation (using 1999 US data [BIER VII phase 2] versus newer models from the Health Protection Agency)
- comparison with digital radiography (with digital radiography assumed to have a dose rate of two-thirds that of computed radiography).

5.12 None of these scenarios reduced the ICER to less than £30,000 using the throughput assumptions TA1 and TA2. The earlier age for cancer diagnosis or the alternative risk data reduced the ICER to less than £30,000 for scoliosis and Scheuermann's disease in adolescents for throughput assumption TA3.

5.13 Threshold analysis was performed to determine what level of additional benefits from imaging improvements would be required to reach levels that might normally be considered cost effective for each of the three throughput assumptions. This showed that additional QALYs required for cost effectiveness ranged from 0.0002 to 0.435, depending on the throughput assumptions and the condition being imaged. Threshold analyses of QALY gains required to reach an ICER of £20,000 under the six additional scenarios listed above varied from less than 0.001 to over 700 depending on the scenario, the condition, and the throughput assumptions.

6 Considerations

- 6.1 The Diagnostics Advisory Committee was informed that the evidence suggests that the EOS system creates images with significant radiation dose reductions compared with other modalities. However, there was uncertainty about the overall impact of that benefit. The External Assessment Group explored one scenario in which cancers were averted at the same time as similar cancers not caused by radiation and one scenario in which cancer occurred at the earlier age of 55. The Committee understood that cancers induced by radiation may occur even earlier, and averting these would result in increased QALYs. The Committee also heard that some rare conditions, such as congenital scoliosis, arising from complex genetic syndromes, might make people more susceptible to radiation damage. The Committee identified no other equality issues.
- 6.2 The Committee noted that the EOS system may provide throughput improvements because it takes simultaneous images in two planes, but no evidence meeting inclusion criteria was available to quantify these improvements.
- 6.3 The Committee noted that for the EOS system to be cost effective, benefits relating to the nature of the image need to translate into health benefits for patients. For example, the full-body weight-bearing image generated by the EOS system should provide more accurate information, which might translate into an improved management strategy, and consequently into a health benefit.
- 6.4 On the basis of clinical advice, the Committee considered that the EOS system could be an important emerging technology and could offer significant benefits from imaging improvements resulting in better clinical decision-making. The imaging improvements include 3D reconstruction, simultaneous PA and lateral imaging, and whole-body imaging in a single image. Health outcome benefits could result from better decisions about surgery, in particular planning hip and knee replacements, for which knowledge of the position of the pelvis can be important, and possibly managing rare skeletal conditions in children. Other health outcome benefits are possible. No evidence was available for the use of the EOS system for these purposes. Thus, the Committee considered further research into these benefits to be necessary and that use of the EOS system in a research setting to develop estimates of these benefits was warranted.

- 6.5 The Committee particularly felt there could be specific benefits from the use of the 3D reconstruction from weight-bearing images for both spinal and lower limb conditions. Such reconstructed 3D images are not currently available with existing imaging equipment and are a unique aspect of the EOS system. The Committee was unclear about the magnitude of any such benefits, although clinical specialists advised the Committee that such benefits may exist. For example, curvature in multiple planes may more accurately predict worsening of scoliosis than the standard approach, which is by measuring the Cobb angle. No data were found to substantiate these benefits.
- 6.6 Based on current evidence, the Committee did not consider that the EOS system would be a cost-effective use of NHS resources given the cost of the system and the size of the benefits associated with radiation dose reduction and possible throughput improvements.
- 6.7 As discussed in section 5.7, the EOS system was evaluated primarily for patients with spinal deformities. The Committee noted that these are not common enough to allow an EOS system to be fully utilised in most settings. In the Committee's view, even adding people with all the conditions included in the scope would not be likely to fully utilise many of the machines that would be needed by the NHS. The EOS system can also be used for other conditions in which conventional radiography would usually be used. The Committee considered that all people having imaging with the EOS system might gain from the reduced radiation dose and the system might provide throughput improvements. The Committee considered that these benefits were likely to be similar to those in people with spinal conditions (see section 5.6). Considering only these benefits and based on current costs and evidence, it is unlikely that the EOS system would represent a cost-effective use of NHS resources. The EOS system might be found to be cost effective if sufficient benefits arising from the imaging improvements are identified in people with spinal conditions or lower limb problems. These benefits would need to be established by further research.

7 Recommendations for further research

- 7.1 Research is needed to quantify the health outcome benefits associated with imaging improvements with the EOS system. Examples of such benefits might include reduced back pain or reduced postural difficulties in people with scoliosis, or longer lasting and less painful joint replacements. Although research into the use of the EOS system is appropriate for all the indications included in the scope, the research most likely to be useful is for planning hip and knee replacement, including patient selection, device selection, and surgical approach. Joint replacement operations are more common than the other indications and the EOS system is thought to be most likely to provide benefit to these patients.
- 7.2 Additional methodological research is needed to determine the most appropriate model structures to assess the benefit arising from radiation dose reduction. Additional work is needed to assess when the radiation-induced cancers actually occur and the impact of the timing of the emergence of cancer on health status.
- 7.3 Research is needed to determine whether, and for which conditions, use of the EOS system for 3D reconstruction provides benefit for diagnosis or treatment planning.

8 Implementation

- 8.1 NICE will support this guidance through a range of activities to promote the recommendations for further research. This will include incorporating the research recommendations in section 7 into the [NICE guidance research recommendations database](#) and highlighting these recommendations to public research bodies. The research proposed will also be put forward to the NICE Medical Technologies Evaluation Programme research facilitation team for consideration of the development of specific research protocols. A costing report was not developed due to limited applicability.

9 Related NICE guidance

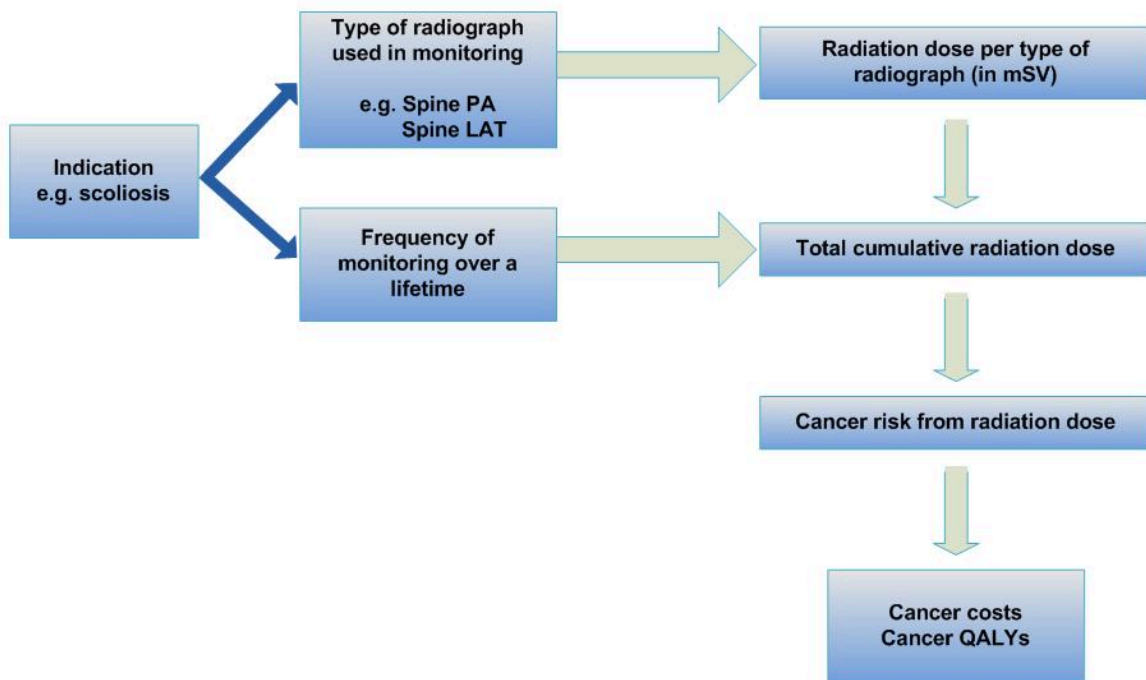
There is no related NICE guidance.

10 Review

No specific time for review has been set, but NICE will monitor improvements in the evidence base for the EOS system to determine when a review would be appropriate.

Andrew Dillon
Chief Executive
October 2011

Appendix A Schematic representation of the modelling approach



Appendix B: Diagnostics Advisory Committee members and NICE project team

A. Advisory Committee members

The Diagnostics Advisory Committee is an independent Committee consisting of 22 standing members and additional specialist members. A list of the Committee members who participated in this assessment appears below.

Standing Committee members

Dr Trevor Cole Consultant Clinical Geneticist, Birmingham Women's Hospital Foundation Trust

Dr Paul O Collinson Consultant Chemical Pathologist, St George's Hospital, London

Professor Ian Cree Director of Efficacy and Mechanisms Programme, NIHR Evaluation, Trials and Studies Coordinating Centre, University of Southampton

Dr Erika Denton National Clinical Director for Imaging, Department of Health

Dr Simon Fleming Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital

Professor Elizabeth (Lisa) Hall Professor of Analytical Biotechnology, Institute of Biotechnology, Department of Chemical Engineering and Biotechnology, University of Cambridge

Professor Chris Hyde Professor of Public Health and Clinical Epidemiology, Peninsula College of Medicine and Dentistry

Professor Noor Kalsheker Professor of Clinical Chemistry, Molecular Medical Sciences, University of Nottingham

Dr Mark Kroese Consultant in Public Health Medicine, Peterborough Primary Care Trust and UK Genetic Testing Network

Professor Dietrich Mack Professor of Medical Microbiology and Infectious Disease, School of

Medicine, Swansea University

Professor Adrian Newland (Chair) Consultant Haematologist, Barts and the London NHS Trust

Dr Richard Nicholas Consultant Neurologist, Heatherwood and Wexham Park Hospital, Imperial Healthcare Trust

Ms Margaret Ogden Lay member

Dr Diego Ossa Global Head, Health Economic and Outcomes Research, Novartis Molecular Diagnostics

Mr Stuart Saw Director of Finance and Procurement, Tower Hamlets Primary Care Trust

Dr Nick Summerton General Practitioner, East Yorkshire

Dr Steve Thomas Senior Lecturer and Consultant Radiologist, University of Sheffield

Mr Paul Weinberger Managing Director, Diasolve Ltd, Pewsley, Wiltshire

Mr Christopher Wiltsher Lay member

Specialist Committee members

Dr Stephanie Clark Chair, Scoliosis Association (UK)

Dr Peter Dangerfield Director of Year 1 MBChB, Liverpool University

Professor Jeremy Fairbank Professor of Spinal Surgery and Consultant Orthopaedic Surgeon, Nuffield Orthopaedic Centre, Oxford

Dr David Grier Consultant Paediatric Radiologist, Bristol Royal Hospital for Children

Mr Eric Hughes Diagnostics Manager, RJAH Orthopaedic Hospital, Oswestry

Dr James Rankine Consultant Musculoskeletal Radiologist, Leeds General Infirmary

B. NICE project team

Each diagnostics assessment is usually assigned to a team consisting of one Technical Analyst (who acts as the topic lead), a Technical Adviser and a Project Manager. In this case the Technical Adviser also served as the topic lead.

Dr Hanan Bell Topic Lead and Technical Adviser

Mr Jackson Lynn Project Manager

Appendix C: Sources of evidence considered by the Committee

A The diagnostics assessment report for this assessment was prepared by the External Assessment Group (EAG): Centre for Reviews and Dissemination/Centre for Health Economics at the University of York.

- McKenna C, Wade R, Faria R et al. EOS 2D/3D X-ray imaging system. March 2011.

B The following organisations accepted the invitation to participate in this assessment as stakeholders. They were invited to attend the scoping workshop and to comment on the diagnostics assessment report and the diagnostics consultation document.

I Manufacturers/sponsors

a The technologies under consideration

- EOS Imaging (previously known as BioSpace Med)

b Comparator technologies

- GE Healthcare

II Professional/specialist and patient/carer groups:

- Scoliosis Association UK
- Limbless Association
- British Institute of Radiology
- Royal College of Paediatrics and Child Health
- Society and the College of Radiographers
- UK National Screening Committee
- Royal Orthopaedic Hospital NHS Foundation Trust

- Health Economics Research Group

Update information

December 2014: Minor maintenance

December 2012: NICE Accreditation logo added

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Accreditation

