National Institute for Health and Clinical Excellence

EOS 2D/3D X-Ray Imaging System

Consultation comments table

Diagnostics Advisory Committee meeting: 7 July 2011

No.	Consultee	Section	Comment	Response
1.	Consultee 2, Specialist Society	1	The NICE evaluation would seem robust based on the current limited application of the technology.	Thank you for your comments.
2.	Consultee 3, Academic body	1	Guidance issued by NICE seems to be the only possible decision given the lack of evidence base. The use of EOS is potentially a big issue for NHS with large budgetary implications so the recommendation for further research is appropriate.	Thank you for your comments.

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3.	Consultee 4, Manufacturer	1.1	We would like to be able to address the final wording and context of this summary draft provisional recommendation. Since this product and the company were never in a position to be able to generate data to evaluate the product for 'routine use in the NHS', we would conclude that this statement be positioned as 1.2. We would like it to be clear that in your assessment of patient benefits in terms of dose the conclusion is based solely on scoliosis patients. Written this way it appears that this is the case for the whole patient population, which is not true. We propose that the elements provided by the company regarding other patient benefits, such as substituting CT scan exams to assess other advantages such as measurements, are equally evidence-based as those developed/used by NICE in your evaluation. We would suggest that this section be modified to reflect the intent of the evaluation and the data that were reviewed. Here is a suggested paragraph for consideration. '*This technology may have a number of potentially significant benefits for patients in terms of radiation dose reduction and its imaging features which include 3D imaging and weight bearing whole body imaging and simultaneous 2 view imaging. Evidence is only available from small patient populations and is therefore insufficient in order for us to consider at this stage its routine use in the NHS. Review of evidence on scoliosis patients indicates insufficient patient benefits in terms of radiation dose to justify its cost. It is recommended that research continues in order to develop evidence about its potentially important clinical benefits'*.	Thank you for your comments. The Committee reviewed these comments and revised the wording for recommendation 1.1. The Committee considered the context of the recommendations is made clear by the remainder of the guidance. The scope of the assessment and the assessment itself included other spinal conditions and conditions of the lower limbs in addition to scoliosis. The modelling included several spinal conditions in addition to scoliosis.

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4.	Consultee Commenter 4, Manufacturer	1.2	We would suggest the following: *'This evaluation was never in a position to be able to generate data to conclude the product's cost effectiveness for routine use in the NHS. At this stage in the product lifecycle, the focus is on generating evidence through research and commercial use'.* We would suggest that this statement be positioned as 1.1.	Thank you for your comments. The Committee considered this point is covered by the nature of the recommendations and the rest of the guidance, including section 7 which proposes additional research.
5.	Consultee 2, Specialist Society	2	We doubt that there will be huge pressure in general hospitals for access to this technology but it may come from paediatric spinal surgeons in specialist spinal centres. Dose limitation is considered in all paediatric imaging and comparison with newer "stitched digital" systems may be worthwhile and should be encouraged. Expanding the use of the technology would appear to be the only way to develop a robust business case and we would support further research in that area.	Thank you for your comments. No changes were found to be necessary. Both the Committee and NICE are of the view that a case for adopting this technology could be made on the basis of further research, if it supported the effectiveness of the technology.
6.	Consultee 2, Specialist Society	3	One of our SCoR reviewers has been an orthopaedic radiographer for 17 years and used plain film imaging of scoliosis for 21 years. She has not seen digital radiography for PA and lateral erect imaging but does now use computed radiography.She feels this amazing technology and literature and images produced for paediatric work appear good. She also feels there would be a place in a dedicated orthopaedic centre.	Thank you for your comments.
7.	Consultee 4, Manufacturer	3.1	Suggest rewording as: The EOS 2D/3D X-ray 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, and ~~simultaneous PA and lateral imaging~~ 3D imaging or where reduce radiation dose is important.	Thank you for your suggestion. The paragraph was reworded to add "3D reconstruction" but the words about simultaneous PA and lateral imaging were kept since they were regarded as an important feature of the device.

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8.	Consultee 4, Manufacturer	3.3	Reword from “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” to “Issues relating to the hips and knees for which 3D or full body or full leg length images are currently requested, such as hip and knee degeneration leading to arthroplasty, including loss of sagittal and coronal balance.”	Thank you for your suggestion. The Committee believes the current wording adequately reflects the issues involved.
9.	Consultee 4, Manufacturer	3.4	Reword as: 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) or CT acquisition (torsion and rotation).	Thank you for your suggestion. The term “multiple images” covers the proposed changes and thus no changes will be made.
10.	Consultee 4, Manufacturer	3.6	We suggest that mention be made of the impact of evidence being excluded (that was originally in the scope of the assessment) has had on the Assessment. The evidence that was eventually reviewed and modelled would not be sufficient to establish whether the product was suitable for cost effective evaluation and be used to establish its suitability for routine use in the NHS We would also draw attention to the following evidence which was submitted but excluded: - All data comparing EOS 3D imaging to CT, such as accuracy of 3D reconstruction of the spine or measurement of torsions of the lower limb, with dose benefit for the patient - Data comparing EOS measurements on the lower limb accuracy versus that of planar radiographs - Preliminary data showing the potential value of EOS 3D parameters for the prognosis of scoliosis and guidance in the therapeutic choice.	Thank you for your comments. All information provided by the manufacturer was given to the external assessment group (EAG), including those arriving after the Diagnostics Assessment Report was completed. The EAG indicated this information did not meet the inclusion criteria. Section 3.6 of the guidance has been changed to say “no evidence meeting the inclusion criteria for the review”. *Note: The consultee provided a list of documents to NICE as part of this comment, and these are available as an appendix to this document.*

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11.	Consultee 2, Specialist Society	4	We would agree with the NICE guidance in that the costs are prohibitive compared with computed and digital methods of imaging. However if we have the potential to reduce dose to patients (and in some areas staff) we need to consider investment in such equipment.	Thank you for your comments. NICE evaluates devices from the perspective of cost-effectiveness. Research into possible additional effectiveness from this device has been proposed at section 7 of the guidance.
12.	Consultee 4, Manufacturer	4.2	Reword for clarity as: 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 ~~with scoliosis~~. 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.	Thank you for your suggestion. The proposed deletion has been made.
13.	Consultee 4, Manufacturer	4.3	We wish to make you aware that the pricing of diagnostic equipment and its' maintenance costs is commercially sensitive and may vary in markets. We would prefer that this be removed and substituted with 'refer to manufacturer for further information' be added.	Thank you for your comment. This information cannot be considered confidential since NICE requires pricing data to be made available in order to perform cost-effectiveness analyses.
14.	Consultee 4, Manufacturer	4.5	We have no issue should NICE decide to remove this if they agree to remove pricing information in 4.3.	Thank you for your comments. Both this paragraph and paragraph 4.3 are essential to the document as described in the response to the comment on section 4.3.

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15.	Consultee 4, Manufacturer	5.1	We would argue that as a pilot it is difficult to agree what is in and out of scope recognised in the interim methods statement March 2010 version 2. Therefore; We would ask that you consider incorporating mention of lower limb data, as it shows more precise values with EOS 3D than with comparator planar radiography. This parameter has been linked in the literature with positive outcomes. We feel that this could have been part of the modelling. We would ask that you consider incorporating mention that by choosing CR as a benchmark this reduced the scope of the benefits that could potentially be considered. EOS is used in instances where CT is sometimes used as well (leg torsion, specific needs on deformative spine).	Thank you for your comment. Section 5.1 refers to the DAR which contains relevant information about the included conditions and available data.

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16.	Consultee 4, Manufacturer	5.4	We would suggest that you consider rewording this statement. We provided NICE with results showing that lower limb alignment obtained with EOS is free from projection bias (measured to be higher than 2° on leg alignment for 22% of the population studied) that were communicated publically in a medical congress. We also provided data showing that EOS 3D measurement data comparing to CT, such as accuracy of 3D reconstruction of the spine or measurement of torsions of the lower limb, with dose benefit for the patient. Your statement currently reads: *'No data 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'.* Suggested rewording for clarity: *'No data from a controlled study published to date 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. CT comparison data were excluded.'*	Thank you for your comment. The paragraph was modified to indicate "No data meeting the inclusion criteria were found ...".

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17.	Consultee 4, Manufacturer	5.5	We would suggest that the statement be clearer to mention that the modelling was done in scoliosis and excluded other patient populations (which were included in the original scope of the assessment) that might be suitable for imaging with EOS due to a lack of evidence. We would ask that you consider the following rewording: The only clinical outcomes assessed came from modelling scoliosis patients with ~~and were restricted to the impact of~~ radiation dose reduction. The original scope of the assessment included other patient populations suitable for imaging with EOS but these were excluded due to a lack of evidence. Although direct evidence was available showing significant dose reductions with the EOS system …	Thank you for your comment. Section 5.6 was reworded as "The only clinical outcomes assessed came from modelling, and were restricted to the impact of radiation dose reduction on people with spinal conditions."
18.	Consultee 4, Manufacturer	5.6	We refer to comment 15 relating to section 4.3 stating that: *'The EOS system costs 3-4 times as much as computed radiography machines and 2–3 times as much as digital radiography machines'.* We believe is of limited value other than confusing the market. We would suggest that you consider you replace value ratios with text 'significantly more'. This ratio is mentioned again in 6.6.	Thank you for your comment, but as mentioned in the response. See response to comment no. 13.
19.	Consultee 4, Manufacturer	6.6	We suggest that the ratios mentioned be removed and replaced with an alternative as per comment 15 section 4.3 and comment 23 section 5.6.	Thank you for your comment. See response to comment no. 13.
20.	Consultee 2, Specialty Society	6	Another point we would want to know is how well does image quality depend on patient size - can it cope with patients who are overweight? In the main, 80% of scoliosis is in the adolescent idiopathic group - who are often slim teenage girls. How well would it image possible overweight neuromuscular patients?	Thank you for your comment. This issue was not examined by the Committee or External Assessment Group.

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21.	Consultee 3, Academic body	6	This evaluation seems to highlight issues about the timing of assessing imaging technologies in particular when they may still be at the technical performance stage (analytical validity and doubts about repeatability) as opposed to the clinical diagnostic performance stage. With no diagnostic accuracy data, no clinical effectiveness data, no evidence of health benefits, no evidence linking reduction in radiation to reduced cancer occurrence, no reliable evidence on radiation dose or imaging throughput, and no relevant UK studies, it is difficult to understand how this technology could even be considered for assessment on clinical and cost effectiveness. In addition EOS is not available in the UK.	Thank you for your comments. EOS is currently being marketed in the UK. Topic selection is done by the Medical Technologies Advisory Committee which selected this topic for evaluation by the Diagnostics Assessment Programme.
22.	Consultee 4, Manufacturer	6.7	We would suggest that the following statements be removed. Referring to the statement that reads: *'Even adding the conditions not examined because of lack of evidence would not be likely to provide sufficient numbers for many of the machines that would be needed by the NHS'.* We believe that this is assumptive and is unnecessary. Also the statement that ends this section which reads: *'This would reduce the likelihood that the EOS system would represent a cost effective use of NHS resources'.* In our opinion this statement is assumptive and unnecessary.	Thank you for your comments. This section has been reworded to take these considerations into account. The words "In the Committee's view" were added to the start of the second sentence. The final sentence has been reworded to "Together these considerations make it unlikely that the EOS would, based on current costs and evidence, represent a cost-effective use of NHS resources."

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23.	Consultee 4, Manufacturer	General/ Section 1	As a pilot, one of the objectives is to experience the challenges in setting up a programme for assessing diagnostic technologies including the development of appropriate methods and processes to form the basis for a substantive Diagnostics Assessment Programme (Interim methods statement March 2010 Version 2). One of the key difficulties with doing assessments of diagnostic tests is that most of the important outcomes are not the direct result of the tests, trials or available data, and that when designing the scope of an assessment the evidence available may in itself not be enough to prove the technology's cost effectiveness to the NHS. We would like mention of the following in order to clarify the context for the evaluation and section 1 seems a logical section for this. *'The EOS 2D/3D X-Ray imaging system has been evaluated for its use in researching the management and ongoing monitoring of orthopaedic patients, particularly those with spinal deformities such as scoliosis, or those with leg length discrepancy or alignment problems. The system is not currently in general use in the NHS'.*	Thank you for your comments. The material suggested for insertion is covered in sections 3, 4, and 5 which describe the nature of the evaluation.
24.	Consultee 1, Specialist Society	General	This review is interesting. It concludes that the EOS system of imaging offers slightly better images, especially in 3D, and involves less radiation but being around 4 times more expensive than CT scanning, is not cost effective. However, is this advice tenable for all possible NHS scenarios, and especially in children? This imaging system may offer a significant advantage to scoliosis assessment in certain children who typically require multiple radiographs for various reasons over many years (e.g. children with cerebral palsy who develop scoliosis), in whom a good quality 3D scan could be obtained more quickly, and with less radiation exposure.	Thank you for your comments. These are precisely the issues that were examined and no evidence was uncovered during the assessment regarding the benefits of 3D scans. The Committee's view was that the level of benefit from reduced radiation exposure was insufficient to justify the additional cost of the system.

promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Appendix A — Table of references provided by the manufacturer as part of comment 10

Title	Format
Breakthrough in three-dimensional scoliosis diagnosis: significance of horizontal plane view and vertebra vectors. *Illés T, Tunyogi-Csapó M, Somoskeöy S. (Pecs Hospital, Hungary)* EuroSpine J. 2010 Sep 5.	Manuscript
Interest of the EOS ® three dimensional reconstructions for the measurement of lower limb clinical parameters *Guenoun B, Zadegan F, Aim F, Hannouche D, Nizard R. (Hôpital Lariboisière, Paris, France)* Podium - EFORT 2010	PowerPoint Presentation
Limb length measurement with the EOS system: comparison with conventional systems. *Sylvain Breton, Eric Stindel, Alban Genu, Matthieu Auffret,Bernard Sénécail and Pierre Forlodou* Poster- ESPR 2010/Podium SOFCOT 2010	Poster + PowerPoint Presentation
Potential applications of a low-dose standing whole body radiography system *M. DE LA SIMONE, C. GOMES, R. NIZARD* Know-How in osteoarticular radiology N°12 – Sauramps Medical	Manuscript
Skeletal landmarks for TKR implantations: Evaluation of their accuracy using EOS imaging acquisition system *B. Schlatterer,I. Suedhoff, X. Bonnet, Y. Catonne, M. Maestro, W. Skalli* Orthopaedics & Traumatology: Surgery & Research (2009) 95, 2—11	Manuscript
Evaluation of workflow in a pediatric radiology department using Ultra Low Dose Digital Imaging *M.Alison, R. Azoulay, B. Tilea, S. Grandjean , T. Lefevre, I. Achour , G. Sebag* Poster - ESPR 2009	Poster
Case Report: Patellofemoral syndrome as unusual complication following THP. Radiological 3D analysis with the EOS® system. *LAZENNEC, Jean Yves, RANGEL, Alfonso, BAUDOIN, Aurelien, SKALLI, Waffa,* *CATONNE, Yves , ROUSSEAU Marc Antoine* Revue Orthopédique	Manuscript
Clinical Case: 3D evaluation of surgical correction of idiopathic scoliosis by vertebral column manipulation *Dr. Ibrahim Obeid - Pellegrin Hospital, Bordeaux, France*	EOS White Paper

Title	**Format**
3D postural balance with regard to gravity line: an evaluation in the transversal plane on 93 patients and 23 asymptomatic volunteers *Jean-Sebastien Steffen • Ibrahim Obeid •Nicolas Aurouer • Olivier Hauger • Jean-Marc Vital •Jean Dubousset • Wafa Skalli* Eur Spine J	Manuscript
Three dimensional visualization and complete 3D characterization of the spine in scoliosis: a preliminary clinical study based on vertebra vectors *Illes, Tamas; TunyogiCsapo, Miklos; Somoskeoy, Szabolcs* Podium – SRS 2010	Podium
Clinical Case: Correction of a major grade secondary scoliosis in cerebral palsy *Pr. Tamas Illes, MD, DSc – University of Pecs*	EOS White Paper
Clinical Case: Degenerative Scoliosis in the elderly *Pr. Jean Dubousset - St. Vincent de Paul Hospital, Paris*	EOS White Paper
3D reconstruction of the spine from biplanar X-rays using parametric models based on transversal and longitudinal inferences *L. Humbert, J.A. De Guise, B. Aubert, B. Godbout, W. Skalli* Medical Engineering & Physics	Manuscript