EOSedge[™]: Value Summary









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- · Service offering to guarantee maximum performance
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Introduction

EOS imaging, part of the ATEC Spine Group, develops advanced imaging and image-based solutions for musculoskeletal pathologies and orthopaedic surgery, enabling healthcare facilities to provide high standards of care for orthopaedic conditions impacting the spine and lower limb. By pioneering low dose 2D full body, weight-bearing imaging, precise modelling, EOSedge solutions aim to enhance patient safety measures, increase efficiencies, and attract patients seeking care.

Originally founded as Biospace Med in 1989, EOS imaging is the result of years of collaboration between world-class physicists, engineers, radiologists, and surgeons. EOS imaging was built by Georges Charpak, a brilliant scientist in the field of radiology and imaging, and recipient of the Nobel Prize in Physics in 1992. The first EOS systems were installed in Europe and North America in 2008.

In June 2021, EOS imaging joins the ATEC group, a provider of innovative solutions dedicated to revolutionising the approach to spine surgery. The association of both companies will create new standards in spine conditions, from diagnosis to follow-up, with a single vision: better informed surgery

EOSedge Solution Overview

Imaging solutions



The EOSedge[™] system provides low dose, full body, stereoradiographic imaging of the patient in a functional position.

Modelling



Patient-specific models created on the sterEOS workstation, provide valuable information along the patient care pathway.

EOSedge solution aims to address today's healthcare delivery considerations

Patient outcomes

- EOSedge provides a global assessment of the skeletal system to make critical treatment decisions.
- The models and associated clinical parameters support physicians in the assessment of musculoskeletal pathologies and the identification of treatment options to improve clinical outcomes.

Patient-centred care

- EOSedge exams are captured in an open-air cabin for a comfortable patient experience.
- EOSedge models and patient- specific reports provide valuable information to analyse conditions and present treatment options to patients.

Patient safety

- EOSedge low dose exams minimise radiation exposure, while supporting the ALARA (As Low As Reasonably Achievable) principle.
- EOSedge Micro Dose exams further reduce radiation exposure for follow-up imaging exams.

Care efficiency

- EOSedge is capable of fast image capture for high patient throughput and ability to maximise number of daily exams.
- EOSedge images and data are accessible to medical professionals, streamlining image workflows to improve departments' efficiency.

Patient attraction

- EOSedge low dose and Micro Dose exams address the needs of highly sensitive paediatric populations.
- EOSedge full body exams, models and patient-specific surgical planning capabilities engage adult patients seeking advanced orthopaedic technologies.

Musculoskeletal imaging

Medical imaging is often the foundation on which diagnosis, planning and postoperative care is based. Therefore, the diagnosis and choice of non-surgical and surgical strategy should be developed from detailed information that allows the surgeon to assess all contributing factors, such as rotation, overall balance, compensatory mechanisms, and alignment to guide treatment.

Several imaging technologies are used to assess musculoskeletal disorders. Magnetic resonance imaging (MRI) and ultrasound are used to analyse cartilages, ligaments, discs, and other soft tissues, while ionising radiation-based technologies, such as conventional radiography (X-ray) and computed-tomography (CT scan) are used to analyse bones. These technologies have several limitations that may impact workflow, patient experience and surgeon's ability to make critical care decisions.

Conventional Radiography (X-ray)	Narrow field of view	Due to the limited detector size, most X-ray systems cannot assess the complete skeletal system and factors that contribute to the disorder in a single acquisition.
	Measurement errors	Stitching errors and magnification errors ¹ may limit the ability to guide treatment.
	2D images	2D views do not account for the 3D nature of the skeletal system ^{2,3} .
	Image Quality	Cone beam exposes a large volume of tissue producing scatter radiation that can cause contrast degradation in the image.
	Radiation dose	Scoliosis monitoring using traditional X-ray imaging may increase the risk of developing cancer up to 5 times ⁴ .
Computed tomography (CT scan)	Not weight- bearing	Images obtained in a supine (lying down) position do not capture functional factors that impact pain and function ⁵ .
	Radiation dose	The use of CT may be the cause of 29,000 future cancer cases in the US ⁶ .

Imaging modalities limitations

Despite limitations, 2D radiography is the most common tool used to diagnose and plan orthopaedic treatment. With surgical demand on the rise, enhanced orthopaedic imaging may be needed to improve outcomes and reduce costs.

EOSedge technology: a new way to image





Innovative low dose X-ray imaging solution

EOSedge low dose solution is unique in the medical imaging market, introducing a fifth modality to improve the safety, speed, and quality of patient exams.

EOSedge is a biplanar system that scan patients in functional position. It employs cutting-edge technology to minimise radiation exposure, delivering reduced dose to the patient.

2D full body images in weight bearing position

Frontal and lateral images are captured simultaneously, allowing for modelling of the spine and/or lower limb to be generated. Reports provide over 100 clinical parameters for use at all stages of patient care.

EOSedge for the Management of Orthopaedic Conditions

EOSedge solution is designed specifically for the management of orthopaedic conditions. EOSedge exams allow for a complete understanding of each patient's skeletal structure using low radiation dose. Our solution helps physicians understand various musculoskeletal conditions – and considerations for global alignment to support precise assessments and clinical guidance. EOSedge provides physicians with comprehensive images of spine, hip, knee, and lower limb conditions across both paediatric and adult care. We serve radiologists, orthopaedic surgeons, and spine surgeons and their care teams. Common adult and paediatric osteo-articular disorders that can benefit from an EOS exam are:

Spine

- Paediatrics: scoliosis, postural disorders
- · Adult: postural disorders, deformative and degenerative spine pathologies

Pelvis and lower limb

- · Pelvis deformities and postural disorders
- · Lower Limb deformities: Leg length discrepancies and alignment disorders

EOSedge solution features and benefits

Exceptional clinical value

- Full body frontal and lateral images in functional position
 - Better comprehension of compensation mechanisms between the spine, hip, and knee thanks to full-body, weight-bearing images.
- Largest acquisition zone(*)
 - Biplanar X-ray images are simultaneously captured with the synchronised vertical movement of both perpendicular beams, allowing for 2 paired images up to 190 cm (6ft 3in) high and 51 cm (20 in) wide to be captured.
 (*) for general X-ray medical devices in weight bearing position
- · High resolution images with homogenous contrast
 - EOSedge is equipped with a high resolution photon counting detector for improved diagnostic capabilities: 100 µm pixel size for spatial resolution up to 5 lp/mm.
 - Exceptional dynamic range (over 131,000 grey levels) allowing good visibility around implants.
- Standardised imaging: no stitching ; 1/1 scale images (no magnification)
 - Accurate 2D measurements in a functional position without magnification or stitching bias thanks to a continuous vertical scanning technique.
- Models of the patient's anatomy provide clinical parameters that are not available with conventional radiography, such as torsion, anteversion and rotation.
- Enhanced decision making: EOS modelling offers well-informed clinical decisions with defined surgical targets from data sets.

Reduced radiation exposure

- EOSedge combines the latest technological innovations (photon counting detector, Flex DoseTM and Micro Dose) that allow minimising radiation exposure while supporting the ALARA (As Low As Reasonably Achievable) principle.
- Flex Dose[™] uses body morphology to modulate radiation throughout scans, delivering homogeneous and optimal image quality as well as further dose reduction to the patient. Flex Dose enables a smart distribution of the dose along the patient.
- The Micro Dose feature consists in optimising the long axis protocols to further minimise
 patient exposure in accordance with the ALARA principle in paediatric follow-up exams.
 The Micro Dose feature is indicated for assessing global skeletal deformities and allows for
 the monitoring of disease progression, particularly for pathologies which require frequent
 monitoring such as scoliosis in paediatric patients.
- Dose reduction versus standard conventional radiographic system (DR) :
 - 5 times less dose on average with an EOSedge low dose compared to DR7,8
 - 28 times less dose on average with an EOSedge Micro Dose compared to DR7

Operational efficiency

- EOSedge is delivering safe, accurate, and consistent imaging data to support the entire spectrum of care of non-surgical and surgical treatments. EOSedge was designed to provide a fast and comfortable patient experience, while streamlining image workflows across physicians at all stages of care.
- Patient-centred experience: EOSedge's open cabin design allows to capture full body images in weight-bearing position, safely, quickly and comfortably. The cabin includes a motorised, enlarged patient platform which enables easy access to a broader range of patients, and faster patient positioning.
- Time saving image delivery: with EOSedge,
 - Full-body images are captured in less than 15 seconds on average for adults
 - Full-spine images are captured in less than 3 seconds on average for children
 - The large acquisition area suppresses the need to stitch the images and the biplanar design allows to capture simultaneous frontal and lateral images avoiding patient repositioning.
- With a capacity to scan up to 150 patients per day9, EOSedge can perform complex exams in less than 4 minutes. EOSedge allows to optimise patient workflows and to improve productivity.

EOSedge in paediatric orthopaedics

Paediatrics musculoskeletal disorders are threedimensional deformities in which imaging plays a key role to define the best therapeutic strategy and control orthopaedic treatments. Some pathologies, such as scoliosis and lower limb deformities require monitoring over time to assess the disease progression and repeated imaging, often performed with multiple images that may need stitching.

The impact of increased radiation exposure from repeated imaging compounds in children with growing cells that are more sensitive to the long-term impact⁹. As such, there is a need to minimise the risk of radiation exposure, while improving the accuracy of the measurements.



Current Challenges

- Patients who require multiple diagnostic radiographic examinations during their childhood and adolescence may have an increased risk of radiation-induced cancers later in life¹⁰.
- Patients treated for adolescent idiopathic scoliosis (average 16 radiographs) had an overall cancer rate 5x higher than that of an age-matched population⁴.

Safe imaging

EOSedge minimises radiation exposure while supporting the ALARA (As Low As Reasonably Achievable) principle. A study conducted by the Center Hospitalier Emile Muller in Mulhouse-France showed that there is 28x less dose on average with an EOSedge Micro Dose spine exam compared to DR⁷ (Frontal and Lateral full spine exam for AIS patients).

Exceptional clinical value

EOSedge supports conservative treatments and surgical planning strategies with a unique combination of 2D long-axis images captured without stitching or magnification bias and precise information.

2D Long-axis images

Are acquired in functional position (standing, sitting, bending), without stitching and magnification, allowing physicians to assess the skeleton under natural stresses, making it possible to analyse a patient's joints, posture and compensatory mechanisms between the spine, pelvis and legs.

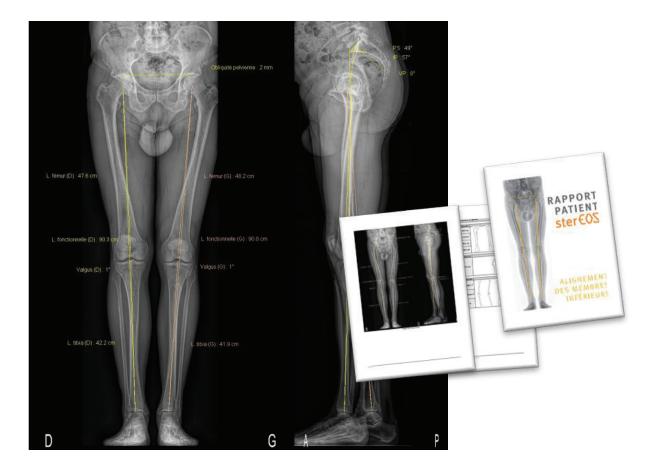


Value in paediatrics lower limb

Children with lower limb length discrepancy require repeated x-rays to monitor leg length and alignment; however, this is balanced by the need to minimise radiation exposure.

A study published in 2013¹¹ is concluding that

"EOS is the ideal modality to assess lower limb alignment in the weight-bearing position. Upright EOS protocols that utilise a faster speed and lower current are more accurate than CT scanograms and conventional radiographs for the assessment of length and also are associated with a significantly lower radiation exposure"



EOSedge in degenerative and deformative adult spine

The most common conditions of the aging spine are related to osteoporosis and osteoarthritis affecting the disk and facet joints or both. Adult spinal degenerative and deformative conditions represent a wide spectrum of disorders including degenerative disc disease, spondylolisthesis, adult idiopathic scoliosis, adult degenerative scoliosis (de novo), age-associated kyphosis as well as postsurgical deformities.

While some spinal conditions do not affect spinal alignment, certain patients have marked spinal deformity with global spinal imbalance resulting in severe disability¹².

In recent years, the assessment of sagittal alignment, which includes lower limb compensatory mechanisms, has been shown to play a key role in the diagnosis and treatment planning of adult spinal pathologies¹³.

Current Challenges

- Adult spine surgery complications and revision remain very high: 18% revision rate at 4 years¹⁴.
- Degenerative spine conditions are frequently associated with a level of deformity and normal alignment is often not restored in short fusion surgery¹⁵.
- Patients with proper post-operative alignment have a better health-related quality of life¹⁶.

EOSedge images extend diagnosis capabilities

EOSedge 2D long-axis images are acquired in functional position (standing, sitting, bending). The gantry opened design and the large detector make it possible to realise dynamic acquisitions such as bending exams.

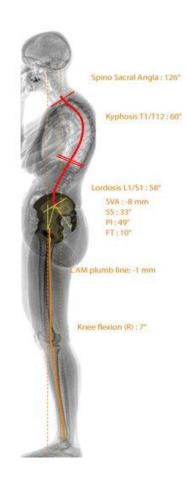


EOSedge enables assessment of global parameters linked to patient outcomes

Sagittal balance assessment and correction, including lower limb compensatory mechanisms, are key when diagnosing and planning spinal surgeries to avoid complications and misalignment.

A full body EOS exam allows the surgeon to understand how the patient compensates the hips, knees and ankles to maintain an upright posture^{17,18}. An expert panel from the French society for spinal surgery recommended weight-bearing long-spine radiographs or EOS imaging before surgical treatment¹⁹.

"[EOS] has allowed the more thorough analysis of these compensatory mechanisms. Spine surgeons can now use EOS imaging to better understand how each patient utilises various compensatory mechanisms, which need to be factored into the degree of deformity correction to achieve optimal postoperative alignment²⁰".





Example of postural assessment patient report

EOSedge in adult lower limb and joint replacement

Leg length discrepancy, alignment disorders or torsion abnormalities of the lower limb are common causes of osteoarthritis and pain in the lower extremity and in the spine. Reliable lower limb measurements are essential for an accurate diagnosis, surgical planning, and post-operative control.

Pre-operative assessment of lower leg length is especially important in patients undergoing total hip arthroplasty (THA), since leg length discrepancy following total hip arthroplasty is a leading cause of patient dissatisfaction after THA²¹. Alignment measurements are keys to understanding the course of knee osteoarthritis and for guiding the conservative and surgical care management²².

Current Challenges

- Approximately 20% of patients might be at risk of possible erroneous preoperative planning due to unreliable 2D measurement of knee alignment (HKA)²³.
- Lower limb length is a common source of patient dissatisfaction and the most common source of litigation after THA. Reported rates ranging from 1% to 50%²⁴.
- 40% of patients undergoing THA have spinal pathologies or spinal malalignment, reinforcing the importance of considering spinopelvic alignment in THA planning²⁵.





Technical specifications

	EOSedge	EOS	X-ray	СТ
Patient in functional position	Yes	Yes + sitting (dedicated optional chair for non- ambulatory patients)	Yes	No: supine position
Image time acquisition	 < 15 seconds to acquire full body images for an adult patient and 5 seconds for a child < 8 seconds to capture frontal and lateral, full spine images on average for adults and 5 seconds on average for children 	Less than 20 seconds to acquire full body images for an adult patient and 15 seconds for a child	++	+++
Exam time	Power to scan up to 150 patients a day9 and deliver complex exams in less than 4 minutes	Average exam time of 4 minutes for a full spine scan in both frontal and lateral views	++	+++
Full body images	Yes - up to 51 cm/20 in (width) x 190 cm/74.8 in (height)	Yes - up to 44.8 cm/17.6 in (width) x 178 cm/70 in (height)	Requires image stitching due to detector limited field of view	Yes
Localised images	Yes	Yes	Yes	Yes
Magnification factor	1:1	1:1	Distortion (depending on patient position)	1:1
Detector	Photon-Counting detector	Gaseous	Manufacturer dependent	Manufacturer dependent
Pixel size	100 µm	250 µm	Manufacturer dependent	Manufacturer dependent
Maximal spatial resolution	5 lp/mm	1,8 lp/mm	Manufacturer dependent	Manufacturer dependent
Radiation	Low dose/Micro Dose/ Flex Dose	Low dose/Micro Dose	Manufacturer dependent	Manufacturer dependent
3D images and parameters	Yes	Yes	No	Yes

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EOSedge system: Digital diagnostic X-ray system. EC conformity Assessment: GMED CE0459, Class IIb. Manufacturer: EOS imaging.

sterEOS workstation: software for review and 3D modelling of biplane radiographic images. EC conformity assessment: GMED CE0459, Class IIa. Manufacturer: EOS imaging.

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