



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne, Director
Health Service Regulation

August 19, 2016

Elizabeth Kirkman
CHS Management Company
2709 Water Ridge Parkway, Suite 200
Charlotte, North Carolina 28217

Exempt from Review

Record #: 2034
Facility Name: Carolinas Medical Center
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace an existing x-ray scanner
County: Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 16, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer



Ms. Elizabeth Kirkman
August 19, 2016
Page 2

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Celia C. Elmman
for

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone
Assistant Chief Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR



Carolinus HealthCare System

August 16, 2016

Ms. Martha Frisone, Assistant Section Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603



RE: Replacement of an X-ray unit licensed under The Charlotte-Mecklenburg Hospital Authority
d/b/a Carolinus Medical Center.

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinus Medical Center (CMC) is planning to replace one of its existing X-ray scanners with new, technologically comparable equipment. CMC intends to purchase an EOS Imaging SterEOS Workstation to replace a Radon Medical Imaging CMP/Eureka – 200 DR Conventional X-ray that was installed in the summer of 2009 and is currently located at CMC. The existing equipment is near the end of its useful life and is at risk for service interruptions due to downtime.

The SterEOS Workstation will be used for the same types of procedures as the existing equipment and it will not be used to provide a new health service. A chart comparing the existing equipment and the replacement equipment is included in Attachment A along with supporting documentation. The equipment is currently in use and documentation provided in Attachment B indicates 4,199 procedures were performed from July 2015 through June 2016.

The total cost to acquire, install and make operational the replacement equipment is \$972,000 which includes construction costs of \$224,000, consultant fees of \$51,000, other fees of \$147,000, and the Replacement Equipment of \$550,000 (\$517,010 for the X-ray, \$10,630 for freight, and \$22,360 for sales tax). Attachment C provides the quote for the X-ray scanner from EOS with equipment costs. Please see Attachment D for a letter documenting the equipment will be taken out of service and removed from North Carolina. The total capital cost schedule and certified cost estimate of the renovation required to install the new equipment are provided in Attachment E.

The North Carolina Certificate of Need statutes provide a definition of replacement equipment in N.C.G.S. 131E-176(22a). The definition requires the replacement equipment be comparable to the existing medical equipment and cost less than \$2,000,000 when installed. The statutes further provide in 131E-184(a)(7) an exemption from certificate of need review for replacement equipment projects if prior notice is provided to the CON Section.

This letter serves as prior notification of our intent to proceed with this project. We would appreciate your written concurrence that this project is exempt from CON review. If you have any questions or require further information regarding this project, please contact me at 704-446-8475.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth Kirkman". The signature is written in a cursive, flowing style.

Elizabeth Kirkman, Assistant Vice-President
CHS Management Company

Attachments

Attachment A

Comparison of Existing and Replacement Equipment

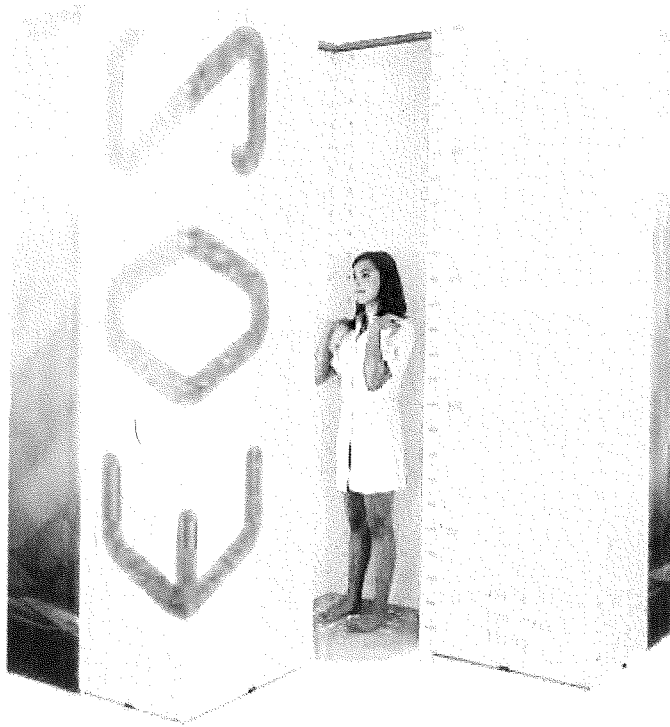
EQUIPMENT COMPARISON

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	CMP/Eureka – 200 DR Conventional X-ray	SterEOS Workstation
Manufacturer of Equipment	Radon Medical Imaging	EOS Imaging Inc.
Tesla Rating for MRIs	N/A	N/A
Model Number	CMP200 DR 65kw	SterEOS
Serial Number	J0101228D09	Not Available Until Installed
Provider's Method of Identifying Equipment	CHS Asset # / Serial #	CHS Asset # / Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	Summer 2009	January 2017
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$70,785	\$972,000
Total Cost of Equipment	\$66,000	\$550,000
Fair Market Value of Equipment	\$23,760	N/A
Net Purchase Price of Equipment	\$66,000	\$550,000
Locations Where Operated	CMC – 1000 Blythe Blvd.	CMC – 1000 Blythe Blvd.
Number Days in Use/To Be Used in N.C. per Year	260	260
Percent of Change in Patient Charges (by procedure)	None	None
Percent of Change in Per Procedure Operating Expenses (by procedure)	None	None
Type of Procedures Currently Performed on Existing Equipment	Chest, Extremities and Spine Scans	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Chest, Extremities and Spine Scans, 2D and 3D Capability

PART C– Product description

EOS

Product Description



Version 3.3

EOS

EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.,
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

Index

1	EOS imaging system description.....	3
2	Gantry	3
3	Acquisition workstation	4
4	Options and accessories	5
5	Training.....	6



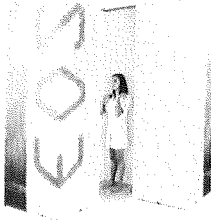
EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

1 EOS imaging system description



The EOS imaging system may acquire two simultaneous orthogonal planar images for a standing or seated patient at an extremely low dose. The scan length is defined by the user and may cover the whole body or a specific area (spine, lower limbs, etc).

EOS is composed of an X-ray gantry and an acquisition workstation.

- The gantry includes a biplane acquisition system. Each plane includes an X-ray source (high heat capacity X-ray tube + high frequency generator), and an X-ray detection system (detectors + very low noise digitisation electronics).
- The acquisition workstation and software enable the download of patient data from the RIS/PACS as well as the selection of acquisition parameters, the control of the different sub-systems to perform the image acquisition, the display of the 2D DICOM images, the printing of the images and their transmission to the hospital network.

2 Gantry

GANTRY

- Gantry made up of a rigid frame holding 2 detectors and 2 X-ray tubes
- Frame movement : vertical scanning motion
- Vertical scanning motion : from 10 to 175cm in increments of 5 mm
- Horizontal acquisition field : from 10 to 44.8 cm adjustable in increments of 5 mm

COMMUNICATION & PATIENT ACCESS

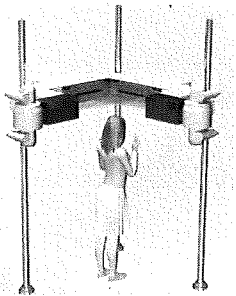
- Width of access to the patient area: 46 cm
- An intercom enables communication with the patient from the acquisition station

X-RAY SOURCES

- Quantity : 2
- X-ray source : model CTR1725 with cooling (3.2 MHU)
- X-ray tube : model DU2506 with a large focal spot (LF) of 0.6 x 1.3 and a small focal spot (SFS) of 0,4 x 0,7 (rating: 140kV at 250mA; 2.5 MHU)
- Power available:
 - LFS : 42 kW per plane
 - SFS : 28kW per plane

GENERATORS

- Quantity : 2
- High frequency technology : 100 kHz
- Nominal power rating: 80 kW, 1 high voltage unit per plane
- kV adjustment : in steps of 1 kV
- mA adjustment : from 10 to 500 mA
- Exposure time adjustment according to the scanned field size : from 1 to 25 s
- Exposure modes: bi-plane or mono-plane (simultaneous Frontal and Lateral, or Frontal or Lateral only)
- Voltage : 400 VAC - 250 A (50 Hz) or 480 VAC – 200 A (60 Hz)



EOS

EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

DETECTORS

- Quantity: 2
- Detector: Linear,AGD technology (Adjustable Gain Detector)
- Calibration : automatic calibration
- Number of pixels/line : 1764/line ; pixel size: 254 μ m
- Digitization depth : 16 Bits ; usable dynamic range: 30 000 levels
- Number of image lines : from 197 to 6890
- Maximum image size: from 2 MB to 70 MB depending on the acquisition area.

3 Acquisition workstation

WORKSTATION

- PC Windows XP : dual core processor (3 GHz, 3 GB RAM)
- Medical LCD monitor : 21 inch colour / 2 million pixels
- Hard drive : 500 GB (300 exams approx)

COMMUNICATION INTERFACES

- Protocols : DICOM3.0 – TCP/IP
- Transfer of images : to the PACS and to the sterEOS workstation in DICOM3.0 format
- Connexion interface to printers: DICOM3.0 Print
- LAN Ethernet : Standard 10/100 base T RJ 45

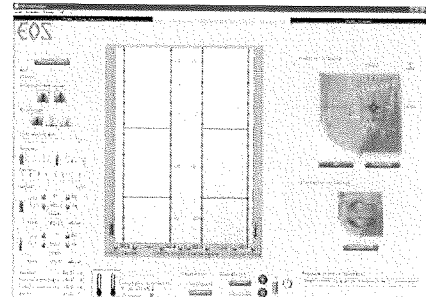
ACQUISITION SOFTWARE

WORKLIST / PATIENT DATA MODE

Worklist display: selection of the exam to be undertaken, automatic population of the patient data fields from the HIS/RIS data (manual filling possible).

ACQUISITION MODE

- Display of the patient data
- Selection of the scanning field (*see option Laser Pole*)
- Selection of acquisition mode: bi-plane or mono-plane (Frontal or Lateral)
- Selection of patient morphotype :
 - **Small Morphotype** : combination of Small Focal Spot and copper spectral filtration allowing dose reduction and improved image quality.
 - **Medium and Large morphotypes** : combination of Large Focal Spot and Aluminum spectral filtration.
- Selection of the contrast enhancement strength that should be applied for each plane (soft, standard, strong) and specific image processing "implant" when the patient has an implant. The "by default" types of image processing and strength of contrast enhancement can be adjusted during the training.
- Adjustment of kV, mA and acquisition speed (auto/manual)
- Prediction of the radiation dose x area product (mGy.cm²)
- Choice and adjustments of the reference plane position , which allows the zoom factor on the displayed image to be modified



EOS

EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

DISPLAY MODE

- Display mode for the images
- Display of the radiation dose x area product (Dose Area Product, mGy.cm²)
- Functions : zoom, gamma, windowing: contrast/ brightness (auto/manual)
- Access to the post-processing window, allowing re-processing of the X-ray with different types of processing and contrast enhancement, similar to those available during acquisition. 3 strengths of contrast enhancement are available for each anatomic area (soft, standard, strong) as well as a specific processing in case there is a metallic implant in the image.
- Image annotation
- Standard 2D Measurements (angles, distances)
- Creation of DICOM secondary captures from the original EOS images
- Choice and adjustments of the reference plane post-acquisition position which allows the zoom factor on the displayed image to be modified
- Exams acquired in a postero-anterior (PA) position can be saved to be displayed on the PACS either in PA or AP. This may be configured during training.
- Sending of images: to the PACS (DICOM data: patient, examination, series...)
- Film composer : film composition and printing



DICOM 3.0 SERVICES

- Verification service (SCU/SCP)
- Modality Worklist Service (SCU)
- Image Storage Service (SCU/SCP)
- Query Services (SCU)
- Option : Retrieve services (SCU)
- Print (SCU)

4 Options and accessories

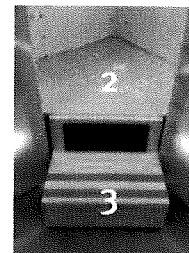
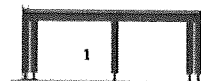
ACCESSORIES - Delivered with EOS system

PLATFORM WITH FOOTSTEP

The platform is removable and includes 3 parts:

- A fixation support (1)
- A removable platform (2)
- An removable footstep (3)

Platform height: 30 cm.



EOS

EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

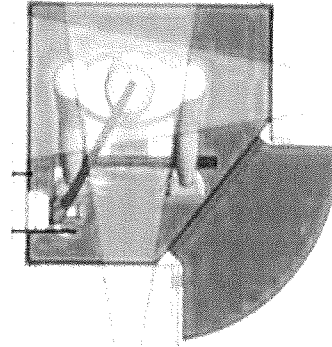
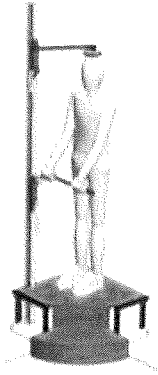
DON'T GUESS. SEE

www.eos-imaging.com

PATIENT STABILIZATION

The patient stabilization accessories include 2 systems:

- Stabilization bar : enables the stabilization of the patient for acquisitions of the lower limbs in AP.
- Posture stabilization device : enables the stabilization of the patient using a pressure pad applied to the head for AP and PA examinations of the spine and the full body.



ACCESSORIES FOR CONTROLLING IMAGE QUALITY

Tools for the Quality audit process are provided. These enable image quality and dose verification.

OPTIONS

LASER POLE



The Laser Pole option optimizes patient flow, by adjusting the length of the acquisition field using a double laser system.

The top laser is positioned by the operator at the point where the scan will start and the bottom laser at the point where the scan will terminate.

The Laser Pole automatically transmits the start and end points of the scan to the workstation, thereby significantly speeding up the patient positioning process.

The installation of the Laser Pole is dependent on there being adequate space in the room. This will be verified in the pre-installation process.

5 Training

A 2 days training session for the EOS system is given by an EOS imaging certified trainer on-site for the equipment hand-over.

The number of designated users is limited to 4 people.

The training session includes several segments to ensure adequate familiarity with the system: system functions, patient positioning, selection of x-ray parameters, image archiving and printing.

Additional refresher training sessions may be purchased as required (Contact an EOS imaging representative for pricing).

EOS

EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

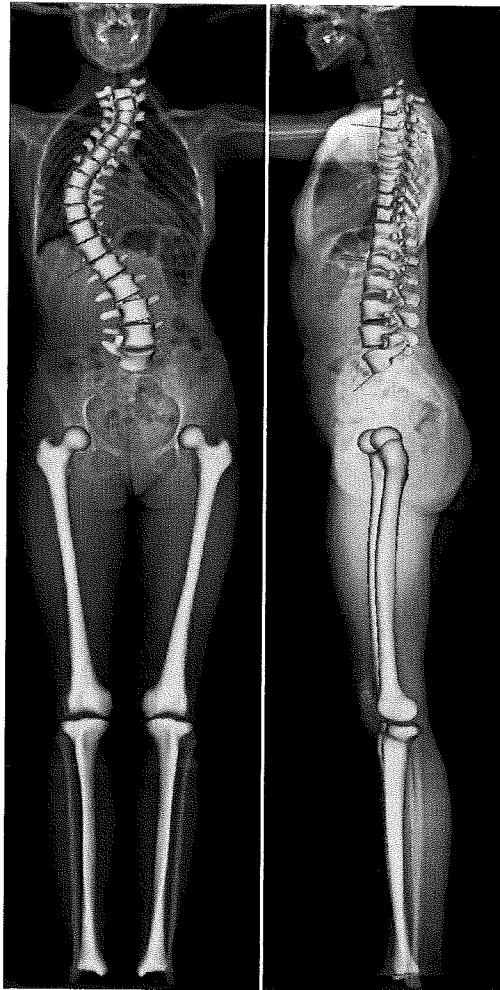
www.eos-imaging.com

sterEOS

Workstation

Product description

Version 1.5



EOS

EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

Summary

<u>1</u>	<u>Description of the sterEOS workstation</u>	9
<u>2</u>	<u>sterEOS functionality</u>	9
<u>3</u>	<u>sterEOS 2D</u>	9
<u>3.1</u>	<u>Tools dedicated to AP and lateral simultaneous acquisitions</u>	10
<u>3.2</u>	<u>Visualization and post-processing</u>	10
<u>3.3</u>	<u>Printing and storage</u>	10
<u>4</u>	<u>sterEOS 3D</u>	11
<u>4.1</u>	<u>3D modeling of the lower limb</u>	11
<u>4.2</u>	<u>3D modeling of the spine</u>	16
<u>4.3</u>	<u>Pelvic parameters</u>	20
<u>4.4</u>	<u>3D toolbox</u>	20
<u>4.5</u>	<u>Patient report</u>	21
<u>4.6</u>	<u>Display and export of 3D models</u>	22
<u>4.7</u>	<u>Contraindication of use</u>	22
<u>5</u>	<u>Training</u>	23



1 Description of the sterEOS workstation

Designed specifically for orthopedic applications, the **sterEOS** workstation offers both a state of the art 2D viewer (**sterEOS 2D**) while also enabling 3D measurements and a 3D weight bearing modeling of the bone envelope using the **EOS** simultaneously acquired planar images (**sterEOS 3D**).

2 sterEOS functionality

WORKSTATION

- PC Windows XP ® SP3 and Windows 7 ®
- Dedicated graphics board
- Medical LCD monitor 21 inch color / 2 million pixel (1 600 x 1 200)
- Microsoft Word® and Excel®
- Reader/Writer CD/16X DVD +/- RW

COMMUNICATIONS INTERFACE

- Image transfer to PACS in DICOM format (Digital Imaging and Communications in Medicine).
- Sending DICOM images to printers (Print True Size available)
- Generate a patient report RTF (Rich Text Format) and DICOM including selected EOS X-Ray images, 3D images, clinical data and users comments

3 sterEOS 2D

sterEOS 2D provides specialized tools dedicated to the post-processing of paired images taken with **EOS**, such as the « Epipolar Line », which allows the User to see the corresponding level on both the AP and the lateral images. **sterEOS 2D** provides state of the art features for the management of DICOM images acquired from **EOS** or from other modalities (except mammography and angiography).



EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

3.1 Tools dedicated to AP and lateral simultaneous acquisitions

- Display of the « Epipolar line » allowing the user to see the corresponding level on both the AP and the lateral EOS images,
- Optimization of the reference plane* positioning allowing accurate 2D measurements on EOS paired images,
- Display of the frontal EOS image automatically in AP.

3.2 Visualization and post-processing

- Retrieval and display of DICOM images
- Magnification
- Optimization of contrast and brightness (automatic or manual)
- 2D measurements (angles, length, circle...)
- Image Text-annotations
- Saving of 2D measurements, text annotations and contrast optimization to local disk creates a secondary capture enabling a reopening with a second review of the images post-treatment.

3.3 Printing and storage

- Printing of images via the DICOM protocol
- Control of the printing size allowing the radiologist to provide a film at any size wanted by the surgeon, for instance the true anatomical size (true size at acquisition and print) and freedom from using calibration tools like balls
- Film Composing before sending to printers (Film Composer)
- Sending of DICOM images to the PACS (Push of one image or a series at the same time...)
- Push of Secondary Captures DICOM to the PACS
- Copy of images from the Patient List to any local repertory or to an external key or disk

**The reference plane determines the image resizing factor used to optimize the measurements in the area of anatomical interest. By default, when images are acquired in EOS, this area is the center of the acquisition space (isocenter) but the operator can optimize this position before the acquisition if so desired.*



EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

4 **sterEOS 3D**

Without any additional radiation, **sterEOS 3D** enables tridimensional clinical measurements and 3D modeling of the bone envelopes of the lower limbs (femur and tibia) and spine.

The method of 3D modeling is based on the semi-automatic detection of anatomical landmarks viewable on AP and lateral **EOS** images. Using a large statistical database and algorithms of contours detection, these landmarks are used to adjust a 3D envelope in order to match the bone contours visualize on the radiographs. 3D clinical parameters are then automatically calculated from the model envelope.

4.1 **3D modeling of the lower limb**

The features of **sterEOS 3D** dedicated to the lower limbs have been specifically designed to help the clinician with the analysis of the deformities and pathologies of the lower limb. The software enables the user to access 3D measurements independently of the patient positioning during the acquisition.

3D orientation of the femoral stem: **sterEOS 3D** provides the clinician with the post-operative verification of the femoral stem 3D orientation. The software allows 3D representation of the femoral stem and provides an automatic calculation of following clinical parameters:

- Implanted femur length
- Femoral stem antetorsion
- Femoral stem offset
- Neck shaft angle



EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

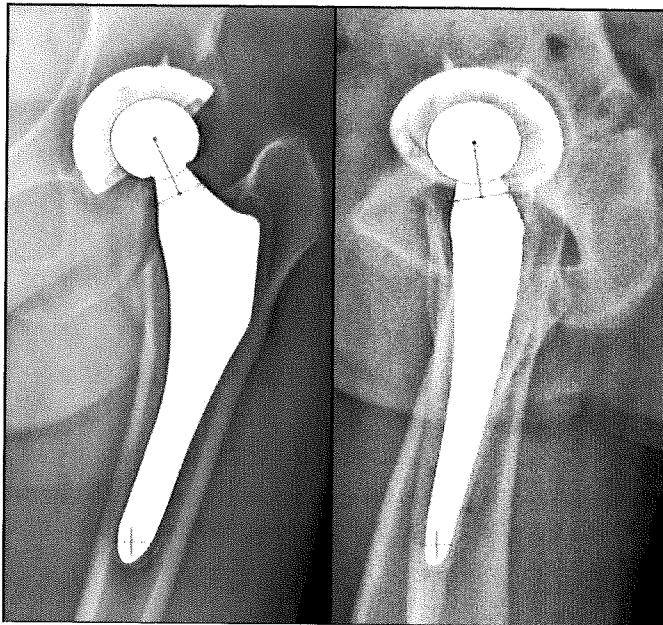


Figure 1 Example of the identification of the femoral stem on EOS frontal and lateral images.

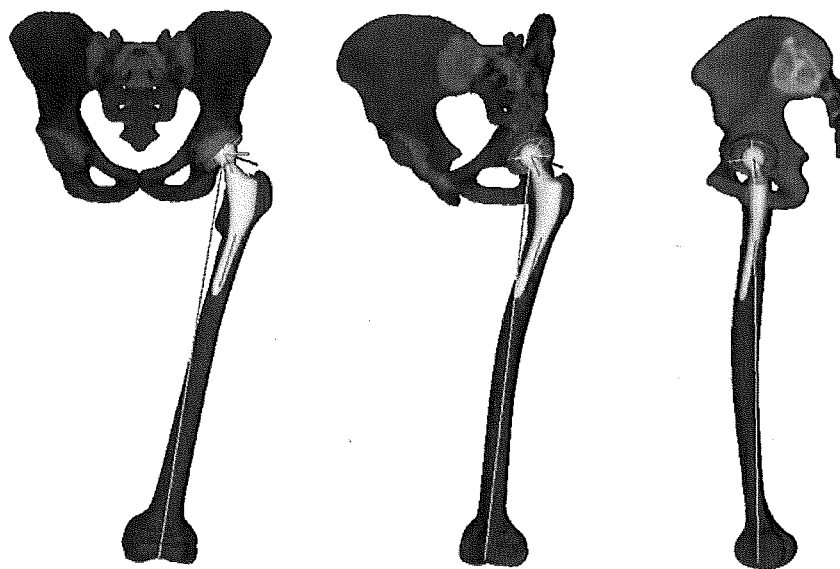


Figure 2 Representation of the 3D orientation of the femoral stem**

*** The 3D envelops of the pelvis, femoral stem and femur do not represent precisely the shape of the bone. Their only purpose is to orient the prosthesis in the space.*

EOS

EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

3D orientation of the acetabular cup: *sterEOS 3D* provides the clinician with support to the postoperative verification of the acetabular cup 3D orientation. The software automatically calculates the 3D functional and anatomical inclinations and anteversions of the border of the acetabular cup.

The functional inclination and anteversion are calculated in a vertical plane going through the center of the acetabulum. These functional measurements describe the 3D weight bearing orientation of the acetabular cup.

The anatomical inclination and anteversion are measured in an anatomical coronal plane linked to the pelvis: the anterior pelvic plane. These anatomical measurements are independent of the patient positioning (standing or sitting) during the acquisition.

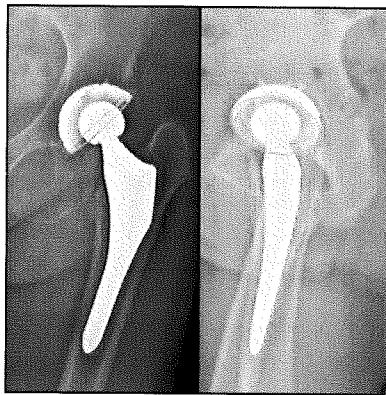


Figure 3 Example of the identification of the border of the acetabular cup on EOS frontal and lateral images.

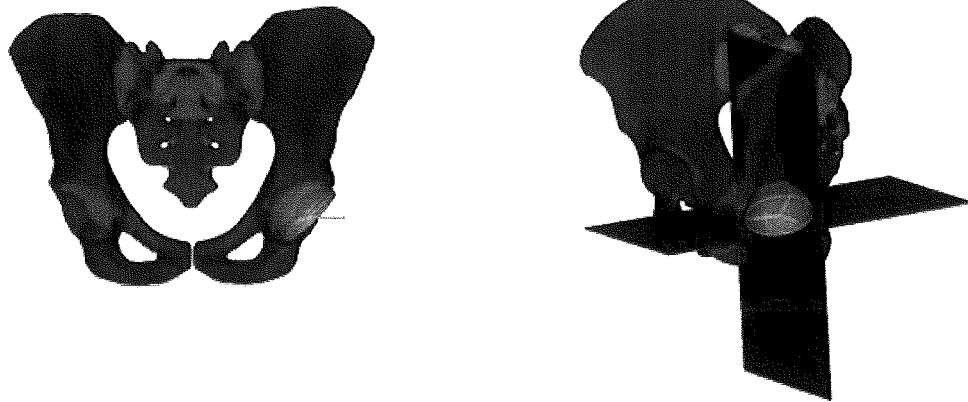


Figure 4 Representation of the 3D orientation of the acetabular cup***.

3D lower limb alignment: The fast 3D lower limb alignment process gives access to reliable leg length measurements and postural angles. Those measurements are independent of the leg orientation and patient position in the EOS system during acquisition.

- Femoral length and tibial length,
- Total length (femoral length + tibial length),
- Varus/Valgus,
- Flessum/Recurvatum,
- Diameter of the femoral head,
- HKS.

3D modeling of the lower limb (femur, tibia): it is possible to complete the lower limb alignment process to obtain a 3D lower limb modeling. The visualization of the 3D modeling can be made from any point of view (top and bottom views, frontal and lateral views). Further clinical parameters may also be computed, including femur and tibia torsions.

- Femoral torsion,
- Tibial torsion,
- Femoro-tibial rotation,
- Femoral offset,
- Femoral neck length,
- Neck shaft angle,
- Femoral mechanical angle,
- Tibial mechanical angle.



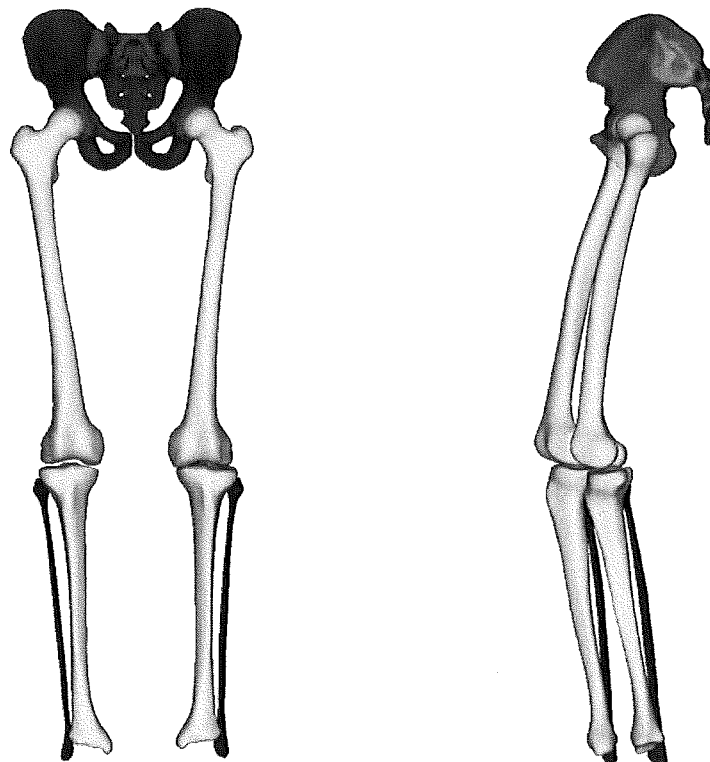


Figure 5 Coronal and sagittal views of the 3D modeling of lower limbs***

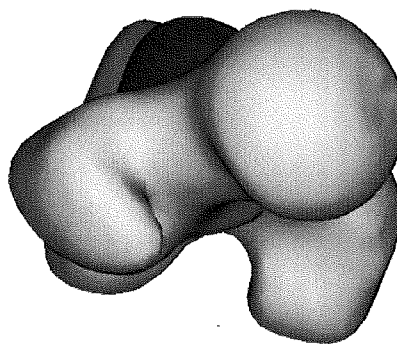


Figure 6 Representation of the femoral torsion in an overhead view.

EOS

EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

4.2 3D modeling of the spine

The features of **sterEOS 3D** dedicated to the spine have been specifically designed to help the clinician with the analysis of the spine deformations and pathologies. All thoracic and lumbar vertebrae may be modeled in 3D, which enables the calculation of tridimensional measurements independent of the patient position in the EOS system.

3D fast modeling: **sterEOS 3D** provides a fast workflow of spine modeling that enables the optimization of the processing time by modeling only the vertebrae related to the calculation of the clinical parameters. Spine modeling may be carried from T1 to L5 and allows:

- The identification of the apical and junctional vertebrae of the scoliosis as well as the automatic calculation of the scoliosis parameters:
 - Cobb angles (up to 3),
 - Axial rotations of the apical vertebrae

- The automatic calculation of the sagittal clinical parameters:
 - Kyphosis T1-T12 and T4-T12,
 - Lordosis L1-L5 and L1-S1.

The 3D modeling time of the spine may be optimized by only calculating the clinical parameters of the scoliosis or of the sagittal balance.



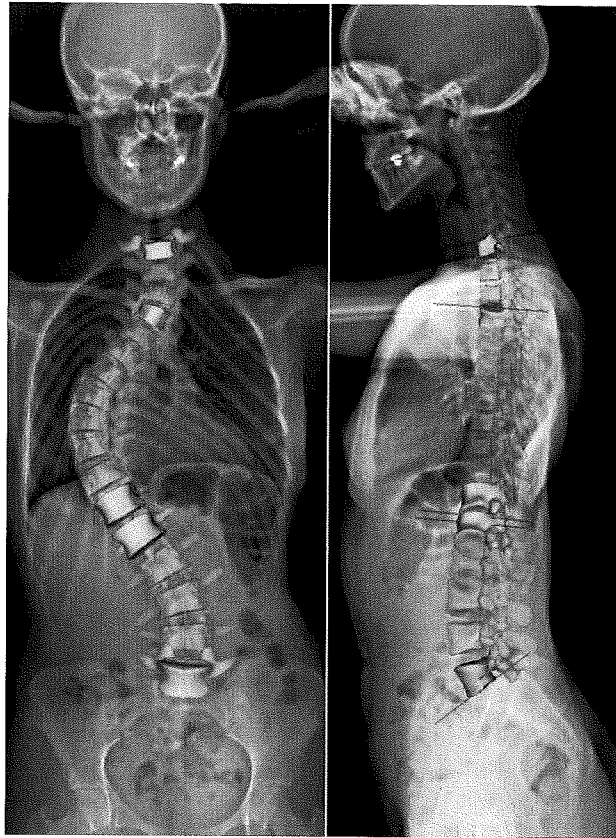


Figure 7 Example of the 3D modeling of the spine.

3D full modeling: sterEOS 3D has a full process of spine modeling that allows the 3D fine modeling of all thoracic and lumbar vertebrae. Additionally to all clinical parameters computed from the fast 3D modeling of the spine, it gives access to the calculation of:

- All vertebrae orientations and inter-vertebral rotations (frontal, lateral, axial) of the spine 3D model.

EOS

EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

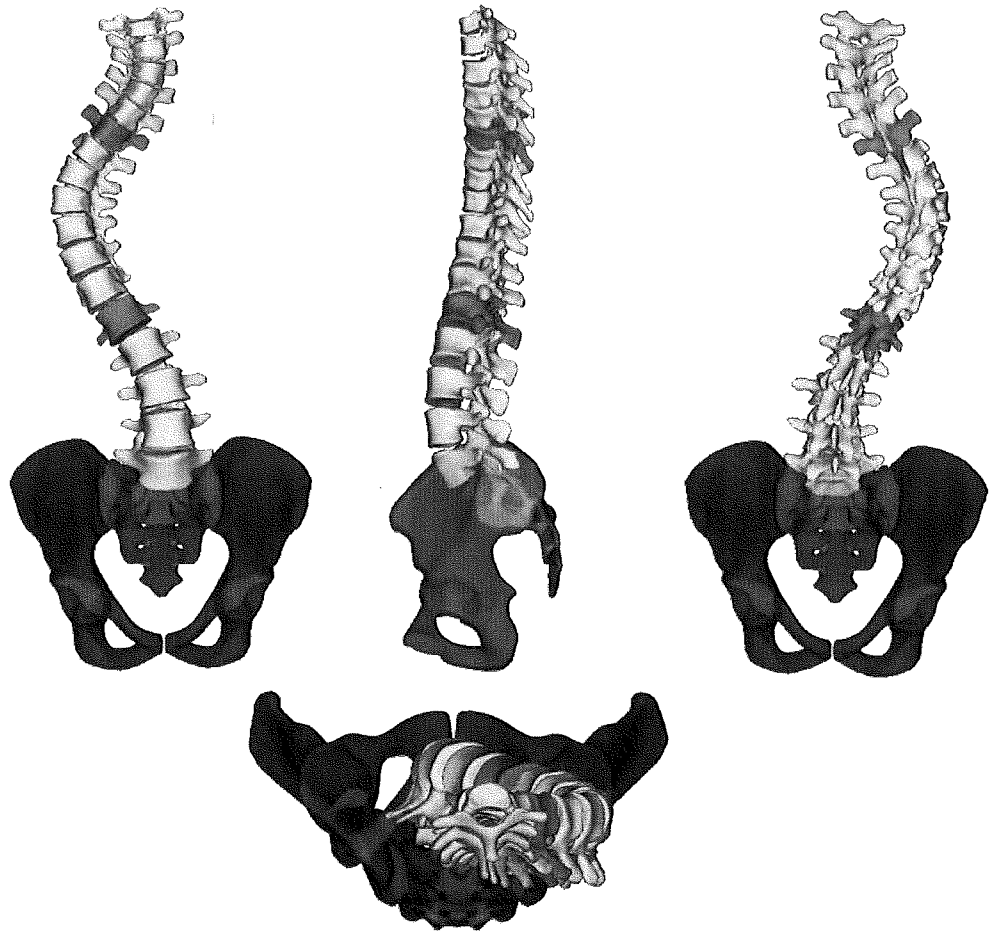


Figure 8 Coronal, sagittal and axial views of a 3D modeling of the spine ***

In order to help the clinician in the analysis of 3D data, a chart displaying axial rotations of all vertebrae is automatically generated and may be included in the patient report. The junctional vertebrae are indicated in blue and the apical vertebrae in yellow (cf. Figure 9).

***The transparent 3D model of the pelvis is displayed as an indication but does not represent any result of 3D modeling from sterEOS 3D.

EOS

EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

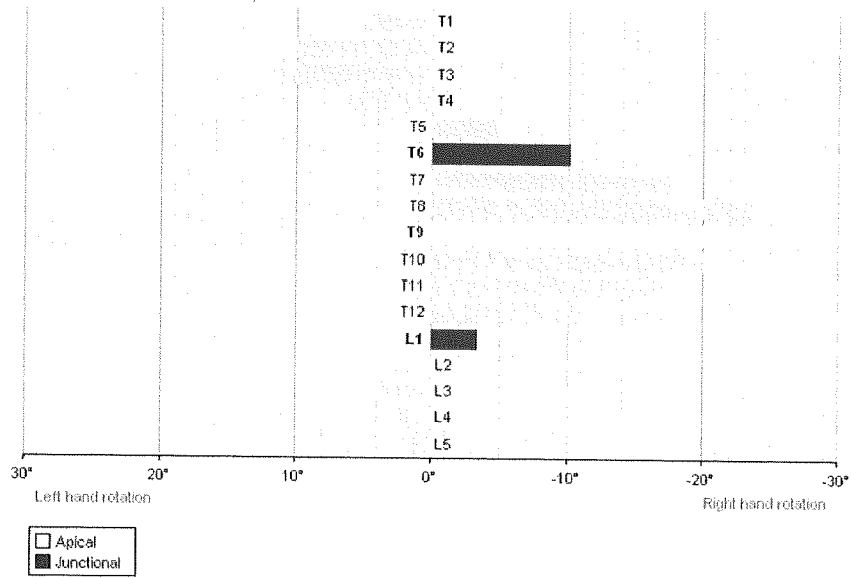


Figure 9 Example of a diagram displaying the axial rotations of the vertebrae.

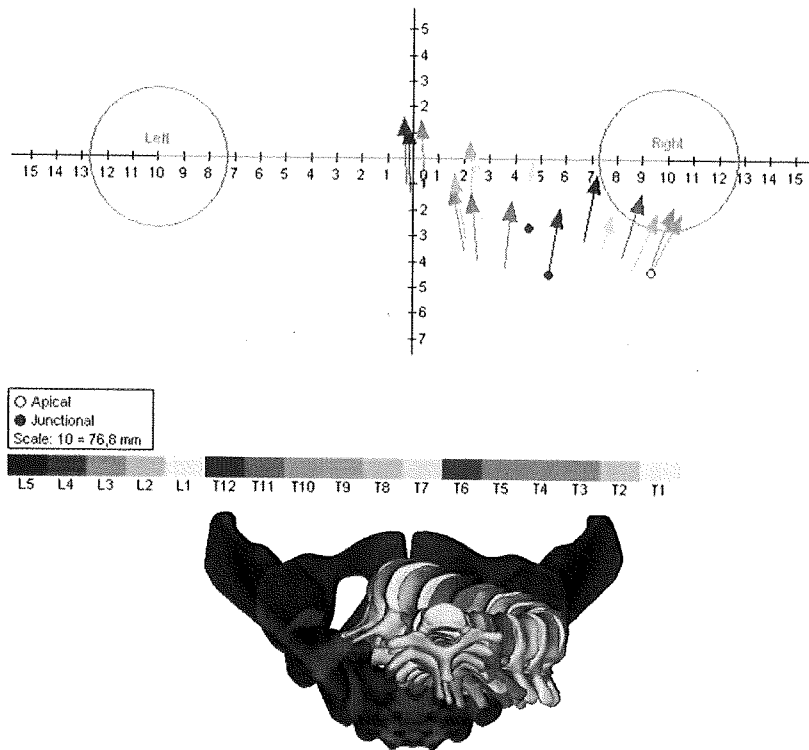


Figure 10 Example of a chart displaying the vertebrae orientations in overhead view and bottom view of the related 3D spine model.

The fast and full 3D spine modeling enable the user to automatically generate a chart displaying the orientations of the vertebrae in overhead view. Each vertebra is represented in the chart by a colored arrow indicating its orientation and distance from the center between the two acetabulums.

This representation may be included in the patient report. It precisely visualizes information provided by a top down view of the 3D spine model (cf. Figure 10).

4.3 Pelvic parameters

sterEOS 3D provides an ultra-fast workflow dedicated to the pelvic parameters. It enables the clinician to access measurements that are independent from the patient position in the EOS system.

- Sacral slope
- Pelvic version and pelvic incidence
- Pelvic obliquity
- Axial rotation of the pelvis

4.4 3D toolbox

Due to the perfect correspondence between the two orthogonal images acquired simultaneously with EOS, the 3D toolbox enables to obtain, in a few clicks, real three-dimensional measurements avoiding common errors linked to X-Ray projection.

- Spheres
- 3-points angles
- 4-points angles
- Rulers
- Text-annotations



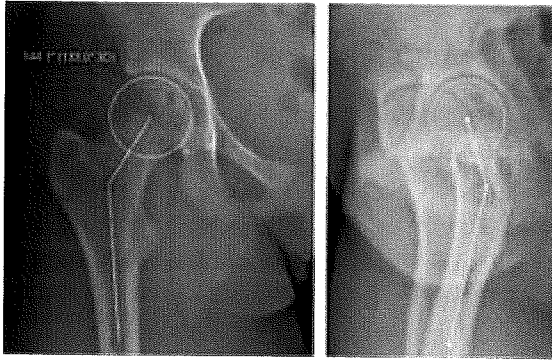


Figure 11 Example of use of the 3D toolbox: 3D measurement of the neck shaft angle.

4.5 Patient report

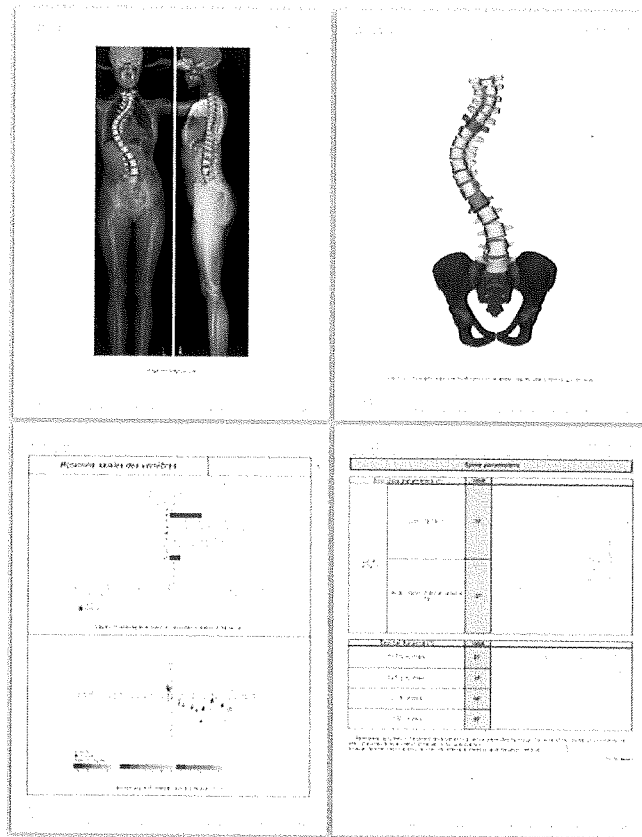


Figure 82 Example of a patient report.

Depending on the user wish, the patient report may contain EOS images with or without 3D models, images with or without 3D models in all views (overhead views, frontal and lateral views) as well as the clinical parameters and charts generated automatically.

The patient report is created in RTF format (Standard format for the standard Word like text editors) and contains information about the patient and the site.

4.6 Display and export of 3D models

sterEOS 3D provides dedicated tools for the visualization and the diffusion of 3D models and 3D measurements.

- The visualization of the 3D models in all orientations of the space (coronal view, sagittal view, axial view, etc...)
- The display management of the 3D models and 3D measurements in order to create a personalized representation only displaying objects of interest
- The save of 3D models in a 3D « Secondary Capture » in DICOM format
- The Excel export of all computed clinical parameters
- The print of 3D models to postscript printers

4.7 Contraindication of use

The 3D models delivered by the sterEOS software can only be used for diagnostic purposes in conjunction with corresponding 2D images. Therefore it displays the 3D relationship between anatomical structures, and at this time we are unable to highlight local bone alterations such as:

- Bones with significant changes in shape geometry following a surgical intervention
- Fractures
- Osteophytes
- Fibrocartilage calluses
- Local bone deformations (hemivertebra, spondylolisthesis, etc...)

3D modeling can become inaccurate and even impossible when anatomical structures or implant landmarks cannot be identified as such in the following cases:

- Prostheses or instruments masking or replacing anatomical markers



EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678) 564,5400

DON'T GUESS. SEE

www.eos-imaging.com

- Certain pathological conditions that alter the bone composition, such as osteoporosis
- Impossibility to differentiate the internal condyle from the external condyle or the internal tibial plate from the external tibial plate
- Femoral stems for which the radiological images do not enable to distinguish the neck of the stem on both AP and lateral views
- Acetabular cups for which the radiological images do not enable to distinguish the internal or external edges on both AP and lateral views

The 3D modeling mode specific to this workstation may only be used on EOS simultaneous AP and lateral images. Simultaneous EOS radiological examinations of oblique view cannot be modeled using this software. Likewise, the sterEOS Workstation cannot perform 3D EOS modeling with AP and lateral images which were taken with the patient's side facing the AP tube and their front facing the lateral tube

The 3D modeling of lower limb is not indicated for patients under 15 years old.

The 3D modeling of the spine is not indicated in following cases:

- Patients under the age of 7 years old
- Spine with one extra or one less vertebra
- Vertebrae with congenital deformations (hemivertebrae, spina bifida...)
- Spondylolisthesis

5 Training

The training for the user of the sterEOS workstation and 3D modeling is managed by an application specialist of **EOS imaging**. The training lasts 3 days for the 3D modeling of the spine and 2 days for the 3D modeling of the lower limbs.

The maximal number of attendees is 4 people.

The training contains several modules enabling the attendees to learn how to use the workstation, the 3D modeling, the display management and export of 3D models.

A training upgrade may be done on demand (training catalog and quote may be asked to any application specialists of **EOS imaging**).



EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60

EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE

www.eos-imaging.com

Attachment B

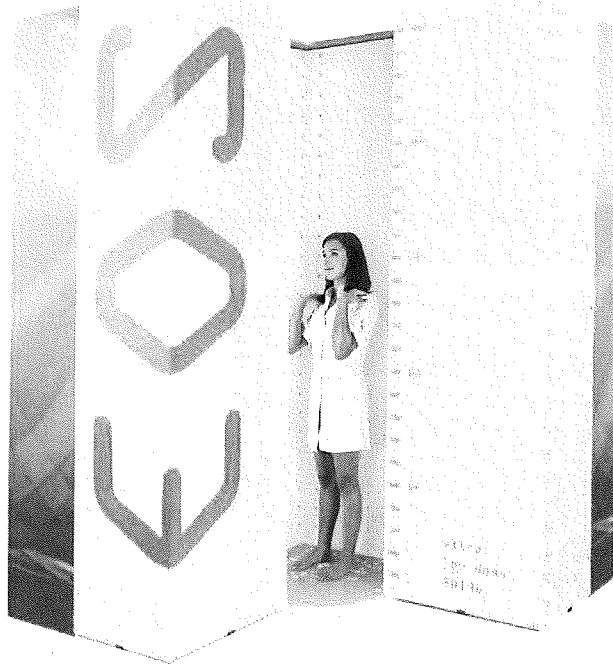
Equipment Use Documentation

Case Volume July 2015-June 2016

Jul-15	386
Aug-15	339
Sep-15	333
Oct-15	373
Nov-15	352
Dec-15	357
Jan-16	347
Feb-16	378
Mar-16	347
Apr-16	291
May-16	305
Jun-16	391
Total	4199

Attachment C

Equipment Vendor Quote



Sales Agreement

Quotation number: # 197 C

Customer:

Carolinas HealthCare System
4828 Airport Center Parkway Bldg. E
Charlotte, NC, 28208

Attn: Vivian Roque
Senior Buyer - Equipment Planning

Site Installation Address:

Carolinas HealthCare System
1000 Blythe Blvd.
Charlotte, NC, 28203

Presented by: Fran Hackett
North America Sales Director
609-558-1962

Date July 13th, 2016

EOS

EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.,
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

EOS imaging is pleased to submit this agreement to the Purchaser for the products and services described herein and at the prices and terms and conditions set forth below, including:

- the Quotation in Part A,
- the Special Terms and Conditions in Part B,
- the Product description in Part C,
- the Installation requirements in Part D,
- the Standard Terms and Conditions and the Software License in Part E,

together with any other special terms or agreements that may be attached to this agreement as additional schedules and/or exhibits (collectively, the "Agreement").

As further described in this Agreement, Product installation costs are included in the total amount due under this Agreement (the "Purchase Price") unless otherwise indicated. Other charges, like transport, insurance and taxes, if any, are in addition to the Purchase Price and are payable by Purchaser upon receipt of each invoice for such charges and/or taxes.

PRODUCT CONFIGURATION	EOS acquisition system with 2 SterEOS workstations and selected options. See Part A
TOTAL PRICE IN US Dollars (\$)	\$550,000- See Part A
PAYMENT TERMS	See Part A
VALID UNTIL	09/30/2016
DELIVERY TERMS	FCA
AVAILABILITY	Approximately 3 months- See Part B
WARRANTY	1 year labor and parts
MAINTENANCE	At the end of initial warranty period (1 year standard) extend maintenance agreements may be purchased at discounted rates. See Part A
REQUESTED DELIVERY DAY	TBD

CUSTOMER AGREEMENT

EOS imaging

BY :

APPROVED BY:

NAME :

NAME: Eric MAULAVE

TITLE :

TITLE: VP Global Sales

DATE :

DATE:



EOS imaging SA
 10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60
 EOS imaging Inc.,
 185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

PART A – FINANCIAL OFFER

All prices are quoted in US Dollars.

Offer Complete System: EOS acquisition system + 1 sterEOS 2D/3D workstation

Ref	Description	Unit price
Complete System		\$ 550,000.00
EOS acquisition system		
	<p><u>Gantry</u> Biplane acquisition system including : 2 X-Ray sources (High heat capacity X-Ray tube + high frequency generator) 2 X-Ray detection systems (detector + very low noise digitization electronics)</p> <p><u>Intercom</u> Enables communication with the patient from the acquisition station</p> <p><u>Accessories</u> Platform with footstep (fixed support + removable platform + removable footstep) Patient stabilization tools: stabilization bar, posture stabilization device, stabilization mirror kit Image quality control tools</p> <p><u>Acquisition workstation</u> Workstation Windows 7 (dual core/3GHZ/4GB RAM) Medical LCD monitor : 21 inch colour/ 2 million pixels Hard drive : 500 GB EOS Acquisition software</p> <p><u>Dicom 3.0 services</u> Verification service (SCU/SCP), Modality Worklist Service (SCU), Image Storage Service (SCU/SCP): Query/Retrieve Services (SCU), Print (SCU) MPPS - Modality Perform Procedure Step (SCU) Storage commitment (SCU) RDSR - Radiation Dose Structure Report (SCU)</p> <p><u>Training on site:</u> Initial training EOS: 2 days / 4 participants</p> <p><u>Service :</u> Installation 1 year warranty (parts and labor included)</p>	
1: SterEOS 2D/3D workstation		
	<p>SterEOS 2D/3D workstation</p> <p><u>Description SterEOS</u> Workstation: PC + Monitor Software sterEOS</p> <p><u>Training on site:</u> Initial training sterEOS Spine + Global Posture Assessment: 3 days / 4 participants Initial training sterEOS Lower Limbs : 2 days / 4 participants</p> <p><u>Service :</u> Installation 1 year warranty (parts and labor included)</p>	
TOTAL (\$)		\$ 550,000.00



EOS imaging SA
10 rue Mercoeur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

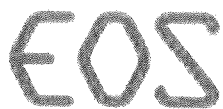
Additional SterEOS 2D/3D Workstation

Reference	Description	Unit price (€)
SterEOS	sterEOS workstation Workstation Software sterEOS. Installation & 1 year warranty (parts and labor included)	50,000.00
TOTAL (\$)		Included

Options

Reference	Description	Unit price (€)
Micro Dose	Allows very low dose acquisition protocols for the purpose of follow-up patient measurements in pediatrics	22,000.00
TOTAL (\$)		Included

Reference	Description	Unit price (€)
Laser Pole	Laser Pole for automatic vertical collimation adjustment Delivery and installation	15,000.00
TOTAL (\$)		Included

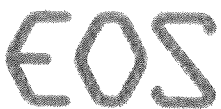


EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

Extended service warranty

Reference	Description	Unit price (€)
1 year Full Service Contract Complete System	Full 1 year Annual Service Contract for EOS and 1 sterEOS: Intervention of EOS field engineer within 24 hours after the call Labor, parts (X-ray tubes and detectors included). Software upgrades (excluding training) Two annual Preventative Maintenance visits	68,600.00
3 years Full Service Contract Complete System	Full 3 years Annual Service Contract for EOS and 1 sterEOS: Intervention of EOS field engineer within 24 hours after the call Labor, parts (X-ray tubes and detectors included). Software upgrades (excluding training) Two annual Preventative Maintenance visits	198,500.00
5 years Full Service Contract Complete System	Full 5 years Annual Service Contract for EOS and 1 sterEOS: Intervention of EOS field engineer within 24 hours after the call Labor, parts (X-ray tubes and detectors included). Software upgrades (excluding training) Two annual Preventative Maintenance visits	285,000.00
Additional sterEOS Service Contract	Full Annual Service Contract for additional sterEOS: Intervention of EOS field engineer within 24 hours after the call Software upgrades (training excluded) Labor, parts	3,500.00
TOTAL (\$)		\$ 0



EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

SUMMARY

Complete System (\$)	\$ 550,000.00
Options (\$) (sterEOS workstation, Laser Pole, Micro Dose)	Included
Extended service warranty (\$)	\$ 0
TOTAL PRICE IN US Dollars (\$)	\$ 550,000.00

Payment

By Bank transfer according to EOS Imaging's Terms and Conditions of Sale:

- 20% down payment upon submittal of with Purchase Order
- 40% due upon delivery
- 40% due upon first clinical use



EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

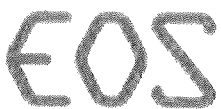
DON'T GUESS. SEE
www.eos-imaging.com

PART B- Special terms and conditions

- Offer valid until 09/30/2016
- Installation included
- On-site training of users included.
- Sale subject to the room compliance with local x-ray protection regulations.
- Connection to a compatible printer is included. Configuration of the printer is the responsibility of the client.
- After sales service may be subcontracted to a local supplier.

Delivery Time

- The average delivery time between order and equipment availability is 3 months.
- The delivery time will be confirmed in the order confirmation from EOS Imaging after receipt of the customer order. The delivery time is only given as an indication. Actual delivery time depends on a number of outside factors such as stock levels and manufacturing cycles.
- The installation is subject to access condition to the final installation site (door widths, access ramps, etc). Additional costs may be charged to the customer should exceptional means (crane ...) be used for the delivery.

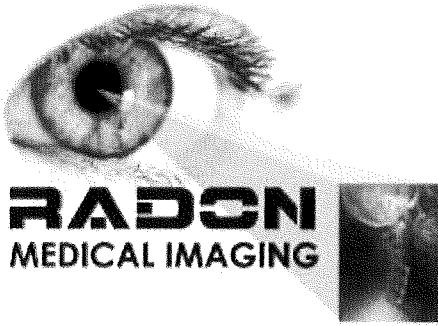


EOS imaging SA
10 rue Mercœur | 75011 Paris France | +33 (0) 155 25 60 60
EOS imaging Inc.
185 Alewife Brook Parkway #410 | Cambridge, MA 02138 USA | +1 (678).564.5400

DON'T GUESS. SEE
www.eos-imaging.com

Attachment D

Equipment Disposal Letter



August 12, 2016

Carolinas Medical Center
1000 Blythe Boulevard
Charlotte, NC 28203
Attn: Chris Hollar
Chris.hollar@carolinashealthcare.org

Dear Chris,

Radon Medical LLC will remove and take possession of the Rad System consisting of a 2009 CPI CMP200 DR 65kW Generator and URS Stand located at CMC Main – 4th Floor Chest Unit Room at no cost to CMC.

The system will be removed from service for either resale purposes or parts by Radon Medical. The system will not be placed back into service by Radon Medical, LLC in North Carolina without proper State approvals.

Please do not hesitate to contact me should you have any questions or concerns.

RADON MEDICAL, LLC

Donna Cloninger
radondc@radonmed.com
L16-400(rev081216)

PO BOX 68 (29342) • 384 PEACHOID ROAD • GAFFNEY, SOUTH CAROLINA 29341
PH: (864) 487-0450 • FAX (864) 487-9955 • EMAIL: radon@radonmed.com

Attachment E

Capital Cost Schedule and Architect Signature

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CMC MMP EOS (OSR #2891392)

Provider/Company: Carolinas HealthCare System

A. Site Costs

(1) Full purchase price of land			
Acres	Price per Acre	\$	
(2) Closing costs			
(3) Site Inspection and Survey			
(4) Legal fees and subsoil investigation			
(5) Site Preparation Costs			
Soil Borings			
Clearing-Earthwork			
Fine Grade for Slab			
Roads-Paving			
Concrete Sidewalks			
Water and Sewer			
Footing Excavation			
Footing Backfill			
Termite Treatment			
Other (Specify)			
Sub-Total Site Preparation Costs			
(6) Other (Specify)			
(7) Sub-Total Site Costs			0

B. Construction Contract

(8) Cost of Materials			
General Requirements		17,525	
Concrete/Masonry		3,300	
Woods/Doors & Windows/Finishes		92,540	
Thermal & Moisture Protection		500	
Equipment/Specialty Items		0	
Mechanical/Electrical		73,965	
Demolition		2,820	
Contingency		29,350	
Sub-total Cost of Materials			220,000
(9) Cost of Labor			Included in #8
(10) Structured Cabling			4,000
(11) Sub-Total Construction Contract			224,000

C. Miscellaneous Project Costs

(12) Building Purchase			
(13) Fixed Equipment Purchase/Lease			550,000
(14) Movable Equipment Purchase/Lease			
(15) Furniture			1,000
(16) Landscaping			
(17) Consultant Fees			
Architect and Engineering Fees		51,000	
Legal Fees		0	
Market Analysis		0	
Other (Specify)			
Other (Abatement)			
Sub-Total Consultant Fees			51,000
(18) Financing Costs (e.g., Bond, Loan, etc.)			

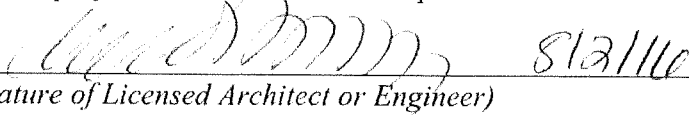
(19) Interest During Construction	<u> </u>
(20) Other (Specify)	<u> </u>
Contingency	<u> 85,000</u>
Administrative Costs and Charged Labor	<u> 48,000</u>
Signage	<u> 3,000</u>
Move Services	<u> 4,000</u>
IS Hardware	<u> 6,000</u>
(21) Sub-Total Miscellaneous	<u> 748,000</u>
(22) Total Capital Cost of Project (Sum A-C above)	<u><u> 972,000</u></u>

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: CMC MMP EOS (OSR #2891392)

Provider/Company: Carolinas HealthCare System

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

 8/2/16
(Signature of Licensed Architect or Engineer)