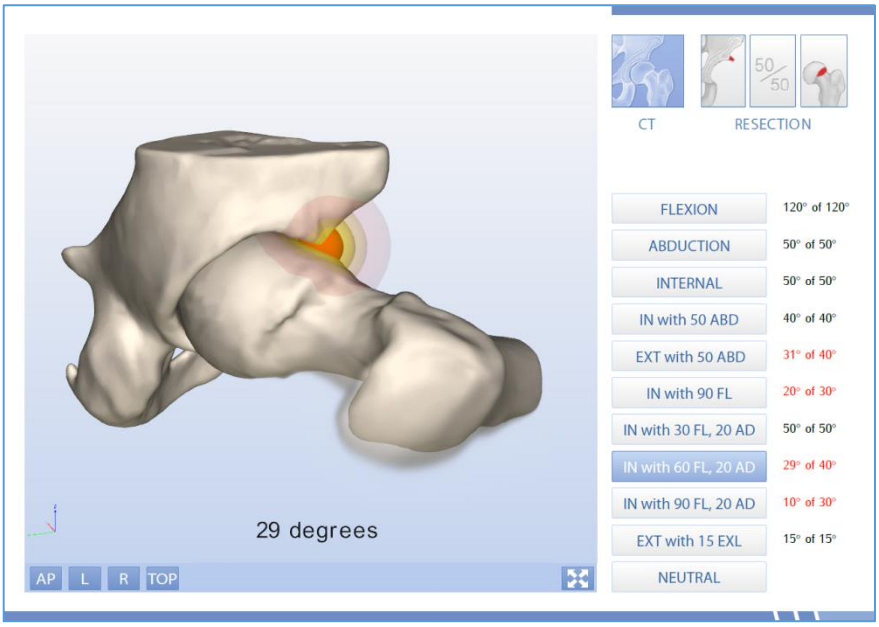
Move Forward™ 3D Motion Simulation Service

USER MANUAL



Move Forward™ 3D motion simulation service

This manual explains how to use the Move Forward 3D Motion Simulation Service and explains what can be seen in the Move Forward 3D motion simulation reports.

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1. General Aspects

1.1. Introduction

All users should read this manual completely. Experienced users can go directly to the sections of the information they need. Improvements and changes to this manual necessitated by typographical errors, inaccuracies of current information, or improvements to programs/equipment may be made by Biomet at any time and without notice. This manual is published by Biomet without any warranty.

1.2. Icons

In this manual the following icons are used:

Manufacturer

Warning! Read instructions for use

Read instructions for use

CE-mark

1.3. Warnings before Use

Please carefully read the following warnings before using the Move Forward 3D motion simulation service.

The Move Forward 3D motion simulation reports are intended for clinical experts only. The reports are computed using analysis software and represent a simplified model of clinical reality. The Move Forward 3D motion simulation reports are not intended as a replacement for established methods used for the diagnosis and evaluation of pathologies and/or injury. Medical and health care providers should exercise their own independent clinical judgement.

The motion simulations of the Move Forward 3D motion simulation service only take into account rigid shapes such as bones and prosthesis components. Soft tissues are excluded from the simulations. Therefore, simulation results are to be considered a conservative estimate, possibly underestimating the extent of motion limitations.

Immediately stop using the Move Forward 3D motion simulation reports if the 3D viewer does not function well or does not activate and call for support via support@clinicalgraphics.com.

It is strongly recommended that users protect against malicious software by installing an up-to-date, reputable antivirus protection and firewall product. Zimmer Biomet takes no responsibility for malicious activity that may result from lack of current, appropriate IT security practices.

1.4. Contraindications

The Move Forward 3D Motion Simulation Service cannot be used for patients who have had previous hip surgeries that include the placement of metal components and for patients with severe arthritis.

1.5. Prerequisites

1.5.1. Internet Connection and Browser

The Move Forward 3D Motion Simulation Service is an online service so you need an internet connection to use the Move Forward 3D motion simulation service.

Although you can also use our website on any of the following internet browsers such as Google Chrome version 52.0 or newer, Mozilla Firefox version 30.0 or newer, Safari version 7.0 or newer, Internet Explorer version 10.0 or newer, and Microsoft Edge version 19.0 or newer, we strongly recommend using Google Chrome as it offers convenient functionality that makes uploading the image data easier.

1.5.2. Image Requirements

The Move Forward 3D Motion Simulation Service is based on either CT-scans or MRI-scans acquired in accordance with our predefined imaging protocols. The CT- and MRI scanning protocols for use of the Move Forward 3D Motion Simulation Service can be requested via support@clinicalgraphics.com. If you are unsure whether the service can be used for the analysis of the images of your patient, please contact support at support@clinicalgraphics.com.

Clinical Graphics reviews each and every image, and reserves the right to reject received images even after the trial period, based on review. Users of the Clinical Graphics' Move Forward 3D motion simulation service are responsible for verifying the quality of imaging sent to Clinical Graphics.

1.5.3. PDF Viewer

To view the Move Forward 3D motion simulation reports you need to have Reader 10.0 or newer installed on your computer. Adobe Reader can be downloaded free of charge at http://get.adobe.com/reader. Please note that Apple computers are shipped with a PDF reader that is not suitable for interactive 3D-PDF files. If you have an Apple computer, you have to install Adobe Reader to view our PDF/FDF files.

Other PDF-readers than Adobe Reader do not support the 3D motion view in the Move Forward 3D motion simulation reports.

1.6. Information security

When uploading image data to our online platform the files are automatically anonymized on **your** end of the connection. Our online platform removes all information that can be used to identify the patient, as defined by HIPAA regulatory requirements. All files are then encrypted and transferred via a secure SSL connection.

Biomet warrants you that the provision of image data via the online platform will occur via an encrypted connection and that this transfer will meet the highest safety standards. Biomet anonymizes your image data before it is uploaded. In order to analyze your image data, Biomet will store it for a minimum period of 30 days. After the 30 day period no guarantee is given that the image data is still available for (re-)processing. PDF reports are available through the online platform for a period of at least 12 months.

When you upload a scan you are asked to fill out a unique order reference that you can use to identify the patient, but that has no meaning for anyone outside of the organization. Please do not use privacy sensitive patient data such as names.

1.7. Ready to get started?

Before you can make your first analysis request a personal Biomet account must be created. If you have not yet received your personal account details, please send us an email at support@clinicalgraphics.com and we will create the account immediately.

Once you have your personal account details you can start the process. To place a request (order) and upload the image data, either follow the 'Tour' (available via your Lightbox) or follow the illustrated steps on the following pages.

The Lightbox is your central overview page that you will see directly after you've signed in to your account (See Figure 1). The Lightbox lists your order requests (jobs) and their status.

The Lightbox is also the place you can download your reports once they are available.

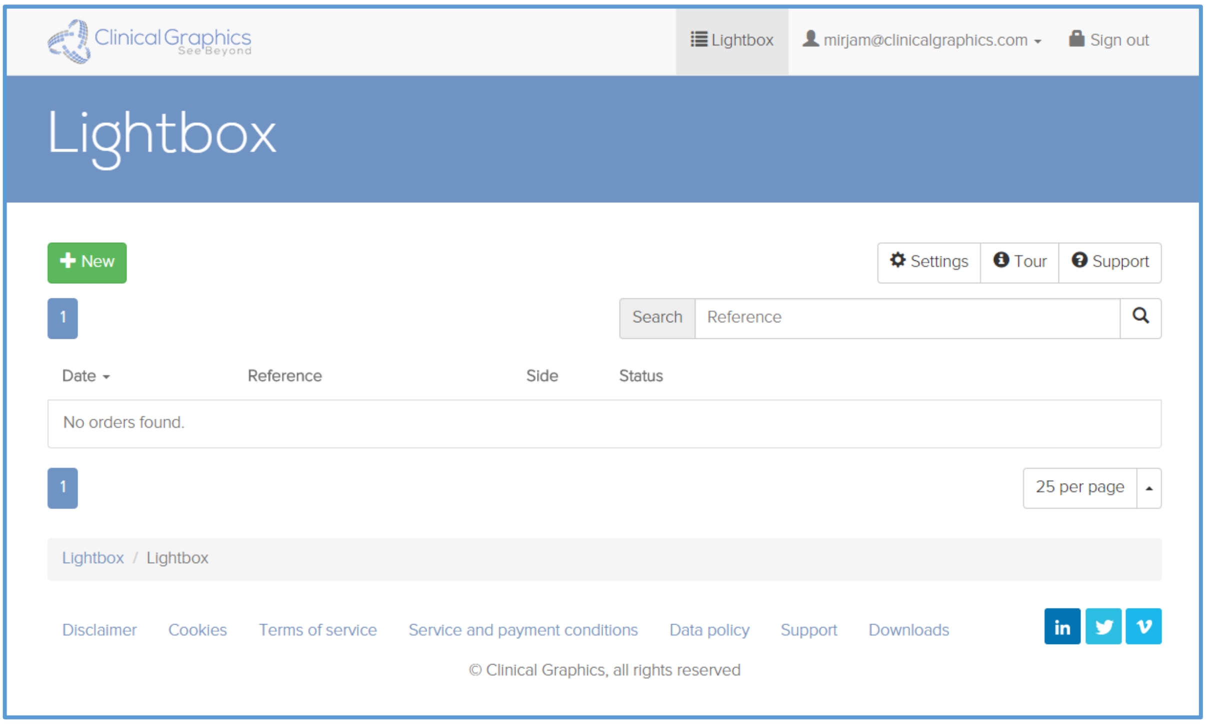


Figure 1 The Lightbox

2. Requesting a Move Forward 3D Motion Simulation Report

1. Log in to our website

Browse to www.clinicalgraphics.com, then press the green **LOGIN FOR PROFESSIONALS** button (See Figure 2).

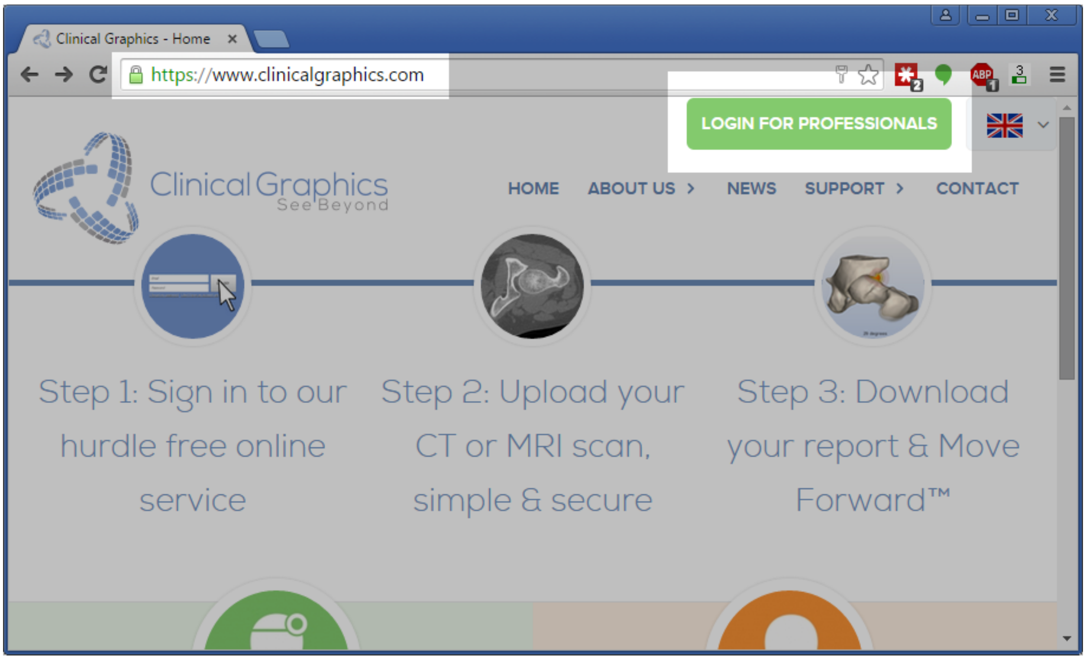


Figure 2 Login button

Now enter your personal account login details (email and password) and click on 'Sign in' (Figure 3).

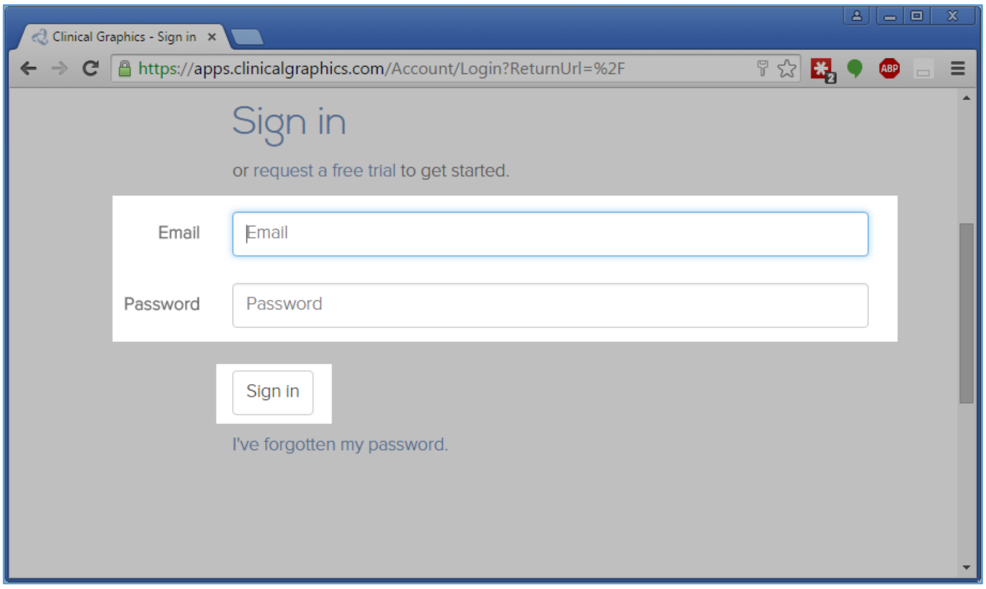


Figure 3 Here you can enter your login details

2. Create an order

Press the '+ New' button (See Figure 4).

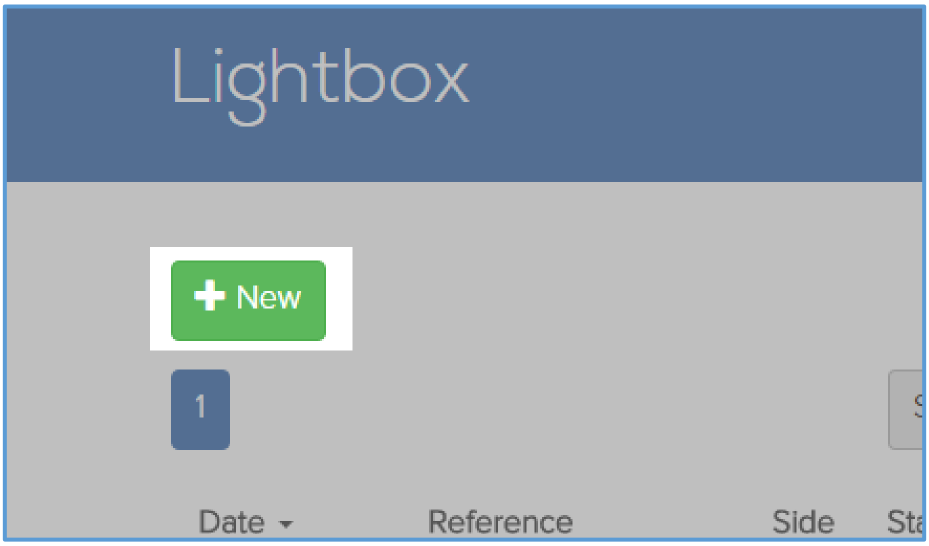


Figure 4 The New button

You will now be presented with a screen where you can enter the specifications of your order (See Figure 5). This will allow you to place request for a colleague, for example.

Select the **Organization** of the Physician who made the request, then select the name of the **Physician**. This will ensure the analysis report is delivered to the requesting physician.

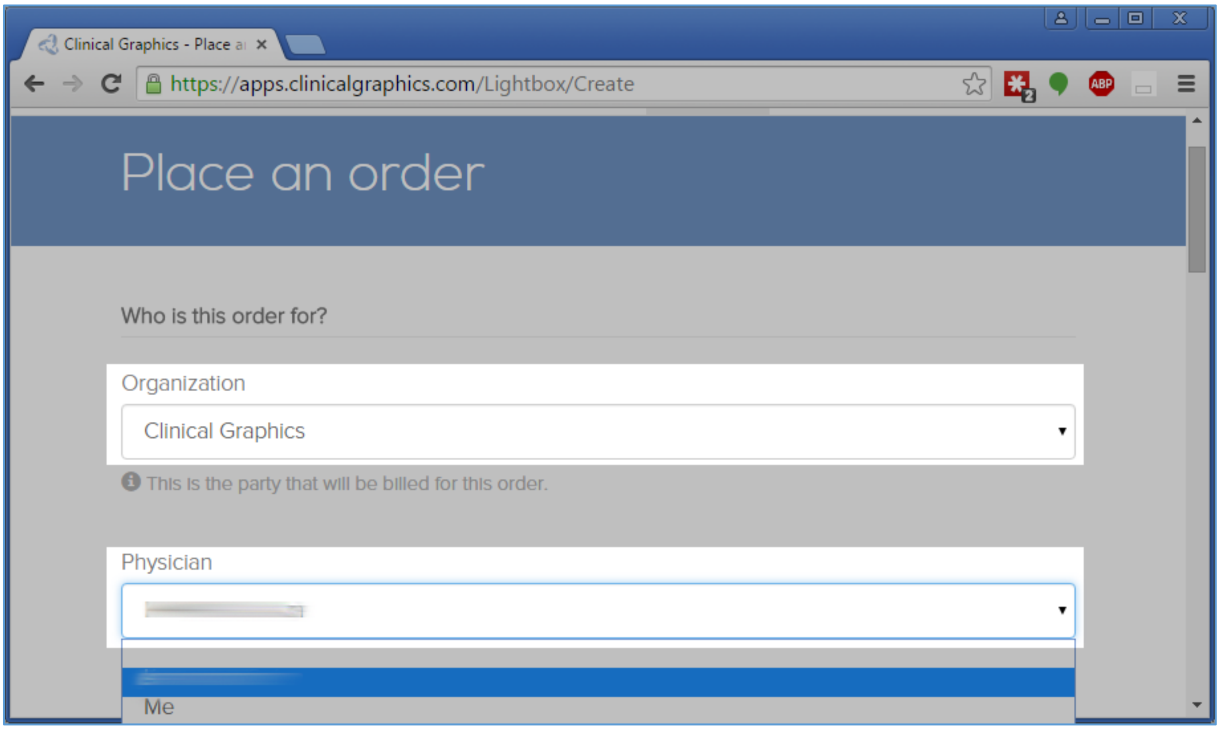


Figure 5 Here you can enter whose request this is

Subsequently enter the details of the request. This would typically include the service type, the joint side that should be analyzed and the image modality (CT or MRI) you are going to upload (See Figure 6).

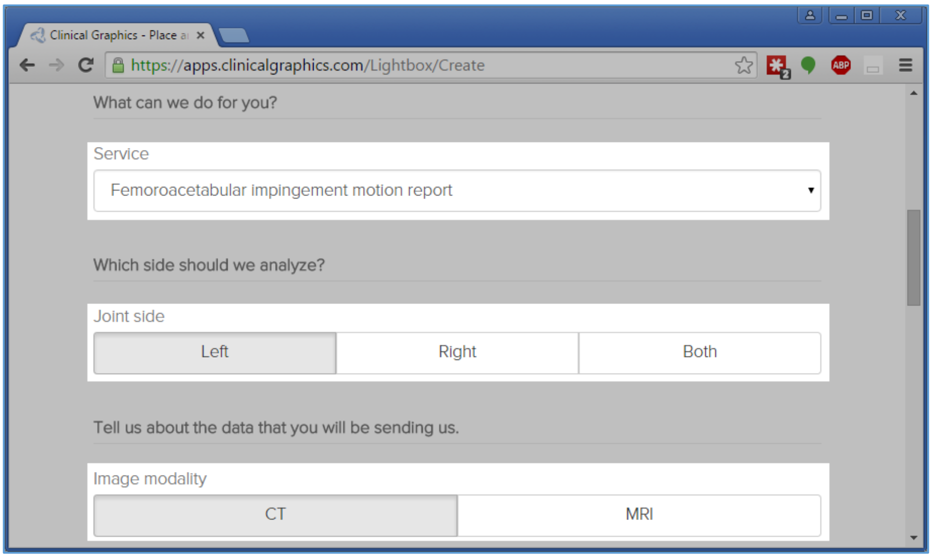


Figure 6 Details on your request can be entered here

Finally, please choose a reference that you can use to identify the patient, but that has no meaning for anyone outside of the organization the request is for, and fill it out at 'Your reference' (See Figure 7) . Typically internal patient IDs are suitable, or birthdates and initials (e.g. 'AB01011999').

Never use privacy sensitive patient data such as names.

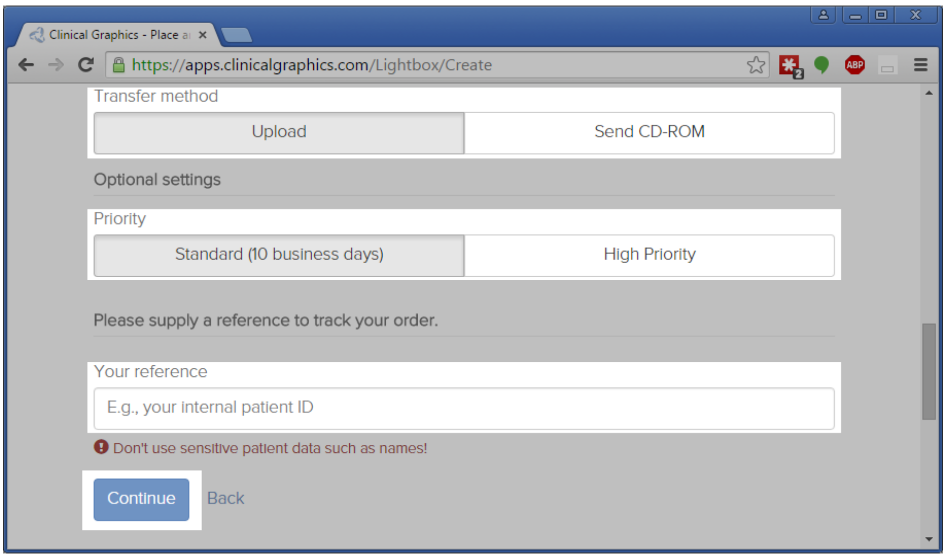


Figure 7 Details on your request can be entered here

Upon confirming your order in the next screen, you will be ready to upload the image data.

3. Upload the image data

You will now be presented with the screen that allows you to upload your DICOM data (See Figure 8). You can either press the 'Upload files' button or drag and drop files in the rectangular area (green arrow).

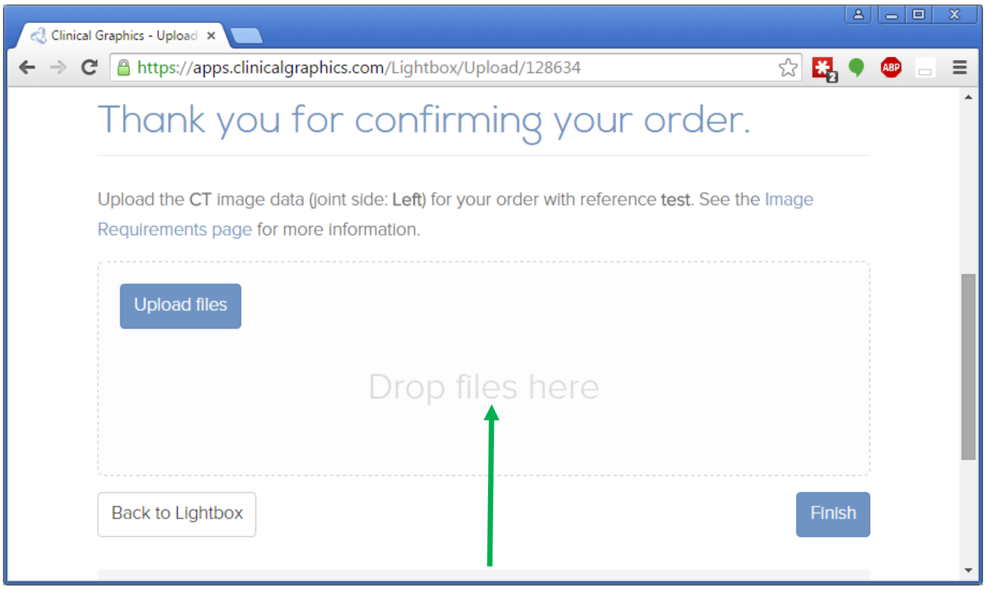


Figure 8 The file uploader

If you do not know where your DICOM files are, but you do have a CD-ROM, it is possible to let the website explore the CD-ROM and find the files. This is only possible when using the internet browser **Google Chrome**. To do so, browse to your CD-ROM drive and open it so that you can see what files are on the CD-ROM (See Figure 9). Now drag and drop all of the visible folders to the rectangular area of the website. Google Chrome will explore those folders and their subfolders to locate DICOM files. It will then start uploading the DICOM files.

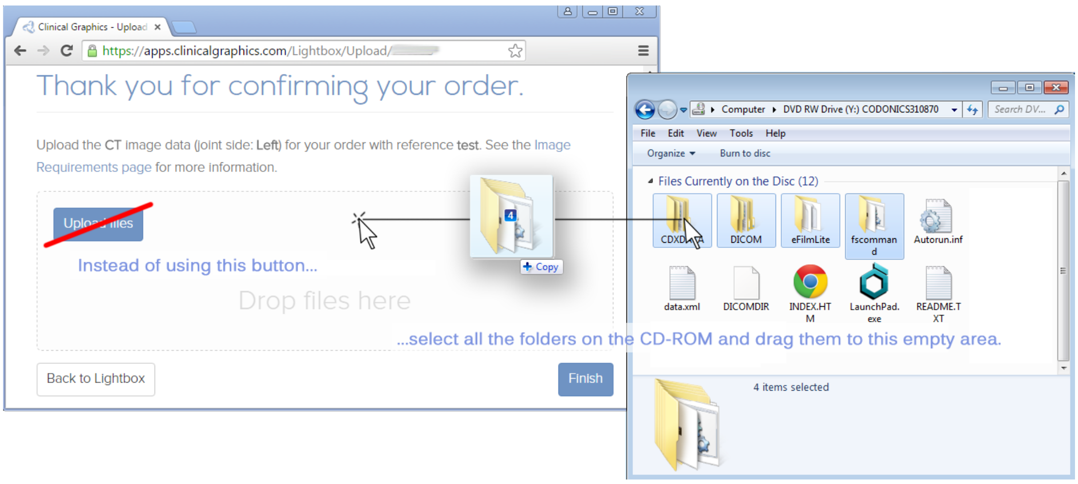


Figure 9 You can drag and drop files using Google Chrome

2.1. What happens after you have placed a request?

When you've successfully created an order and uploaded your image data, you will receive an automatically generated order confirmation via email that tells you that we're on the move.

Within a maximum of 10 working days the Move Forward 3D motion simulation report will be ready and it will be available via our secure web platform.

You will again receive an automatically generated email with a secured link to download the report.

3. Viewing the Move Forward 3D Motion Simulation Reports

3.1. PDF Viewer

To view the Move Forward 3D motion simulation reports you need to have Reader 10.0 or newer installed on your computer. Adobe Reader can be downloaded free of charge at http://get.adobe.com/reader. Please note that Apple computers are shipped with a PDF reader that is not suitable for interactive 3D-PDF files. If you have an Apple computer, you have to install Adobe Reader to view our PDF/FDF files.

3.2. Summary Page

On page 1 you will find your order details and a summary of the report.

3.3. 3D Viewer

Page 2 contains the 3D motion view. This 3D viewer enables you to see the joint from all angles in 3D motion. Before you can use the 3D viewer, you need to activate it.

3.3.1. Activation

To activate the 3D viewer open the Move Forward 3D motion simulation report and scroll to the 3D view on page 2 (See Figure 10). To activate the 3D view, click on the green activation button. The interactive view is now activated.

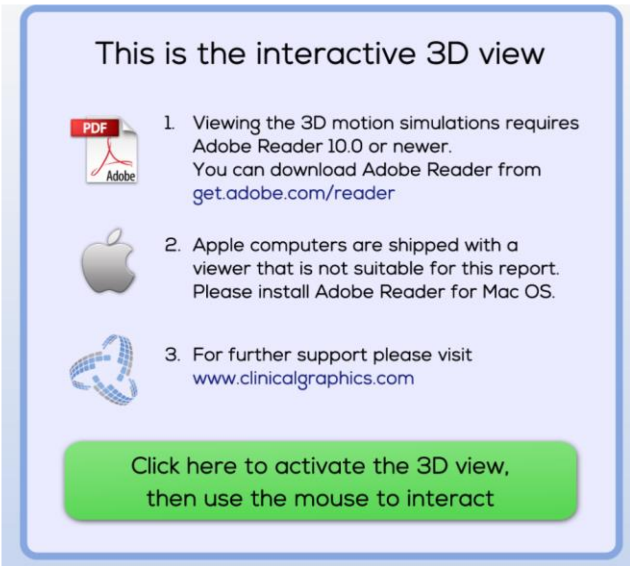


Figure 10 The 3D view activation window

If the 3D viewer is not working, please check if Adobe Reader version 10.0 or newer has been installed on your computer.

3.3.2. Camera interaction in the 3D View

There are several ways to change the camera view point (See Figure 11).

- To rotate the camera, click and hold the left mouse button anywhere in the blue area (e.g. the red dot). Drag towards any direction to rotate the viewpoint (e.g. the red arrow)
- At the bottom left there are four buttons: AP, L (LEFT), R (RIGHT) and TOP, corresponding with the viewpoint they represent. The MAXIMIZE VIEWPORT button can be used to enlarge the 3D viewer to fit the size of your screen

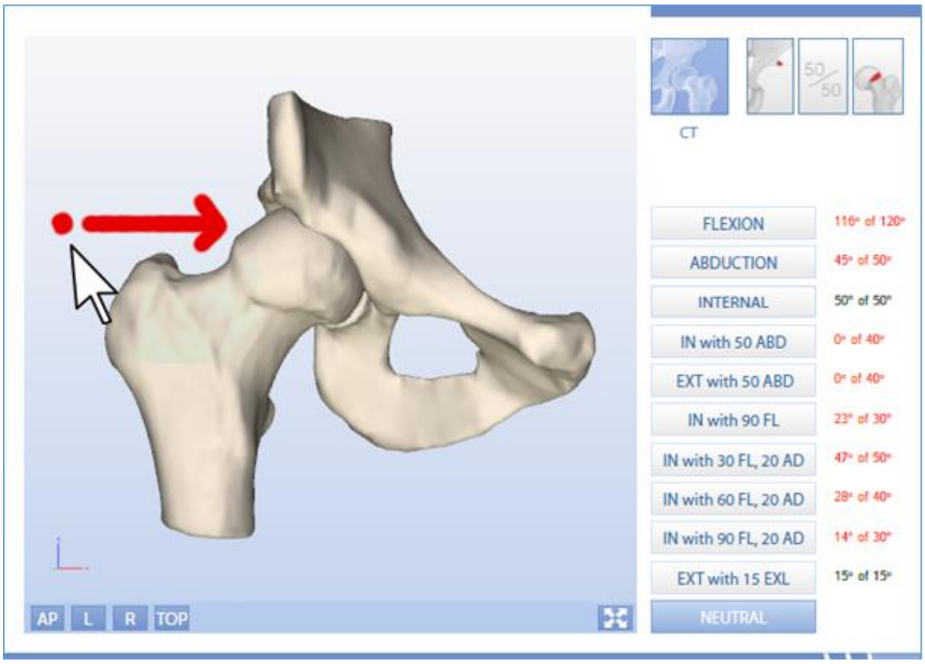


Figure 11 Camera interaction

If the image modality button has been selected (see selected CT button in blue in Figure 11) you are looking at the scan image.

In this example (see Figure 11) you are looking at a 3D bone model reconstructed from a CT-scan. If this was a MR-based report the first button would have been named ‘MR’.

3.3.3. 3D Motion simulations

Reports contain 10 different 3D motion simulation tests, ranging from basic flexion to complex combined motion patterns.

On the right of the viewer you will see, from top to bottom, the buttons to start the motion simulations (See

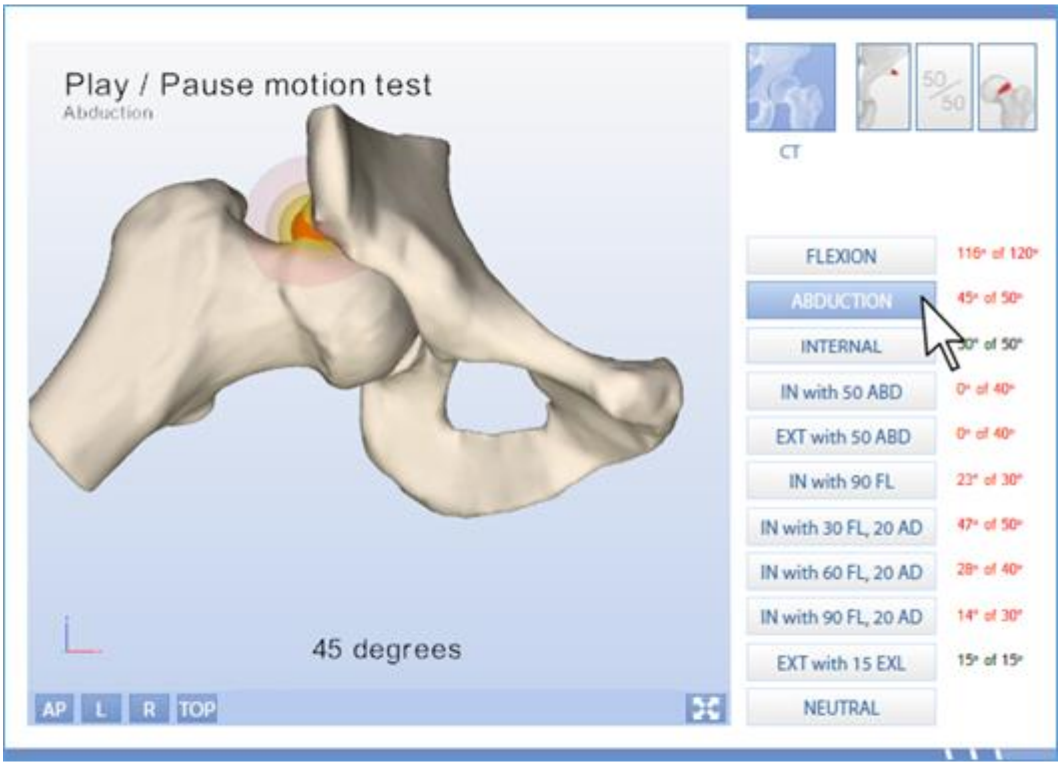


Figure 12). Each button represents a motion pattern. If you click on one of the buttons the respective motion pattern will be played. You can pause playback by pressing the same button a second time.

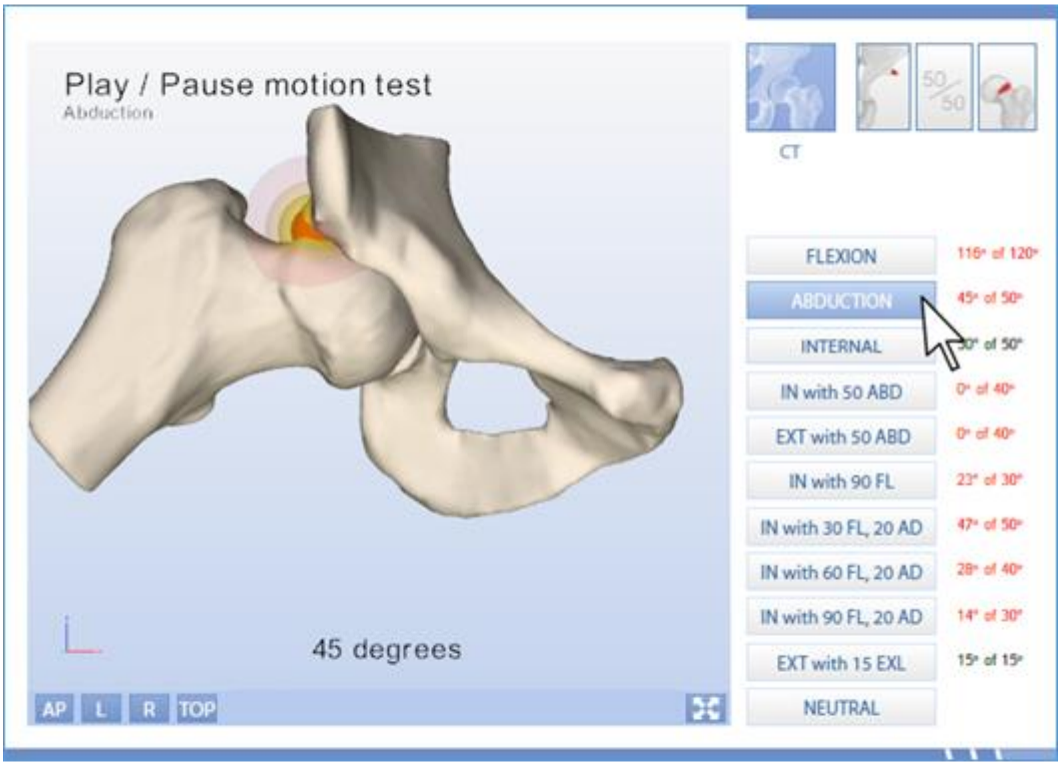


Figure 12 Motion simulation buttons

The exact points of bone on bone contact are highlighted in the report when playing the motion simulation tests (See Figure 12).

Example: The abduction motion test button in Figure 12 plays the range of motion test of this joint. The test is executed until 50 degrees of abduction is reached, which approximates the average range of motion of an asymptomatic adult hip. However, the test encounters a motion limitation at 45 degrees of abduction (see the first value in red next to the arrow).

The definitions of the individual motion tests are described in Table 1.

3.3.4. Range of motion target end points

The target end points for each of the motion tests were derived from the range of motion analysis of 81 asymptomatic adult hip joints (42 male, 39 female). A study report can be requested by contacting the support team at support@clinicalgraphics.com. For each motion test the average range of motion was determined and rounded to a multiple of 10.

Because the motion simulations do not take into account soft tissue constraints there are four motion tests for which the target end points have been further limited. These motion tests and reduced target end points are:

- Internal Rotation: reduced target of 50°
- Internal Rotation with 50 degrees of Abduction: reduced target of 40°
- External Rotation with 50 degrees of Abduction: reduced target of 40°
- Extension with 15 degrees of External Rotation: reduced target of 15°

Motion simulations beyond these end points appear unrealistic and may erroneously raise a concern of joint hypermobility, which is beyond the capabilities of the motion simulation software.

Table 1 Motion Tests and their range of motion targets.

Button label	Motion test	Range of motion target end points
FLEXION	Flexion	120°
ABDUCTION	Abduction	50°
INTERNAL	Internal Rotation	50°
IN with 50 ABD	Internal Rotation with 50 degrees of Abduction	40°
EXT with 50 ABD	External Rotation with 50 degrees of Abduction	40°
IN with 90 FL	Internal Rotation with 90 degrees of Flexion	30°
IN with 30 FL, 20 AD	Internal Rotation with 30 degrees of Flexion and 20 degrees of Adduction	50°
IN with 60 FL, 20 AD	Internal Rotation with 60 degrees of Flexion and 20 degrees of Adduction	40°
IN with 90 FL, 20 AD	Internal Rotation with 90 degrees of Flexion and 20 degrees of Adduction	30°
EXT with 15 EXL	Extension with 15 degrees of External Rotation	15°
Neutral	Return to the Neutral Position	-

3.3.5. Intersection zones

When simulated motion is limited, the Move Forward 3D motion simulation report provides intersection zones that show you which areas of the bones overlap at the end points of the motion tests.

To see the intersection zones, press the buttons in the top right corner (see Figure 13). There are three buttons:

1. The button on the right (see arrow Figure 13) shows you the intersection zone of the femur.
2. The button on the left shows you the intersection zone of the acetabulum.
3. The center button labeled as 50 / 50 shows you 50% of the intersection zone of the femur and 50% of the intersection zone of the acetabulum.

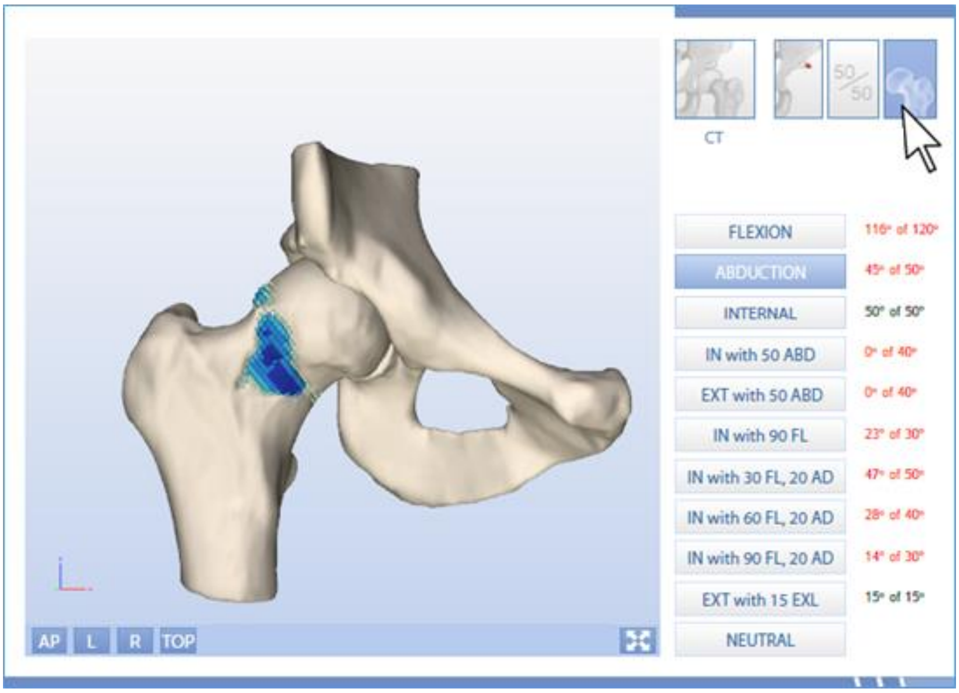


Figure 13 Intersection zone visualization

When an intersection zone visualization is activated the motion simulations are updated to show you the range of motion of the joint <u>without</u> the intersection zone. You can then verify that the full range of motion can be reached for a configuration without the highlighted intersection zone.

The intersection zones are visualized using different colors that represent how deep an intersection zone is in a particular area. The darker the spheres the deeper the intersection zone is, in accordance with the color scheme in Figure 14.

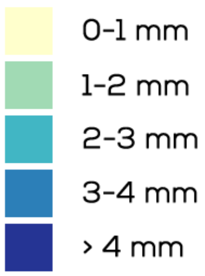


Figure 14 Color schemes for intersections

Pressing an intersection zone button for a second time causes the zone depth visualization to disappear. You will now be able to see the bones without the intersecting zones of the bone. Pressing the button a third time causes the visualization to reappear (See Figure).

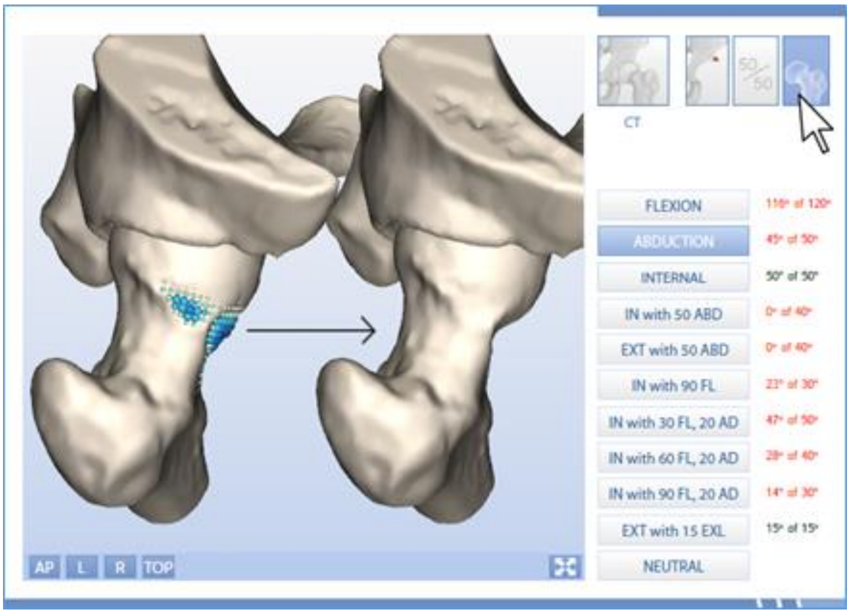


Figure 14 Clicking the button twice shows you the post-intersection shape of the bone

The visualization of the intersection zones and their 3D motion simulations should not be interpreted as an instruction to remove specific areas of bone in a surgical procedure.

3.4. Morphological Analysis

The remaining pages of the report contain several morphological parameters which were calculated by the image analysis software. Because there are multiple ways by which some of these parameters can be defined this section explains the general working of the morphological analysis algorithms.

3.4.1. Femoral head diameter

The femoral head diameter is calculated by mathematically fitting a sphere to the proximal part of the femur.

3.4.2. Femoral neck diameter

The femoral neck diameter is calculated by mathematically fitting a diagonal cylinder to the proximal part of the femur.

3.4.3. Neck inclination

The femoral neck inclination is calculated as the angle between the femoral neck line and the femoral shaft line. These lines are determined by finding the narrowest parts of the femoral neck and proximal femoral shaft.

3.4.4. Clockwise alpha angles

The report includes a total of 7 clockwise alpha angles. ‘Clockwise’ means that we calculate the alpha angle for multiple planes that are oriented clockwise around the femoral neck. In our reports we include 7 of these ‘hours’, i.e. 7 planes for which we calculate the alpha angle: 9, 10, 11, 12, 1, 2 and 3 o’clock.

Alpha angles are calculated by mathematically fitting a sphere to the femoral head. For each of the clockwise planes intersections with this sphere provide a circle. The angle is calculated at the center of the circle, its two legs formed by the neck line and the line between the center of the circle and the point where the femoral head contour leaves the circle. This latter point has a detection threshold, which is configured at 1.0 mm. In practice this means that bumps of the femoral head are not detected when they are lower than 1.0 mm.

Inherent to how the alpha angle is calculated a high or low alpha value may be picked up by the software, depending on the height of local 'bumps' at the bone surface. The algorithm has been configured to detect bumps that are higher than 1 mm. Bumps that are lower than 1 mm will not lead to an elevated alpha angle.

3.4.5. Femoral neck version

Femoral neck version (femoral torsion) is calculated as an angle between the femoral neck line and the line between the distal femoral condyles, projected in a plane perpendicular to the femur's long axis.

3.4.6. Acetabular coverage

Acetabular coverage is calculated in accordance with the method presented by Dandachli 2008: Dandachli, W., Kannan, V., Richards, R., Shah, Z., Hall-Craggs, M., Witt, J., 2008. Analysis of cover of the femoral head in normal and dysplastic hips: New CT-based technique. J Bone Joint Surg Br 90-B, 1428–1434. The method projects the circular area of the femoral head upwards. Areas of the circle that 'hit' the acetabular roof count towards the coverage surface area. The coverage percentage is the amount of covered area divided by the total circular area of the femoral head. The Anterior Pelvic Plane through the centers of the femoral heads determines what is considered posterior and anterior.

3.4.7. Lateral center edge (LCE) angles

The report includes a total of 3 clockwise LCE angles. 'Clockwise' means that we calculate the LCE angle for multiple planes that are oriented clockwise around the femoral neck. In our reports we include 3 of these 'hours', i.e. 3 planes for which we calculate the LCE angle: 11, 12 and 1 o'clock.

For each clockwise plane the lateral center edge angle is defined by a straight line upwards through the center of the femoral head and a second line through the center of the femoral head, passing through the most superolateral margin of the acetabulum.

3.4.8. Sourcil angle

The Sourcil angle evaluates the inclination of the acetabular roof. The 'acetabular sourcil' is referred to as the sclerotic weight-bearing portion of the acetabulum. The angle is defined by two lines on the AP pelvic plane. The first line is a line parallel to the horizontal axis of the pelvis running through the most inferior point of the sclerotic acetabular sourcil. The second line is a tangential line extending from the medial to lateral edges of the sclerotic acetabular sourcil.

3.4.9. Acetabular version

Acetabular version is defined by a line perpendicular to the horizontal axis of the pelvis and a second line that connects the posterior and anterior wall of the acetabulum. In the report this parameter is calculated at the center level of the femoral head sphere and at a 2nd level halfway between the femoral head center and the acetabular roof.

4. Performance

The Move Forward 3D Motion Simulation Service is provided via proprietary image analysis software operated by our production staff. Staff members monitor and correct the virtual bone morphology (i.e. 3D models) as generated by the software based on the provided image data. As part of this process local deviations of the virtual bone morphology relative to the true physical bone morphology may occur. Below you will find a summary of the effect of these deviations on the performance of the software.

4.1. Performance using a Physical Phantom

By using a physical anatomical phantom a 3D dataset was generated that is exempt from imaging artifacts and subjective interpretation of the images. The physical phantom contained a gel that mimics soft tissue and cadaveric pelvis and femur bones. The bones were digitized using a high-resolution laser scanner (Argon ATOS triple scan 16M). The phantom was scanned in a CT-scanner (Toshiba Aquilion ONE ViSION) and two MRI-scanners (MRI-scanner 1: Philips Achieva 3.0T, MRI-scanner 2: GE Discovery MR750 3.0T). The software's output using these CT- and MRI-scans as input was compared to the algorithmic output using the laser scanned 3D models.

The performance test results are reported in Table 2.

Table 2 Performance test results of the anatomical phantom experiment. The anatomical phantom experiment mimics ideal circumstances leading to relatively small errors in the device outputs for the different modalities.

Output Parameter	*Maximum error for CT-Scan (Toshiba Aquilion ONE ViSION)*	*Maximum error for MRI-Scan (Philips Achieva 3.0T MRI-scanner)*	*Maximum error for MRI-Scan (GE Discovery MR750 3.0T MRI-scanner)*
Motion tests 1-10	*2°*	*3°*	*2°*
Intersection zone: 0.5 inch from the femoral head center	*0.4 mm*	*0.6 mm*	*0.4 mm*
Intersection zone: 1.0 inch from the femoral head center	*0.9 mm*	*1.3 mm*	*0.9 mm*
Femur head diameter	*1 mm*	*0 mm*	*0 mm*
Femur neck diameter	*1 mm*	*0 mm*	*0 mm*
Femur alpha angles	*3.4°*	*1.6°*	*1.7°*
Femur neck inclination	*0.9°*	*2.2°*	*2.7°*
Femur neck version	*1.1°*	*0.2°*	*1.9°*
Acetabular coverage	*0.4 %*	*0.0 %*	*1.1 %*
Acetabular cup diameter	*0 mm*	*1 mm*	*1 mm*
Center edge angles	*1.0°*	*1.1°*	*2.8°*
Sourcil angle	*1.9°*	*0.7°*	*0.8°*
Acetabular version	*0.7°*	*0.8°*	*1.8°*

4.2. Performance relative to Clinical Expert Segmentations

In a series of 10 CT-scans (Siemens SOMATOM Definition 64-slice CT-scanner), 10 MRI-scans (Philips Achieva 3.0T MRI-scanner) and 10 additional MRI-scans (Siemens MAGNETOM Skyra 3T MRI-scanner), the performance of the software and our production processes was evaluated relative to the segmentations corrected and approved by three clinical experts (orthopedic surgeons specializing in hip pathology).

Performance test results are reported in Table 3.

Table 3 Performance test results of the software and our production processes, relative to the software's output as generated from clinical expert segmentations, a delineation process that incidentally involves some level of subjectivity.

Output Parameter	*Maximum error for CT-Scans (Siemens SOMATOM Definition 64-slice CT-scanner, n=10)*	*Maximum error for MRI-Scans (Philips Achieva 3.0T MRI-scanner, n=10)*	*Maximum error for MRI-Scans (Siemens MAGNETOM Skyra 3T MRI-scanner, n=10)*
Motion tests 1-10	*10°*	*6°*	*4°*
Intersection zone: 0.5 inch from the femoral head center	*2.2 mm*	*1.3 mm*	*0.8 mm*
Intersection zone: 1.0 inch from the femoral head center	*4.4 mm*	*2.6 mm*	*1.8 mm*
Femur head diameter	*1 mm*	*1 mm*	*0 mm*
Femur neck diameter	*1 mm*	*0 mm*	*0 mm*
Femur alpha angles	*9.4°*	*9.8°*	*9.3°*
Femur neck inclination	*0.4°*	*1.6°*	*5.0°*
Femur neck version	*0.5°*	*1.2°*	*1.6°*
Acetabular coverage	*0.6 %*	*1.0 %*	*0.8 %*
Acetabular cup diameter	*1 mm*	*1 mm*	*1 mm*
Center edge angles	*3.2°*	*3.3°*	*4.3°*
Sourcil angle	*3.0°*	*1.6°*	*1.0°*
Acetabular version	*1.7°*	*2.5°*	*4.4°*

4.3. Performance of 3D Motion Simulations in Cadaver Experiments

In a cadaveric study the performance of the 3D motion simulations was evaluated. The range of motion of five cadaveric hips was recorded using an electromagnetic tracking system. Upon modification of the hip joints a total of 13 of 30 recorded range of motion end-points were restricted by more than 5°. The software detected 12 of these 13 end point limitations and detected no false positives. The undetected end point limitation was caused by tension of the soft tissues, which is outside the capabilities of the 3D motion simulation software. The median error of the detected end point limitations was 1.9° (interquartile range 1.1° - 4.4°). The maximum absolute error was 5.4°. This study was published in *Röling, Maarten A., et al. "A quantitative non-invasive assessment of femoroacetabular impingement with CT-based dynamic simulation - cadaveric validation study." BMC musculoskeletal disorders 16.1 (2015): 50.*

5. CT Protocol

Version 1.4

5.1. Introduction

To use the Move Forward 3D motion simulation service you need a CT or MRI-scan acquired in accordance with our predefined protocols. This document describes the MR protocol required to perform Move Forward 3D motion analysis.

5.2. Why do we need this protocol?

Two aspects of the CT scan are important for the Clinical Graphics' Move Forward 3D motion simulation service:

1. Detailed imaging of bone in the joint area.
2. Morphological context: how are the acetabulum and femoral head oriented relative to the remainder of the bones?

5.3. Patient preparation

We require the patient to be in a supine position. Legs should be parallel in a neutral position. Please instruct the patient to lie still during the scan. The foot, knee and hip must be properly immobilized and therefore not allow movement during the entire scan.

5.4. Series

Below we have provided a description of the series required for our service.

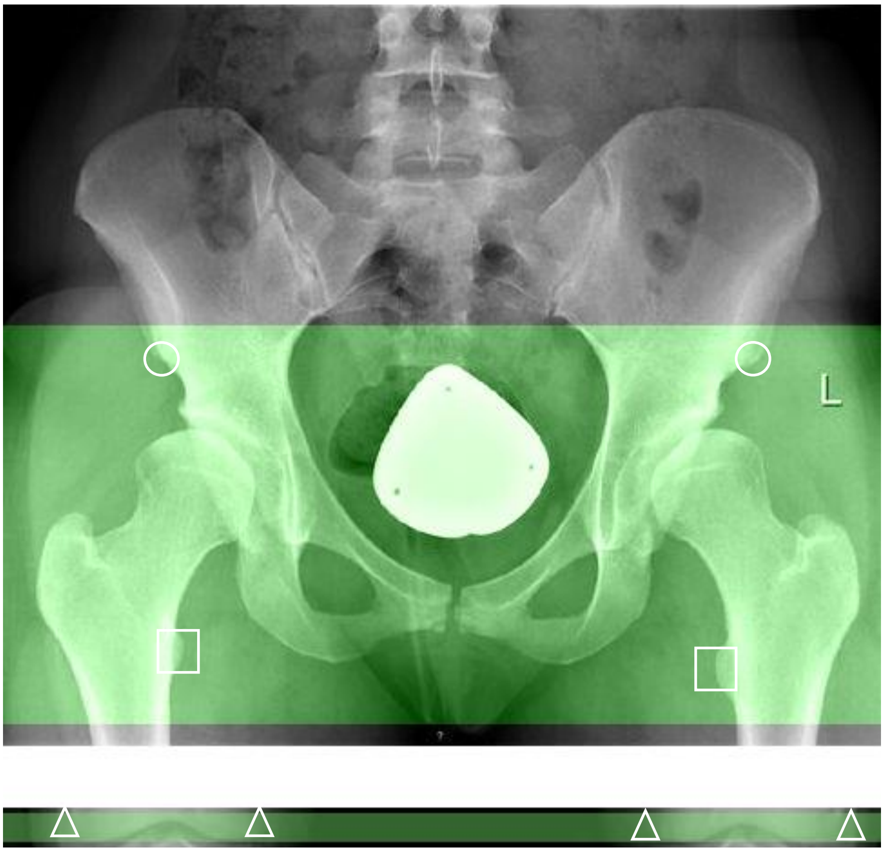
5.4.1. Pelvis

Reconstruction:	Transversal/Axial
Scan area:	Pelvis visible with both the **anterior superior iliac spine landmarks** (ASIS) as the upper limit (+0.5 cm, please make sure the actual bone protrusion is clearly visible). Proximal femur visible with the **trochanter minor** as the lower limit (again +0.5 cm, please make sure the actual bone protrusion is clearly visible).
Resolution:	Slice thickness of 1.0 mm or smaller and an in-slice resolution of 0.7 x 0.7 mm.
Kernel:	Standard "body" or "bone".

5.4.2. Knees

Reconstruction:	Transversal/Axial (acquired immediately after Series 1, without moving the patients' legs)
Scan area:	10 slices at the level of the knee epicondyles.
Resolution:	Slice thickness of 1.0 mm or smaller and an in-slice resolution of 0.7 x 0.7 mm.
Kernel:	Standard "body" or "bone".

5.4.3. Example image of the required scan area in green



Example of scan area. The circles depict the Anterior Superior Iliac Spine (ASIS) points. The Squares show the Trochanter minor, and the triangles are where the epicondyles can be found.

5.4.4. Example of DICOM image Meta data

0018,0022	Scan Options:	HELICAL MODE
0018,0050	Slice Thickness:	1.000000
0018,0060	kVp:	120
0018,0090	Data Collection Diameter:	500.000000
0018,1100	Reconstruction Diameter:	349.000000
0018,1110	Distance Source to Detector:	949.075012
0018,1111	Distance Source to Patient:	541.000000
0018,1120	Gantry/Detector Tilt:	0.000000
0018,1150	Exposure Time:	800
0018,1151	X-ray Tube Current:	204
0018,1152	Exposure:	2
0018,1160	Filter Type:	BODY FILTER
0018,1210	Convolution Kernel:	BONEPLUS
0028,0010	Rows:	512
0028,0011	Columns:	512
0028,0030	Pixel Spacing:	0.681641\0.681641

6. MRI Protocol

6.1. Introduction

To use the Move Forward 3D motion simulation service you need a CT or MRI-scan acquired in accordance with our predefined protocols. This document describes the MR protocol required to perform Move Forward 3D motion analysis.

6.2. Why do we need this protocol?

Two aspects of the MRI scan are important for the Clinical Graphics' Move Forward 3D motion simulation service:

3. Detailed imaging of bone in the joint area.
4. Morphological context: how are the acetabulum and femoral head oriented relative to the remainder of the bones?

6.3. Patient preparation

We require the patient to be in a supine position. Legs should be parallel in a neutral position. Please instruct the patient to lie still during the scan. The foot, knee and hip must be properly immobilized and therefore not allow movement during the entire scan.

6.4. Magnet strength

The MRI-scanner should have a magnet with a strength of 3 Tesla.

6.5. Frame Of Reference

The sequences should be acquired with an identical *Frame Of Reference*.

The Region of Interest (ROI) should incorporate both the hip and the knee area. By including both in the same ROI we make sure the image coordinates of the two sequences relative to each other are correct. In other words: the knee images will be located between 30 and 50 cm below the hip images, depending on the length of the femur.

6.6. Sequences

6.6.1. Overview

A total of 3 sequences are required. They must all be provided in the axial/transverse image plane. The detailed hip joint sequence (A) should include at least the AIIS point down to and including the trochanter minor.

Sequence	What do we want to image?
A. Detailed hip joint (unilateral)	The bone morphology of the femoroacetabular joint
B. Context pelvis (bilateral)	The morphological context of the acetabulum
C. Context knee (uni- or bilateral)	The morphological context of the proximal femur

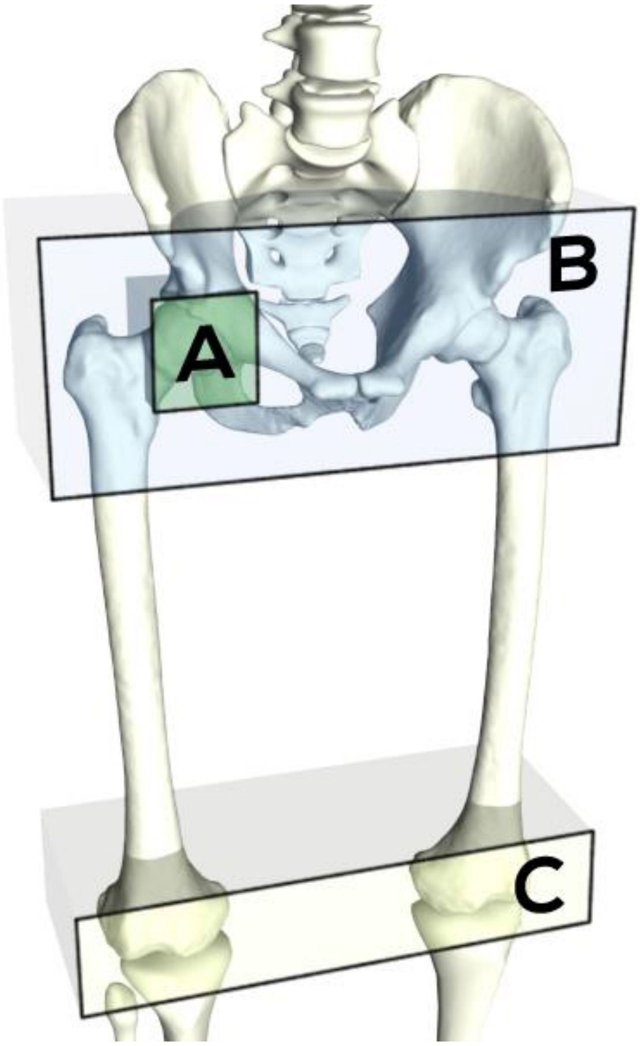


Figure 15 Sequences of the MR protocol.

6.6.2. Sequence A: The detailed hip joint sequence

Sequence A is a high resolution volumetric fast-spin gradient echo sequence. This type of sequence is branded differently per manufacturer. Examples are:

- Philips THRIVE sequence.
- Siemens VIBE sequence.
- GE LAVA sequence.
- Toshiba QUICK 3D sequence.

The sequence should be capable of producing high resolution slices with a thickness of 1.0 mm with a sharp contour that separates bone and surrounding tissue in the joint area (see Figure 2 for example images).

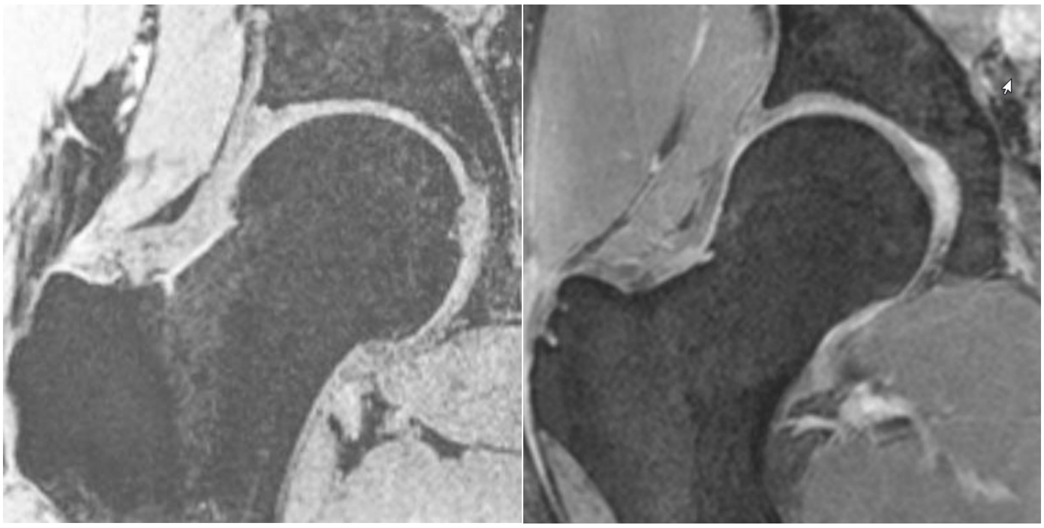


Figure 16 Philips Achieva THRIVE sequence (left) and Siemens Skyra VIBE sequence (right). These sequences have an isotropic resolution of 1.0 mm, providing great detailed images of the hip joint.

Coil

The Lower Limb coil or comparable is required.

Setup

- The THRIVE, VIBE, LAVA or QUICK 3D sequence should be used.
- The images should have an isotropic resolution of 1.0 mm x 1.0 mm x 1.0 mm or higher.
- The anterior inferior iliac spine anatomical landmark should be visible in the scanned region.
- The lesser trochanter should be visible in the scanned region.
- The pubic tubercle should be visible in the scanned region.
- The posterior acetabulum wall should be visible in the scanned region.

6.6.3. Sequence B: The pelvis context sequence

A separate image sequence that provides the pelvis context is required. This pelvis sequence can be of low resolution and is required to measure acetabular version and inclination. The pelvis sequence can either be a T1 or T2 sequence.

The anterior superior iliac spine (ASIS) anatomical landmarks should be visible.

Coil

The Integrated Spine or Body coil is required.

Setup

- The anterior superior iliac spine anatomical landmarks should be visible in the scanned region.
- T1 and T2 sequences are acceptable.

6.6.4. Sequence C: The knee context sequence

A separate image sequence that provides the knee context is required. This knee sequence can be of low resolution and is required to measure femoral version. The knee sequence can either be a T1 or T2 sequence.

The knee epicondyles should be visible.

Coil

The Integrated Spine or Body coil is required.

Setup

- The knee epicondyles should be visible in the scanned region.
- T1 and T2 sequences are acceptable.

7. Support

If you have any questions or require support using the Move Forward 3D Motion Simulation Service, please do not hesitate to contact us at support@clinicalgraphics.com.

For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.Third party product names used in this document are for identification purposes only and are the property of their respective owners.