Instructions for Use

HipStudio Analysis

Document name	R-DND-034_Instructions for Use_HipStudio Analysis_INCL ANNEX
Version number	01
Version date	20260508

Table of Contents

1. Version History

Version	Date	Author	Summary of Changes	Sections
01	2026-05-08	Tim Van Cleynenbreugel	Initial version	All

2. Product Description

2.1 Intended Use and Indications for Use

HipStudio Simulation Service is a patient-specific report used to support orthopedic surgeons and other qualified healthcare professionals in pre-operative clinical decision-making. HipStudio Simulation Service provides a morphological analysis of a skeletally mature hip with potential Developmental Dysplasia of the Hip (DDH) or femoroacetabular impingement (FAI), including quantitative measurements, kinematic simulations, and visualizations that describe hip anatomy, femoral head coverage, range of motion, and impingement morphology.

2.2 Contraindications

The HipStudio Simulation Service should not be used in the following circumstances:

- Patient CT imaging data that does not meet Replasia's minimum imaging requirements as specified in the HipStudio Simulation Service CT Scan Protocol. Non-conforming scans may result in inaccurate measurements or unreliable simulations.
- Patients with significant structural hip deformity that precludes reliable generation of three-dimensional anatomical models from the submitted CT data.
- Patients who are pregnant. CT imaging is contraindicated in pregnancy.
- Patients for whom CT imaging is otherwise contraindicated.

2.3 Warnings

- **Clinical judgment required.** This report must be read and interpreted by a qualified physician. The physician must rely on their own independent professional clinical judgment when making diagnosis and treatment decisions. This report does not constitute a diagnosis, surgical instruction, or treatment recommendation.
- **Complement, not replace.** This report is intended to complement — and not replace — established clinical diagnostic methods and the independent clinical judgment of the treating physician.
- **Skeletally immature patients.** This report has not been validated for use in skeletally immature patients. It should not be used in patients who have not reached skeletal maturity.
- **Scan quality dependency.** The accuracy of all measurements and simulations is dependent on the quality and resolution of the submitted CT imaging data. Scans that do not meet the CT Scan Protocol requirements may result in inaccurate or unreliable outputs.
- **Bony anatomy only.** This report provides quantitative measurements and visualizations of bony hip anatomy only. The kinematic simulation is based exclusively on bone-to-bone contact and does not account for soft tissue structures including cartilage, labrum, ligaments, or periarticular muscles. Range of motion results should be interpreted as conservative estimates; actual functional range of motion may differ.

- **3D vs. 2D measurements.** Measurements in this report are derived from three-dimensional CT-based models and may differ from measurements obtained from two-dimensional radiographs or fluoroscopic images. Direct numerical comparison with radiograph-based reference values should be made with caution.
- **Patient-specific interpretation.** Patient-specific factors — including age, sex, body weight, physical condition, and ethnicity — should be considered when interpreting the analysis results.
- **Physician responsibility.** The physician retains full responsibility for all clinical decision-making and for the patient's surgical treatment.
- **Prescription only.** Federal law (USA) restricts this device to sale by or on the order of a physician.

2.4 Precautions

- The measurements and simulations in this report are based solely on the imaging data submitted for the case. Results reflect the anatomical state at the time of imaging and may not account for subsequent changes in the patient's condition.
- Reference ranges for morphological parameters are drawn from published literature as cited in the report. The physician should consider the source population and methodology of each reference when interpreting deviations from the stated normal range.

2.5 Legal Disclaimer

The HipStudio Simulation Service analysis report is generated by Replasia BV using proprietary software. This report provides an objective analysis of the medical images submitted by the ordering physician and does not contain clinical advice, judgment, recommendations, or interpretations of data. Replasia BV makes no representations or warranties regarding the fitness of this report for a particular purpose, its accuracy or completeness, or that it will be free from errors. Medical professionals must exercise independent clinical judgment when interpreting and using this report.

Replasia BV is not responsible for the use or implementation of this report or for any decisions based thereon, and cannot be held liable for any damages, whether direct, indirect, or consequential, resulting therefrom.

3. Service Overview

3.1 How to Use the HipStudio Simulation Service

The HipStudio Simulation Service is a physician-initiated service. The workflow from the physician's perspective is as follows:

Step 1 — Prepare and submit CT imaging data

Obtain a CT scan of the patient's pelvis and femurs in accordance with the HipStudio Simulation Service CT Scan Protocol (available at www.replasia.com/scanprotocols). Submit the DICOM imaging data, together with the required surgeon information (email, full name), and any specific case comments to Replasia via the secure file transfer portal at www.replasia.com/transfer.

Patient identifiers (name or initials, patient ID, date of birth, sex) should be retained in the DICOM files where possible, as these are extracted from the DICOM images and (after pseudonymisation) included in the report for case tracking and quality verification. After receipt, Replasia pseudonymizes the data before processing, and the original DICOM files containing full patient identifiers are deleted. If patient identifiers are replaced with a local identifier before submission, the physician must ensure that a reliable link between the submitted identifier and the correct patient is maintained in their own records.

Step 2 — Receive the analysis report

Replasia will process the submitted imaging data and deliver a structured PDF analysis report to the ordering physician within the agreed service turnaround time. The report will be made available via the same secure portal or by an agreed delivery method.

Step 3 — Review the analysis report

Open the PDF analysis report on a standard computer, laptop, or any device capable of rendering PDF documents. Read the report in conjunction with the patient's full clinical presentation, including history, physical examination findings, and other diagnostic information.

3.2 CT Scan Requirements

CT imaging data must be acquired in accordance with the HipStudio Simulation Service CT Scan Protocol. Key requirements are summarised below. The full protocol is available at www.replasia.com/scanprotocols.

Parameter	Requirement
Scanner type	Multi-detector row CT, ≥ 16 detector rows, helical mode
Preferred scan range	Complete pelvis including sacrum, and full bilateral femurs including condyles

Parameter	Requirement
Acceptable scan range	Complete pelvis including sacrum, proximal femurs ≥ 10 cm below lesser trochanter, and distal femurs ≥ 10 cm
Minimal scan range	Complete pelvis including sacrum, and bilateral proximal femurs ≥ 10 cm below lesser trochanter
Gantry tilt	None
Reconstruction	Axial images only; no MPRs or reformats
Kernel	Moderate / STANDARD / SOFT TISSUE (no edge enhancement or bone algorithm)
Slice thickness	Preferred: 1.00–1.50 mm | Acceptable: ≤ 3 mm
Slice increment	Preferred: 0.50–0.75 mm | Acceptable: ≤ slice thickness
Matrix	512 × 512
File format	Uncompressed original DICOM

Patient positioning: feet first supine, level pelvis, legs extended side-by-side, arms raised above the head or folded away from the pelvis. Remove all non-fixed metal items before scanning. Pregnancy is a contraindication to CT imaging.

4. Reading the Analysis Report

4.1 Report Structure

The HipStudio Simulation Service analysis report is a structured PDF document delivered bilaterally for the left and right hip. It contains the following sections:

Section	Content
Cover page	Case reference, patient reference, physician, report date
Case Overview	Case details (patient demographics, analysis parameters, report creation information) and case notes
Analysis Summary	Overview table of all quantitative measurements for both hips, with colour-coded range bars where applicable
Anatomical Analysis	Detailed bilateral measurements and 3D visualizations: femoral head coverage, femur morphology, acetabulum morphology, pelvic orientation
Range of Motion	Bilateral kinematic simulation results: range of motion values and movement test outcomes
Femoroacetabular Impingement Analysis (where applicable)	CAM and pincer deformity assessment and impingement visualization
Disclaimer	Legal disclaimer
Product Details	Device label
Annex I: References	Scientific references for all normative values
Annex II: Glossary	Measurement definitions and methodology for all parameters
Annex III: Data Verification	Input files and software version used to generate this report

4.2 Analysis Summary — Reading the Range Bars

The Analysis Summary presents all quantitative measurements for both hips in a single overview table. For parameters with an established population reference, a colour-coded horizontal range bar is shown alongside the numerical value. Parameters without an established population reference (such as femoral head diameter and acetabular cup diameter) are reported as absolute values only, without a range bar.

The range bars indicate the position of the patient's measurement relative to the normative reference range from published literature:

Colour	Meaning
Green (centre)	Within the normal range (between ±1σ from the mean)
Orange	Between 1σ and 2σ from the mean (68–95% of the reference population)
Red	Beyond 2σ from the mean (outside 95% of the reference population)

The tick mark on the bar indicates the patient's measured value. The physician should interpret range bar results in the context of the patient's full clinical presentation. A measurement outside the normal range is not by itself diagnostic.

4.3 Anatomical Analysis — 3D Visualizations

The Anatomical Analysis section presents measurements alongside three-dimensional renderings of the patient's bony anatomy derived from the submitted CT data. Each measurement is illustrated with annotated 3D views to support visual interpretation.

Visualizations are shown for both the right and left hip. The orientation of each view is indicated by anatomical direction labels (Anterior, Posterior, Lateral, Medial, Craniocaudal) and by a reference body figure.

Colormaps are used in some visualizations to indicate continuous spatial variation:

- **Femoral head coverage polar plot:** the blue line represents the patient's measured radial coverage; the green contour indicates the average normal value; orange and red contours indicate the 1σ and 2σ population boundaries respectively.
- **Femoral head sphere deviation colormap:** red areas indicate bone surface protruding beyond the fitted sphere; blue areas indicate surface below the sphere.
- **CAM deformity colormap:** indicates the deviation of the femoral cam surface from a healthy model, in millimetres (0–1, 1–2, 2–3, >3 mm).
- **Acetabular impingement colormap:** indicates the distance of the acetabular rim edge from the 2σ upper normal coverage boundary, in millimetres.

4.4 Range of Motion

The Range of Motion section reports the result of a kinematic simulation of hip joint mobility based on the patient's bony anatomy. Results represent bone-to-bone contact limits only and do not account for soft tissue structures. Reported values should be interpreted as conservative estimates of maximum achievable range of motion.

The Case Overview section of the report specifies the Range of Motion Method used for the case. Two methods are available: simplified and equidistant. More information on each method can be found in Appendix A.21.

For motions where the simulation limit exceeds the measurement range (i.e. the physiological range of a healthy hip joint), values are reported as "> [maximum]°".

Movement tests (FABER, FADIR, Sitting) are reported as PASS or with a quantitative endorotation measurement indicating the degree of motion at which bone-to-bone contact occurs.

4.5 FAI Analysis

The FAI Analysis section provides:

- **CAM Deformity Assessment:** a colormap of the deviation of the femoral cam surface from a healthy anatomical model, shown from anterior, posterior, and lateral views. Areas of greater deviation indicate potential CAM morphology.
- **Acetabular Impingement Assessment:** a colormap indicating areas of the acetabular rim that exceed the 2σ upper boundary of normal femoral head coverage, representing potential pincer morphology or overcoverage.

These visualizations identify the location and extent of potential impingement morphology to support the physician's pre-operative assessment. They do not constitute a clinical diagnosis of FAI.

5. Troubleshooting and Contact

If you have questions about this report, require technical support, or wish to discuss findings with Replasia, please use the following contact details:

Email	support@replasia.com
Website	www.replasia.com
Address	Replasia BV, Interleuvenlaan 62 box 26, 3001 Leuven, Belgium

For questions about CT imaging submission, refer to the CT Scan Protocol available at www.replasia.com/scanprotocols or contact Replasia at the above address.

6. Cybersecurity

Patient imaging data submitted to Replasia is handled in accordance with Replasia's data protection policies and applicable data protection regulations in the jurisdictions in which the service operates. Data is transmitted via a secure, encrypted file transfer platform (TLS 1.2 or higher). Patient data is pseudonymized before processing and stored on access-controlled cloud infrastructure.

Replasia's data protection practices are described in Replasia's Privacy Notice available at www.replasia.com/privacy-policy.

For data protection enquiries, contact Replasia at support@replasia.com.

---

7. Adverse Event Reporting

If you become aware of a serious incident or near-incident involving the HipStudio Simulation Service — including situations where use of this report may have contributed or could have contributed to patient harm — please report this to Replasia immediately at support@replasia.com.

In the European Union, serious incidents involving medical devices should be reported to the competent authority of the Member State in which the incident occurred.

In the United Kingdom, serious incidents should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card scheme at www.mhra.gov.uk/yellowcard.

In the United States, serious incidents involving medical devices may also be reported to the FDA through MedWatch: www.fda.gov/safety/medwatch.

Appendix A: Parameter Reference

The following appendices describe each parameter reported in the HipStudio Simulation Service analysis report. For each parameter, the method of measurement, clinical significance, relevant considerations, and normative reference are provided.

A.1 Femoral Head Coverage

Total Coverage and Load-Bearing Coverage

Method: The femoral head coverage is calculated by projecting acetabular rim points onto the femoral head sphere and marking the covered area. Total coverage is expressed as the percentage of the entire femoral head sphere surface (minus the surface area inside the femoral neck) that is covered. Load-bearing coverage is expressed as the percentage of the top hemisphere (superior half) that is covered.

Significance: Femoral head coverage quantifies the degree to which the acetabulum encloses the femoral head. Reduced coverage is a primary morphological feature of DDH and is associated with increased contact stress on the articular cartilage.

Considerations: Coverage values are derived from bony anatomy only. Cartilage thickness and labral contribution to coverage are not accounted for. Results should be interpreted alongside other coverage parameters and clinical findings.

Normal reference: Total coverage 42%–49.2% [Fritz et al., 2019]; Load-bearing coverage 64.9%–77.9% [Slullitel et al., 2024]

A.2 LCEA (Lateral Center-Edge Angle)

Method: The LCEA is measured as the angle between a vertical line through the femoral head center and a line from the femoral head center to the lateral acetabular edge at the 12 o'clock position. Note: LCEA values in this report are measured from the lateral bone edge, not the sourcil, which generally produces larger angles compared to radiographic measurement [Wylie et al., 2017].

Significance: The LCEA is the most widely used radiographic measure of lateral femoral head coverage. Values below 20° are generally considered dysplastic; values between 20° and 25° are borderline.

Considerations: The measurement methodology differs from conventional AP radiograph-based LCEA. Direct numerical comparison with radiograph-derived values should be made with caution.

Normal reference: 25°–35° [Welton et al., 2023]

A.3 AASA (Anterior Acetabular Sector Angle)

Method: The AASA is measured as the angle between the hip joint axis and the line from the femoral head center to the most anterior acetabular edge point, measured in the transverse plane at femoral head center height.

Significance: The AASA quantifies anterior acetabular coverage. Reduced AASA may indicate anterior undercoverage, which is relevant in DDH and anterior instability.

Normal reference: 53°–67° [Verhaegen et al., 2023]

A.4 PASA (Posterior Acetabular Sector Angle)

Method: The PASA is measured as the angle between the hip joint axis and the line from the femoral head center to the most posterior acetabular edge point, measured in the transverse plane at femoral head center height.

Significance: The PASA quantifies posterior acetabular coverage. Reduced PASA may indicate posterior undercoverage; increased PASA may contribute to posterior impingement.

Normal reference: 92°–108° [Verhaegen et al., 2023]

A.5 HASA (Horizontal Acetabular Sector Angle)

Method: The HASA is the sum of AASA and PASA, representing the total angle between the most anterior and posterior acetabular rim points relative to the femoral head center, in the transverse plane.

Significance: The HASA provides a composite measure of total transverse acetabular coverage.

Normal reference: 145°–175° [Verhaegen et al., 2023]

A.6 Extrusion Index

Method: The Extrusion Index is calculated as the distance from the acetabular rim to the most lateral point of the femoral head sphere along the hip joint axis, divided by the femoral head diameter, expressed as a percentage.

Significance: The Extrusion Index quantifies the proportion of the femoral head that lies lateral to the acetabular rim. Elevated values indicate uncoverage and are associated with DDH.

Normal reference: < 25% [Welton et al., 2023]

A.7 Tönnis Angle

Method: The Tönnis angle (acetabular index) is measured as the angle between the inter-femoral head axis and a line connecting the lateral acetabular rim to the lunate surface transition point, both at the 12 o'clock position.

Significance: The Tönnis angle reflects the inclination of the weight-bearing acetabular surface. Elevated values indicate an upsloping acetabular roof and may result in hip instability. A negative Tönnis angle is indicative of a decreased inclination of the acetabular roof and may result in hip impingement.

Normal reference: 0° - 10° [Tönnis et al., 1987]

A.8 Femoral Head Diameter

Method: The femoral head diameter is the diameter of the sphere that is fitted to the articular surface of the femoral head.

Significance: Femoral head diameter is a key parameter for characterization of proximal femoral morphology and bilateral symmetry assessment.

Considerations: Reported in millimetres for both the right and left femoral head separately. No population-based normative range is applied; values are reported as absolute measurements.

A.9 Neck-Shaft Angle

Method: The neck-shaft angle is measured as the angle between the femoral neck axis and the proximal femoral shaft axis in the coronal plane.

Significance: The neck-shaft angle characterizes proximal femoral geometry. Elevated values (coxa valga) or reduced values (coxa vara) may influence hip joint mechanics and are relevant to surgical planning.

Normal reference: 123°–136° [Toogood et al., 2009]

A.10 Femoral Anteversion

Method: The femoral anteversion is calculated using Murphy's method [Murphy et al., 1987]. The femoral neck axis is defined as the line connecting the center of the femoral head sphere to the centroid of the femoral neck isthmus. The posterior condylar axis is defined as the line connecting the posterior aspects of the medial and lateral femoral condyles. Anteversion is the angle between these two axes in the transverse plane.

Significance: Femoral anteversion affects hip joint kinematics and is an important determinant of combined anteversion (McKibbin Index). Abnormal anteversion contributes to impingement risk and may influence surgical planning for both DDH and FAI.

Normal reference: 0.5°–19° [Toogood et al., 2009]

A.11 Alpha Angle

Method: The alpha angle is measured at the 12, 1, 2, and 3 o'clock positions of the femoral head-neck junction. The alpha angle is defined as the angle between the femoral neck axis and the line from the center of the femoral head sphere to the point where the femoral head surface deviates beyond the fitted sphere radius.

Significance: The alpha angle is the primary quantitative indicator of CAM morphology. Values above 55° at any clock position are generally considered indicative of CAM deformity.

Considerations: The alpha angle is measured from the 3D CT model and may differ from values measured on 2D radial MRI or Dunn-view radiographs. Elevated alpha angles should be interpreted alongside the CAM deformity colormap in the FAI Analysis section of this report.

Normal reference: < 55° [standard clinical threshold]

A.12 Acetabular Cup Diameter

Method: The acetabular cup diameter is the diameter of the sphere that is fitted to the articular surface of the acetabulum.

Significance: Acetabular cup diameter characterizes acetabular morphology and supports bilateral symmetry assessment. No population-based normative range is applied; values are reported as absolute measurements.

A.13 Distance Between Acetabular and Femoral Centers

Method: The Euclidian distance is calculated between the center of the fitted femoral head sphere and the center of the fitted acetabular sphere.

Significance: The distance between the acetabular and femoral centers reflects the congruency and centering of the femoral head within the acetabulum. A small distance indicates a well-centered femoral head. An increased distance may indicate joint incongruency or lateral subluxation of the femoral head, as may be seen in DDH.

Considerations: This measurement is derived from the fitted geometric spheres and reflects bony anatomy only. It does not account for cartilage thickness. No population-based normative reference is currently established for this parameter.

A.14 Acetabular 3D Inclination

Method: The acetabular axis is calculated as the weighted average of normal vectors within the acetabular cavity. Inclination is the angle between this axis projected in the coronal plane and the vertical axis.

Significance: Acetabular inclination (abduction angle) characterizes the orientation of the weight-bearing acetabular surface. Abnormal inclination is relevant to joint loading and surgical correction planning.

Normal reference: 42°–54° [Verhaegen et al., 2024]

A.15 Acetabular 3D Anteversion

Method: The acetabular axis is calculated as the weighted average of normal vectors within the acetabular cavity. Anteversion is the angle between this axis projected in the transverse plane and the coronal plane.

Significance: Acetabular anteversion characterizes the anterior opening of the acetabulum. Abnormal anteversion contributes to instability (retroversion) or impingement risk.

Normal reference: 17°–31° [Verhaegen et al., 2024]

A.16 Acetabular In-Plane Anteversion

Method: The acetabular rim points are identified at the level of the femoral head center in the transverse plane. In-plane anteversion is the angle between the line connecting these rim points and the sagittal plane.

Significance: In-plane anteversion provides a complementary measure of acetabular version and is used in the McKibbin Index calculation.

Normal reference: 17°–31° [Verhaegen et al., 2024]

A.17 Acetabular 3D Tilt

Method: The acetabular axis is calculated as the weighted average of normal vectors within the acetabular cavity. Tilt is the angle between this axis and the anterior-posterior axis in the sagittal plane.

Significance: Acetabular tilt reflects the sagittal orientation of the acetabulum.

Normal reference: 13.3°–24.5° [Köhnlein et al., 2009]

A.18 Acetabular Cartilage Area

Method: The acetabular cartilage area is measured as the surface area of the marked lunate surface.

Significance: The acetabular cartilage area reflects the size of the weight-bearing articular surface and is relevant to understanding joint loading distribution.

Normal reference: 1980–2594 mm² [Verhaegen et al., 2024]

A.19 McKibbin Index

Method: The McKibbin Index is calculated as the sum of femoral anteversion (FV) and acetabular in-plane anteversion (AV). Results are classified based on the combination of FV and AV ranges, where each is categorized as increased (> 25°), normal (10°–25°), or decreased (< 10°).

Significance: The McKibbin Index provides insight into the combined version of the hip joint. A strongly increased index predisposes to posterior impingement; a strongly decreased index predisposes to anterior impingement.

Considerations: Interpretation should account for both individual components (FV and AV) and their combination. The classification matrix provided in the report indicates the combined stability profile.

A.20 Pelvic Orientation Parameters

APP Angle (Anterior Pelvic Plane Angle)

Method: The anterior pelvic plane (APP) is constructed from the right and left anterior superior iliac spines and the pubic symphysis. The APP angle is the angle between this plane and the vertical (caudal-cranial) reference line in the sagittal plane.

Significance: The APP angle characterizes pelvic tilt in the sagittal plane. Pelvic tilt influences the functional orientation of the acetabulum in standing, sitting, and other postures and is relevant to the interpretation of all acetabular orientation measurements.

Normal reference: -3° to +9° [Verhaegen et al., 2024]

Spinopelvic Tilt

Method: The midpoint of the sacral endplate and the midpoint of the hip joint axis are determined. Spinopelvic tilt is the angle between the line connecting these two midpoints and the caudal-cranial reference line.

Significance: Spinopelvic tilt characterizes the sagittal position of the pelvis relative to the vertebral column. It reflects the degree of anterior or posterior pelvic tilt and is an important determinant of functional acetabular orientation across postures. Pelvic mobility — the change in spinopelvic tilt between standing and sitting — influences effective acetabular anteversion during activities of daily living and is relevant to impingement and instability risk in functional positions.

Normal reference: 6°–16° [Verhaegen et al., 2024]

Pelvic Incidence

Method: The midpoint of the sacral endplate is determined and a plane is fitted to the sacral endplate rim. Pelvic incidence is the angle between a line perpendicular to the sacral endplate plane and a line connecting the sacral midpoint to the midpoint of the hip joint axis.

Significance: Pelvic incidence is a fixed morphological parameter unique to each individual that does not change with posture. It is geometrically equal to the sum of spinopelvic tilt and sacral slope, and determines sagittal spinal alignment requirements. Higher pelvic incidence values require greater lumbar lordosis to maintain upright posture and influence the relationship between pelvic position and functional acetabular orientation across activities.

Normal reference: 42°–66° [Verhaegen et al., 2024]

Sacral Slope

Method: The sacral endplate is identified and a plane is fitted to it. Sacral slope is the angle between the fitted sacral endplate plane and the horizontal reference line.

Significance: The sacral slope characterizes the orientation of the sacral endplate relative to the horizontal plane and reflects the sagittal position of the sacrum. Together with spinopelvic tilt and pelvic incidence, it defines the spinopelvic alignment. Changes in sacral slope reflect pelvic rotation in the sagittal plane and are relevant to the assessment of overall sagittal balance and functional hip posture.

Normal reference: 35°–53° [Verhaegen et al., 2024]

A.21 Range of Motion Parameters

Method: Range of motion values are computed by kinematic simulation based on the patient's bony anatomy. The simulation incrementally moves the femur through each motion arc until bone-to-bone contact

is detected. Results represent the maximum range of motion before bone-to-bone contact and do not account for soft tissue contributions.

The Range of Motion Method used for the case is stated in the Case Overview section of the report. Two methods are available [Puls et al., 2010]:

- **Simplified:** The femur rotates around a fixed hip joint center during simulation. Bone-to-bone contact is detected directly on the outer bony surfaces of the femur and acetabulum. This method provides a conservative estimate of the maximum range of motion before osseous impingement.
- **Equidistant:** The hip joint center is computed dynamically at each motion step by maintaining an equidistant joint space between fitted femoral and acetabular spheres. This method has been shown to detect the location and extent of femoroacetabular impingement with higher accuracy than fixed-center methods in certain cases.

Significance: ROM simulation identifies motion limitations arising from bony morphology. Results support the assessment of functional hip mobility and the anticipated effect of bony surgical correction on range of motion.

Considerations: Reported values are conservative estimates. Soft tissue contributions (cartilage, labrum, capsule, musculature) are not modelled. Actual functional ROM may differ from reported values.

Motion	Normal reference
Flexion	121 ± 13° [Roach & Miles, 1991]
Extension	19 ± 8° [Roach & Miles, 1991]
Abduction	42 ± 11° [Roach & Miles, 1991]
Adduction	30.5 ± 7.3° [Roaas & Andersson, 1982]
Endorotation	36 ± 9° [Roach & Miles, 1991]
Exorotation	45 ± 10° [Roach & Miles, 1991]
Endorotation @ 90° Flexion	33 ± 7° [Simoneau et al., 1998]
Exorotation @ 90° Flexion	36 ± 7° [Simoneau et al., 1998]

Movement Tests

FABER (Flexion, Abduction, External Rotation): reported as PASS if no bone-to-bone contact occurs within the test motion arc, or with a quantitative measure if contact is detected.

FADIR (Flexion, Adduction, Internal Rotation): reported with the endorotation angle at which bone-to-bone contact occurs at 90° flexion and adduction. The threshold for the test is 30° endorotation.

Sitting: reported as PASS if no bone-to-bone contact occurs during the simulated seated position.

Appendix B: References

[1] Roaas A and Andersson GBJ. Normal range of motion of the hip, knee and ankle joints in male subjects, 30–40 years of age. *Acta Orthop Scand.* Apr;53(2):205–208, 1982.

[2] Fritz B, Agten CA, Boldt FK, Zingg PO, Pfirrmann CWA, and Sutter R. Acetabular coverage differs between standing and supine positions: model-based assessment of low-dose biplanar radiographs and comparison with CT. *Eur Radiol.* Oct;29(10):5691–5699, 2019.

[3] Tönnis et al. General radiography of the hip joint. In: *Congenital Dysplasia and Dislocation of the Hip in Children and Adults.* Berlin: Springer, 10.1007/978-3-642-71038-4:100–142, 1987.

[4] Simoneau GG, Hoenig KJ, Lepley JE, and Papanek PE. Influence of hip position and gender on active hip internal and external rotation. *J Orthop Sports Phys Ther.* Sep;28(3):158–164, 1998.

[5] Verhaegen JCF, DeVries Z, Horton I, Slullitel PA, Rakhra K, Beaulé PE, and Grammatopoulos G. Acetabular sector angles in asymptomatic and dysplastic hips: Defining dysplasia and thresholds to guide management. *J Bone Joint Surg Am.* Nov 1;105(21):1709–1720, 2023.

[6] Verhaegen JCF, DeVries Z, Rakhra K, Speirs A, Beaule PE, and Grammatopoulos G. Which acetabular measurements most accurately differentiate between patients and controls? A comparative study. *Clin Orthop Relat Res.* Feb 1;482(2):259–274, 2024.

[7] Wylie JD, Kapron AL, Peters CL, and Aoki SK. Relationship between the lateral center-edge angle and 3-dimensional acetabular coverage. *Orthop J Sports Med.* Apr;5(4):2325967117700589, 2017.

[8] Slullitel PA et al., Kamenaga T, Ritacco L. Prediction of 3-dimensional coverage surface area of the femoral head in hip dysplasia through conventional computed tomography. *Orthopaedic Journal of Sports Medicine,* 12(3), 2024.

[9] Roach KE and Miles TP. Normal hip and knee active range of motion: the relationship to age. *Phys Ther.* Sep;71(9):656–665, 1991.

[10] Welton KL, Kraeutler MJ, Garabekyan T, and Mei-Dan O. Radiographic parameters of adult hip dysplasia. *Orthop J Sports Med.* Feb 28;11(2), 2023.

[11] Puls M, Ecker TM, Tannast M, Steppacher SD, Siebenrock KA, and Kowal JH. The equidistant method - a novel hip joint simulation algorithm for detection of femoroacetabular impingement. *Comput Aided Surg.*, 15(4-6):75-82, 2010.

[12] Stephen B Murphy, Sheldon R Simon, Peter K Kijewksi, Robert H Wilkinson, and N Thorne Griscom. Femoral anteversion. *JBJS*, 69(8): 1169-1176, 1987.

[13] Toogood PA, Skalak A, and Cooperman DR. Proximal femoral anatomy in the normal human population. *Clin Orthop Relat Res.* Apr;467(4):876–85, 2009.

[14] Köhnlein W, Ganz R, Impellizzeri FM, and Leunig M. Acetabular morphology: implications for joint-preserving surgery. *Clin Orthop Relat Res.* Mar;467(3):682–91, 2009.

Appendix C: Key Terms

Term	Definition
DDH	Developmental Dysplasia of the Hip — a condition in which the hip socket does not fully cover the femoral head
FAI	Femoroacetabular impingement — abnormal contact between the femur and acetabulum due to bony morphology
CAM morphology	Abnormal bone at the femoral head-neck junction that can cause impingement during hip flexion and internal rotation
Pincer morphology	Overcoverage of the femoral head by the acetabular rim, potentially causing rim-based impingement
DICOM	Digital Imaging and Communications in Medicine — standard format for medical imaging data
CT	Computed tomography
3D model	Three-dimensional surface reconstruction of bony anatomy derived from CT imaging data
ROM	Range of motion
Bone-to-bone contact	Simulated contact between the femoral and acetabular bony surfaces during kinematic simulation
Normative range	The range of values observed in an asymptomatic reference population, as reported in published literature
APP	Anterior Pelvic Plane — a reference plane constructed from the anterior superior iliac spines and the pubic symphysis
LCEA	Lateral Center-Edge Angle
AASA	Anterior Acetabular Sector Angle
PASA	Posterior Acetabular Sector Angle
HASA	Horizontal Acetabular Sector Angle

Term	Definition
FABER	Flexion, Abduction, External Rotation — a clinical hip impingement/instability test
FADIR	Flexion, Adduction, Internal Rotation — a clinical hip impingement test

Appendix D: Symbols Glossary

The following symbols are used in the HipStudio Simulation Service device label (Product Details page). All symbols conform to ISO 15223-1:2021 *Medical devices — Symbols to be used with information to be supplied by the manufacturer.*

Symbol	Symbol title	ISO 15223-1 reference	Meaning
	Unique Device Identifier	§ 5.7.10	Indicates a carrier that contains unique device identifier information
	Catalogue number	§ 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Manufacturer	§ 5.1.1	Indicates the medical device manufacturer
℞ Only	Prescription only	21 CFR 801.109(b)(1); 21 CFR 801.15(c)(1)(i)(F)	Federal law restricts this device to sale by or on the order of a physician