Instructions for Use

HipStudio Analysis

Document name	R-HSA-65_Instructions for Use_HipStudio Analysis
Version number	02
Version date	20260806

Table of Contents

1. Version History

Version	Date	Author	Summary of Changes	Sections
01	08-JUL-2026	Tim Van Cleynenbreugel	Initial version	All
01	06-AUG-2026	Tim Van Cleynenbreugel	Small update	All

2. Product Description

2.1 Intended Use and Indications for Use

The HipStudio Analysis is a patient-specific clinical analysis report intended to support orthopedic surgeons and other qualified healthcare professionals in the pre-operative clinical assessment and treatment planning of skeletally mature patients with hip conditions.

The analysis report is intended to provide quantitative morphological measurements, three-dimensional visualisations and kinematic simulation results of the patient's hip anatomy, derived from patient CT imaging data.

The HipStudio Analysis is intended to support — and not replace — the independent clinical judgement of qualified healthcare professionals. It in intended to be used in conjunction with established clinical assessment and diagnostic methods.

2.2 Contraindications

The HipStudio Analysis 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 Analysis CT Scan Protocol. Non-conforming scans may result in inaccurate measurements or unreliable simulations.
- Patients where the submitted imaging data or the patient’s anatomy does not permit reliable three-dimensional anatomical reconstruction and analysis.
- Patients who are pregnant. CT imaging is contraindicated in pregnancy.
- Patients for whom CT imaging is otherwise contraindicated.
- Skeletally immature patients (growth plates not closed), as the reference values and simulation parameters are validated for skeletally mature anatomy only.

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.
- **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.** 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 estimates of bony impingement-free motion; 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.
- **Spinopelvic tilt correction.** Morphological and kinematic measurements derived from CT imaging performed in the supine position may differ from the patient's functional anatomy in a standing or weight-bearing position. Where a supplementary standing radiograph has been submitted and a tilt correction applied, this is indicated in the report. Where no such correction has been applied, the clinician should consider this limitation when interpreting reported parameters.
- **Physician responsibility.** The physician retains full responsibility for all clinical decision-making and for the patient's surgical treatment.

2.4 Precautions

- The measurements and simulations in this report are based solely on the imaging data submitted for the case and reflect the patient's anatomy at the time of imaging. This report may no longer be valid following subsequent imaging or changes in the patient's clinical condition or anatomy.
- 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.
- The HipStudio Analysis should be used as one input among several in the clinical decision-making process. Over-reliance on the patient-specific clinical analysis report without integration with the patient's full clinical picture, physical examination, and other diagnostic information may lead to suboptimal clinical decisions.

2.5 Legal Disclaimer

The HipStudio 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. Workflow Overview

3.1 How to Request and Use the HipStudio Analysis

The HipStudio Analysis is requested and used by the ordering physician 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 Analysis 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 clinical analysis report to the ordering physician within the agreed delivery timeframe. 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 analysis report on a standard computer, laptop, or any device capable of rendering this type of 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 Analysis 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
Acceptable scan range	Complete pelvis including sacrum, proximal femurs ≥ 10 cm below lesser trochanter, and distal femurs ≥ 5-10 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 Analysis report is a structured 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. Actual functional range of motion may differ.

The Case Overview section of the report specifies the Range of Motion Method used for the case. Two methods are available: simplified and equidistant [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 an estimate of the 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.

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.

In case distal femur imaging is included in the CT-scan, the Range of Motion results are referenced to a knee-forward femur position; otherwise the as-scanned femur orientation is used.

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 Replasia 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 Analysis — 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

Detailed definitions, measurement methodology, clinical significance, and normative references for all parameters reported in the HipStudio Analysis report are provided within the analysis report itself, in the Annex II Glossary and Annex I References sections.

Appendix B: 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 C: Symbols Glossary

The following symbols are used in the HipStudio Analysis 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