INSTRUCTIONS FOR USE

Orthopaedic Planning and Analysis Software

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Intended Use

The Orthopaedic Planning and Analysis Software is intended to be used for pre-operative planning and post-operative evaluation of total joint replacements.

Materials

The Orthopaedic Planning and Analysis Software is Class IIa standalone medical device software. The code is compiled in a computer aided engineering package to perform motion analysis.

A suite of macros and custom software apply the same physical manoeuvres and test conditions to any number of patient inputs. A unique three-dimensional model is created for each individual that defines the position of the implant components in the joint.

The knee model simulates a single leg deep knee bend, replicating conditions of the Oxford knee rig, considered an industry standard for biomechanical testing of total knee replacement systems. The hip module assesses the allowable range of motion for known dislocation manoeuvres.

Software Modules and Functions

Surgery	Analysis Type
Total Knee Arthroplasty	Post-Operative
	Pre-Operative
Total Hip Arthroplasty	Post-Operative
	Pre-Operative

Indications

Pre-operative analysis is indicated for total knee replacement and total hip replacement where the implant system is supported by the software.

Post-operative analysis is indicated for patients who have received a total knee or hip replacement where implant geometry is supported by the software.

Contraindications

The Orthopaedic Planning and Analysis Software is contraindicated for:

- Patients in which total knee or hip arthroplasty is contraindicated
- Significant orthopaedic deformities, e.g. fused knee, hip or ankle.
- Patients who are unable to comply with imaging requirements
- Patients currently receiving ionising radiation treatment or scans for other medical conditions
- Implant systems which are not supported by the software – if unsure of whether a knee or hip arthroplasty system can be analysed, contact your product representative or 360 Med Care before placing a booking or requesting patient imaging.

Conditions Affecting Performance, Side Effects and Adverse Effects

The accuracy of the analyses is dependent on a number of factors:

- Quality of CT or MRI scans – the prescribed 360 Med Care imaging protocol has been designed to minimise the radiation dosage, while retaining sufficient detail in the structures for a patient specific three dimensional model of the joint.
- Provision of correct implant system details (manufacturer, model, and size for a post-operative analysis) to import matching implant geometry into the model.
- Required anatomical landmarks can be identified on patient imaging.

360 Med Care requires patient details and imaging for pre-operative analyses a minimum of five weeks prior to the surgery date. For requests submitted after this time, delivery of the report cannot be guaranteed; however, all attempts will be made to accommodate requests at short notice.

Incorrect use of the pre-operative analysis information may lead to poor functional outcomes including, but not limited to, knee instability, dislocation, increased wear debris, pain, decreased range of motion and soft tissue impingement.

Warnings and Precautions

- The information generated by the software are range of motion predictions of the total joint replacement, derived from a three-dimensional model constructed using the patient's bone geometry.
- The information applies only to the patient identified, listed implant models and side of analysis. The information is single-use only and must be used by the date stated in each report.
- The range of motion results must not be used to alter the treatment regime of another patient.
- The range of motion results must not be used to treat a side other than what is specified in the analysis.
- Post-operative analysis information must not be used in pre-operative planning
- The information applies only to controlled motion events (deep knee bend in the Knee Module, range of motion in the Hip Module) and must not be used to draw conclusions outside the simulated actions.

Restrictions and Limitations on Use

Use of information generated with the Orthopaedic Planning and Analysis Software is restricted to registered orthopaedic surgeons. The analyses information may be used by implant manufacturers for authorised purposes, including evaluation and design of total joint replacement systems.

Report Contents and Interpretation of Results

The results of the analysis are presented in PDF format.

360 Med Care takes all feasible measures to ensure that the report file is not corrupted and free from malware. In the event of a corrupted or infected file, do not attempt to open the report. Contact your product representative or 360 Med Care for a replacement file.

Knee Report(s)

The following definitions are applied and are considered to be measurements by this device, in either the preoperative, the postoperative or both reports:

- Femoral component flexion - flexion angle of the femoral component with respect to the sagittal mechanical axis of the femur
- Tibial component slope - flexion angle of the tibial component with respect to the sagittal tibial mechanical axis
- Femoral component varus / valgus rotation – alignment of the femoral component with respect to the coronal mechanical axis of the femur
- Tibial component varus / valgus rotation – alignment of the tibial component with respect to the coronal mechanical axis of the tibia
- Femoral component internal / external rotation – alignment of the femoral component with respect to the epicondylar axis (sulcus of medial epicondyle to most prominent aspect of lateral epicondyle) in the transverse plane
- Tibial component internal / external rotation – alignment of the tibial component with respect to Insall line (PCL insertion to the medial third of the tibial tuberosity) in the transverse plane
- Preoperative tibio-femoral alignment – angular measurements between the coronal, saggital and transverse plane reference axes of the tibia and femur in the preoperative imaging reference frame
- Preoperative femoral alignment – angular measurements between the surgical trans-epicondylar axis (TEA), whiteside's reference and the posterior condylar axis (PCA)
- Distal femoral resection – measurements of offset distance between the distal condylar visually identified most distal point and the simulated resection cut plane for the lateral and medial condyles respectively
- Posterior femoral resection – measurements of offset distance between the posterior condylar visually identified most posterior point and the simulated resection cut plane for the lateral and medial condyles respectively
- Posterior tibial resection – measurements of offset distance between the visually identified central plateau point and the simulated resection cut plane for the lateral and medial plateaus respectively
- In the beta version of the knee analyses, the Dynamic Knee Score (DKS) summarises the biomechanics of a total knee replacement during a simulated deep knee bend. It allows results of patient specific knee analyses to be compared and is intended to be used for this purpose. The DKS is not intended to be a prediction of patient reported outcome measures.
- Preoperative and postoperative reports are generated from CT based data, from a non-weight bearing joint and cannot account for soft tissue considerations when performing a TKR.

To derive the DKS, analytics were run on a reference data set. The rank percentile is the percentage of reference data sets below the reported DKS. In determining DKS sensitivity, all other component placement variables are held constant.

Hip Report(s)

The following definitions are applied and are considered to be measurements by this device, in either the preoperative, the postoperative or both reports:

- Target Offset: The amount of offset reconstruction (increase or decrease) intended by the surgeon from the patient's pre-operative measurement.
- Planned Offset: The resulting change in hip offset after completion of the templating process.
- Target Leg Length: The amount of leg length reconstruction (increase or decrease) intended by the surgeon from the patient's pre-operative measurement.
- Planned Leg Length: The resulting change in leg length after completion of the templating process.
- Cup Inclination: The abduction angle of the acetabular cup as per Murray's* radiographic definition.
- Cup Anteversion: The internal/external rotation angle of the acetabular cup as per Murray's* radiographic definition.
- Pelvic Tilt: The angle on a sagittal plane formed between the anterior pelvic plane (APP) to the frontal plane.
- Pelvic Mobility: The difference in pelvic tilt between the standing and relaxed seated X-ray. This measure is used to determine the stiffness of the patient's spinopelvic alignment using Feng's* definition.
- Femoral Anteversion: The angle formed on an axial plane between the femoral neck axis, defined by the head centre and piriformis fossa and the posterior condylar axis.
- Stem Anteversion: The angle formed on an axial plane between the stem neck axis, defined by the head centre and piriformis fossa. and the posterior condylar axis.
- Standard Alignment: The implant alignment that is the default alignment indicated by the surgeon preference.
- Functional or ROM Alignment: The implant alignment that has been derived from the Orthopaedic Planning and Analysis Software.

**Murray, D.W., The definition and measurement of acetabular orientation. The Journal of Bone and Joint Surgery. British volume, 1993. 75(2):228-32*
*Feng, J.E., *Techniques for optimising acetabular component positioning in total hip arthroplasty*. *The Journal of Bone and Joint Surgery. British volume, 2019. 7(2): e5*

The software version number, use-by date and date of analysis can also be found on the report. If any assistance in interpreting the kinematic results is required, contact your product representative or 360 Med Care.

Preoperative Planning

Size and position of the knee (femoral, tibial and patellar) and hip (femoral and acetabular) implant component are pre-operatively planned by 360 Med Care according to approved surgeon preferences. Please contact 360 Med Care to provide your surgical planning preferences.

Limits of Accuracy of Reported Measurements

Pre-operative measurements for the knee include a ±1mm and ±1deg error based on repeatability testing. For the knee, there are two exceptions to this: the tibial-femoral axial alignment has an error range of ±1.5 deg and the Whiteside/Antero-posterior axes have an error range of ±3 deg. Planned component sizes include ±1 variation based on repeatability testing.

Post-operative knee component placement values are reported to an accuracy of ±1.5 degrees as defined by repeatability testing.

The limits of accuracy of DKS sensitivity are characterised by an output range defined by a standard deviation of 30.2% in the preoperative scenario, and 40.6% in the postoperative scenario.

Pre- and post-operative measurements for the hip include ±3deg error based on repeatability testing. There are two exceptions to this: the femoral anteversion measurement and analysed range of motion tolerance is ±5deg.

Functional version, and functional combined version have an average error ±2° ($\sigma = 1.5°$). A worst case error of (±10°) can occur for patients with a small femur in conjunction with excessive functional femoral rotation.

Disclosure of Residual Risk

Within the Orthopaedic Planning and Analysis Software, there remains a risk that the patient may have physical characteristics which are different to the population described in literature and captured in the simulation platform, which could lead to the resulting biomechanics from the simulation not being representative of realistic knee kinematics. This residual risk has been reduced as far as possible but the user should be aware when using the device.

System Requirements for Viewing Report

The report is best viewed on a personal computer and requires Adobe Acrobat Reader. The latest version of Adobe Acrobat Reader can be downloaded from www.get.adobe.com/reader/ Refer to www.adobe.com for minimum system requirements prior to installing software. It is recommended that the instructions for use and each report is downloaded prior to surgery as an internet connection may not be available during planned use of the instructions for use and/or reports(s).

Symbols Used (EN ISO 15223-1)

 5.1.1	Manufacturer	EC REP 5.1.2	Authorized Representative in the European Community
 5.4.4	Caution	 5.4.3	Consult instructions for use
 5.1.4	Use-by date	2797	Notified Body
 5.4.2	Do not re-use	CE	European Conformity

Please contact your product representative, or 360 Med Care at compliance@360med.care, for the Product Information or for further information.