

This document is only valid on its print date. If you are unsure of the print date, re-print the document to ensure you are using the latest version of the instructions, which is available at www.smaio.com.

A user manual to help users get started using the software is available on request at contact@smaio.com.

1. Manufacturer's identification



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2. Device identification

Commercial name of the software: KEOPS Balance Analyzer 3D V1.1.5

3. Statement of intended use

KEOPS Balance Analyzer 3D software is intended for assisting surgeons, healthcare professionals and service providers in viewing and measuring images as well as planning spine surgeries. The device includes tools for measuring anatomical components.

4. Indications, users targeted and target population

KEOPS Balance Analyzer 3D software is indicated for assisting spine pathologies diagnostic and spinal surgeries planification.

KEOPS Balance Analyzer 3D software can be used by health professionals (orthopedic surgeons, neurosurgeons, radiologists), trained for spine imaging and pathologies and by service providers (imaging technician, clinical study technician) also trained for spine imaging and pathologies.

Clinical judgement and experience in spine surgery are required to properly use the software.

The target population for using the KBA3D software includes any patient eligible for whom an x-ray imaging can be prescribed and that can hold a standing position.

The comparison between the parameters measured and those of the normal population is limited to Caucasian population (male and female) between 18 and 81 years old.

5. Composition of the medical device

Not applicable, standalone software (SaaS)

6. Clinical benefit / performance / mechanism of action

Clinical benefit

No information on the expected direct clinical benefit for the patient was associated with the use of KBA3D.

Performance claims

KEOPS Balance Analyzer 3D software can be used to:

- Provide measurement of key (spino-pelvic) parameters
- Make a comparison between the parameters measured and those of the normal population
- Help surgeons to plan surgical corrections to the spinal column (levels / degree of correction), help them with diagnosis and planning surgery
- View the spinal column in 3D using two 2D X-ray images simultaneously

Accuracy (uncertainty) of KEOPS Balance Analyzer 3D software

KEOPS Balance Analyzer 3D is a medical device with a Class IIa measuring function. Its accuracy has been assessed using a DICOM image containing known morphological dimension and location landmarks. Accuracy on linear and angular measurements have been assessed as follows:

	Uncertainty of KBA3D
Curvature Angle (Cobb, °)	± 0.65°
Lateral displacement (LD, mm)	± 0.57 mm
C7 vertebral tilt in frontal plan (C7 tilt, °)	± 0.04°
C7 vertebral tilt in frontal plan (C7 tilt, mm)	± 0.48 mm
Femoral heads slope (FHS, °)	± 0.11°
Femoral heads slope (FHS, mm)	± 0.59 mm
Shoulders slope (ShS, °)	± 0.06°
Shoulders slope (ShS, mm)	± 0.3 mm
Pelvic obliquity (PO, °)	± 0.05°

Mechanism of action

KEOPS Balance Analyzer 3D software is available on a platform, the operating principle of which follows the steps below:

1. Loading of sagittal and frontal "long standing" X-ray images of the spinal column, which have been taken simultaneously with two perpendicular sources, and into which it is possible to zoom and to perform various adjustments enabling the "contouring" of vertebrae, as well as different aspects of the spinal column and the pelvis, to be viewed.
2. Manual recording of anatomical landmarks and measurement of shape and position parameters, which are then compared with those for a normal population in order to identify potential differences.
3. Performing a 3D reconstruction of the femoral heads, sacral plate, and the spinal column based on the 2D X-ray images provided and viewing the 3D positioning of vertebral bodies.
4. Simulating the effects of surgery for the relevant levels using geometric modelling in providing related shape and positioning parameters measurements (disc/vertebra/height/angulation), main curvatures description and global balance assessment...
5. Simulating the effects associated with surgery on a spinopelvic alignment and above the fusion; this simulation is performed at the discretion of the surgeon and provides related shape and positioning parameters calculation (the software does not predict compensation mechanisms).

7. Prerequisites prior to use and instructions for use

KEOPS Balance Analyzer 3D software can be accessed at www.keops-spine.fr.

The instructions for use are detailed in the user manual. Please read it before using the device.

- ✦ System requirements:
 - Computer: Mac or PC with a minimum screen size of 13.3 inches
 - Internet connection: 1024 Kb/s or higher
 - Web browser: Google Chrome in its latest version
- ✦ Recommended environment:
 - Standard office environment with standard noise and lighting levels, excluding operating rooms.

- ✦ Notes:
 - The software cannot be used on smartphones or tablets.
- ✦ Use to perform measurements from x-rays, not in case of an emergency.

8. Warning, precautions for use, contraindications and residual risks

Warning

KEOPS Balance Analyzer 3D software is designed as a decision support system for people with appropriate medical training and should not be used as the sole basis for making clinical decisions relating to patient diagnosis, treatment or care. All information derived from the software must form the subject of a clinical examination of its plausibility prior to use in the treatment of patients. Any deviation from the application of the program's medical information, other than the original design or the intended use, is not recommended and is viewed as misuse of the software.

The software requires large profile view x-ray images in which the femoral heads are visible, up to C7 vertebra. The quality of the image loaded will have a significant impact on the accuracy of the reconstruction and the suitability of the resulting planning.

It is also recommended that file in JPEG, BITMAP, GIF, TIFF formats to have at least a resolution of 1024*768 pixels, with 96ppi resolution, not to alter the zooming features.

Precautions for use

Not applicable

Contraindications

Not applicable

Residual risk

Not applicable

9. Side effects

Not applicable, standalone software (SaaS)

10. Storage / handling / disposal

Not applicable, standalone software

11. Lifetime/useful life

The lifetime of a device is considered as the time from manufacture until the device ceases to fulfil its intended use. It could be consequently considered as Shelf life + Useful life.

- As KBA3D is a SaaS, Shelf life is not applicable, the software is available online (no physical support), always up to date.
- SMAIO has decided to limit the useful life of its software to 5 years.

12. Information for the patient if he/she is not the user

Not applicable, standalone software intended for spinal column specialists.

13. Single-use medical devices

Not applicable, standalone software (SaaS)

14. Version of the instructions

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15. Vigilance

Any adverse events linked to the use of the device must be reported to SMAIO at vigilance@smaio.com and to the competent authority of the Member State in which the user and/or patient is based.

16. Meaning of symbols used

Symbol	Description	Standards
	Medical device	ISO 15223-1, 5.7.7
	Manufacturer	ISO 15223-1, 5.1.1
	Country of manufacture Date of manufacture	ISO 15223-1, 5.1.3 ISO 15223-1, 5.1.11
 www.smaio.com/ifu	Read the instructions for use on the website	ISO 15223-1, 5.4.3
	CE marking of conformity	MDR 2017/745 Annex V
	Unique device identifier	ISO 15223-1, 5.7.10