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 are available at www.smaio.com.

1. Manufacturer's identification

S.M.A.I.O
2, Place Berthe Morisot – Parc Technologique
69800 Saint-Priest – FRANCE
Tel.: +33 (0)4 69 84 23 02
Website: www.keops-spine.com

2. Device identification

Commercial name of the software: KEOPS Balance Analyzer 3D

3. Statement of intended use

The KEOPS Balance Analyzer 3D is intended for assisting healthcare professionals in viewing and measuring images as well as planning spine surgeries. The device allows surgeons and service providers to perform spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for design and placement of surgical implants.

4. Indications for use and users targetted

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 the spine imaging and pathologies and by service providers (imaging technician, clinical study technician) also trained for spine imaging and pathologies.

Clinical judgment and experience are required to properly use the software.

5. Composition of the medical device

Not applicable, standalone software (SaaS).

6. Clinical benefit / performance / mechanism of action

Clinical benefit

The KEOPS Balance Analyzer 3D software:
- does not produce a diagnosis as such but only provides information for detecting physiological parameters that differ from those observed within a normal population, information that must be assessed by health professionals
- is not a therapeutic device
- has no interactions with the human body (non-invasive device)

For health professionals, the added value of a piece of software such as KEOPS Balance Analyzer 3D is that it provides information that:
- provides a better understanding of the pathology
- helps the surgeon to simulate different correction strategies and helps him/her decide which is the most appropriate
- improves communication with the patient by showing him/her which treatment can be offered

Performance

KEOPS Balance Analyzer 3D software can be used by health professionals (orthopaedic surgeons, neurosurgeons) to:

- Provide measurements of parameters to assess the patient's sagittal and frontal balance
- 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 of KEOPS Balance Analyzer 3D software

KEOPS Balance Analyzer 3D is a Moderate of concern software.

Its accuracy has been assessed using a DICOM image containing known morphological dimension and location landmarks. Accuracy or linear and angular measurements have been assessed as follows:

Parameter	Accuracy
Pelvic incidence	+/- 0.78°
Pelvic tilt	+/- 0.25°
Sacral slope	+/- 0,64°
Barrey ratio	+/- 0.5%
Lordosis L1S1	+/- 1.25°
Lordosis L4S1 / Lordosis L1S1	+/- 3%
Kyphosis T12C7	+/- 2°
SSA	+/- 0.7°

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 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.
5. Simulating the effects associated with surgery on a pelvic level and above the fusion; this simulation is performed at the discretion of the surgeon (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.com.

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

KEOPS Balance Analyzer 3D requires at least 1024 Kb/s Internet connection, and the recommended navigator is Google Chrome in its last available version.

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.

Contraindications

Not applicable

Residual risk

Not applicable

9. Side effects

Not applicable, standalone software (SaaS)

10. Storage / handling / disposal

Not applicable, standalone software

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

Not applicable, standalone software intended for spinal column specialists.

12. Single-use medical devices

Not applicable, standalone software

13. Version of the instructions

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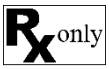
14. Vigilance

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 country in which the user and/or patient is based.

15. Meaning of symbols used

Symbol	Description	Standards
	Medical device	ISO 15223-1, 5.7.7
	Manufacturer	ISO 15223-1, 5.1.1
	Country of manufacturer Manufacturing date	ISO 15223-1, 5.1.11 ISO 15223-1, 5.1.1

Symbol	Description	Standards
	Read the instructions for use on the website	ISO 15223-1, 5.4.3
	CE marking of conformity	MDD 93/42/CE Annex XII
	Unique device identifier	ISO 15223-1, 5.7.10
	Prescription device	21 CFR Part 801