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.

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

2. Device identification

Device trade name of the software: KBA3D v2.3.0

3. Statement of intended use

The KBA3D v2.3.0 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. Clinical judgment and experience are required to properly use the software.

4. Indications, users targeted and target population

KBA3D v2.3.0 software is indicated for assisting spine pathologies diagnostic and spinal surgeries planification.

KBA3D v2.3.0 aims to achieve three objectives:

1. From two perpendicular patient's standing x-rays including patient's spine and pelvis from femoral heads to the cervical levels (included), provide 3D scaled representation of the femoral heads, sacral plate and vertebral bodies. Provide related shape and positioning parameters measurements (disc/vertebra/height/angulation), main curvatures description and global balance assessment…
2. Simulate potential effects of a spine surgery on spinopelvic alignment and provide related shape and positioning parameters calculation.
3. Visualize implant positioning relative to spinopelvic representation (pre-op versus realigned) to establish possible implant selection scenarios.

Users targeted
KBA3D v2.3.0 software can be used by health professionals (orthopaedic 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.

Target population
The patient population targeted with the use of the KBA3D v2.3.0 software includes patients requiring imaging measurements and planning of surgical procedures.

5. Composition of the medical device

Not applicable, standalone software (SaaS).

6. Clinical benefit / performance / mechanism of action

Clinical benefit

The KBA3D v2.3.0 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 KBA3D v2.3.0 is that it provides information that:
- allows a better understanding of the pathology
- helps the surgeon 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

KBA3D v2.3.0 software sagittal balance measurements accuracy

Parameter	Accuracy
Pelvic incidence	± 0.69°
Pelvic tilt	± 0.14°
Sacral slope	± 0.55°
Barrey ratio	± 2.03%
Lordosis L1S1	± 1.17°
Lordosis L4S1 / Lordosis L1S1	± 0.38%
Kyphosis T12C7	± 1.66°
SSA	± 0.57°

KBA3D v2.3.0 software coronal measurements accuracy

Parameter	Accuracy
Curvature Angle (Cobb, °)	± 0.65°
Lateral displacement (LD, pixel)	± 1.89 pixel
C7 vertebral tilt in frontal plan (C7 tilt, °)	± 0.04°
C7 vertebral tilt in frontal plan (C7 tilt, pixel)	± 1.59 pixels
Femoral heads slope (FHS, °)	±0.11°
Femoral heads slope (FHS, pixel)	± 1.95 pixels
Shoulders slope (ShS, °)	± 0.06°
Shoulders slope (ShS, pixel)	± 1 pixel
Pelvic obliquity (PO, °)	± 0.05°

Mechanism of action

KBA3D v2.3.0 software is available on a platform; the operating principle of the software 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.
-Manual recording of anatomical landmarks and measurement of shape and position parameters, which are then compared with those of a normal population in order to identify potential differences.
-Performing a 3D reconstruction of the spinal column based on the 2D X-ray images provided and viewing the 3D positioning of vertebral bodies.

2/
-Simulating the effects of surgery for the relevant levels using geometric modelling.
-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).

3/
Providing guidelines for designing a spinal rod based on the corrections validated by the surgeon and generating a 3D model of the rod.

7. Prerequisites prior to use and instructions for use

KBA3D v2.3.0 software can be accessed at www.keops-spine.com.

A user manual including a detailed description of the software is available on request at contact@smaio.com.

- System requirements:
  - Computer: Mac or PC with a minimum screen size of 13.3 inches,
  - KBA3D can be accessed from PC (Windows) or Mac (MacOS) using Google Chrome.
- 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.

Cybersecurity – Rules and Recommendations

For cybersecurity purposes, it is recommended to:

- Keep web browser up to date;
- Keep anti-virus up to date;
- Use protected networks;

The following features are deployed to protect the system:

- The connection is protected by SSL certificate and a strong password strong policy:
  - No empty password. Passwords of at least 8 characters including the use of three or more of the following: uppercase letters, lowercase letters, symbols, and numbers are required.
  - Password is not visible in plaintext; password encryption is not stored, transfer and storage of user passwords in plaintext is prohibited.
  - Password changes are required at least every 90 days.
  - 10 password history disallows re-use of a previous password.
  - Enact account/IP address is locked after 5 attempts to access an account with either invalid password / username.
  - Application requires a user to set their own password after an administrator reset or on first use of the account.

- Password recommendations:
  - Use unique user credentials and passwords.
  - Ensure the KEOPS password differs significantly from the email account password used to receive it.
  - Prefer using an email account protected by two-factor authentication (2FA) with verification via the user's mobile phone.

- KBA3D is a SaaS and the backup features are performed by the database/software hosting vendor; the available version is always the most up to date for all the end users.

The security mechanisms correspond to:

- Encryption of flows.
- Placement of security equipment (firewall, IDS/IPS probes, proxies, ...);
- Network monitoring mechanisms.
- Internet access via SSL certificate (HTTPS, FTPS, etc.).

As KBA3D is a SaaS:

- There is no interface ports or other interfaces.
- The available version is always the most up to date for all the end users. Consequently, there is no download version.
- There is no configuration recovery.
- There are no hardware components associated.

In case a user detects an intrusion or incident, the user must first report the vulnerability to the Administrator (keops@smaio.com) to check the log activities; it is required from the user to update his/her password.

If the incident is occurring on live, it is recommended to the user to disable internet access (unplug net access or deactivate Wi-Fi) of the vulnerable computer and contact Administrator from another computer and internet access.

8. Precautions, warning, limitations, contraindications and residual risks

Precautions

- Do not share patient identifiable information via chat, notes, or email.
- Only left-hand profile can be analyzed by the software.
- Download only anonymous images, without personal data.
- Make sure to report the same orientation than the one used for the radiographic image, as the orientation is important to obtain a correct 3D representation, a realistic calculation of the parameters and relevant simulation of the rod.
- Carefully review the result of the reconstruction of vertebrae detected on the radiograph. This process is automated and may contain inaccuracies in certain cases. Ensure that all vertebrae are correctly identified and make manual adjustments if necessary to ensure reliable results.
- Modifying a point after running a simulation will reset the simulation, including the corrections and the designed rod.
- If calibration is not performed, measurements will be recorded in pixels based on image resolution.
- If the image is DICOM, calibration is performed automatically and displayed in the status panel.
- The software does not predict compensation mechanisms.

Warning

- KBA3D v2.3.0 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 treatments of patients. Any use of software's medical information that deviates from its original design or intended purpose is discouraged and considered misuse.
- KBA3D requires large profile view x-ray images in which the femoral heads are visible, up to C7 vertebra.
- The quality of the loaded image has a significant impact on the accuracy of the reconstruction and the suitability of the resulting planning.
- It is also recommended that files in JPEG, PNG formats have a minimum definition of at least 1024*768 pixels, with 96ppi resolution, in order to not to alter the zooming functions.

Limitations

The software is not intended to predict the results of the surgery as S.M.A.I.O does not provide tools to carry out the planning.

Therefore, regarding implant positioning and correction impact, accuracy levels provided by S.M.A.I.O are solely based on theoretical calculation rules that are decorrelated from the outputs of the surgery.

Contraindications

Not applicable

Residual risks

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

14. Version of the instructions

See page footer

15. Vigilance

Any adverse events linked to the use of the device must be reported to S.M.A.I.O at usvigilance@smaio.com and to the FDA.

16. Meaning of symbols used

Symbol	Description	Reference
	Manufacturer	ISO 15223-1, 5.1.1
	Date of manufacture Country of manufacturer	ISO 15223-1, 5.1.3 ISO 15223-1, 5.1.11
	Read the instructions for use on the website	ISO 15223-1, 5.4.3
	Unique device identifier	ISO 15223-1, 5.7.10
	Prescription device	21 CFR Part 801