KBA3D v2.2.0
INSTRUCTIONS FOR USE

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

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2. Device identification

Device trade name of the software: KBA3D v2.2.0

3. Statement of intended use

The KBA3D v2.2.0 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 v2.2.0 software is indicated for assisting spine pathologies diagnostic and spinal surgeries planification.

KBA3D v2.2.0 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, provide 3D scaled representation of the femoral heads, sacral plate, and the 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 v2.2.0 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 v2.2.0 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 v2.2.0 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 v2.2.0 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 v2.2.0 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 v2.2.0 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 v2.2.0 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 selecting implants as part of performing elective surgery and dispose of a predefined list of implants.

7. Prerequisites prior to use and instructions for use

KBA3D v2.2.0 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,
  - 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.

Cybersecurity – Rules and Recommendations

For cybersecurity purposes, it is recommended to:

- keep web browser Chrome up to date;
- Keep anti-virus up to date;
- Avoid unprotected networks;

The following features are deployed to protect the system:

- The connection is protected by SSL certificate and a password strong policy:
  - Require passwords of at least 8 characters including the use of three or more of the following: Uppercase letters, lowercase letters, symbols, and numbers;
  - Does not contain any hardcoded password;
  - Password renewal every 90 days;
  - System memorizes last 10 passwords to prevent redundance of passwords;
  - The user does create to set their own password after an administrator reset or on first use of the account;
  - Prohibit Users from adopting passwords that are identical to their unique identifier;
  - In the case of 5 unsuccessful attempts to log in, the system locks the login web page and blocks user IP; the system displays a disclaimer and gives contact details to contact the administrator.

- 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 software can be accessed from PC (Windows) or Mac (MacOS) using Google Chrome.

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. Warning, limitations, contraindications and residual risks

Warning

KBA3D v2.2.0 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 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.

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 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

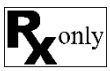
14. Version of the instructions

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
	Medical device	ISO 15223-1, 5.7.7
	Unique device identifier	ISO 15223-1, 5.7.10
	Prescription device	21 CFR Part 801