

Kinetigram Customer Release Notes

1 Administrative Information

<i>Software-Version (Client):</i>	V1.5.0
<i>Kinetigram™ Suite Version:</i>	V2.4 Note: Kinetigram Suite includes: Kinetigram Client, Server and Data Processor
<i>Manufacturer:</i>	Bioniks 2156 Central Avenue Alameda, CA 94501 USA help@bioniks.net +1 (510) 747-1947 http://www.bioniks.net
<i>Document #:</i>	320-00201-EN-US-DO-03 Rev 11 2025-01
<i>Instructions for Use:</i>	320-00201-EN-US-DO-02 Rev 9 2025-01
<i>European Authorised Representative:</i>	CMC Medical Devices & Drugs, S.L. C/ Horacio Lengo n18 C.P 29006 Málaga, Spain
<i>Importer:</i>	European Union MedEnvoy Global BV Prinses Margrietplantsoen 33 – Suite 123 2595 AM The Hague The Netherlands



2 Product Description

Kinetigram is Software as a Medical Device (SaMD) consisting of a software application that takes 3D kinematic data input and outputs calculated measurements (this function planned for a later release, currently the required data is stored for later processing). The intent is to use the software as a tool for physicians to help understand a patient's mobility.

Upper extremity joint function is evaluated by tracking performance of two movement protocols: reachable and functional workspace. For reachable workspace, patient is asked to move the extended arm in vertical and horizontal planes at various angles based on given video instructions. The observed reachable workspace is assessed by the relative surface area of the total workspace and the relative surface areas of the quadrants. For functional workspace protocol, the patient is asked to reach with their hand at various points of the body (e.g. hip, shoulder, mouth) during the motion sequence. The performance is evaluated by automatically detecting whether the different points were achieved or not and by assigning a proximity index for each point.

3 Indications for Use

3.1 *Commercial Use*

The Kinetigram is Software as a Medical Device intended to be used with the Microsoft Kinect for Xbox One to evaluate upper extremity joint function using 3D kinematic data capture in adults. The product is intended for use by medical professionals amongst other available patient parameters as a motion analysis tool.

3.2 *Investigational Use*

The Kinetigram is Software as a Medical Device intended to be used with the Microsoft Kinect for Xbox One to evaluate upper extremity joint function using 3D kinematic data capture in adult and pediatric patients (pediatric ages 5-17). The product is intended for use by medical professionals amongst other available patient parameters as a motion analysis tool.

Currently available in Australia and New Zealand as an investigational device.

4 New Features and Enhancements

- UI Updates:
 - Addition of two new languages: Korean and Thai. This includes UI translations, video translations and IFU translations. This version is not registered as medical device in Thailand, South Korea or North Korea.
 - Character counter was added for free text entry fields.
 - New warning when switching languages and the Client has lost focus.
- Enhanced performance and security: Kinetigram server is now hosted as Azure Web app.
- Added support for Pediatric indication. This functionality is available for investigational use only. See CAUTION in section 7.

5 Issues Fixed

- Issue # PRODPR-7: Client SW hangs when switching languages
- Issue # PRODPR-10: IFU does not include explicit instruction on session deletion
- Issue # PRODPR-11: Additional Information - Reason for Change character limits
- Issue # PRODPR-12: Incorrect EndDateTime in MySQL Tenant DB
- Issue # PRODPR-13: Anthropometry zero height/weight
- Issue # PRODPR-14: Data Processor error characterization
- Issue # PRODPR-16: Session deletion (Data Processor 1.3.1) - document and revert soft delete
- Issue # PRODPR-17: Session deletion (Data Processor 1.3.1) - update database procedures
- Issue # PRODPR-18: Kinect session updates (Kinetigram Server 1.4.1) - document and reprocess affected sessions
- Issue # PRODPR-19: Kinect session updates (Kinetigram Server 1.4.1) - update database procedures
- Issue # PRODPR-15: Kinetigram Data Processor - Invalid Gender

6 Known Issues

- Issue # 230-00201-REC-18: Software unrelated issue in Microsoft Azure
- Issue # PRODPR-4: RWS Session Processing Failure

7 Cautions

All medical devices, including Kinetigram, has inherent potential risk associated with its use. However, it has been determined, based on the likelihood and severity of those risks, that the benefits of its intended use outweigh the potential risk.

CAUTION (United States): Federal law restricts this device to sale by or on the order of a physician.

CAUTION – Investigational Device: Australia (all uses), New Zealand (all uses), All regions (use in pediatric populations aged 5-17)

Please see the Instructions for Use document for a full listing of the cautions.