

Kinetigram Customer Release Notes

1 Administrative Information

<i>Software-Version (Client):</i>	V1.3.0
<i>Kinetigram™ Suite Version:</i>	V2.2 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-GB-DO-03 Rev 8 11/2022
<i>Instructions for Use:</i>	320-00201-EN-GB-DO-02 Rev 7 11/2022
<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

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.

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

4 Issues Fixed

- Issue # 49348: Bioniks is now compliant with General Data Protection Regulation (GDPR) in the EU.
- Issue # 230-00201-REC-05: Invalid Fax Number. Fax number was removed from the About Box.
- Issue # 230-00201-REC-09: AER vs EAR. Labeling was updated to use "European Authorised Representative".
- Issue # 230-00201-REC-10: Azure B2C Usernames
- Issue # 230-00201-REC-11: Border Flicker. Instructions for Use updated to better defined required monitor connection
- Issue # 230-00201-REC-13: Subject Identifier Free-Text Format. Subject identifier template is now loaded from a tenant specific cloud configuration.
- Issue # 230-00201-REC-15: General security issue
- Issue # 230-00201-REC-16: General security issue
- Issue # 230-00201-REC-17: General security issue

5 Known Issues

- Issue # 230-00201-REC-18: Software unrelated issue in Microsoft Azure

6 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 benefit if its intended use outweigh the potential risk.

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