

Kinetigram™ Data Processor Customer Release Notes

1 Administrative Information

<i>Software Version (Data Processor):</i>	V1.2.0
<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-DO-06 Rev 4 11/2022
<i>Instructions for Use, Data Interpretation:</i>	320-00201-DO-05 Rev 4 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.

The Data Processor module adds motion analysis functionality to the Kinetigram suite. For the Reachable Workspace (RWS) protocol, 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 defined by the cardinal body planes. For the Functional Workspace (FWS) protocol, the patient is asked to reach with their hand to seven landmarks of the body (i.e. back pocket, stomach, shoulder, opposite shoulder, mouth, top of the head, and back of the head) during the motion sequence based on given video instructions. 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 # 230-00201-REC-01: Image Scaling. The generated graphics is now properly scaled when running in headless mode.
- Issue # 230-00201-REC-02: Re-processing sessions. This release allows for re-processing of sessions marked for re-processing.
- Issue # 230-00201-REC-03: Note parsing. Notes containing special characters such as single and double quotations are now correctly processed.
- Issue # 230-00201-REC-04: Memory consumption. Memory leak in data processing of large tenants has been fixed.
- Issue # 230-00201-REC-06: Scores Table Scaling. Tables produced in graphical summaries are now properly scaled when running in headless mode.
- Issue # 230-00201-REC-07: Batch Processing Doubles. Session that are re-processed in two different batches resulting in invalid output. This issue was resolved as part of the service procedure for processing session data.

- Issue # 230-00201-REC-09 AER vs EAR. Labeling was updated to use “European Authorised Representative”.
- Issue # 230-00201-REC-12: Data Processor, v1.1.0, Tenant Naming. Service procedure updated.
- Issue # 230-00201-REC-19: Data Processor, v1.1.0, Export of Multiple Skeletons

5 Known Issues

- Issue # 230-00201-REC-14: Data Export Session Valid Parameter. Issue related to internal service process and data transfer.

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.