

Kinetigram™ Data Processor Customer Release Notes

1 Administrative Information

<i>Software Version (Data Processor):</i>	V1.0.0
<i>Kinetigram™ Suite Version:</i>	V2.0 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 2 12/20
<i>Instructions for Use, Data Interpretation:</i>	320-00201-DO-05 Rev 2 12/20
<i>Authorized European Representative:</i>	CMC Medical Devices & Drugs, S.L. C/ Horacio Lengo n18 C.P 29006 Málaga, Spain



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 # 49348: Bioniks is now compliant with General Data Protection Regulation (GDPR) in the EU.

5 Known Issues

N/A – No known issues for this release version.

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.