

## Kinetigram Customer Release Notes

### 1 Administrative Information

|                                            |                                                                                                                                                                                                          |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Software-Version (Client):</i>          | V1.4.1                                                                                                                                                                                                   |
| <i>Kinetigram™ Suite Version:</i>          | V2.3<br>Note: Kinetigram Suite includes: Kinetigram Client, Server and Data Processor                                                                                                                    |
| <i>Manufacturer:</i>                       | Bioniks<br>2156 Central Avenue<br>Alameda, CA 94501<br>USA<br><a href="mailto:help@bioniks.net">help@bioniks.net</a><br>+1 (510) 747-1947<br><a href="http://www.bioniks.net">http://www.bioniks.net</a> |
| <i>Document #:</i>                         | 320-00201-EN-US-DO-03 Rev 10 2023-10                                                                                                                                                                     |
| <i>Instructions for Use:</i>               | 320-00201-EN-US-DO-02 Rev 8 2023-10                                                                                                                                                                      |
| <i>European Authorised Representative:</i> | CMC Medical Devices & Drugs, S.L.<br>C/ Horacio Lengo n18<br>C.P 29006<br>Málaga, Spain                                                                                                                  |
| <i>Importer:</i>                           | European Union<br>MedEnvoy Global BV<br>Prinses Margrietplantsoen 33 – Suite 123<br>2595 AM The Hague<br>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 New Features and Enhancements**

- 21 CFR Part 11 compliance: added capabilities to maintain and download audit logs of all data changes (edits, additions and deletions), and document reasons for changes made to data
- UI Updates: Added ability to delete patients, groups and sessions, UI elements to configure the UI for specific studies, configuration for height and weight limits
- Enhanced security: Time synchronization between UI and server, cloud host and database architecture improvements, new and updated role permissions.

## **5 Issues Fixed**

- Issue # PRODPR-1: Network/Wifi connection troubleshooting added to IFU.
- Issue # PRODPR-2: Monitor connection and wake-up troubleshooting added to IFU.
- Issue # PRODPR-3: Configuration for limits on height and weight.

## **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.

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