

Kinetigram Customer Release Notes

1 Administrative Information

<i>Software-Version (Kinect Client):</i>	V1.6.0
<i>Software-Version (Orbbec Client):</i>	V2.0.1
<i>Kinetigram™ Suite Version:</i>	V3.0
	Note: Kinetigram Suite includes: Kinect Client, Orbbec 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 13 2026-06
<i>Instructions for Use:</i>	320-00201-EN-US-DO-02 Rev 10 2026-06
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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 a 3D camera 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 a 3D camera 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

- Addition of new client module, V2.X, for Orbbec Femto camera
- New Orbbec Client:
 - Updates to client architecture to support compatibility with future cameras
 - Modernize the UI platform from UWP to WinUI
 - Camera setup screen includes display of infrared (IR) and color video
- Various service configuration and performance improvements

5 Issues Fixed

- Issue # PRODPR-20: Session deletion (Kinetigram Server v1.4.1)
- Issue # PRODPR-22: Kinetigram Client, Incorrectly Linked RWS Protocol Toggle Parameter
- Issue # PRODPR-23: MySQL Flexible Server version 8.0 extended support (1 June 2026)
- Issue # PRODPR-26: PostgreSQL server enhancement

6 Known Issues

- Issue # PRODPR-21: UI patient parameter toggle
- Issue # PRODPR-24: Azure B2C issue
- Issue # PRODPR-25: PostgreSQL server enhancement

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.