Kinetigram™ Data Processor Customer Release Notes

1 Administrative Information

Software Version (Data Processor):	V1.6.0
Kinetigram™ Suite Version:	V3.1 Note: Kinetigram Suite includes: Kinect Client, Orbbec Client, Server, and Data Processor
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Instructions for Use, Data Interpretation:	320-00201-DO-05 Rev 8 2026-10
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CE MD

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

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.

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

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, New Zealand and Georgia as an investigational device.

4 New Features and Enhancements

- Security and performance enhancements

5 Issues Fixed

- Issue # PRODPR- 31: Correct label for Date of Manufacture on Data Processing About Box

6 Known Issues

- Issue # 230-00201-REC-18: Software unrelated issue in Microsoft Azure
- Issue # PRODPR-4: RWS Session Processing Failure
- 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 benefit of its intended use outweighs 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), Georgia (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.