Kinetigram Customer Release Notes

1 Administrative Information

Software-Version (Kinect Client):	V1.7.0
Software-Version (Orbbec Client):	V2.1.0
Kinetigram™ Suite Version:	V3.1 Note: Kinetigram Suite includes: Kinect Client, Orbbec Client, Server, and Data Processor
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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.

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, New Zealand and Georgia as an investigational device.

4 New Features and Enhancements

- Orbbec Client UI Updates:
    - Addition of one new languages: Georgian. This includes UI translations, video translations and IFU translations. This version is not registered as medical device in Georgia.
- Enhanced performance and security
- PRODPR-32: Improved accuracy of floor distance for Orbbec Client
- PRODPR-33: Improved ordering of multiple-skeletons for Orbbec Client

5 Issues Fixed

- Issue # PRODPR-28: Orbbec camera power loss status, verification steps and client update
- Issue # PRODPR-29: Security Update
- Issue # PRODPR-30: Kinetigram Orbbec Client automatic logout
- Issue # PRODPR-31: Correct label for Date of Manufacture on Data Processing About Box

6 Known Issues

- Issue # PRODPR-21: UI patient parameter toggle

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), 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.