

Kinetigram Customer Release Notes

1 Administrative Information

Software Version: V1.0.1

Manufacturer: Bioniks
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2 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.

3 Issues Fixed

N/A – initial commercial release.

4 Known Issues

N/A – there are no known issues that impact the use of Kinetigram.

5 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.