Kinetigram™ Data Interpretation Instructions for Use

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

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BIONIKS

Symbol	Standard / Regulation	Standard Reference No. / Symbol Title Definition / Definition
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.4.3 / Consult instructions for use / Indicates the need for the user to consult the instructions for use.
	US FDA Title 21 CFR 801.109: Prescription Devices.	Prescription Device / Product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Medical Device Regulation (MDR)	MDR Article 20 The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.
	Medical Device Regulation (MDR)	MDR 23.1 (g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.1.1 / Manufacturer

Symbol	Standard / Regulation	Standard Reference No. / Symbol Title Definition / Definition
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.1.2 / Authorized Representative in the European Community
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.7.7 / Indicates the item is a medical device
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.1.6 / Catalogue Number
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.1.8 / Importer
	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements	5.7.10 / Unique Device Identifier
	N/A	Indicates Information intended for the user and appears in an on-screen pop-up box

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1 Introduction

1.1 Indications for Use

1.1.1 Commercial Use

The Kinetigram™ is Software as a Medical Device intended to be used with 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. Kinetigram™ is intended to be used for multiple patients and multiple use.

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1.1.2 Investigational Use

The Kinetigram™ is Software as a Medical Device intended to be used with 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. Kinetigram™ is intended to be used for multiple patients and multiple use.

Currently available in Australia and New Zealand as an investigational device.

1.2 Prescription Guidelines

No specific guidelines are provided outside of the indications for use. If used as part of a clinical study, refer to the study protocol on when it is appropriate to use the Kinetigram™ software.

1.3 Required Skills or Knowledge

Users of Kinetigram are typically clinicians or physical therapists (PT), kinesiologists, or clinician assistants, who are supervised by clinicians. Users are trained on this document and other training material provided by Bioniks.

1.4 Intended Clinical Benefits

The Kinetigram software provides a sophisticated tool to clinical practitioners that helps diagnose and manage degenerative shoulder conditions and other impairments of the upper extremity. Kinetigram is a unique clinical movement analysis system that can be used for physical assessment in medical settings, athletic training, and personal fitness contexts. The software captures the joint motion trajectories during a pre-defined series of movements. The data captured is provided as input to a biomechanical model (Data Processor subsystem) that filters the dynamic kinetic data to: 1) improve accuracy; 2) calculate joint movements; and 3) extract test-specific movement parameters.

Additionally, the Kinetigram platform provides the ability to track a subject's progress over time. Given that the user interface, camera data, and biomechanical model are applicable to the entire upper body skeleton, Kinetigram offers a comprehensive approach to treatment for upper body musculoskeletal conditions. By quantifying how people move, Kinetigram provides the potential for new insight into injury risk as well as recovery processes. This can provide adjunct information to guide appropriate use of surgery and non-surgical care to make treatment more effective and cost efficient.

1.5 Safety Information – Definitions

Caution – Information regarding any special care to be exercised for safe and effective use of the Kinetigram™ software.

1.6 Safety Information – List of Cautions

Caution: Do not use the results of the software alone to make decisions on patient treatment.
Caution: Do not run other software programs while conducting procedures.

1.7 Other Annotations

Terms used in this Instructions for Use:

***Note*:** Information that will help you in the proper operation of the software or interpretation of the resulting information provided.

Important: Directions which if not followed can lead to misdiagnosis and/or loss of use of patient data.

1.8 Information, Error and Warning Messages

There is no user interface associated with the Kinetigram Data Processing module, and therefore no specific messaging is directly communicated to the end user as part of a processed data set. In the event that a processing failure occurs, flags and messaging associated with processed metrics for a session will be embedded into the output dataset.

2 Kinetigram™ Platform

Bioniks Kinetigram™ cloud-connected software platform interfaces with either Microsoft Kinect™ or Orbbec Femto Bolt depth camera and standard Windows 11 computer to provide an intuitive user interface for motion assessment. It allows the practitioner to enter patient information, select from a suite of video-guided physical assessments, and record patient's performance of the motion protocols. The Kinetigram™ application is linked to a cloud-based database that allows for geographically distributed clinical sites to easily collect kinematic data. The use of instructional videos that the patient follows ensures consistent performance and timing between sessions. Kinetigram™ includes protocol videos and a user interface in 13 different languages (English, English GB, Dutch, German, Spanish, US Spanish, French, Canadian French, Italian, Danish, Korean, , Thai, and Georgian).

The Kinetigram™ platform implements two major upper-extremity assessment protocols:

- **Reachable Workspace (RWS)** to assess the limits to gross range of motion of the shoulder
- **Functional Workspace (FWS)** to assess an individual's ability to reach with their hand at various target points on the body (hip, back pocket, shoulder, opposite shoulder, mouth, top of the head, and back of the head).



Figure 1: Different measurement session parameters captured by the Kinetigram™ application for the assessment of the Reachable and Functional Workspace motion protocols.

3 Data Acquisition and Processing

Kinetigram™ captures raw skeletal data from 25 body joints as shown in

Appendix A: Measurement Data Export Format, Section 10.2. The raw kinematic data consists of the time series of 3D joint positions captured with the acquisition rate of 30 Hz. The raw skeletal data, however, are not anatomically correct and certain joints may suffer from large variability and significant bias. Kinetigram™ improves on the raw data by introducing kinematic filtering based on biomechanical skeletal model of the upper body (i.e. skeletal rig) which takes into consideration patient-specific parameters such as height and gender. The process is referred to as 'rigification'. The resulting skeletal model omits the lower extremity joints as well as the joints of the hand and fingers not used in the analysis. The model is applied to each recorded frame. The process of rigification generates corrected joint positions as well as kinematic model states (i.e. angles), which are used by the RWS and FWS algorithms. Post-processed raw data are not part of the general data transfer but are available on request from Bioniks.

4 Reachable Workspace (RWS)

4.1 Analysis

The Reachable Workspace (RWS) protocol is aimed to assess the limits to gross range of motion of the shoulder. The patient is instructed to move with their stretched arm through several planes of movement in vertical (lateral, frontal) and horizontal directions (belt, shoulder, above head levels). Instructions given during the video-guided data collection are provided in Appendix B: Video Protocol Transcripts for reference.

The performance of the protocol is assessed by analyzing (1) the relative trajectory of the movement from the shoulder center point to the wrist and (2) the relative trajectory of movement from the shoulder center point to the elbow. The range of motion is summarized by the reachable workspace envelope and its normalized area. The reachable workspace envelope is further divided into four quadrants in front of the body (Q1-Q4) and an additional fifth quadrant (Q5) for the back extension of the arm. The division to quadrants is determined by the vertical and horizontal body planes aligned with the shoulder center point of the tested side as shown in Figure 2.

The total surface of the workspace and the surface of the quadrants is quantified by the RSA score. The RSA score is unitless as it is defined by the absolute surface area (ASA), and normalized by the estimated radius of the trajectory cluster. The RSA score represents a portion of an ideal hemisphere with a unit length, which has RSA value of 1.0. The maximal value for RSA of each quadrant is 0.25. Due to numerical computation, the computed score may end up somewhat larger than maximum (+0.05).

Each session of the reachable workspace protocol is analyzed separately for shoulder-to-wrist trajectory as Standard RWS (Figure 2), also referred to as just RWS, and shoulder-to-elbow trajectory as Elbow RWS (Figure 3). Although both models incorporate the same type of scores, the analysis of the elbow motion eliminates the contribution of the elbow contraction to the total workspace envelope. Elbow RVS values are typically smaller than Standard RWS values.

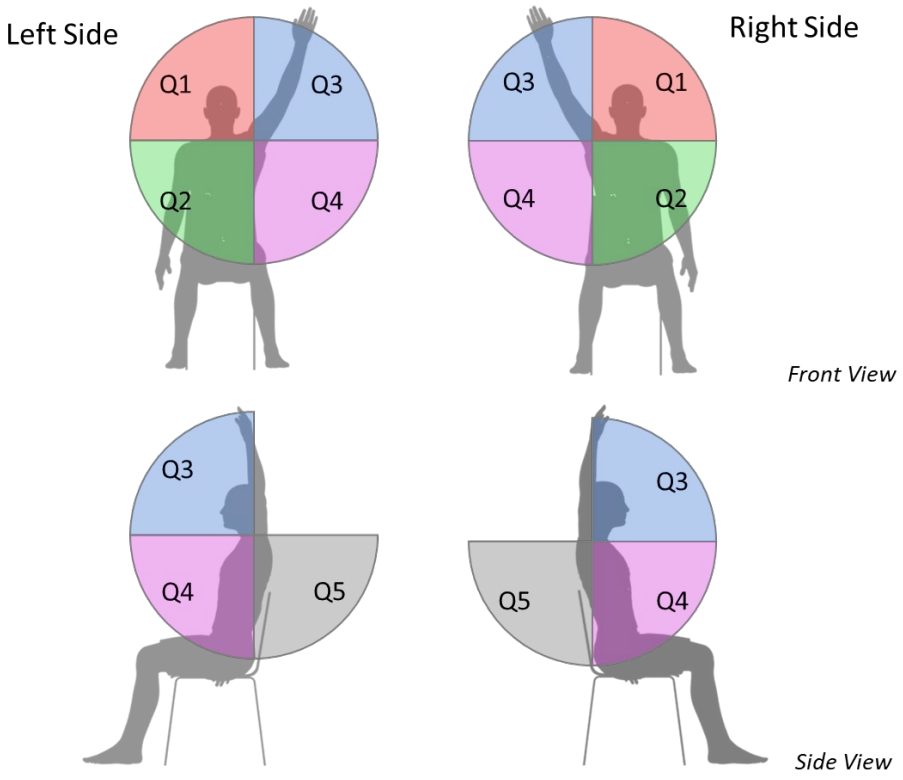


Figure 2: Standard Reachable Workspace as defined by the wrist-to-shoulder trajectory, shown with the division into five quadrants

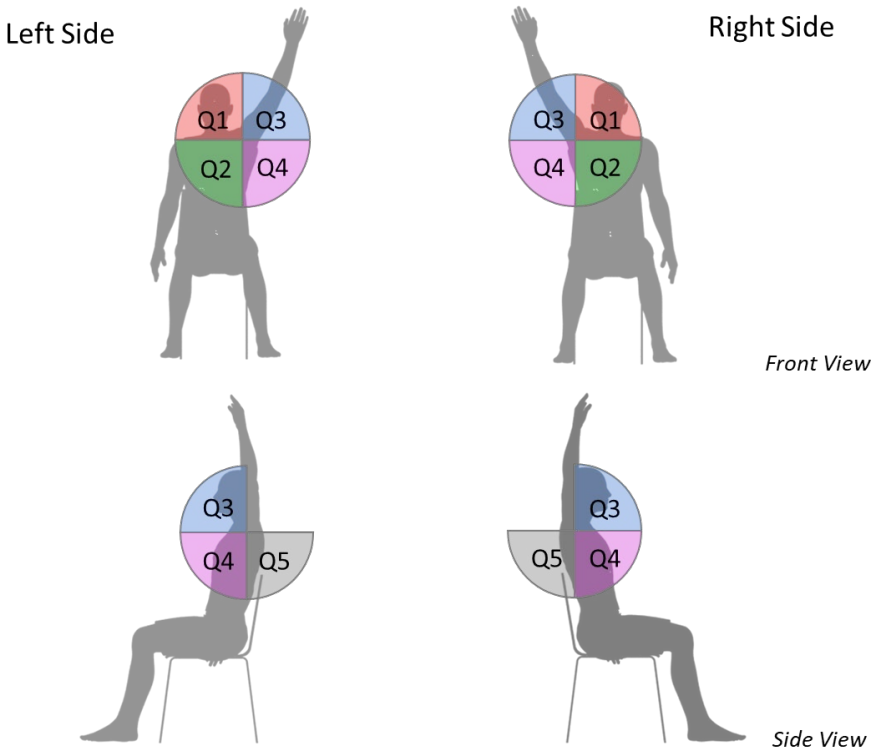


Figure 3: Elbow Reachable Workspace as defined by the elbow-to-shoulder trajectory, shown with the division into five quadrants

4.2 RWS Protocol Parameters

The following RWS protocol parameters are captured during the assessment by the Kinetigram™ application:

- **Body Side:** [Left, Right]

  The evaluation is performed either with the left or right arm. The videos for both body sides are approximately (within 1-2 seconds) synchronized in motion guidance for all video conditions.

- **Level:** [High, Low]

  The default level for the assessment is the 'High' module which includes all the RWS motion segments and should be applied to majority of patients. In addition, the Kinetigram™ provides 'Low' module which excludes the motion segments above the shoulder, shortening the overall assessment. According to Kinetigram™ Instructions for Use, the 'Low' module should **only** be used with very low functional individuals who cannot raise their arm to shoulder level (e.g. maximal frontal flexion of extended arm at about 45 degrees). As indicated in Kinetigram™ Instructions for Use, 'High' module should be applied when functional ability is unclear or unknown.

- **Weight:** [None, Weighted]

  Kinetigram™ allows for the assessment of the RWS protocol without or with an additional weight attached to the wrist. The default weight setting in the software is for 500g. The data outputs either report '0.0' for no weight condition, or the value of the pre-set weight in grams for a weighted protocol (e.g. '500.0').

- **Video Speed:** [Normal, Slow]

Default video speed for Kinetigram™ is set to 'Normal'. This corresponds to the assessment length of about 90 seconds for the 'High' protocol and 60 seconds for the 'Low' protocol. The slower version of the videos is available for subjects who may have difficulty following the instructions (e.g. elderly). There the video instructions are slowed down by approximately 30%. The total assessment time for 'High' protocol is about 115 seconds and the total assessment time for 'Low' protocol is about 100 seconds.

4.3 RWS Clinical Scores

For the RWS protocol, the following clinical scores are reported by the Kinetigram™ Data Processing module:

- **Q1 RSA:**

  Q1 RSA score represents the portion of the reachable workspace envelope in the upper contralateral quadrant. The maximal value of the score is 0.25. Patients who qualify for 'low' module of the reachable workspace protocol are expected to have Q1 RSA value zero or close to zero.

- **Q2 RSA:**

  Q2 RSA score represents the portion of the reachable workspace envelope in the lower contralateral quadrant. The maximal value of the score is 0.25.

- **Q3 RSA:**

  Q3 RSA score represents the portion of the reachable workspace envelope in the upper ipsilateral quadrant. The maximal value of the score is 0.25. Patients who qualify for 'low' module of the reachable workspace protocol are expected to have Q3 RSA value zero or close to zero.

- **Q4 RSA:**

  Q4 RSA score represents the portion of the reachable workspace envelope in the lower ipsilateral quadrant. The maximal value of the score is 0.25.

- **Q5 RSA:**

  Q5 RSA score represents the portion of the reachable workspace envelope in the dorsal quadrant defined by the back extension of the arm. The maximal value of the score is 0.25

- **Total RSA (1-4):**

  Total RSA (1-4) score represents the reachable workspace as defined by the sum of the RSA values of quadrants Q1 to Q4. The score captures the frontal portion of the reachable workspace of the shoulder. The maximal value of the score is 1.0.

- **Total RSA (1-5):**

  Total RSA (1-5) score represents the reachable workspace as defined by the sum of the RSA values of the quadrants Q1 to Q5. The score captures the combined reachable workspace of the frontal backward range of motion of the shoulder. The maximal value of the score is 1.25.

4.4 Performance Characteristics

The Data Processor computes the relative Reachable Workspace surface area with an accuracy within +/- 0.05 given a complete trajectory of arm movement (under ideal and noisy [+/-1cm] condition).

4.5 Additional Disclaimers

- Accuracy of Kinetigram may be reduced from specified for pediatric subjects.
- If the subject is unable to follow prescribed motions, the data may not be correctly computed.

5 Functional Workspace

5.1 Analysis

The Functional Workspace protocol is aimed to assess an individual's ability to reach with their hand at various target points on the body. The protocol includes seven targets: 1) hip, 2) back pocket, 3) shoulder, 4) opposite shoulder, 5) mouth, 6) top of the head, and 7) back of the head. During the assessment, the patient is instructed to reach these landmarks on their body in a sequential order. At the end of the assessment, the evaluator must enter their observations for the seven targets and whether the patient was able to reach the target (i.e. touch the part of the body with their hand or fingertips) or not. This information on reachability is encoded in the reports in binary form: '0' for not reaching the target and '1' for reaching the target.

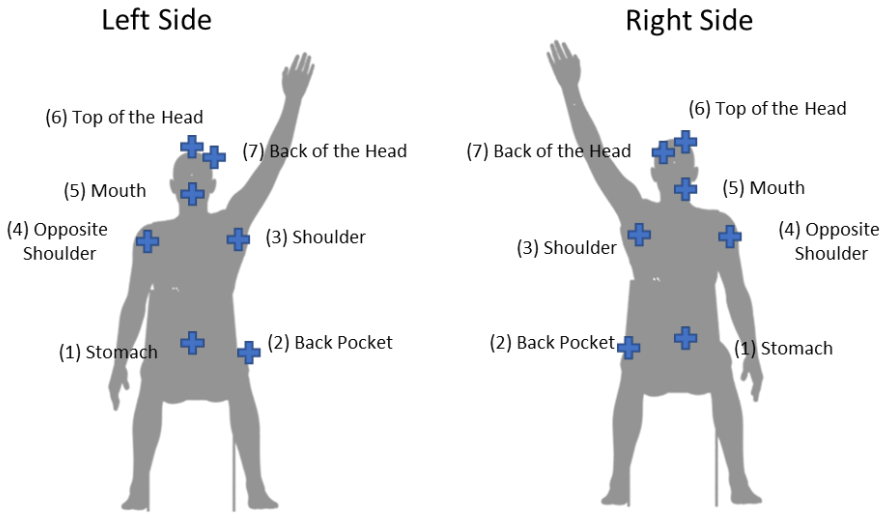


Figure 4: Seven body landmarks (targets) for the Functional Workspace protocol

Due to higher variability of the hand and finger tracking as compared to tracking other joints, the Kinetigram™ FWS algorithm performs the analysis of the reachability using the wrist joint. The algorithm tracks the body landmarks given the input raw skeletal joints and the height-scaled biomechanical model of the patient. Since the algorithm cannot detect direct contact of the hand with the body, the reachability is determined based on the scaled distance from the inferred body landmarks. The distance from each of the seven landmarks is also normalized by an individual's hand length.

A distance threshold defined by a multiplier of the hand length is set around each landmark to determine when the hand enters the proximity region of the target. The minimal distance reached is noted and the reachability score is assigned to '1'. If the hand does not get close enough to the target, the reachability score is set to '0'. In addition, a confidence index between 0.0 and 1.0 is computed for each detected target. Confidence index close to 1.0 indicates higher likelihood that the target was reached.

Note: Since the criteria for detection is different for the algorithm (i.e. based on wrist proximity) as compared to the evaluator's observations (i.e. based on hand touch), the assigned detection rates may not always match.

FWS protocol instructions given during the video-guided feedback are provided in Appendix B: Video Protocol Transcripts for reference.

5.2 FWS Protocol Parameters

The following FWS protocol parameters are captured during the assessment by the Kinetigram**™** application:

- **Body Side:** [Left, Right]

  The evaluation is performed either with the left or right arm. The videos for both body sides are approximately (within 1-2 seconds) synchronized in motion guidance for all video conditions.

- **Video Speed:** [Normal, Slow]

  Default video speed for Kinetigram™ is set to 'Normal'. This corresponds to the assessment length of about 38 seconds. The slower version of the videos is available for subjects who may have difficulty following the instructions (e.g. elderly), therefore the video instructions are slowed down by about 30%. This corresponds to the assessment length of about 45 seconds.

5.3 FWS Clinical Scores

For the FWS protocol, the following clinical scores are reported by the Kinetigram™ Data Processing module:

- **Observed Target # Reachability:**

  Observed target reachability represents the observations made by the evaluator that were reported manually through the Kinetigram™ application. If a patient was able to touch the body landmark (target #), a score of 1 is assigned; otherwise a score of 0 is assigned. Observed target reachability is reported for each of the seven body landmarks.

- **Detected Target # Reachability:**

  Detected target reachability represents the observations determined by the algorithm based on the wrist motion analysis. If a patient is able to reach the proximity of the target (given the threshold), a score of 1 is assigned; otherwise a score of 0 is assigned. Detected target reachability is reported for each of the seven body landmarks.

- **Minimal Distance to Target #:**

  Minimal distance to target represents the minimal normalized distance (i.e. normalized to the hand length) between the wrist and the target when a reach to target was detected. Minimal distance is reported for each of the seven body landmarks.

- **Confidence Index #:**

  Confidence index between 0.0 and 1.0 is assigned to each target detection. The confidence score is a function of the target proximity obtained from the joint motion trajectories. The higher the confidence score, the more likely the target reachability was reliably determined. If target reachability is 0, then the confidence score is by default set to 1.0.

5.4 Performance Characteristics

The Data Processor determines the Functional Workspace proximity for reached targets (body landmarks) to be at least within 1.5 hand length distance (under ideal and noisy [+/-1cm] condition).

5.5 Additional Disclaimers

- Accuracy of Kinetigram may be reduced from specified for pediatric subjects.
- If the subject is unable to follow prescribed motions, the data may not be correctly computed.

6 Anthropometry

Kinetigram™ application also keeps track of the anthropometric data of patients as entered during their sessions. When creating a new patient, the user is required to enter patient's *gender*, *height*, *weight*, and *hand dominance*. During each session, height, weight, and specific arm measurements are also recorded.

The recorded arm measurements for each body side include:

1. Sternum-ACJ (Sternum to Acromioclavicular Joint)
2. ACJ-Olec (Acromioclavicular Joint to Olecranon)
3. Olec-UlnSty (Olecranon to Ulnar Styloid)
4. ACJ-UlnSty (Acromioclavicular Joint to Ulnar Styloid)

Note: Entering anthropometry data (i.e. arm measurements) is optional in the Kinetigram**™** client application. Thus, arm measurement information may not always be available for each recorded measurement session.

Note: If evaluator is unable to take a measurement, the output value is reported as '0.0'.

7 Data Outputs

The data summaries include the following three categories of data: (1) Reachable Workspace (RWS) analysis, (2) Functional Workspace (FWS) analysis, and (3) Anthropometry.

Important: Refer to specific Data Transfer Agreement for actual end-user variable names, categories, and data types. The list below is a general overview of the data values relevant for the data analysis as part of the Kinetigram**™** processed outputs.

7.1 Reachable Workspace:

Note: Reachable workspace can be analyzed for shoulder-to-wrist and shoulder-to-elbow trajectories. Both analyses report the same type of output scores as listed in the table below.

Output Variable	Description
Location Id	Site location identifier
Patient Id	Patient identifier
Session Date & Time	Date and time of the measurement session
Session Id	Internal unique (per tenant) session identifier
Protocol Level ['High', 'Low']	Protocol module used for the assessment. 'High' module includes motions above the shoulder, 'Low' module includes only motions below the shoulder level.
Protocol Speed ['Normal', 'Slow']	Protocol video speed used for the assessment
Weight (g)	Value of the added wrist weight as recorded by the evaluator

Output Variable	Description
Tested Side ['Left', 'Right']	Assessed side of the body
Data Rigified? [0, 1]	If '1', data was produces on rigified sequence; else if '0', data was produced on raw skeleton sequence
Notes	Optional session notes entered by the evaluator
Radius*	Radius of the reachable workspace envelope sphere defined by the motion data (mm).
Radius Residual*	Residual of the sphere fitting to the motion trajectory (mm). Value of the residual implies the deviation of the motion data from a spherical trajectory. Noisy trajectories will, in general, have higher value of the residual.
Q1 RSA	Relative Area of the quadrant Q1 of the reachable workspace envelope. Range: 0.0-0.25 (±0.05 deviation)
Q2 RSA	Relative Area of the quadrant Q2 of the reachable workspace envelope. Range: 0.0-0.25 (±0.05 deviation)
Q3 RSA	Relative Area of the quadrant Q3 of the reachable workspace envelope. Range: 0.0-0.25 (±0.05 deviation)
Q4 RSA	Relative Area of the quadrant Q4 of the reachable workspace envelope. Range: 0.0-0.25 (±0.05 deviation)
Q5 RSA	Relative Area of the quadrant Q5 of the reachable workspace envelope. Range: 0.0-0.25 (±0.05 deviation)
Total RSA (1-4)	Total Relative Surface Area of Quadrants Q1-Q4 of the reachable workspace envelope. Range: 0.0-1.0 (±0.05 deviation)
Total RSA (1-5)	Total Relative Surface Area of Quadrants Q1-Q5 of the reachable workspace envelope: Range: 0.0-1.25 (±0.05 deviation)
Q1 ASA*	Absolute Area of the quadrant Q1 of the reachable workspace envelope (m^2)
Q2 ASA*	Absolute Area of the quadrant Q2 of the reachable workspace envelope (m^2)
Q3 ASA*	Absolute Area of the quadrant Q3 of the reachable workspace envelope (m^2)
Q4 ASA*	Absolute Area of the quadrant Q4 of the reachable workspace envelope (m^2)
Q5 ASA*	Absolute Area of the quadrant Q5 of the reachable workspace envelope (m^2)
Total ASA (1-4)*	Total Absolute Workspace Area of Quadrants Q1-Q4 of the reachable workspace envelope (m^2)
Total ASA (1-5)*	Total Absolute Workspace Area of Quadrants Q1-Q5 of the reachable workspace envelope (m^2)

Important: Values marked with * are intermediate outputs of the computation and are reported for reference only. Values marked with * should not be used as clinical outcome scores. Outcome scores are marked in **Bold**.

7.2 Functional Workspace:

Output Variable	Description
Location Id	Site location identifier
Patient Id	Patient identifier
Session Date & Time	Date and time of the measurement session
Session Id	Internal unique (per tenant) session identifier
Protocol Speed ['Normal', 'Slow']	Protocol video speed used for the assessment
Tested Side ['Left', 'Right']	Assessed side of the body

Output Variable	Description
Data Rigified [0, 1]	If '1', data was produces on rigified sequence; else if '0', data was produced on raw sequence
Notes	Optional session notes entered by the evaluator
FWS Target Status*	Observed target status code as reported by the software. The value encodes the 7-bit value that represents the order of targets, expressed in a binary form with the following order of bits: [8][7][6][5] [4][3][2][1]. For example, reaching all targets, 0111 1111b -> 127 or reaching first four targets: 0000 1111b -> 15
Observed Target #1 Reachability	Observed Target 1 (Belt Level) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Observed Target #2 Reachability	Observed Target 2 (Back Pocket) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Observed Target #3 Reachability	Observed Target 3 (Shoulder) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Observed Target #4 Reachability	Observed Target 4 (Opposite Shoulder) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Observed Target #5 Reachability	Observed Target 5 (Mouth) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Observed Target #6 Reachability	Observed Target 6 (Top of the Head) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Observed Target #7 Reachability	Observed Target 7 (Back of the Head) as recorded by the evaluator in Kinetigram™ client application. '0' – target not reached, '1' – target reached.
Detected Target #1 Reachability	Detected Target 1 (Belt Level) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Detected Target #2 Reachability	Detected Target 2 (Back Pocket) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Detected Target #3 Reachability	Detected Target 3 (Shoulder) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Detected Target #4 Reachability	Detected Target 4 (Opposite Shoulder) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Detected Target #5 Reachability	Detected Target 5 (Mouth) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Detected Target #6 Reachability	Detected Target 6 (Top Head) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Detected Target #7 Reachability	Detected Target 7 (Back of the Head) as calculated by the software given the distance and detection threshold. '0' – target not reached, '1' – target reached.
Min Distance Target #1*	Distance index to Target 1 (Belt Level) normalized to hand length
Min Distance Target #2*	Distance index to Target 2 (Back Pocket) normalized to hand length
Min Distance Target #3*	Distance index to Target 3 (Shoulder) normalized to hand length
Min Distance Target #4*	Distance index to Target 4 (Opposite Shoulder) normalized to hand length
Min Distance Target #5*	Distance index to Target 5 (Mouth) normalized to hand length
Min Distance Target #6*	Distance index to Target 6 (Top Head) normalized to hand length
Min Distance Target #7*	Distance index to Target 7 (Back of the Head) normalized to hand length
Conf Index Target #1	Confidence index for Target 1 (Belt Level). Range: 0.0-1.0
Conf Index Target #2	Confidence index for Target 2 (Back Pocket). Range: 0.0-1.0

Output Variable	Description
Conf Index Target #3	Confidence index for Target 3 (Shoulder). Range: 0.0-1.0
Conf Index Target #4	Confidence index for Target 4 (Opposite Shoulder). Range: 0.0-1.0
Conf Index Target #5	Confidence index to Target 5 (Mouth). Range: 0.0-1.0
Conf Index Target #6	Confidence index for Target 6 (Top of the Head). Range: 0.0-1.0
Conf Index Target #7	Confidence index for Target 7 (Back of the Head). Range: 0.0-1.0
Dist Threshold Target #1*	Detection threshold for Target 1 (Belt Level) normalized to hand length
Dist Threshold Target #2*	Detection threshold for Target 2 (Back Pocket) normalized to hand length
Dist Threshold Target #3	Detection threshold for Target 3 (Shoulder) normalized to hand length
Dist Threshold Target #4*	Detection threshold for Target 4 (Opposite Shoulder) normalized to hand length
Dist Threshold Target #5*	Detection threshold for Target 5 (Mouth) normalized to hand length
Dist Threshold Target #6*	Detection threshold for Target 6 (Top of the Head) normalized to hand length
Dist Threshold Target #7*	Detection threshold for Target 7 (Back of the Head) normalized to hand length

Important: Values marked with * are intermediate outputs of the computation and are reported for reference only. Values marked with * should not be used as clinical outcome scores. Outcome scores are marked in **Bold**.

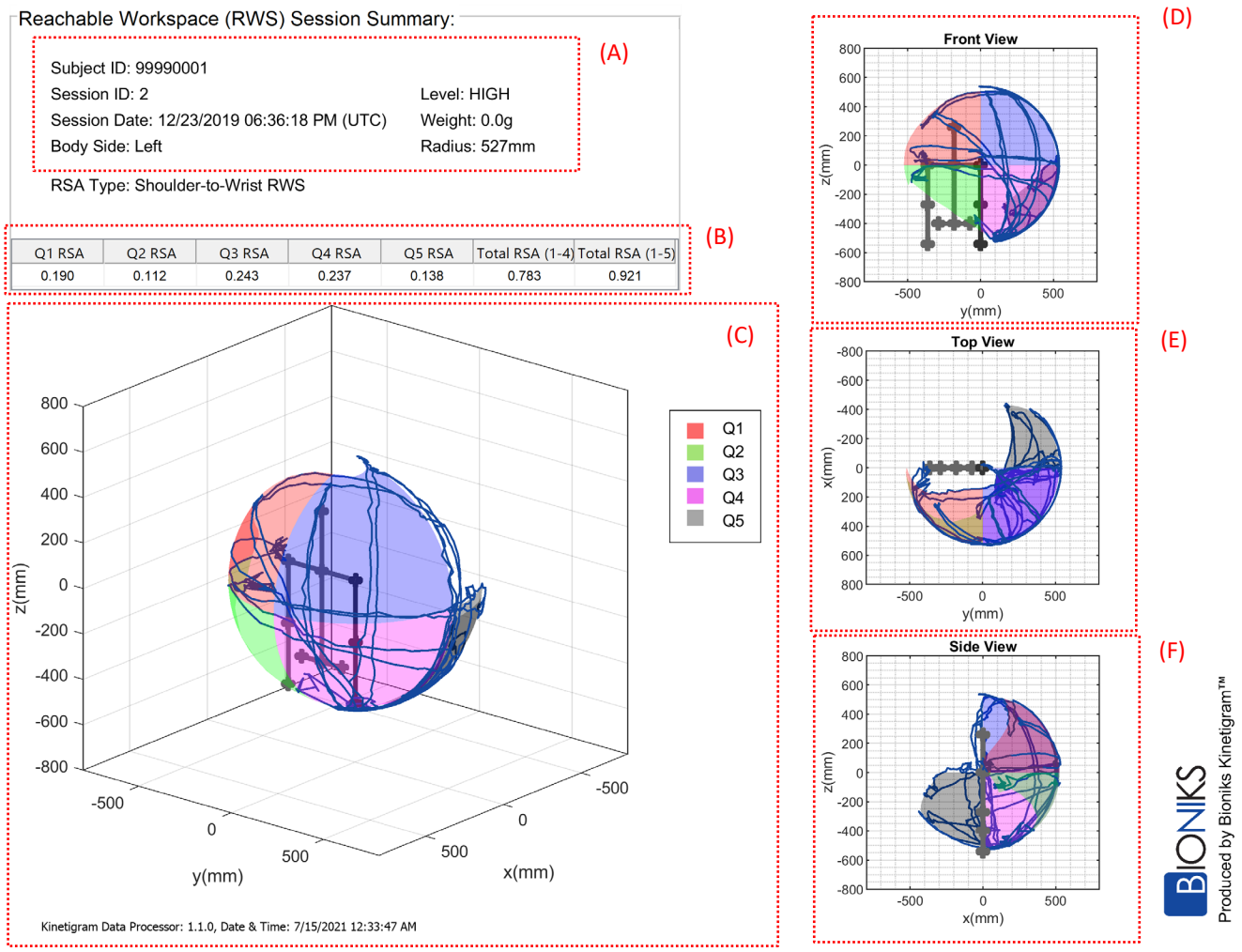
7.3 Anthropometry:

Output Variable	Description
Location Id	Site location identifier
Patient Id	Patient identifier
Session Date & Time	Date and time of the measurement session
Weight	Weight (kg)
Height	Height (cm)
Hand Dominance	Hand Dominance
Gender	Gender
Left Clavicle Length	Left Clavicle Length (cm), measured as distance between Sternum to Acromioclavicular Joint
Left Upper Arm Length	Left Upper Arm Length (cm), measured as distance between Acromioclavicular Joint to Olecranon
Left Forearm Length	Left Forearm Length (cm), measured as distance between Olecranon to Ulnar Styloid
Left AC to Wrist Distance	Left AC to Wrist Distance (cm), measured as distance between Acromioclavicular Joint to Ulnar Styloid
Right Clavicle Length	Right Clavicle Length (cm), measured as distance between Sternum to Acromioclavicular Joint
Right Upper Arm Length	Right Upper Arm Length (cm), measured as distance between Acromioclavicular Joint to Olecranon
Right Forearm Length	Right Forearm Length (cm), measured as distance between Olecranon to Ulnar Styloid
Right AC to Wrist Distance	Right AC to Wrist Distance (cm), measured as distance between Acromioclavicular Joint to Ulnar Styloid

Note*:* Values are reported as entered in the Kinetigram™ application. Other than unit conversion, where applicable, no other processing is performed on the input values.

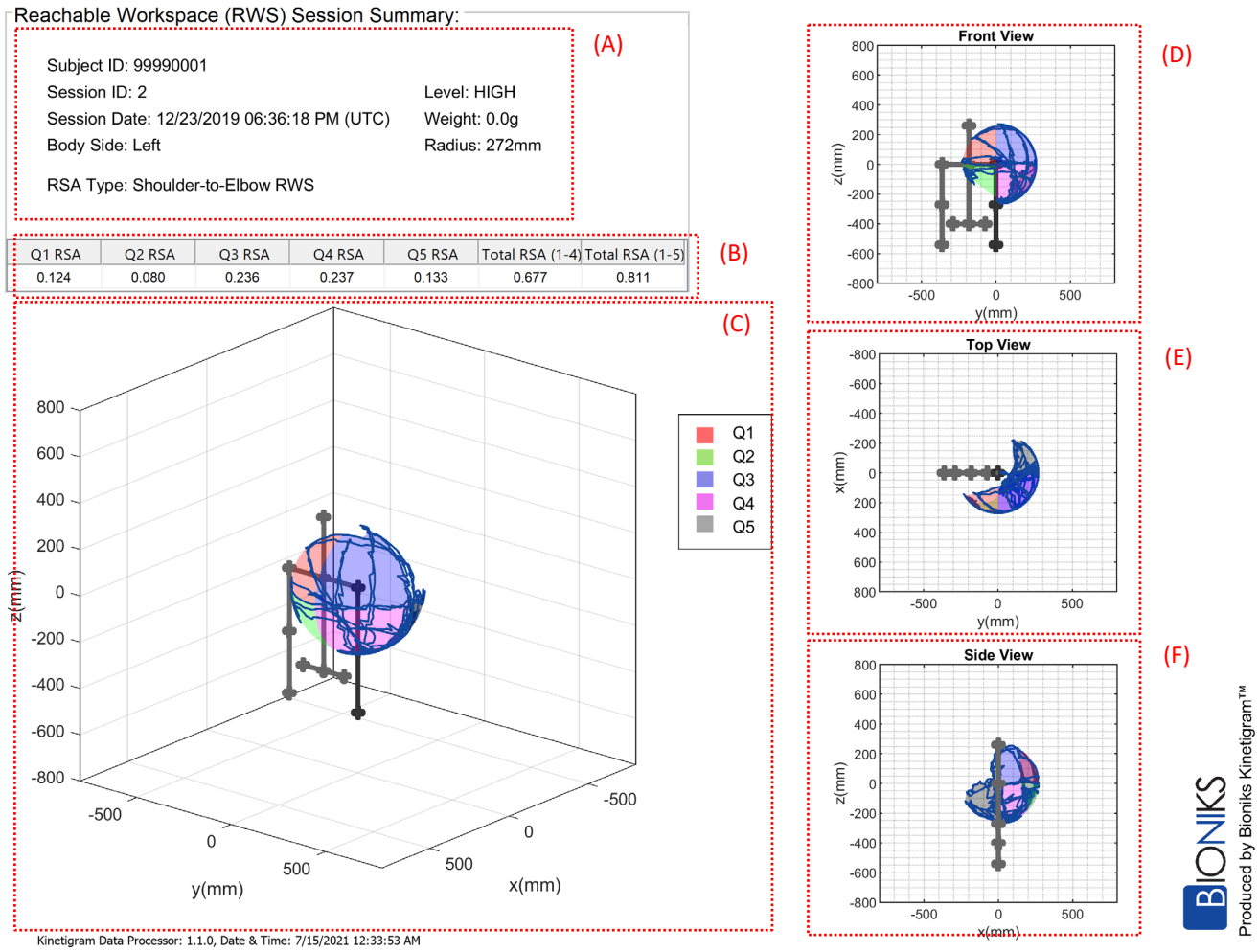
7.4 Graphical Report

Reachable Workspace:



Graphical report for the Standard Reachable Workspace analysis (shoulder-to-wrist):

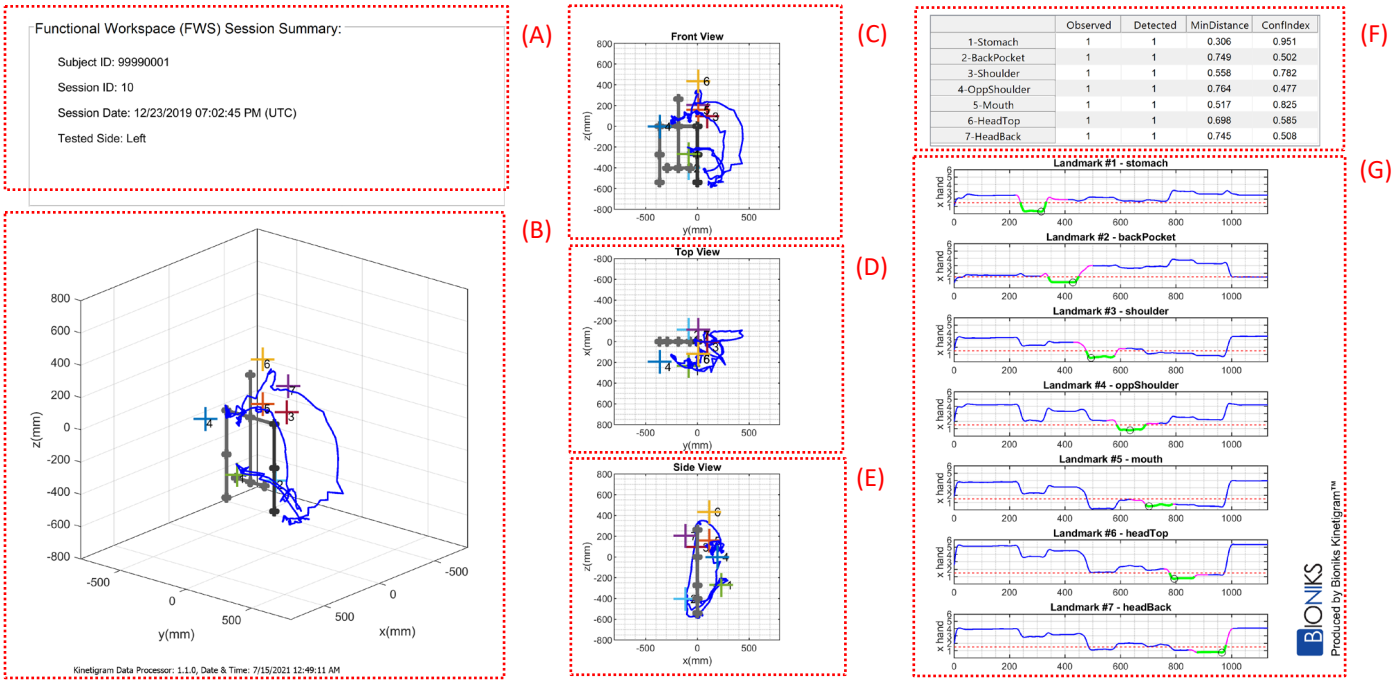
A – Session metadata with subject information (Note that session date/time is reported in UTC time).
B – Summary of reachable workspace clinical scores.
C – Three-dimensional plot of the reachable workspace envelope. The colors represent the different quadrants considered in the computation. Blue line represents the observed wrist trajectory transformed into the body-centric coordinate system. Stick figure depicts patient skeleton model of the upper body scaled for their height.
D – Front view of the reachable workspace envelope. Tested arm appears in the center of the grid.
E – Top view of the reachable workspace envelope. Tested arm appears in the center of the grid.
F – Side view of the reachable workspace envelope. Tested arm appears in the center of the grid.



Graphical report for the Elbow Reachable Workspace analysis (shoulder-to-elbow):

A – Session metadata with subject information (Note that session date/time is reported in UTC time).
B – Summary of reachable workspace clinical scores.
C – Three-dimensional plot of the reachable workspace envelope. The colors represent the different quadrants considered in the computation. Blue line represents the observed elbow trajectory transformed into the body-centric coordinate system. Stick figure depicts patient skeleton model of the upper body scaled for their height.
D – Front view of the reachable workspace envelope. Tested arm appears in the center of the grid.
E – Top view of the reachable workspace envelope. Tested arm appears in the center of the grid.
F – Side view of the reachable workspace envelope. Tested arm appears in the center of the grid.

Functional Workspace:



Graphical report for Functional Workspace analysis:

A – Session metadata with subject information (Note that session date/time is reported in UTC time).
B – Three-dimensional plot of the functional workspace tracing. Blue line represents the observed wrist trajectory transformed into the body-centric coordinate system. Stick figure depicts patient skeleton model of the upper body scaled for their height. Targets are labeled and their location is shown with colored crosses. Note that the location of the targets is adjusted for the wrist location.
C – Front view of the functional workspace tracing. Tested arm appears in the center of the grid.
D – Top view of the functional workspace tracing. Tested arm appears in the center of the grid.
E – Side view of the functional workspace tracing. Tested arm appears in the center of the grid.
F – Summary table of the Functional Workspace scores with the following columns:

- 'Observed' – evaluator reported reachability
- 'Detected' – Kinetigram™ reported reachability
- 'MinDistance' – minimal distance of the wrist from the landmark (normalized to hand length).
- 'ConfidenceIndex' – computed confidence score for reachability detection. The value is set to 1 if the target was not reached.

G – Timeseries of the distance scores for the seven body landmarks. Y-axis represents the distance normalized to individual's hand length and x-axis represents the frame count. The computed distance is shown with blue line. Purple line shows the search interval for a specific target as defined by the video feedback timings. Green line represents the detected peak range when target reachability is detected. Red horizontal line represents the distance threshold used for the reachability detection.

8 Reporting

Any serious incident that has occurred in relation to the device should be reported to the Bioniks and the

governing regulatory authority in your country (known as competent authority). A serious incident is an event that has led to any of the following:

- Death
- Serious deterioration in the health of the subject, that resulted in any of the following:
    - (i) life-threatening illness or injury,
    - (ii) permanent impairment of a body structure or a body function,
    - (iii) hospitalization or prolongation of patient hospitalization,
    - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment or a body structure or a body function,
    - (v) chronic disease,
- fetal distress, fetal death or a congenital physical or mental impairment or birth defect;

Please inform Bioniks by sending an email to help@bioniks.net and providing the product version number (found in the About Box), date of the incident, and details about the incident.

9 Decommissioning

Decommissioning of Kinetigram software is performed by Bioniks Service. The Kinetigram client application is removed from all accounts on the installed computer and all configuration files are deleted. The Kinetigram Server and Data Processor are cloud deployed services and are decommissioned at end of life for the product suite. If an account requires subject and user data to be removed from cloud resources and/or processed data, decommissioning will be handled according to the agreement with the account owner (e.g., data archiving, data removal).

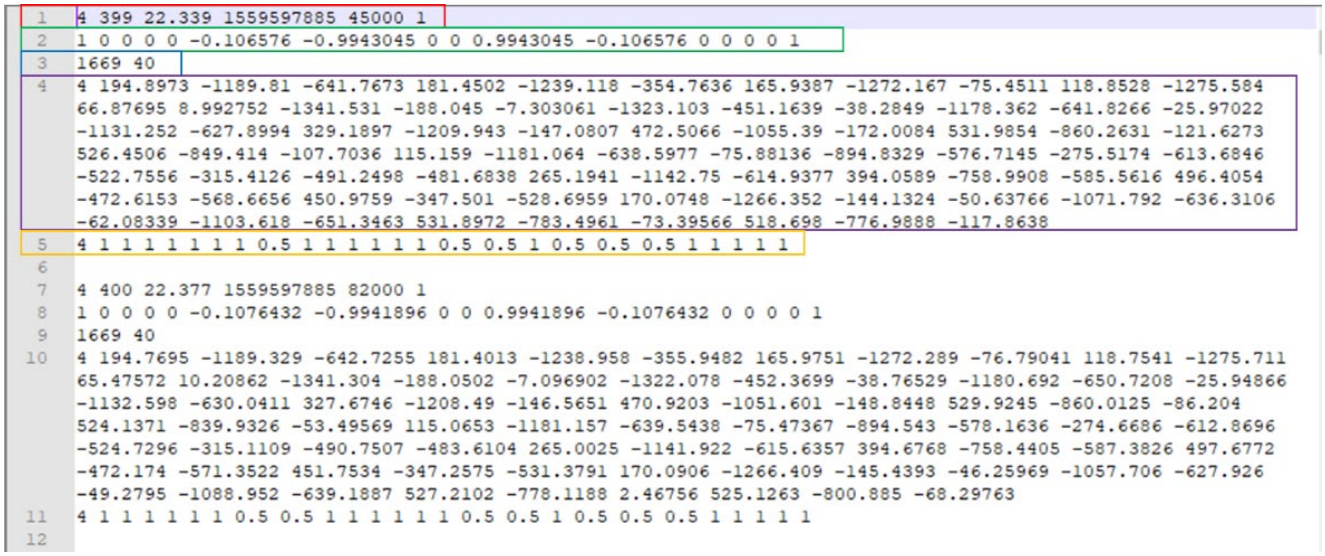
Please, contact Bioniks Service for decommissioning of Kinetigram software at help@bioniks.net.

10 Appendix A: Measurement Data Export Format

10.1 File Format

Using the Export Data function in the Kinetigram™ UI produces and ASCII file that contains measurement (skeleton) data for selected session. The file is saved in this default format: *[patient_id]_[YYYY-MM-dd]-[Evaluation Name].txt*, unless the user chooses a custom name during file export.

The skeleton data is stored inside the exported ASCII file in the following format (each line is defined below).



```
1  4 399 22.339 1559597885 45000 1
2  1 0 0 0 0 -0.106576 -0.9943045 0 0 0.9943045 -0.106576 0 0 0 0 1
3  1669 40
4  4 194.8973 -1189.81 -641.7673 181.4502 -1239.118 -354.7636 165.9387 -1272.167 -75.4511 118.8528 -1275.584
   66.87695 8.992752 -1341.531 -188.045 -7.303061 -1323.103 -451.1639 -38.2849 -1178.362 -641.8266 -25.97022
   -1131.252 -627.8994 329.1897 -1209.943 -147.0807 472.5066 -1055.39 -172.0084 531.9854 -860.2631 -121.6273
   526.4506 -849.414 -107.7036 115.159 -1181.064 -638.5977 -75.88136 -894.8329 -576.7145 -275.5174 -613.6846
   -522.7556 -315.4126 -491.2498 -481.6838 265.1941 -1142.75 -614.9377 394.0589 -758.9908 -585.5616 496.4054
   -472.6153 -568.6656 450.9759 -347.501 -528.6959 170.0748 -1266.352 -144.1324 -50.63766 -1071.792 -636.3106
   -62.08339 -1103.618 -651.3463 531.8972 -783.4961 -73.39566 518.698 -776.9888 -117.8638
5  4 1 1 1 1 1 1 1 0.5 1 1 1 1 1 1 0.5 0.5 1 0.5 0.5 0.5 1 1 1 1 1
6
7  4 400 22.377 1559597885 82000 1
8  1 0 0 0 0 -0.1076432 -0.9941896 0 0 0.9941896 -0.1076432 0 0 0 0 1
9  1669 40
10 4 194.7695 -1189.329 -642.7255 181.4013 -1238.958 -355.9482 165.9751 -1272.289 -76.79041 118.7541 -1275.711
   65.47572 10.20862 -1341.304 -188.0502 -7.096902 -1322.078 -452.3699 -38.76529 -1180.692 -650.7208 -25.94866
   -1132.598 -630.0411 327.6746 -1208.49 -146.5651 470.9203 -1051.601 -148.8448 529.9245 -860.0125 -86.204
   524.1371 -839.9326 -53.49569 115.0653 -1181.157 -639.5438 -75.47367 -894.543 -578.1636 -274.6686 -612.8696
   -524.7296 -315.1109 -490.7507 -483.6104 265.0025 -1141.922 -615.6357 394.6768 -758.4405 -587.3826 497.6772
   -472.174 -571.3522 451.7534 -347.2575 -531.3791 170.0906 -1266.409 -145.4393 -46.25969 -1057.706 -627.926
   -49.2795 -1088.952 -639.1887 527.2102 -778.1188 2.46756 525.1263 -800.885 -68.29763
11 4 1 1 1 1 1 1 0.5 0.5 1 1 1 1 1 1 0.5 0.5 1 0.5 0.5 0.5 1 1 1 1 1
12
```

1. Line 1

   [format version = 4] [frame number] [time since start in seconds] [unix epoch time seconds] [unix epoch time microseconds] [number of detected skeletons]

   NOTE: The following lines are included only if at least one skeleton was detected.

2. Line 2

   [row-major homogenous transformation matrix (4x4); 3D camera in world coordinate system]

3. Line 3

   [format flags] [delimiter format]

4. Line 4

   [format version] [x y z world coordinates for all 25 joints in units of mm]

   NOTE: Refer to Vector of 3D coordinates below to see the order of data points relative to skeletal joints

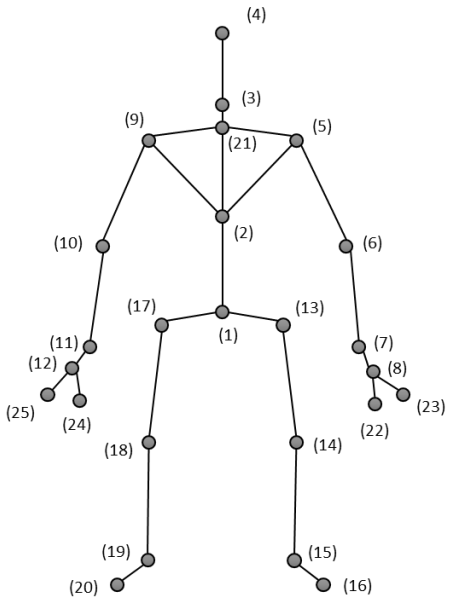
5. Line 5

   [format version] [joint visibility for all 25 joints: 0-not visible, 0.5-infered, 1-visible]

10.2 Vector of 3D Coordinates for all 25 Joints

The [x y z] coordinates for all 25 joints are listed in the following order:

1. SpineBase
2. SpineMid
3. Neck
4. Head
5. ShoulderLeft
6. ElbowLeft
7. WristLeft
8. HandLeft
9. ShoulderRight
10. ElbowRight
11. WristRight
12. HandRight
13. HipLeft
14. KneeLeft
15. AnkleLeft
16. FootLeft
17. HipRight
18. KneeRight
19. AnkleRight
20. FootRight
21. SpineShoulder
22. HandTipLeft
23. ThumbLeft
24. HandTipRight
25. ThumbRight



11 Appendix B: Video Protocol Transcripts

Instructional Video:

You are about to watch a video demonstration of different arm movements. The goal of the exercise is to measure how the shoulder moves in all directions. Try to follow along with the movements and speed as best as you can. Your arm should only be lifted up as high as it can go.

You will start with your arm along the side of your body. You will be asked to move your arm up to the side,

then lift your arm at 45 degrees which is diagonally away from your body

and finally lift your arm up in front of you. When asked to move your arm across your body, it will be to the opposite hip at the belt level and to the opposite shoulder, if you are able to do so. You are allowed to bend your elbow during these two actions, for everything else keep your arm straight. Briefly pause at the end of all arm movements.

Remember don't bend your elbow,

keep your back against the chair, don't twist to the side

and don't lean forward.

Please listen to the cues and follow the arm movements shown on the screen.

Reachable Workspace - HIGH FUNCTIONING

Starting with your arm by your side, palm facing forward and thumb facing to the side, lift your arm by your head as high as it goes.

Then come to a 45-degree angle and lift your arm by your head as high as it goes.

Then bring your arm forward and up as high as it goes.

Then bring your arm across your body as high as it goes.

Bring your hand to your side, at the belt level and move it across your body towards your opposite hip, you may bend your elbow. Then go back and move it behind you as far as it goes.

Next, with your arm straight, bring your hand to your shoulder level and move it across your body towards your opposite shoulder, you may bend your elbow. Then go back and move it behind you as far as it goes.

Then lift your hand above your shoulder level and move it across your body.

Now with your palm facing your leg, thumb facing forward, stretch your arm behind you as far as it goes and hold for a moment.

Reachable Workspace - LOW FUNCTIONING

Starting with your arm by your side, palm facing forward and thumb facing to the side, lift your arm as high as it goes.

Then come to a 45-degree angle and lift your arm as high as it goes.

Then bring your arm forward and up as high as it goes.

Then bring your arm across your body as high as it goes.

Bring your hand to your side, at the belt level and move it across your body towards your opposite hip, you may bend your elbow. Then go back and move it behind you as far as it goes.

Now with your palm facing your leg, thumb facing forward, stretch your arm behind you as far as it goes and hold for a moment.

Functional Workspace – Right Side

Start with your right hand by your side. Bring it to the front of your body at the belt level, then to your back pocket, up to your right shoulder, then to your left shoulder. If you're able to, bring your hand to your mouth, touch the top of your head and finally touch the back of your head. Now bring your hand back to the start position by your side.

Functional Workspace – Left Side

Start with your left hand by your side. Bring it to the front of your body at the belt level, then to your back pocket, up to your left shoulder, then to your right shoulder. If you're able to, bring your hand to your mouth, touch the top of your head and finally touch the back of your head. Now bring your hand back to the start position by your side.

European Authorised Representative:

CMC Medical Devices & Drugs, S.L.
C/ Horacio Lengo n18
C.P 29006
Málaga, Spain

Importer:

European Union
MedEnvoy Global BV
Prinses Margrietplantsoen 33 – Suite 123
2595 AM The Hague
The Netherlands

CE MD

Note: To obtain a paper copy of these Instructions for Use, please contact the Bioniks team (help@bioniks.net).