Kinetigram™ Instructions for Use

CAUTION (United States): Federal law restricts this device to sale by or on the order of a physician.
Document # 320-00201-EN-US-DO-02 Rev 11, 2026-10

Manufacturer:
Bioniks
2156 Central Avenue
Alameda, CA 94501
USA
help@bioniks.net
+1 (510) 747-1947
http://www.bioniks.net



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
	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

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	5.7.7 / 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	5.1.5 / Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified
	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

Table of Contents

1 Introduction 7
1.1 Indications for Use 7
1.1.1 Commercial Use 7
1.1.2 Investigational Use 7
1.2 Prescription Guidelines 7
1.3 Required Skills or Knowledge 7
1.4 Intended Clinical Benefits 7
1.5 Safety Information – Definitions 7
1.6 Safety Information – List of Cautions 7
1.7 Other Annotations 8
1.8 Software Version and Screenshots 8
1.9 Information, Error, and Warning Messages 8
2 Getting Started 9
2.1 Hardware and Software Requirements for Kinetigram 9
2.2 Installation 10
2.3 Setting Up the Environment 10
2.4 Initial Hardware Setup 11
2.5 Laptop Use 14
3 Initial Login 15
3.1 Starting application 15
3.2 Language Selection 16
3.3 Account Request and User Login 16
3.4 Password Reset 16
3.5 Initial Kinect v2 Setup 16
3.6 Initial Orbbec Camera Setup 18
3.7 Data Validation Test 19
3.8 How to Download Instructions for Use and Customer Release Notes 19
4 Data Changes 21
4.1 Editing Existing Record 21
4.2 Deleting Existing Record 21
4.3 Deleting a Session 22
5 User Management 23

5.1 User Management / Microsoft Azure Account Management 23
5.2 Create / Delete Users 23
5.3 User Management Page 23
5.4 Kinetigram User Types 24
6 Managing Study Groups 25
6.1 Creating New Group 25
6.2 Editing Existing Group 26
6.3 Deleting Groups 27
7 Managing Patients 27
7.1 Adding New Patient 28
7.2 Editing Existing Patient 28
7.3 Deleting Existing Patient 29
8 Instructions for Collecting Motion Data (Manual of Operations) 30
8.1 Step 1: Selecting Patient for Measurement 30
8.2 Step 2: Measure Study Participant's Upper Extremity Parameters 33
8.3 Step 3: How to Determine Whether to Use the High or Low Function Module 35
8.4 Step 4: Perform RWS/FWS Assessment – Begin Data Collection 38
8.5 Double Checking the Data 47
8.6 Camera System Check when taking Measurements 48
8.7 Additional References 50
9 Kinetigram Use in Pediatric Population 50
9.1 Introduction 50
9.2 System Setup 50
9.3 Subject Placement & Instructions 51
9.4 Additional Safety Considerations 52
9.5 Additional Disclaimers 52
10 Video Protocol Transcripts 54
11 Performance Characteristics 55
12 Troubleshooting 55
12.1 Server Connection Issue 55
12.2 Kinect Camera Issues 57
12.3 Orbbec Camera Issues 58
12.4 Software and Hardware Issues 59
12.5 Other Issues - Contact Bioniks Team 60
12.6 Remote Access for Bioniks Team Support 61

13 Audit Logs 61
14 Reporting 61
15 Decommissioning 62
16 Appendix A: Measurement Data Export Format 63
16.1 File Format 63
16.2 Vector of 3D Coordinates for all 25 Joints 64

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 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. Kinetigram is intended to be used for multiple patients and multiple use.

1.1.2 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.

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.
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).

1.7 Other Annotations

Terms used in this Instructions for Use:

Notes: 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.

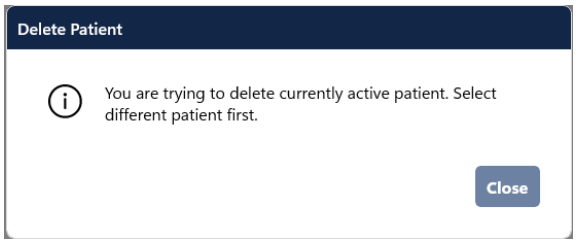
1.8 Software Version and Screenshots

This document is designed for use with both **Kinect Client** and **Orbbec Client**. While the majority of the functionality is consistent across both versions, any differences specific to each client are clearly outlined within the instructions. There may be slight differences in the user interface between the different versions of Kinetigram. In cases where these differences are minor, screenshots will be provided for only one version to illustrate the functionality. For significant differences, specific instructions and visuals are updated and included for each client version to ensure clarity.

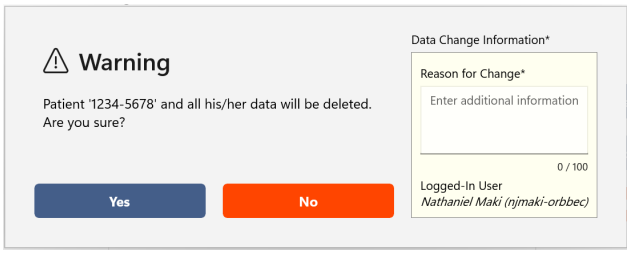
1.9 Information, Error, and Warning Messages

Within the software the following pop-up boxes may be encountered. Note that the term Warning and the symbol for warning is the standard Windows-type computer warning and not the regulatory definition of warnings (where there is reasonable evidence of an association of a serious hazard with the use of the software). Risk assessment of the device has shown there are no risks that could lead to serious hazards with this device.

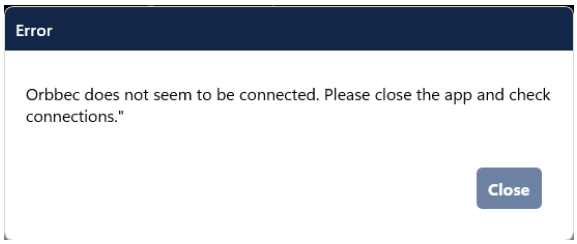
Information messages are indicated with the pop-up box with the symbol ⓘ, e.g.:



Warnings in the software are indicated with the pop-up box that includes symbol ⚠, e.g.:



Errors in the software are indicated with the pop-up box that is titled Error, e.g.:



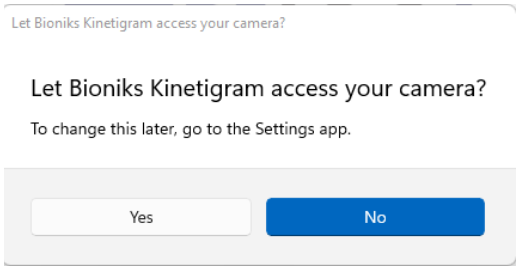
2 Getting Started

2.1 Hardware and Software Requirements for Kinetigram

The Kinetigram software requires the following hardware configuration to operate:

- If using **Kinect V2 Camera system**
  - Microsoft Kinect sensor for Xbox One with Kinect Adapter for Windows (Xbox One S/Xbox One X)
  - Standard PC (desktop or laptop) with the minimum hardware and software requirements:
    - CPU: Quad-core i5 2.1 GHz, 64-bit
    - RAM: 8GB
    - Dedicated USB 3.0 Bus (Intel or Renesas chipset)
    - Graphics Card: DX11 Capable Graphics Card (e.g., Intel 4400+, Nvidia GeForce GT 640+)
    - Windows 11 Operating System: 64-bit, version 22H2 (Build 22621)
    - Latest Kinect Sensor drivers obtained through Windows Update
- If using any **Orbbec Camera system**
  - Orbbec Femto Bolt camera
  - Standard PC (desktop or laptop) with the minimum hardware and software requirements:
    - CPU: Intel Core 7-240H Series 2, 10 cores, 64-bit
    - RAM: 16GB
    - Dedicated USB 3.0 Bus (Intel Chipset)
    - Graphics Card: Nvidia GPU with CUDA 11.0+ support (e.g., Nvidia GeForce RTX 5060+)
    - Windows 11 Operating System: 64-bit, version 22H2 (Build 22621)

- Note: Initial connection of the 3D camera may require setting permissions to allow the software to access the camera output. This should be done by Bioniks Service personnel during software installation.



- Active internet (Ethernet or WiFi) connection

The TV monitor should have the following minimum specifications:

- Diagonal dimension: 21in (53.3cm)
- Resolution: 1920x1080

2.2 Installation

Installation of Kinetigram must be performed by Bioniks team personnel.

2.3 Setting Up the Environment

- To correctly track the movement during performance of Kinetigram protocols, the camera must be positioned at the distance of about **90 in (230 cm) for Kinect** and **72 in (182 cm) for Orbbec** from the participant and the height of 45 in (115 cm) as shown in the figures below. The 3D camera should be pointed towards the participant, while the angle should be adjusted so that the camera captures their feet and the tip of the arm when fully extended above the head. The location of the chair and TV stand should be marked with tape for easy placement for subsequent testing sessions. Assessment should always be performed in the same location if possible.

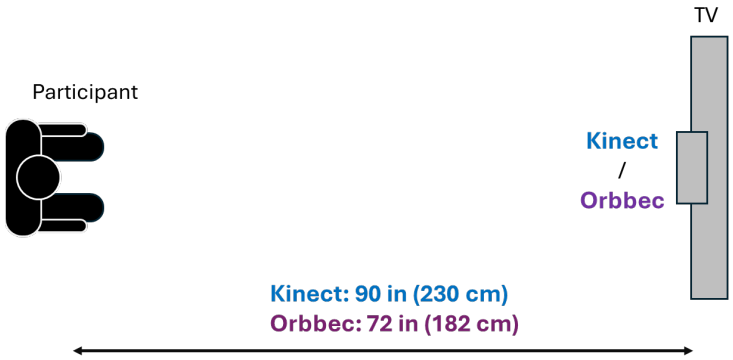


Figure 1: Kinect setup. Top View.

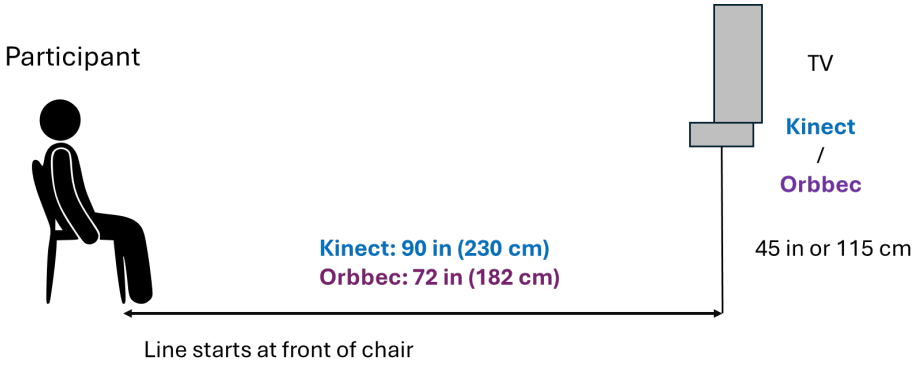


Figure 2: Kinect setup. Side View.

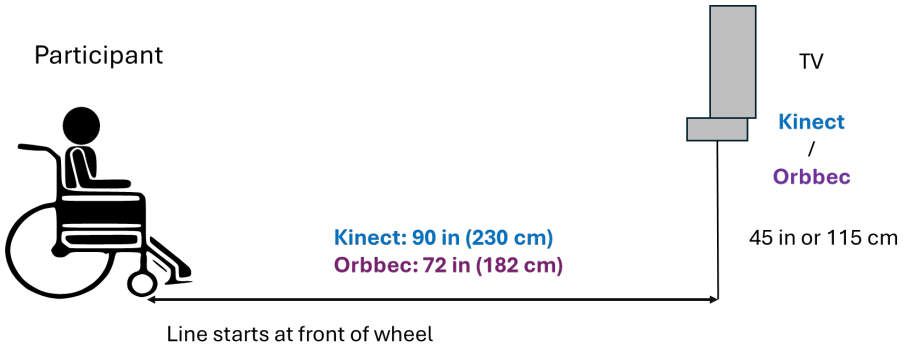


Figure 3: Kinect setup for patient in wheelchair. Side View.

Additional Requirements:

- **Note:** Make sure there is enough lighting in the room. Insufficient light may reduce the frame rate of the capture.
- **Note:** There should not be any visual obstruction between Kinect sensor and participant. Please try to remove as much clutter around the space/room.
- **Note:** There should not be any nearby objects, clutter, window or curtain behind the participant.
- **Note:** Participant should have no loose articles of clothing.
- **Note:** Family member should not be in proximity of the participant.
- ***Important:*** If space is limited, do not try to move the camera sensor away from the edge of the shelf. Contact Bioniks for additional troubleshooting.
- ***Important:*** Make sure the participant is at least 3 to 4 ft (0.91m to 1.22m) away from a wall to provide clearance during movement.
- ***Important:*** Avoid direct sunlight on the sensor and the participant as it may interfere with the measurement.
- ***Important:*** Make sure all connection and power cables are secured to avoid tripping/falling.

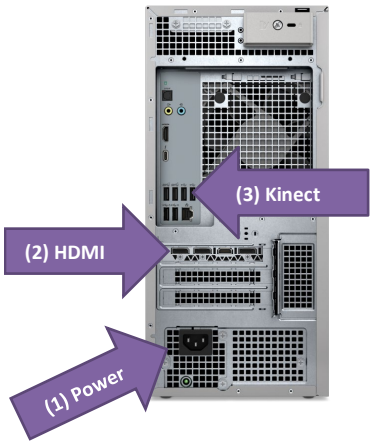
2.4 Initial Hardware Setup

If using **Kinect v2**

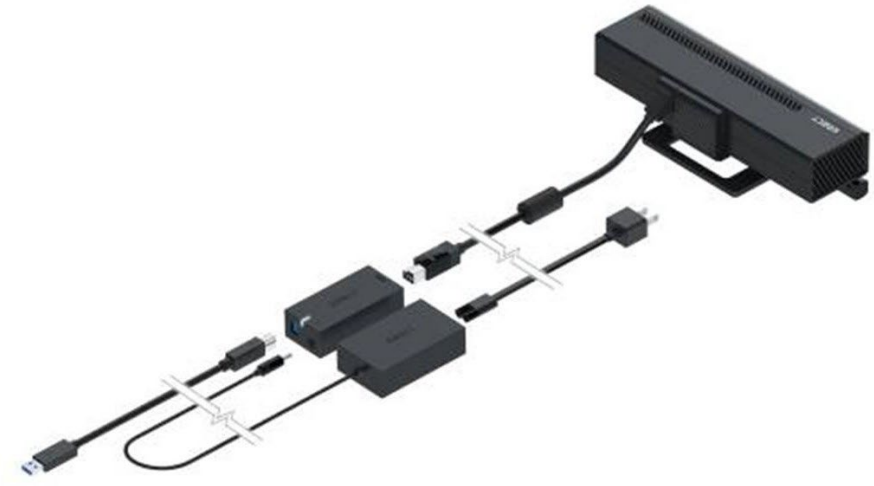
- Connect all components to the computer as shown in the figure below. The layout of the ports may be different depending on the desktop/laptop model used. Refer to the Study Manual for more details, if applicable.
    - Connect HDMI cable to the TV and the other side to the PC video output.
    - Connect Microsoft Kinect USB adapter to the back of the PC or USB3 port of the laptop (any of the

blue USB3 slots with SS symbol).

- Connect the power cable/adapter.



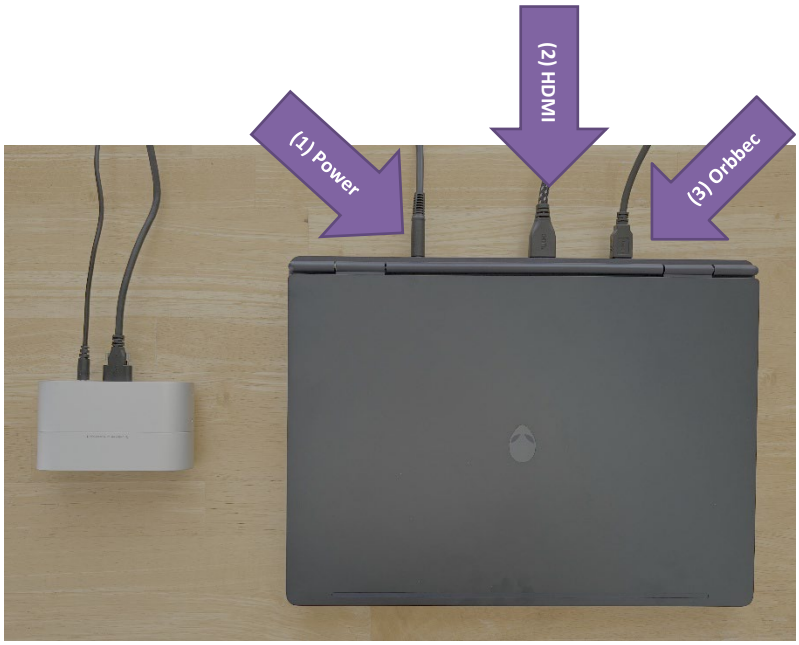




- Further information about Microsoft Kinect camera can be found at Microsoft Support page: https://support.xbox.com/en-US/help/hardware-network/kinect/kinect-for-windows-v2-setup-with-adapter

If using **Orbbec Camera**:

- On the laptop computer, connect all components as shown in the figure below (this may have been done already during the initial equipment assembly). Please check that all cables are secure and connected properly before connecting them to the laptop.



  - Connect the laptop to the power adapter (**arrow 1**).
  - Connect one end of the HDMI cable to the TV HDMI -1 port and the other end to the PC video HDMI cable input (**arrow 2**).
  - Connect all the components of Orbbec as shown:



  - Additional information about the Orbbec camera is available on the support pages provided by Orbbec: https://www.orbbec.com/developers/device-support/

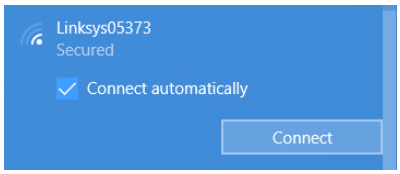
- Orbbec Femto Bolt camera regulatory compliance and certificates can be obtained at: https://doc.orbbec.com/documentation/Orbbec Femto Bolt Documentation/Regulatory Compliance and Certificates (Femto Bolt)

- Once all hardware components are connected, turn on the TV (monitor) and then press the power button on the laptop. You can now access the computer and begin the Initial Login process.

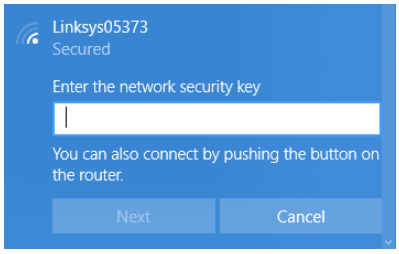
Connect Ethernet or Wi-Fi

Check with IT Personnel if the computer can be connected to the wired internet. If so, the Ethernet cable for the clinic/hospital network should be connected on the back of the PC. Windows may need to be configured manually for internet access.

If using Wi-Fi, select your Wi-Fi network by clicking on the symbol on your login screen taskbar. Select Connect:



And enter your security key:



Check with your IT Personnel to obtain the required registration credentials.

- Connect Mouse and Keyboard

The mouse and keyboard can be connected to any of the free USB ports. If using wireless mouse and keyboard, a USB dongle will be supplied. The dongle should be inserted into one of the front USB ports or free USB port on the laptop. Make sure that you turn on or enable the power on your wireless keyboard and mouse.

Once all of the hardware components are connected, turn on the TV (monitor) and press the power button on the PC. You are now ready to access the computer and start the Initial Login process.

2.5 Laptop Use

If using a laptop for Kinetigram, the laptop should adhere to the same specifications as outlined in Section 2.1. The laptop should always be powered by the external power supply when collecting data. External screen can be used via HDMI or other display connector. The camera sensor should always be connected to USB 3.0 or higher USB slot, marked with the symbol SS. Avoid connecting other USB devices to the same side of the laptop.

3 Initial Login

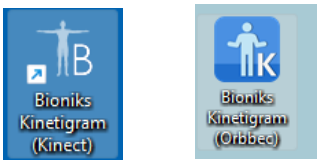
3.1 Starting application

Once you turn on the computer, you will be prompted with the Windows 10 login screen where you can use your credentials to log into Windows. For computers configured by Bioniks, you will be provided with login information for two pre-configured accounts: Standard Windows User account and Administrative Windows User account. The Standard Windows User account should be used to perform the measurements with Kinetigram software while the Administrative Windows User account can be used to manage the computer (e.g. performing necessary updates, installing software etc.).

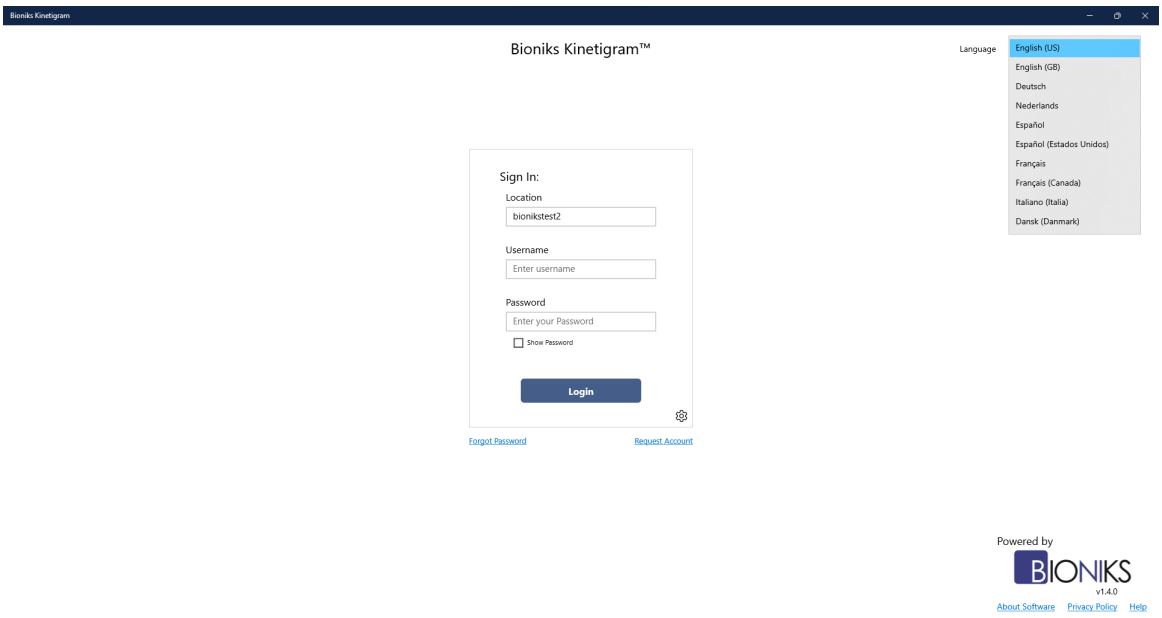
Important: For security reasons, the app should only be used under the Windows Standard User (non-administrative) account.

Important: Before running the Kinetigram application, ensure that the computer is connected to the Internet, either through wireless (Wi-Fi) or wired (LAN) connection. Active internet connection is required to operate the software.

Once you log into the computer, open Bioniks Kinetigram program on the Desktop or through the Start menu. Select the applicable version of the Kinetigram application that is installed under your account.



Once Bioniks Kinetigram is started, the application will display the Login Page.



***Important*:** Do not run any other software while conducting procedures as the software may interfere with data collection.

3.2 Language Selection

Prior to logging in to Kinetigram, select the preferred language for the user interface (on the login page). To do this, click on the language selector drop down menu (upper right corner), and select preferred language. Note, the language can be changed at any time during a session by logging out of the software and returning to the login page. Additionally, the audio portion of the patient measurement videos are provided in the local language and can be independently selected on the measurement page. As with the user interface, video language can be changed at any time. Default audio language is pre-set with the installation of the software.

3.3 Account Request and User Login

Kinetigram Login information is managed by Bioniks through Microsoft Azure B2C authentication service[1]. A request for new users should be sent to help@bioniks.net.

3.4 Password Reset

If you forget your password, you can request a password reset from the Kinetigram login page by clicking on the Reset Password link. The link will open a web form where you can request the password reset. You will need to enter your username and email address used to sign up for the account. If account is verified, instructions to reset the password will be sent to this email address. If you do not know your username, please send email to help@bioniks.net for further instructions.

3.5 Initial Kinect v2 Setup

Before performing the first measurement and each time the system is repositioned, you should ensure that the Kinect camera is set up correctly. Please refer to the sections 2.3for positioning the Kinect camera and chair and setting up the system hardware.

Once the Kinect is correctly connected, you should verify that the camera sees the participant. To open the camera view, select Kinect Setup from the Menu. Kinect System Check window will open. The Kinect System Check performs several diagnostics checks to ensure that the system is properly set up for recording:

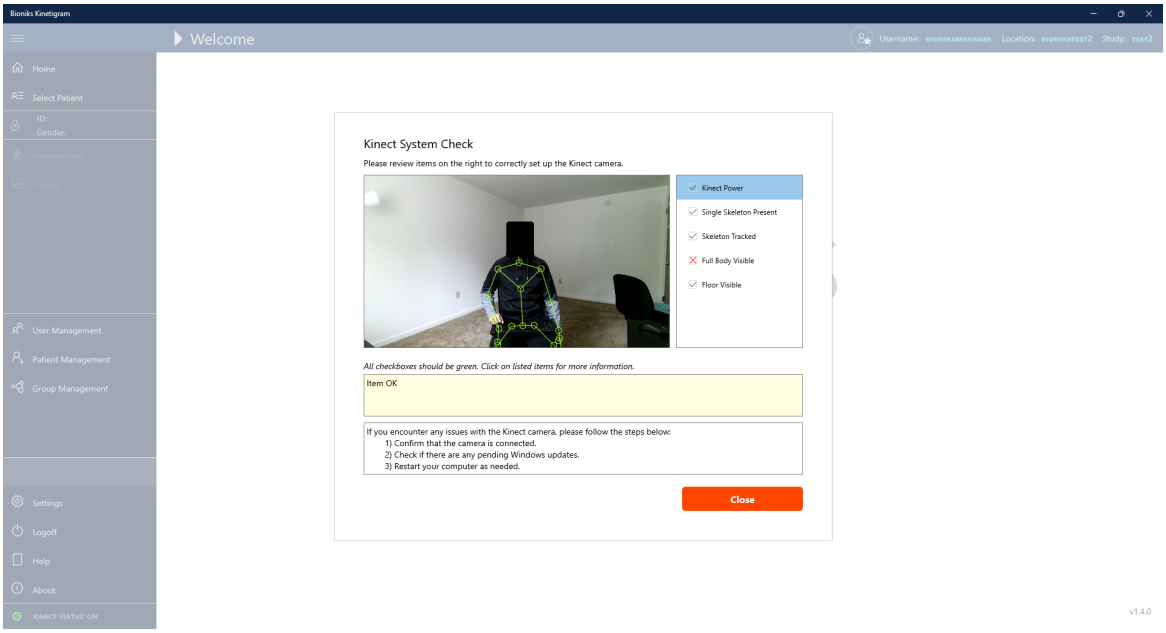
1. Kinect Power – checks that the Kinect camera is powered and running with at least 15 FPS
2. Skeleton Tracked – checks that the skeleton tracking is active
3. Single Skeleton Present – checks that only one person is tracked
4. Full Body Visible – checks that the tracked skeleton is fully visible and not occluded
5. Floor Visible – checks that the Kinect system is able to detect the floor and confirms that the vertical distance from the floor is at least 31.5 in (80 cm)

If the item check has passed, a green checkmark will be shown: ✓ .

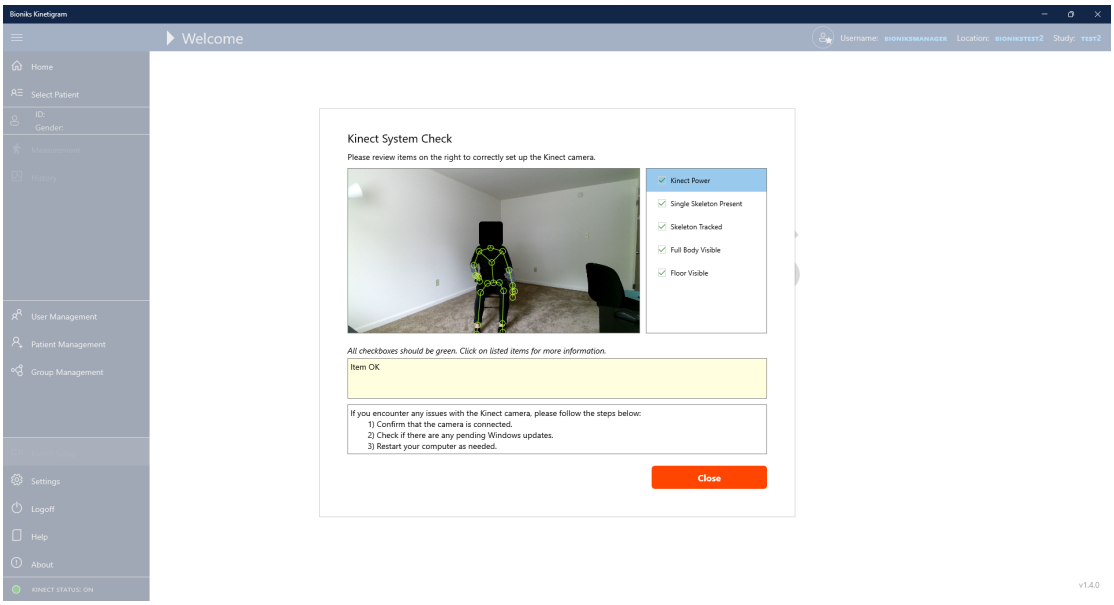
If the item check has failed, a red checkmark will be shown: ✗ .

To obtain more information on each item, select the item from the list. The information on how to mitigate the issue will be shown in the yellow rectangular area. In the figure below, the participant is too close to the camera and their feet are not showing, therefore Full Body Visible item is checked with a red checkmark.

[1] https://learn.microsoft.com/en-us/azure/active-directory-b2c/overview



Once the participant is moved further to the back, all five checkmarks are green, and the system is correctly set up for the measurement.



The following tips may be helpful to obtain all green checkmarks:

- Position the chair at the correct distance as shown in Figure 1 and Figure 2.
- Ensure that the Kinect camera is at correct height according to Figure 2.
- Ensure that there is no direct sunlight on the subject or camera that would interfere with the tracking.
- Ensure that correct chair is used for the assessment.

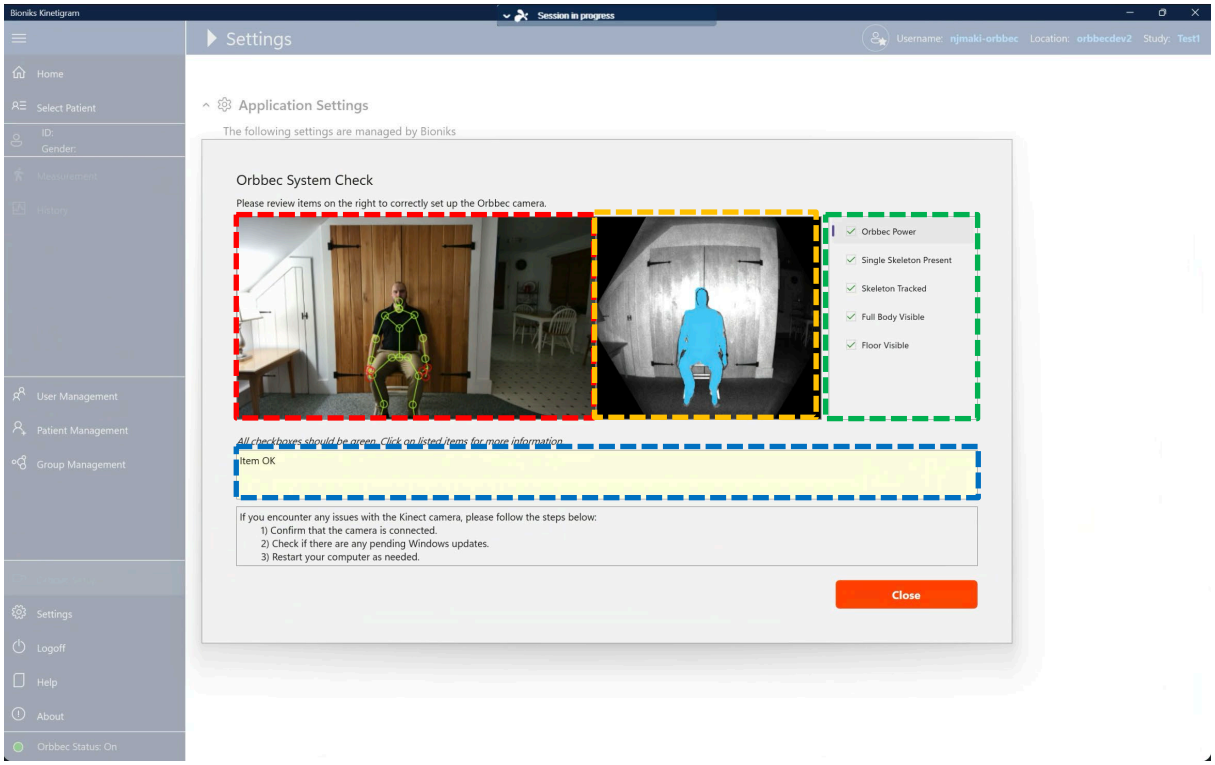
- Adjust/point/tilt the camera so that the subject's feet are visible in the image. Make sure the full body is visible (when arm is fully extended above the head) and feet are apart on the ground.
- Ensure that the floor in front of the subject is free of obstacles.
- Ensure that the Kinect camera is mounted at least 31.5 in (80 cm) off the ground.

Important: Ensure that all Kinect System Check items are checked as valid to perform measurements with participants.

3.6 Initial Orbbec Camera Setup

Ensure that the Orbbec camera is connected to the computer and correctly set up if the system was moved since last assessment. Run Orbbec Setup from the menu.

- Ensure that the IR view (right side), highlighted in **Orange**, has the full avatar (light blue figure) visible in the scene, even if parts of the subject are not fully visible in the color view, highlighted in **Red**.
- Ensure that the Diagnostic check, highlighted in **Green**, shows all green checkmarks across the board, that upon selection, report **Item OK**, in the box highlighted in **Blue**.



The following tips may be helpful to obtain all green checkmarks:

- Position the chair at the correct distance as shown in Figure 1 and Figure 2.
- Ensure that the Orbbec camera is at correct height according to Figure 2.
- Ensure that there is no direct sunlight on the subject or camera that would interfere with the tracking.
- Ensure that correct chair is used for the assessment.
- Adjust/point/tilt the camera so that the subject's feet are visible in the image. Make sure the full body is visible (when arm is fully extended above the head) and feet are apart on the ground.

- Ensure that the floor in front of the subject is free of obstacles.
- Ensure that the Orbbec camera is mounted at least 31.5 in (80 cm) off the ground.

Important: Ensure that all Orbbec System Check items are checked as valid to perform measurements with participants.

3.7 Data Validation Test

Important: Before collecting data on study participants, each evaluator is required to collect a validation dataset that is verified by the Bioniks team.

The evaluator should use a volunteer (healthy) to test under the Control Group. Use the following protocol as an example:

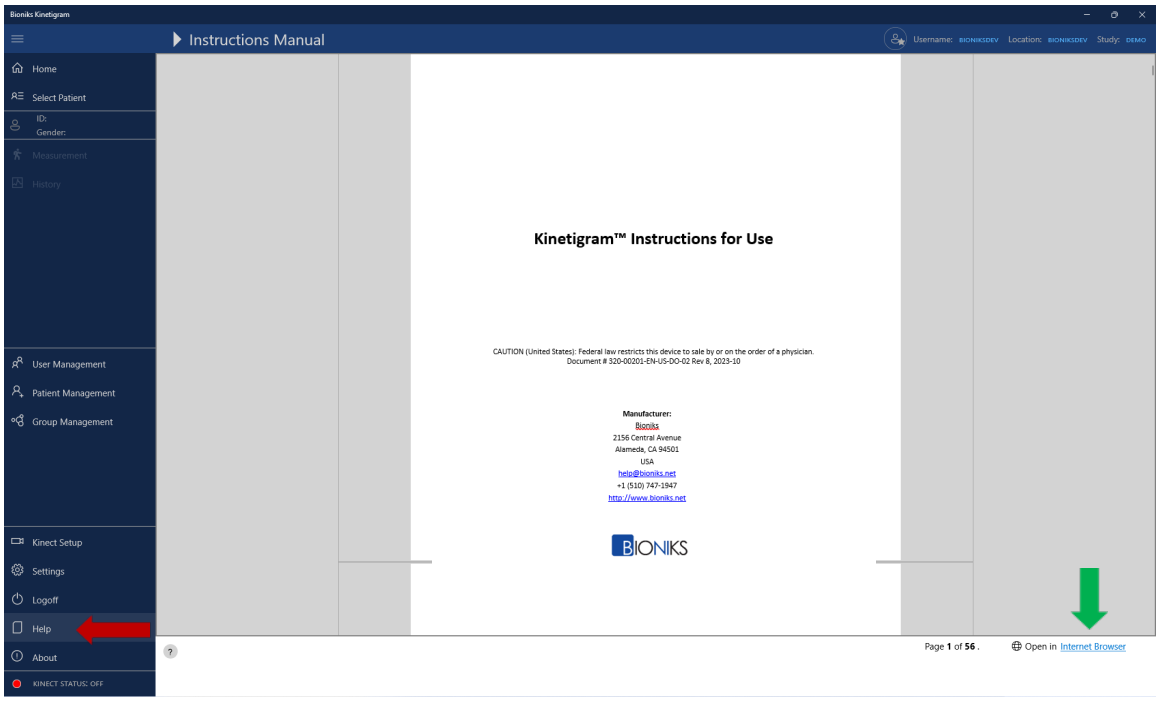
Evaluation	***Module***	***Level***	***Speed***	***Side***	***Weight***
1	Reachable Workspace (RWS)	High	Normal	Right	No
2	Reachable Workspace (RWS)	High	Normal	Left	No
3	Reachable Workspace (RWS)	High	Normal	Right	Yes, 500g
4	Reachable Workspace (RWS)	High	Normal	Left	Yes, 500g
5	Functional Workspace (FWS)	High	Normal	Right	No
6	Functional Workspace (FWS)	High	Normal	Left	No

Refer to section “Instructions for Collecting Motion Data (Manual of Operations)” (7) on how to perform these measurements. Once the data is collected, the evaluator should contact the Bioniks team to perform the data analysis.

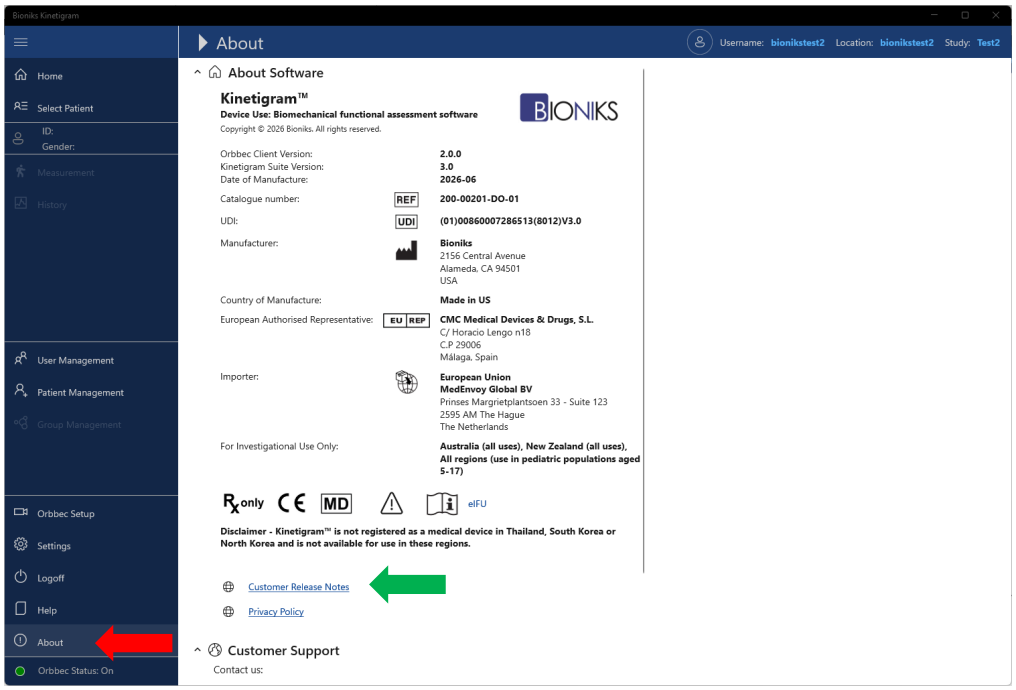
Important: For clinical studies, refer to study-specific Manual of Operations for the data collection protocol for Quality Control (QC).

3.8 How to Download Instructions for Use and Customer Release Notes

The *Instructions for Use* are available to view within the Kinetigram application by selecting Help in the menu (red arrow). Use <PgUp>/<PgDn> keys or your mouse scroller to change between pages in the document. You can also use <Ctrl>+<Mouse Scroll> to zoom in/out the document. For better viewing experience or printing, you can open the *Instructions for Use* in external PDF Viewer by clicking on Open in Internet Browser link at the bottom of the screen (green arrow).



Customer Release Notes are accessible by clicking on the About button in the menu (red arrow) and clicking on the link to Customer Release Notes link (green arrow). This will open the Bioniks website where the Customer Release Notes can be opened by clicking on the link for the desired language in the default PDF Viewer on your system (e.g., Edge, Acrobat Reader).



4 Data Changes

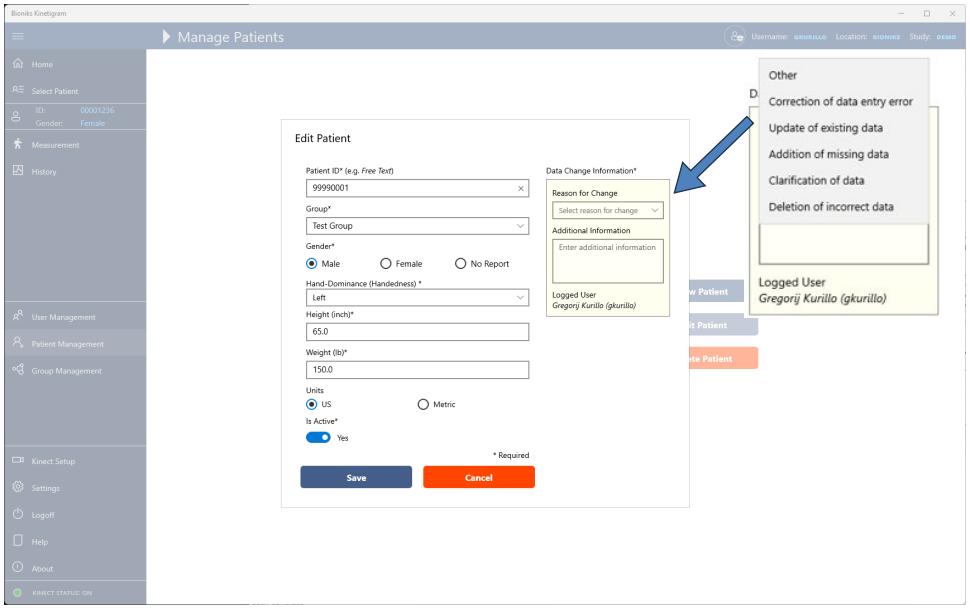
The Kinetigram software is designed to record all changes to patient, group, session, and anthropometric data, including deletions. These changes require user to provide a "reason for change" that is captured in the edit dialogs for each data type. This is necessary to fulfill audit requirements associated with the FDA regulation: 21 CFR Part 11, for electronic records.

The reason for change dialog includes two fields:

1) Reason For Change: A pre-defined drop-down selection (**required**)
2) Additional Information: An open entry box to provide any additional information, **required** when the reason for change is "Other".

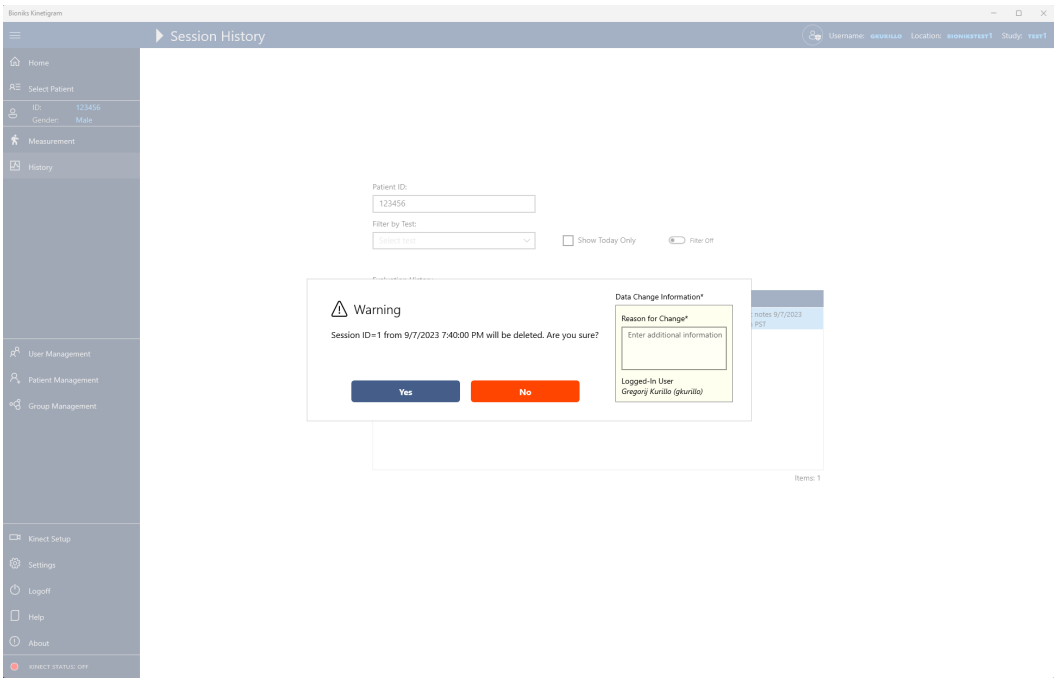
4.1 Editing Existing Record

Below is an example dialog for editing patient information, with a pop-out showing the pre-defined list of available items in the Reason for Change list:



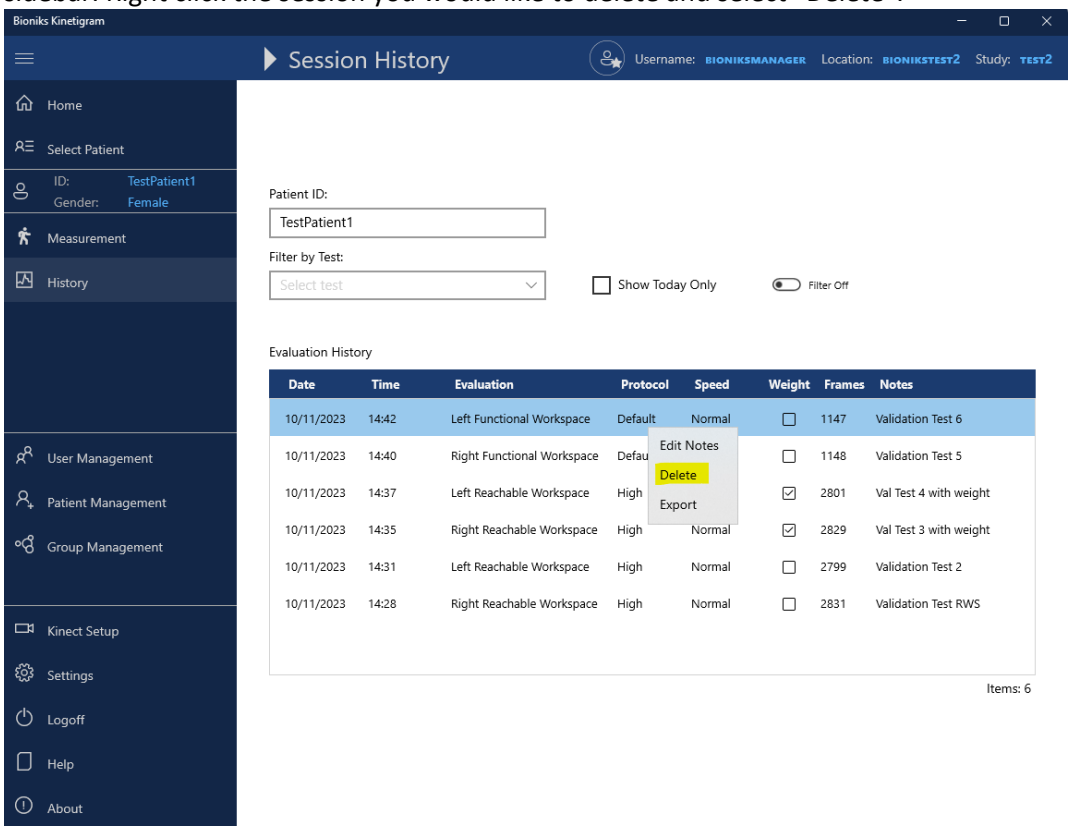
4.2 Deleting Existing Record

When deleting a record, such as a subject with no data or a recorded session (for specific instructions on deleting a session see 4.3), a warning dialog is presented. This dialog prompts the user to enter a reason for deleting the data under the Reason for Change section before proceeding with the deletion of the record. Note that activities related to deleting records can only be executed by Power Users.



4.3 Deleting a Session

Sessions can only be deleted by users who have Power User or Administrator privileges. To delete a session for a specific patient, click on "Select Patient", select the patient from the list, and then navigate to “History” on the sidebar. Right click the session you would like to delete and select “Delete”.



After selecting “Delete”, the warning dialog seen in 4.2 is presented. Fill out the Reason for Change and select “Yes”. The session will then be removed from the list shown in “History”.

5 User Management

5.1 User Management / Microsoft Azure Account Management

Kinetigram User information and authentication is managed by Microsoft Azure B2C authentication service. The authentication service is built on the Azure Active Directory (Azure AD) identity platform, an enterprise-grade cloud identity and access management solution. Accounts that are required for Kinetigram access are local accounts (local to the Azure directory) only, stored in a single secure cloud space managed by Bioniks, on servers in the US. No authentication or personal information is shared or retrieved from third party services such as social media platforms. The Azure framework and Bioniks Kinetigram application are compliant with the General Data Protection Requirement (GDPR). Therefore, the following individual rights are maintained:

- Bioniks will never share any information with a third party.
- Users can see and edit all data associated with their identity.
- User account and all data related to a user’s identity can be deleted.
- Breach notifications must be communicated to a site if they occur.

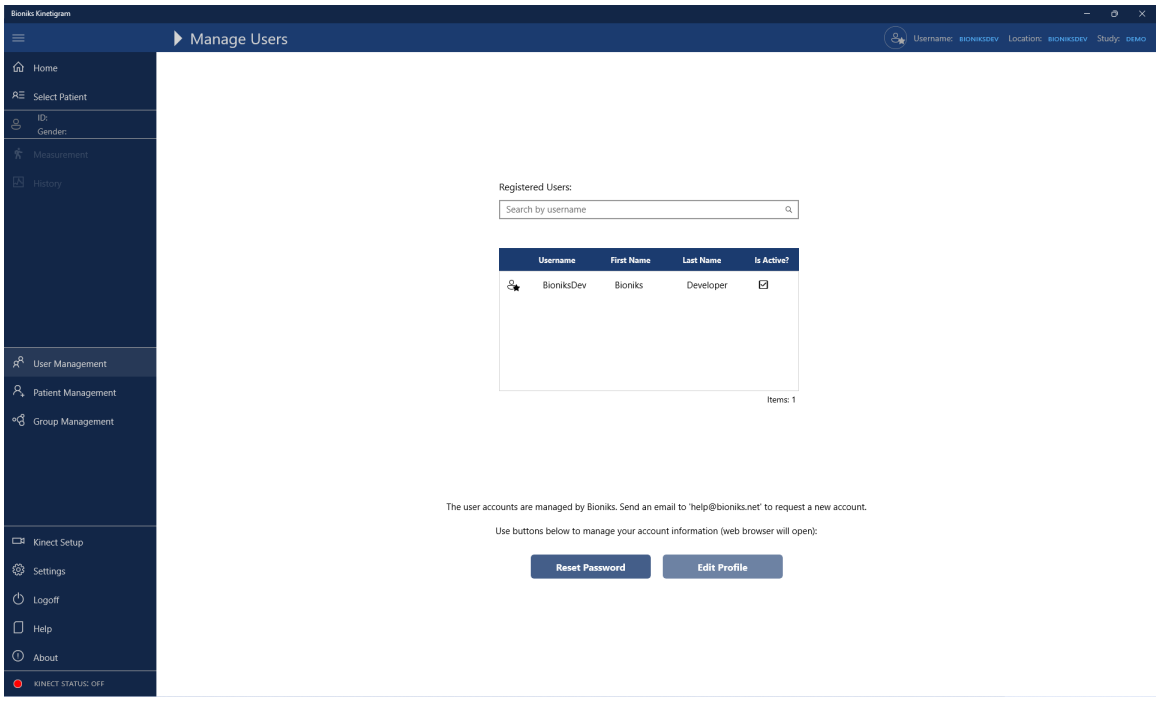
Email Bioniks service at help@bioniks.net for questions regarding user management and GDPR. Privacy Policy can be accessed at the Login page or the following address: http://docs.bioniks.net/kinetigram/privacy.html

5.2 Create / Delete Users

A request for new users or removal of users should be sent to help@bioniks.net. The process for creating a new account is described in section 3.3.

5.3 User Management Page

User Management page in the application displays the list of current active users assigned to the site. The page includes links to update your own account information (Edit Profile button) or reset the password (Reset Password button).



5.4 Kinetigram User Types

Kinetigram software operates with three types of users who have different level of privileges to operate the application:

1. **Standard User**: assigned to site evaluator(s)
2. **Power User**: assigned to a site manager
3. **Administrator**: assigned to Bioniks Administrator
4. **Auditor:** additional role assigned to Administrator users

Each user has different authorizations for different tasks within the application (see chart below).

Authorized tasks	*Standard User*	*Power User*	*Administrator*	*Auditor*
Change your own account information	**x**	**x**	**x**	
Change your own password	**x**	**x**	**x**	
Create/edit/delete study groups		**x**	**x**	
Create/edit new patients	**x**	**x**	**x**	
Delete patients		**x**	**x**	
Delete measurement sessions		**x**	**x**	
Access to export logs	**x**	**x**	**x**	
Access to audit logs				**x**

The authorization level is indicated by the user icon (refer to chart above) displayed in the top-right corner of the application title bar:



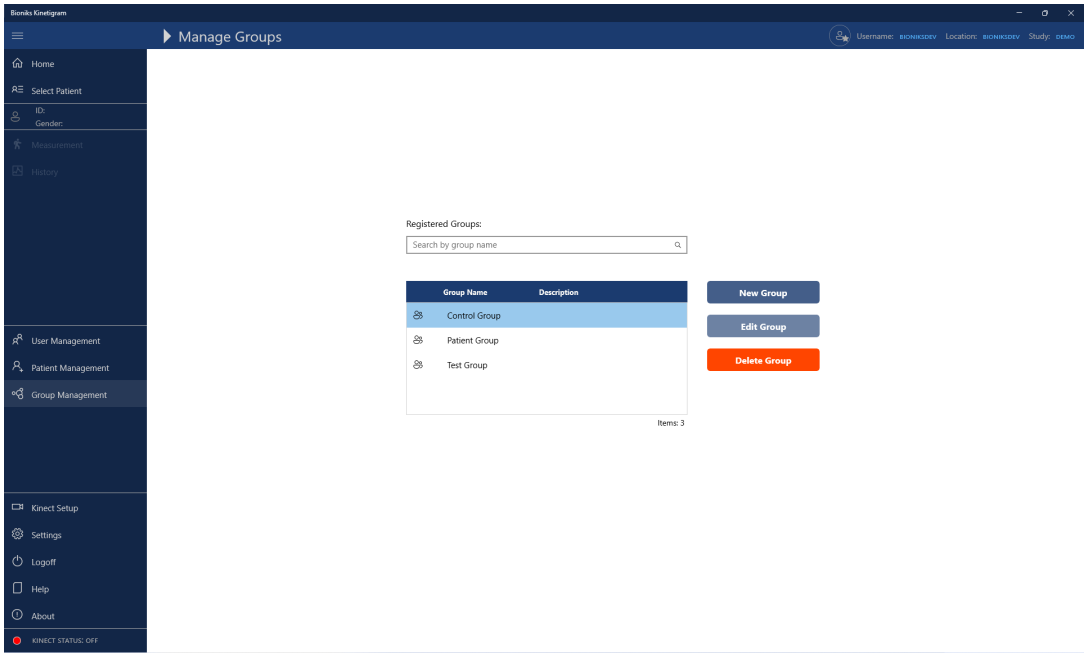
6 Managing Study Groups

Study groups are used to organize participants into groups to easily discriminate participants that belong to a particular study or to distinguish patients from controls. Several study groups may be predefined when you run the system for the first time. Additional groups can be added as needed.

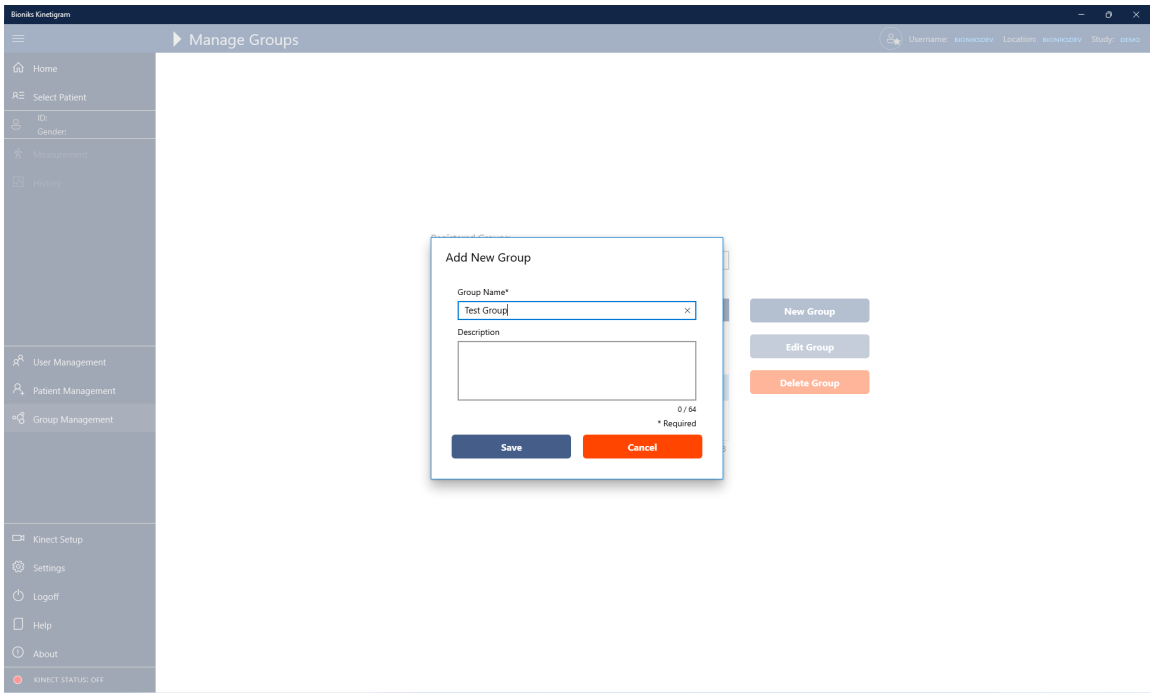
To manage groups, select Group Management from the menu.

6.1 Creating New Group

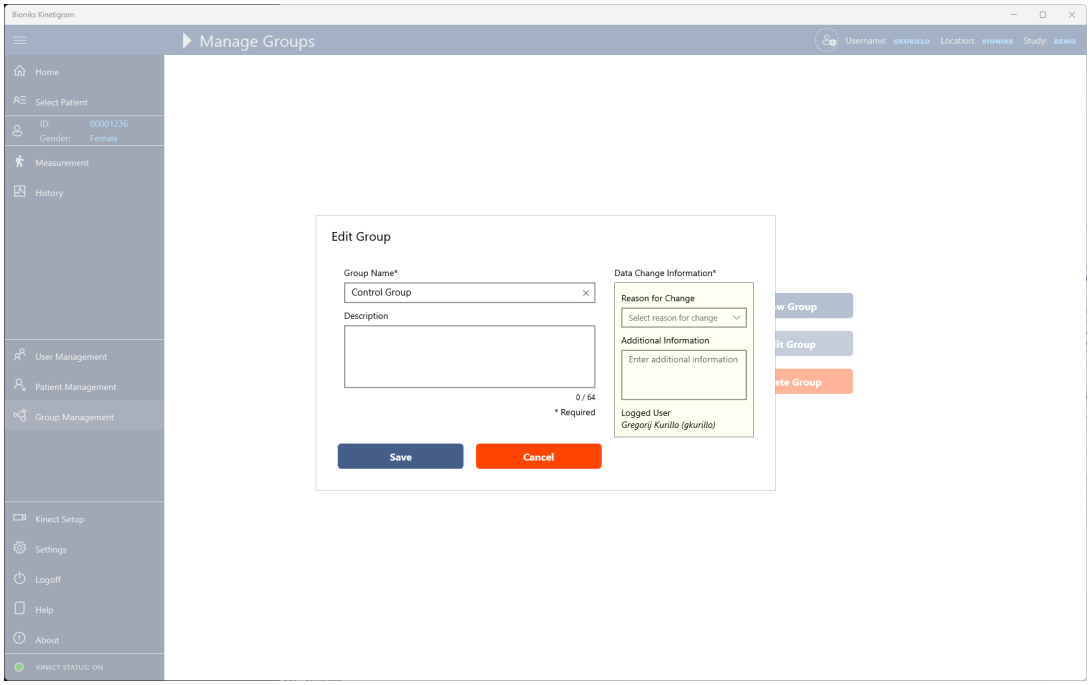
Only Managers can create new Groups under Group Management. The active groups are listed on the Group Management Page.



To add a new group, select the Group Name and add Description/comments. Group name should be unique. The system will not allow you to create two groups with the same name.



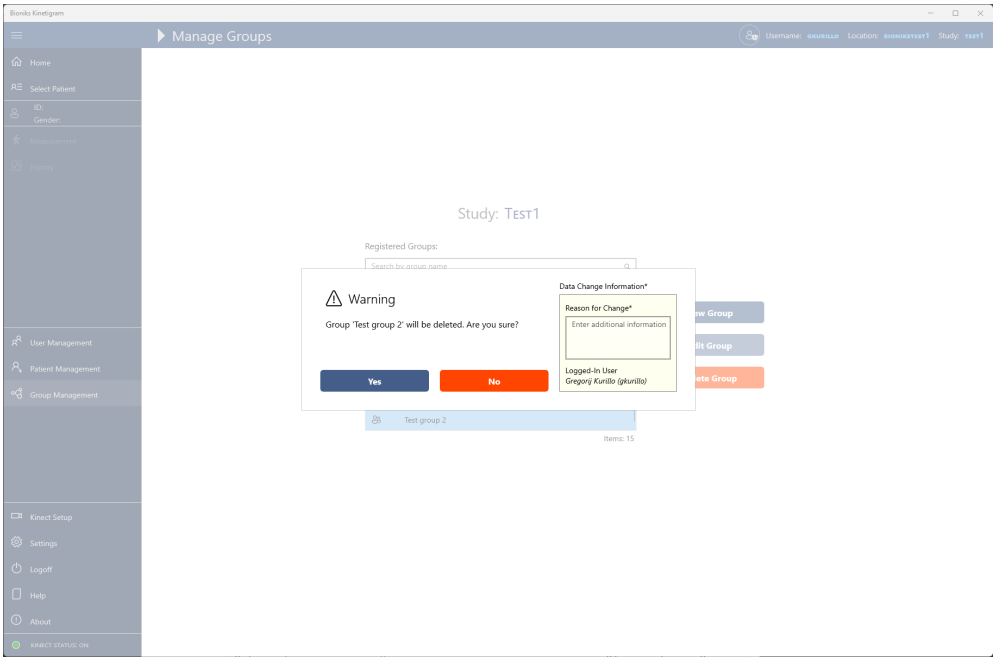
6.2 Editing Existing Group



You can edit an existing group from Group Management Page. To edit an existing group, first select the group from the list, and press the Edit Group button. Edit Group window will display. Once you are done editing the group information, press Save to update the information or Cancel to discard the new information.

6.3 Deleting Groups

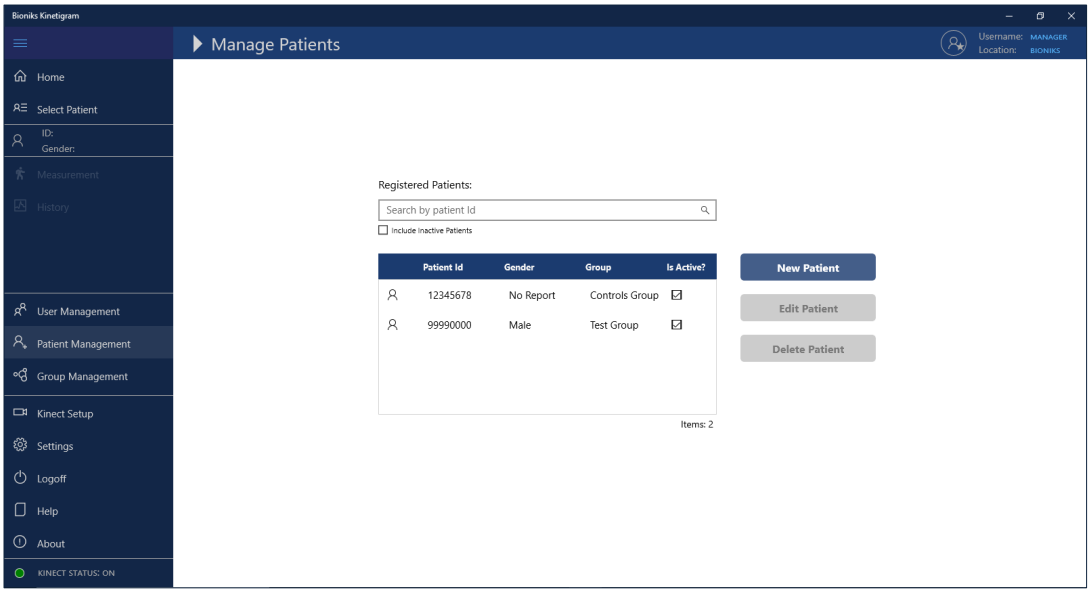
To delete an existing Group, go to Group Management Page and select the group you wish to delete from the list. Press Delete Group button and enter Reason for Change (see Section 4 for more information regarding changes).



Important: A group will not be deleted if it has patients assigned to it. First, reassign all patients belonging to the group through the Edit Patient dialog, and then delete the group.

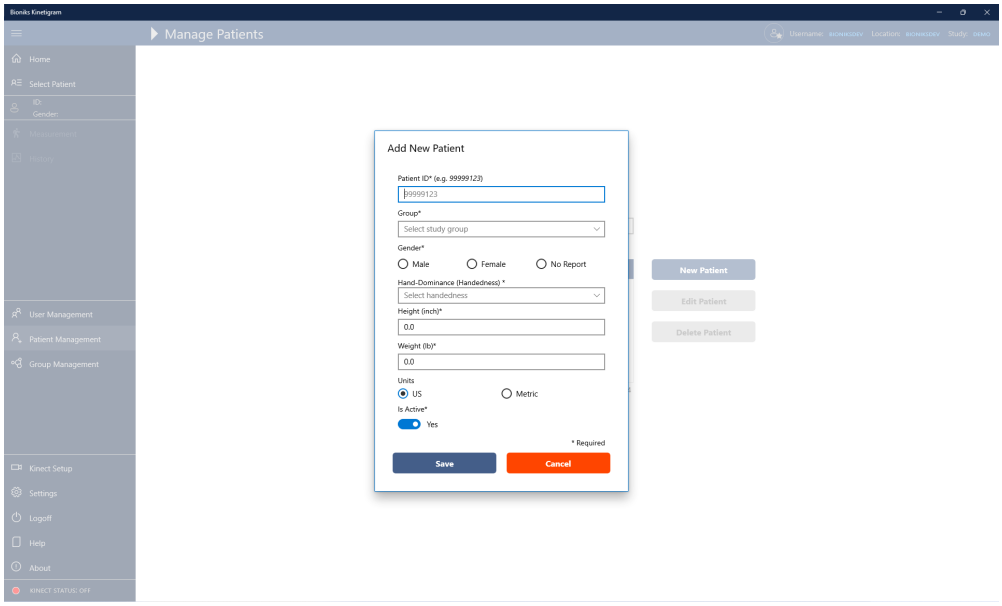
7 Managing Patients

To manage patients, select Patient Management from the menu. You can search for existing patients by entering patient ID into the search box. You can include patients that are deactivated in the search.



7.1 Adding New Patient

To add a new patient, select New Patient from the list. In Add New Patient dialog, enter Patient ID, Study Group, Gender, Height, Weight and Handedness.



The height and weight information can be entered either in Metric units (height in *cm*, weight in *kg*) or US units (height in *inches*, weight in *lb*). The dialog will automatically convert between the two when switching the units via the Units radio box. Press Save to save the patient information.

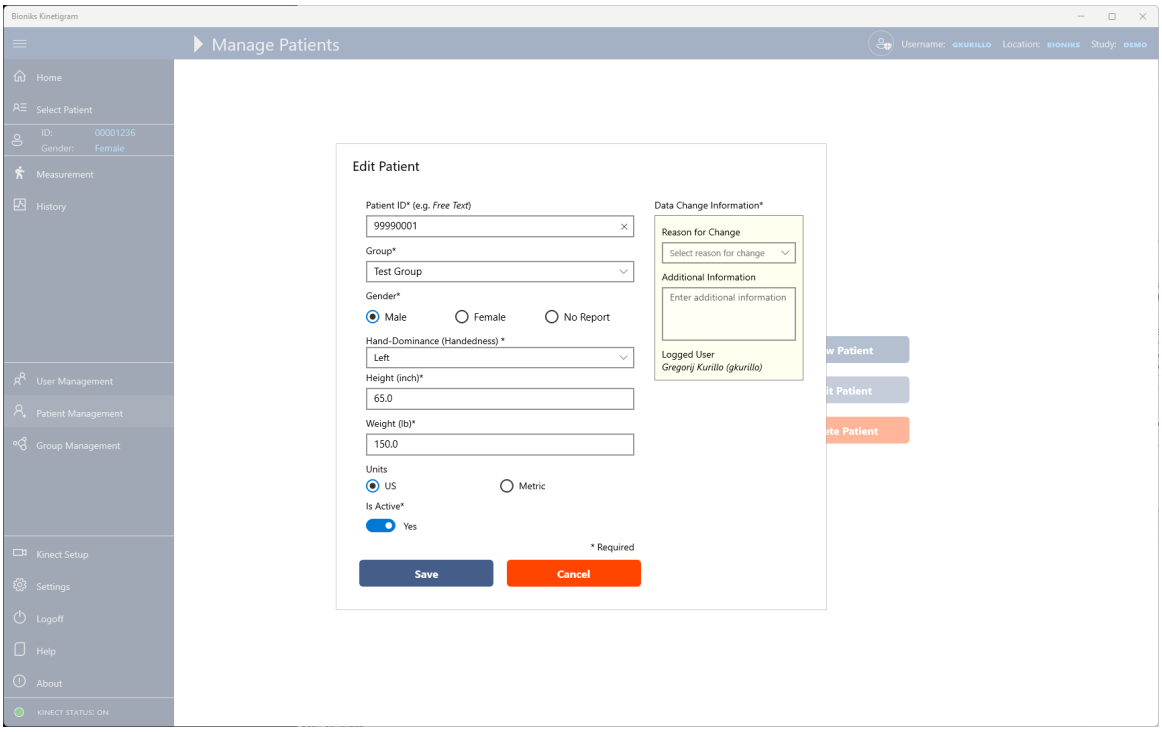
Note: The patient ID may be restricted to a specific format. Bioniks Administrator can specify the patient ID format on the server. The patient ID format may appear differently than the displayed in screenshots in this document.

Note: The option 'No Report' is currently disabled in this version of the Kinetigram app.

Important: Make sure to comply with labeling/ID requirements of the study. Do not add any other identifiable information.

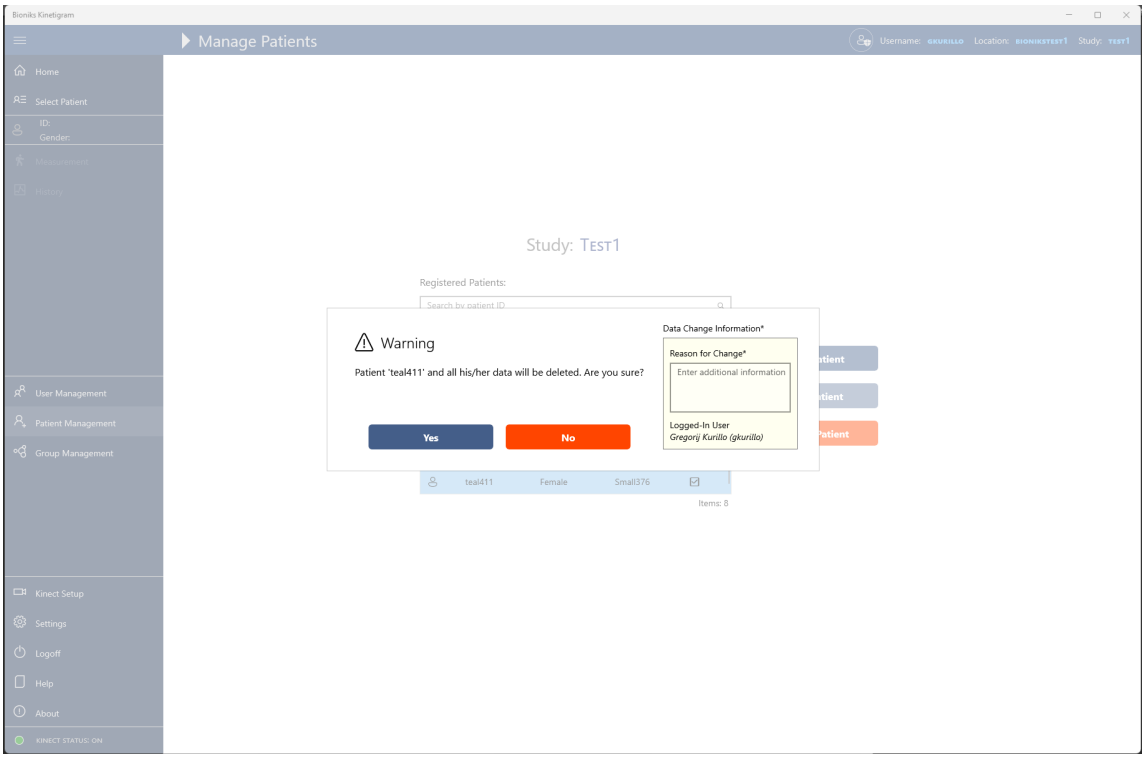
7.2 Editing Existing Patient

To edit existing patient information, select the patient you wish to edit from the list on Patient Management Page and press the Edit Patient button. After the information is updated, you can save the information by pressing Save button or discard by pressing Cancel button.



7.3 Deleting Existing Patient

To delete an existing patient, go to Patient Management and select the patient you wish to delete from the list. Select Yes when prompted to delete the patient and enter Reason for Change (see Section 4 for more information regarding changes).



Important: Patients with existing Capture data cannot be deleted from the app - they can only be deactivated. You can reactivate the patient by listing all patients (including inactive patients) from the Patient Management Page and editing the patient information.

8 Instructions for Collecting Motion Data (Manual of Operations)

Important: Carefully follow the instructions below to perform the measurements with study participants.

Frequency of administration: The measurement should be administrated as identified by the study protocol the Kinetigram is intended to be used with.

Duration of administration: Each test takes approximately 1-2 min. The total time of testing is about 15-20 min. The duration of assessment can vary depending on the condition of the patient and other extraneous factors.

Time of administration: Since the measurement requires physical movement, which may be exerting for some participants, the measurement should be administered at least 15 min after a meal.

Measurement Protocol and Methods:

To collect the motion data for each visit, the following steps should be followed:

1. Select existing patient (or create new patient if needed)
2. Collect upper extremity anthropometric measurements
3. Determine if patient is low or high functional
4. Capture data according to the protocol
5. Check that all data was collected

Note: Video language can be changed per subject preference prior to measurements with 3D-Camera.

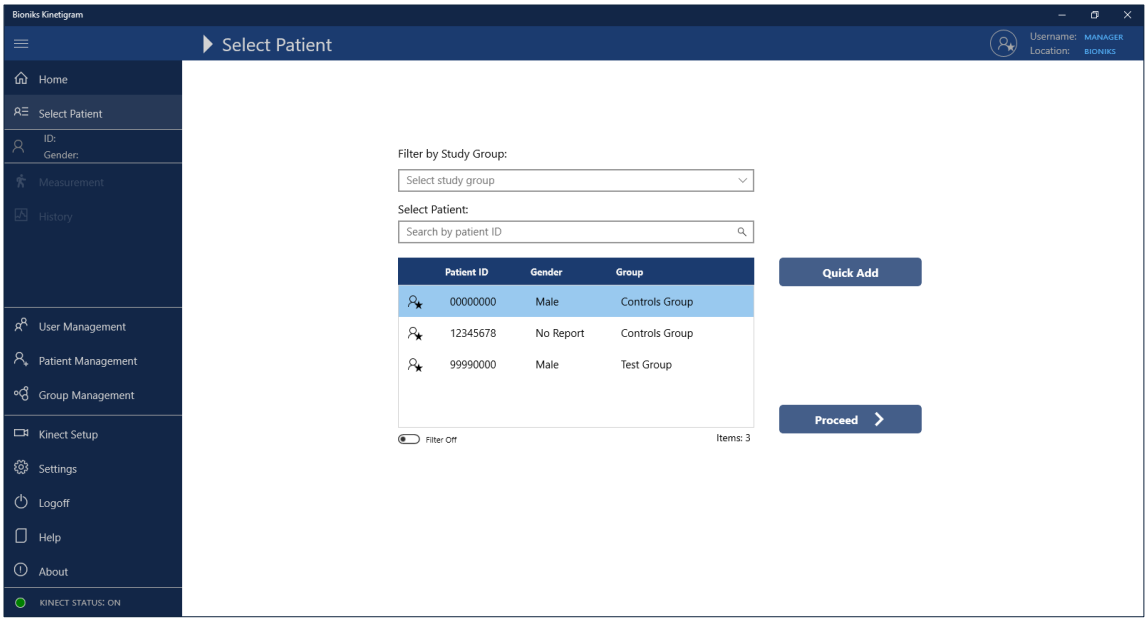
Important: The computer should be turned on and connected to the Internet at least 30 minutes before taking measurements with the Kinetigram application to complete any pending Windows Updates.

8.1 Step 1: Selecting Patient for Measurement

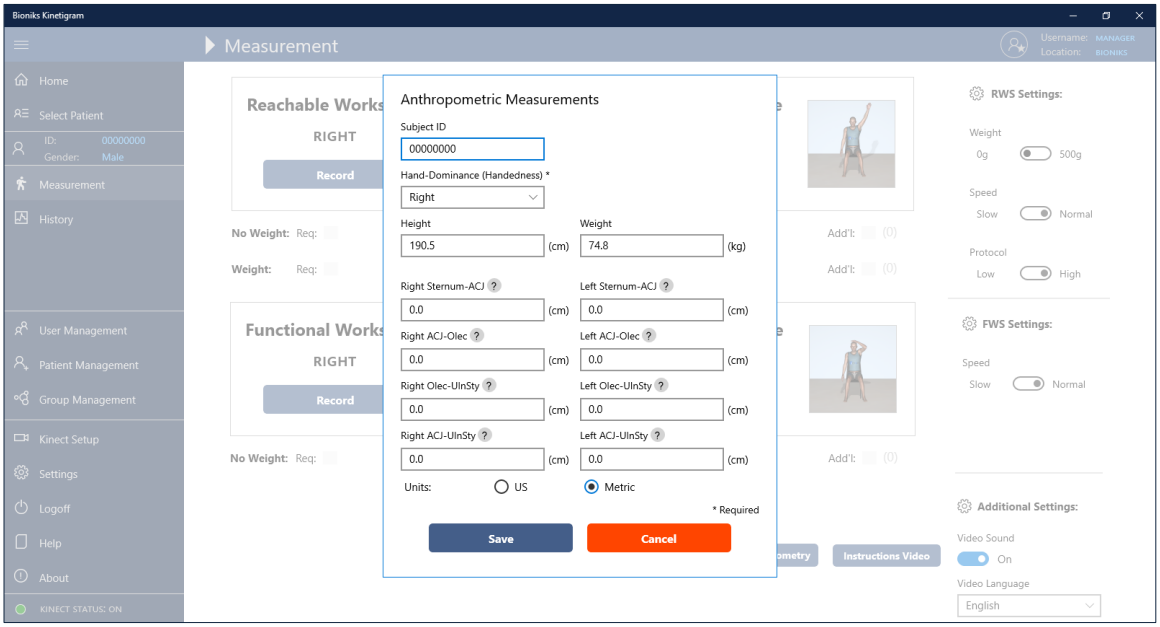
To select the patient for the measurement, pick Select Patient from the menu. The page will display a list of all active patients. The list can be filtered by selecting appropriate study group. To find the patient, you can select the patient from the list or type in patient ID. Note that the search box will automatically filter patients that match the typed input pattern. The search filters can be reset by pressing Filter toggle switch below the list.

If this is participant's first visit, you can create their information by pressing Quick Add button or entering their information in the Patient Management section.

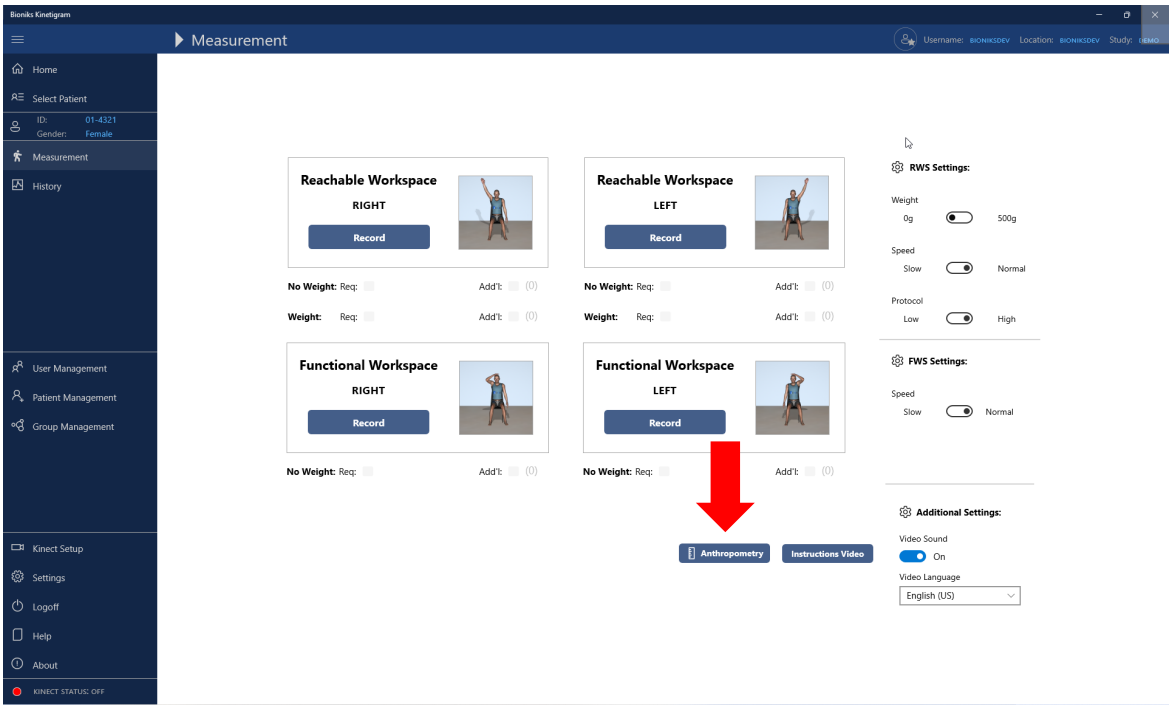
Next, select the patient from the list and press Proceed button.



If this is patient's first visit for the day, you will be automatically presented with the Anthropometric Measurements dialog.



Alternatively, the dialog can be accessed by pressing button Anthropometry on the Measurement Page.


Bioniks Kinetigram
Measurement
Username: BIONIKSDEV Location: BIONIKSDEV Study:
Home
Select Patient
ID: 01-4321
Gender: Female
Measurement
History
User Management
Patient Management
Group Management
Kinect Setup
Settings
Logoff
Help
About
KINECT STATUS: OFF
Reachable Workspace
RIGHT
Record
No Weight: Req: Add'l: (0)
Weight: Req: Add'l: (0)
Reachable Workspace
LEFT
Record
No Weight: Req: Add'l: (0)
Weight: Req: Add'l: (0)
Functional Workspace
RIGHT
Record
No Weight: Req: Add'l: (0)
Functional Workspace
LEFT
Record
No Weight: Req: Add'l: (0)
Anthropometry
Instructions Video
RWS Settings:
Weight
0g 500g
Speed
Slow Normal
Protocol
Low High
FWS Settings:
Speed
Slow Normal
Additional Settings:
Video Sound
On
Video Language
English (US)

8.2 Step 2: Measure Study Participant's Upper Extremity Parameters

For each visit, there are **FOUR** arm measurements that need to be collected for each side of the body:

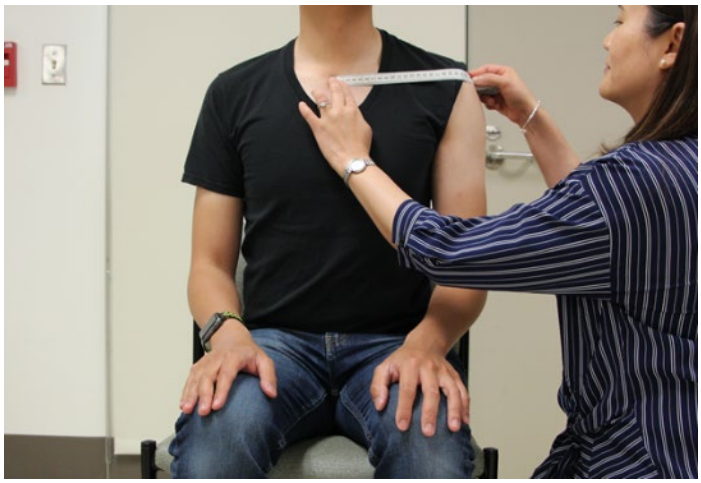
1. Sternum-ACJ (Sternum to Acromioclavicular Joint)
2. ACJ-Olec (Acromioclavicular Joint to Olecranon)
3. Olec-UlnSty (Olecranon to Ulnar Styloid)
4. ACJ-UlnSty (Acromioclavicular Joint to Ulnar Styloid)

In addition to participant's height, weight and handedness, collect the four measurements for each side and enter them into Anthropometry dialog.

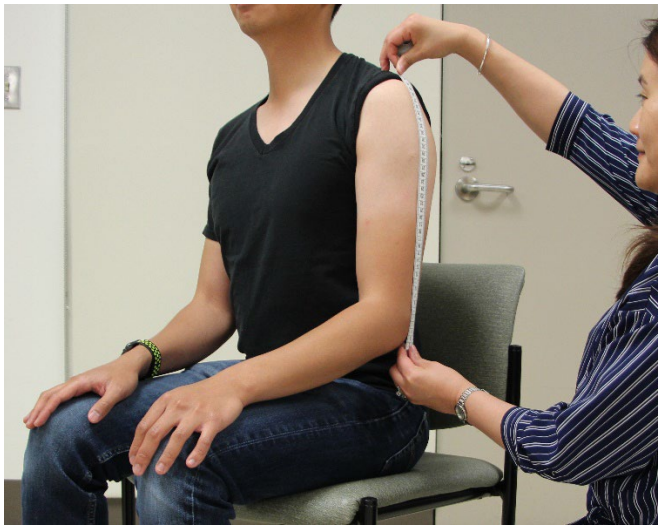
Important: The parameters should be measured with a soft centimeter measuring tape for greater accuracy.

Please, see below how to correctly obtain these measurements:

1. **Sternum-ACJ** (Sternum to Acromioclavicular Joint)



2. **ACJ-Olec** (Acromioclavicular Joint to Olecranon)



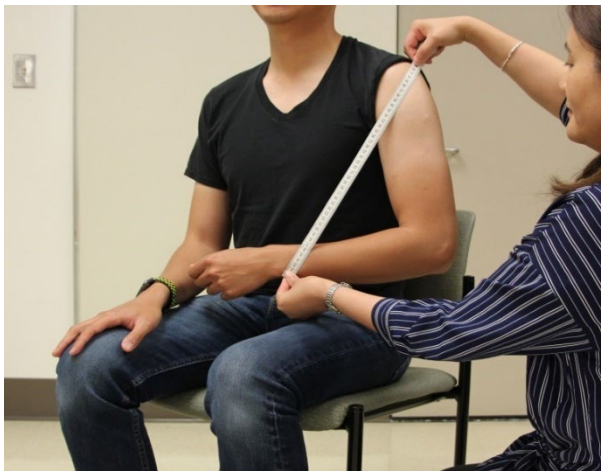
3. **Olec-UlnSty** (Olecranon to Ulnar Styloid)



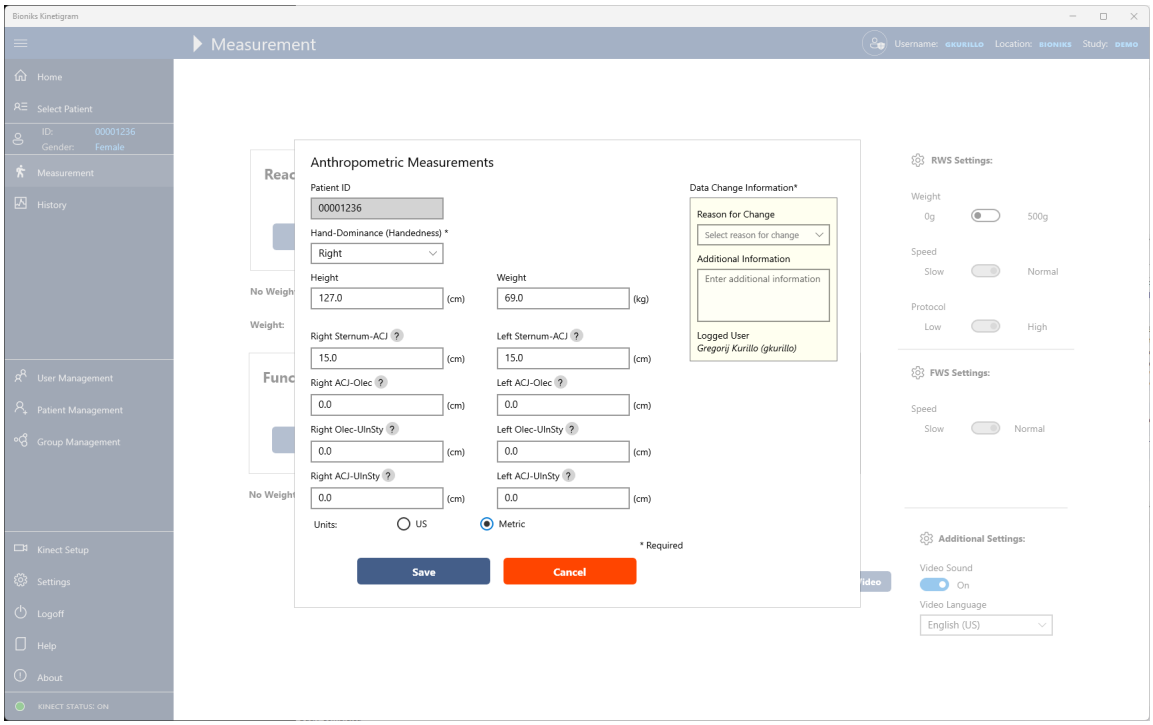
4. **ACJ-UlnSty** (Acromioclavicular Joint to Ulnar Styloid) in full elbow extension



* If an elbow contracture is present, please measure from the **ACJ to the Ulnar Styloid** as shown below (we are measuring the hypotenuse of the triangle).



Enter the measured values into the dialog and press Save to store them.
Note: If a measurement cannot be performed, enter "0" for that value.



If you need to edit the measurements after they have been saved, they can be updated for the current visit by selecting Anthropometry button on the Measurement Page.

Note, that the Anthropometry form has the following limitations for the measurements. Data outside this values will not be accepted. Please, contact Bioniks if different ranges are required for a clinical study.

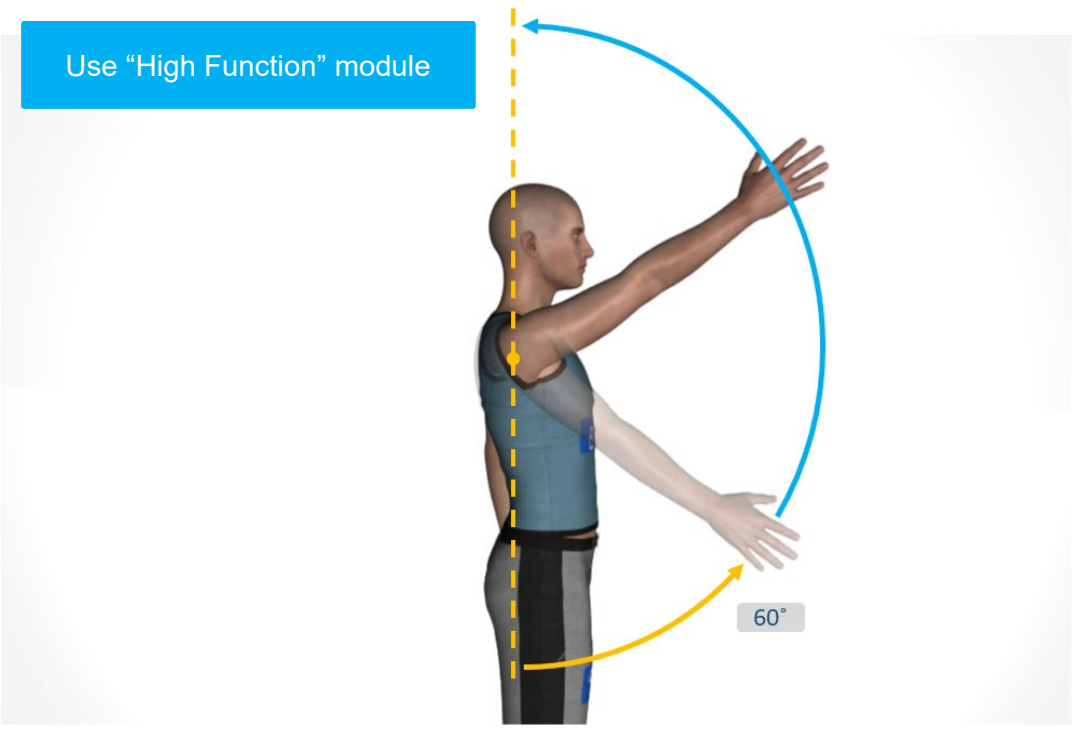
Measure	US Units*		Metric Units	
	Minimal Value	Maximal Value	Minimal Value	Maximal Value
Height	48.0 in	84 in	122 cm	214 cm
Weight	50.7 lb	500.4 lb	23 kg	227 kg
Sternum-ACJ	2.0 in	12.2 in	5 cm	31 cm
ACJ-Olec	5.1 in	20.1 in	13 cm	51 cm
Olec-UlnSty	5.1 in	20.1 in	13 cm	51 cm
ACJ-UlnSty	11.8 in	35.0 in	30 cm	89 cm

*Software uses metric units internally. US units are approximate.

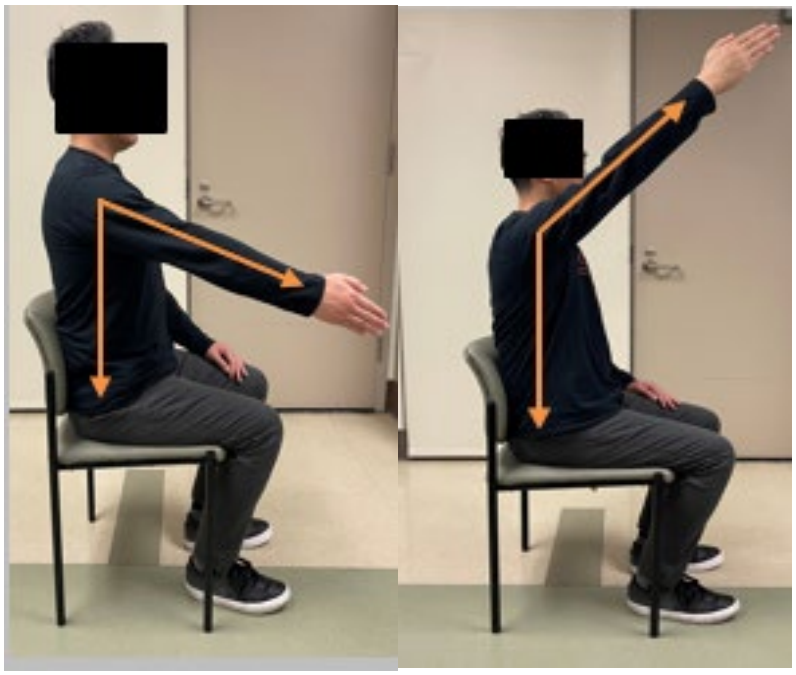
8.3 Step 3: How to Determine Whether to Use the High or Low Function Module

Note: The **LOW Function** assessment module may be disabled and not available for your study protocol.

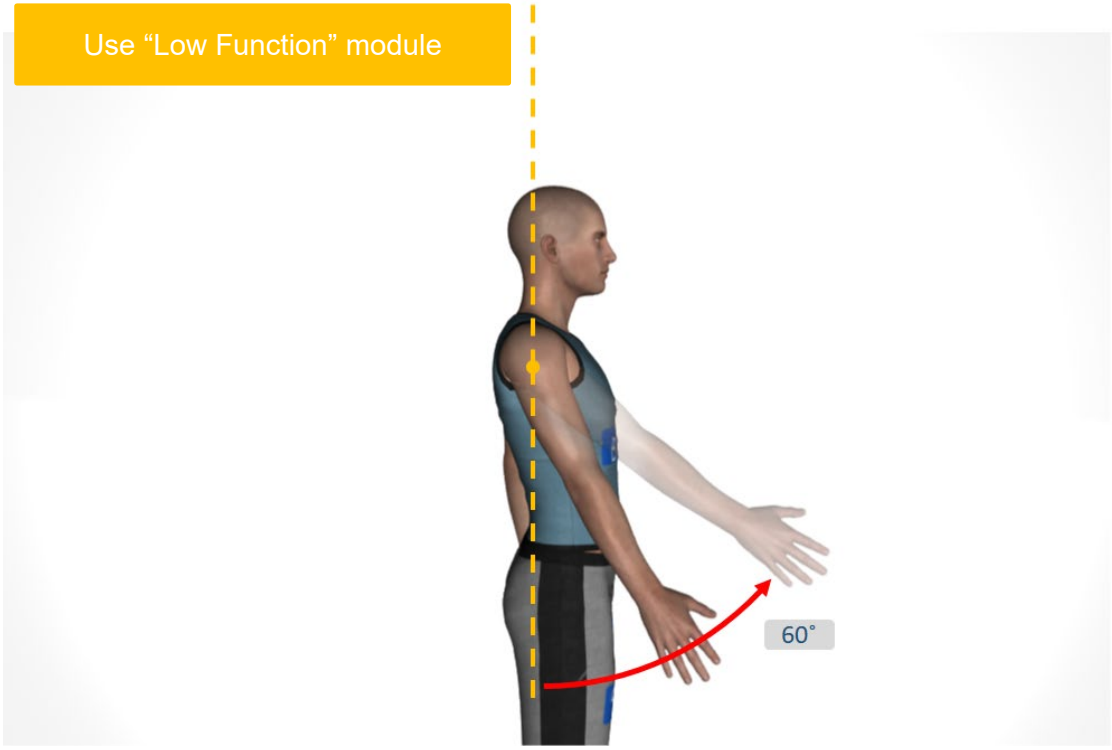
A. With the participant sitting upright in chair, ask the participant to raise his/ her testing arm as high as he/she can (shoulder forward flexion). If the participant can raise his/her arm to >60° **or above shoulder level (as pictured below)**, you should choose the **HIGH Function** assessment module.



For Example:



B. With the participant sitting upright in the chair, ask the participant to raise his/her testing arm as high as he/she can. If the participant can only raise his/her arm to <60° or **below shoulder level (as pictured below)**, you should choose the **LOW Function** assessment module.



For Example:

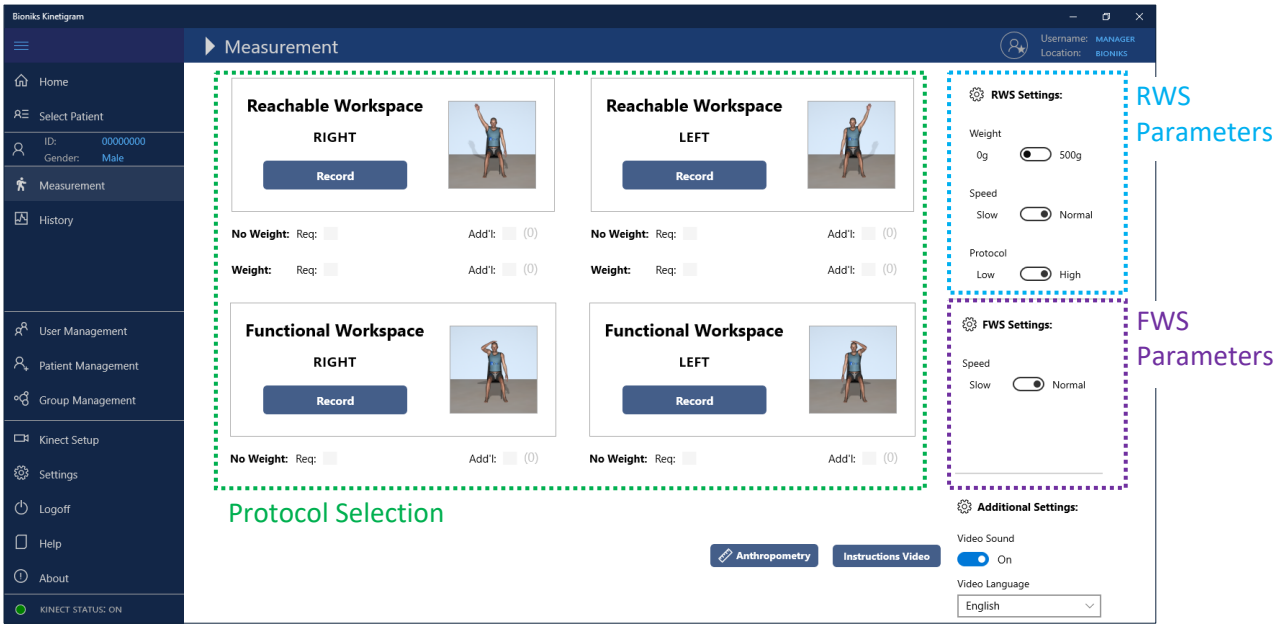


Note: If a participant is borderline (approximate shoulder flexion at 60°), then the **HIGH Function** assessment module should be picked as default. The **LOW Function** assessment module is for clearly weak participants having a difficult time raising their arm up without using any compensatory maneuvers.

8.4 Step 4: Perform RWS/FWS Assessment – Begin Data Collection

Once you have taken the upper extremity anthropometric measurements and determined participant's functional level, you can start the measurement protocol.

The measurements are performed while observing a video-guided protocol. The Kinect camera captures user's movement and records their joint information. No video information of the participant is stored at any point. In order to select the correct video protocol, the selection must be made on the main Measurement Page shown below.



The following **protocol** is an example of the Reachable and Functional Workspace assessments performed by a participant during a visit. To set up correct parameters for the measurement, please make selections according to the table below for each sequence:

Evaluation	*Module*	*Side*	*Weight*
1	Reachable Workspace (RWS)	Right	No
2	Reachable Workspace (RWS)	Left	No
3	Reachable Workspace (RWS)	Right	Yes, 500g
4	Reachable Workspace (RWS)	Left	Yes, 500g
5	Functional Workspace (FWS)	Right	No
6	Functional Workspace (FWS)	Left	No

Note: In general, all protocols should be performed at **normal speed**, unless participant has difficulty following the movements. In that case, select **low speed**. The low-speed videos are slowed down for about 20%.

Note: Language for the audio tracks in the video-guided protocols can be selected depending on patient preference. This does not change the language displayed in the user interface. Audio file language is selected in the Additional Settings and can be changed at any time.

Important: Please, select appropriate functional level for each side. The participant may not have the same ability on each side.

Note: Before each measurement, the participant should be shown the instructional video by clicking the Instructional Video button on the bottom of the Measurement page.

Applying the Wrist Weight:

When using the wrist weight, the weight should be secured over the participant's wrist joint using the attached Velcro straps. The straps should be tight enough to prevent the weight from sliding down the arm when the arm is moved around. Check with the participant not to over-tighten the straps. Make sure that the Velcro strap is not sticking out.

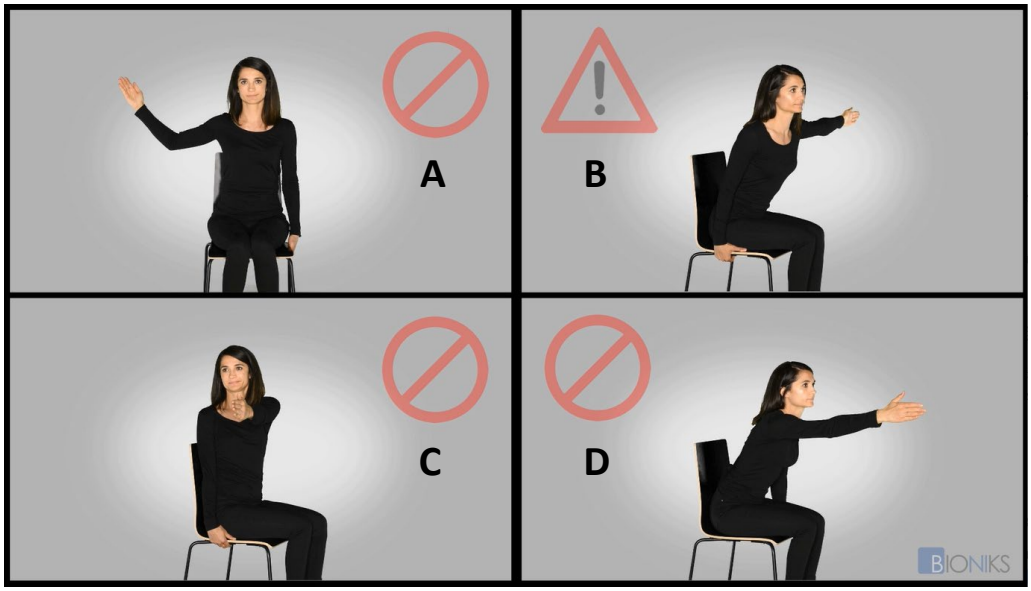




Remember, at the end of each RWS measurement you are asked to confirm whether the weight was used or not and to enter any notes relevant to the measurement.

Before Starting Measurement:

- ***Important:*** For Reachable Workspace (RWS) measurement, make sure that the participant is seated with their back against the chair, does not twist to the side and lean forward, and does not bend the



elbow unless instructed to do so.

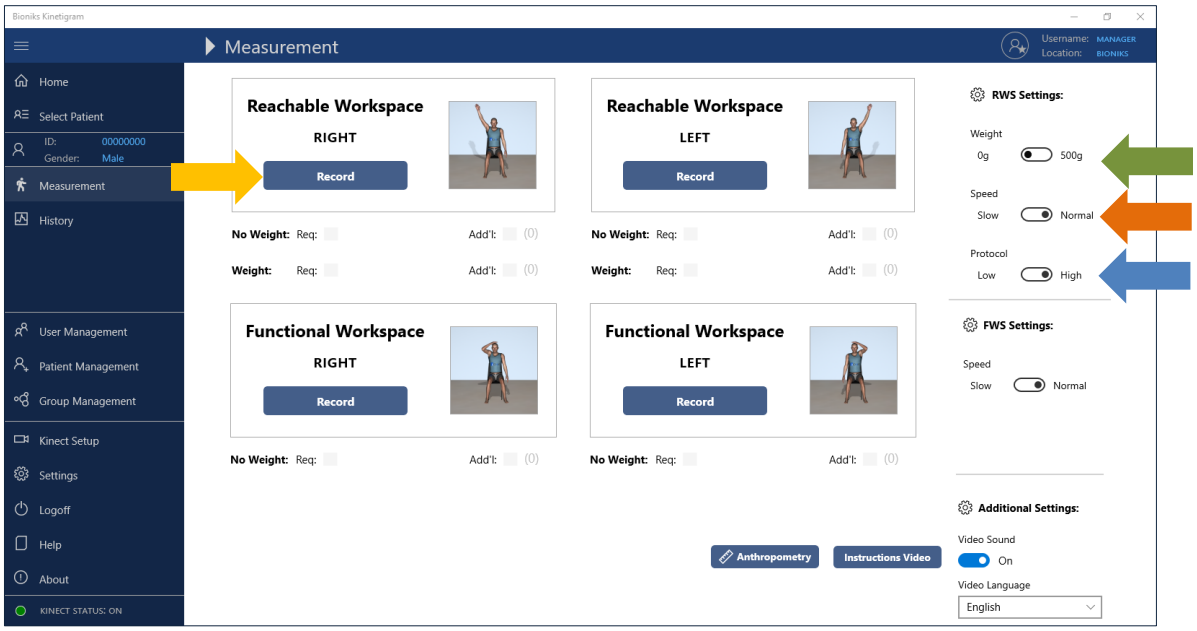
Box	Instructions
A	Don't bend your elbow
B	Keep your back against the chair
C	Don't twist to the side
D	Don't lean forward

- ***Important***: Positioning of subject for Functional Workspace (FWS) measurement: subject is seated with their back against the chair, upright, head and trunk straight.
- During FWS assessment ensure that there is no cervical/neck flexion, trunk flexion or rotation, no excessive compensatory movement (e.g. swinging of the arms); participant should perform smooth and well controlled movements.

Reachable Workspace (RWS):

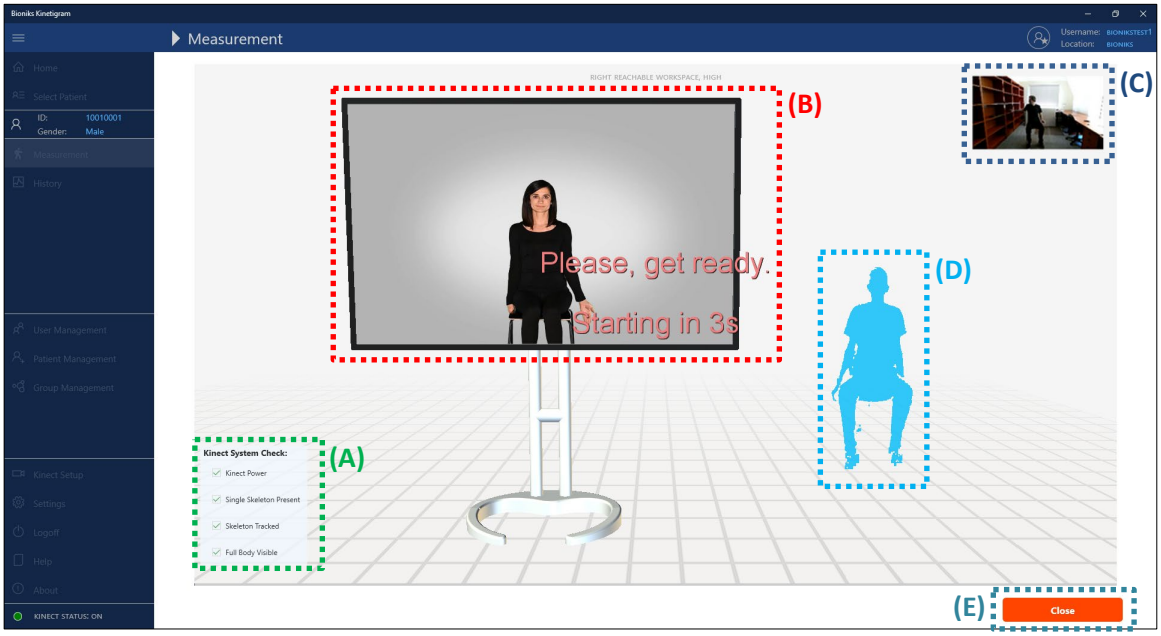
Evaluation 1: RWS Right Side, No Weight

- First perform the RWS measurement for **no-weight** condition on the **right side**. Make sure that the toggle switch for the Weight is not active (green arrow):
- Select video playback Speed (orange arrow). **Normal** speed to start with. If participant is unable to follow when doing the protocol, repeat the measurement by selecting **Slow** speed.
- If the participant was able to forward flex his/her arm at or above shoulder level, then the **High** functioning Protocol should be clicked (blue arrow).
- When participant is ready, begin data collection by pressing the Record button under Reachable Workspace – RIGHT module. (yellow arrow).



This will open the measurement page with the video-guided protocol. The video guidance page has the

following elements:



Video guidance page elements: A – Camera System Check, B – Video Feedback, C –Camera View, D – Feedback View, E - Close/Stop Recording

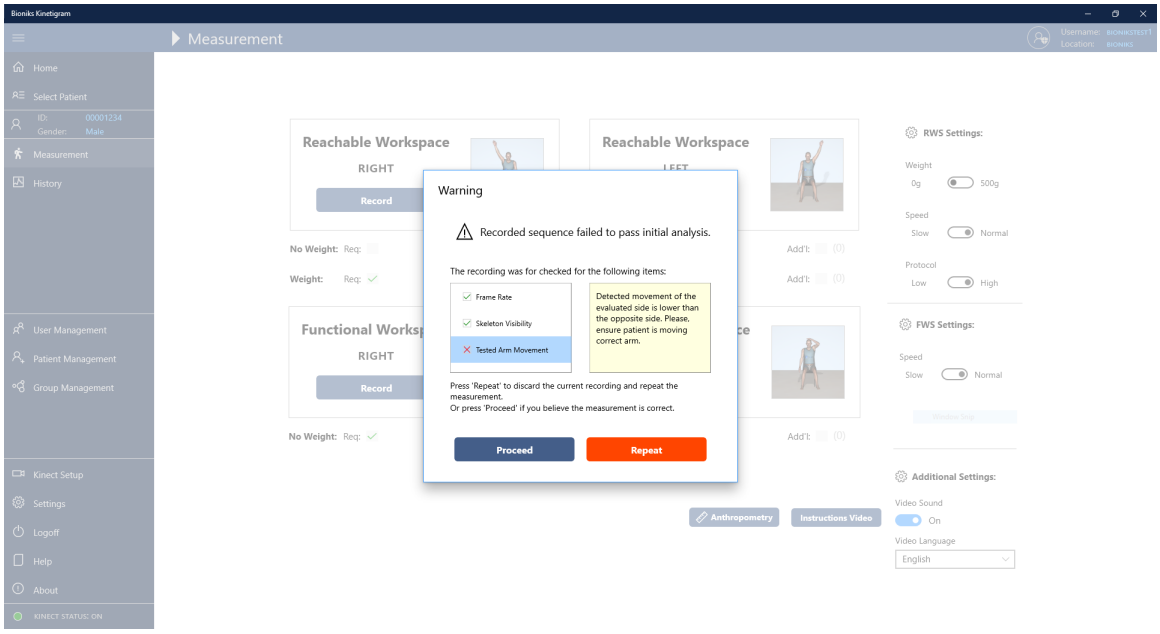
The page displays a countdown timer during the first 5 seconds which allows the participant to prepare themselves. During this time, the system also checks for proper measurement conditions using the Kinect System Check module. The results of this check are displayed in the left corner. If any of the items fail, (Kinect/Orbbec) System Check window will be displayed. See Section 9 below for troubleshooting.

Once the countdown is completed, the patient should follow the instructions in the video and perform the movement alongside. During the recording, the sign Recording is displayed in the top left corner. Progress bar at the bottom of the feedback screen indicates the relative position of the video playback.



The recording is automatically stopped when the video ends. If needed, you can stop recording at any time by pressing Stop Recording button. When the recording stops, the label on the button will change to Close.

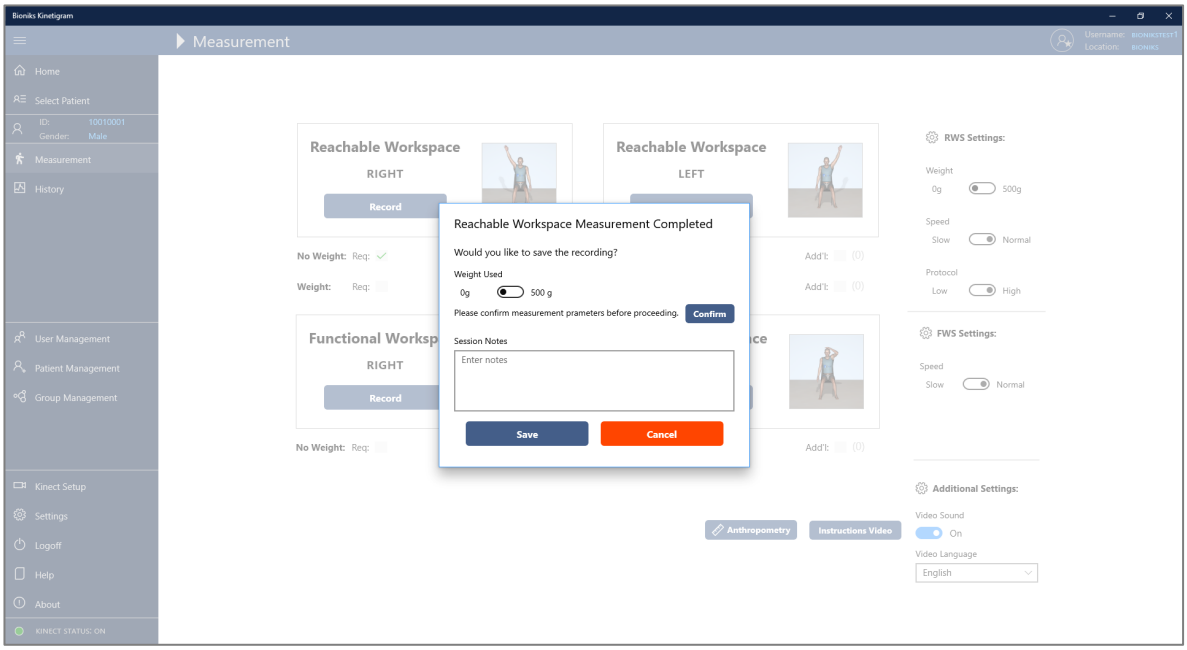
At the completion of the recording, the recording sequence is checked for validity. If the recording sequence is determined not to be valid, the following warning will appear:



The information for each listed item can be clicked on for more explanation.

Important: If you receive this warning, you should carefully examine the information. It is advised that you repeat the measurement by pressing the Repeat button, which will take you back to the Measurement page.

If the recording was successful, you will be presented with the Save Measurement dialog.

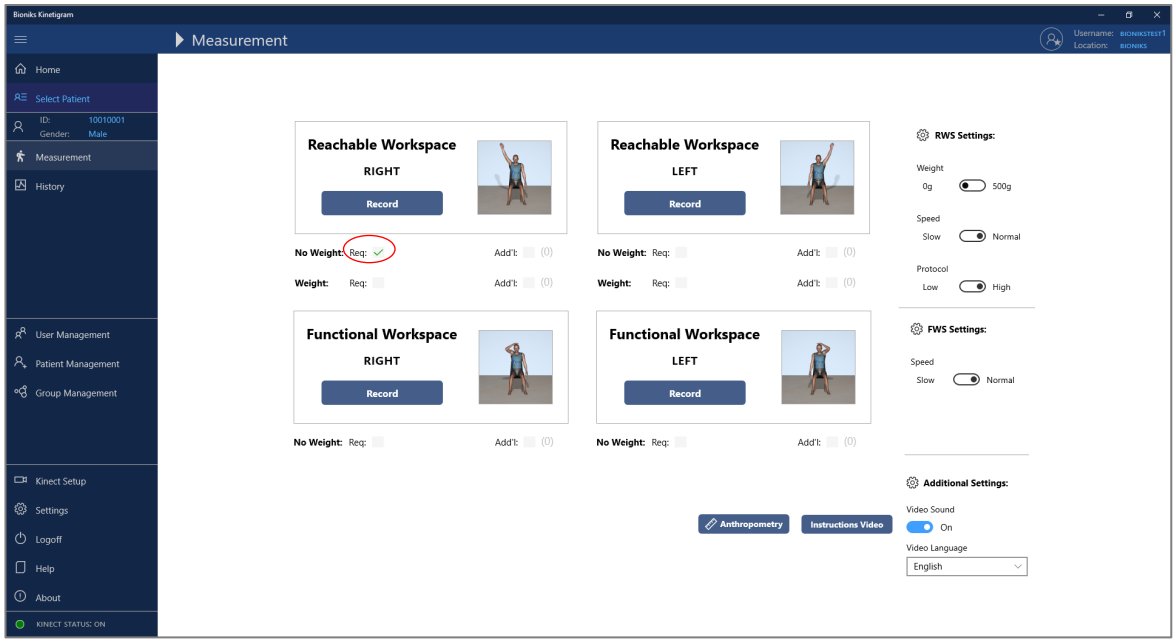


For Reachable Workspace protocol, check that the parameter for the weight corresponds to the condition of the measurement (patient not wearing the wrist weight = weight 0g, patient wearing the wrist weight = weight 500g). Confirm this by pressing Confirm button; this will enable you to save the measurement.

Enter any relevant notes to the measurement that may pertain to the measurement session. For example, “participant was not feeling well”.

Press Save to store the measurement, or press Cancel to discard the measurement results. Note that once you press Cancel, no data from the session will be stored!

Once the data are saved, you will return to the menu page. Note that once a session is recorded, it will show up as a green checkmark under corresponding module (circled in red below). Req boxes mark the required evaluations, while Add’l mark any additional sessions that were recorded. Note, that session counters are reset for each day.



Note: For all remaining measurements, follow the same process as outlined above for evaluation 1. Refer to above figures for configuring RWS and FWS settings described below.

Evaluation 2: RWS Left Side, No Weight

Repeat the RWS assessment for the **Left Arm, Without Weight**.

- If the participant was able to forward flex his/her arm at or above shoulder level, then choose **HIGH** level, otherwise use **LOW** module (and follow as above).
- At the completion of the recording, press Save to save the assessment data if you are satisfied with the participant's performance

Evaluation 3: RWS Right Side, Weight

Repeat the RWS assessment for the **Right Arm, with Weight**

- Participant remains on the same Functional Level, so there will be **NO** change in the Protocol option (Low or High).
- Apply **ONE wrist weight (500g)** to participant's **Right wrist,** and select Weight = 500g.
- When ready to start, click Record.
- At the end of the assessment, make sure the weight option is accurate. Then click Save to save the assessment if you are satisfied with the participant's performance.
- Type in any brief notes you may have regarding this assessment, as described previously. Otherwise, click Cancel and repeat the assessment.

Evaluation 4: RWS Left Side, Weight

Repeat the RWS Assessment for the **Left Arm, with Weight**.

- Participant remains on the same Functional Level, so there will be **NO** change in the Protocol option (Low or High).

- Please apply **ONE wrist weight (500g)** to participant's testing wrist. In this case, weight will be applied to participant's **Left wrist** (follow as detailed above).
- At the end of the assessment, make sure the weight option is accurate. Then, click Save to save the assessment if you are satisfied with the participant's performance. Type in any brief notes you may have regarding this assessment, as described above. Otherwise, click Cancel and repeat the assessment.

Note: If the participant was unable to forward flex his/ her testing arm to shoulder level, then choose the **LOW** level Protocol from the RWS Assessment. Then follow steps as previously described.

Important: A participant can have ONE arm that is **HIGH** level functioning, with the other arm being **LOW** level functioning, during the same visit.

Functional Workspace (FWS) Assessment (option may not be available):

Similar as above can be followed for the functional workspace assessment, however **NO WEIGHT** is used here.

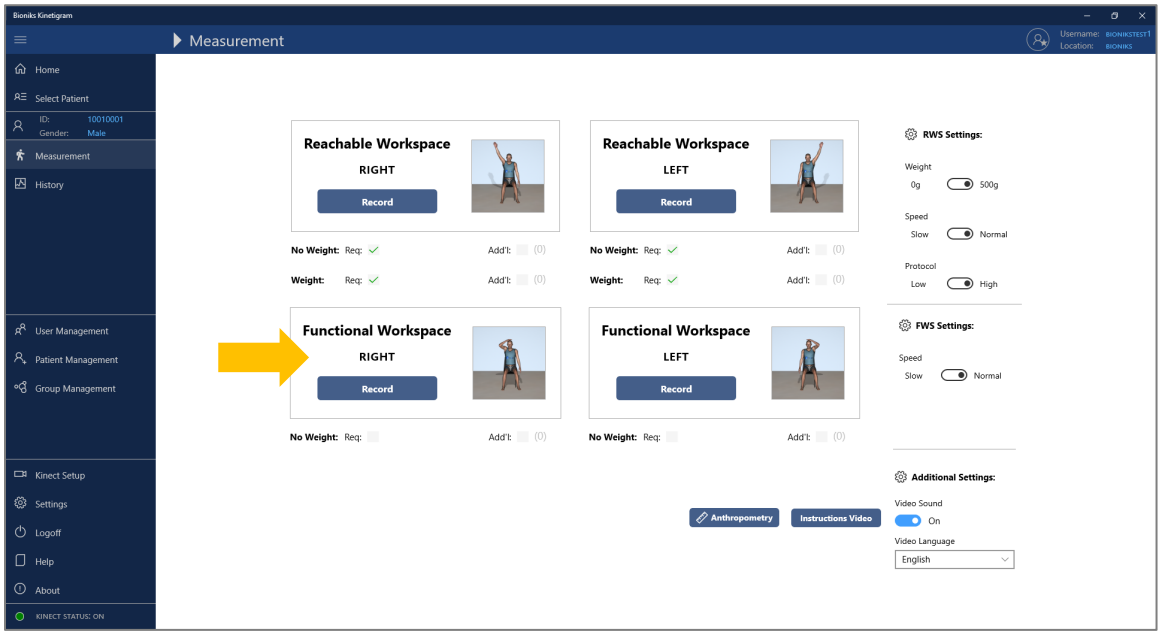
Important: Observe the participant and note whether they are able to reach the required targets. You will need to enter those observations at the end of the measurement.

For a body target to be considered as achieved, NO compensatory movements are allowed. Examples of compensation are: ✓ Shoulder Hiking ✓ Shoulder Internally Rotating ✓ Shoulder Shrugging ✓ Head Flexing/ Bending ✓ Head Turning/Rotating ✓ Trunk Flexing/ Bending ✓ Trunk Turning/ Rotating ✓ Arm Swinging ✓ Use of momentum

Note: If the movement looks different from what a healthy control would make, then consider it "not achieved".

Evaluation 5: FWS Right Side

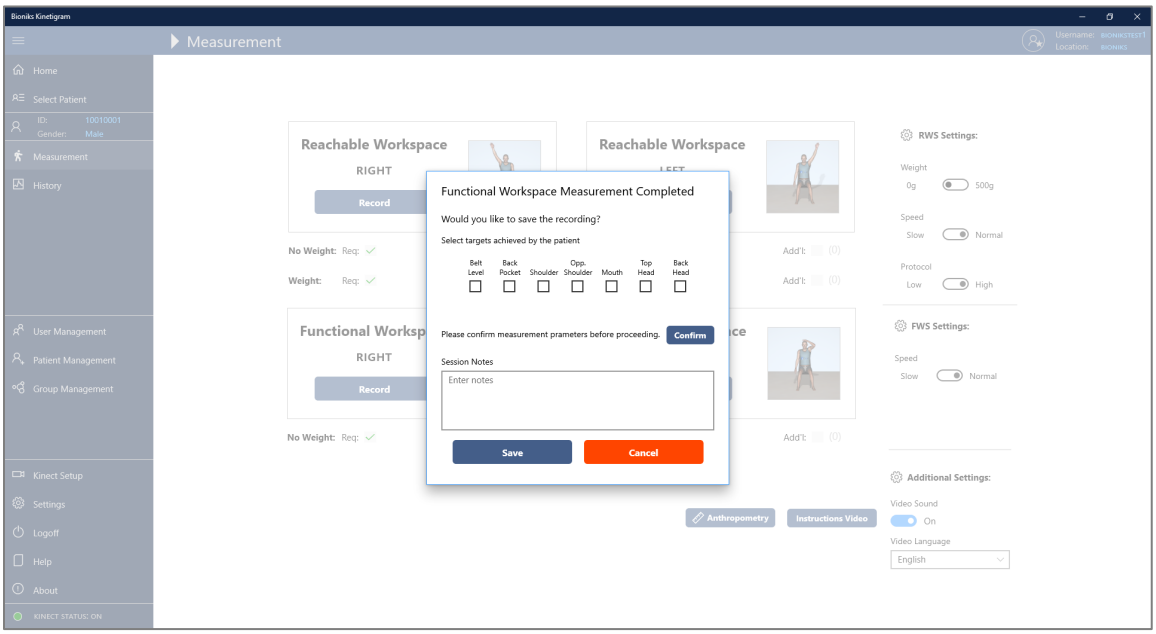
Start with **the right side** for the functional workspace module.



Patient follows the video protocol:



At the end of the assessment, you will be presented with the following dialog for the FWS:



Check the target checkboxes that you observed the patient reaching. Note that the patient must **TOUCH** the targets for it to count, just like in the video. After reviewing the observations, click on Confirm to confirm the entered parameters.

At this point you can also enter any notes and observations that pertain to the assessment, for example ‘patient reported pain’. Then, click Save to save the assessment if you are satisfied with the participant’s performance. Otherwise, click Cancel and repeat the assessment.

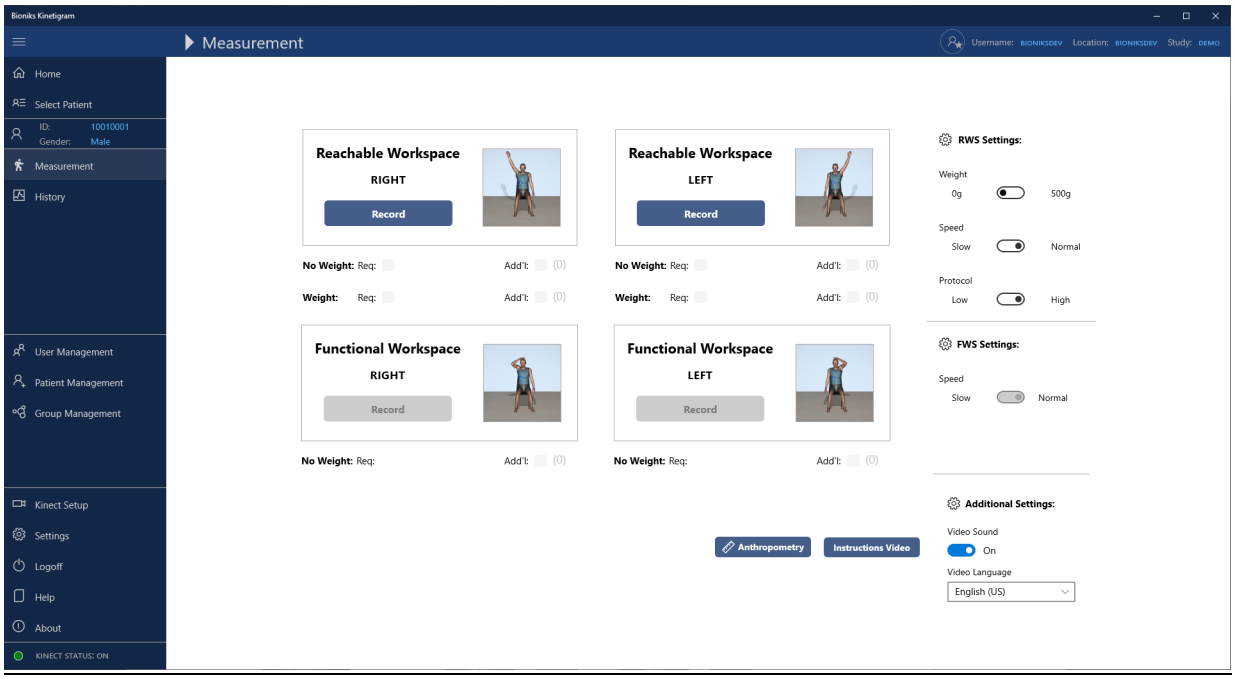
Evaluation 6: FWS Left Side

Repeat the same procedure for FWS on the left side.

After the measurement, check the target checkboxes that you observed the patient reaching. Note that the patient must **TOUCH** the targets for it to count, just like in the video. After reviewing the observations, click Confirm to confirm the entered parameters.

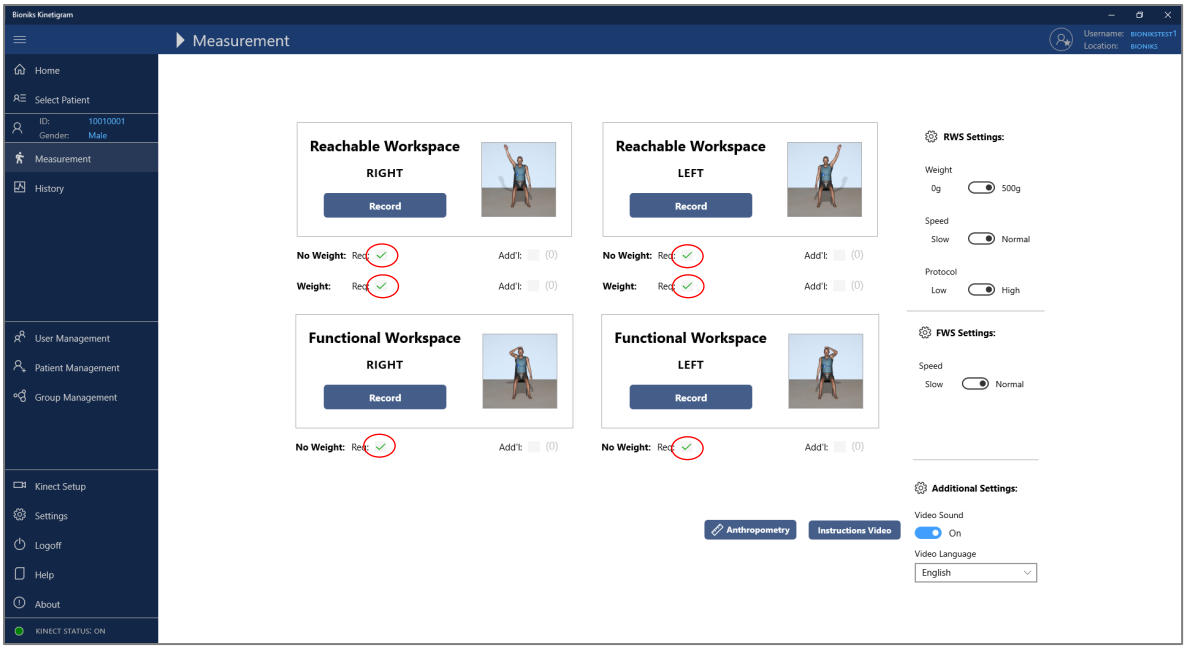
At this point you can also enter any notes and observations that pertain to the assessment, for example 'patient reported pain'. Then, click Save to save the assessment if you are satisfied with the participant's performance. Otherwise, click Cancel and repeat the assessment.

Note: Functional Workspace (FWS) Assessment option may not be available for all studies. If FWS module is not available, the recording buttons will be disabled:

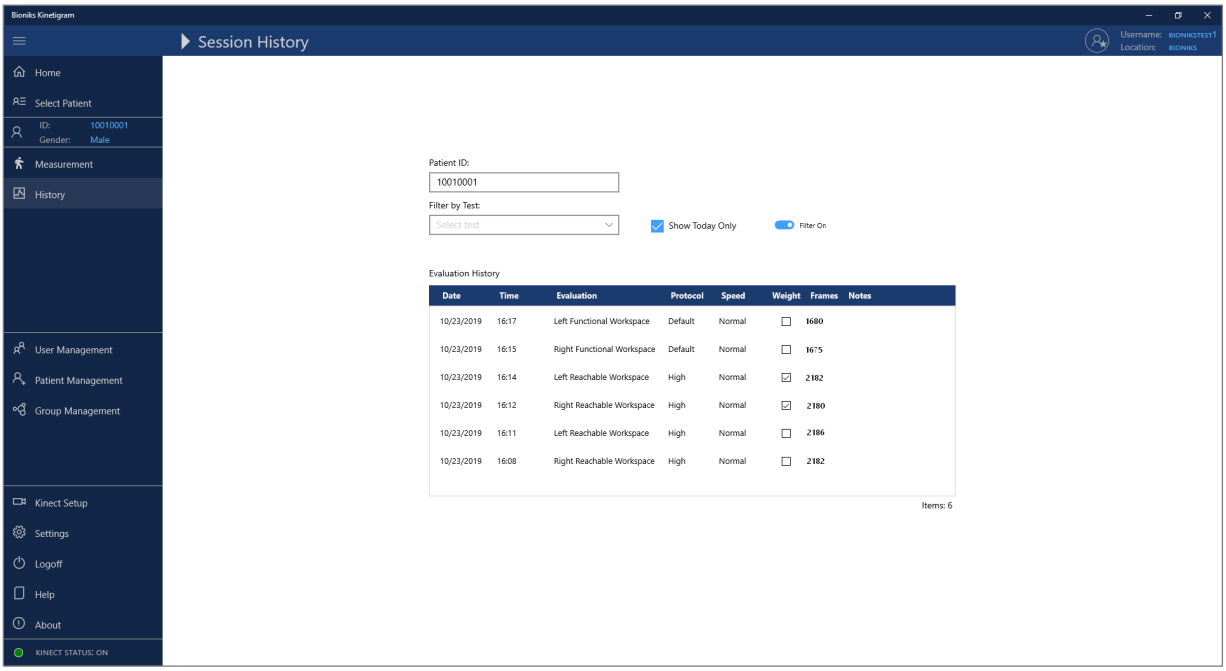


8.5 Double Checking the Data

You should be able to view all of the assessments recorded under this study participant in the main page. This should include all previous assessments for this participant. Completed assessments are marked with a green check mark (see red circled images below).



You should also confirm the assessments by clicking on the History page on menu. This will open the History page with all of the patient's recordings to date. Note you can filter by the evaluation type. From this page, you can download the raw ASCII data for each measurement by right-clicking on a measurement and selecting Download Data. Refer to Appendix A for a description of the ASCII data file format.



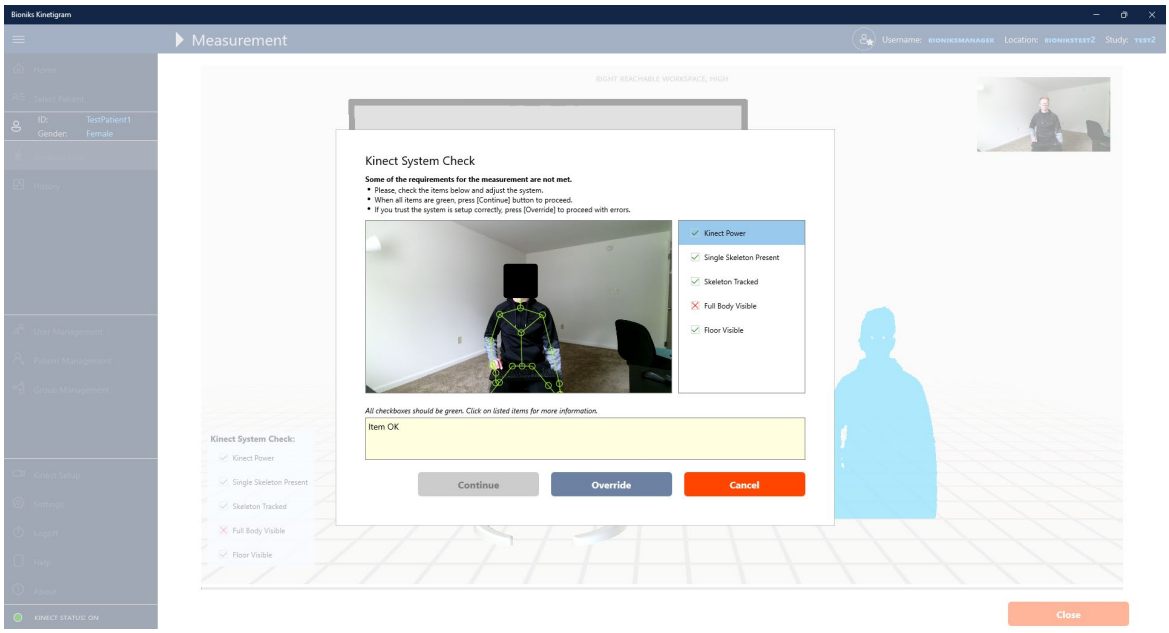
8.6 Camera System Check when taking Measurements

The Camera System Check is performed at the start of each measurement session to ensure the validity of the

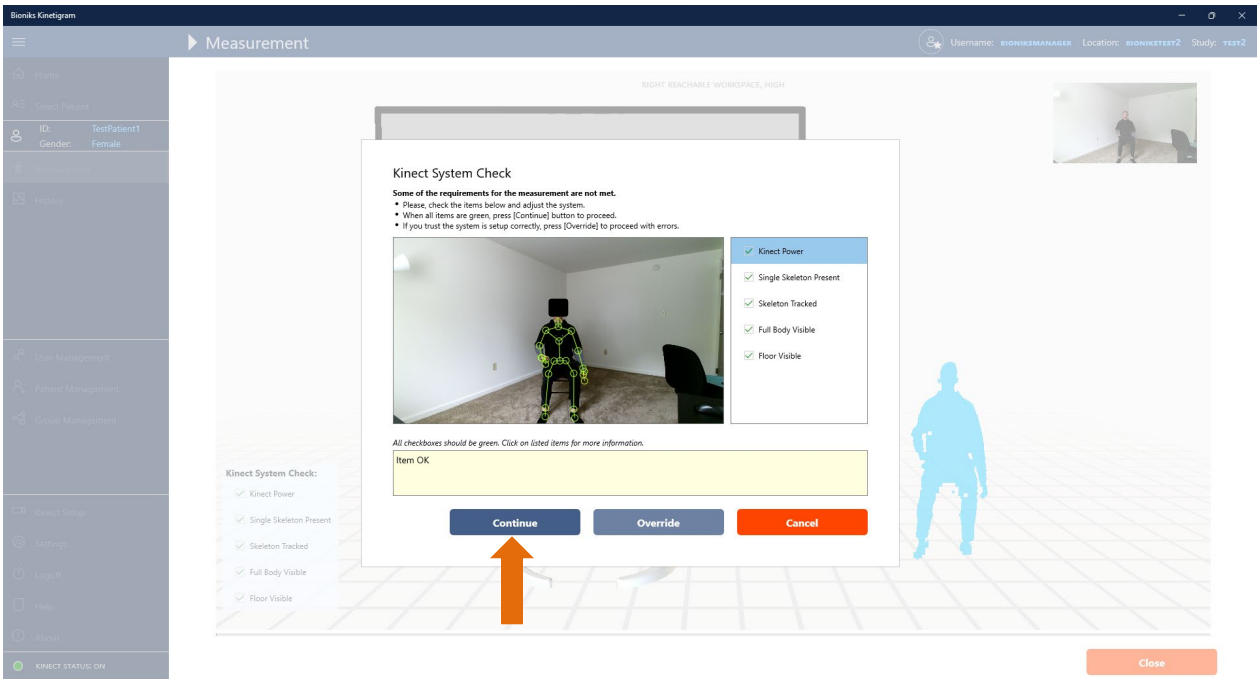
data. As noted previously, all items should have green checkmarks in the beginning of the measurement.

In case of errors, a dialog will pop up and pause the measurement. The Camera System Check dialog provides information on which items are not valid. You can click on the list to get more information on how to correct the issue.

Note: While the dialog appearance may vary between Kinect and Orbbec versions, the functionality remains consistent across both platforms.



Once all issues have been corrected, the Continue button will be enabled to continue with the measurement. The window will close and the countdown will restart so that the patient can get ready for the measurement.



The Camera System check also provides option to continue measuring with errors by pressing Override button.

Important: Override of the System Check should only be used in case you are certain that the measurement will not be affected by the identified issues (e.g. feet are visible but not detected by the system due to shoe material).

If you are not ready to proceed with the measurement, you can also press Cancel and return to the initial screen.

8.7 Additional References

Note for RWS & FWS data entry (optional to use)
High Function Assessment Module
Low Function Assessment Module

You may use the template on the next page to record measurements and collect data while evaluating a patient. This form is provided to assist you in collecting and organizing information that will be entered into the Kinetigram.

9 Kinetigram Use in Pediatric Population

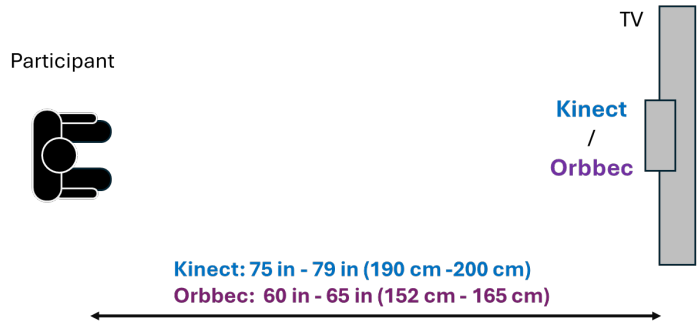
9.1 Introduction

The Kinetigram has investigational use indication for the pediatric population ages 5-17-year old with a minimum height of 100 cm. For data to be collected accurately, the child must be able to follow all directions and movements on their own, without physical assistance from the evaluator. Data capture with the pediatric population requires more involvement from the evaluator and additional levels of instructions: (1) time spent physically showing children the proper movements, and (2) mirroring of the movements during the data collection to help guide children through the entire protocol. As outlined below, certain adjustments are required for most children under the age of 15.

9.2 System Setup

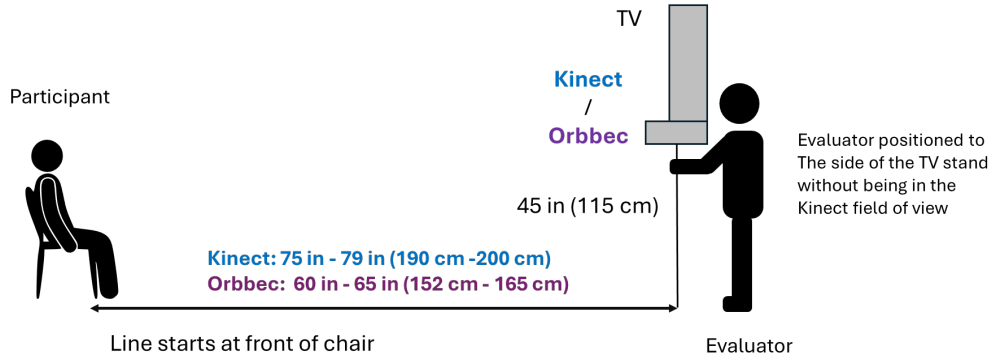
Testing on the Kinetigram for the pediatric population will require the use of a height-adjustable armless chair. The height of the chair should be adjusted to achieve short sitting of ~90 degrees of knee flexion, with feet flat on the floor. Chair should be checked for stability and evenness prior to subjects being seated.

For children under the age of 15, the 3D-Camera can be moved closer to a distance of 75-79 inches (190 – 200 cm) for Kinect and 60-65 inches (from the front leg of the chair to get a better view of the smaller subjects. 3D-Camera placement may be maintained at the height of 45 in (115 cm) as shown in the figure below. The camera should be pointed towards the participant, while the angle should be adjusted so that the camera captures their feet and the tip of the arm when fully extended above the head. The location of the Chair and TV stand should be marked with tape for easy placement for subsequent testing sessions. Assessments should always be performed in the same location if possible.



The protocol for children requires that evaluators mirror the movements for children during the data collection to ensure that they follow the right movements (see details below). This requires that the testing room has enough space next to the TV stand for the evaluator to stand while performing the movements without being in the 3D-Camera field of view. For best positioning, the evaluators should be at least one arms-length (in the lateral plane) away from the TV mobile setup.

A visual of the setup can be seen below:



9.3 Subject Placement & Instructions

Similar to the data collection for adults, all children must first watch the video instructions. After watching the video instructions, all children must then receive additional, explicit, instructions on the placement of movements to be tested prior to any data collection. This requires a hands-on demonstration by the evaluator and includes holding the child's arm and physically showing them all the testing positions for each arm. This should be done on each arm independently. If needed, another practice with the child mirroring the evaluator performing the protocol may be done before actual testing is performed and recorded.

During the actual testing and data collection, the evaluator must continue to follow along with the video and mirror the movements (to provide visual feedback) for the child while verbally cueing if needed. If the voiceover from the video is too distracting, the evaluator can turn the video audio off and the evaluator can verbally cue the child while mirroring the arm motions at the same time; keeping pace and order of the protocol. The only time the process of mirroring can be excluded, is if the child is at least 15 years of age and they have demonstrated an ability to follow the protocol from start to finish on their own.

The testing protocol for children should remain as listed in the original protocol. If the protocol includes wrist weights (500 g) collection of data with the wrist weights should always occur after the unweighted assessments. If the subject is too tired from the first recordings, the weighted collections can be skipped. Please note the reason for the skipping of the weighted assessments for either arm in the last assessment notes section, if not performed.

If a wrist weight other than 500 g is required by the protocol, please contact Bioniks team to confirm that the weight (type and amount) is allowed and configured in the software system.

The following limitations are used for measurements in pediatric population. Data outside these values will not be accepted. Please, contact Bioniks if different ranges are required for a clinical study.

Measure	US Units*		Metric Units	
	Minimal Value	Maximal Value	Minimal Value	Maximal Value
Height	39.4 in	84 in	100 cm	214 cm
Weight	33.0 lb	500.4 lb	15 kg	227 kg
Sternum-ACJ	1.6 in	12.2 in	4 cm	31 cm
ACJ-Olec	3.9 in	20.1 in	10 cm	51 cm
Olec-UlnSty	3.9 in	20.1 in	10 cm	51 cm
ACJ-UlnSty	7.9 in	35.0 in	20 cm	89 cm

9.4 Additional Safety Considerations

Additional safety considerations with children must be followed. The chair must be stable on its own with no platforms blocking the area under or in front of the chair. The adjustable chair must be checked for stability prior to any child being placed on it.

Proper judgement must be used regarding the use of the wrist weight, despite the actual age of the child. To use the wrist weight, it must be wrapped securely around the subject's wrist without it sliding or falling off. The evaluator must confirm ahead of time that the child is able to lift their arm to their 'normal' level with the weight on, in order to do the weighted testing.

9.5 Additional Disclaimers

See **Performance Characteristics** for more information on the accuracy of the assessment in pediatric patients.

Reachable Workspace (RWS) and Functional Workspace (FWS) Source Document
(Optional)

*This form is provided to assist you in collecting and organizing information that will be entered into the RWS and FWS Kinetigram

Subject ID: _____ **Date: _____**

Sex (please circle): Male / Female **Hand Dominance** (please circle): Right / Left

Height: _____ cm **Weight**: _____ Kg

I. Reachable Workspace (RWS)

Upper Extremity Length Measurements (please perform measurement at **every visit**):

		Right	Left
1	**Sternum-ACJ (Suprasternal notch to Acromicoclavicular Joint)**	cm	cm
2	**ACJ-Olec (Acromioclavicular Joint to Olecranon)**	cm	cm
3	**Olec-UlnSty (Olecranon to Ulnar Styloid)**	cm	cm
4	**ACJ-UlnSty (Acromioclavicular Joint to Ulnar Styloid)**	cm	cm

Right Arm	**Left Arm**
Yes / No	Yes / No

Can the participant forward flex their arm to 60 degrees or above? (Please circle)

If **YES**, select **High Functional Module**
If **No**, select **Low Functional Module**
*Please note that during a visit one arm may be determined to be High Functioning while the other one may be Low Functioning.

II. Functional Workspace (FWS) – please observe whether the participant is able to touch these SEVEN body targets and check the appropriate boxes to indicate "Yes".

	Body Targets	Right	Left
1	**Belly button**		
2	**Back pocket**		
3	**Same shoulder**		
4	**Opposite shoulder**		
5	**Mouth**		
6	**Top of head**		
7	**Back of head**		

10 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.

11 Performance Characteristics

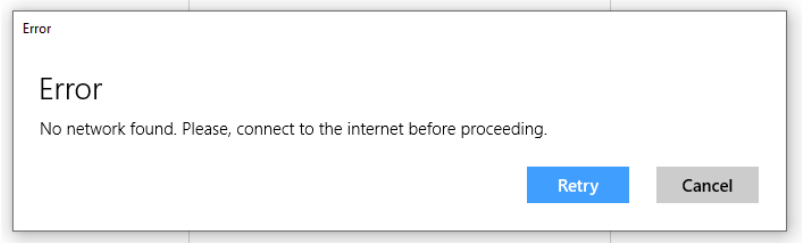
Kinetigram client application records motion by tracking the position of 25 body landmarks (joints) in three-dimensional space with the minimum frame rate of 15Hz and the maximum frame rate of 30Hz. The measurements stored by the software are recorded in the unit of millimeter and include timestamps with millisecond precision for each recorded frame.

Note that for pediatric subjects, the accuracy of Kinetigram may be reduced. If a subject is unable to follow the prescribed motions, the data may not be correctly computed.

12 Troubleshooting

12.1 Server Connection Issue

Issue 1: Network not found.
Error Message: On application load, the following error message is displayed:



Reason: The computer is not connected to the Internet. The app requires Internet connection.
Solution: Check your internet (Wi-Fi or Wired) connection. Contact your IT personnel if unable to connect to the internet. If using a mobile hotspot Wi-Fi connection or similar limited bandwidth connection, ensure the mobile hotspot or the computer is placed in a location that receives adequate signal strength.

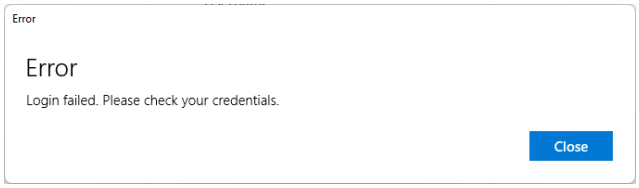
Issue 2: Pages become unresponsive; content doesn't load.

Error Message: *Server connection error...* [Error message may include other information related to server communication]



Reason: The application is unable to reach the server.
Solution: Check your internet connection. If needed, close the application and login again. If using a mobile hotspot Wi-Fi connection or similar limited bandwidth connection, ensure the mobile hotspot or the computer is placed in a location that receives adequate signal strength.

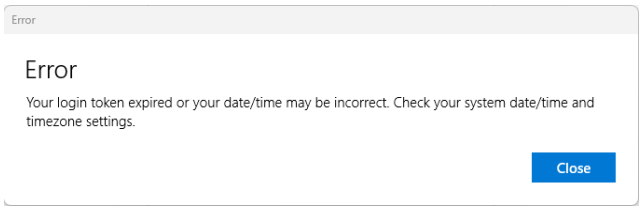
Issue 3: Cannot log in
Error Message: Login failed message, please check your credentials



Reason: Your credentials are incorrect.
Solution: Check your credentials. If the credentials you are using are correct and you tried to reset the password, contact Bioniks team at help@bionks.net.

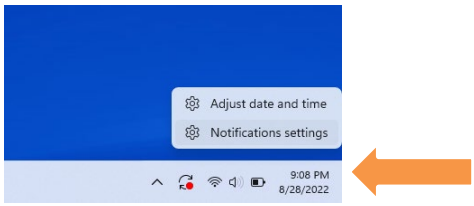
Issue 4: Cannot log in with correct credentials

Error Message: Your login token expired or your date/time may be incorrect. Check your system date/time and timezone settings.



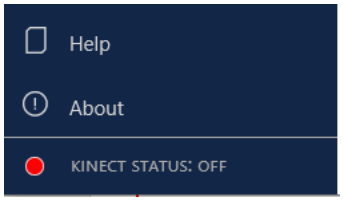
Reason: Your computer date/time or timezone may be incorrect.

Solution: Check the Windows clock/date on your computer. Incorrect time may prevent the authentication on the server. To adjust the date/time, right-click on the date/time in the taskbar (orange arrow).



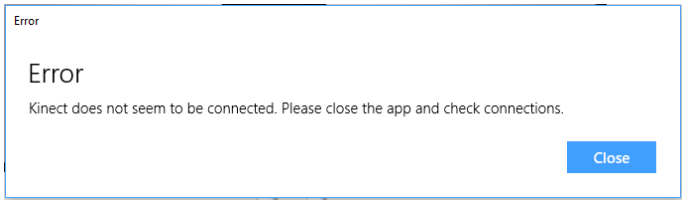
12.2 Kinect Camera Issues

Issue 1: Kinect status bar under the menu has red indicator and shows OFF status.



Reason: Kinect may not be connected to the computer.
Solution 1: Exit application. Check if Kinect is connected to the power outlet. Check if Kinect power supply has power. The light on the connector should be yellow or white.
Solution 2: Exit application. Check if Kinect is connected to the correct USB 3.0 port on the computer as described in the set-up section.
Solution 3: Check to see if there are any pending Windows updates. Restart computer and install any pending updates.
Solution 4: Exit application. Restart the computer. Run the application again.

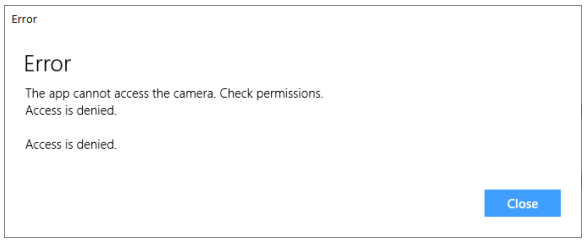
Issue 2: Kinect video is frozen or black screen appears during measurement session.
Error Message: *Kinect does not seem to be connected. Please close the app and check connections.*



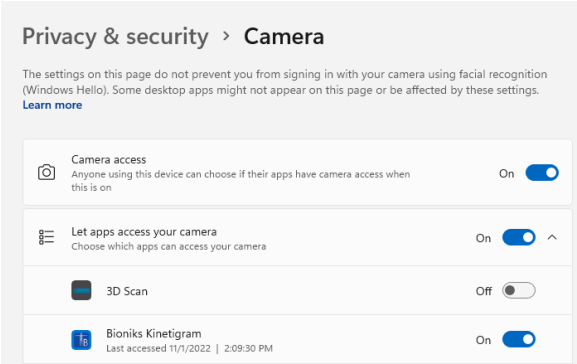
Reason: Kinect may not be connected to the computer.
Solution 1: Exit application. Check if Kinect is connected to the power outlet. Check if Kinect power supply has power. The light on the connector should be yellow or white.
Solution 2: Exit application. Check if Kinect is connected to the correct USB 3.0 port on the computer as described in the set-up section.
Solution 3: Check to see if there are any pending Windows updates by searching for 'Check for updates' in Windows Search Bar. Restart computer and install any pending updates.
Solution 4: Logout and exit application. Restart the computer. Run the application again.

Issue 3:

Error Message: The app was denied access to the camera. Access is denied.

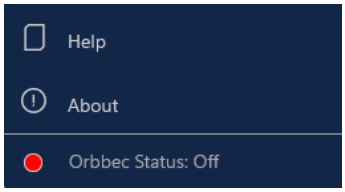


Reason: The app is restricted from accessing the camera
Solution: Search for Privacy Settings in Windows task bar search. Select Camera under App Permissions and ensure Bioniks Kinetigram has access to the camera enabled (toggle switch to On).

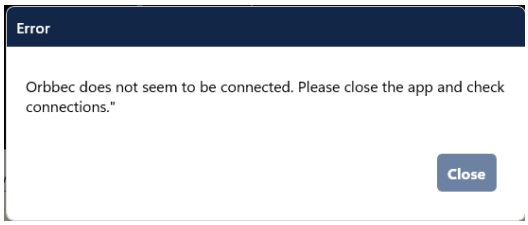


12.3 Orbbec Camera Issues

Issue 1: Orbbec status bar under the menu has red indicator and shows OFF status



And/or Error Message: *Orbbec does not seem to be connected. Please close the app and check connections.*



Reason: Orbbec camera may not be connected to the computer.
Solution 1: Exit application. Check if Orbbec camera is connected to the power outlet.
Solution 2: Exit application. Check if Orbbec camera is connected to the correct USB 3.0 port on the computer as described in the set-up section.
Solution 3: Exit application. Restart the computer. Run the application again.

Additional Camera Troubleshooting

Orbbec Femto camera includes a light indicator on the back side, next to the USB connector.

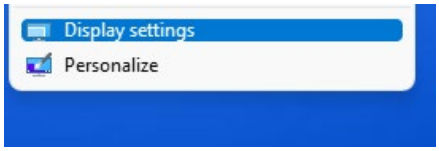


The light indicates the following:

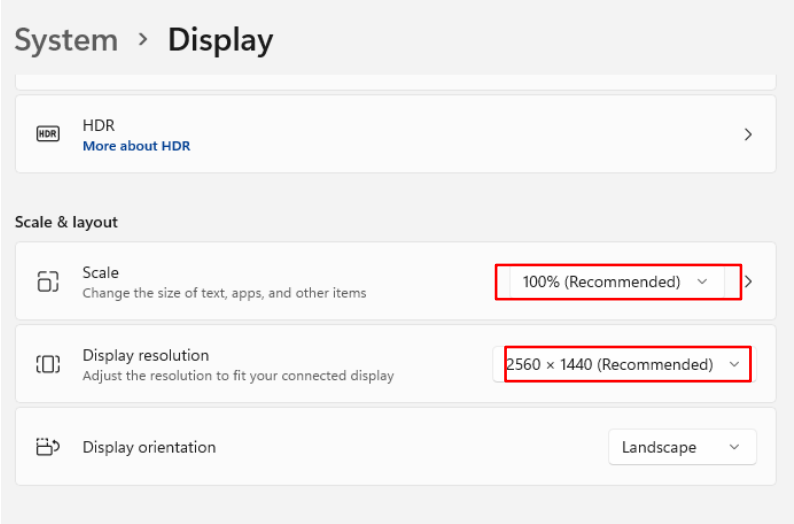
Light Status	*Indication*
Solid white	Normal operation
Blinking orange	Insufficient power -> check camera is connected to power outlet
Blinking white	Abnormal USB connection -> check data cable and connections

12.4 Software and Hardware Issues

Issue 1: Software UI has very large or very small text and/or parts of the application are occluded.
Solution: Close the app. Check your display settings. Right click on the Windows desktop and select Display Settings:



Select your Display and adjust Text Scaling and Resolution. Recommended resolution is 1920x1080 (scaling 100%). However, for different display sizes, the two parameters may need adjustment (e.g. 4K monitor may work best with 3840x2160px and 225% scaling).



Restart Kinetigram application after resetting the display size.

Issue 2: Software suddenly freezes and becomes unresponsive.
Solution: Try closing the application. If the application can be closed. Restart the application.

Issue 3: Software suddenly crashes (window disappears).
Solution: Try to restart the application. If that does not solve the issue, restart the computer.

Issue 4: Power outage happens during the assessment.
Solution: Wait for the power to come back on and start the computer. Start the Kinetigram application, log in with your credentials, and select the patient that is being evaluated. The evaluation that was not completed due to the power outage will have to be repeated.

Issue 5: Computer does not start or load.
Solution: Contact Bioniks team at help@bionks.net

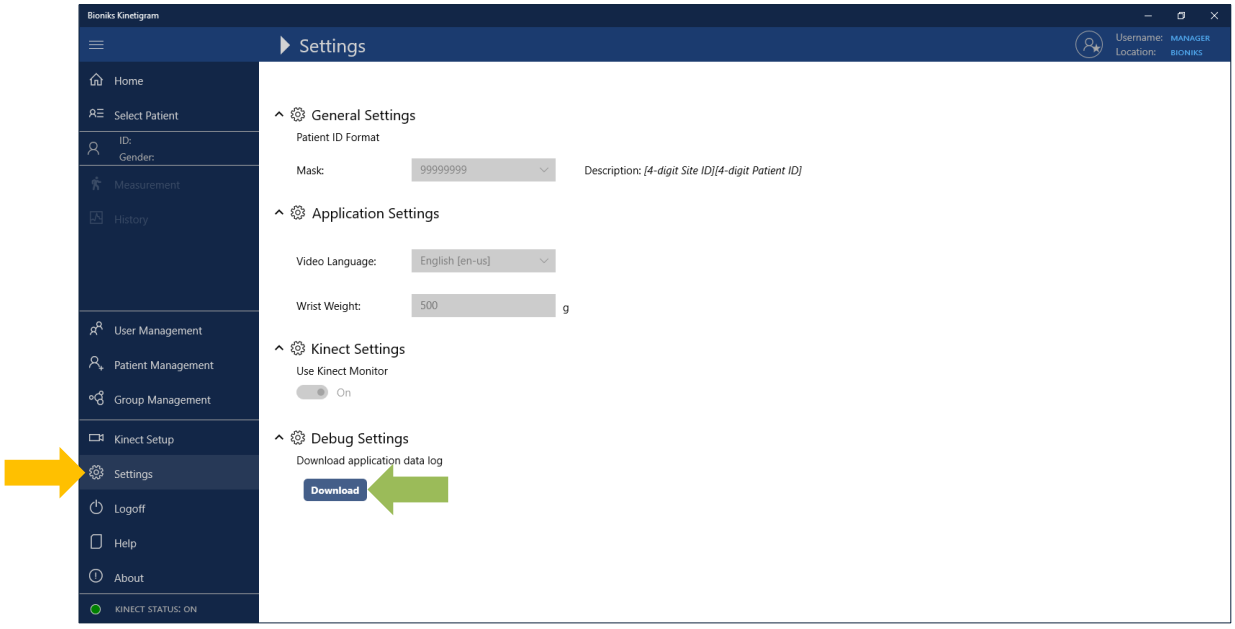
Issue 6: Display not properly showing the application or does not "wake up" when attempting to access the software.
Solution: Confirm that the display cable is connected and is connected to the correct port: NVIDIA HDMI port (if available). If the problem persists, turn off the display and turn the display back on. If the above two steps do not correct the problem, contact Bioniks Service at help@bionks.net.

12.5 Other Issues - Contact Bioniks Team

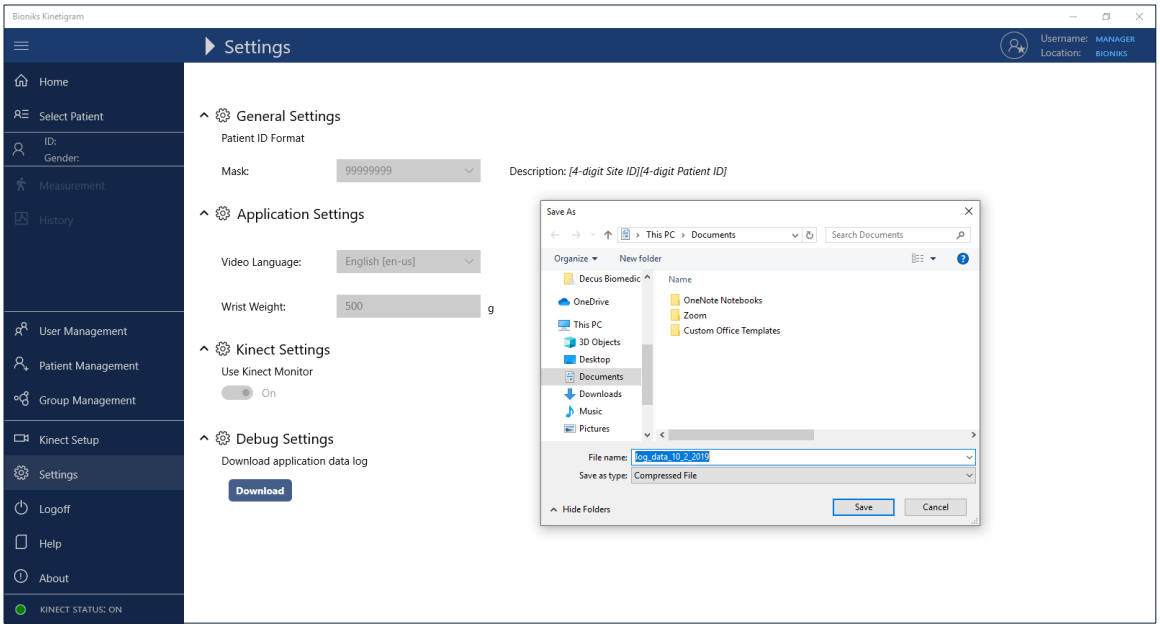
If the solutions above do not resolve your issue, please contact Bioniks team at help@bioniks.net

Take screenshots of the errors, if possible.

You may be asked to provide software log files. The logs can be downloaded from the Settings Section. Select Settings from the menu (yellow arrow) and then click on the Download button under Logging (green arrow).



You will be prompted to save the file.



Save the file and e-mail it to Bioniks Team.

12.6 Remote Access for Bioniks Team Support

If the issue with Kinetigram application or computer cannot be resolved over e-mail, Bioniks Team may need to access the computer remotely. The computer is typically pre-installed with Remote Access software, either Splashtop . If additional steps are needed, Bioniks Team will provide specific instructions.

13 Audit Logs

Access to audit logs is available only to users with Auditor role. This role is typically reserved only for Bioniks Administrator. The audit logs for active tenant are accessible by selecting Setting from the Menu. To download the logs, click on Download button in Audit Logs section and select the destination file on your local computer. Click on Save and wait until the download is completed. The audit logs are provided in Comma-separated values (CSV) format.

14 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.

15 Decommissioning

Decommissioning of Kinetigram software is performed by Bioniks Service at the end of use. The Kinetigram application is removed from all accounts on the computer system and all configuration files are deleted. The Kinetigram application does not store any subject or user data on the local system. Subject and user data are stored on the dedicated cloud space. If the tenant account is also terminated, the user and subject data will be handled according to the agreement with the tenant account owner (e.g., data archiving, data removal).

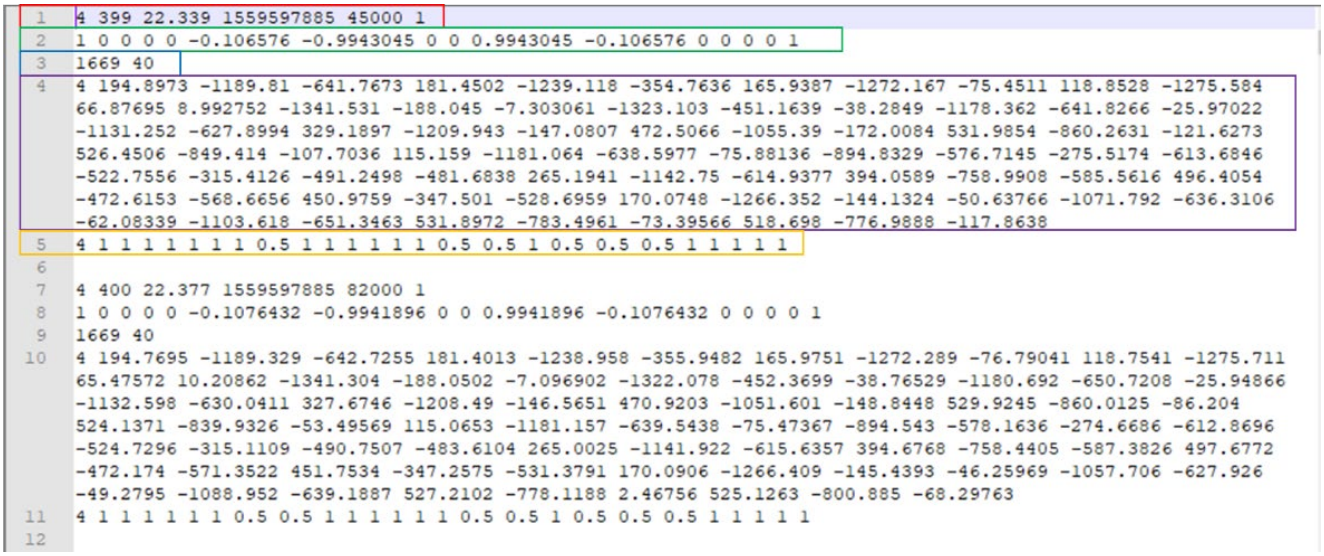
Please, contact Bioniks Service for decommissioning of Kinetigram software at help@bioniks.net.

16 Appendix A: Measurement Data Export Format

16.1 File Format

Using the Export Data function in the Kinetigram UI produces and ASCII file that contains measurement (skeleton) data for a one measurement. 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); Kinect 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

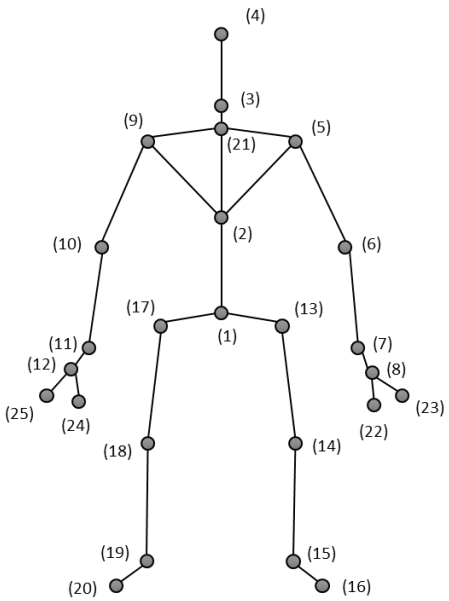
5. Line 5

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

16.2 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



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).