

Kinetigram Instructions for Use

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

Table of Contents

1	Introduction.....	5
1.1	Indications for Use	5
1.2	Prescription Guidelines	5
1.3	Safety Information – Definitions	5
1.4	<i>Safety Information</i> – List of Cautions.....	5
1.5	<i>Other Annotations</i>	5
2	Getting Started	6
2.1	Hardware and Software Requirements for Kinetigram	6
2.2	Installation	6
2.3	Setting Up the Environment	6
2.4	Initial Hardware Setup	8
3	Initial Login	11
3.1	Starting application	11
3.2	User Login.....	12
3.3	Initial Kinect Setup	12
3.4	Data Validation Test.....	15
3.5	How to Download Instructions for Use and Customer Release Notes	15
4	User Management.....	17
4.1	Creating New User	18
4.2	Editing Existing User.....	19
4.3	Deleting/Deactivating Existing User.....	20
5	Managing Study Groups	22
5.1	Creating New Group.....	22
5.2	Editing Existing Group.....	23
5.3	Deleting Groups	24
6	Managing Patients.....	25
6.1	Adding New Patient	25
6.2	Editing Existing Patient.....	26
6.3	Deleting Existing Patient	26
7	Instructions for Collecting Motion Data (Manual of Operations)	28
7.1	Additional References.....	52
8	Video Protocol Transcripts	54

9	Troubleshooting	56
9.1	Server Connection Issue.....	56
9.2	Kinect Issues	56
9.3	Software and Hardware Issues	57
9.4	Other Issues - Contact Bioniks Team	58
9.5	Remote Access for Bioniks Team Support	59
10	Quick Reference (one-pager)	61

1 Introduction

1.1 Indications for Use

The Kinetigram is Software as a Medical Device intended to be used with the Microsoft Kinect for Xbox One to evaluate upper extremity joint function using 3D kinematic data capture in adults. The product is intended for use by medical professionals **amongst other available patient parameters** as a motion analysis tool.

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 Safety Information – Definitions

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

1.4 Safety Information – List of Cautions

Caution: Do not use the results of the software alone to make decisions on patient treatment.

Caution: Do not run other software programs while conducting procedures.

1.5 Other Annotations

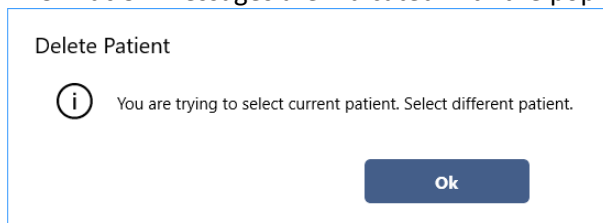
Terms used in this Instructions for Use:

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

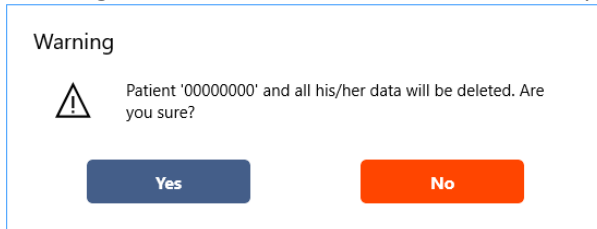
Important: Directions which if not followed can lead to misdiagnosis and/or loss of use of patient data.

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.

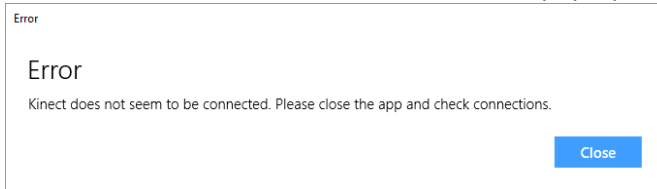
Information messages are indicated with the pop-up box with the symbol ⓘ, e.g.:



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:

- Microsoft Kinect sensor for Xbox One, model 1414
- Standard PC (desktop or laptop) with the minimum hardware 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+)

The PC should have the following software configuration:

- Windows 10 Operating System, 64-bit, version 1803 (April 2018 Update) or higher
- Installation of Microsoft Kinect for Windows SDK 2.0 (version 2.0.1410 and higher)

The TV monitor should have the following minimum specifications:

- Diagonal dimension: 21"
- Resolution: 1920x1080

2.2 Installation

Installation of this version 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" (230 cm) from the participant and the height of 45" (115cm) as shown in the figures below. The Kinect 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.

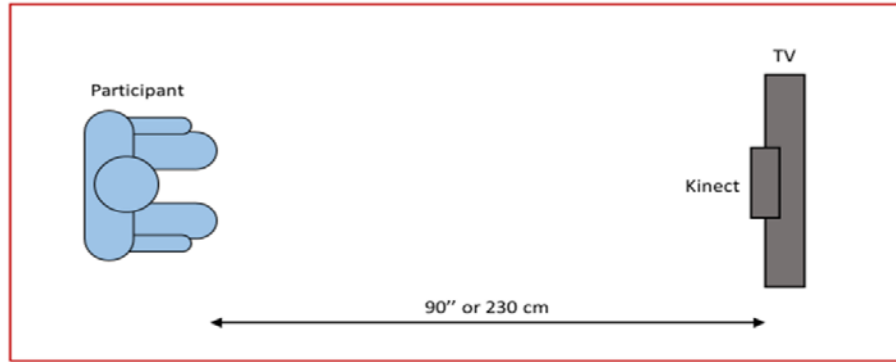


Figure 1: Kinect setup. Top View.

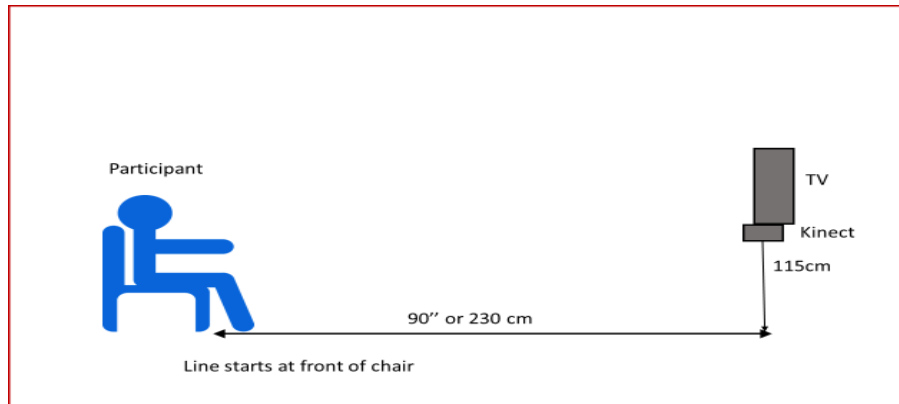


Figure 2: Kinect setup. Side View.

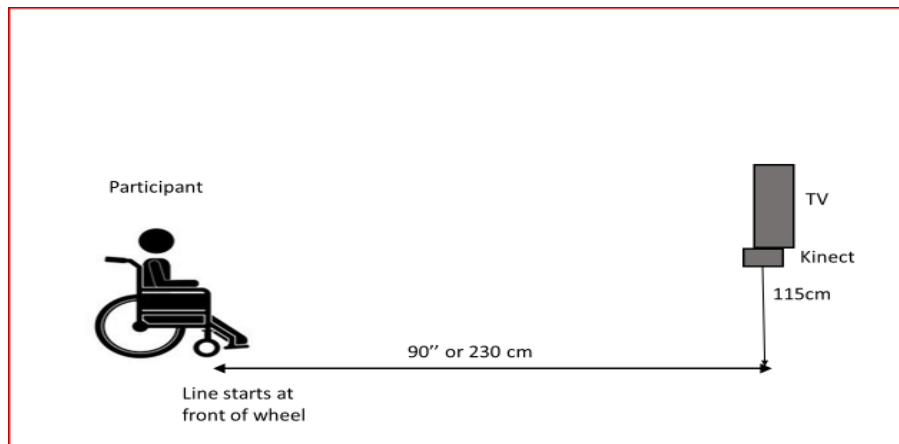


Figure 3: Kinect setup for patient in wheelchair. Side View.

Additional Requirements:

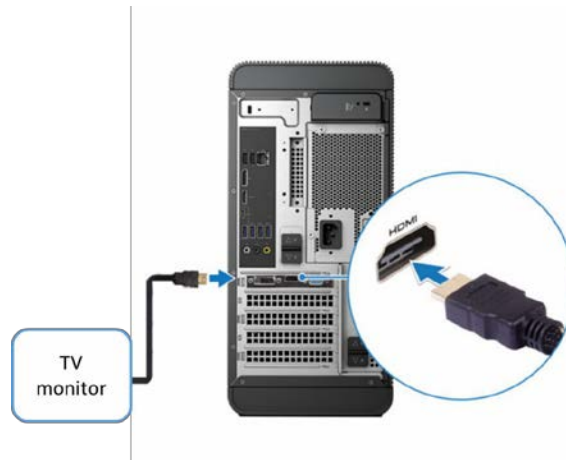
- **Note:** Make sure there is enough lighting in the room. Insufficient light may reduce the frame rate of the capture.
- **Note:** There should not be any visual obstruction between Kinect sensor and participant. Please try to remove as much clutter around the space/room.
- **Note:** There should not be any nearby objects or clutter behind the participant.
- **Important:** Make sure the participant is at least 3-4 ft. 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.

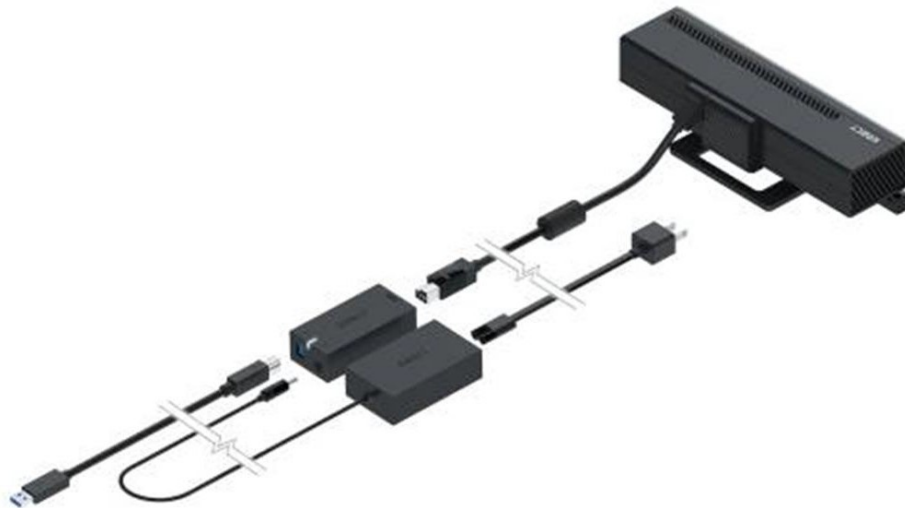
2.4 Initial Hardware Setup

On the backside of the desktop computer, connect all components as shown in the figure below:

- Connect HDMI cable to the TV and the other side to the PC video input (as shown below, and this may have been done already in setup from the previous equipment assembly section. Please check to make sure it is connected properly):



- Connect all of the components of Microsoft Kinect as shown:



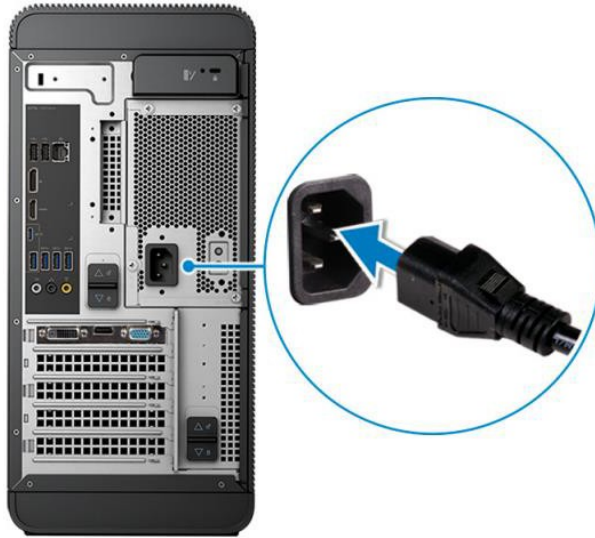
- Connect Microsoft Kinect USB adapter to the back of the PC (any of the blue USB3 slot **except the first one!**):



Further information about Microsoft Kinect camera can be found at Microsoft Support pages:

- Kinect for Windows
<https://support.xbox.com/en-US/xbox-on-windows/accessories/kinect-for-windows-info>
- Set up Kinect for Windows v2 or an Xbox Kinect sensor with Kinect Adapter for Windows
<https://support.xbox.com/en-US/xbox-on-windows/accessories/kinect-for-windows-v2-setup>

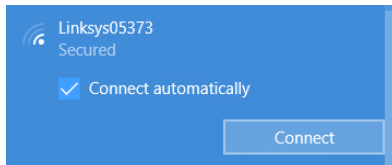
- Connect the power connector:



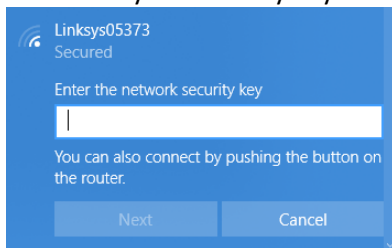
- Connect Ethernet or Wi-Fi

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”:



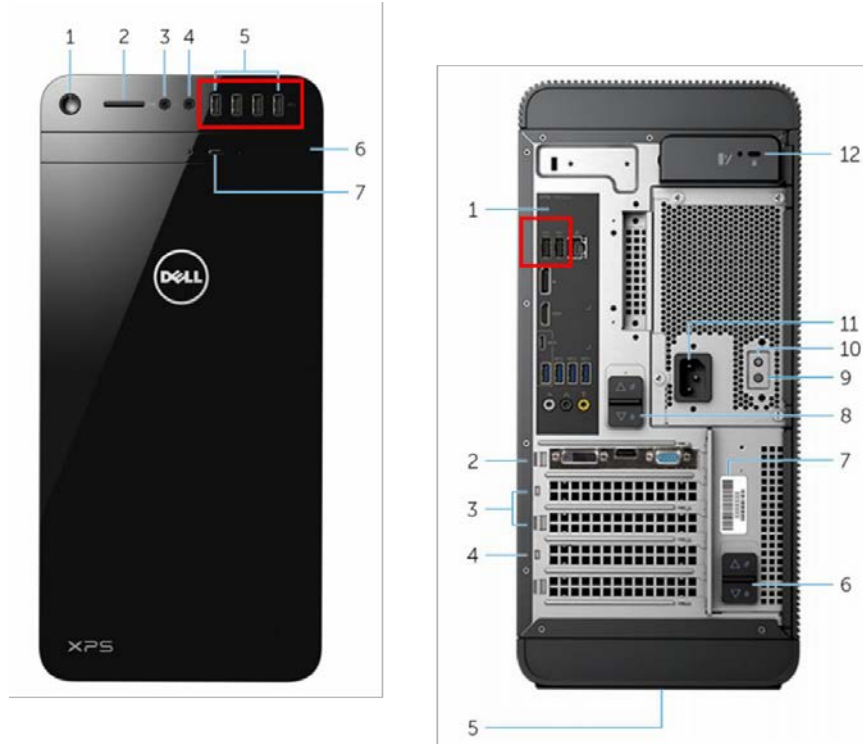
And enter your security key:



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

- Connect Mouse and Keyboard

The mouse and keyboard can be connected either in the front or in the back of the PC USB ports (marked in red color below). If using wireless mouse and keyboard, a USB dongle will be supplied. The dongle should be inserted into any USB port available. 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.

3 Initial Login

3.1 Starting application

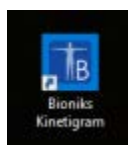
The computer with Kinetigram may be configured in two possible ways:

Desktop Mode:

Once you turn on the computer, you will be prompted with the Windows 10 login screen where you can use your credentials to log in. For computers configured by Bioniks, the Bioniks Administrator will provide Windows login information for a Site Coordinator (Manager) that has administrative privileges to allow the Manager to add or edit Windows user accounts. Additionally, a Site User account is included on the computer (login information provided by Bioniks) that has Standard User privileges. This account can be used for all operations in the Kinetigram software and should generally be used most of the time.

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

Once you log into the computer, open “Bioniks Kinetigram” program on Desktop.



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

Bioniks Kinetigram

Language: English

Sign In:

Location
Bioniks

Username
gregorij

PIN

☐ Show PIN

Login Cancel

Powered by
BIONIKS
v Version 0.0.1

Once the application successfully starts, ensure that the computer is connected to the Internet, either through wireless (Wi-Fi) or wired (LAN) connection.

Note: Ensure that the computer is connected to the Internet while performing the data collection.

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

3.2 User Login

Kinetigram initial Login information will be provided by Bioniks Administrator. Once logged in, you can create additional users. Please refer to section User Management (4) for more information.

3.3 Initial Kinect 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 section Initial Hardware Setup (2.4) to check the placement of the Kinect and the chair.

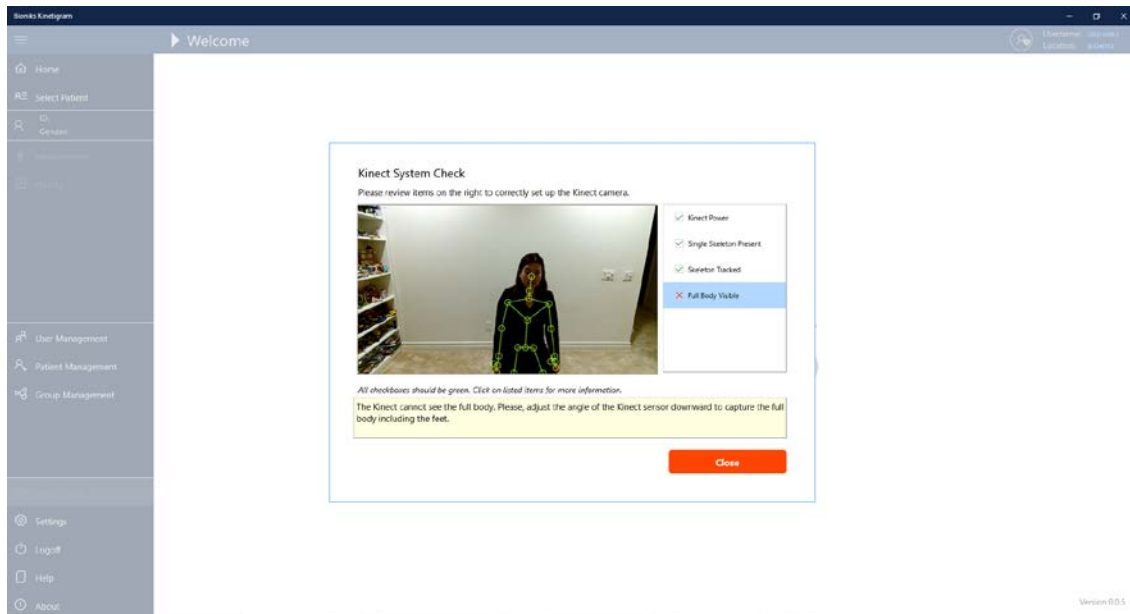
Once the Kinect is correctly connected, you should verify that the camera sees the participant. To open the camera view, select “Kinect Setup” from the Menu. Kinect System Check window will open. The Kinect System Check performs several diagnostics checks to ensure that the system is properly set up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

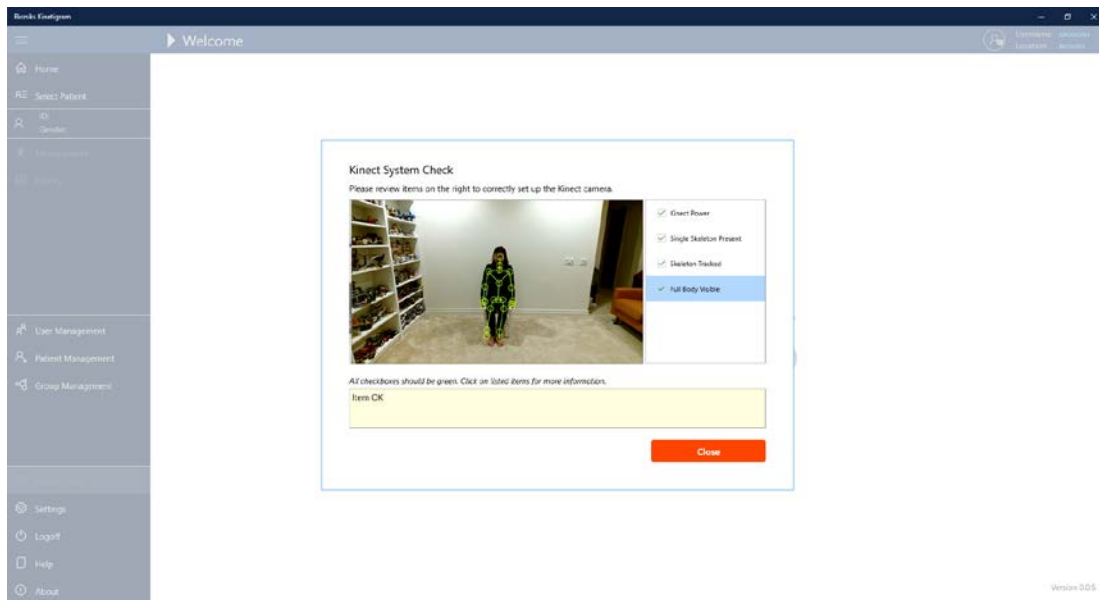
If the item check has passed, a green checkmark will be shown: .

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 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.

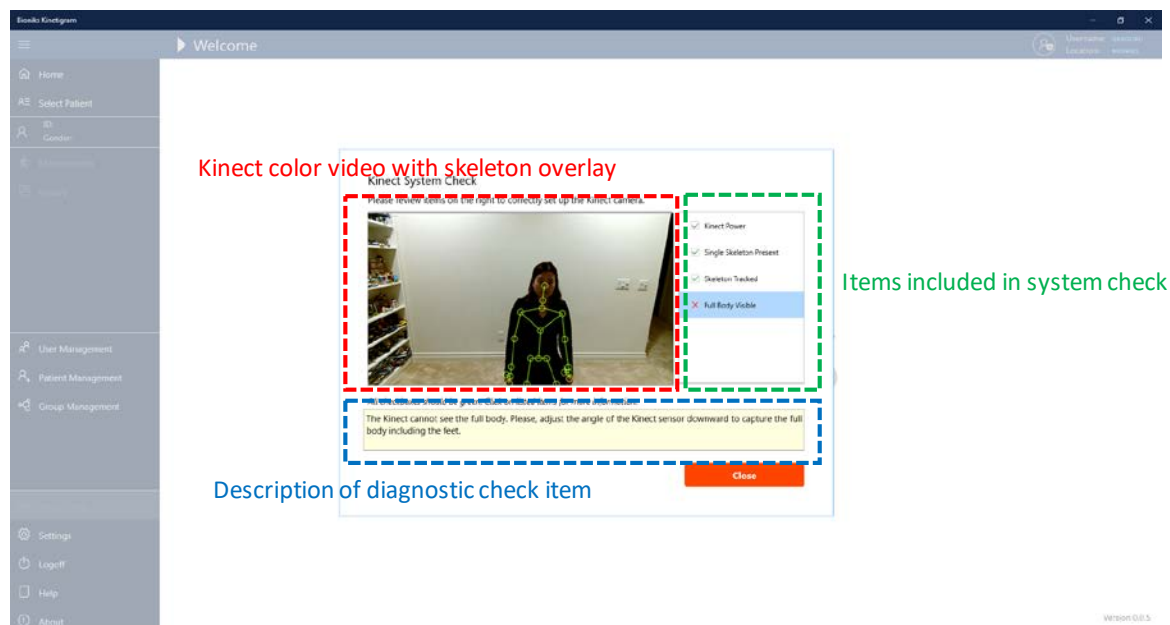


Once the participant is moved further to the back, all four checkmarks are green and the system is correctly set up for the measurement.



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.



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

3.4 Data Validation Test

Important: Before collecting data with study participants, each evaluator should collect validation dataset that would be examined and verified by Bioniks team.

The evaluator should use a volunteer control (healthy) subject for this test. The data of the following protocol should be collected:

<i>Evaluation</i>	<i>Module</i>	<i>Level</i>	<i>Speed</i>	<i>Side</i>	<i>Weight</i>
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 are collected, the evaluator should contact the Bioniks team given the contact information in this manual to perform the data analysis.

3.5 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 (green 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 PDF Viewer” link at the bottom of the screen (red arrow).

Kinetigram Instructions for Use

Books Kinetigram

Instructions Manual

Username: [resources](#)
Location: [resources](#)
Logout

Home

Select Patient

ID

Gender

Measurement

History

User Management

Patient Management

Group Management

Kinect Setup

Settings

Logout

Help

About

Kinetigram Instructions for Use

Notes for RW5 and FWS data entry (optional to use or not)

*This form is provided to assist you in collecting and organizing information that will be entered into the RW5 and FWS.

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 patient visit):

	Right	Left
1. Sternum ACJ (Suprasternal notch to Acromioclavicular 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

Can the participant forward flex his/her arms to or above shoulder level? (Please circle)

Right Arm
Yes/No

Left Arm
Yes/No

YES - High Functional Module **No - Low Functional Module**

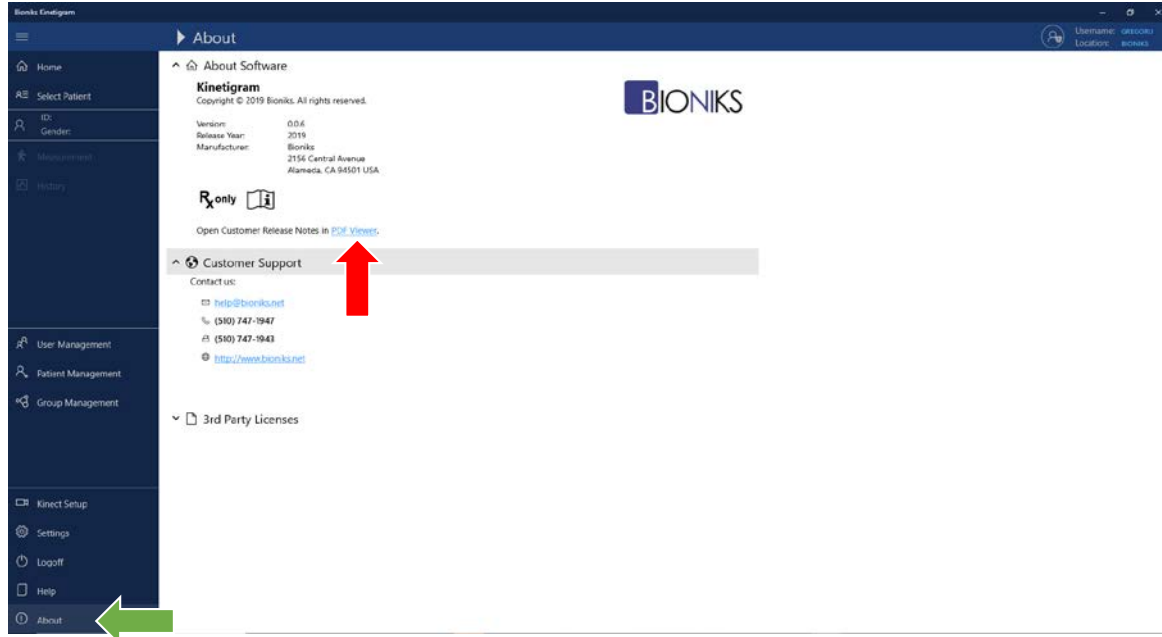
*Please note that the same participant can have one high functioning arm, with the other arm being low functioning during the same visit.

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

Body Targets	Right	Left
1. Belt Level		
2. Back Pocket		
3. Same Shoulder		
4. Opposite Shoulder		
5. Mouth		
6. Top of head		
7. Back of head		

Page 56 of 58 [Open in PDF Viewer](#)

Customer Release Notes are accessible by clicking on the “About” button in the menu (green arrow) and selecting “Open Customer Release Notes in PDF Viewer” link (red arrow). This will open the document in default PDF Viewer on your system (e.g., Edge, Acrobat Reader).



4 User Management

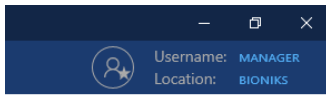
Note that the Kinetigram software operates with three types of users who have different level of privileges to operate the application:

1. **User:** assigned to Evaluators
2. **Manager:** assigned to Site Coordinator/Manager
3. **Admin:** assigned to Bioniks Administrator

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

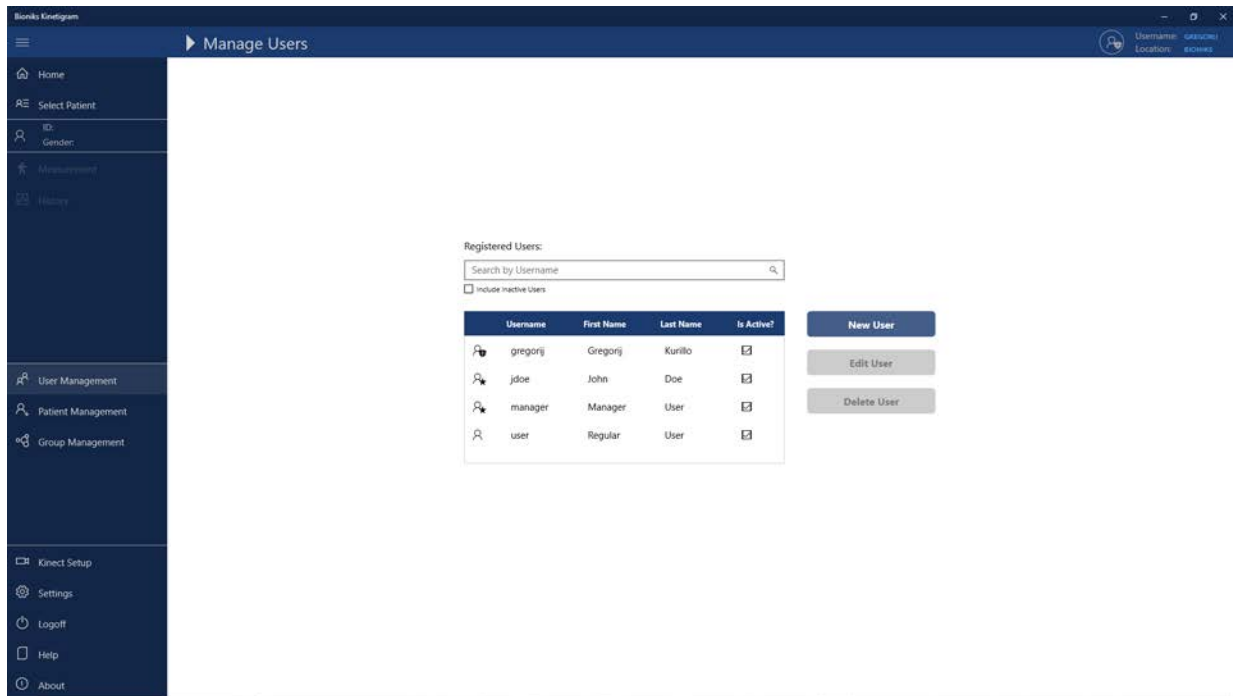
<i>Authorized tasks</i>	 <i>User</i>	 <i>Manager</i>	 <i>Administrator</i>
Change your own account information	x	x	x
Change your own PIN#/password	x	x	x
Change account administration role		x	x
Create/edit new users		x	x
Create/edit/delete study groups		x	x
Create /edit new patients	x	x	x
Access to export logs		x	x
Deactivate user accounts		x	x
Create multiple manager accounts		x	x
Can set Patient ID format in Settings page			x

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



- Initial login must be done by the Site Coordinator. Login information will be provided by a Bioniks Administrator by e-mail.
- Once login is successful, go to User Management located in the left-side menu.

User Management Page displays the list of current users, and allows changing their PIN #s, account information, and setting up new accounts.



4.1 Creating New User

To add a new user account for evaluators:

- Select “New User.”
- Enter first and last name of the user.
- Enter Username and password.
Note: The system requires users to have unique usernames. For example, select user’s first name initial and last name (e.g. John Doe, username: jdoe).
- Select user’s role (User, Manager, or Administrator).
Note: You will not be able to upgrade a role higher than your role.
- Select “Save” to save the information and to add the new user to the system.

The screenshot displays the Kinetigram software interface. On the left is a vertical sidebar with navigation options: Home, Select Patient, ID, Gender, Management, and Users. The main area is titled 'Manage Users'. In the center, a 'Add New User' dialog box is open. It contains the following fields: 'Title' (a dropdown menu set to 'Research Assistant'), 'First Name' (text input with 'John'), 'Last Name' (text input with 'Demo'), 'Username*' (text input with 'testuser'), and 'PIN*' (password input with four dots). Below these is the 'Role' section with three radio buttons: 'User', 'Manager' (which is selected), and 'Administrator'. There is also an 'Is active' toggle switch set to 'Yes'. At the bottom of the dialog are 'Save' and 'Cancel' buttons. To the right of the dialog, outside the box, are three buttons: 'New User', 'Edit User', and 'Delete User'. The top right of the window shows user information: 'testuser', 'testuser', and 'testuser'.

Users may change their username and PIN # after their account is set up and they log into the system for the first time.

Important: Each Evaluator should have their own account and should use their account when evaluating a participant.

4.2 Editing Existing User

You may also edit an existing user from User Management Page. Select the user you wish to edit and click on “Edit User”. This will bring up the Edit User dialog where the information can be changed. Click on “Save” when done editing.

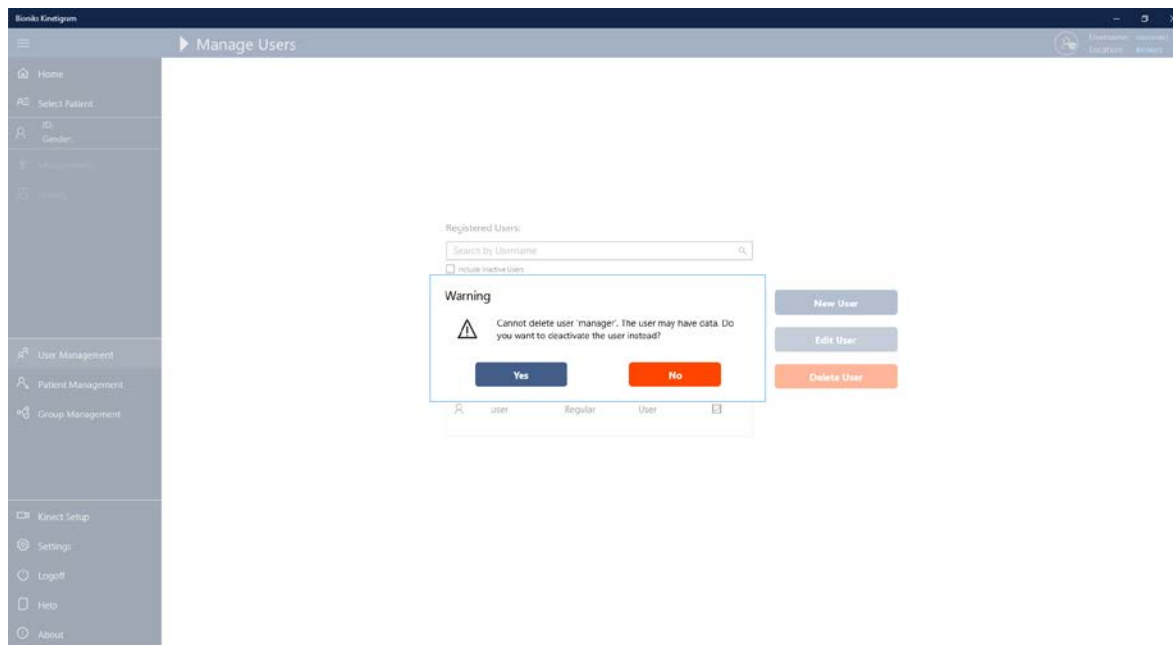
The screenshot shows the 'Manage Users' page in the Kinetigram application. A central 'Edit User' dialog box is open, allowing modification of user details. The dialog includes fields for Title (a dropdown menu currently set to 'Research Assistant'), First Name (containing 'John'), Last Name (containing 'Demo'), Username (containing 'testuser'), and Password (masked with four asterisks). Below these fields, the 'Role' is set to 'Manager' via a radio button, with options for 'User' and 'Administrator' also present. An 'Is active' toggle switch is currently turned 'Yes'. At the bottom of the dialog are 'Save' and 'Cancel' buttons. To the right of the dialog, three buttons are visible: 'New User' (grey), 'Edit User' (grey), and 'Delete User' (orange). The left sidebar contains navigation links: Home, Select Patient, ID, Gender, Management, History, User Management, Patient Management, Group Management, Kinet Setup, Settings, Logout, Help, and About. The top right corner shows user information: Username: admin, Location: Kinet.

4.3 Deleting/Deactivating Existing User

To delete a user, go to User Management Page and select the user you wish to delete from the menu. Press “Delete User” button. You will be asked to confirm deleting the user. If you press “yes”, user will be permanently deleted.

This screenshot shows the 'Manage Users' page with a 'Warning' dialog box displayed. The dialog contains a warning icon and the text: 'Selected user will be deleted: manager. Are you sure?'. It has 'Yes' and 'No' buttons for confirmation. Above the dialog, there is a search bar labeled 'Registered Users' with a search icon and a checkbox for 'Include inactive users'. Below the dialog, a table of users is partially visible with columns for user icons, usernames, and roles. The right side of the page features the same 'New User', 'Edit User', and 'Delete User' buttons as seen in the previous screenshot. The sidebar and top navigation remain consistent with the previous image.

Note: If user has patient recordings, the user cannot be deleted. The system will prompt an option to deactivate user. Deactivated users will not show on the default user listing and cannot log in to the system.



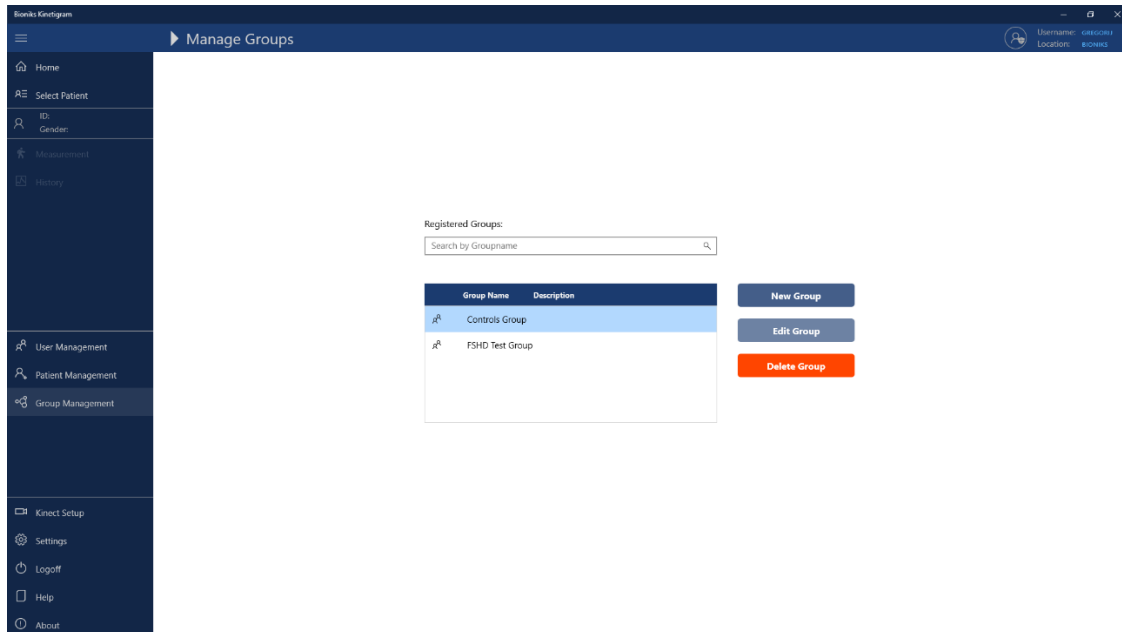
5 Managing Study Groups

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.

5.1 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.

The screenshot shows the 'Manage Groups' page in the Bionix Kinetigram application. A modal dialog titled 'Add New Group' is open. It contains a text input field for 'Group Name*' with the value 'Test Group' and a small 'x' icon to clear the field. Below it is a larger text area for 'Description'. At the bottom of the dialog are 'Save' and 'Cancel' buttons. To the right of the dialog, there are three buttons: 'New Group' (blue), 'Edit Group' (blue), and 'Delete Group' (orange). The background shows a sidebar with navigation options like Home, Select Patient, User Management, Patient Management, Group Management, Kinet Setup, Settings, Logoff, Help, and About.

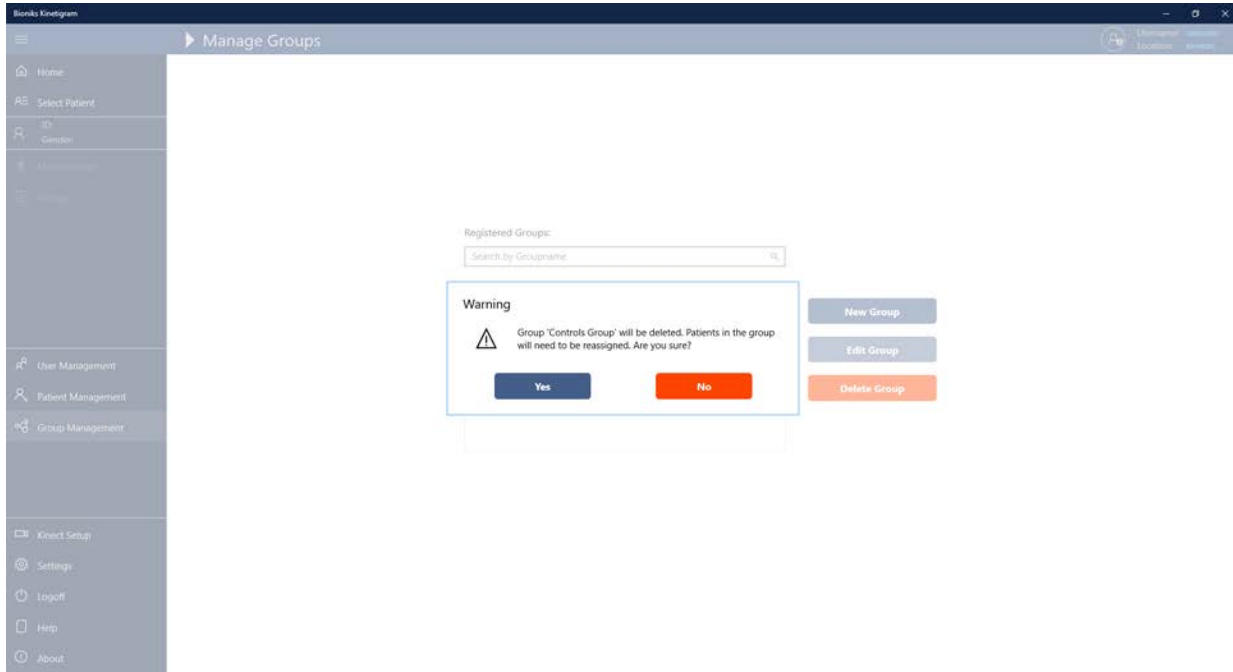
5.2 Editing Existing Group

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.

The screenshot shows the 'Manage Groups' page in the Bionix Kinetigram application. A modal dialog titled 'Edit Group' is open. It contains a text input field for 'Group Name*' with the value 'Control Group' and a small 'x' icon to clear the field. Below it is a larger text area for 'Description'. At the bottom of the dialog are 'Save' and 'Cancel' buttons. To the right of the dialog, there are three buttons: 'New Group' (blue), 'Edit Group' (blue), and 'Delete Group' (orange). The background shows a sidebar with navigation options like Home, Select Patient, User Management, Patient Management, Group Management, Kinet Setup, Settings, Logoff, Help, and About.

5.3 Deleting Groups

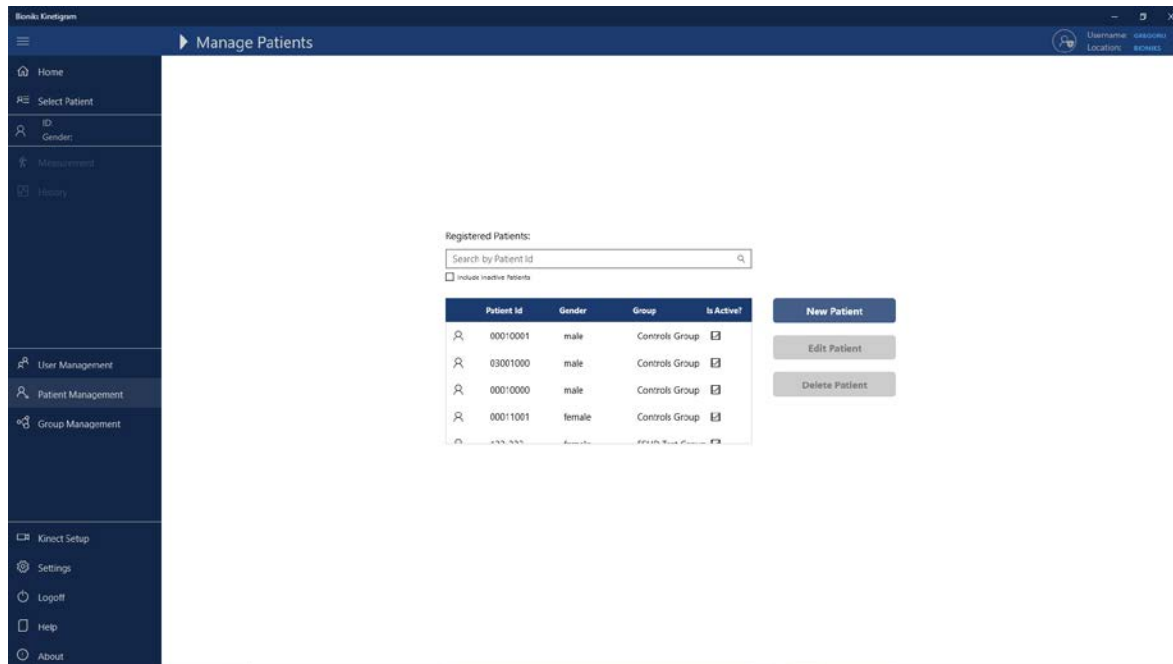
To delete an existing Group, go to Group Management Page and select the group you wish to delete from the list. Press “Delete Group” button.



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.

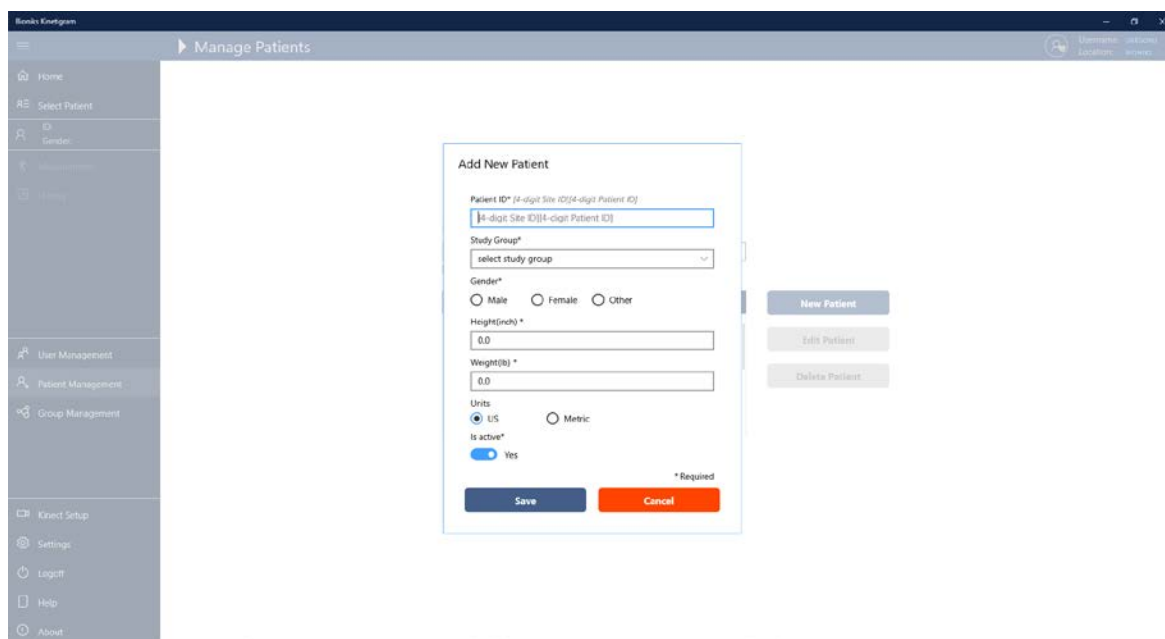
6 Managing Patients

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.



6.1 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, and Weight.



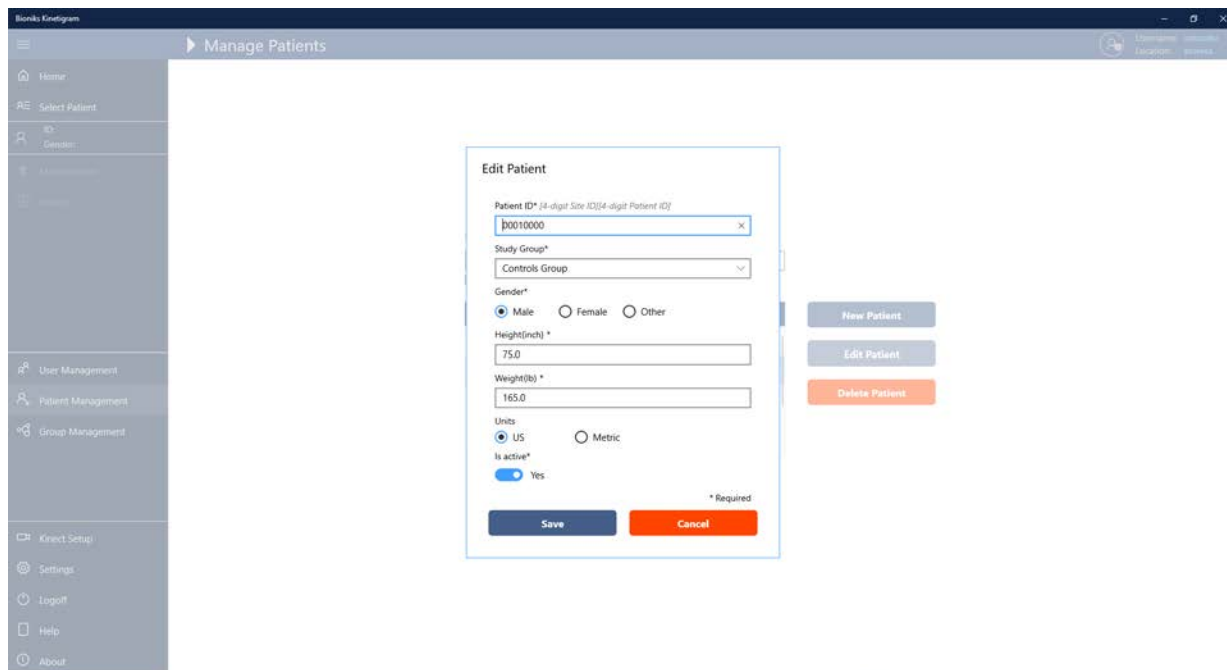
The height and weight information can be entered either in Metric units (height in *cm*, weight in *kg*) or US units (height in *inches*, weight in *lb*). The dialog will automatically convert between the two when switching the units via the Units radio box. Press “Save” to save the patient information.

Note: The patient ID may be restricted to a specific format. Bioniks administrator can specify the patient ID format via “Settings” Page. The patient ID format may appear differently than the displayed screenshots in this document.

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

6.2 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.



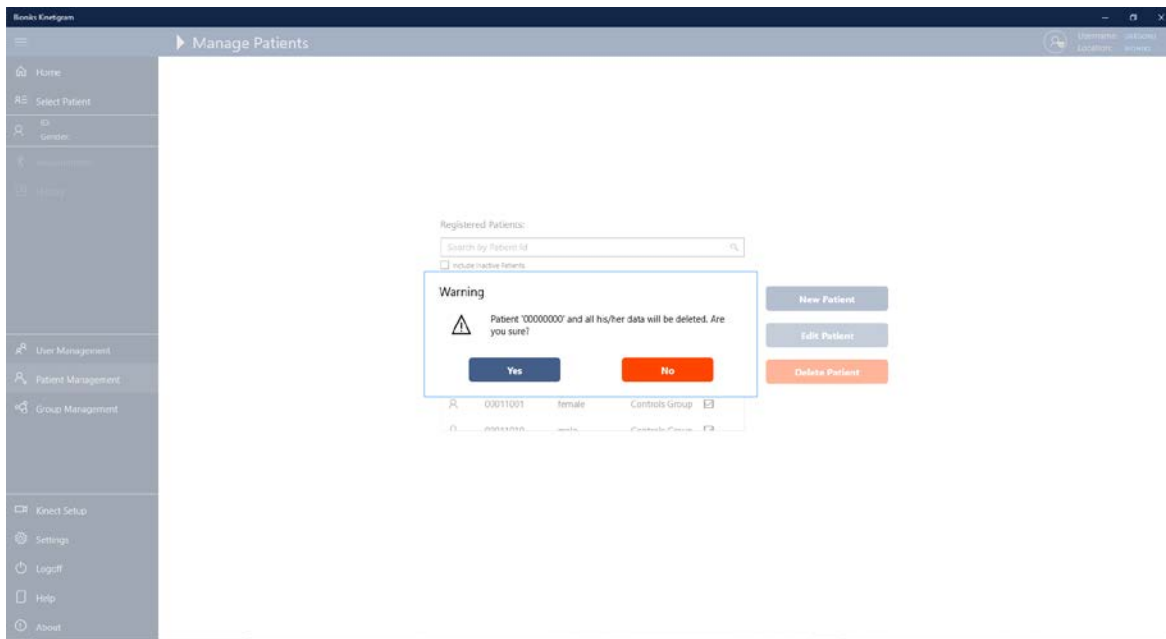
The screenshot displays the Bioniks Kinetigram application window. The left sidebar contains navigation links: Home, Select Patient, ID, Gender, Administration, Settings, User Management, Patient Management, Group Management, Kinet Setup, Settings, Logout, Help, and About. The main area is titled 'Manage Patients'. A modal dialog titled 'Edit Patient' is open, containing the following fields and controls:

- Patient ID*** (4-digit Site ID)(4-digit Patient ID): A text input field with the value '00010000' and a clear button (X).
- Study Group***: A dropdown menu showing 'Controls Group'.
- Gender***: Radio buttons for Male (selected), Female, and Other.
- Height(inch) ***: A text input field with the value '75.0'.
- Weight(lb) ***: A text input field with the value '165.0'.
- Units**: Radio buttons for US (selected) and Metric.
- Is active***: A toggle switch set to 'Yes'.
- Buttons at the bottom: 'Save' (blue) and 'Cancel' (orange).

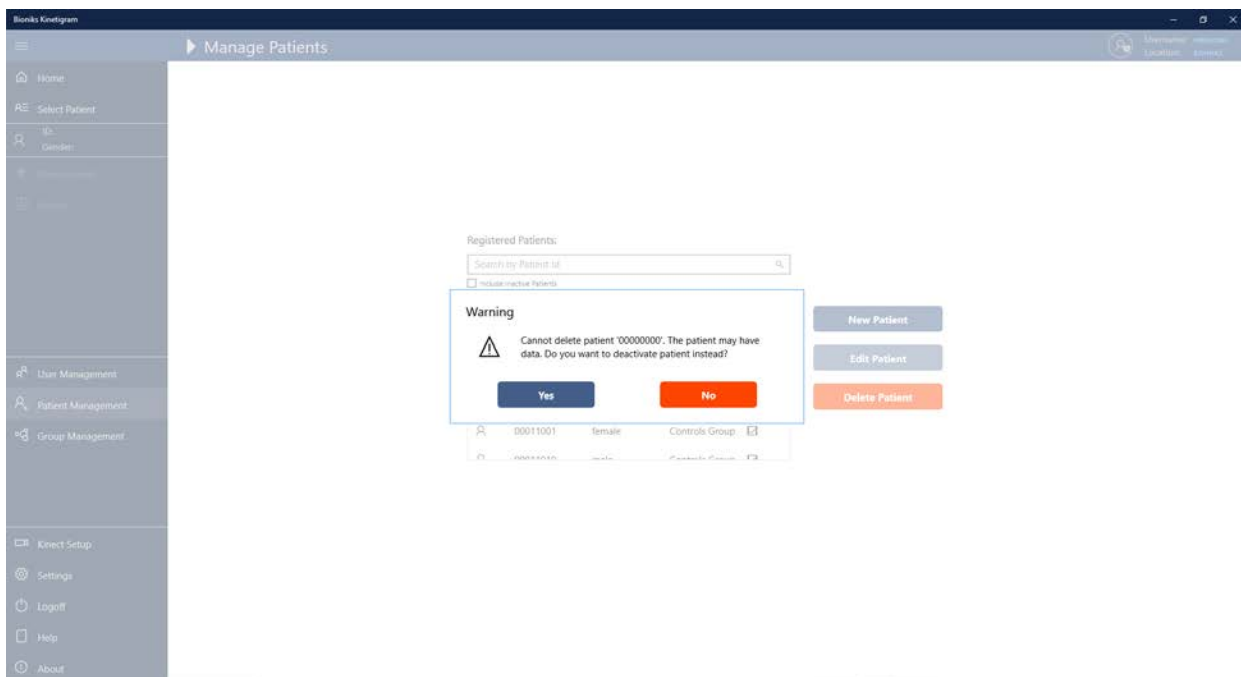
On the right side of the dialog, there are three buttons: 'New Patient' (blue), 'Edit Patient' (blue), and 'Delete Patient' (orange).

6.3 Deleting Existing Patient

To delete 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.



Important: Patients with existing Kinect 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.



7 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 administered 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:

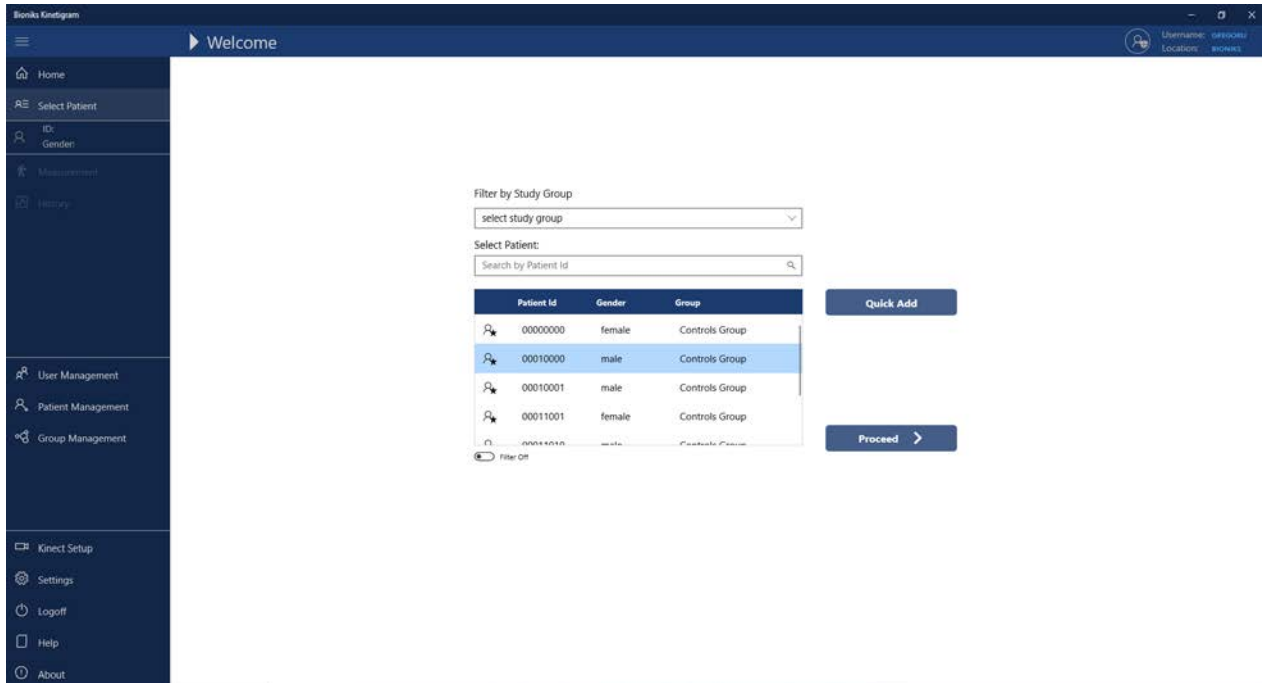
1. Select existing patient (or create new patient if needed)
2. Collect upper extremity anthropometric measurements
3. Determine if patient is low or high functional
4. Collect Kinect data according to the protocol
5. Check that all data were collected

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.

The screenshot shows the Kinetigram software interface. On the left is a sidebar with navigation options: Home, Select Patient, Measurement (selected), History, User Management, Patient Management, Group Management, Kinect Setup, Settings, Logoff, Help, and About. The main area is titled 'Measurement'. In the center, an 'Anthropometric Measurements' dialog box is open. It contains the following fields: Subject ID (00011001), Height (150.1 cm), Weight (58.1 kg), Right Sternum-ACI (0.0 cm), Left Sternum-ACI (0.0 cm), Right ACI-Olecranon (0.0 cm), Left ACI-Olecranon (0.0 cm), Right Olecranon-Ulnar Styloid (0.0 cm), Left Olecranon-Ulnar Styloid (0.0 cm), Right ACI-Ulnar Styloid (0.0 cm), and Left ACI-Ulnar Styloid (0.0 cm). The units are set to Metric. There are 'Save' and 'Cancel' buttons at the bottom of the dialog. In the background, the Measurement page shows 'Reachable Workspace' and 'Functional Workspace' for 'RIGHT' and 'LEFT' sides, each with a 'Record' button. On the right, there are 'RWS Settings' (Weight: 500g, Speed: Normal, Protocol: High) and 'FWS Settings' (Speed: Normal). At the bottom right, there are 'Additional Settings' (Video Sound: On) and buttons for 'Anthropometry' and 'Instructions Video'.

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

This screenshot shows the Measurement page of the Kinetigram software. It features four workspace panels: 'Reachable Workspace RIGHT', 'Reachable Workspace LEFT', 'Functional Workspace RIGHT', and 'Functional Workspace LEFT'. Each panel includes a 'Record' button and 'No Weight' and 'Weight' input fields. To the right of these panels are the 'RWS Settings' (Weight: 500g, Speed: Normal, Protocol: High) and 'FWS Settings' (Speed: Normal). At the bottom right, there are 'Additional Settings' (Video Sound: On) and buttons for 'Anthropometry' and 'Instructions Video'. A large red arrow points directly to the 'Anthropometry' button.

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 and weight, collect the four measurements for each side and enter them into Anthropometry dialog.

Important: The parameters should be measured with the 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)



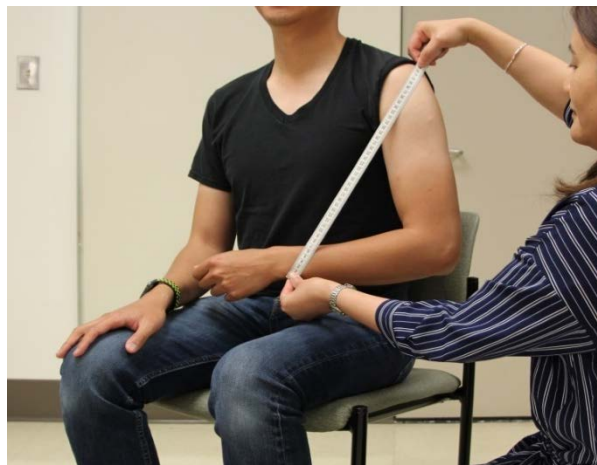
3. **Olec-UlnSty** (Olecranon to Ulnar Styloid)



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.

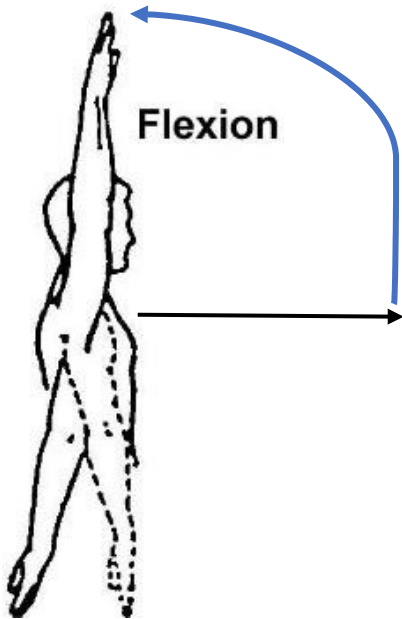
Note: If a measurement cannot be performed, enter “0” for that value.

The screenshot displays the Bionix Kinetigram software interface. On the left is a sidebar menu with options: Home, Select Patient, ID (00010000), Gender (Male), Measurements, History, User Management, Patient Management, Group Management, Kinect Setup, Settings, Logout, Help, and About. The main window is titled 'Measurement' and contains several sections. A central dialog box titled 'Anthropometric Measurements' is open, showing fields for Subject ID (00010000), Height (190.5 cm), Weight (74.8 kg), and various joint range of motion measurements (Right and Left Sternum-ACJ, Right and Left ACJ-Olecranon, Right and Left Olecranon-Ulnar Styloid, Right and Left ACJ-Ulnar Styloid) in centimeters. The 'Metric' unit is selected. To the right of the dialog are 'RWS Settings' (Weight: 500g, Speed: Normal, Protocol: High) and 'PWS Settings' (Speed: Normal). At the bottom right, there are 'Additional Settings' including 'Video Sound' (On). The background shows 'Reachable Work' and 'Functional Work' sections with 'Record' buttons and 'Add'l' links.

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.

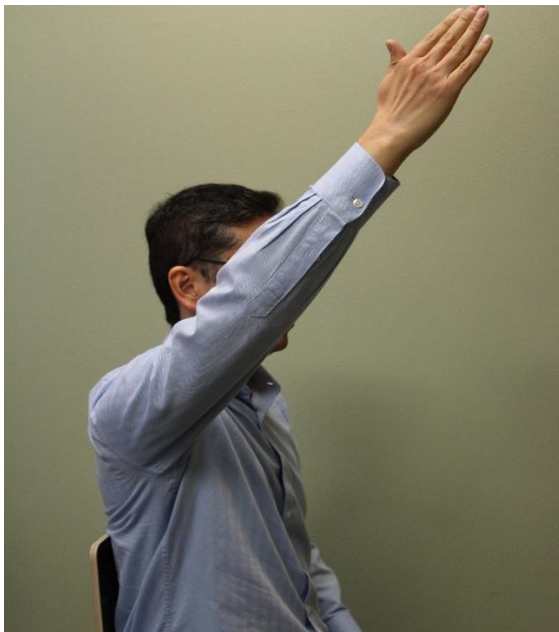
Step 3: How to Determine Whether to Use the High or Low Function Module

- 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 **at or above shoulder level (as pictured below)**, you should choose the **“HIGH Function”** assessment module.

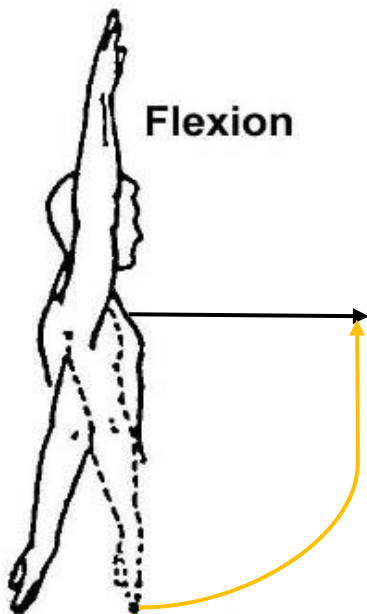


Use “High Function” module

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 areas **below shoulder level (as pictured below)**, you should choose the **“LOW Function”** assessment module.



Use “Low Function” module

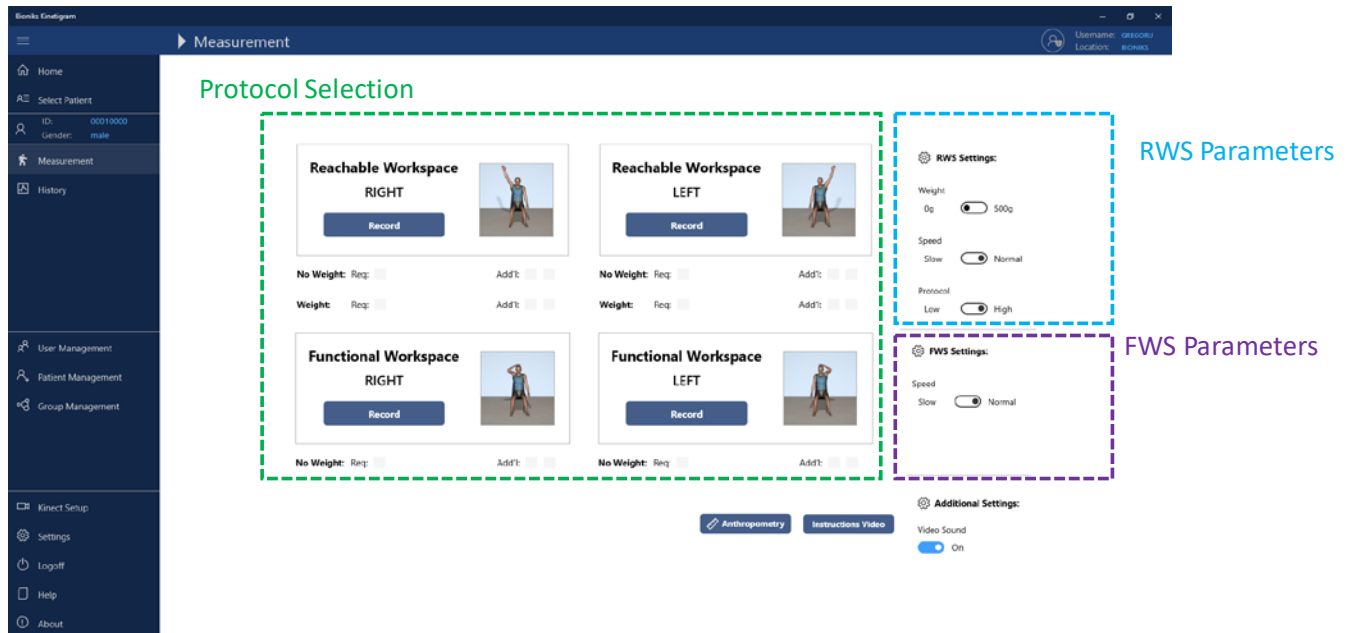
For Example:



Step 4: Perform Kinect 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.



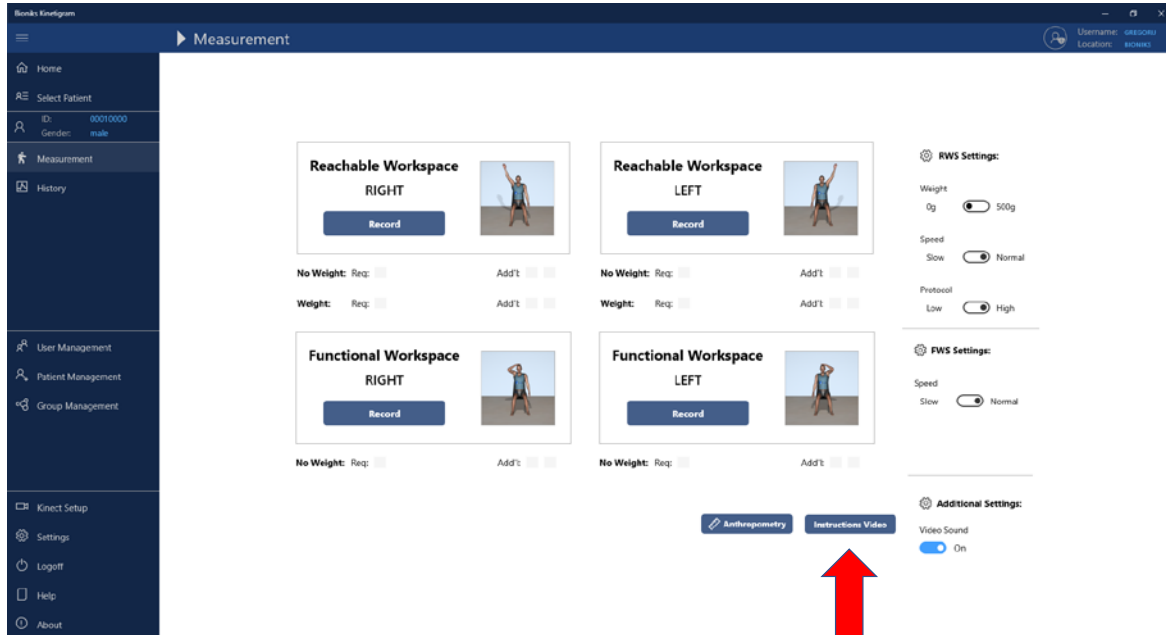
The following **protocol** should be performed for the assessment of each participant during their visit:

<i>Evaluation</i>	<i>Module</i>	<i>Side</i>	<i>Weight</i>
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%.

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

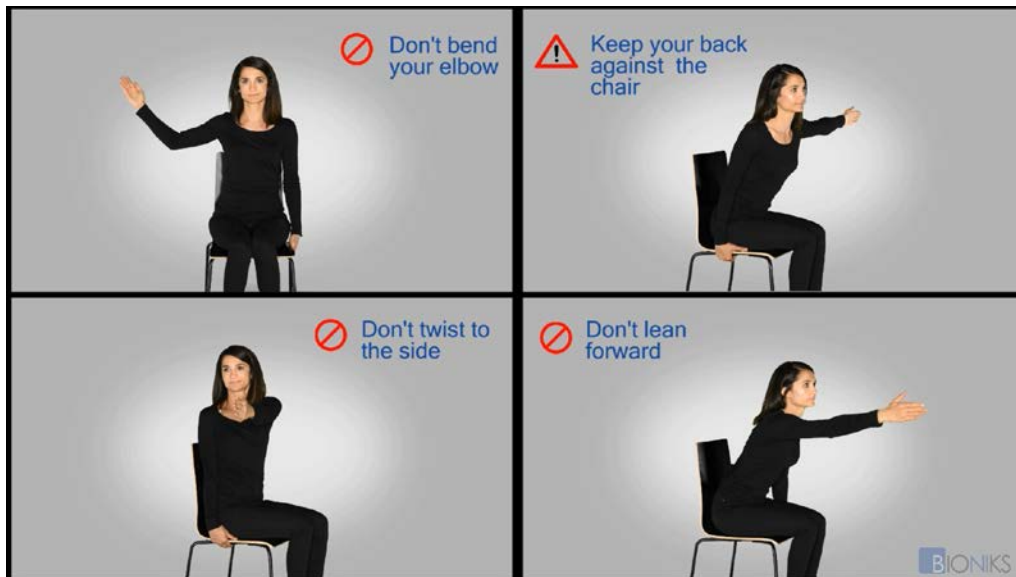
Before each measurement, the participant should be shown the **Instructional Video**:



To setup correct parameters for the measurement, please make selections according to the table above for each sequence.

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.

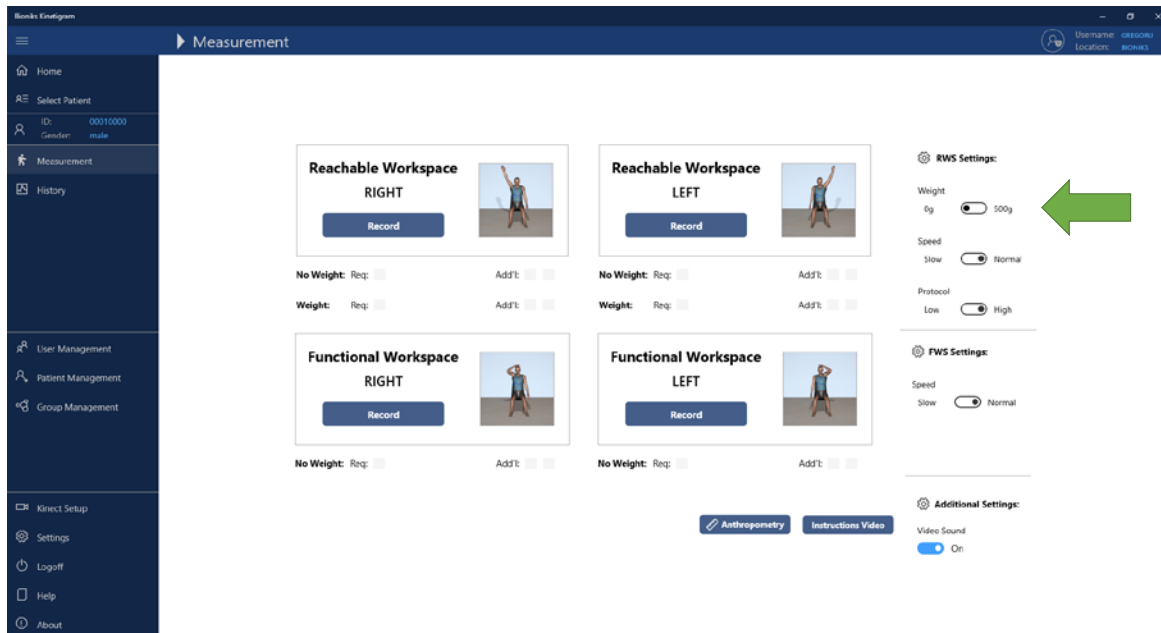


- **Important:** Positioning of subject for Functional Workspace (FWS) measurement: subject is seated with their back against the chair, upright, head and trunk straight.
- During FWS assessment ensure that there is no cervical/neck flexion, trunk flexion or rotation, no excessive compensatory movement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

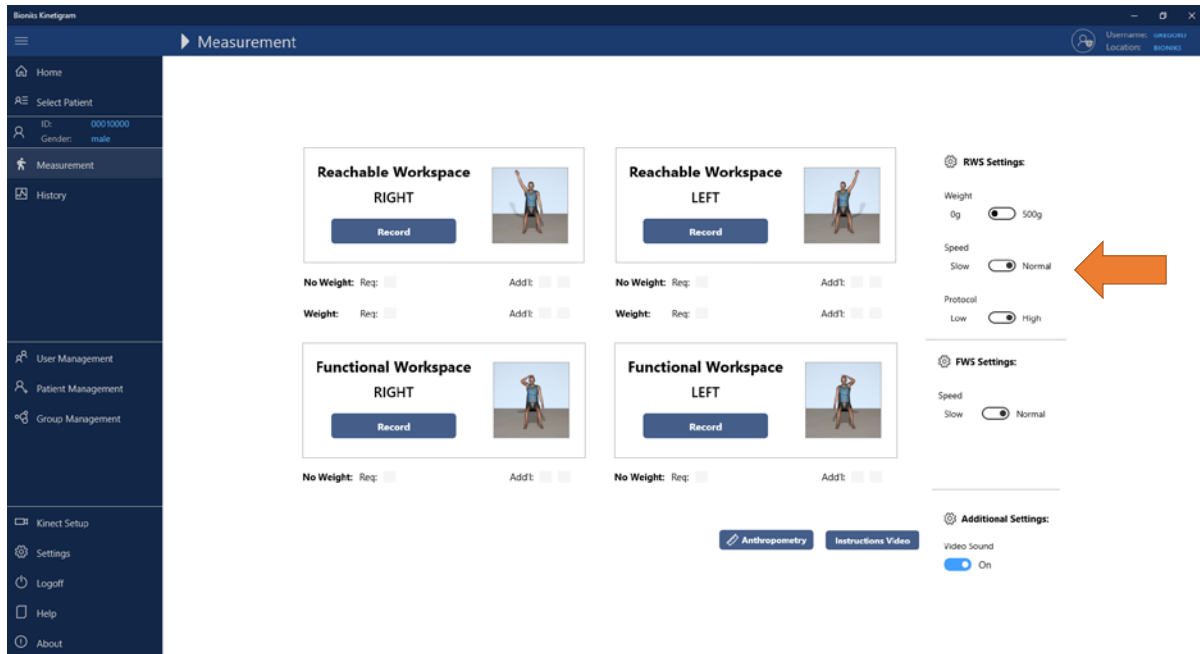
Reachable Workspace (RWS):

Evaluation 1: RWS Right Side, No Weight

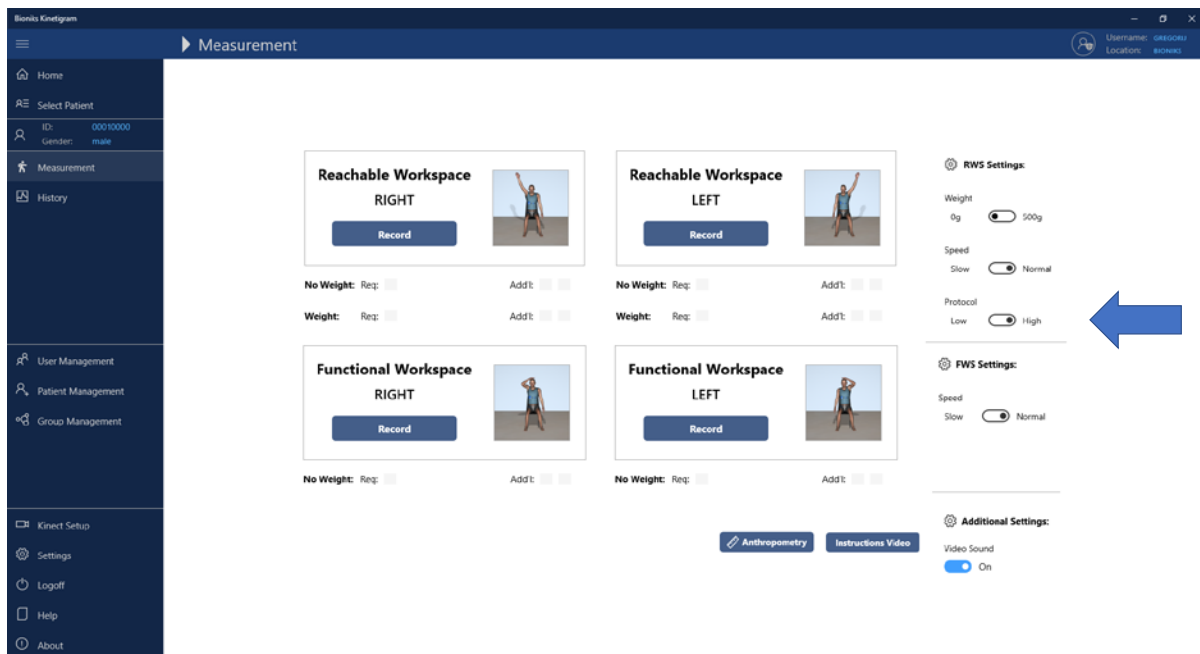
First perform the **RWS measurement** for **no-weight** condition on the **right side**. Make sure that the toggle switch for the weight is not active (green arrow):



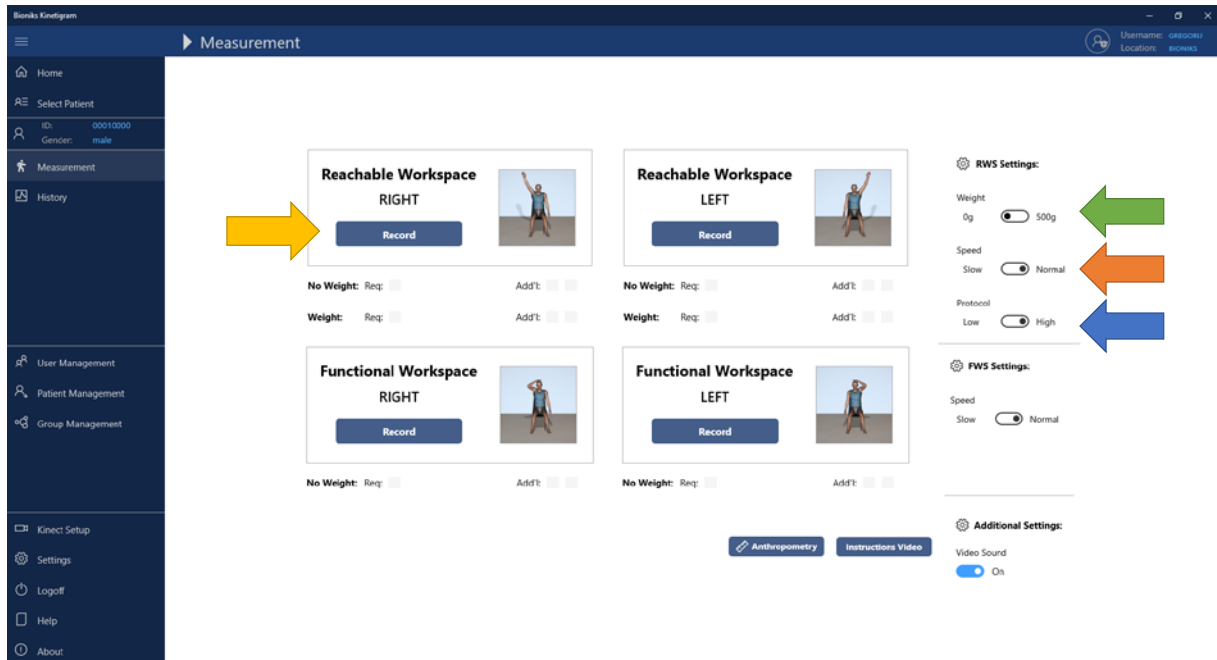
Select video playback speed (orange arrow). Normal speed to start with. If participant is unable to follow when doing the protocol, repeat the measurement with lower speed.



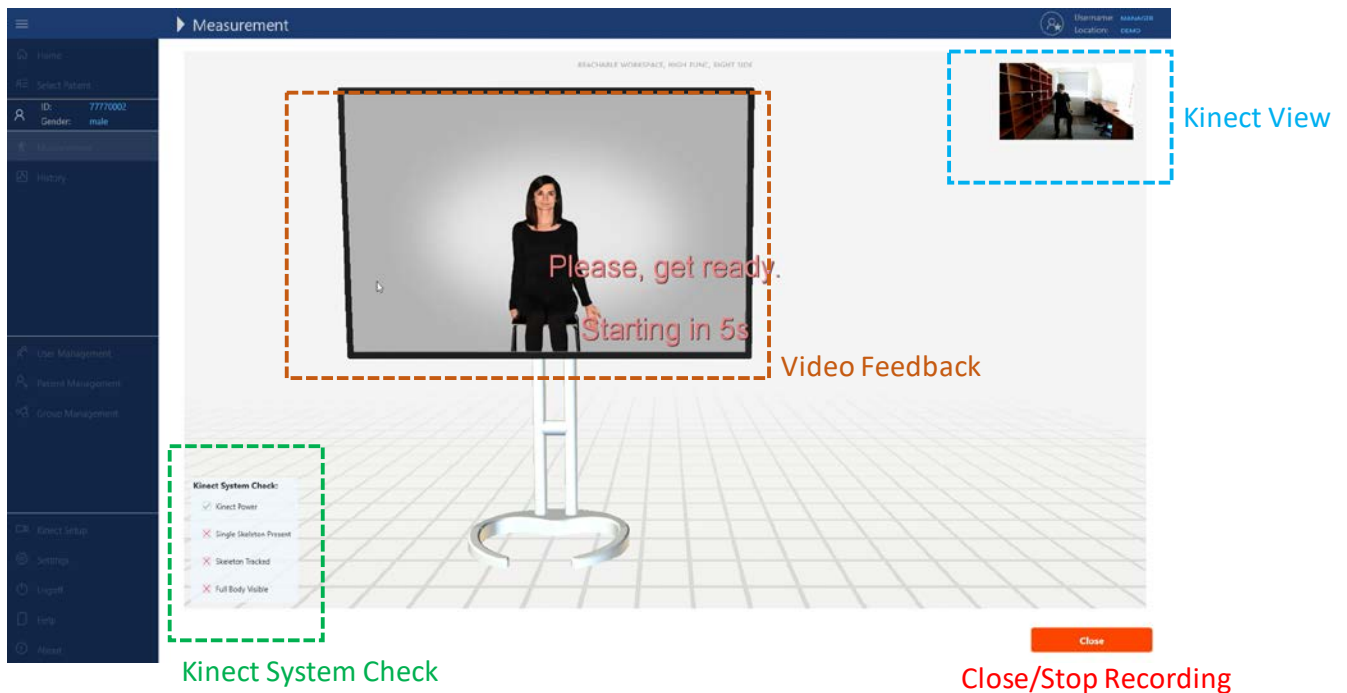
If the participant was able to forward flex his/her arm at or above shoulder level, then the “**HIGH**” functioning module should be clicked (blue arrow).



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:



The page displays a countdown timer during the first 5 seconds which allows the participant to prepare

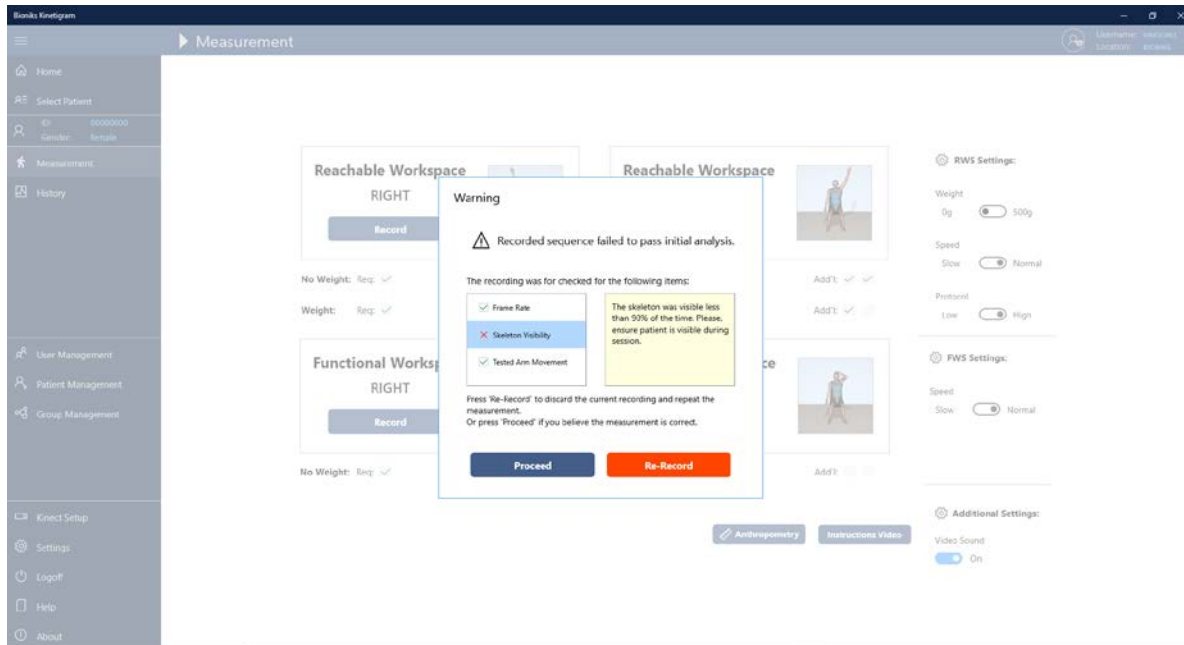
themselves. During this time, the system also checks for proper measurement conditions using the Kinect System Check module. The results of this check are displayed in the left corner. If any of the items fail, Kinect System Check window will be displayed. See Section 9 below for troubleshooting.

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.



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”.

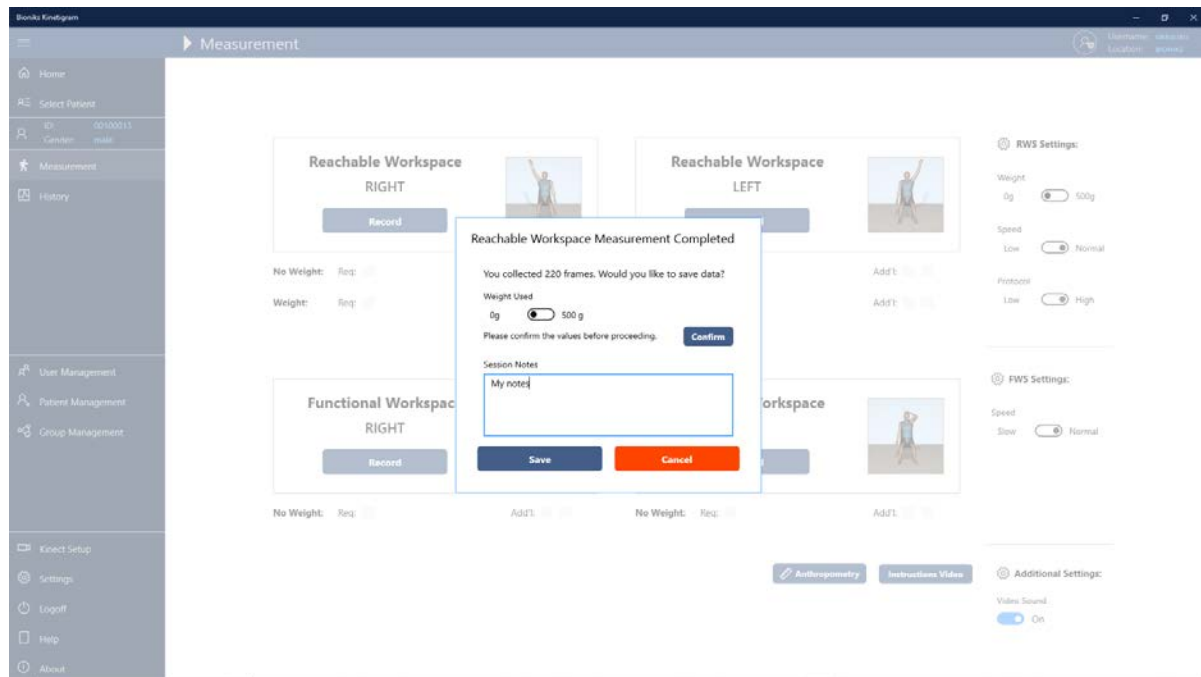
At the completion of the recording, the recording sequence is checked for validity. If the recording sequence is determined not to be valid, the following warning will appear:



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 “Re-Record” button, which will take you back to the measurement page.

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

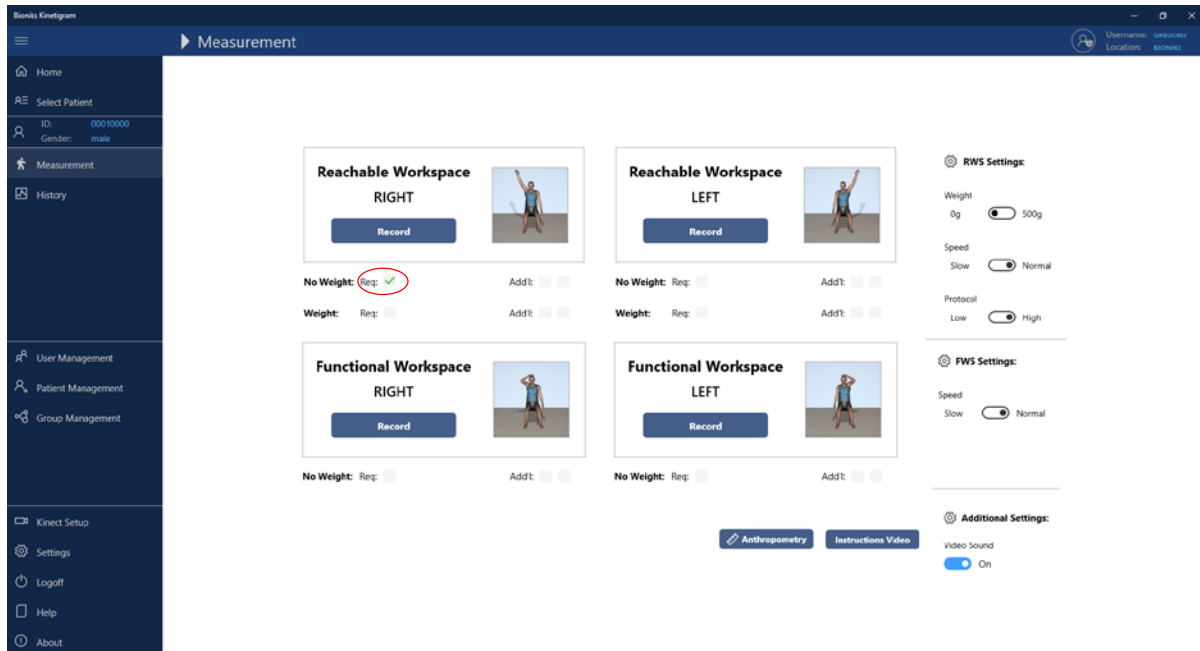


For Reachable Workspace protocol, check that the parameter for the weight corresponds to the condition of the measurement (patient not wearing the wrist weight = weight 0g, patient wearing the wrist weight = weight 500g). Confirm this by pressing “Confirm” button; this will enable you to save the measurement.

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

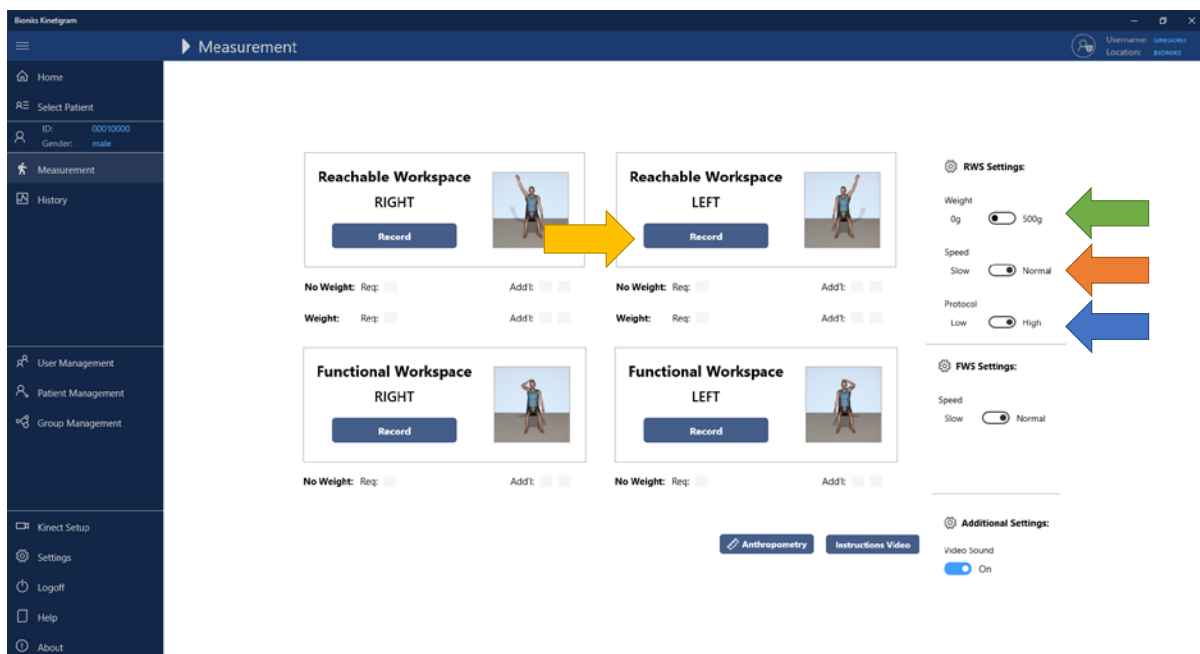
Press “Save” to store the measurement, or press “Cancel” to discard the measurement results. Note that once you press “Cancel”, no data from the session will be stored!

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.



Evaluation 2: RWS Left Side, No Weight

Following similar steps, now repeat the RWS assessment 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).

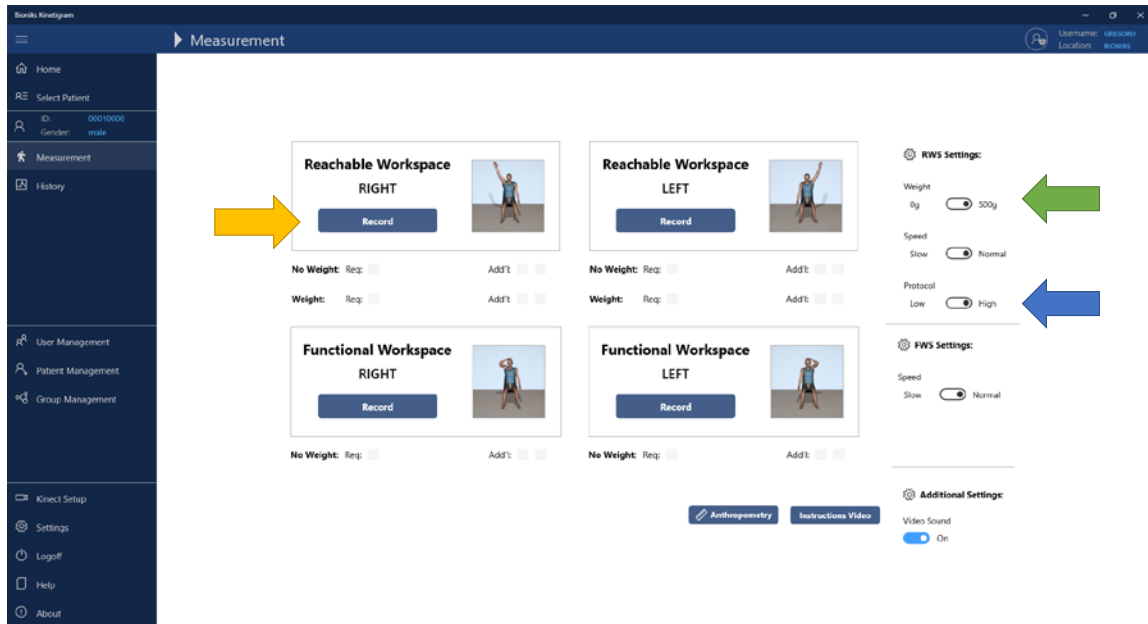


At the completion of the recording, press “Save” to save the assessment data if you are satisfied with the participant’s performance.

Evaluation 3: RWS Right Side, Weight

Now repeat the RWS Assessment and begin with **Right Arm, with Weight**

- Participant remains on the same Functional Level, so there will be **NO** change in the Level option (blue arrow).
- Please apply **ONE wrist weight (500g)** to participant's **Right wrist**, and make sure to select "weight (500g)" (green arrow).
- When ready to start, click "Record" (yellow arrow).

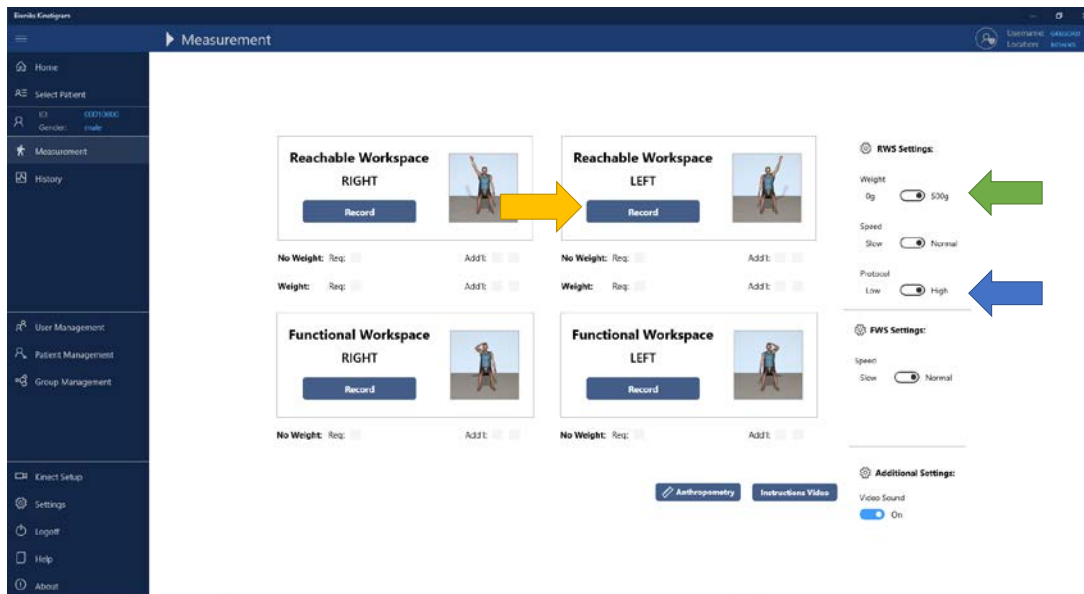


At the end of the assessment, make sure the weight option is accurate. Then, click "Save" to save the assessment if you are satisfied with the participant's performance. Type in any brief notes you may have regarding this assessment, as described previously. Otherwise, click "Cancel" and repeat the assessment.

Evaluation 4: RWS Left Side, Weight

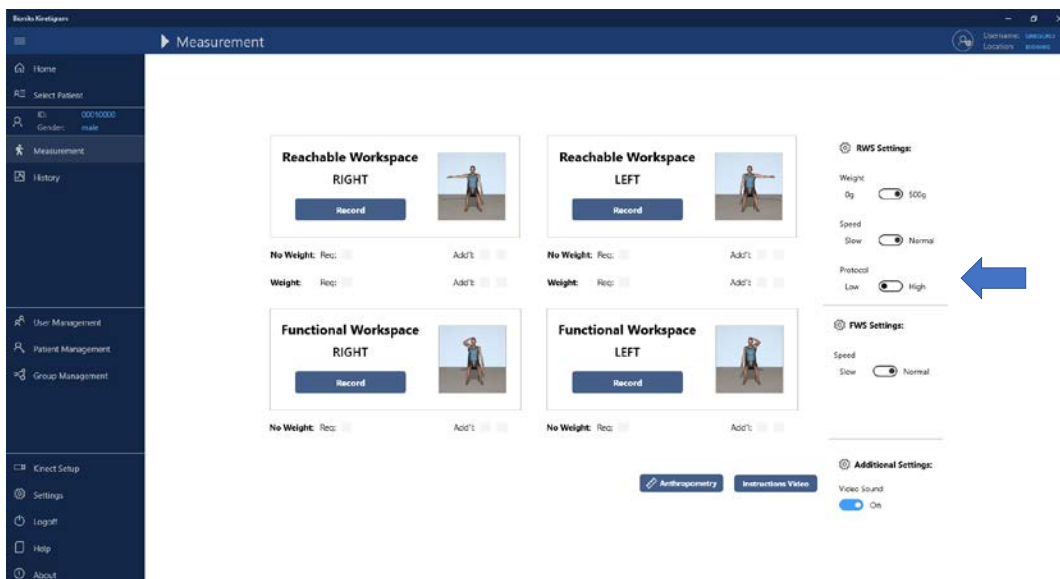
Now repeat the RWS Assessment and begin with **Left Arm, with Weight**.

- Participant remains on the same Functional Level, so there will be **NO** change in the Level option (blue arrow).
- Please apply **ONE wrist weight (500g)** to participant's testing wrist (green arrow). 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.

HOWEVER, if the participant was **UNABLE** to forward flex his/ her testing arm to shoulder level, then choose the “**LOW**” level module from the RWS Assessment (blue arrow). 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.

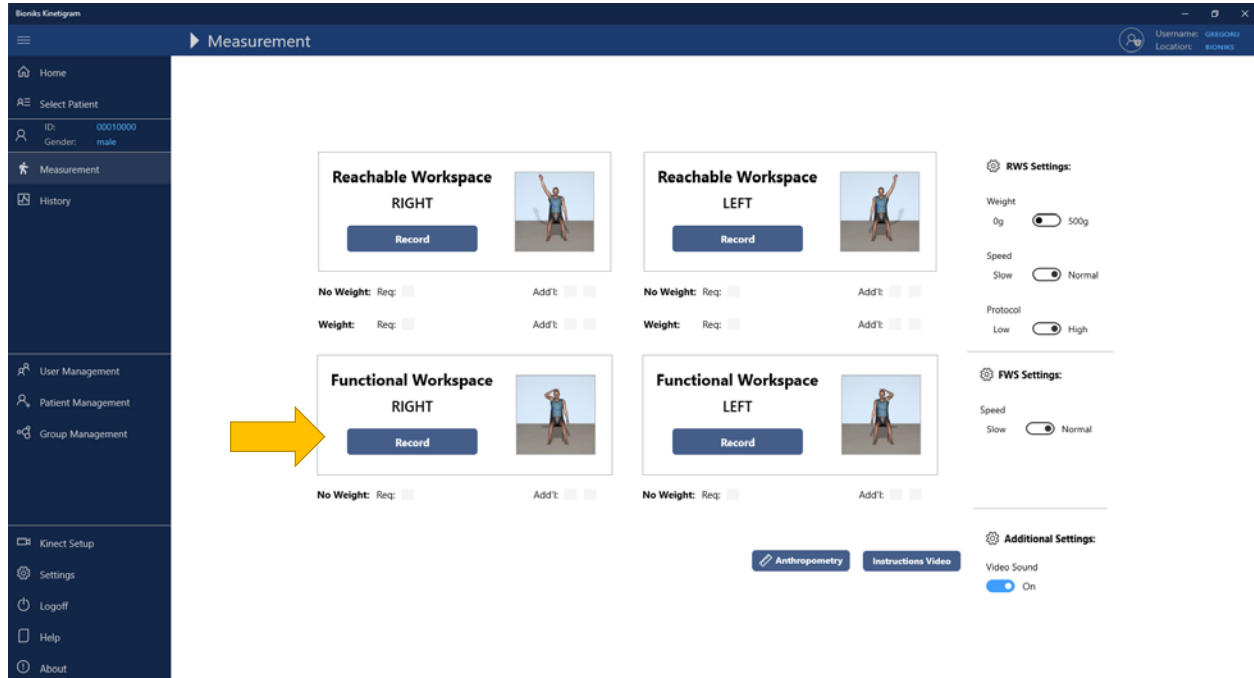
Functional Workspace (FWS) Assessment:

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!

Evaluation 5: FWS Right Side

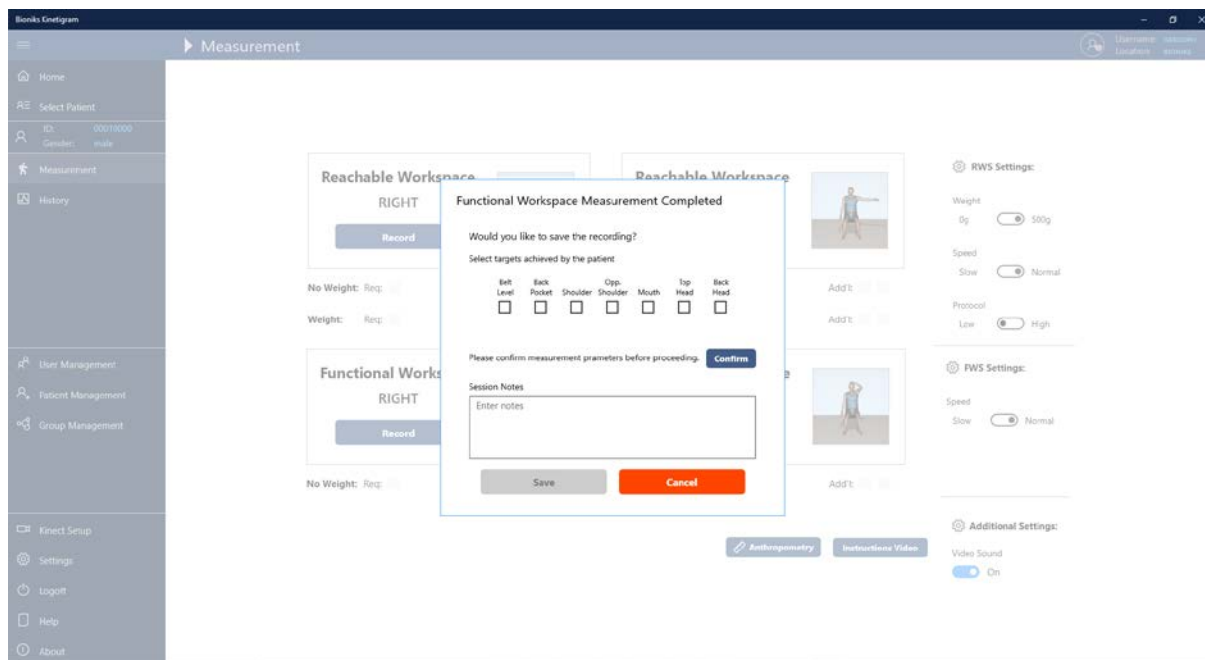
Start with **the right side** for the functional workspace module.



Patient follows the video protocol:



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



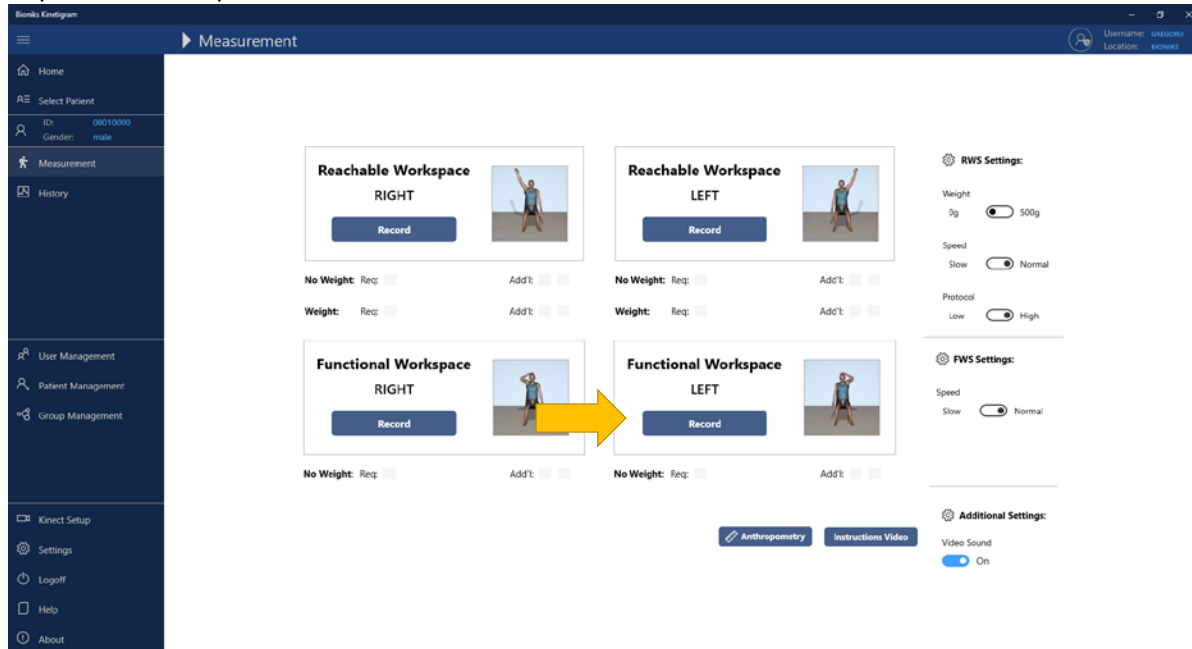
Check the target checkboxes that you observed the patient reaching. Note that the patient has to TOUCH the targets in order for it to count, just like in the video. After reviewing the observations, click on “Confirm” to confirm the entered parameters.

At this point you can also enter any notes and observations that pertain to the assessment. 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.

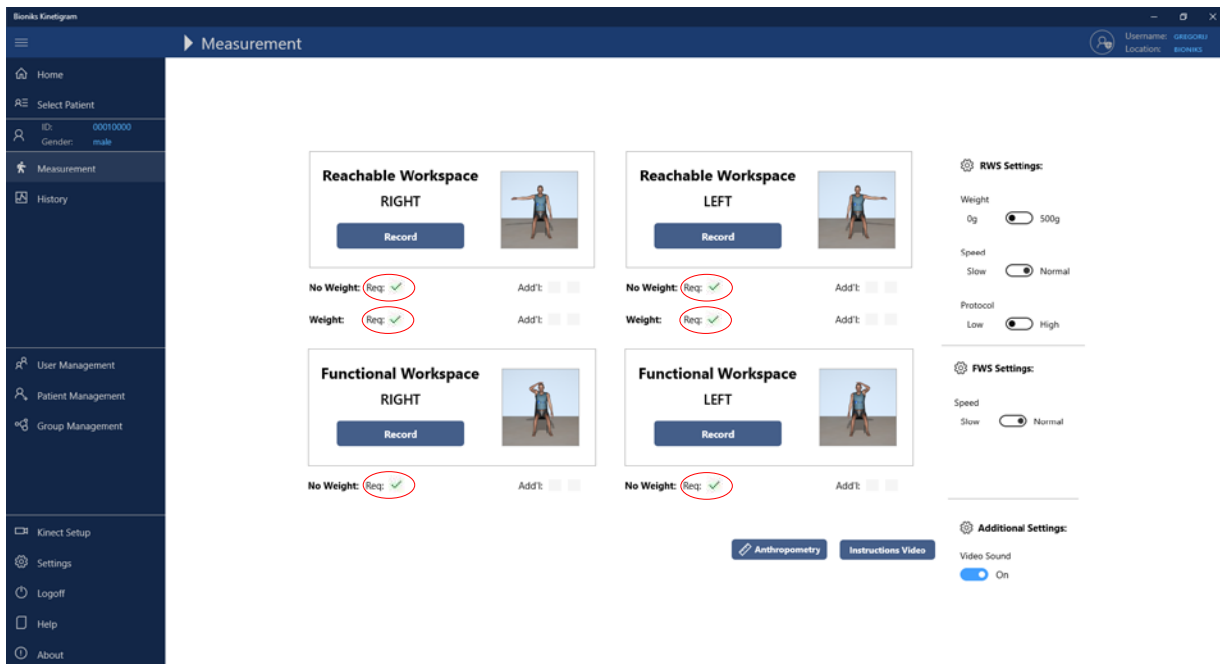


After the measurement, check the target checkboxes that you observed the patient reaching. Note that the patient must TOUCH the targets in order for it to count, just like in the video. After reviewing the observations, click “Confirm” to confirm the entered parameters.

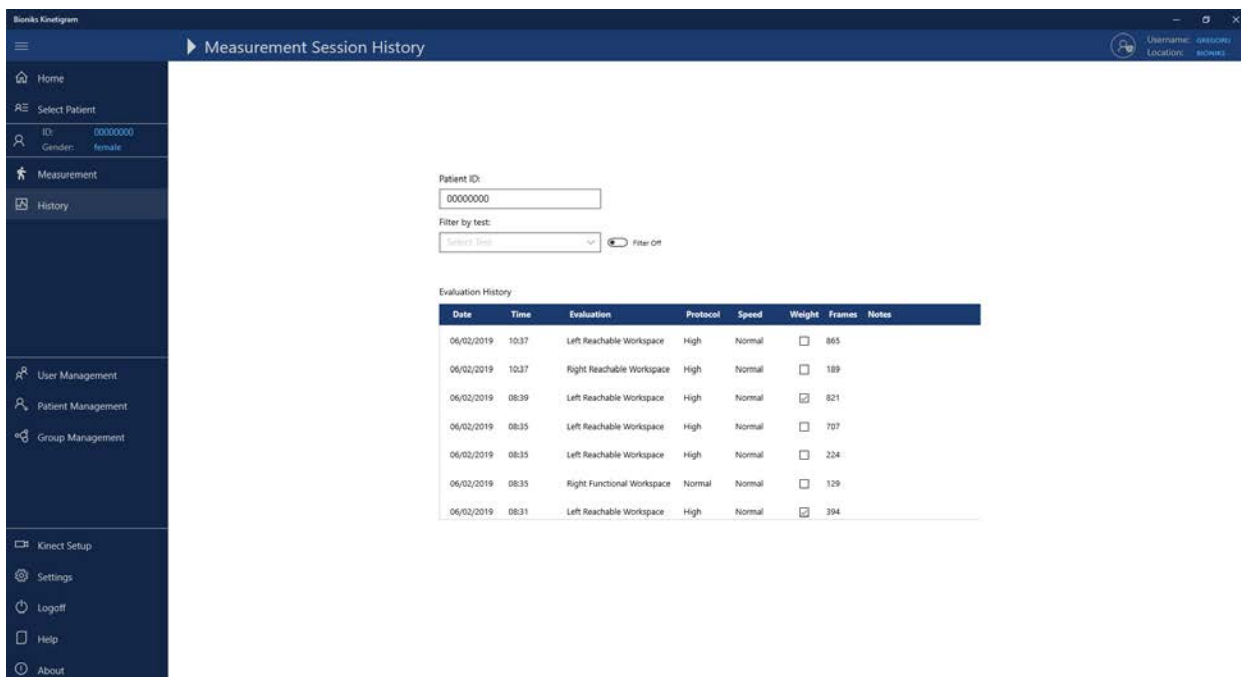
At this point you can also enter any notes and observations that pertain to the assessment. Then, click “Save” to save the assessment if you are satisfied with the participant’s performance. Otherwise, click “Cancel” and repeat the assessment.

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).



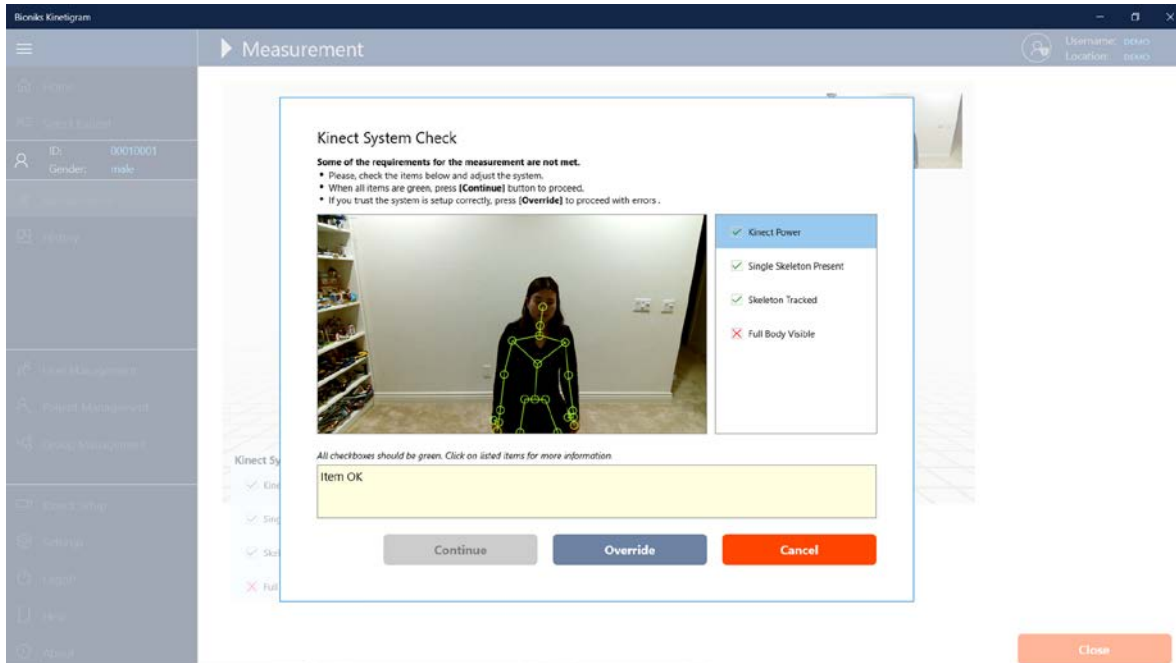
You should also confirm the assessments by clicking on the “History” page on menu. This will open the History page with all of the patient’s recordings to date. Note you can filter by the evaluation type.



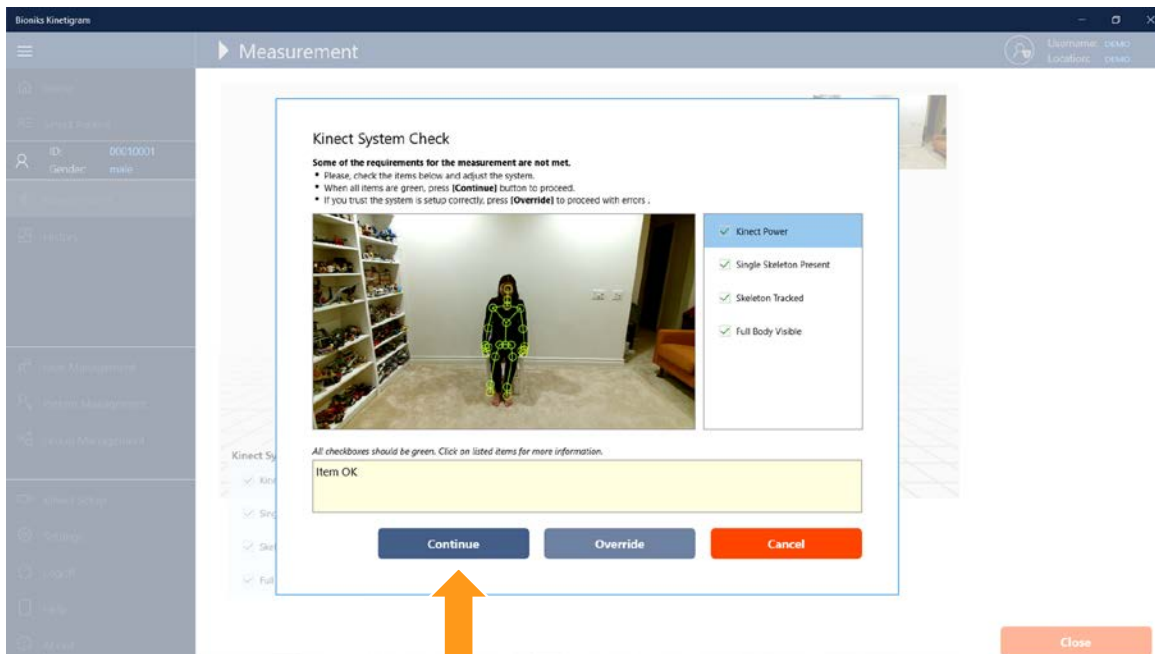
Kinect System Check

The Kinect 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 Kinect 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.



Once all issues have been corrected, “Continue” 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 Kinect System check also provides option to continue measuring with errors by pressing “Override” button.

Important: Override of Kinect 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.

7.1 Additional References

Note for RWS & FWS data entry (optional to use or not 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.

Notes for RWS and FWS data entry (optional to use or not)

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

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 patient visit):

		Right	Left
1	Sternum-ACJ (Suprasternal notch to Acromioclavicular 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

Can the participant forward flex his/her arm to or above shoulder level? (Please circle)

Right Arm Yes/ No

Left Arm Yes/ No

YES = High Functional Module

No = Low Functional Module

*Please note that the same participant can have one High Functioning arm, with the other arm being Low Functioning during the same visit.

II. Functional WorkSpace (FWS) – please observe whether the subject is able to touch these SEVEN body targets and check the appropriate boxes to indicate “Yes”

	Body Targets	Right	Left
1	Belt Level		
2	Back Pocket		
3	Same Shoulder		
4	Opposite Shoulder		
5	Mouth		
6	Top of head		
7	Back of head		

8 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

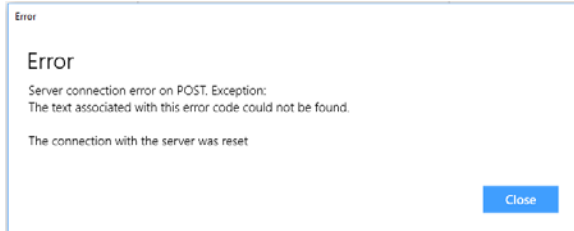
Start with your left hand by your side. Bring it to the front of your body at the belt level, then to your back pocket, up to your left shoulder, then to your right shoulder. If you're able to, bring your hand to your mouth, touch the top of your head and finally touch the back of your head. Now bring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

9 Troubleshooting

9.1 Server Connection Issue

Issue 1: Pages become unresponsive; content doesn't load.

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



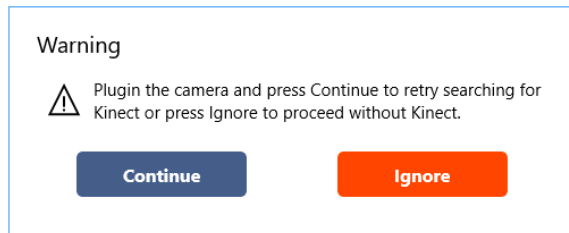
Reason: The server process on the computer has likely terminated and has to be restarted.

Solution: Exit the application and restart the computer. Run the application again.

9.2 Kinect Issues

Issue 1: Warning appears after login, stating that the Kinect was not found.

Error:



Reason: Kinect may not be connected to the computer.

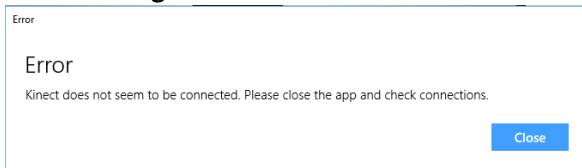
Solution 1: Exit application. Check if Kinect is connected to the power outlet. Check if Kinect power supply has power. The light on the connector should be yellow or white.

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: 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.

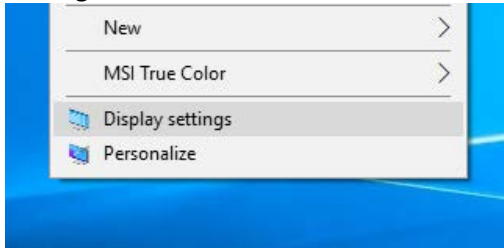
Solution 2: Exit application. Check if Kinect is connected to the correct USB 3.0 port on the computer as described in the set-up section.

Solution 3: Exit application. Restart the computer. Run the application again.

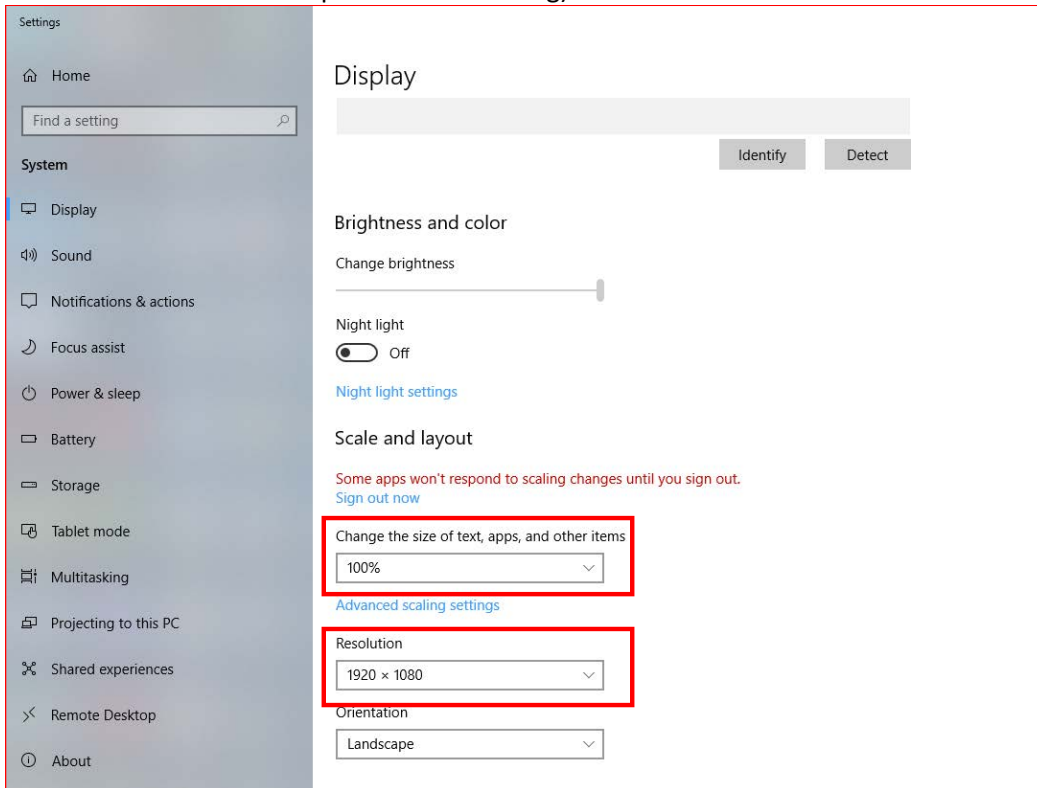
9.3 Software and Hardware Issues

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.

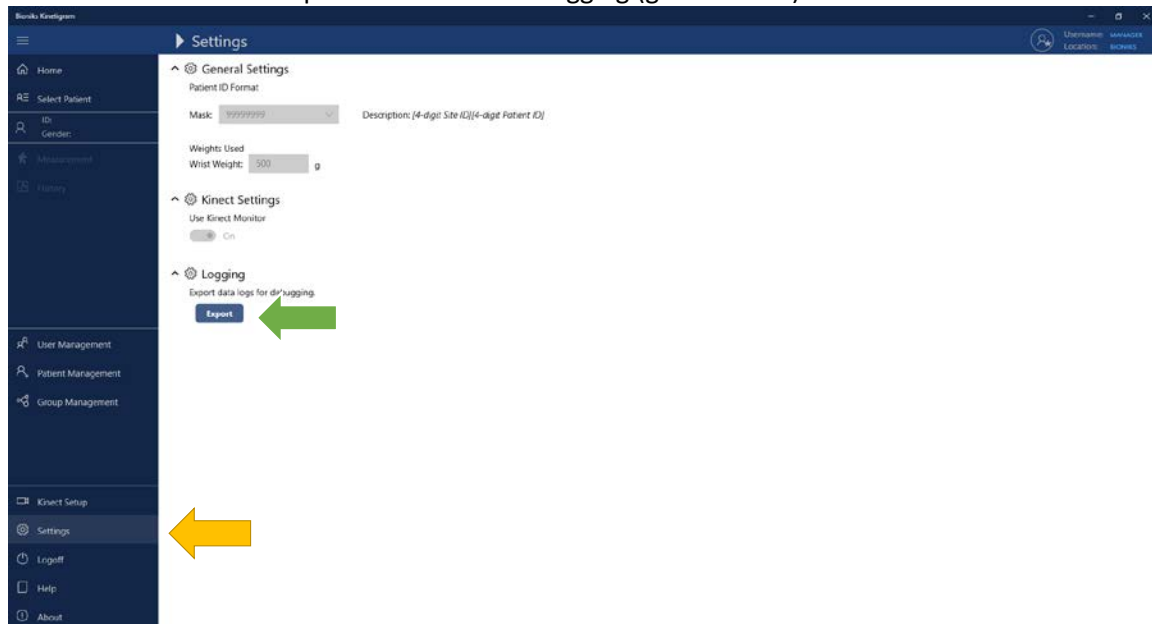
Solution: Contact Bioniks team at help@bioniks.net

9.4 Other Issues - Contact Bioniks Team

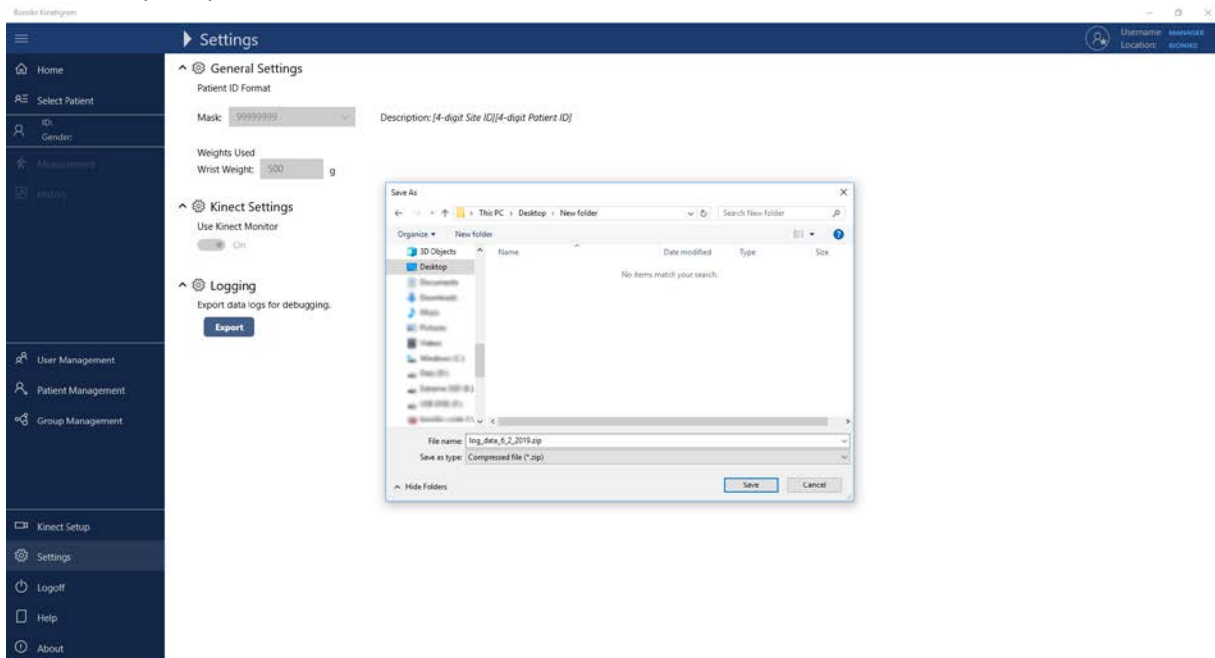
If the solutions above do not resolve your issue, please contact Bioniks team at help@bioniks.net

Take screenshots of the errors, if possible.

You may be asked to provide software log files. The log files can only be accessible by the Site Coordinator (manager). The logs can be downloaded from the Settings Section. Select Settings from the menu (yellow arrow) and then click on the “Export” button under Logging (green arrow).



You will be prompted to save the file.



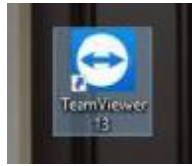
Save the file and e-mail it to Bioniks Team.

9.5 Remote Access for Bioniks Team Support

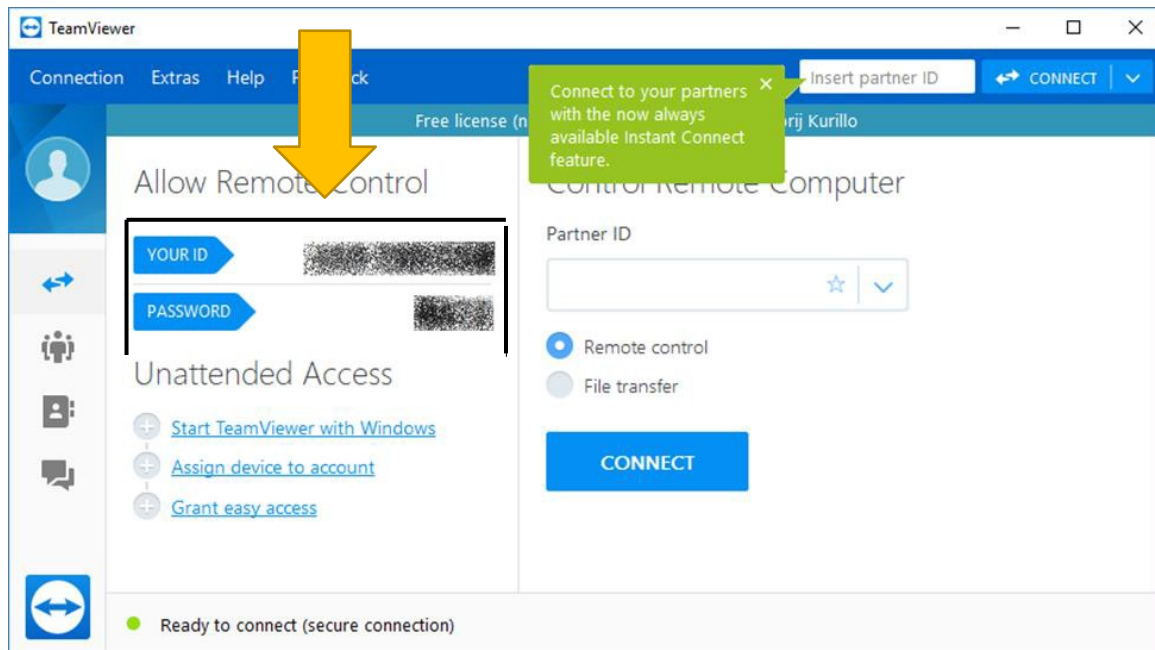
If the issue cannot be resolved over e-mail, Bioniks Team may need to access the computer remotely. Please follow instructions below on how to provide access.

Remote Access

To enable remote access, run TeamViewer* from the Start menu, or click on the TeamViewer icon on Desktop to open TeamViewer.



Please contact Bioniks team (help@bioniks.net) on how to provide TeamViewer ID and Password (see below) prior to your remote connection. Do not close the TeamViewer App.

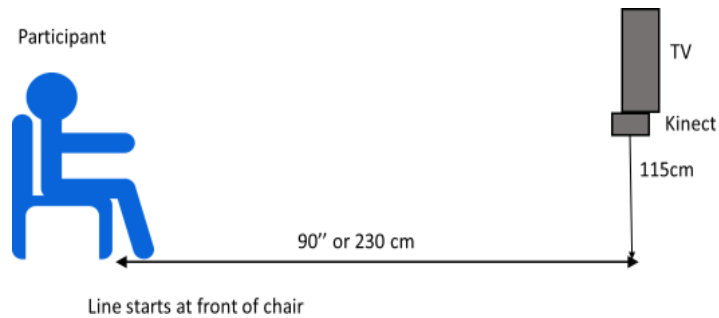


* If TeamViewer is not installed on your computer, it can be downloaded from:
<https://www.teamviewer.com/en-us/download>

The installation may require administrative access that was given to the Study Coordinator.

10 Quick Reference (one-pager)

KINECT SETUP:



ASSESSMENT PROTOCOL:

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

MEASUREMENT PAGE:

Bioniks Kinogram

Measurement

Home

Select Patient

ID: 00010000

Gender: male

Measurement

History

User Management

Patient Management

Group Management

Kinect Setup

Settings

Logoff

Help

About

Protocol Selection

Reachable Workspace RIGHT

Record

No Weight: Req: Add'l:

Weight: Req: Add'l:

Reachable Workspace LEFT

Record

No Weight: Req: Add'l:

Weight: Req: Add'l:

Functional Workspace RIGHT

Record

No Weight: Req: Add'l:

Weight: Req: Add'l:

Functional Workspace LEFT

Record

No Weight: Req: Add'l:

Weight: Req: Add'l:

RWS Settings:

Weight: 0g 500g

Speed: Slow Normal

Protocol: Low High

FWS Settings:

Speed: Slow Normal

Additional Settings:

Video Sound: On

Anthropometry

Instructions Video

RWS Parameters

FWS Parameters