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# Instructions For Use -Humero Tech C1-

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### **Company Information**

Titin KM Biomedical Corporation is headquartered in Bozeman, MT.

Mission Statement: To provide cutting edge, reliable equipment for the betterment of global health outcomes.

### **Contact Information**

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### Humero Tech C1 Purpose

#### Intended Use:

• The Humero Tech C1 (the C1) is a medical device that can assist with improving the strength, active range of motion, and motor control of the shoulder complex.

#### Indications for Use:

• The C1 can be utilized by any individual suffering from a shoulder pathology, including postoperative status, or when a deficit in power is noted.

### Scientific Technology/Operating Principal

• The C1 combines a multitude of traditional technologies to offer an advanced shoulder rehabilitation and strengthening device.

#### Claims

- The primary claims for The C1 come from the intended use statement:
  - The device may help improve:
    - Active range of motion of the shoulder.
    - Strength of the shoulder complex.
    - Motor control of the shoulder complex.
- The secondary claims include, but are not limited to, the following:
  - Tracking of patient recorded data.
  - The ability to determine dynamic strength of shoulder motions.
  - The ability to determine the excursion with which a shoulder movement or exercise was completed.

### **Device Information**

Device Description:

- The Humero Tech C1 is a Class I Medical Device listed under product code BXB with the FDA.
- The C1 is a seated exercise device designed primarily to provide users with a
  better way to strengthen the important musculature of the shoulder complex. By
  completing strengthening exercises, users will also be working on active range of
  motion and motor control of the shoulder complex. The device has been
  designed to be used bilaterally, with the seat and headrest being adjustable to
  achieve ideal positioning. There are two different resistance mechanisms within
  the device that provide resistance to the user depending upon which axis the
  movement is occurring. The resistance of each axis is controlled through the
  custom software application running on the included tablet.
- The C1 is run by an application with many functionalities and features. From controlling the resistance present with exercise completion to providing recorded data, our software plays a vital role in the function of the C1.
- The C1 consists of numerous components including:
  - The Chair
    - The physical location for the user to sit and properly utilize the device.
  - Elbow Rest
    - An adjustable feature that allows for an increased amount of external support, in multiple positions, during exercise completion.
  - Resistance Mechanism (aka "Universal Joint" or "U-Joint")
    - The component(s) that provide resistance to a user's motion during an exercise session.
  - Telescoping Shaft
    - The telescoping shaft is a movable component that allows for increased range of motion during exercise completion.
  - Wrist Ring
    - The wrist ring serves as the primary attachment between the user and the device.
  - Wrist Brace
    - The wrist brace is to be donned by the user and serves as the connection point between the user and the wrist ring.

- Ball Grip
  - Attachment option that allows the user to interact with the device using a ball grip, rather than the wrist ring and brace, connecting to the telescoping shaft.
- Monitor Arm
  - The tablet arm extends from the back of the device to the front, allowing for easy viewing and control of the tablet during exercise completion.
- Monitor
  - The monitor is included with your subscription/purchase of The C1 and is responsible for displaying and allowing interaction with the Titin KM Biomedical application.
- USB-C Cable
  - The USB-C cable is responsible for the connection between the monitor and the main control board located in the enclosure on the back of the chair.
- Power Cable/Adaptor
  - The cable that is plugged into an appropriate outlet and is used to power the chair.

# **Contraindications and Precautions to Use**

The following list is not intended to be all-inclusive. Always consult with your healthcare provider prior to using The C1.

#### Contraindications for Use:

- Undiagnosed injury
- Presence of an acute fracture
- Presence of an unstable fracture
- Any mechanical or electrical failure of The C1 that has not been appropriately addressed by Titin KM Biomedical
- Any user with sensitivities to materials used in construction of the device

#### Precautions for Use:

- Acute Injury
- Osteopenia
- Osteoporosis
- Muscle strains
- Soft tissue sprains
- Pregnancy
- Cancer
- Conditions involving spasticity
- Conditions resulting in decreased volitional control of the upper extremity
- Cognitive deficits that do not allow for proper use of the device
- Any user with sensitivities to materials used for construction of the device

### **Risks and Benefits:**

There are potential risks and benefits that come with utilization of any equipment used during a rehabilitation and/or strengthening program. Regarding the C1, there are a number of benefits that exist when compared to the equipment commonly used for shoulder rehabilitation programs. The following list includes a few of the potential associated benefits with utilizing The C1:

- Improved shoulder function
  - Use of the C1 has the potential to increase the strength and range of motion of the shoulder complex
  - - The C1 contains technology that delivers resistance to the user in a unique manner that addresses many of the limitations seen with equipment currently utilized during shoulder rehabilitation and strengthening
- Recorded data
  - The C1 can gather a large volume of data points that will provide information to medical providers regarding certain metrics of the shoulder complex's function
- Monitoring Status
  - The C1 makes it easy to reference, review and gather data which allows for easy monitoring of a patient's status
- The C1 has been developed to target the tissues and musculature primarily involved in the proper function of the shoulder complex. While this list is not all-inclusive, The C1 has the potential to positively affect the following tissue(s) and pathologies:
  - Soft tissues that may benefit from use of The C1:
    - All segments of the deltoid muscle
    - Biceps brachii
    - Triceps brachii
    - All segments of the trapezius muscle
    - Rhomboids, Serratus Anterior and additional scapular stabilizers
    - Supraspinatus
    - Infraspinatus
    - Teres Minor
    - Subscapularis
    - Teres Major
    - Latisimus Dorsi
    - Pectoralis Major and Minor

- Some of the shoulder pathologies which may benefit from use of The C1 include, but are not limited to, the following:
  - Shoulder instability
  - Shoulder dislocations and subluxations
  - Surgical recovery
  - Muscle strains
  - Joint sprains
  - Soft tissue injuries
  - Tendinopathies
  - Generalized weakness

NOTE: Use of The C1 to rehabilitate or train any musculoskeletal structure, either acute or chronic, should not be performed without prior consultation with the appropriate medical professional or active medical professional guidance.

Use of the C1 for shoulder rehabilitation and performance does not come without risk. The following list includes potential risks:

- Injury exacerbation/aggravation
  - If using this device with either a pathology or an injury, there is the risk of exacerbation/aggravation to the injury and/or symptoms.
- Injury
  - As with participation in any exercise routine or rehabilitative plan of care, there is risk for injury to occur. On The C1, these risks primarily include injuries to the upper extremity and/or shoulder complex. Secondary sites at which injuries may occur include, but are not limited to, the following: cervical spine, thoracic spine, pectoral region and elbow region.

### **Expectations with The C1**

### Participating in an Exercise Session:

- All movement performed on The C1 will be under the control of the user including, but not limited to, the speed of movement as well as the total excursion
- Users will be able to see their movements, in real time, on the tablet screen
- Easily adjustable resistance in both the x/y plane (toward/away from the user and forward/back) and the z plane (telescoping up/down)
- The device will record a plethora of data during exercise completion

#### Following the Exercise Session:

• Users and medical providers will be able to review the data from the completed exercise session in the user's profile under the date which the session was completed. *Note: Units referenced in the device are normalized and not calibrated for local conditions thus should be viewed as approximate.* 

### **User Size**

NOTE: This expectation focuses on linear measurements of the body, not weight. To see the max allowable weight, please refer to the "General Specifications" section.

When determining if a user can complete all exercises to the fullest extent, some body measurements may need to be taken. Due to the user being in a seated position, and the wide range of body size/proportion, height alone is not the determining factor to whether a person can complete all exercises to their fullest extent. The measurement that will determine this is a modification of the sitting vertical reach height. This measurement should be taken from the surface from which the person is sitting to their wrist joint when the arm is positioned vertically, and their shoulders are kept flat.

Anyone with a measurement at or below **approximately 49 inches** can expect to be able to complete all possible exercises to the fullest extent.

This is not to say that a person with a measurement greater than 49 inches cannot use, and benefit from, the device. There are multiple exercises and routines that can still be completed to their full extent, however, some overhead exercises may need to be modified. As always, consult with the appropriate medical personnel to determine the appropriate course of action in this scenario.

## **General Warnings and Precautions**

Customer safety is at the forefront of what is important to us here at Titin KM Biomedical. While our devices are developed to be safe and effective, this device does have electronic components and moveable parts. Power cords/adaptors, and other components of the device can create potential safety risks that may result in physical injury or device damage, especially if misused. To reduce these risks, follow the instructions contained within this manual, observe all warnings on the product and in the operating instructions, and review the information included in this document carefully. This will help to minimize the risk to yourself, and those using the device, from hazards while creating a safer environment.

The following are General Warnings and Precautions.

#### Precautions:

- Ensure all fasteners are secure and in place before each use.
- Prevent the device, and especially its electrical components, from getting unnecessarily wet.
- Ensure the general area around the device is free and clear of any obstructions and debris.
- Take care when plugging/unplugging any cords into/out of the device.
- When a session is complete, or when the device is not being used, ensure all components are moved out of walking paths.
- Units referenced in the device are normalized and not calibrated for local conditions thus should be viewed as approximate.
- Users under the age of 18 years old without the appropriate medical, fitness, or coaching supervision.
- Extension cords and related devices
  - Ensure that extension cords, surge protectors, uninterruptible power supplies, and power strips that you use are rated to handle the electrical requirements of the product. Never overload these devices. If power strips are used, the load should not exceed the power strip input rating. Consult an electrician for more information if you have questions about power loads, power requirements, and input ratings.

#### **General Warnings:**

- A Power cords and power adapters
  - Use only the power cords and power adapters supplied by the product manufacturer.
  - The power cords shall be safety approved for the country it is being used in.
  - Never wrap a power cord around a power adapter or other object. Doing so can stress the cord in ways that can cause the cord to fray, crack, or crimp. This can present a safety hazard.
  - Always route power cords so that they will not be walked on, tripped over, or pinched by objects.
  - Protect power cords and power adapters from liquids. For instance, do not leave your power cord or power adapter near sinks, tubs, toilets, or on floors that are cleaned with liquid cleansers. Liquids can cause a short circuit, particularly if the power cord or power adapter has been stressed by misuse. Liquids also can cause gradual corrosion of power cord terminals and/or the connector terminals on a power adapter, which can eventually result in overheating.
  - Ensure that all power cord connectors are securely and completely plugged into receptacles.
  - Do not use any power adapter that shows corrosion at the ac input pins or shows signs of overheating (such as deformed plastic) at the ac input pins, or anywhere, on the power adapter.
  - Do not use any power cords where the electrical contacts on either end show signs of corrosion or overheating or where the power cord appears to have been damaged in any way.
  - To prevent possible overheating, do not cover the power adapter with clothing or other objects when the power adapter is plugged into an electrical outlet.

### Plugs and Outlets

- If a receptacle (power outlet) that you intend to use with the C1 appears to be damaged or corroded, do not use the outlet until it is replaced by a qualified electrician.
- Do not bend or modify the plug. If the plug is damaged, contact Titin KM Biomedical to obtain a replacement.

- Do not share an electrical outlet with other home or commercial appliances that draw large amounts of electricity; otherwise, unstable voltage might damage your device or attached devices.
- Some devices are equipped with a three-pronged plug. This plug fits only into a grounded electrical outlet. This is a safety feature. Do not defeat this safety feature by trying to insert it into a non-grounded outlet. If you cannot insert the plug into the outlet, contact an electrician for an approved outlet adapter or to replace the outlet with one that enables this safety feature.
- Never overload an electrical outlet. The overall system load should not exceed 80 percent of the branch circuit rating. Consult an electrician for more information if you have questions about power loads and branch circuit ratings.
- Be sure that the power outlet you are using is properly wired, easily accessible, and located close to the equipment.
- Do not fully extend power cords in a way that will stress the cords.
- Be sure that the power outlet provides the correct voltage and current for the product you are installing.
- Carefully connect and disconnect the equipment from the electrical outlet.
- Injury Due To Use
  - There are risks associated with utilization of The C1. To minimize the chance of sustaining a new injury or worsening of a current injury, always consult the appropriate medical provider and use The C1 in accordance with what is described in this User Manual.
  - Using The C1 involves the user moving against a selected amount of resistance. Because of this, the possibility exists for the user to suffer from a strain, or worse injury, from improper use. Increased caution must be taken if using The C1 in the rehabilitation process following an injury. To decrease the risk of new or worsened injuries, users should always consult with the appropriate medical personnel prior to use.
- Pinch points
  - The C1 contains a number of moving parts to allow for bilateral use and proper positioning. There are various components that must be either fastened or released to allow, or not allow, adjustments. When manipulating some of these components, the possibility exists for a pinch to occur which could result in an injury to the user. To avoid this type of injury, avoid hasty adjustments and always use caution when adjusting the device.

- Tripping hazard
  - There are components of the C1, such as the legs, resistance mechanism, and various cords that are located close to the ground. If not careful, these components could pose a tripping hazard and result in injury to an individual. To lessen the risk of tripping over these components, always be alert and cautious when moving around the device.
- Skin Irritation
  - Because the user may don a wrist brace to connect into the device, there
    is the potential for skin irritation to occur. This risk may be further
    increased as the user sweats during exercise completion. To lessen the
    risk of skin irritation, users should ensure they do not have any
    sensitivities to materials contained within the wrist brace. To further lessen
    the risk of skin irritation, do not wear the wrist brace for prolonged periods
    of time, and use a stockinette over the hand/wrist.
  - Skin irritation may also be caused if the user has any sensitivities to materials on the device that they may come into contact with. Users should consult the list of contained materials to ensure they do not have any sensitivities to the materials used in device construction. The list of contained materials can be found in the "General Specifications" section.
- Accessories
  - The only accessories to be utilized with The C1 are those provided by Titin KM Biomedical. The use of additional accessories not provided by Titin KM Biomedical may lead to injury, malfunction of the device, and voiding of warranty.

### **Terms Used in This Manual**

As you are reading through this manual, it will be beneficial to know and understand the terms listed below.

<u>Recorded Data</u>: Information provided by the device in which numerical values provide information as to what is being analyzed.

<u>Dynamic Strength:</u> The term used to describe the strength metric derived from the device and shown to the user.

<u>Contraindication</u>: A condition or circumstance that suggests or indicates that a particular technique or treatment should not be used in the case in question.

### **Instructions for Setup**

### **Mechanical Setup**

There is little mechanical setup before the device is ready to use. This section will describe, in detail, how to properly set up the mechanical components of the device prior to a session.

- Attach and plug in all relevant components, if not already done.
  - Secure tablet to the end of the monitor arm.
  - 3 D-SUB cables and a power supply cable into the bottom of the power box on the backside of the backrest.
- Plug the device into a power source.
  - USB-C cable plugged into the power box on the backside of the backrest and into the tablet.
- Pull out the U-joint to its operating position.
- Attach the wrist ring, or another approved attachment, to the telescoping shaft.

The procedure to place the U-Joint into its operating position is as follows:



1. Twist the Handle counterclockwise to loosen.



NOTE: Do not twist the handle all the way out, only loosen enough for the Universal Joint to be movable.

2. Pull the Universal Joint out until it hits a stop (operational position).



3. Tighten the Handle by twisting clockwise to lock the horizontal position in place.



#### **Tablet Setup**

- Turn on the tablet.
- Create a security pin for the tablet.
- Connect the tablet to Wi-Fi.

### **Application Setup**

- Log into your company's account.
- Choose a user.

### **User Adjustment**

The C1 can be adjusted to comfortably accommodate a wide range of individuals for exercise completion. To ensure the most effective results while using the device, it is recommended that it be adjusted for each individual user at the start of a session. These adjustments are detailed below:

### • Seat Height and Headrest

The seat height, headrest height, and headrest horizontal position can all be adjusted in order to optimize the ergonomics of the user during exercise completion. Device positioning should be checked and adjusted before each session. The process for adjustment is the same for the seat height, as well as the headrest height and horizontal position. The figure below shows the main chair assembly and location of the various knobs needed to adjust the seat height, headrest height, and headrest horizontal position.



Adjustment knobs shown in their locked position.

The process for adjustment is as follows:

1. Pull the adjustment knob for the component to be adjusted (seat or headrest) all the way out and hold. (*Seat adjustment knob shown below. The adjustment knobs for the headrest are operated in the same manner*).



2. Adjust seat height, headrest height, and headrest horizontal placement to the desired positions.



**3.** Once the seat height, headrest height and horizontal position have been set, release the adjustment knob. **Make sure the adjustment knob has moved all** 

the way back into the locked position by attempting to move the position of the component adjusted.

• Universal Joint Adjustment

The Universal Joint can be adjusted rotationally for better performance during exercise completion as well as to accommodate a wide range of users. It can also be adjusted horizontally for use or storage. *During use, the Resistance Mechanism should be pulled all the way out horizontally (refer to the "Mechanical Setup" section, Pg. 13).* 

The procedure to adjust the Universal Joint rotationally around the chair is as follows:



NOTE: this is the same procedure for the Elbow Rest rotational adjustment

1. Pull the cam handle, located underneath the seat, all the way up.



2. Rotate the Universal Joint (or Elbow Rest) to the desired position. *There is a clock plate around the pivot center to ensure the desired position is correct and corresponds with what the app directs (if applicable).* 



3. Once the Universal Joint (and/or Elbow Rest) are in the desired position, push the cam handle all the way down to lock them into position.

Note: If the cam handle seems harder to close than usual, check to see that the gear teeth have meshed together. If they have not, lift the cam handle slightly and wiggle the elbow rest and/or U-Joint to ensure the teeth are meshed before reclosing.

- Elbow Rest Adjustment
  - The Elbow Rest can be adjusted rotationally (see the Resistance Mechanism Adjustment section), vertically (height), and angularly (distance from the user). Additionally, there are position indicator numbers for the height position of the elbow rest to ensure repeatable positioning. The angle of the Elbow Rest Pad can be adjusted individually as well.



Elbow Rest <u>height</u> adjustment:

1. Pull the Height Adjustment Handle out

**CAUTION**: The Elbow Rest is spring loaded. When pulling the height adjustment handle out make sure to keep a hand on the pad to resist it extending unintentionally and **DO NOT** keep your face directly over the pad

2. Once the Height Adjustment Handle has been pulled out, allow the Elbow Rest to rise to the desired height, or press down on the pad to lower its position. You can use the position indicator numbers to determine the correct position if needed.

NOTE: Do not force the elbow rest to extend out, allow the internal spring to extend the arm at its own speed

3. While holding the elbow pad in the desired position, push the Height Adjustment Handle closed to lock the Elbow Rest height

Elbow Rest distance or angle adjustment:

1. Pull the Height Adjustment Handle Out

**CAUTION**: The Elbow Rest is spring loaded. When pulling the height adjustment handle out make sure to keep a hand on the pad to resist it extending unintentionally and **DO NOT** keep your face directly over the pad.

2. Firmly push and hold the Elbow Rest as far down as it will go to unlock the elbow rest angular position.



3. Adjust the angle of the Elbow Rest to the desired position by tilting it in or out



4. Upon raising the Elbow Rest Pad, the Lock Pin should retract into position, locking the Elbow Rest angle.

NOTE: Make sure the Elbow rest is locked in place by attempting to change the angle and ensuring it does not move.

- 5. Reposition the Elbow Rest Pad to the desired height.
- 6. Push the Height Adjustment Handle closed to lock the Elbow Rest Height into place.

Elbow Rest Pad angle adjustment:

1. Using your fingers, pull the Pad Adjustment Handle up and hold.



2. Tilt the Elbow Rest Pad to the desired position.



3. Release the Pad Adjustment Handle from your fingers. The angle of the Elbow Rest Pad is now locked in place.

• Monitor Arm and Tablet Adjustment

The Monitor Arm has the ability to be moved to either side of the C1 as well as have its height adjusted on either side. The arm can be moved to various positions to best accommodate the user. The tablet can also be disconnected from the monitor arm.



The procedure to move the Monitor Arm to one side or the other of the C1, or adjust the height of the Monitor Arm, is as follows:

1. Pull the Adjustment Knob all the way out and hold. NOTE: This is the same type of adjustment knob as shown in the Seat Height and Headrest Adjustment section.

2. Rotate the Monitor Arm to the desired side, or to a different notch for height adjustments.



NOTE: The Headrest may need to be adjusted to a higher and/or more forward position (Referenced in the Seat Height and Headrest Section) and the Monitor Arm will need to be hinged back in order to rotate the Monitor Arm to the opposite side of the C1.

3. Once the Monitor Arm is in the desired position, release the Adjustment Knob to lock the position of the arm. **Make sure the Adjustment Knob** has moved all the way back into the locked position.

Once the side and height of the Monitor Arm have been set, the arm can be adjusted into the best position for you, it will swivel around the two (2) hinge locations. The tablet can also be swiveled about its joint.



Note: When not in use, fold the monitor arm so that it is not likely to be caught or hit by anyone walking by or near the device.

The procedure to connect or disconnect the tablet from the monitor arm is as follows:

1. Orient the tablet towards the slide mount so that the slide mount lever is sliding into the tablet receiver first, as shown below.



Note: The slide mount will be attached to the Monitor Arm.

- 2. Slide the tablet onto the slide mount. Ensure that the slide mount lever clicks over the locking ridge and is fully engaged. The slide mount lever can be pulled up to ease this process if needed.
- 3. Plug the USB-C cable into the tablet. The angle of the tablet can be adjusted while attached to the slide mount for best user visibility.
- 4. To remove the tablet from the monitor arm, first disconnect the USB-C cable from the tablet.
- 5. Lift the slide mount lever to disengage and slide the tablet off the mount.

### **Operating Instructions**

Note: The C1 should not be used for any purposes other than its intended use and as is stated throughout this User Manual.

### Initial Setup for Exercise Session:

- A process must be followed prior to beginning an exercise session on The C1:
  - Adjust the seat and headrest height to the user
  - Decision of whether to use the elbow rest
    - If used, it will need to be positioned appropriately (See "Elbow Rest Adjustment").
    - If not using the elbow rest for exercise completion, it can be positioned to the opposite side of the u-joint and raised under the Monitor Arm to provide stabilization for the Monitor Arm.

  - Exercises/Programs to be completed during the session will need to be selected.
  - The user will need to put on the appropriate (right or left) wrist brace or use another approved attachment/grip.
  - The U-Joint will need to be positioned appropriately for the first exercise (and adjusted for each additional exercise as needed)
  - The correct pivot point (shoulder, elbow, elbow 45, and elbow 90) will need to be selected or set.
  - The wrist ring will need to be attached to the telescoping arm
  - $\circ$  The wrist brace will need to be connected to the wrist ring

### **Mechanical Operation**

#### • Putting on the Wrist Brace

1. Ensure all tightening straps are loose. Place your hand in the wrist brace with the Quick Attach mechanism positioned towards the bottom of the wrist.



Note: Left hand and brace shown above.

2. Tighten the brace using the tightening straps.



Note: Tightening straps use Velcro.

#### • Taking off the wrist brace

Removing the wrist brace is the opposite of putting it on.

#### • Connecting the wrist brace to the wrist ring

The wrist brace should only be attached to the wrist ring after having put the brace on. Attaching the wrist brace to the wrist ring can be done following the below steps:

1. Slide the quick attach into the wrist ring receiver.



- 2. Listen for a click. This means the quick attach is properly seated. If a click is not heard, the wrist brace is not properly attached to the wrist ring and the user should not begin exercise completion until it is properly attached.
- 3. Ensure the quick attach is locked in before use by pulling the wrist backwards.

NOTE: It is recommended to attach the wrist ring to the telescoping shaft before attaching the wrist brace to the ring.
### • Disconnecting the wrist brace from the wrist ring

The wrist brace should only be disconnected while the user is still wearing it. Removing the wrist brace from the wrist ring can be done in one simple step.

1. Pinch the two quick attach tabs and slide the wrist brace out of the receiver.



Note: View from below the wrist.

### Connecting the wrist ring to the telescoping arm

1. Using one hand, depress and hold the release lever on top of the telescoping shaft.





2. Insert the attachment piece of the wrist ring into the top of the telescope.



3. Release the Lever on top of the telescoping assembly.



- 4. Ensure the wrist ring is seated before use by pulling up on the wrist ring and ensure it stays connected to the telescoping assembly.
- Disconnecting the wrist ring from the telescoping arm

Removal of the wrist ring is the opposite of attachment.

### • Using the Wrist Ring

The wrist ring has the ability to freely rotate or lock this rotation in a fixed position.

- Don the wrist brace and attach it to the wrist ring.
- To lock the wrist ring in place, toggle the release lever down.
- To allow free rotation, toggle the wrist ring release lever up.



Note: Release lever shown in the locked position.

# **Software Operation**

# **Initial Set Up**

### **Connecting to the Device**

- Prior to plugging the device into a wall outlet, ensure that the telescoping shaft is fully depressed to its most collapsed position.
- Plug the power supply for the device into the underside of the control box on the right side of the seat back and then plug the power supply into a standard wall outlet
- Insert the USB-C plug from the end of the device monitor arm into the monitor.

## **Software Overview**

### Account Types

- Provider Account
  - Will have access to all client data stored under this account type as well as access to all exercise and program banks.
- Client Account
  - A single person login with access to only his/her individual data, the exercise bank, and program banks.
  - This is the account type that patients will use when not working directly with their overseeing provider

### Creating a New Provider Account

With delivery of The C1, all provider accounts for a single location will be created by the Titin KM Biomedical team. The creation of a provider account will generate a temporary password that will be sent to the email associated with the provider account.

Upon initial login with the temporary password, the provider will be prompted to create a new password, a PIN code, and asked to accept the Private Health Information Disclaimer and End User License Agreement to proceed. Without accepting the agreements, the provider will not be able to continue.

To create a new client account, see "Creating a New Client" (pg.40).

### Logging In

- 1. Input the email into the appropriate field.
- 2. Input password into the appropriate field.
  - The eye icon, at the end of the password field, gives the ability to view or hide the password.
    - A "\" through the eye will result in the password being hidden.
    - If there is not a "\" through the eye, the password will be viewable.
    - To alternate between viewable or hidden, tap the eye icon.
- 3. Press "Sign In".
- 4. Immediately following logging in, a popup screen will present the option to start a session or not.
  - Pressing "No" will navigate the user to the "Active Session" screen with no client selected, or as anonymous

NOTE: Any sessions ran as "anonymous" will not be savable for future review of the recorded data

- Pressing "Yes" will prompt the user to input a PIN code, if using a HIPAA compliant device, to access the client list from where a client can be selected and a session initiated. See "Starting a New Session" (pg. 42).
- 5. By checking the "Remember Details" box, the application will remember the next full log in credentials used and save the user information.
  - When performed, the user will be prompted to create a 6-digit PIN for future access.
  - Saved user accounts will be listed above the credential boxes. Tapping a username prompts the user to input the established PIN for access instead of requiring the full input of the username and password.
  - Credentials are saved locally and not to a cloud meaning each device a provider has access to will need to have credentials saved and a PIN created for access.

### Logging Off

It is good practice to log out of an account when not in use and upon completion of a session on the device, regardless of what type of account is logged in. The procedure for logging out is as follows:

- 1. Open the menu by pressing the Main Menu icon (three horizontal bars) located in the top left corner of the display.
- 2. Press the "Sign Out" button located at the bottom of the ensuing menu.

NOTE: After 10 minutes of inactivity, the application will automatically log out of the current account

#### Forgotten Password

Should a password be forgotten, select the "Need help?" button and follow these steps:

- 1. Press the "Need help?" button.
- 2. Press "Send Reset Code".
- 3. Retrieve the verification code from the supplied email and return to the Titin KM Biomedical application.
- 4. Input the verification code along with a new password.
- 5. Confirm the new password
- 6. Press "Change Password" to reset the password and log in with the new credentials.

## **Software Navigation**

The top display bar is present from every page in the application and can be used for easy navigation around the application.

#### Main Menu

- The icon of three stacked lines, located in the top left corner of the display, is the main menu. Pressing this button will open a dropdown with the various pages of the application that may be visited.
  - Active Session
    - $\circ~$  All exercises, programs, and tests will be performed on this page.
    - Provides live tracking of movements being performed.
    - Displays real-time data with exercise completion.
  - Clients
    - A list of all the clients registered under the currently logged in provider account.
  - Exercises
    - A list of all exercises available to be performed.
  - Programs
    - A list of all programs available to be performed.

NOTE: A Client Account will show "My Profile" instead of "Clients"

- The gear icon, located at the top right corner of the Main Menu, will open a settings screen.
- The button labeled "Sign Out" at the bottom of the Main Menu will log the user out of the application.

## **Creating a New Client**

- To create a new client, perform the following:
  - 1. Navigate to the client bank
  - 2. Press the "+" icon located in the top right corner of the clients page.
  - 3. Input the required information for the client's profile.

NOTE: A client email is optional. If provided, the email of the client, will be used to deliver a temporary password to the client to set up the client's individual "Client Account".

- 4. Identify the pivot points for the shoulder and elbow by performing the following steps:
  - a. Set pivot points with the U-Joint at either the 3 o'clock (for right arm) or 9 o'clock (for left arm) position.
  - b. Place the end of the telescoping arm, without an attachment connected, at the necessary pivot point (shoulder, elbow, elbow with shoulder in 45 degrees of abduction, elbow with shoulder in 90 degrees of abduction) of the identified side with the client in a seated and relaxed position.
    - i. Pivot point locations:
      - 1. Shoulder: place the end of the telescoping arm at the front of the shoulder
      - 2. Elbow: place the end of the telescoping arm on the tip of the elbow
      - 45 Pivot Point: With the shoulder abducted 45 degrees, place the end of the telescoping arm on the tip of the elbow
      - 90/90 Pivot Point: With the shoulder abducted 90 degrees, place the end of the telescoping arm on the tip of the elbow

NOTE: Pivot points may be set while referencing either side of the body so long as the U-Joint is in the correct corresponding position: 3 o'clock for the right shoulder and 9 o'clock for the left shoulder

- c. Press the corresponding button "Shoulder Pivot Point", "Elbow Pivot Point", "90/90 Pivot Point", and "45 Pivot Point".
  - After successfully setting the pivot points, the text in parenthesis will change from "Unset" to "Updated".

NOTE: Pivot points only need to be set for one side of the body as the software will automatically place the contralateral pivot points when switching between right hand and left hand use.

4. Press "Save" to create the new client.

NOTE: Clients may initially be created without setting pivot points. Prior to the start of the first session for a given client, however, users will need to set the appropriate pivot points for accurate data metrics.

- After creating a new client, an automated email will be sent to the email address associated with the new client account, if an email for the client was supplied. This email will contain a temporary password used for the initial login to the account with the client's email address being the username.
- Upon logging in for the first time, clients will be prompted to change their password as well as accept all user and private health information disclaimers and agreements.

#### **Pivot Points**

Appropriately identified pivot points are necessary for correct calculation of many of the data points that are being generated by use of the device.

Physical pivot points for the shoulder and elbow, and elbow at varying degrees of shoulder abduction will be identified and saved for a client upon profile creation or prior to the first session run for a given client.

The corresponding pivot point for an exercise is identified upon exercise creation. All exercises require a pivot point:

- Shoulder: Exercises where the main axis of rotation is around the shoulder, these are generally long lever motions with the elbow extended.
- Elbow: Used for Internal and External Rotation from 0 degrees of shoulder abduction.
- 90/90 Elbow: Used for Internal and External Rotation performed with the shoulder in 90 degrees of abduction.
- 45 Elbow: Used for Internal and External Rotation performed at 45 degrees of shoulder abduction.

*NOTE:* See "**Creating a New Exercise**" (pg.53) for how to identify the pivot points for an exercise.

NOTE: The correct type and location of pivot point will automatically load with each new exercise.

NOTE: For accurate metric data, ensure that the correct pivot point is loaded for a selected exercise.

## **Starting a New Session**

- Starting a new session can be performed from either the client's profile page or the active session screen.
  - To start a session from a client's profile page, complete the following steps:
    - 1. Navigate to the desired client's profile page
    - 2. Select the "Start Session" button located at the top of the SESSIONS column
    - 3. Select either:
      - a. "Select Program": Opens the Program Bank to select a "program", or grouping of exercises, that run together. Selecting the desired program opens the Exercise Setup popup.
      - b. "Select Exercise": Opens the exercise bank for selection of specific exercises. Once all exercises have been selected, press "Run Selected" to open the Exercise Setup popup

NOTE: Individually selected exercises will automatically be ordered by U-Joint position to limit the amount of position changes throughout a run session. If it is desired that exercises be ran in a specific order, they may be grabbed and reordered by pressing and holding the 3 stacked lines beside the exercise name after it is selected and dragged to the desired position.

- 4. On the Exercise Setup popup box, indicate the following:
  - a. Number of sets and reps for the user to complete on the first exercise
    - i. The set and rep scheme indicated for the first exercise will carry forward to each new exercise, however, can be modified as needed
  - b. Select which side to perform the exercise on
    - i. The default side for the client running the routine will be selected but may be changed if necessary
  - c. Confirm that the physical positioning of the U-Joint matches the designated positioning for the exercise in the software
- 5. When ready, select "Start (exercise name)" at the bottom of the Exercise Setup box. This will transition the user to the active session screen with the first exercise loaded.
- 6. Press "Run" to begin the exercise
- The User will be prompted to "Set Reference Motion" where he/she moves through the desired range for the selected exercise
- 8. After establishing the "Reference Motion" the next prompt "Start Exercise" will initiate the exercise.
  - a. Both of the two previous prompts will start themselves as the progress meter moves to the end or may be advanced by pressing the button.
- To start a session from the Active Session screen, perform the following:
  - 1. Press "Start Session" in the bottom right corner
  - 2. Select the following on the ensuing popup:
    - a. "Choose New Client": Identify the desired client after inputting the PIN code if using a HIPAA account
    - b. "Continue as (currently selected client)": Perform a new session under the currently loaded client

- c. "Cancel" To cancel starting a session and return to the active session screen
- 3. After selecting a new client or continuing with the already identified client, select one of the following from the ensuing popup:
  - a. "Select Program": Opens the Program Bank to select a "program", or grouping of exercises, that run together. Selecting the desired program opens the Exercise Setup popup.
  - b. "Select Exercise": Opens the exercise bank for selection of specific exercises. Once all exercises have been selected, press "Run Selected" to open the Exercise Setup popup
- 4. On the Exercise Setup popup box, indicate the following:
  - a. Number of sets and reps for the user to complete on the first exercise
    - i. The sets and reps scheme indicated for the first exercise will carry forward to each new exercise, however, can be modified as needed
  - b. Select the hand side to perform the exercise
  - c. Confirm that the physical positioning of the U-Joint matches the designated positioning for the exercise in the software
- 5. When ready, select "Start (exercise name)" at the bottom of the Exercise Setup box. This will transition the user to the active session screen with the first exercise loaded.
- 6. Press "Run" to begin the first exercise
- The User will be prompted to "Set Reference Motion" where he/she moves through the desired range for the selected exercise
  - 8. After establishing the "Reference Motion" the next prompt "Start Exercise" will initiate the exercise.
    - a. Both of the two previous prompts will start themselves as the progress meter moves to the end or may be advanced by pressing the button.

# Tests

Tests are designed to take a snapshot of shoulder function, at periodic intervals, for comparison over longer periods of time.

- Only a single recording for ARoM and Strength tests will be saved each day. If multiple recordings are performed in a single day, only the most recent will be saved for future reference.
- When running a tests program, the six cardinal motions of shoulder Flexion, Extension, Abduction, Adduction, Internal Rotation, and External Rotation will be automatically run, in that order.

NOTE: If it is desired to have multiple sets of data for review within a single day, users may perform the motions as a "Session" and print, or simply reference, the data from the session analysis screen of the client profile page. See "Starting a New Session" (pg.42) on how to start a session or "Reviewing Session or Tests Data" (pg.50) on reviewing and printing data.

### Taking An ARoM Test

To perform either an initial or updated test of ARoM, perform the following steps:

- 1. Navigate to the desired client profile page.
- 2. In the main body of the display and at the top of the first column, switch from the "Sessions" tab to the "tests" tab.
- 3. Press "Start Test" located at the top of the "Tests" column.
- 4. Select "Run ARoM" on the ensuing pop-up.
- 5. Press "Run" located in the bottom right corner of the screen to begin the first motion.

NOTE: Ensure the client has his/her arm positioned at the start point of the desired testing motion prior to pressing run

- 6. Perform as many controlled repetitions of the identified motion as desired and then press "End Exercise" once the client has completed the final repetition for the motion.
  - If more than one repetition is performed, an average of all reps is shown in the analysis
- 7. Repeat steps 5 and 6 to progress through all six motions.

NOTE: Users may skip any motion by pressing the "Skip" button located in the bottom right of the screen prior to pressing "Run"

8. After pressing "End Exercise" on the sixth motion, a "Test Analysis" screen will appear. Pressing "Save" will record the Test session.

NOTE: Pressing anywhere on the screen off the "Test Analysis" pop-up will allow the user to leave, without saving the session, by pressing "Close Anyway" on the ensuing pop-up

### Taking a Dynamic Strength Test

To perform either an initial or updated test of Dynamic Strength, perform the following steps:

- 1. Navigate to the desired client profile page.
- 2. In the main body of the display and at the top of the first column, switch from the "Sessions" tab to the "Tests" tab.
- 3. Press "Start Test" located at the top of the "Tests" column.
- 4. Select "Run Strength" on the ensuing pop-up.
- 5. Press "Run" located in the bottom right corner of the screen to begin the first motion.

# NOTE: Ensure the client has his/her arm positioned at the start point of the desired testing motion prior to pressing run

- 6. Perform as many controlled repetitions of the identified motion as desired and then press "End Exercise" once the client has completed the final repetition for the motion.
  - If more than one repetition is performed, an average of all reps is shown in the analysis
- 7. Repeat steps 5 and 6 to progress through all six motions.

# NOTE: Users may skip any motion by pressing the "Skip" button located in the bottom right of the screen prior to pressing "Run"

8. After pressing "End Exercise" on the sixth motion, a "Test Analysis" screen will appear. Pressing "Save" will record the test session.

NOTE: Pressing anywhere on the screen off the "Test Analysis" pop-up will allow the user to leave, without saving the session, by pressing "Close Anyway" on the ensuing pop-up

## **Active Session Screen**

The "Active Session" screen is the main screen of the application. From this screen, users will perform all exercises, programs, and tests.

Directly underneath the top bar display, the name of any loaded exercises or programs, as well as the currently loaded client, will be displayed.

### **Adjusting Resistance**

- On the right side of the screen, users will see a box with "XY Resistance" and "Z Resistance", along with a "+" and "-" button separated by a value from 0-100.
  - Pressing either the "+" or "-" beside "XY Resistance" will increase or decrease the resistance applied in the forward/backward and right/left directions of the telescoping arm from 0 (no resistance) to 100 (max resistance).
  - Pressing either the "+" or "-" beside "Z Resistance" will increase or decrease the resistance applied in the up/down directions of the telescoping arm from 0 (no resistance) to 100 (max resistance).
- Adjusting field of view
  - The field of view for the live tracking may be changed by dragging the slider at the right side of the active session screen in the box labeled "Field of View" to the left or right.

NOTE: Based on the plane of movement for a selected exercise, changing the field of view may offer a better visualization of the live tracking of a motion on-screen.

### **Adjusting U-Joint Position**

- The U-Joint position is defined as positions around a clock face that is visible at the base of the seat shaft where the U-Joint connects to the device base.
- The on-screen U-joint position is adjusted using the slider bar on the right side of the active session screen labeled "U-Joint: 'X' O'clock".
- Exercises will automatically load with the on-screen U-Joint position at the setting identified when the exercise was initially created.

NOTE: It is <u>critical</u> to ensure that the on-screen U-Joint position matches the physical U-Joint position for accurate metrics and presentation of live tracking. NOTE: For accurate comparison of exercises and metrics across sessions, it is <u>critical</u> to ensure that both the on-screen and physical position of the U-Joint is in the same position for exercises that are to be compared. You may reference the position of the U-Joint from previous sessions within the "Client" profile to ensure accurate positioning. See "**Reviewing Session or Tests Data**" (pg. 50).

#### **On-Screen Data Display**

- Force
  - The amount of force being applied by the user against the resistance mechanism, at any time, is displayed in the running graph labeled "Force" near the top right corner of the screen.
  - The Force is displayed as a moment (torque) in foot-pounds (ft-Lbs) and constantly updates as a user moves.
  - If while at high resistance settings a user moves at a rate beyond the intended safe speed, the graph will display output in a "red zone".
     <u>Prolonged use</u> in this range is considered outside the intended function and may result in damage to the device.
- Last Rep Metrics
  - Located in the bottom left of the screen are four different metrics that update with each repetition performed.
    - "Rep" displays the number of repetitions completed.
    - "Set" displays the number of sets completed.
    - "Strength" displays the calculation of dynamic shoulder strength for the last repetition completed. Strength is displayed in Titin Watt Units (TWU).
    - "Motion" displays the excursion from the start of a motion to the end of the motion. Motion is displayed as a degree starting at 0 and increasing.

#### Setting Targets

- Below the "Last Rep" data in the bottom left of the screen, there are two pin icons. The icon with a "+" attached to it will place a target circle on the live tracking field. The icon with a "-" attached to it will remove the last placed target circle on the live tracking field.
  - Target circles are placed at the point where the yellow box corresponding to the user's hand is positioned when the pin with a "+" is pressed.

#### **On-Screen Buttons**

- "Start Session"
  - When an exercise is not actively loaded, a button labeled "Start Session" is present in the bottom right of the screen. By pressing this button, the process to start a new session will begin.

NOTE: See "**Starting a New Session**" (pg. 42) for more details on starting a session

- The following buttons are present when an exercise or program is loaded to be performed:
  - o "Run"
    - Pressing this button will start the currently loaded exercise and must be pressed as each new exercise loads to begin tracking
    - After pressing "Run", the following buttons will appear.
      - "End Set"
        - Pressing this button will end the current set of an exercise, regardless of how many repetitions have been completed.
        - Once a set has ended, the next set will start.
        - If pressed on the last set of an exercise, the exercise will end and the "Exercise Set-Up" pop-up will load with the next exercise.
        - If pressed on the last set of the last exercise in a series, the "Session analysis" pop-up will open and prompt the user to save the session.
      - "End Exercise"
        - Pressing this button will end the current exercise, regardless of how many sets have been completed, and either load the next exercise to be performed or finish the session if already on the final exercise of the program.
  - o "Skip"
    - Pressing this button will skip the exercise that has been loaded.
    - Once this button is pressed, the user will either be transitioned to the next exercise in the program or, if no additional exercises remain, will open the "Session Analysis" pop-up and prompt the user to save the session.

- Data is not recorded for skipped exercises and will not be displayed when reviewing the session analysis.
- "Clear"
  - Pressing this button will clear any loaded exercises or programs resulting in no data from the session being saved.

## **Clients Bank**

The "Clients" page displays a list of all the clients created under a specific provider account.

A search bar, located under the top display bar, helps users easily locate the desired client from the client bank.

• Using the drop down located on the right side of the search bar allows a user to filter searches based on selected criteria

### **Editing Client Information**

- From within a client profile, press the "Edit" button located in the bottom left of the screen.
  - Any information, aside from the email address, may be updated, including pivot points.
- Press "Save" to finalize edits made to a client profile.

### **Reviewing Client Data**

- Users are able to review all data recorded for a client within the client's profile.
- The client profile page is divided into 3 main sections:
  - The column along the left side of the screen displays client identification information.
  - The three (3) boxes located along the top of the screen display a quick view of the metrics in regard to the six (6) cardinal motions.
    - The first has the following options to adjust
      - Dates of service for comparison
      - Motion to compare
    - The second and third boxes will show the net change in either ROM or Power respectively, between the dates selected and the chosen motion.

- Green shading indicates a positive change between the first and second date while red shading indicates a negative change between the two dates.
- An in-depth review of data, for both sessions and metrics, is in the three
  (3) columns which make up most of the display.
  - Alternate between "Sessions" and "Tests" by pressing the respective tab located at the top of this section.

### **Reviewing Session or Tests Data**

Reviewers can switch between sessions and tests recorded on different arms by using the "Right/Left" toggle located at the left side of the client profile screen

- Sessions
  - With the "Sessions" tab selected, a user may select a desired date of service in the first column.
  - Once a date of service is selected in the first column:
    - The second column will display:
      - Program name
      - Hand completed with
      - Exercises completed
    - Also in the second column, the user will have the ability to name the session by pressing "Name Session" or watch a playback of the session by pressing "Play Session".
    - By selecting a performed exercise in the second column, the third column will display data relating to completion of that specific exercise, including:
      - Reps
      - Sets
      - The selected U-Joint position
      - Peak and mean dynamic shoulder strength
      - Peak and mean motion
      - Resistance settings for both X/Y and Z
  - Naming a session
    - The ability to name a session gives users a convenient way to identify and separate various sessions for later review. To name a session, follow these steps:

- After selecting the desired date of service in the first column, press the "Name Session" button located at the bottom of the second column.
- Insert the desired name and press "Save".
- The name of the session will now be displayed beside the date and time of the session in the first column.

### • Tests

- This tab will display both Motion and Strength tests that have been recorded.
- With the "Tests" tab selected, a user may select either Motion or Strength, on a specific date of service, in the first column.
- The data associated with each movement that was tested on that date will then populate in the box to the right for easy review.
- Printing data
  - A print feature is available for both "Sessions" and "Tests". To print a comparison sheet, perform the following steps:
    - 1. In the first column, press the printer icon located in the top right corner with either "Sessions" or "Tests" selected. Once pressed, a screen will populate with all available dates to be printed.
    - 2. Users may select as many dates as desired and press "Preview" to view a digital version of the printed product.
    - 3. When ready, press "Print" to identify a printer location and print the comparison document.

NOTE: You will need to connect your tablet to a printer connected to the same WiFi network as the tablet to print comparison sheets.

- Data extraction
  - Data pertaining to either a session or a test may be extracted and emailed to the user of the logged in account by performing the following steps:
    - 1. With either "Sessions" or "Test" selected, press the icon of a file with an arrow (beside the printer icon) located at the top of the column
    - 2. Select the date of service from which to extract data
      - a. Multiple dates may be selected
    - 3. Press "Export"
  - Once "Export" is pressed, an email will be sent to the user currently logged in (either the provider or client). This email will contain a zip file

with the extracted data from the selected session(s). Once the file is unzipped, the data will be accessible.

### **Deleting Clients**

- To delete a client:
  - Navigate to the desired client profile and press the red "Delete" button in the bottom left of the screen.
  - On the following pop-up, pressing "Delete" will confirm the deletion and pressing "No" will cancel the deletion and return the user to the client profile.

# **Exercises Bank**

The exercise bank contains all the exercises created, and saved, under a provider account.

### **Creating a New Exercise**

- Ensure the desired handedness is selected from the top display prior to creating a new exercise as it is necessary for the identified U-Joint position to correlate to a handedness.
- Press the "+" button located in the top right corner of the exercises screen.
- Input the required information.
  - Identify the appropriate U-Joint position for exercise completion
    - The best positioning of the U-Joint will be that in which the exercise can be completed with the least amount of restriction
    - Of note, the position of the U-Joint may vary slightly with each user based on the user's body habitus

NOTE: Most exercises will likely be able to be performed from the same U-Joint position, regardless of user. However, if it is necessary to change the U-Joint position for a given user, it can be accomplished on a situation-by-situation basis. Of note, ensure that the physical location of the U-Joint matches the U-Joint position on the tablet.

 The designated U-Joint position may be changed from the active session screen prior to the start of the exercise, if needed.

- The pivot point selected when creating an exercise will be the point that loads from the client's profile when an exercise is programed to be completed.
- A user can add a "Tag" to created exercises
  - Type the tag in the box with text "Type here..."
  - Once the tag has been entered, press the "Enter" button
  - Repeat this process for all desired tags
  - The newly created tags will populate above the input box
- Once all information has been input, press either "Record Exercise" or "Save"
  - The "Record Exercise" button allows the user to create a reference motion for the exercise.

NOTE: Recording a reference motion can be beneficial for maintaining a consistent movement pattern during exercise completion. With a reference motion, only repetitions consistent with that motion will be counted. This, however, can become restrictive for clients who have differing body dimensions and limb lengths from the individual who created the reference motion. These differences may result in the user following a different arc of motion and, thus, not having the repetitions or data accurately tracked.

• The "Save" button will save the exercise after confirming that the user wishes to do so without saving a reference motion.

#### Searching the Exercise Bank

• A search bar is present near the top of the exercise bank screen which provides users the ability to conveniently locate exercises by searching either the name of the exercise or by U-Joint positioning.

NOTE: When performing multiple exercises in sequence, it can be helpful to build the routine by U-joint positioning. Building routines this way can be more efficient for the user and client and limit the amount of U-Joint position changes between exercises.

#### Using tags

- Tags can be assigned to exercises in effort to group exercises together based on a commonality. These Tags provide another convenient method of searching.
  - When searching by a Tag, all exercises assigned that Tag will be displayed.

- To use Tags as a filter in the exercise bank, press the bookmark icon located to the right of the search bar. Following this, a list of Tags will populate. Select the desired Tag(s) to filter by and locate the exercises.
- Creating tags
  - When creating an exercise, there is a box to the right that is open for free text. This box allows is the location in which a user will input any desired Tag.
    - It is necessary to press "enter" at the end of typing each tag to confirm the tag.
    - Multiple tags may be created for each exercise.
    - Users may also utilize Tags already created by pressing "Show all" in the top right corner and then selecting the desired Tags.
- Editing tags
  - Tags may be deleted from, or added to, an exercise from the edit exercise button described in the following section.
  - Removing Tags
    - Press the icon of two, overlapping tags to the right of the search bar
    - This will populate a list of all the created Tags
    - To remove a Tag, press the garbage can icon located to the right of the tag
    - Select the appropriate response on the following pop-up to either confirm or cancel the deletion of the Tag

#### **Editing An Exercise**

- Press the icon of a pencil located at the far right of each exercise line.
- Edit the necessary information on the ensuing pop-up.
- Tags may be edited at this point as well.
- Press "Save".

#### **Deleting An Exercise**

- Press the icon of a red trash can located at the far right of the exercise line
- Confirm or cancel the deletion of the exercise by selecting the appropriate response on the ensuing pop-up.Users will be asked to confirm their desire to delete a selected exercise by either pressing "No" or "Delete" on the pop-up screen.
- Deleted exercises cannot be recovered and a new exercise will need to be created.

## **Programs Bank**

The program bank contains all programs created under a provider account.

Programs are previously created groupings of exercises that will run in the identified sequence.

Users may utilize programs to create specific protocols or routines that are frequently used by their clients.

#### **Creating a New Program**

- Press the "+" located at the top right corner of the programs screen.
  - Name the program.
  - Start selecting exercises from the "Available Exercises" column to be placed into the program by adding a checkmark to the box in front of the exercise name.
    - Exercises may be located by using the search bar below the program name.
      - Users may filter searches for exercises by either name or U-Joint position as well as filter by tags by pressing the tag button located at the far right of the search bar and selecting the desired tags.
  - As exercises are selected, they will appear in the next column labeled "Selected Exercises".
  - Reordering exercises
    - Exercises in the "Selected Exercises" column may be reordered as desired by pressing and holding the stacked four lines to the right of the exercise name and dragging the exercise to the desired position in the program.
  - Tags may be added to the program using the free text box located within the "Tags" section located at the top right corner of the "Create Program" pop-up.

NOTE: Be sure to press "Enter" after typing the desired tag to confirm the tag.

• Press "Save".

## Device

Check for Application updates by pressing the "App Update" button.

Check for Firmware updates by pressing the "Firmware Update" button.

# **Included Accessories and Proper Use**

### Accessories and Uses

- Ball Grip
  - The ball grip can be used in place of the Wrist Ring and Brace for more freeform movement.
  - The Ball Grip attaches to the telescope in the same manner as the Wrist Ring (Pg. 31).
  - Consult with your provider/physical therapist/trainer before use.



# **Recorded Data**

With The C1, there is a substantial amount of data that can be gathered, tracked, and analyzed. The term "data" is referring to the information provided by the device in which numerical values provide information as to what is being analyzed.

The C1 is capable of determining and recording the approximate motion with which a shoulder exercise is completed, number of repetitions and even dynamic strength feedback.

The unique dynamic strength values for shoulder movements and during exercise completion are created using an algorithm contained within the Titin KM application. The C1 gathers specific data (time, distance, speed and resistance) and computes a dynamic strength value, this is then output in a unique unit of Titin Watts.

# **Device Maintenance**

The device is designed so that maintenance should be rarely needed. Maintenance that may need to be and can be performed by the user/owner is outlined below. For any other concerns or issues please reference the troubleshooting section or contact Titin KM Biomedical.

## Adjusting the Cam Handle

If you notice the U-Joint is wobbly or moves during use it may be necessary to increase the clamping force of the cam handle.

1. Open the cam handle and remove the screw circled in red.



2. To increase the clamping force rotate the gear so the indicator mark is moved towards the front of the device as shown below. *Note: keep the indicator mark towards the bottom of the device.* 



3. Put the screw back in and tighten.

- 4. Repeat steps 1-3 for the other side. Ensure the gear position indicators are in the same relative positions.
- 5. Close the cam handle. If the cam handle needs to be tightened further, repeat steps 1-4. If the cam Handle is too tight after adjustment go back to step 2 and rotate the gear so the indicator mark moves to the rear of the device.
- 6. Ensure both screws are reinstalled and tight.

### Tightening the Monitor Arm

It is unlikely to happen, but in the case that the Monitor Arm begins to droop inward or will not hold its position when the tablet is connected to it you will need to tighten the hinges.

This procedure applies to both hinges on the Monitor Arm, though in most cases you will only need to tighten one.

- 1. Locate the hinge that is drooping or rotating during use.
- 2. Locate the screws on the wide side of the hinge and rotate the monitor arm so that they are accessible.
- 3. Tighten both screws until the tension is high enough to hold the monitor arm in place during use.



## Elbow Rest Clamp Tightening

In the case that the elbow rest extends while clamped, or slides down during use you may need to tighten the clamping mechanism.

- 1. Open the clamp and allow the elbow rest to fully extend.
- 2. Locate the clamp adjusting screw.



- 3. Tighten the clamp adjusting screw. *Note: this should not need to be adjusted much.*
- 4. Close the clamp. Check to see that it is not too difficult to close and that it holds the elbow rest in place.
- 5. Repeat steps 1-4 if needed.

# **Proper Cleaning Procedures**

It is good practice to wipe down any parts of the device that come into contact with the user after each use. (Headrest, Backrest, Elbow Rest, and Wrist Guard). More thorough cleaning procedures are outlined below.

### Seat, Backrest, and Headrest

To clean the seat, backrest, headrest and elbow rest cover from debris or dust use a vacuum or light brush. For light stains use a soft cloth moistened with mild soap and water to rub them out. For more stubborn stains rubbing alcohol is acceptable. *Note: avoid using rubbing alcohol on the Titin KM graphic on the backrest.* To disinfect the seat, headrest, backrest, or elbow rest cover a bleach solution is best: use a bleach that contains 6% hypochlorite in a 20:1 water to bleach mix, and allow it to thoroughly dry afterwards.

### Wrist Brace

The wrist brace will need to be washed frequently depending on usage and user cleanliness. To wash the wrist brace: machine wash on a gentle cycle with cool water, air dry. *Note: The use of a stockinette over the hand and wrist should decrease the frequency at which the wrist brace will need to be cleaned.* 

### Mechanical/Electrical Components and Ports

Frame components and Covers should be wiped down with a soft cloth moistened with water and mild soap if necessary. Ports and connectors should only be cleaned out with gentle blasts from canned compressed air.

### Tablet

For instructions on how to properly clean the tablet provided with The C1, please refer to the User Manual specific to the tablet.

# **Proper Storage**

### Tablet

When the tablet provided with The C1 is not being utilized, the tablet should be turned off. Removal from The C1 is not necessary.

### Device

When the device is not being utilized, ensure the device is stable and in a safe location. If the device is not in use, appropriately remove the power cord from the power source. Fold the arm that holds the tablet in so it is close to the device and does not pose a risk of any sort.

### Environment

The C1 should always be kept and stored in a temperature and humidity controlled environment. The ideal setting for device storage would be within a clinical setting or athletic training facility. As The C1 contains electrical components, it should not be exposed to water or kept/stored in an area where water may come into contact with the device.

# **Device Disposal**

## Returning The C1

If, at any point in time, you feel you no longer would like to have The C1 in your facility, please contact Titin KM Biomedical via phone or email. With this communication, we will set up a date and time in which Titin KM personnel will come to your facility to retrieve the device.

Do not sell or throw away the device.

# Troubleshooting

Malfunction	Solution
Application not opening	1. Restart the Tablet
Can't login to application	1. Ensure email and password are input and spelled correctly.
Unable to save patients/exercises/programs	1. Confirm that the tablet is connected to Wi-Fi.
Device loses resistance or movement tracking	<ol> <li>Follow the steps below:         <ul> <li>Set the device resistance to zero.</li> <li>Ensure the telescope shaft is fully depressed.</li> <li>Unplug the device from its power source for at least 30 seconds.</li> <li>Unplug the USB cable from the tablet.</li> <li>Plug the device back into its power source.</li> <li>Wait 30 seconds and plug the USB cable back into the tablet.</li> <li>Ensure the "OK to Connect" message is displayed and press OK.</li> <li>Attempt to use the device.</li> <li>If resistance or movement tracking is still lost repeat this process one more time before moving to solution 2.</li> </ul> </li> <li>If after two (2) attempts to follow solution 1, resistance and movement tracking are still lost please contact customer support.</li> </ol>
Base arms (U-Joint, Elbow Rest) are loose or wiggle when the cam handle is closed.	Refer to "Device Maintenance" section (pg. 55).
Elbow Rest is lifting on its own	Refer to "Device Maintenance" section (pg. 55).

The monitor arm is falling or
drooping when the device is
being used.

If any of these solutions do not correct the problem, or for any issue not discussed in the above table, please contact Titin KM Biomedical and we will work with you to provide a solution.

# **Warranty Information**

All new C1 devices are covered under a two (2) year warranty. Refurbished units are covered under a one (1) year period. This covers all mechanical and software aspects of the device as long as the device is used as stated in this User's Manual. Use of the C1 outside of designed intent, will void the warranty or covered maintenance agreement (ref. Customers MSA). If an issue arises with your device, please contact Titin KM Biomedical Corporation to have the issue resolved.

For customers under a <u>service contract</u> this does not apply, see contract details for device service and repair agreements.

Titin KM Biomedical Corporation

703 Bridger Drive - Unit B-3, Bozeman, MT 59715

PHONE: +1 (406) 219-1132

EMAIL: <a href="mailto:support@titinkmbiomedical.com">support@titinkmbiomedical.com</a>
## **General Specifications**

Electrical Specifications: 100-240 Vac, 1.5-0.6 A, 50-60 Hz. Device weight: 58 Lbs

<u>Footprint</u>: The device will need a minimum footprint of 4'x4' to operate. Max user weight: 350 Lbs

## Materials a User Could Come Into Contact With:

- ABS
- Acetal/Delrin
- Acrylic
- Aluminum
- Alloy Steel
- Brass
- $\circ \quad \text{Iglide R} \\$
- Neoprene
- Nylon
- Polycarbonate
- Polyester
- Polyethylene
- Polyurethane
- PVC
- SBR Rubber
- Spring Steel
- Stainless Steel
- TPE
- UHMW
- Zinc

## CALIFORNIA PROPOSITION

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. For more information: www.P65Warnings.ca.gov