EVJ™

User’s Manual

Original Instructions

This manual supports the BTE Technologies Evaluator, Model EVJ.
Instructions for use and technical description are included.

40090001 Revision B, CO 5545
Date of Publication: 2021-03-12

Manufacturer's Information

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WARRANTY

We guarantee that the BTE Technologies rehabilitation products are free of manufacturer defects in both workmanship and material. We will replace or repair defective parts or equipment for a period of time and in accordance with the conditions set forth below:

This warranty covers the structure and framework for 1 year of normal institutional use. All mechanical components including bearings, bushings, pulleys, and glides are warranted from manufacturer defects in both workmanship and material for a 1-year period under normal use.

This limited warranty is in lieu of all warranties, expressed or implied, and all other obligations or liabilities on the part of BTE Technologies. We neither assume nor authorize any person to assume any other obligation or liability in connection with the sale of this product.

Under no circumstances shall BTE Technologies be liable by virtue of this warranty or otherwise, for damage to any person or property whatsoever for any special, indirect, secondary, or consequential damage of any nature however arising out of the use or inability to use this product.

This limited warranty applies only while the BTE Technologies product remains in the possession of the original purchaser and has not been subject to accident, misuse, abuse, unauthorized modification, failure to follow instructional use, failure to do proper maintenance, incorrect adjustments, or failure due to cause beyond the manufacturer's control.

DISCLAIMER

The information presented in the manual is given in good faith and is to the best of our knowledge accurate. However, anyone who uses this information in any way does so entirely at his or her risk. Neither BTE Technologies its officers nor their representatives can accept any responsibility for any damage or injury incurred as a result of information presented here except under the terms of the product warranty.

CLASS A DIGITAL DEVICE

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Table of Contents

Section 1 – Safety and Regulatory Information

I. Warnings and Cautions

WARNING

The heart rate watch is not intended for use with clients that are in life-threatening circumstances or in a condition that precludes performing activities required for physical assessment.

WARNING

Do not modify this equipment without authorization of the manufacturer.

CAUTION

Portable Load Cell (PLC) and PLC attachments shall not be serviced while in use with a client. Inspections of these components shall be performed prior to use.

Electromagnetic Field Warning

The heart rate watch charger contains magnets that could affect pacemakers and implantable cardioverter defibrillators (ICDs). Consult physician or device manufacturer before using the watch.

II. Electromagnetic Interference

The Evaluator EVJ should not cause electromagnetic interference with any other equipment. The equipment needs to be placed into service according to electromagnetic compliance information provided in Appendix A of this manual.

The heart rate watch charger contains magnets that could affect pacemakers and implantable cardioverter defibrillators (ICDs). Consult physician or device manufacturer before using the watch.

III. Operating Voltage

5 VDC

IV. General Description

The Evaluator EVJ is an apparatus for measuring active range of motion of the joints of the extremities and spinal segments and isometric muscle strength.

V. Permissible Environmental Conditions

Permissible Environmental Conditions for Transport and Storage:

Ambient temperature: -20° C to +40° C
Relative humidity: 30% to 90%
Atmospheric pressure: 550 hPa to 1060 hPa

Permissible Environmental Operating Conditions

Ambient temperature: +10° C to +40° C
Relative humidity: 30% to 75%
Atmospheric pressure: 700 hPa to 1060 hPa

VI. Product Description, Use, and Applications Specifications

Product: Evaluator

Model: EVJ

Short Description

A portable measurement system for quantifying musculoskeletal strength and range of motion.

General Description

The Evaluator is a system used to assess physical capacity of specific human functions. The device is used to quantify muscle strength and range of motion as related to the performance of physical and functional tasks. The system can be easily transported from one location to another.

The system includes load cells, mechanical adapters for various applications, tool communication hardware, control module, software, heart rate monitor* (wrist watch), range of motion (ROM) equipment, and storage/transport cases. Calibration weights and fixtures allowing in-field calibration are also included.

** Heart rate monitoring is included to help clinicians decide whether the evaluation and testing needs to be terminated to reduce risks to the client's health. During physical demand analysis, heart rate monitoring provides a data point for determination whether the client gives the maximum effort. The device is not intended for use with clients that are in life-threatening circumstances or in a condition that precludes performing activities required for physical assessment.*

Intended Use

The Evaluator EVJ is intended to be used for musculoskeletal testing. Applications include occupational and physical therapy and industrial rehabilitation.

Intended Medical Indication

The system is intended to quantify muscle strength and range of motion of the spine and joints of the upper and lower extremities.

Contraindications

Contraindications for use include conditions where tensile strength of tissues and/or structures is compromised, i.e. healing bone fractures and tendon, ligament, and muscle repairs.

Intended Patient Population

General Population; anyone whose muscle strength or range of motion needs to be measured. There are no age, weight, or height restrictions.

Intended Anatomical Applicability

Evaluation of the musculoskeletal system.

Intended User Profile

Health professionals

Intended Conditions of Use

Office or clinic setting; The device can be taken by clinicians to employer sites or to a patient's home.

Frequency of Use

There is no frequency of use restrictions for this device.

Essential Performance

The device does not have any essential performance characteristics.

Essential Functions

- Provides means to measure muscle strength associated with push, grip, and pinch
- Provide means to assess range of motion
- Records data
- Saves results to a client record database
- Create reports presenting results and trending

Frequently Used Functions

Measurement of muscle strength and range of motion and reporting of those measures are the most frequently used functions of the device.

Use of Energy Source

An electric power source is required for system communication and computing purposes.

Transfer of Energy to Patient

There is no transfer of energy to the patient as the device is only used for measuring isometric forces and range of motion

Operating Principle

The Evaluator is a device that supplies a means for assessing strength, range of motion, and positional tolerances, through the use of a hand grip, pinch gauge, range of motion equipment, and push/pull equipment.

The device contains any combination of tools such as a hand grip, pinch gauge, portable load cell, goniometer, inclinometer, and Functional Range of Motion (FROM) Board. The Evaluator measures isometric push/pull forces applied to the tool by the client and the duration of time force is applied. The data collected allows the program to track a client's capabilities through multiple calculated variables. Reports are generated from a software program that can be used to evaluate a client's capabilities over single or multiple uses of the Evaluator.

Applied Parts

Evaluator EVJ applied parts include all tools, tool attachments, heart rate monitor, and the Bluetooth Hip Unit (BHU). All applied parts are type B.

Performance Characteristics

Hand Grip has the capability to measure push forces in range of 1 lb. to 200 lbs. (+/-0.75 lb.)

Pinch Gauge has the capability to measure push forces in range of 1 lb. to 45 lbs. (+/-0.2 lb.)

Portable Load Cell (PLC) has the capability to measure push and pull forces in range of 1 lb. to 300 lbs. Tolerances are: +/-0.75 lb. in 1 - 100 lbs. range and +/-2 lbs. in 101 - 300 lbs. range.

Goniometer has the capability to measure 0 to 360 degrees of movement in 1 degree increments (+/-3 degrees).

Inclinometer has the capability to measure 0 to 360 degrees of movement in 1 degree increments (+/-1 degrees).

Heart rate system allows for constant and real time monitoring during testing. The system measures the heart rate in beats per minute and functions within 33 feet of the BHU.

VII. Basic Safety Testing

There are no tests that have to be performed in the field to ensure basic safety other than preventative inspection described in the Troubleshooting and Maintenance section.

VIII. Servicing

No parts shall be serviced or maintained while in use with a patient.

Upon request, BTE will provide circuit diagrams, component parts lists, descriptions, calibration instructions, or other information to assist service personnel to repair parts.

IX. Connections

Hosting Device	Port	Connected Device
Control Module	USB	Bluetooth Dongle
BHU	RJ45	Tools

X. Environmental Protection

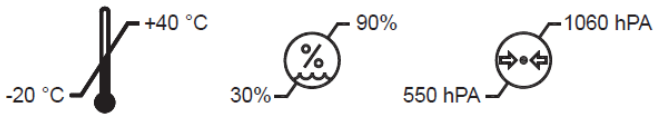
At the end of the equipment service life, dispose the device components in accordance with all local state and federal laws for electronics recycling.

XI. Markings

A. Explanation of Symbols and Certification Markings

Manufacturer		Temperature Limit	
Authorized Representative in the European Community		Humidity Limitation	
Catalogue Number (Product and Model Number)		Atmospheric Pressure Limitation	
Serial Number		CE Conformity Marking	
Certification Mark		Medical Device	

B. Caution and Warning Markings on Equipment

Electromagnetic Field	
Follow Instructions for Use	
General Warning Sign	
Type B Applied Part	
Do Not Modify Equipment	**WARNING**: Do not modify this equipment without authorization of the manufacturer.
Direct Current	⎓ **--- --- ---**
Permissible Environmental Conditions for Transport and Storage	

XII. Instructions for Incorporating EVJ Into IT Network

Definitions

EHR Electronic Health Records

HL7 Health Level Seven International - A not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information

Responsible Organization Entity accountable for the use and maintenance of a medical electrical equipment or a medical electrical system

Your EVJ could have the capability to be connected to an IT network to electronically send evaluation and/or test results to the intended recipient. Results (bare reports) can be communicated via HL7 to EHR systems. The device is not intended to receive any input from an IT network.

The networking characteristics must be any network that conforms to IEEE standards, and is capable of communicating with Windows based devices. The configuration can be any configuration compatible with Windows based devices.

Technical specifications include an IPv4 or IPv6 network controlled by some form of DHCP and an accessible Gateway and DNS server.

IT network failure will prevent sending evaluation and/or test results via the network to the intended recipient. Results are saved on the system control unit.

Connection of the EVJ to an IT network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

The Responsible Organization should identify, analyze, evaluate and control these risks.

Subsequent changes to the IT network could introduce new risks and require additional analysis.

Changes to the IT network include:

- Changes in the network configuration
- Connection of additional items to the network
- Disconnecting items from the network
- Update of equipment connected to the network
- Upgrade of equipment connected to the network

XIII. Information Regarding EC Declaration of Conformity

BTE Technologies has issued the EC Declaration of Conformity declaring that the Evaluator, Model EVJ meets the provisions of the European Union medical device regulations and applicable directives. The declaration may not apply to each unit.

Product information in regard to the Medical Device Directive 93/42/EEC:

Manufacturer	BTE Technologies 7455-L New Ridge Road Hanover, MD 21076 USA Telephone: 410.850.0333 www.btetechnologies.com
Product Identification	**Product Name:** Evaluator **Model:** EVJ
Device Classification	Class I Rule 12
Route to Compliance	Annex VII of the Medical Devices Directive
Intended Purpose	The Evaluator EVJ is intended to be used for musculoskeletal testing. Applications include occupational and physical therapy and industrial rehabilitation.
Authorized Representative	Emergo Europe Prinsessegracht 20 2514 AP, The Hague The Netherlands

A copy of the EC Declaration of Conformity can be obtained by sending a written request to BTE at the address above.

Notice to Customers Located in the European Union

Emergo Europe is BTE Technologies' Authorized Representative in the European Union as noted in section "Information Regarding EC Declaration of Conformity". The Authorized Representative's function is described in the Council Directive concerning medical devices. BTE Technologies Customer Service is your point of contact for technical support.

Section 2 – Hardware Setup

I. Introduction to the EVJ

The EVJ is a scalable mobile evaluation system that provides clinicians with the ability to perform testing not only in the clinic but offsite. Offsite usage can include employer locations, research/educational institutions, or a patient's home. The system can be used to measure strength and range of motion.

The tools available to you are dependent upon the package purchased. Available Packages are:

Hand Grip Package, which is the base package includes:

the BTE Hand Grip, Heart Rate Monitor, Bluetooth Hip Unit and dongle/transmitter, RJ45 cables, and a control module with the EVJ software programs.

Strength Package which includes:

the Portable Load Cell and various attachments and Pinch Gauge.

Range of Motion Package which includes:

a Dual Inclinometer and Goniometer and varying length arms.

Additionally, all hardware required for calibration and/or verification of the tools with load cells is provided in each appropriate package as shown.

A. Hardware Setup and Preparation

In preparation for hardware setup, remove the control module, Bluetooth Hip Unit (BHU), Bluetooth dongle, Heart Rate System, Hand Grip, verification weight and fixture, and all cables and cords.

1. Setup of Control Module and Associated Hardware

(includes BHU, Bluetooth dongle, Heart Rate System)

Fully charge the batteries as they are not charged prior to shipping. Refer to the manufacturer's instructions regarding use of the charger and batteries.

Prepare the control module by connecting power cord to control module and power source. Once the control module is powered on, insert the BHU dongle into an available USB port of control module.

Plug the Heart Rate USB charger into a USB port of the control module. Attach the watch to the charger. **Do not use the HR watch dongle**; the BHU dongle will detect the watch. Refer to the manufacturer's instructions regarding setup and use of the HR system.

Once the 2 batteries are fully charged, insert them into the BHU.

2. Establishing Tool Communication within the EVJ Software

(refer to *Figure 1* – Tool Calibration window)

Using the icon on the Desktop, now open the EVJ software 

. From the Hamburger Menu (upper left corner of window), select Tool Calibration. Be sure the BHU is powered on and check that the communication symbol is green. Proceed to connect the Hand Grip to the BHU and verify its communication with the software. When connected, red icons associated with the tool will turn green. Proceed to verify the Hand Grip Tool.

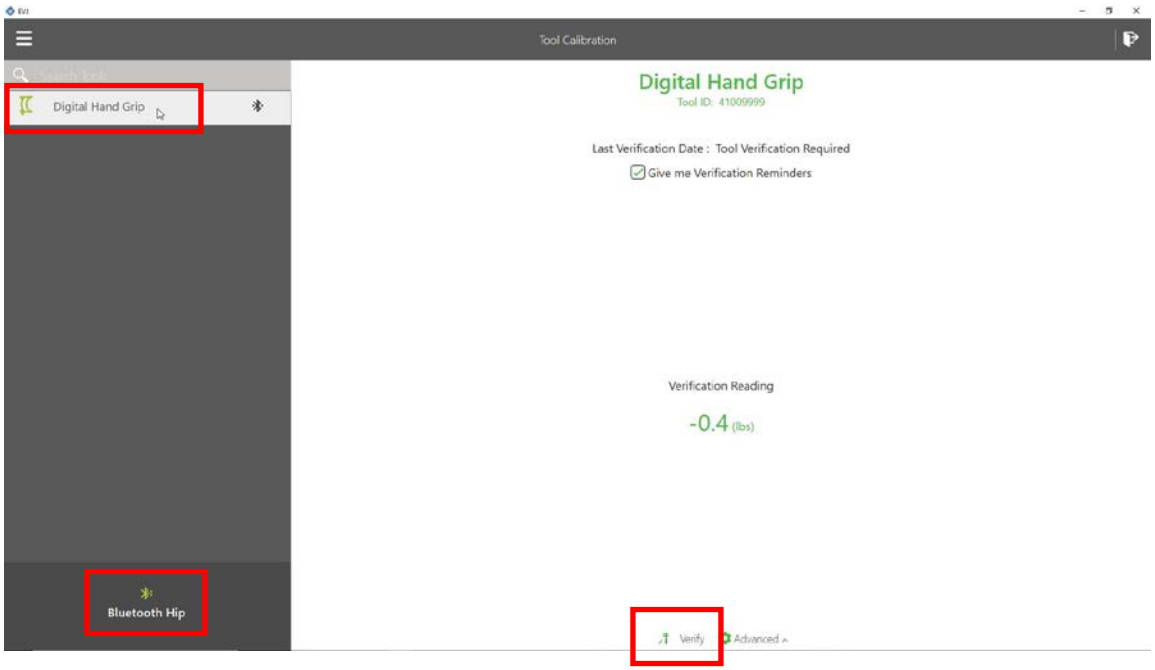


Figure 1

IMPORTANT NOTE:

Be aware that should additional packages be purchased, the associated tools must also be configured in order for the EVJ software to communicate with them. The BTE Tool Suite is used to discover and configure those tools (Portable Load Cell, Pinch Gauge, Dual Inclinometer, and/or Goniometer). Refer to II. BTE Tool Suite, page 17 for related instructions. Upon completion of this task, proceed with calibration and/or verification of the tools.

3. Tool Calibration and Verification

The calibration and verification processes are performed to ensure the accuracy of the load cell readings of tools. Prior to first use, each tool must be calibrated and/or verified.

To calibrate and/or verify the tools, refer to the instructions provided in the software as they will walk you through the process for each tool. In general, you will place a tool into the required housing/block and/or attach appropriate fixture. This is followed by placement or attachment of designated weight fixture. Place requested weight on to the weight fixture. The software will indicate whether the tool passed or failed calibration and/or verification.

Should calibration and/or verification fail,

- check that correct weight is being used
- remove weight and check that tool is set up correctly using the appropriate block and/or fixture(s). Then proceed through same process shown on screen.

a. Tool-specific Calibration and Verification Information

Hand Grip –

Calibration of the Hand Grip is performed at the factory. Therefore, verification only is necessary in the field. To verify the Hand Grip is measuring accurately, go to Tool Calibration which is found in the Hamburger Menu (upper left corner of Client Records window). Be sure the BHU is powered on. Connect the Hand Grip to the BHU using an RJ45 cable. The Hand Grip tool icon will turn green once connection is established. Click on the tool name, in this case Hand Grip. Information about Hand Grip will appear on the screen including: *(Figure 2)*

Tool ID

Last Verification Date

Give me Verification Reminders (with check box)

Live Verification Reading

To initiate the Verification process, click on the Verify icon located at the bottom of the window *(Figure 1)*. **Remove handle(s) from the hand grip** and proceed to set up the Hand Grip as shown on screen. In general, you will place the Hand Grip into the circular base and then place the 5 lb./ 2.27 kg weight fixture on to the posts of the tool *(Figure 2a)*. The Verification Reading will indicate whether the tool passed or failed *(Figure 2b)*. If it passes, click the Save button.

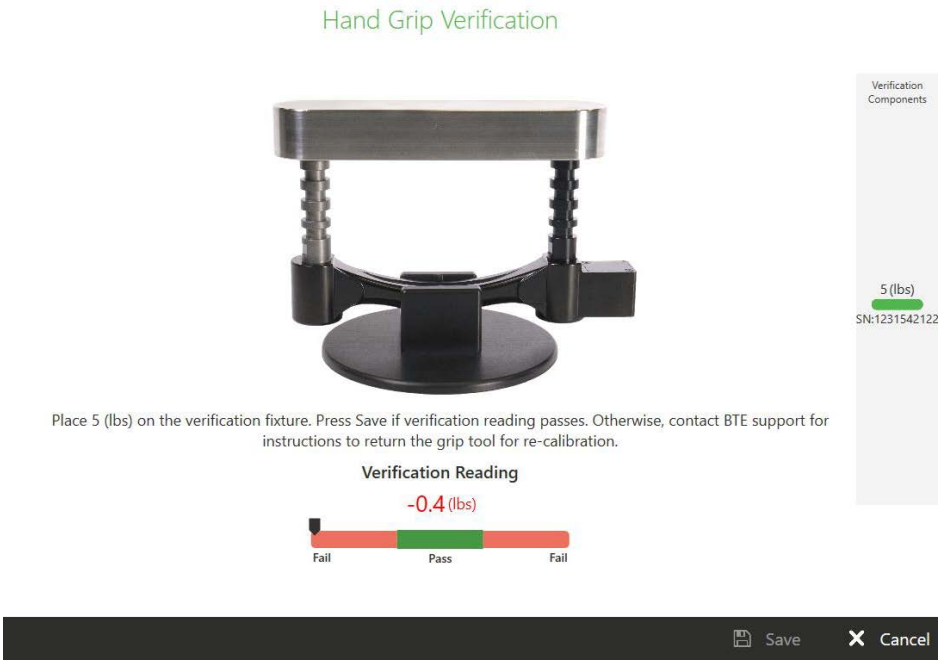


Figure 2a

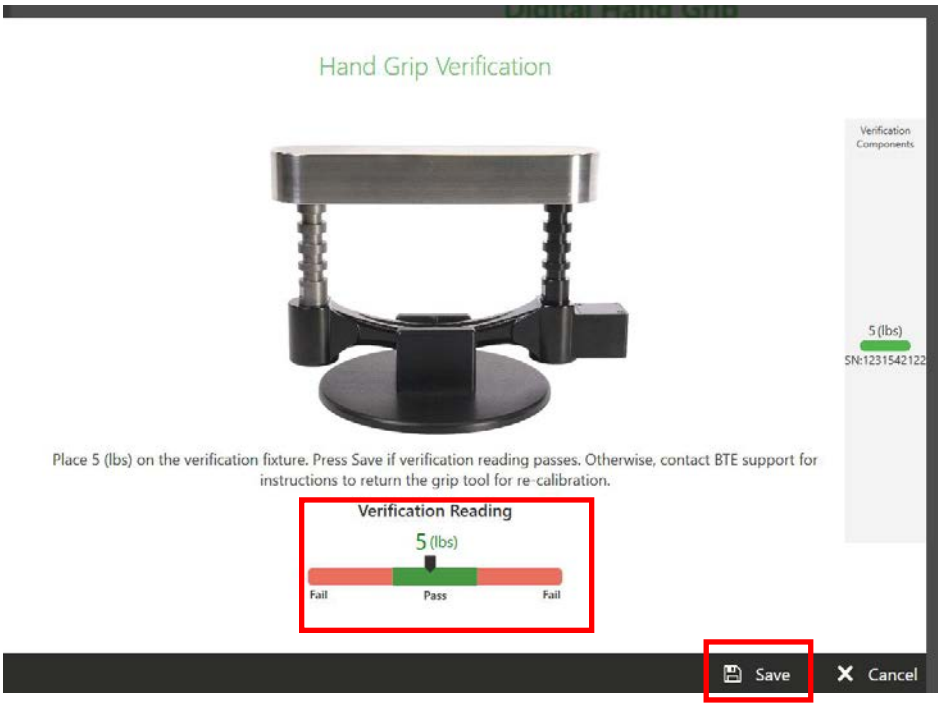


Figure 2b

Failure to Verify

Should the Hand Grip fail verification, check that the tool is firmly seated in the base. Remove and then replace the weight making sure it is fully loading the posts. If you have followed these steps and still cannot get the Hand Grip to pass verification, contact BTE Technologies.

Portable Load Cell (PLC) and Pinch Gauge -
Both calibration and verification of these tools are performed in the field. Should you purchase these tools, it will be necessary to calibrate them prior to use. After the initial calibration, only verification is needed. Should a tool not pass verification after two attempts, recalibration will be required.

For calibration and verification, go to Tool Calibration located in the Hamburger Menu. Be sure the BHU is powered on. Connect tool to the BHU using an RJ45 cable. The tool icon should turn green once connection is established. Click on the tool name. Information about that tool will appear on the screen including:

Tool ID

Last Calibration Date

Last Verification Date

Option to get Verification Reminders

Live Verification Reading

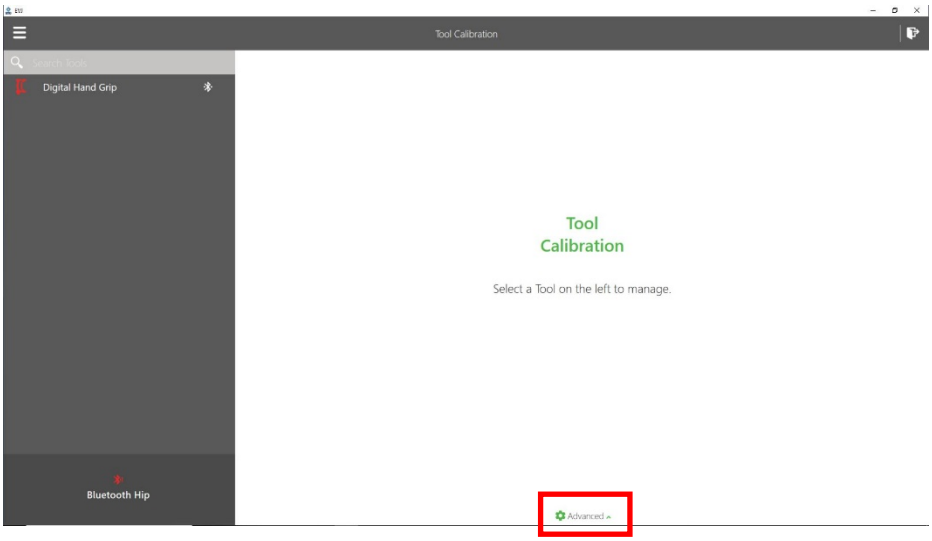


Figure 3

To calibrate and verify the PLC and/or Pinch Gauge, click the Advanced icon to access the tool specific instructions (*Figure 3*). Select the Calibrate icon located at the bottom of the window and then proceed to follow the instructions that appear on screen. The process will be described across 4 windows:

#1 shows initial setup of tool and calibration fixture and where zero weight is established *(Figure 4a)*

#2 shows placement of the weight fixture *(Figure 4b)*

#3 provides instruction related to the weights to be placed on the weight fixture; this is the calibration step in the process *(Figure 4c)*

#4 provides instruction related to the weight to be placed on the weight fixture; this is the verification step in the process *(Figure 4d)*

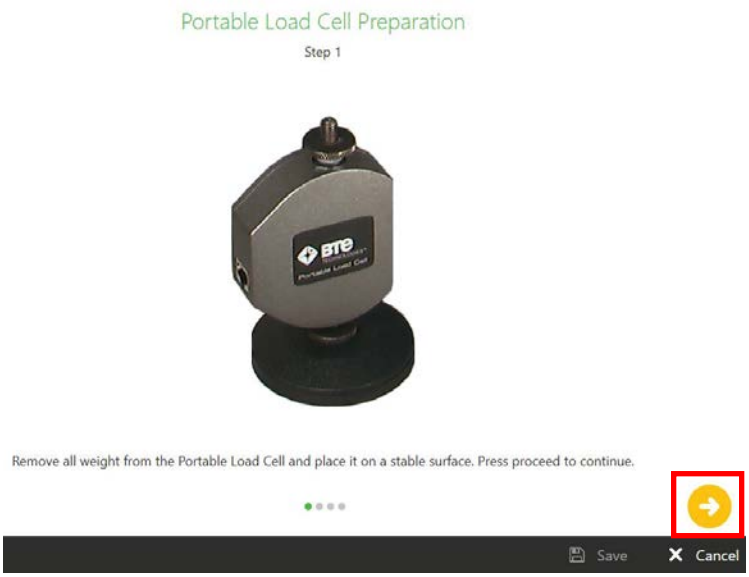


Figure 4a

Figure 4b

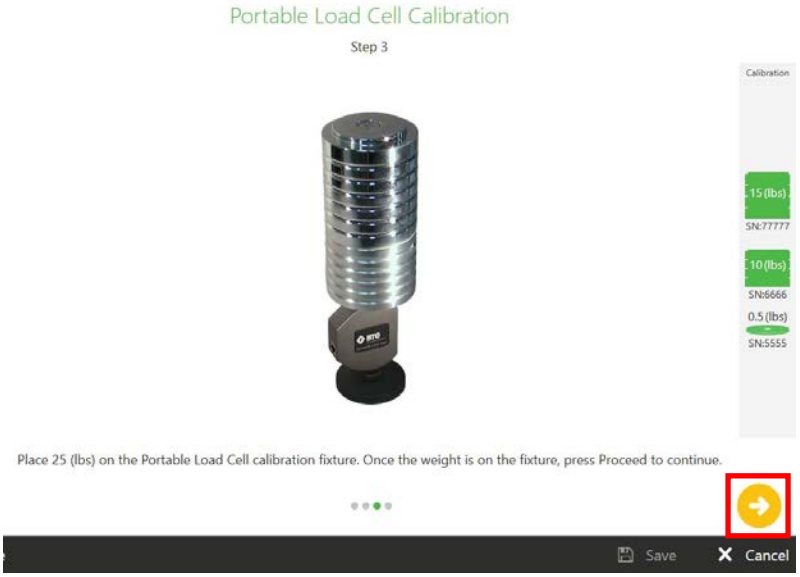


Figure 4c

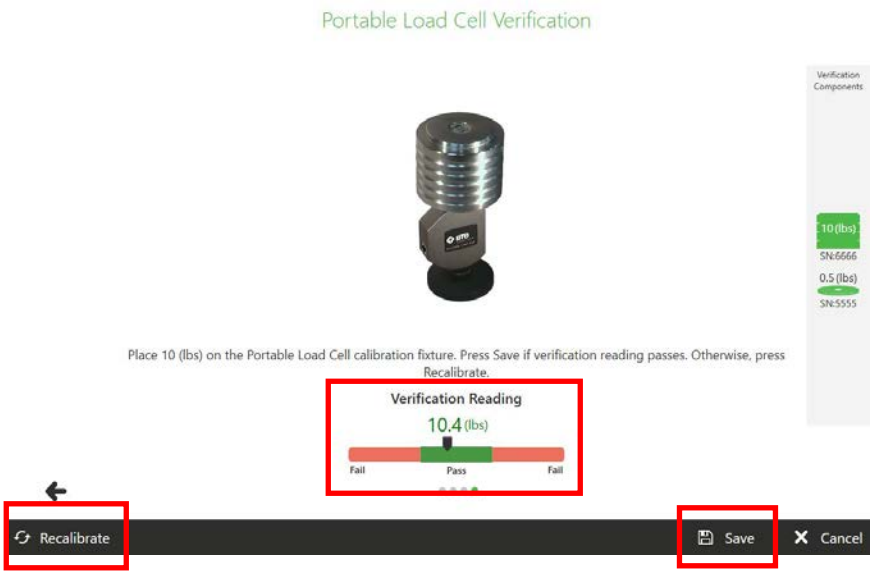


Figure 4d

At Step 4, the Verification Reading will indicate whether the tool passed or failed. If it passes, click the Save button.

To verify only, click on the Verify icon located at the bottom of the window *(Figure 5)*. Follow the instructions provided on screen. In general, you will place the tool into the required housing and/or attach appropriate fixture(s). Place requested weight on to the weight fixture. The software will indicate whether the tool passed or failed verification.

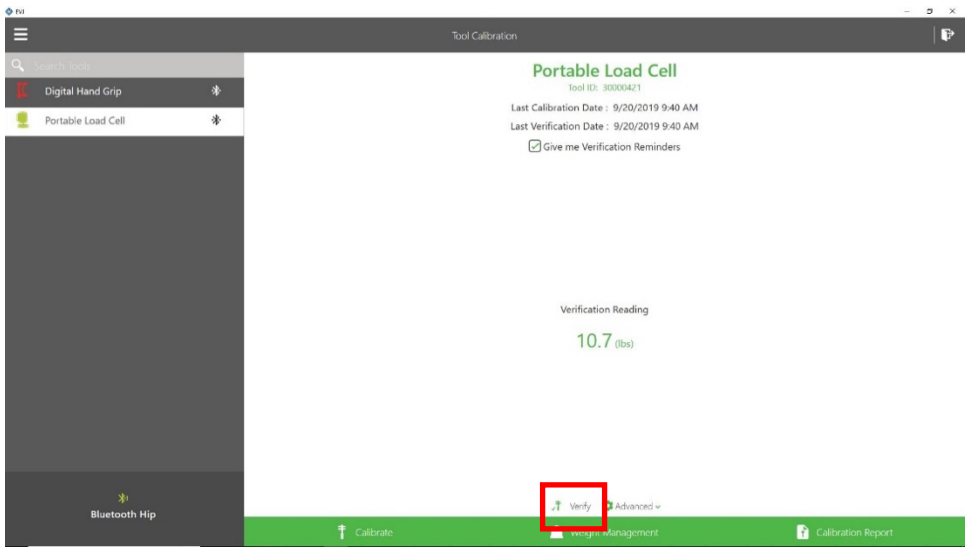


Figure 5

b. Unable to Calibrate or Verify

If you are having trouble completing calibration or verification of the Portable Load Cell, review the troubleshooting information below.

If calibrating tool:

- Ensure that the tool is placed on a sturdy and level surface during calibration and/or verification.
- Make sure the calibration disk is not on the tool for the first step of the calibration process.
- At Step 4, remove the weights from the calibration disk before placing the verification weight on the disk, allowing the load cell of tool to return to a minimal weight.
- Click on Recalibrate (found at lower left corner of verification step window) and repeat all steps but wait 3 seconds between applying the weight and clicking on the Proceed button.
- Specific to the PLC, make sure to attach the Round Pad to the interface screw and place the Round Pad on the table. The calibration disk should be attached to the permanent screw.

B. Introduction to Available Tools and Devices

1. Hand Grip Dynamometer

Introduction

The Hand Grip Dynamometer, also known as the Hand Grip, is used to measure hand grip strength up to 250 lb./113 kg. Through the use of multiple attachment points and protocols, a client's hand grip strength can be evaluated for safe, maximum force capacity, comparison to available comparative/normative data, and consistency of effort.

Hand Grip Handles

The Hand Grip comes with 2 different handles, the concave (gray) and convex (blue) *(Figure 6)*. The concave grip is used for all standardized hand grip tests and may be used for custom tests. The convex grip is provided to simulate custom applications and can also be used as a handle for the user in order to provide support of the tool and guide the pace of alternating repetitions during testing.

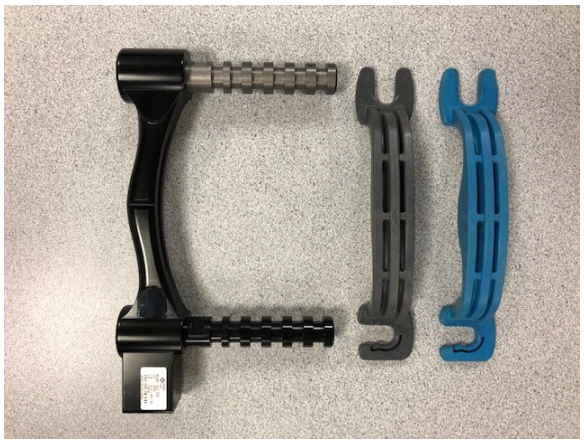


Figure 6

Note: The concave grip handle is asymmetrical in thickness. To correctly attach the concave handle to the hand grip posts, ensure the U-shaped connector is attached to the black upper

post and the C-shaped connector is attached to the grey bottom rung (the end that has the RJ45 port). The convex grip is symmetric, so it may be positioned in either direction.

Hand Grip Positions

The Hand Grip was designed such that the detachable grip handle may be located in 5 different positions. Be sure to read each protocol to determine in which position the grip must be.

Note: Position 1 is closest to the Hand Grip base.

Note: Position 6 is unique to the BTE Hand Grip. The primary use is to provide attachment point for the convex handle which permits the user to support and transfer tool from side to side during testing.

Utilizing the Hand Grip Dynamometer

Connect the Hand Grip to the BHU via the RJ45 cable. If you are at a test window, check that tool connection icon is green. If not at test window, you may also go to Tool Calibration to check status.

Identify the appropriate rung position for the concave handle. The Setup Notes that accompany the pre-programmed Hand Grip Tests (5-Rung and Rapid Exchange Grip Protocol and the Hand Grip – Three Trials Position 2 Test) provide that information. Apply concave grip handle in correct orientation; U-shaped connector at top and C-shaped connector at base of hand grip.

2. Portable Load Cell (PLC)

Introduction

The Portable Load Cell's primary use is to measure push and pull forces up to 500 lb/227 kg. Some of the applications of the Portable Load Cell (aka PLC) are manual muscle testing, task specific strength testing, documenting point tenderness, and determining the forces required for specific tasks at the workplace or at home (physical demands analysis).

Available attachments and accessories are shown below *(Figure 7)*. Attachments include: Straight Bar Handle, D-Handle, Round Handle Round Pad, Concave Pad, Rectangular Pad, Small Square Pad. In addition, several accessories are provided to help simulate tasks including Narrow Corner, Wide Corner, Snap, and Extension Bar. Lastly, the 1/2" wrench that is provided with the system can be used to tighten and loosen the nut on the interface screw.

Figure 7

Setting up the PLC

For Manual Muscle Testing – attach Round Pad, D-Handle, or Straight Bar Handle to the base of the PLC via the Interface Screw and the Concave Pad to top (tool/client interface) *(Figure 8)*. If necessary, tighten the knurled nut onto the base attachment to increase stabilization.

Figure 8

For Point Tenderness – attach the Round Pad to the base of the PLC and the Small Square Pad to top (tool/client interface). *(Figure 9)*

Figure 9

For Task-specific testing– for example:

Push – attach Straight Bar, Bilateral Bar, D-Handle, or Small Round Handle to the base of the PLC and the Round Pad, Narrow Corner, Wide Corner to top in order to adequately interface with object to be pushed *(Figure 10)*.

Pull - attach Straight Bar, Bilateral Bar, D-Handle, or Small Round Handle to the base of the PLC and the Snap connector to the top. Snap connector can then be anchored to object to be pulled *(Figure 11).*

Figure 10

Figure 11

Utilizing the Portable Load Cell

Connect the PLC to the BHU via the RJ45 cable. If you are at a test window, check that tool connection icon is green. If not at test window, you may also go to Tool Calibration to check status.

Identify the appropriate attachments and accessories based on test/task to be measured. **Be sure they are securely affixed to the PLC.**

3. Pinch Gauge

Introduction

The Pinch Gauge *(Figure 12),* also known as the Pinch Dynamometer, is used to measure finger strength up to 50 lb/23 kg.

Figure 12

Utilizing the Pinch Gauge

Connect the Pinch Gauge to the BHU via the RJ45 cable. If you are at a test window, check that tool connection icon is green. If not at test window, you may also go to Tool Calibration to check status.

4. Dual Inclinometer

Introduction

The Dual Inclinometer is used to evaluate range of motion while allowing for sections to be tested in isolation. This is accomplished by a sensor in each Inclinometer side which calculates the rotational displacement, and then subtracting or adding the two values to arrive at a true range of motion value.

The Dual Inclinometer is comprised of two sensors: the master and the remote *(Figure13)*. The master side is identified by the button switch on the front side. In addition, the master side is connected to the BHU via an RJ45 cable. A link cable then connects the remote to the master. Depending on the testing situation, you may choose to use the master side alone or use both Inclinometer sides together.

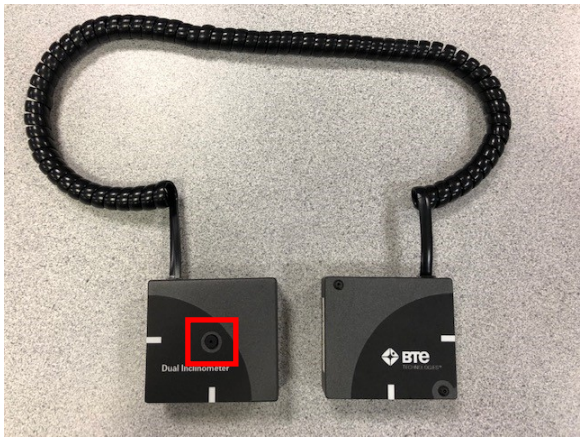


Figure13

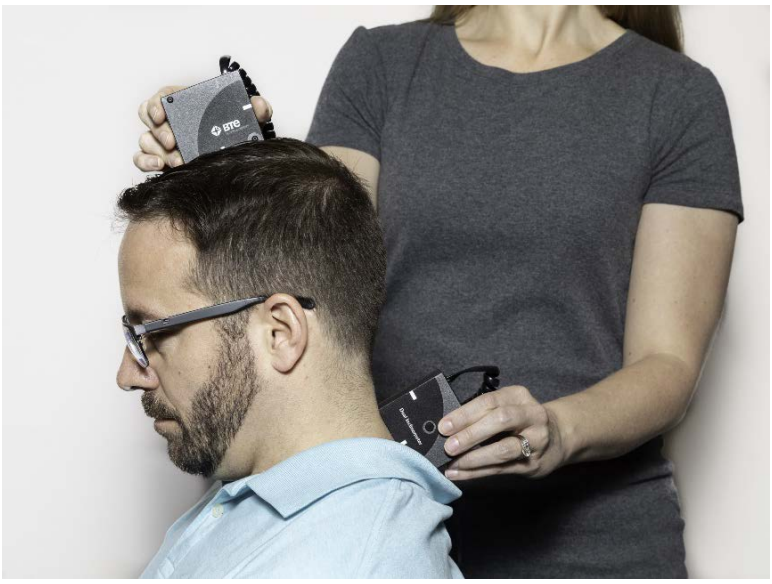


Figure14

Note that whenever you are testing with the Dual Inclinometer, the sides must always be positioned in the same plane (as shown in Figure 14). The sensors are not able to accurately measure the change in angle if the sides are not properly facing each other.

Utilizing the Dual Inclinometer

Connect the master inclinometer to the BHU via the RJ45 cable. If you are at a test window, check that tool connection icon is green. If not at test window, you may also go to Tool Calibration to check status.

Determine if measurement to be taken requires use of both sides or only one (the master side) and proceed accordingly. For compound joint movement, use both Inclinometer sides by placing one side distally and one side proximally to the joint being assessed. Be sure no other joints are involved in the compound movement and make certain to align the sides in the plane of movement. For isolated joint movement, use a single Inclinometer side by placing it distally in the plane of movement of the joint being assessed.

Collecting Data

The Dual Inclinometer is most useful in its ability to measure spinal range of motion. The most common evaluations are related to the cervical spine, thoracic spine, lumbosacral spine, sacral hip flexion/extension, gross combined hip and spinal flexion/extension, and straight leg raise.

The inclinometers are used to capture the start point and end point of the available range of motion; in other words, they measure the arc of motion demonstrated by the client. Therefore, a motion is measured by pressing the button on the master inclinometer at the beginning point of the range or arc of motion and then again at the end point of the range or arc of motion.

5. Goniometer

Introduction

The goniometer is the recognized standard tool for measuring range of motion of joints of the extremities.

The BTE Goniometer tool uses a sensor to calculate the amount of displacement in degrees and arrive at a true range of motion value.

Included with the Goniometer are three different types of arms: 2 short arms, 1 medium arm, and 1 long arm (*Figure 15).* The various lengths of arms facilitate the measurement of the range of motion of smaller joints, such as in the hand and foot, as well as larger joints, such as the knee, hip, and shoulder *(Figure 16).*

Figure15

Figure16

Utilizing the Goniometer

Connect the goniometer to the BHU via the RJ45 cable. If you are at a test window, check that tool connection icon is green. If not at test window, you may also go to Tool Calibration to check status.

Determine which combination of arms (short, medium, or long length) are appropriate for the joint to be measured and attach to goniometer. The arms are screwed into the top of the goniometer so they may be easily removed and attached. Make sure they are tight once screwed in.

Collecting Data

The goniometer is used to capture the start point and end point of the available range of motion; in other words, they measure the arc of motion demonstrated by the client. Therefore, a motion is measured by pressing the button on the goniometer at the beginning point of the range or arc of motion and then again at the end point of the range or arc of motion.

6. Bluetooth Hip Unit (BHU) and Bluetooth Dongle

The Bluetooth Hip Unit (BHU) serves as a transmitter of data. With a tool attached, the BHU captures the data from the tool and transmits it to the receiver which is the Bluetooth dongle. The data is then captured by EVJ software.

There is no on/off switch for the BHU. It will automatically turn on if moved and will shut off after period of no movement. Since it uses rechargeable batteries. It is best to keep spare batteries in the charger and put fresh batteries in the BHU each day.

7. Heart Rate Monitor/Watch

The Heart Rate (HR) System is comprised of the HR monitor watch and USB Bluetooth 4.0 low energy radio adapter (the dongle). Additional item includes the USB charging adapter that comes with the watch. **The Bluetooth (dongle) of the HR system is not needed as the dongle associated with the BHU will recognize the watch.**

The watch uses two green LEDs and an electro-optical cell which are integrated into the back plate of the watch. The LEDs shine light into the skin, which enables the electro-optical cell to detect the pulsing volume of blood flow.

Electromagnetic Field Warning

The heart rate watch charger contains magnets that could affect pacemakers and implantable cardioverter-defibrillators (ICDs). Consult physician or device manufacturer before using the watch.

Using the Heart Rate System

Step 1. Fasten the HR watch snugly on your arm above, not on, the wrist bone.

Note: Wear it higher on the forearm if you have a small wrist.

Step 2. Press and hold the HR button until the watch beeps and the display says FIND.

Step 3. Hold your arm still until the watch beeps again and displays heart rate.

Notes:

1) It takes a few seconds for heart rate to register.
2) With proper fit, there should be no visible light between the watch and skin. Make necessary adjustments in fit.

Refer to the manufacturer's Quick Start Guide and Warranty and Regulatory booklet for additional information related to set up and use of the HR system.

II. BTE Tool Suite

The function of the BTE Tool Suite is to configure which tools can communicate with the software. Once configured, the software only recognizes and communicates with those tools.

Tool Configuration is required only if Hand Grip is replaced and/or other package(s) are purchased.

A. How to Configure Additional Tools

Prior to using additional or replacement tools, it is necessary to configure those tools. Doing so allows the EVJ software to communicate with them. The BTE Tool Suite is used to discover and configure the tools. The following instructions will take you through this process.

Locate the BTE Tool Suite icon on the Desktop 

and open that program.

Figure 17

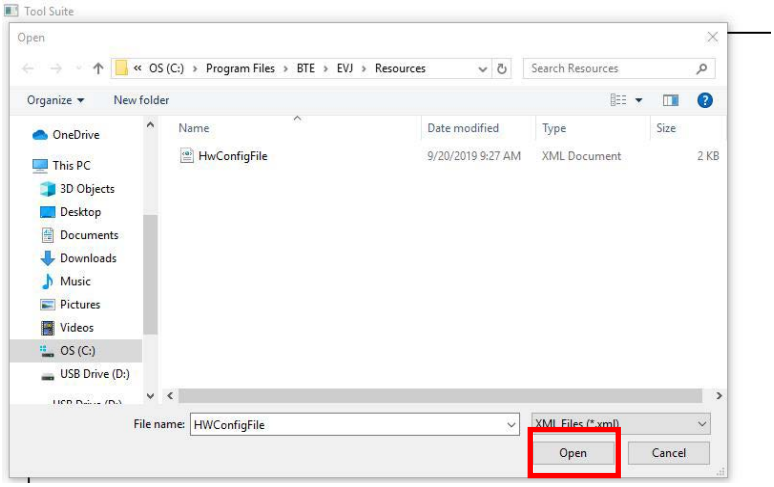


Figure18

Open the Hamburger Menu and select ‘Load Configuration’ *(Figure 17)*. Select the current hardware configuration file ‘HwConfigFile” and click Open *(Figure 18)*.

The BHU/transmitter, dongle/receiver, and Hand Grip information will be displayed *(Figure 19)*. Activate/Power on the Bluetooth Hip Unit (BHU) by simply moving it (there is no ON/Off switch). Proceed to attach the new tool to the BHU using a RJ45 cable. Click the Discover button. The software will search for the tool and once discovered, the tool icon and ID will appear in the window. After adding newly acquired tools, click the Hamburger Menu icon in the upper left corner of the window and click ‘Save Configuration’ (refer to Figure 17).

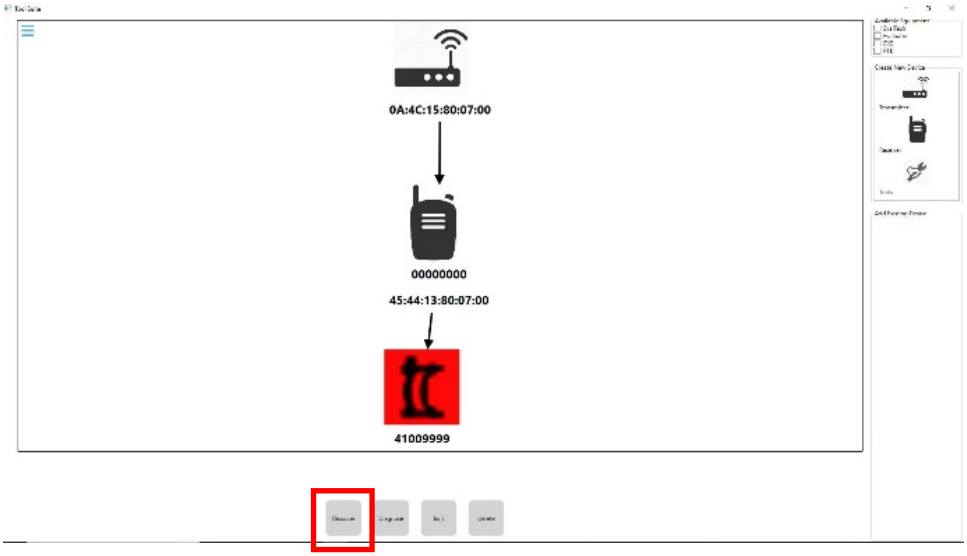


Figure 19

Then select the Exit option from the Hamburger Menu or use Close icon to close the BTE Tool Suite.

B. Editing the Saved Tool Configuration

Should a tool replacement ever be necessary, the replacement tool must be discovered, and the Configuration file saved. The existing tool can remain or may be deleted from the configuration file. To change a tool, go to the BTE Tool Suite. Open the Hamburger Menu and select ‘Load Configuration’. From the tool configuration presented, choose the tool to be replaced and click Delete button. Connect the replacement tool to BHU, click the Discover button, and wait for the software to add it to the existing configuration. Once recognized, return to the Hamburger Menu and select ‘Save Configuration’. Click Yes when asked if you want to replace the existing file and then exit the BTE Tool Suite.

Likewise, should you acquire additional tools through the purchase of the Strength and /or Range of Motion Package(s), follow the above instructions. Additionally, the new tools will require entry of licensing keys in order to be recognized by the EVJ software. Refer to Section 7 - Global Management – Settings – License Manager for instructions related to that process.

Section 3 – Overview of Software

I. Software Navigation

The user interface of the EVJ software consists of various elements. Navigation through the software is primarily icon driven. Input controls include checkboxes, radio buttons, dropdown lists, buttons, toggles, text fields, and data fields. Additionally, colors are used to indicate that you are working at the global or administrative level versus the client level.

A. Color Scheme

To assist your navigation through the software, be aware that the color blue indicates that you are working at the Client Level. More than likely, you are creating a new client or have selected an existing client and are moving through testing and reporting areas of the software.

The color green is indicative of working at the Global Level where administrative functions are managed. For example, choosing settings for the software, creating and/or editing tests, and generating global reports to name a few of those functions.

The color orange is used to denote reporting functions at both the Global and Client levels.

B. Buttons and Icons

The following information will familiarize you with the most commonly used buttons and icons. Some are labeled and are therefore self-explanatory, and some are not. Below is a list of unlabeled buttons and icons within the software:


Add / Create New


Edit


Cancel and Close


Proceed


Go Back


Return to Client Records


Hamburger Menu


List


Client


Test


Global Reports


Client Reports

Range of Motion

Strength

State of communication of tools (red, green)

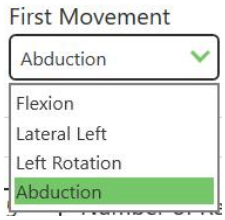
*Note that buttons and icons specific to one topic only will be presented with that content in subsequent Sections.

C. Input Controls

Input Controls used in the software include:

checkbox – click to select and deselect

radio button – click to choose option, function



dropdown list – choose from pre-populated options

text field – place cursor in field and enter appropriate information

II. Primary Access Points

The Client Records window serves as the ‘home page’ of the software. The two primary access points for the software are available here. They are the Hamburger Menu located in the left upper corner and the Client List located in the upper right corner of the window.

A. Hamburger Menu

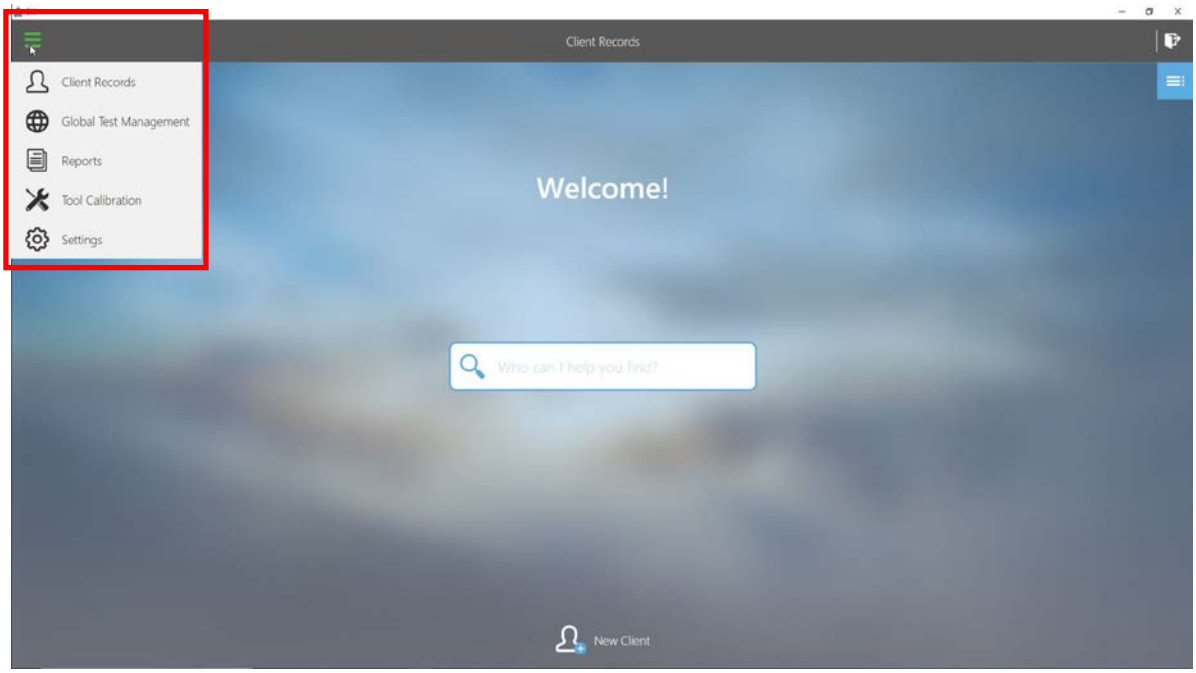


Figure 1

The Hamburger Menu provides access to the administrative options in the software (*Figure 1)*.

These include:

- Client Records
- Global Test Management
- Reports
- Tool Calibration
- Settings

B. Client Options

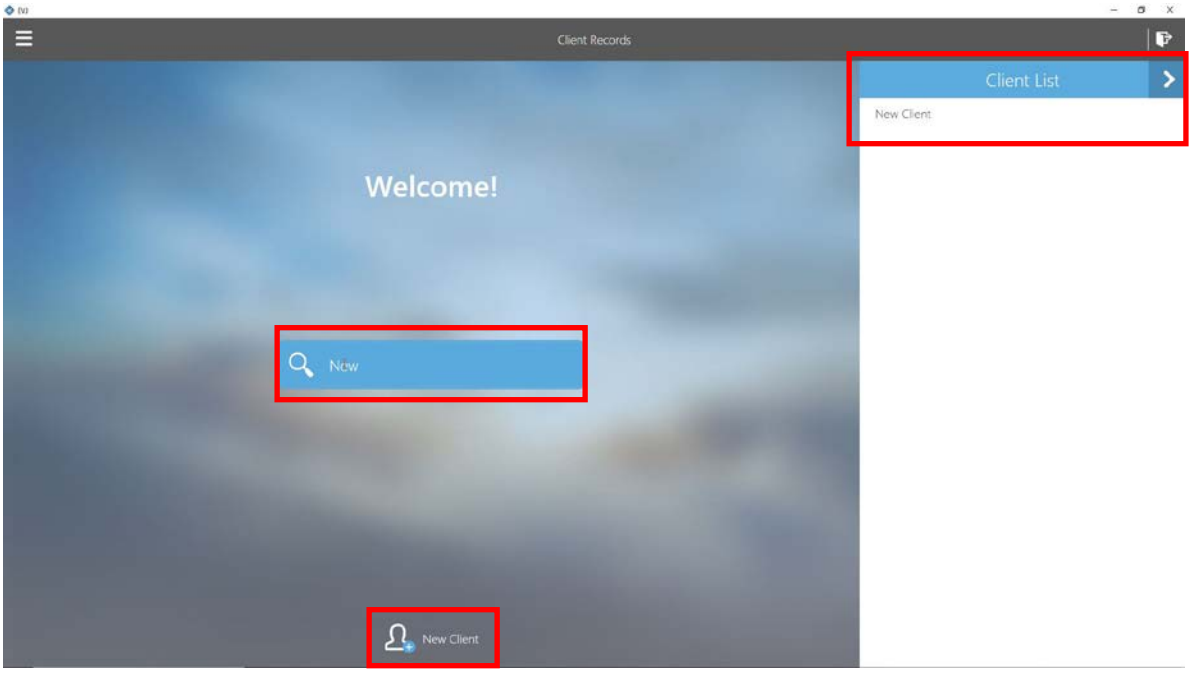


Figure 2

There are several options that provide access to client information.

Access to Clients include *(Figure 2)*:

Adding New Client

Choosing Existing Client using the List or Search options

These options will be discussed in Section 4 – Getting Started.

Section 4 – Getting Started

I. Software Setup

In preparation for using the software, there are several recommendations to offer. First, select the language and the units of measure for the software in the “Settings” section (*Figure 1*). Next, create basic tests you plan to use. These can include range of motion (ROM) and strength tests.

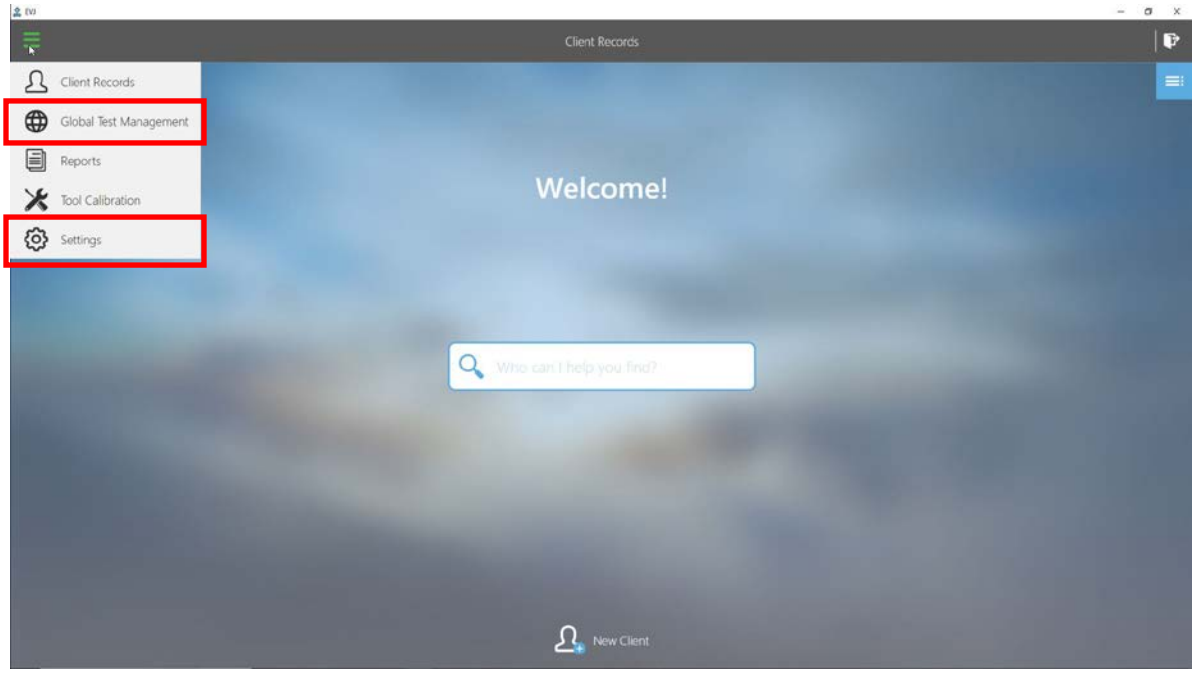


Figure 1

A. Settings

Ensure the language and units of measure selections are appropriate for you. To do so, open the Hamburger Menu and select Settings.

1. Language

Choose the Language option and select desired language, English or Japanese. Save your selection.

2. Units

Click the Back button to return to the items in the Settings list and select Units. Choose the units of measure you wish to use, Imperial or Metric. Save your selection.

B. Global Test Management

Next, it is suggested that you begin to create or build your Test Lists. To do so, open the Hamburger Menu and select Global Test Management (*Figure 2*). There are 3 lists – Strength, Range of Motion, and All (Tests).

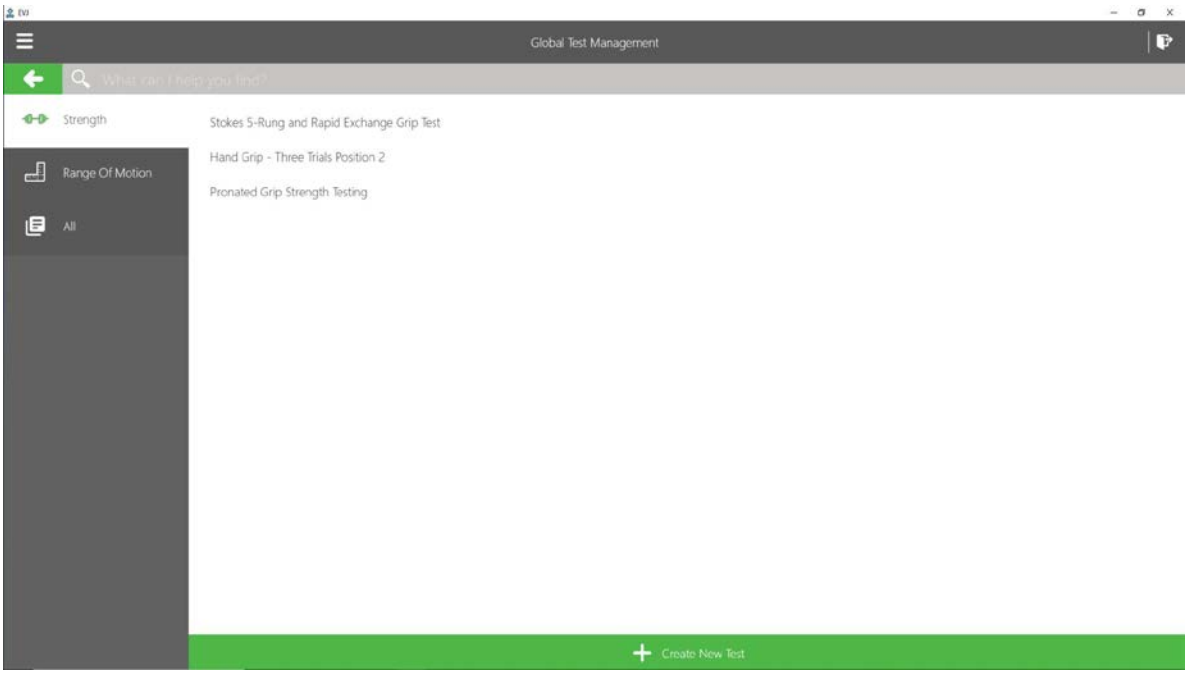


Figure 2

The pre-set Strength Test List contains one protocol and one single test. All are referenced hand grip tests. The protocol consists of two tests, 5-Rung Hand Grip and Rapid Exchange Grip (REG) Tests.

The 5-Rung Hand Grip Test which is comprised of one repetition performed in each of the five rung positions, provides data related to the shape of the curve and identifies the power position. That power position is then used when administering the REG Test. Instructions for these tests are offered within the software. Data from this protocol will not be stored unless you complete all parts of the protocol.

Additionally, there is one standalone pre-defined hand grip test, Hand Grip – Three Trials Position 2.

Any other strength test using available tools which can include the hand grip, pinch gauge, and portable load cell will need to be created. And, there are no pre-defined tests for Range of Motion. Tests are easily created within several minutes, depending on what content is entered at the Setup Notes tab. And, the test lists are customized by you, eliminating extraneous tests that you potentially would not use. The following instructions take you through the process of creating new tests.

1. Creating New Tests

   To create a new test, open Administration Menu, select Global Test Management, and choose a Test Type (Strength or ROM).

   If Strength is chosen:

   Click on Create New Test. Select Device to be used; options are Hand Grip, Pinch Gauge, or Portable Load Cell (Default = Hand Grip) (*Figure 3a*). Click OK to proceed with creation of a new test (or Cancel to return to the Global Test Management window).

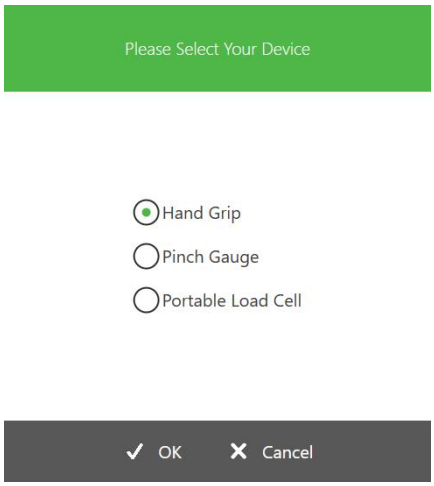


Figure 3a

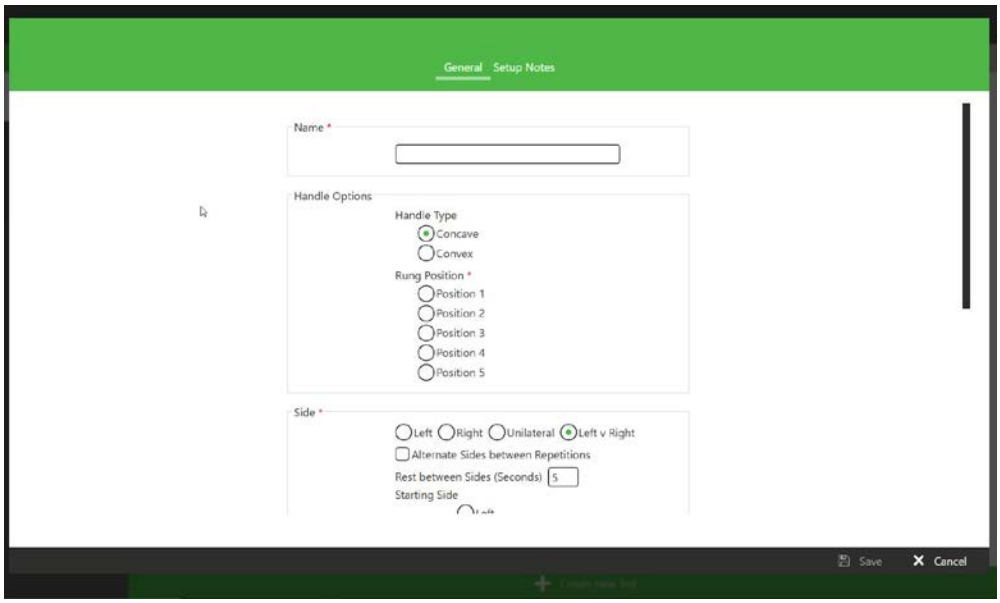


Figure 3b

Complete the fields presented at the General Tab: (note that all fields marked with an asterisk must be completed)

If Hand Grip is chosen (*Figure 3b*):

(Test) Name* - provide a test name or brief description of test that will allow you to identify each test when scrolling through Global Test List.

Handle Options – select Handle Type and designate Rung Position* to be used

Side* – choose one of 4 options. If Left vs Right is chosen, select if you want to alternate sides between repetitions (if unchecked, repetitions will be performed consecutively per side), identify the Starting Side, and define the duration in seconds of the rest period between sides.

Repetitions* – define the following parameters related to repetitions: Number and Duration of Repetitions and Rest between Repetitions

Load Cell Starting Threshold – is the amount of force applied to tool required to trigger each repetition

Force Collection – designate the force data to be reported for the test (average per trial, peak per trial, or both)

Heart Rate – select Use Heart Rate (HR) if you want HR data collected during performance of test

If Pinch Gauge or Portable Load Cell is chosen:

Test) Name* - provide a test name or brief description of test that will allow you to identify each test when scrolling through Global Test List.

Side* – choose one of 4 or 5 options. (The PLC offers an additional Side option of Both which infers a bilateral activity (both hands on one attachment). If Left vs Right is chosen, select if you want to alternate sides between repetitions (if unchecked, repetitions will be performed consecutively per side), identify the Starting Side, and define the duration in seconds of the rest period between sides.

Repetitions* – define the following parameters related to repetitions: Number and Duration of Repetitions and Rest between Repetitions

Load Cell Starting Threshold – is the amount of force applied to tool required to trigger each repetition

Force Collection – designate the force data to be reported for the test (average per trial, peak per trial, or both)

Heart Rate – select Use Heart Rate (HR) if you want HR data collected during the performance of test

Next, select the Setup Notes tab (optional). Define any information required to ensure test is performed in the same manner across clients and/or across test sessions. Setup Notes can include specifics related to the hardware being used, client positioning, and/or instructions to be read to client (*Figure 4*).

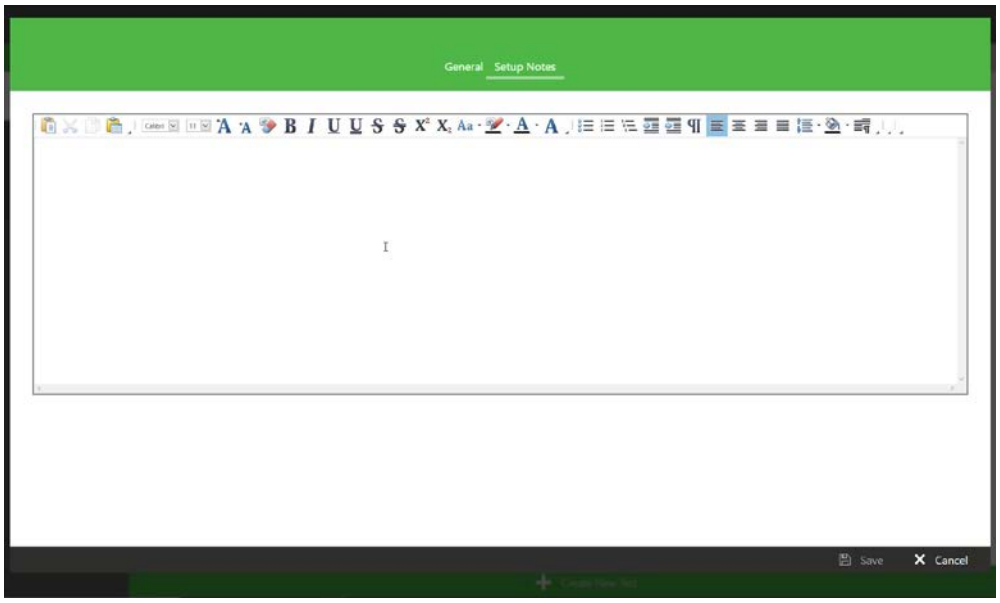


Figure 4

Review the information at both tabs and then click to Save the new test. Cancel will delete all information.

If Range of Motion is chosen:

Click on Create New Test. Select Device to be used; options are Dual Inclinometer and Goniometer (Default setting = Dual Inclinometer) (*Figure 5a*). Click OK to proceed with creation of new test (or Cancel to return to the Global Test Management window).

Provide the requested information on the General Tab: (note that all fields marked with an asterisk must be completed)

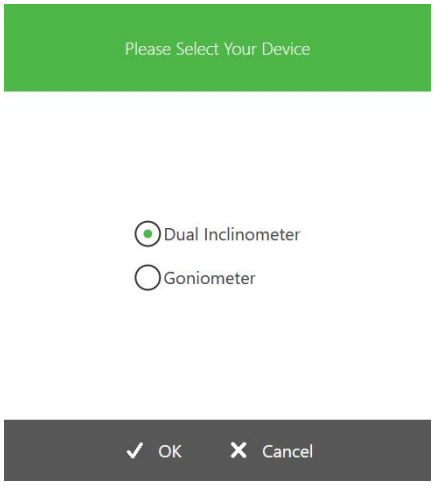


Figure 5a

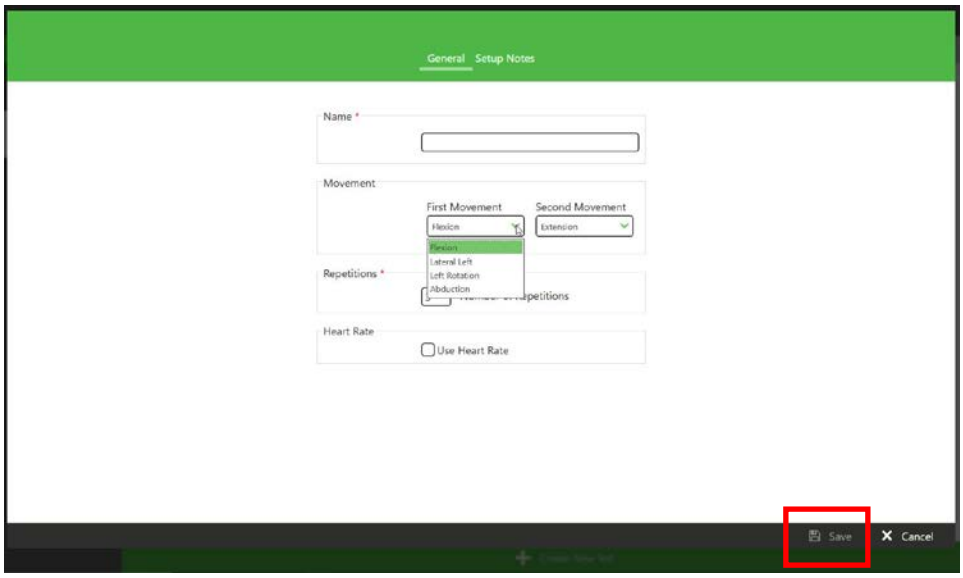


Figure 5b

If Dual Inclinometer is chosen, that information includes (*Figure 5b*):

(Test) Name* - provide a test name or brief description of test that will allow you to identify each test when scrolling through Global Test List.

Movement* – select the first movement to be measured from the dropdown list. The Second Movement will automatically be selected based on the First Movement selected.

(Number of) Repetitions*

Heart Rate – select Use Heart Rate (HR) if you want HR data collected during performance of test

If Goniometer is selected, address the following test parameters:

(Test) Name*

Side* - choose one of 4 options. If Left vs Right is chosen, select the Starting Side

(Number of) Repetitions*

Heart Rate – select Use Heart Rate (HR) if you want HR data collected during performance of test

Next, select the Setup Notes tab (optional). Define any information required to ensure test is performed in the same manner across client test sessions and/or across clients. Setup Notes can include specifics related to the hardware being used (for example position of tool, tool attachment used), client positioning, and/or instructions to be read to client.

Review the information entered and then click to Save the new test. Cancel will delete all information.

2. Editing Tests

Once saved, you do have the ability to edit a test. To do so, go/return to the Global Test Management window.

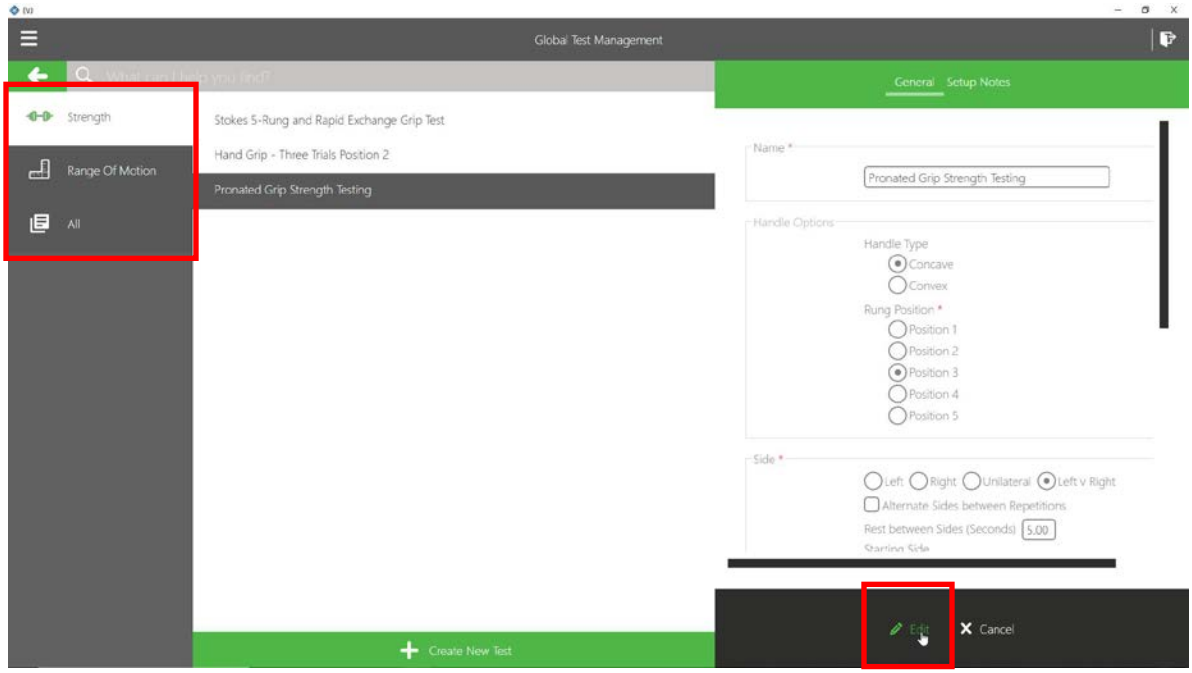


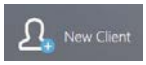
Figure 6

Choose the appropriate Test Type (Strength or Range of Motion) or All (Tests) (*Figure 6*). Select the test to be edited from the list. A third column will open that presents the selected test parameters. Click or tap the Edit button which opens the test window. Proceed to make necessary edits at the General and/or Setup Notes tab(s). Once completed, click Save or Cancel.

NOTE: Be aware that these changes will not be reflected in a Client's List of Tests.

Section 5 – Client Management

I. Adding New Client

From the Home Page, click the Add New Client button 

at the bottom of the Client Records window. The New Client window will open.

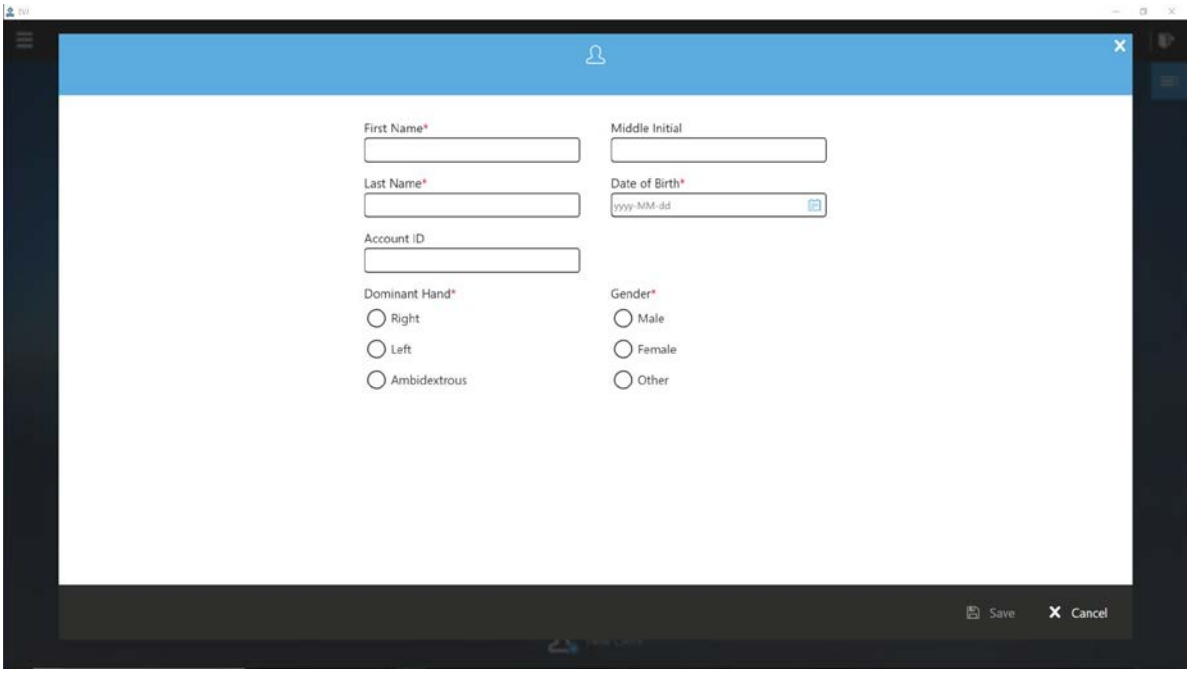


Figure 1

Provide the following information (note that a red asterisk denotes a required information): *(Figure 1)*

First Name*	Middle Initial
Last Name*	Date of Birth*
Account Number	Dominant Hand*
Gender*	

Once you have reviewed the information entered, click to save. Cancel will result in loss of entered information.

II. Choosing Existing Client

There are two options available to retrieve an existing client: *(Figure 2):*

- Client List – click on Client List icon  located in upper right area of Client Records window; scroll the list and select name
- Search option – enter client's name into search field and select it from the list presented

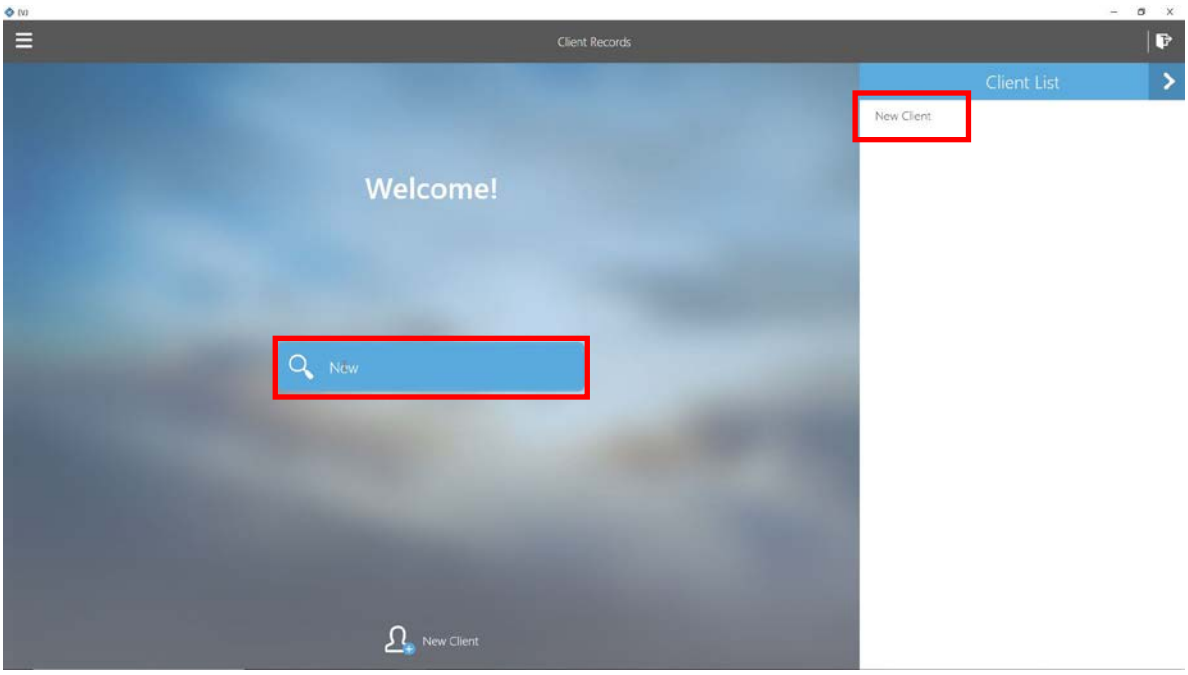


Figure 2

III. Client Overview

After saving the New Client information or selecting an existing client, the software will advance to the Client Overview window. Here you can edit the previously entered client information, assign and manage tests to be administered for this client, and view and print reports.

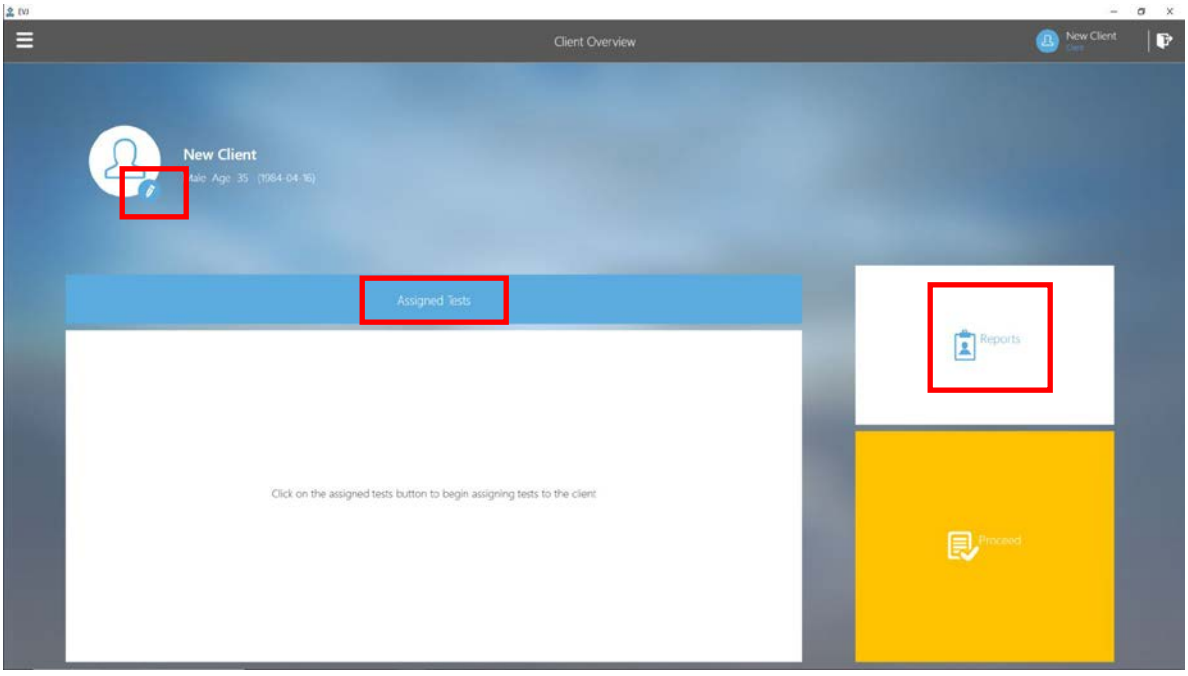


Figure 3

A. Edit Client information

To edit or complete remaining text fields, click on the pencil icon located to the left of the client's name  , make edits, and then save the information.

B. Assign and Manage Tests/Exercises (using pre-programmed)

The Client Management window is used to assign and manage tests. You can return to this list in order to include additional tests at a later date.

To assign tests, click on the Assign(ed) Tests banner *(Figure 3)*. This will provide access to Global Test Management. Select Strength or Range of Motion or All (Tests), choose the tests you wish to administer from the global test lists and assign them to the client's list of tests *(Figure 4)*.

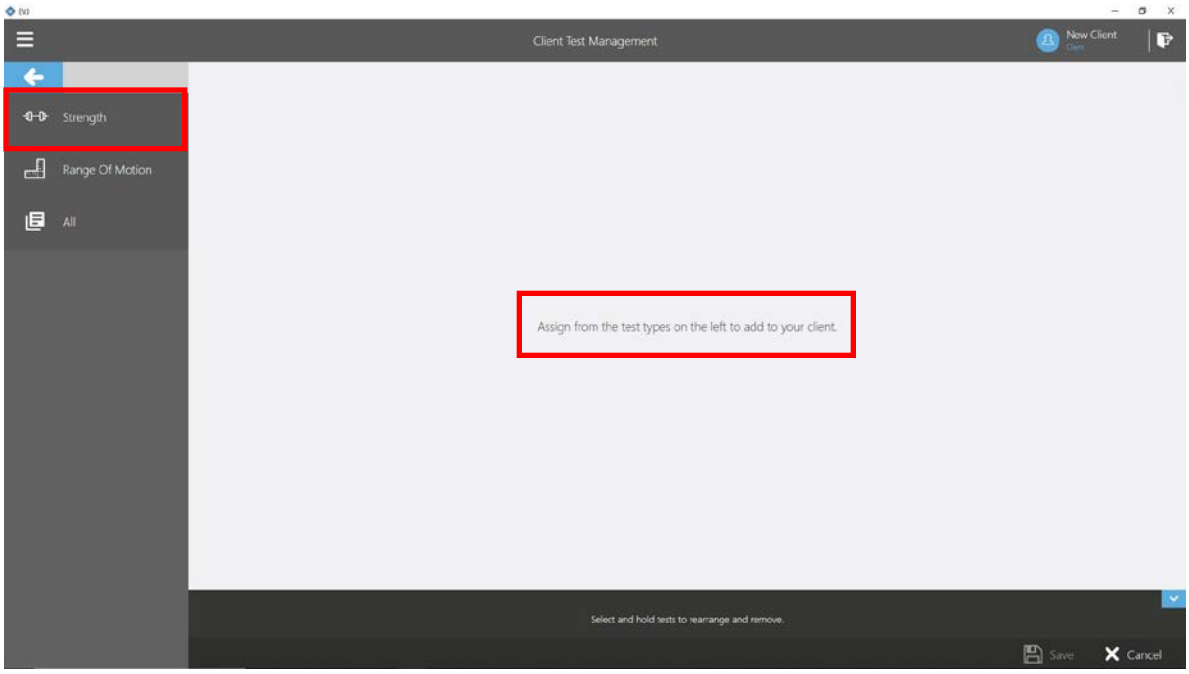


Figure 3

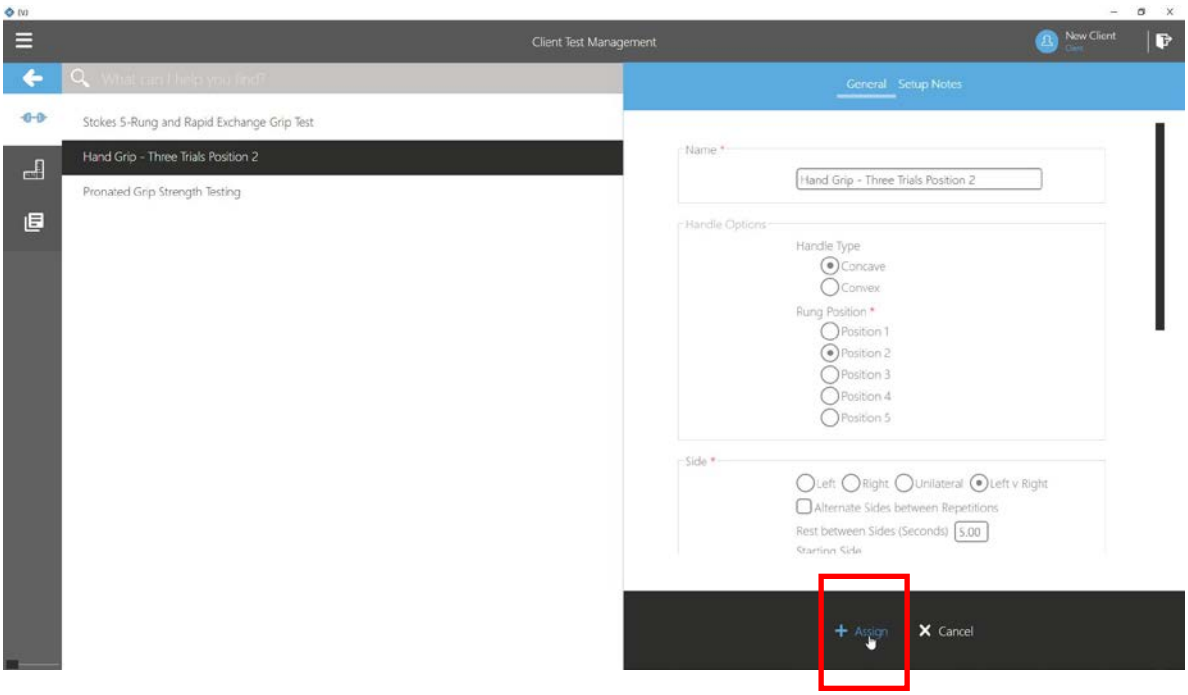


Figure 4

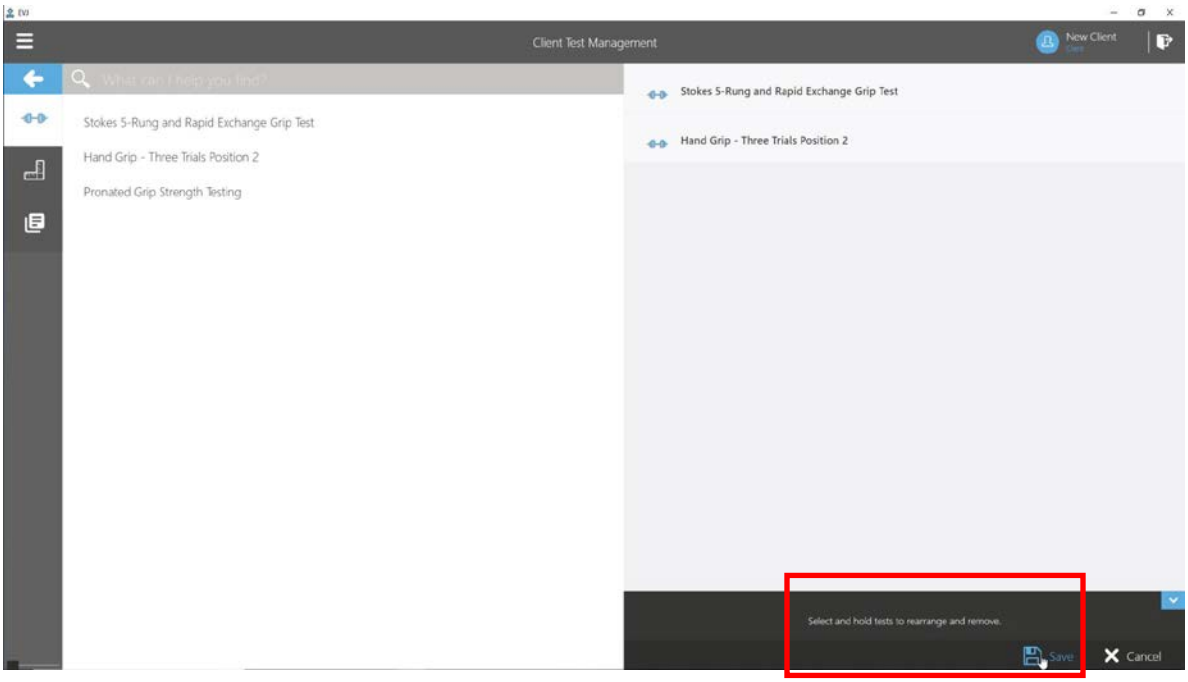


Figure 5

Review the list to ensure the tests are in the order you prefer *(Figure 5)*. To reorder a test, select and hold the test and move it to the desired position in the list. To remove a test from the list, select and hold the test and drag it to the bottom of the screen. Once you have the final list, click Save. If you are ready to proceed with testing, do so by clicking the Proceed button *(Figure 6)*. Section 6 addresses Test Execution.

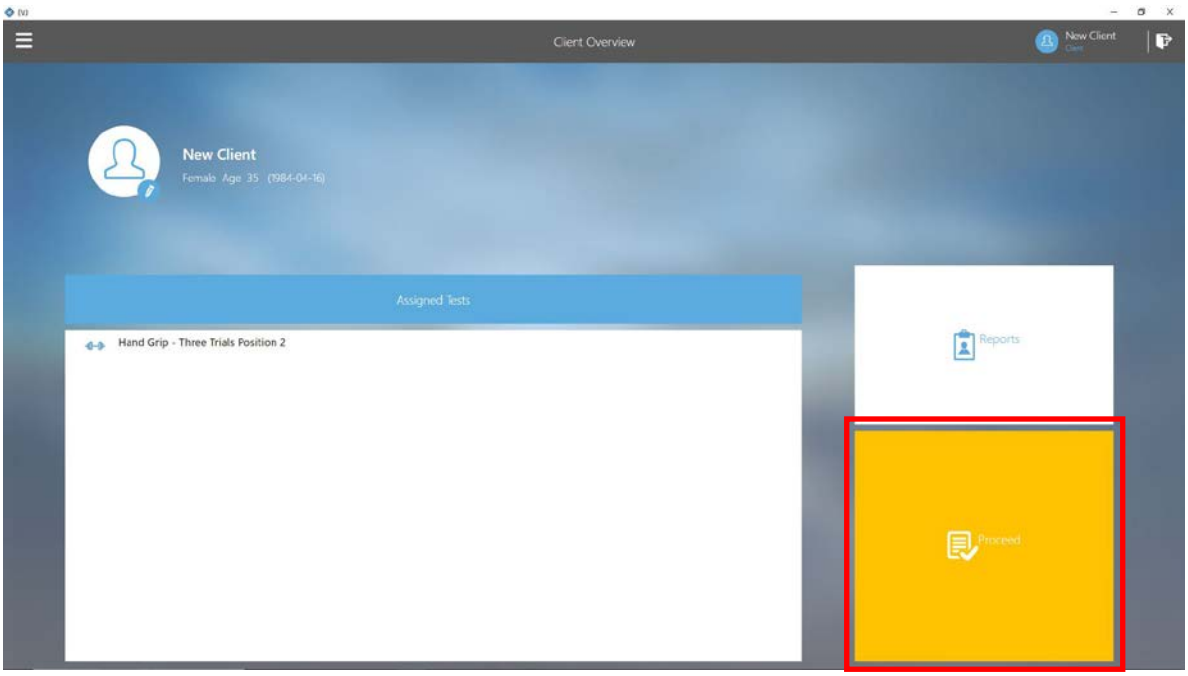


Figure 6

C. Reports

The remaining icon/button on the Client Overview window is Reports *(Figure 7)*. Once you have completed testing, you will return here to generate a document or export client test data as xlsx file. Documents may be printed or exported in various file formats (such as pdf, html, xls, etc.).

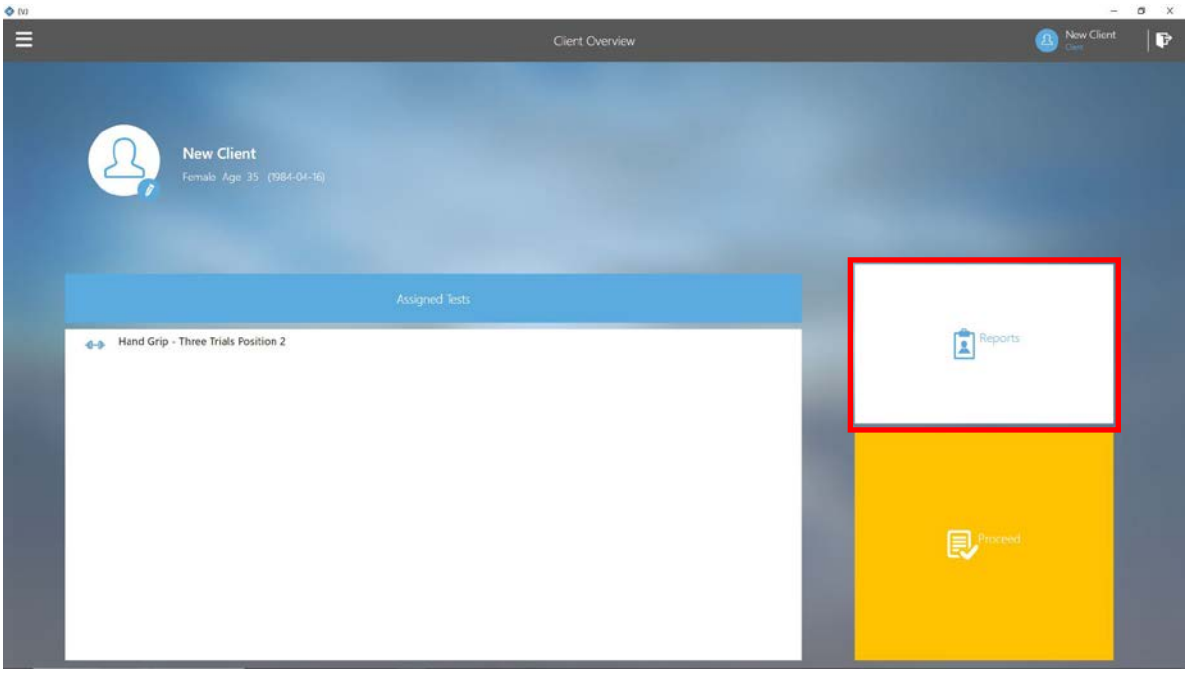


Figure 7

Reports and data exports can be generated based on tool and/or date range *(Figure 8)*.

By Tool – Select tool from the options presented. All test data associated with that tool will be shown. This includes Test Name, Test Date, and Client's Age. If no tool is selected, test data of all tools used will be shown.

By Test Date – To define a date range use the calendar icons.

Use the Select /Deselect All option as an additional means of defining the test data to be included in a report or to be exported. Selection may also be done by choosing specific rows.

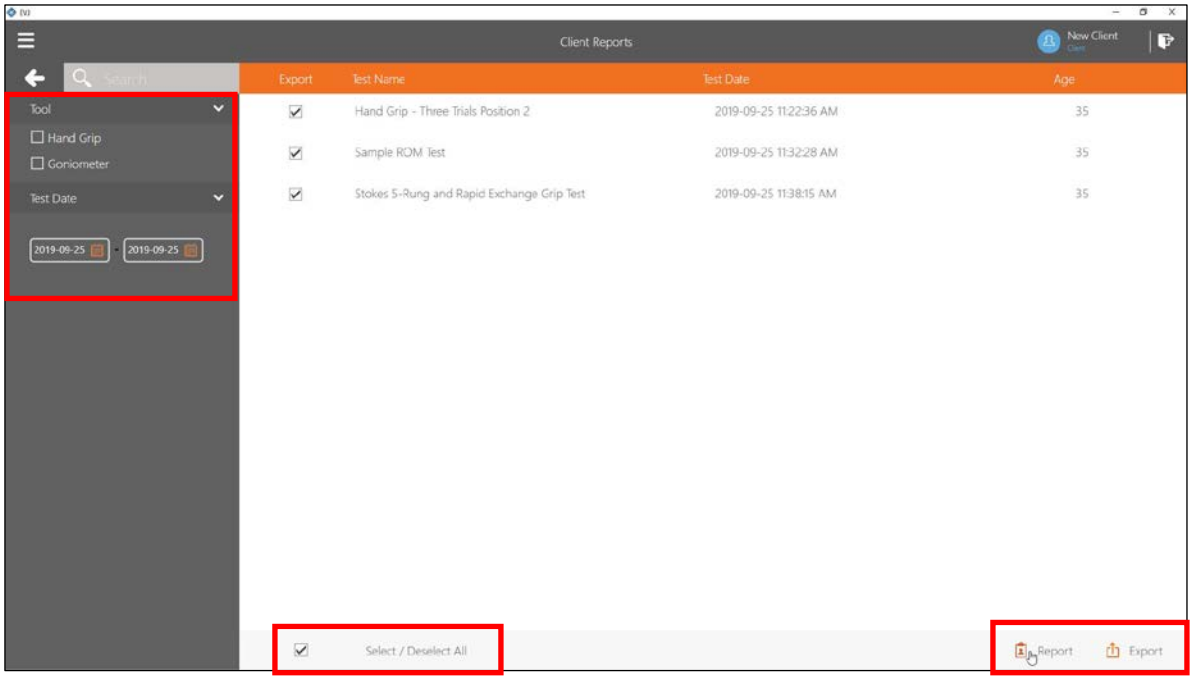


Figure 8

Detailed information about Reports is provided in Section 6 – Test Execution, pages 11 – 13.

Section 6 – Test Execution

I. Brief Review of Tool Setup

Be sure the BHU dongle/receiver is inserted into a USB port of the control module. Note that the Bluetooth dongle that is included with the heart rate watch is not needed as the dongle associated with the BHU will recognize the watch.

Simply move the BHU to power it on. Make sure it has recently charged batteries.

Connect the desired tool (Hand Grip, Pinch Gauge, Portable Load Cell, Goniometer, or Inclinometer) to the BHU using an RJ45 cable.

II. Test Execution

Please be aware that the information being presented here assumes that users possess the clinical knowledgeable necessary to measure extremity and spinal range of motion. This includes placement/alignment of the measurement device in relation to associated anatomical landmarks, positioning of client, etc.

First select the desired client from the Client List. The Client Overview window provides access to Test Execution. Click the Proceed button in order to enter that area. The test list appears on the left side of the window. Only tests which you had previously assigned in the Client Test Management window (section 5 of this manual) will appear in the list. You can click on the Assigned Tests banner to add tests before proceeding to the Test Execution screen.

To proceed with testing, select the test to be performed first *(Figure 1)*. Review the Setup Notes for instructions. These may include setup notes related to hardware, client positioning instructions, and/or test instructions to be read to the client. Once you are ready to start the test, click the Proceed button (lower right corner of window).

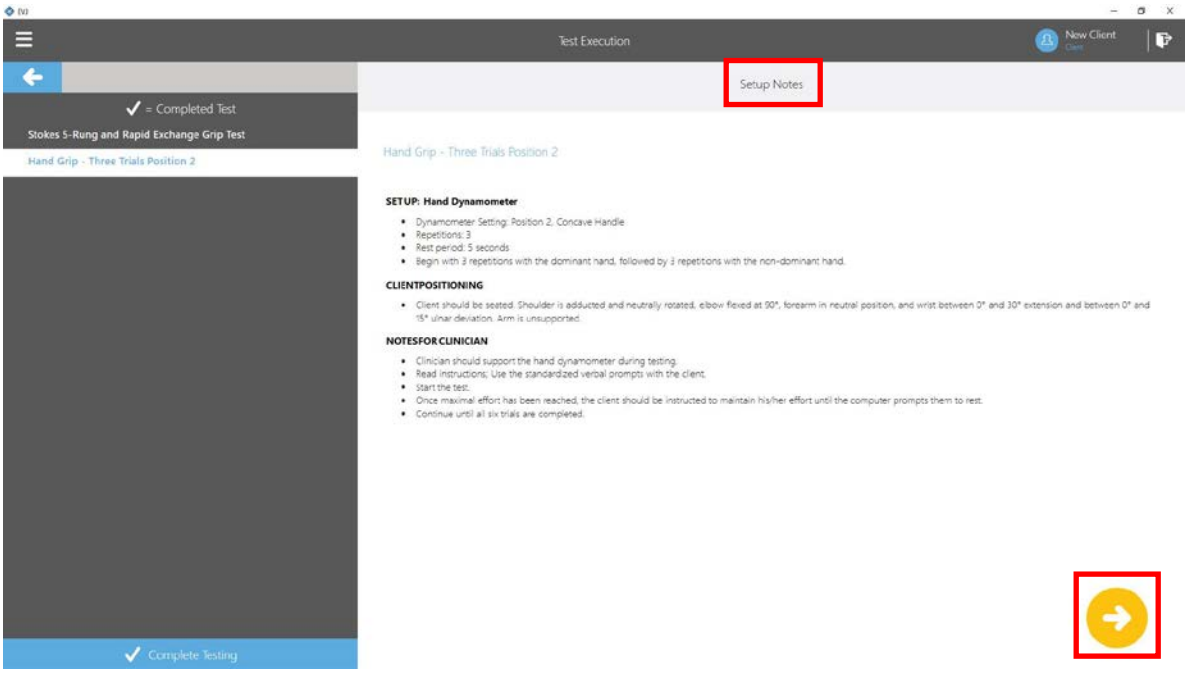


Figure 1

Remember to verify the tool is connected to the BHU and the BHU light is on to signify that it is powered on before starting a test.

A. Strength Tests

The Test Execution window for Strength tests includes Test Name, Side(s), graphic display of force vs time, repetition counter, a repetition timer, and timer for total test time. Additionally, there is an indicator of tool communication status at bottom of window *(Figure 2)*. If communication is established, the indicator will be green; if, no communication, it will be red *(Figure 3)*. Additionally, popup windows will provide some assistance *(Figure 4)*.

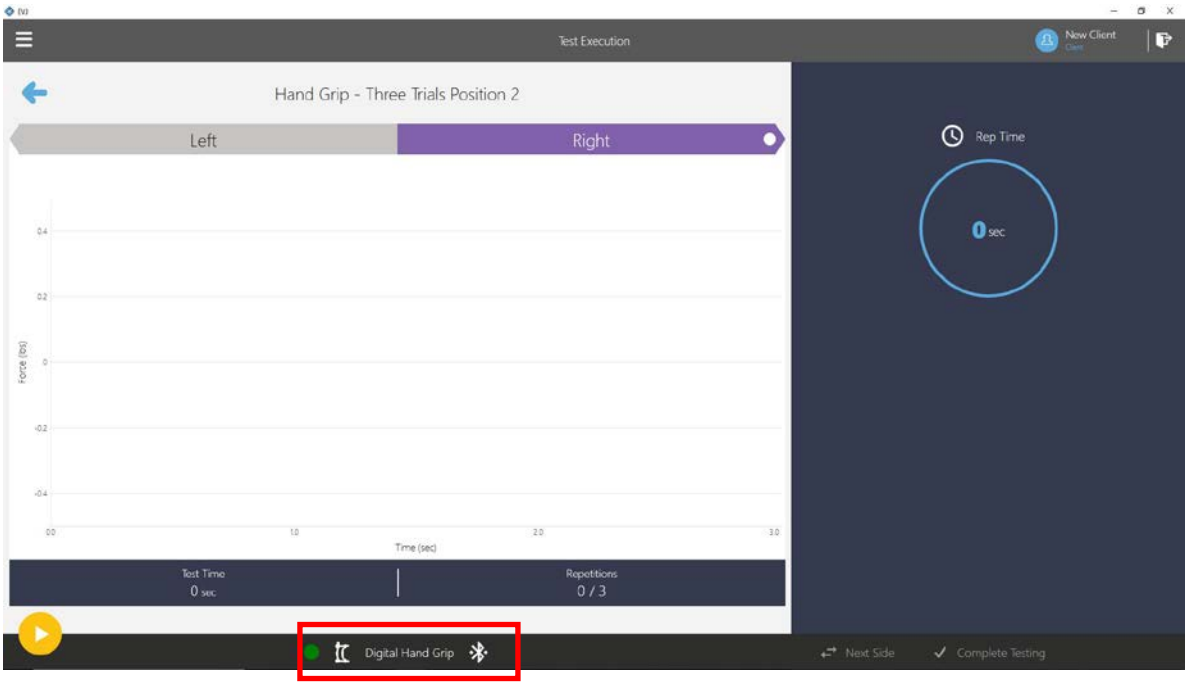


Figure 2

Figure 3

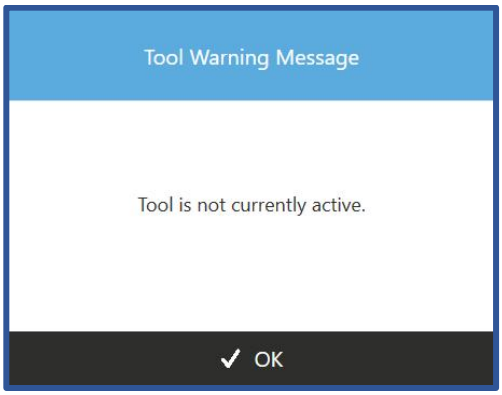


Figure 4

1. Test Execution

To execute a Strength test, select the first side to be tested if not already designated and then click the Proceed button. Perform the total number of repetitions for each side *(Figure 5)*.

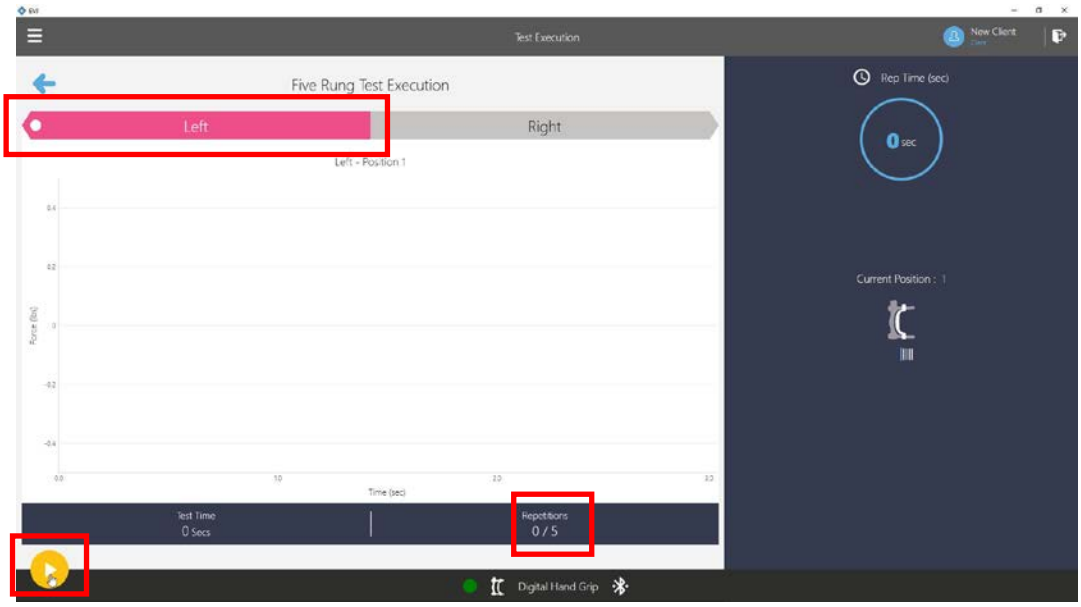


Figure 5

After completing all repetitions for both sides, click the Next button. The Test Results window is now available *(Figure 6)*. Review the data. Determine if any repetitions need to be re-done. If a re-do is needed, select the desired repetition and click Redo Repetition button. (Refer to page 86 for additional information). If no re-do is necessary, click to save the data.

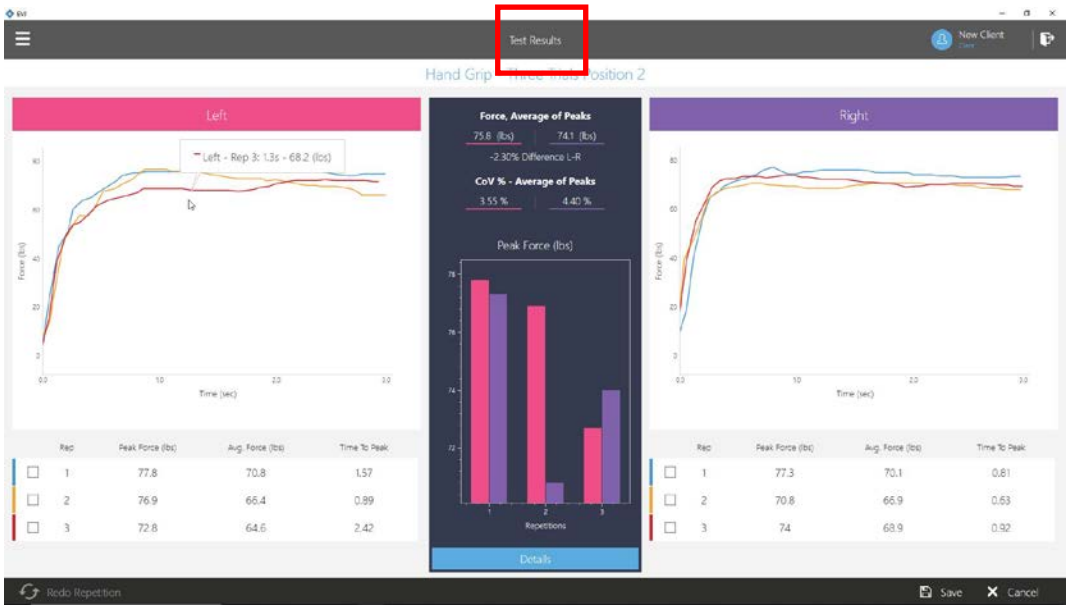


Figure 6

2. Available Test Data Displays

The Test Results and Result Summary windows present the data collected along with appropriate/associated calculations. The contents of these two windows are as follows:

Test Results window includes:

- Force, Time graph(s)
- Peak Force, Average Force, or Both for each repetition
- Time to Peak of each repetition
- Force, Average of Peaks for each side
- Percent Difference between sides
- Coefficient of Variation (CoV)
- Bar graph comparing peak force of repetitions between sides

Click the Details button to view the Result Summary which includes: *(Figure 7)*

- Bar graphs of Peak Force per side (note that scaling is based on the highest score)
- Maximum Peak Force
- Force, Average of Peaks
- Percent Difference between sides
- Coefficient of Variation (CoV) (variation in peak forces per side)

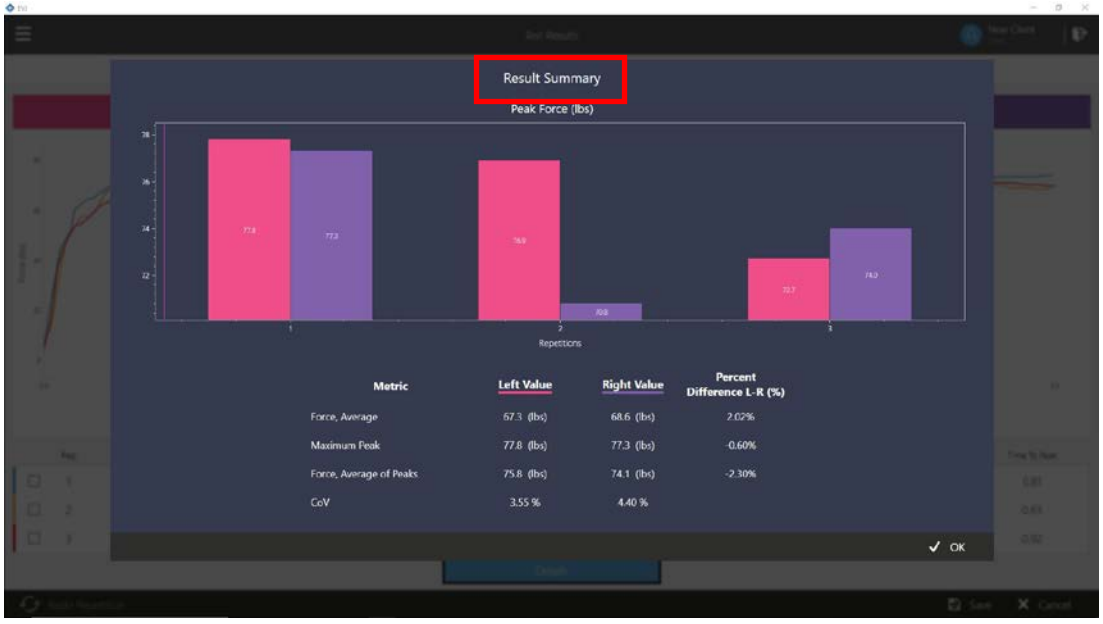


Figure 7

B. ROM Tests

The Test Execution window for ROM tests includes Test Name, Movement(s), graphic display of degrees of motion vs time, repetition counter, a repetition timer, and timer for total test time. Additionally, there is an indicator of tool communication status at bottom of window. If communication is established, the indicator will be green; if, no communication, it will be red.

1. Test Execution

To perform a ROM test, select the first movement to be performed if not already designated and then click the Proceed button *(Figure 8)*. To record ROM data, click the button on the master inclinometer or the goniometer to start the repetition or use the Start Repetition button on screen.

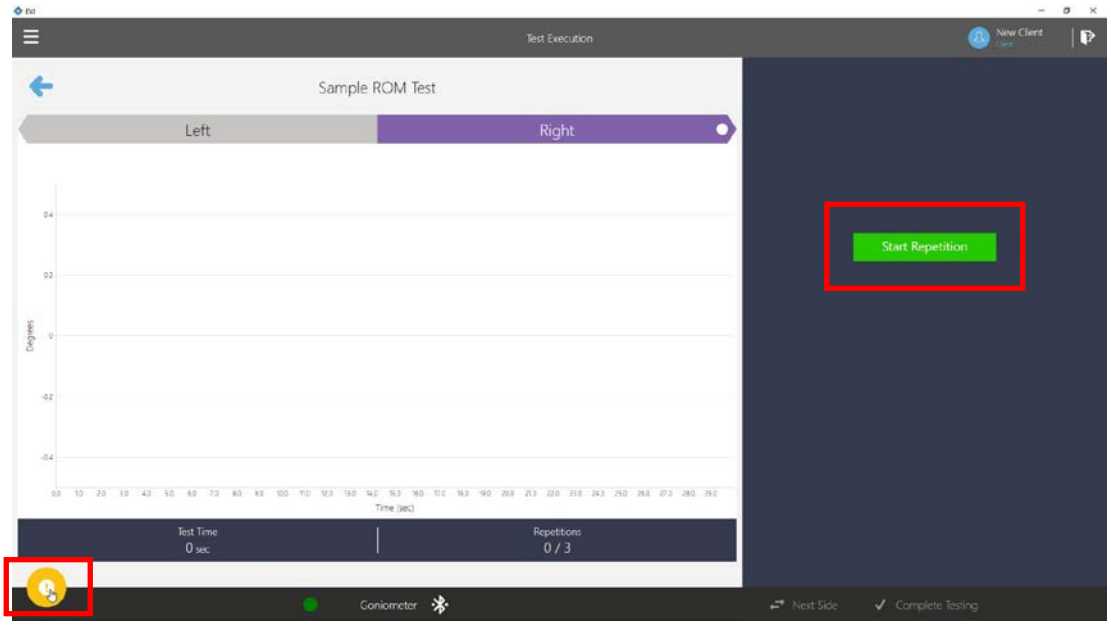


Figure 8

Once the repetition is active, the movement will be displayed on the graph. The ‘x’ axis represents time in seconds and the ‘y’ axis degrees of movement *(Figure 9)*. Instruct client to move to end point of range at which time you will click the button to stop the repetition (or use Stop Repetition button on screen).

Figure 9

Continue to perform the total number of repetitions for each movement. After completing all repetitions for all movements, click the Next button. The Test Results window is now available *(Figure 10)*. Review the data. Determine if any repetitions need to be re-done. If a re-do is needed, select the desired repetition and click Redo Repetition button. (Refer to page 86 for additional information). If no re-do is necessary, click to save the data.

2. Available Test Data Displays

The Test Results and Result Summary windows present the data collected along with appropriate/associated calculations. The contents of these two windows are as follows:

Test Results window includes:

Degrees, Time graphs for movement(s)

Peak Degrees and Time to Peak for each rep

Average (Avg) of Peaks for movement(s)

Percent Difference between movements, if applicable

Coefficient of Variation (CoV) (variation in peak degrees per side)

Bar graphs of Peak Degrees per movement

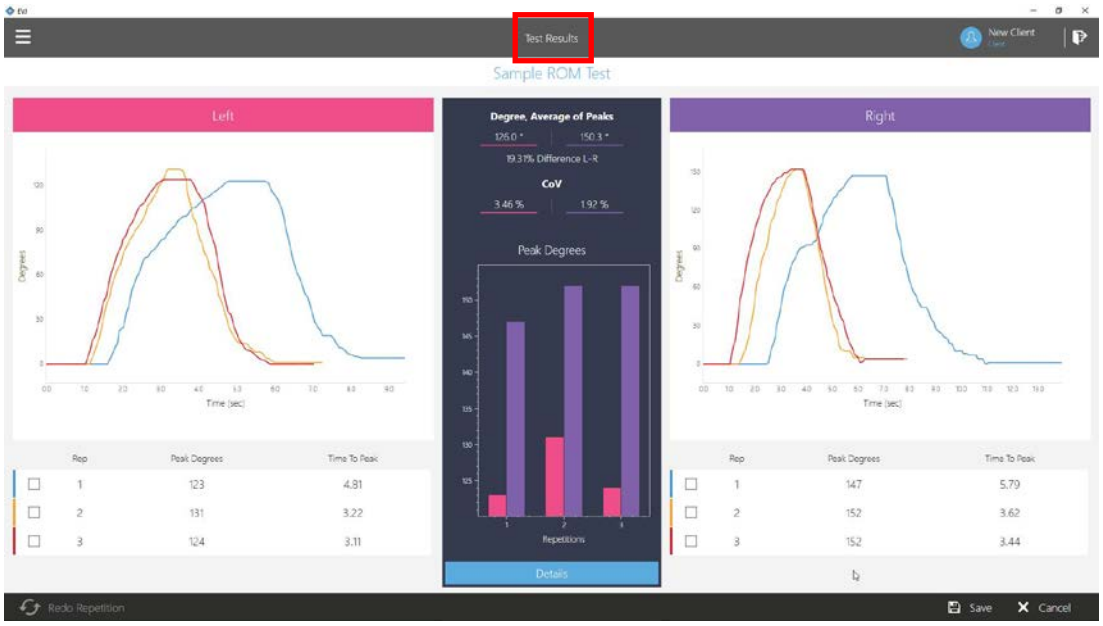


Figure 10

Click the Details button to view the Result Summary which includes: *(Figure 11)*.

Bar graphs of Peak Degrees per movement

Maximum Peak of range of movement

Degree Average of Peaks

Percent Difference between movements, if applicable

Coefficient of Variation (CoV) (variation in peak degrees per side)

Figure 11

C. To Re-Do a Repetition

If a repetition needs to be redone, click the box to the left of repetition to be redone *(Figure 12)*. The Redo Repetition icon (lower left corner of Test Results window) becomes active. Clicking on that icon will prompt a pop-up window asking, “Are you sure you would like to re-do Rep X of the X side”.

Figure 12

By clicking OK, you are returned to the test execution window. Start the test, repeat the repetition, and return to the Test Results window. Although the data remains for the original repetition, it is not included in any calculations.

D. Test Termination

Common to all tests is the ability to terminate a test prior to completing. Should circumstances present that require stopping a test before completion, a pop-up window will appear alerting you that “This action will terminate the test” *(Figure 13)*. Clicking OK to stop the test will lead to a second pop-up altering you to loss of any data already collected *(Figure 14)*. Cancel will return you to the test in order to complete the test.

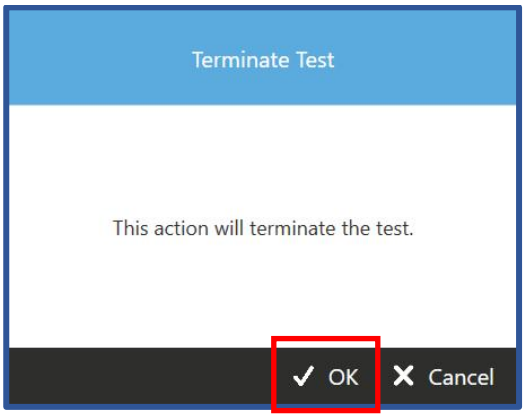


Figure 13

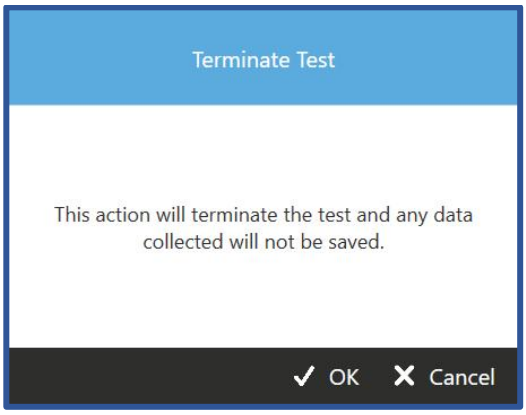


Figure 14

E. Complete Testing and Reporting

Once you have completed the test session, click on the Complete Testing button located at the lower left corner of the Test Execution window *(Figure 15)*. Doing so will take you directly to Client Reports where all saved tests for the selected client are listed. Report content can be filtered by Tool and/or Test Date(s). Tests may be selected or deselected for inclusion in or exclusion from the report *(Figure 16)*.

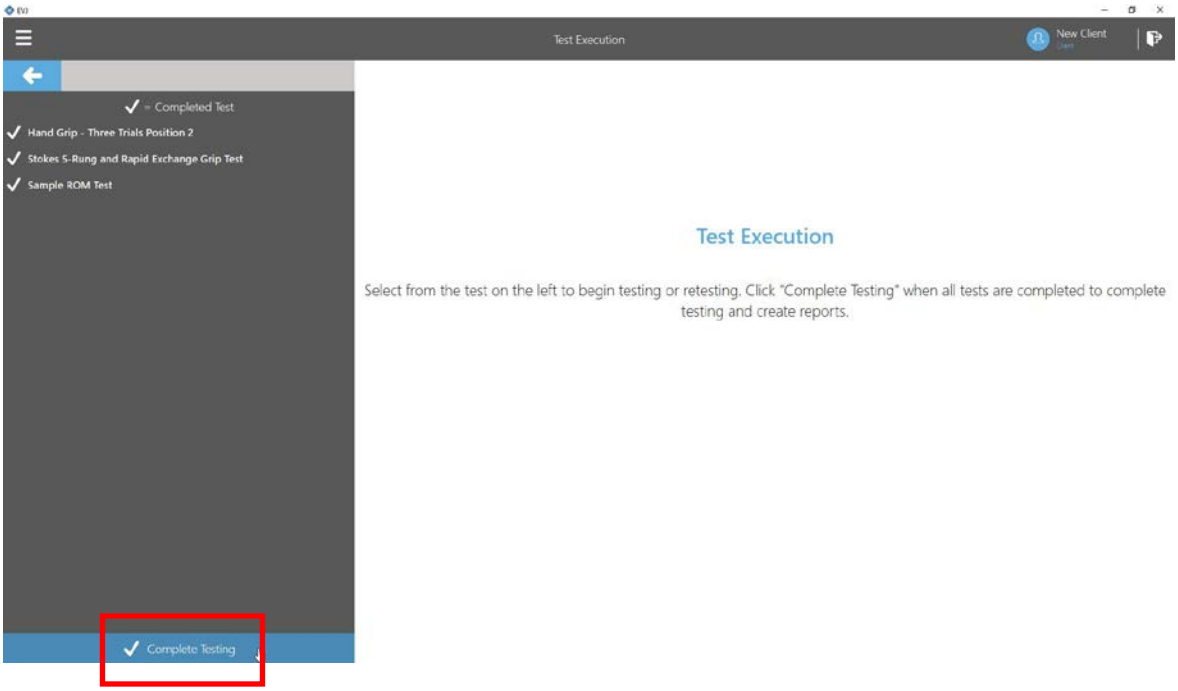


Figure 15

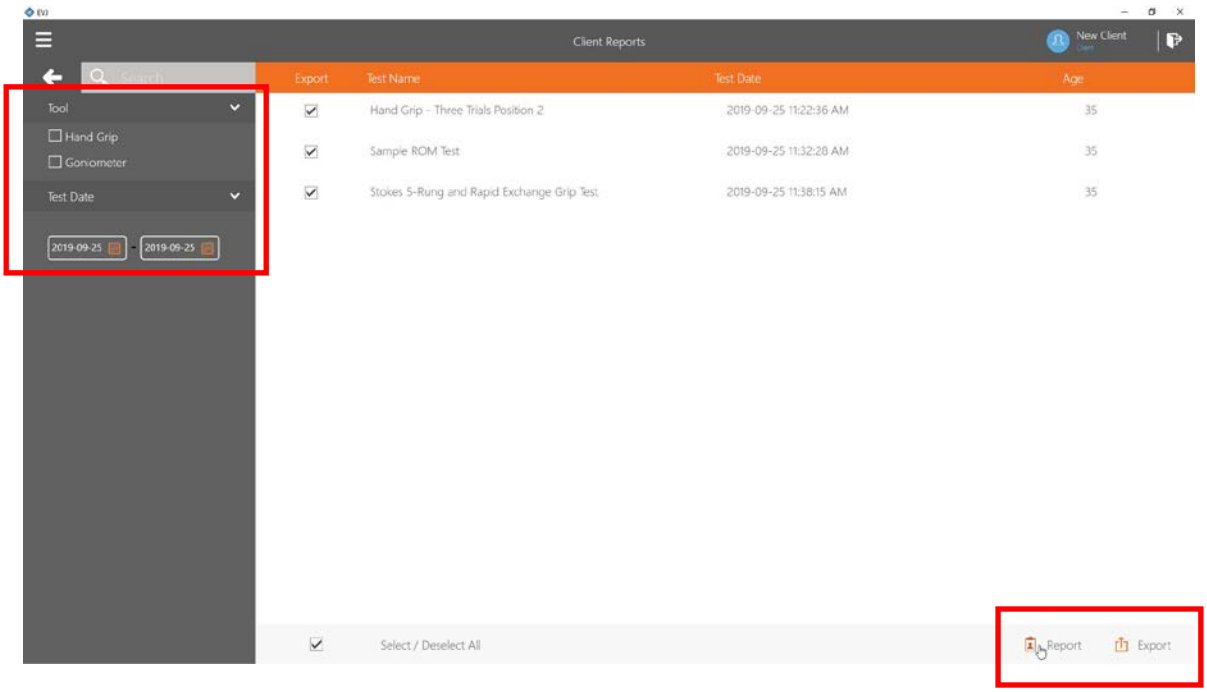


Figure 16

It is possible to generate a report and export test data as an Excel document. Should you click on the Report option, a preview of the report is presented *(Figure 17)*. You can review the data via the Preview and/or proceed to other options (printing, creating pdf, and/or exporting the document, by clicking on File.

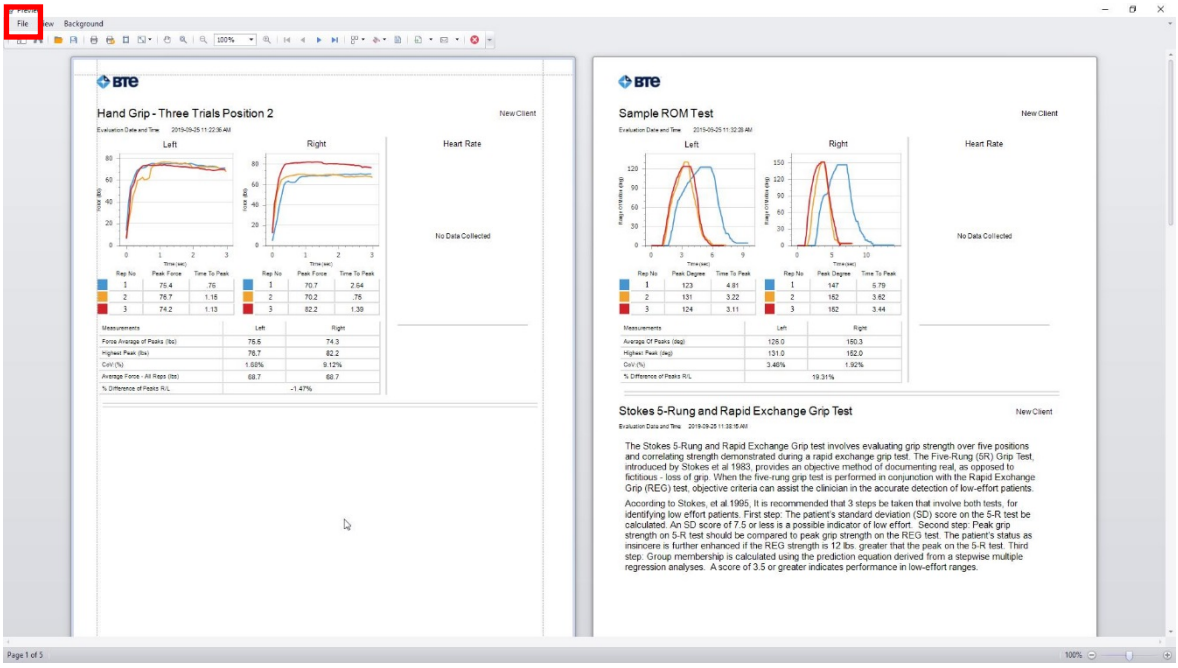


Figure 17

You do have the ability to return to Reports for a specific client at a later time by way of the Client Overview window.

Section 7 – Global Management – Reports, Settings

I. Reports

From the Global Management option, it is possible to generate reports based on data from the total client population tested *(Figure 1)*. When entering the Demographic Reports window, all saved tests are listed by Test Name and Date and Client Name, Age, and Gender. The tests can be then sorted by Tool, Gender, Dominant Hand, Test Date, and Age. (Note that options offered are dependent upon the data saved.)

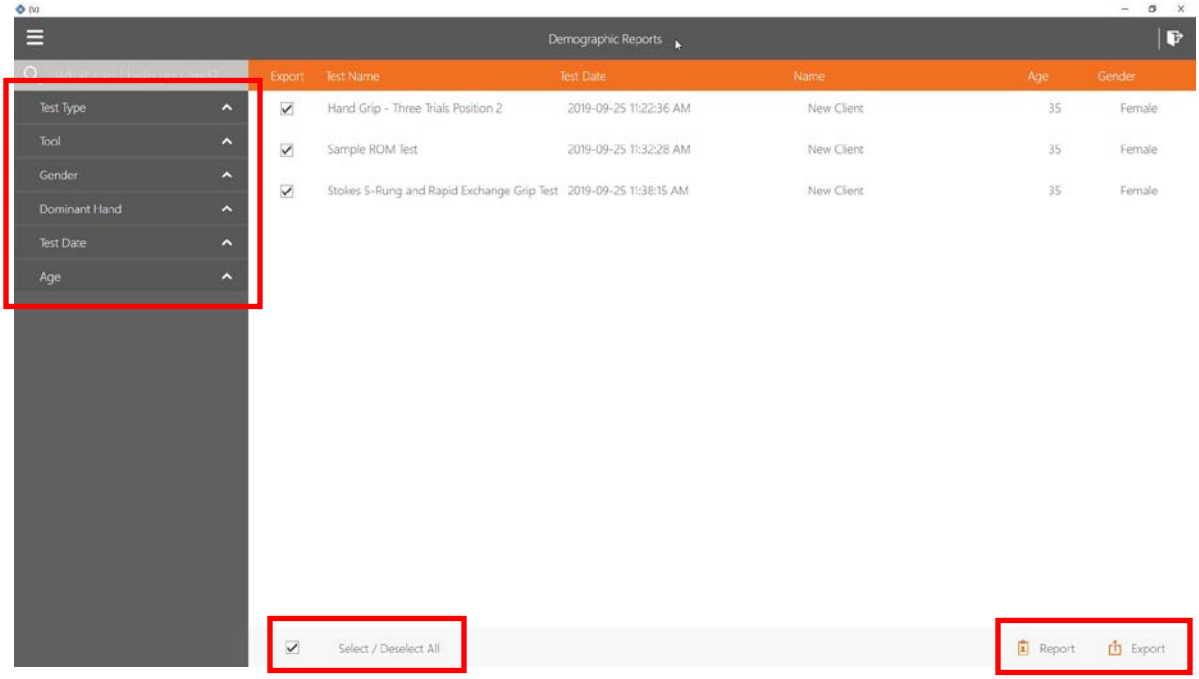


Figure 1

Reports can be generated to view, print, and/or save. Additionally, there is the option to export data as an Excel document. To export, tests in this list can be selected or deselected individually or globally by using the check box locate by each test or using the global setting at the bottom of the window (Select / Deselect All).

II. Settings

Settings deal with configuration and administrative tasks related to the software. Included under Settings are:

A. Language

English and Japanese are the current available languages. Select desired language and save that selection.

B. Units of Measure

Imperial or Metric are the available units of measure. Choose unit of measure and save the selection.

C. Database (Export and Restore Functions)

Export and Restore functions are offered here. Export will create a backup zip file of the database to be saved at location of your choice. A backup file can then be used to restore the database should that become necessary. These functions also allow for multiple databases to be used for specific testing purposes.

D. License Manager

Should additional tools be acquired via the purchase of the Strength and/or Range of Motion Packages, an Activation Key is required in order for the EVJ software program to recognize them.

License management is part of the purchase process. It can be addressed prior to receipt of the tools. Simply provide a License Request Key to BTE Customer Service who will issue a Product Key and Activation Key that you will enter into the License Manager.

To access the License Manager, select Settings which is found in the Hamburger Menu. Then choose License Manager *(Figure 2)*. To obtain a License Request Key that you will provide to BTE Customer Service, click the Enter License Key button located at the bottom of the window. Record or copy the License Request Key contained in the second text field. Click OK to close the pop-up window.

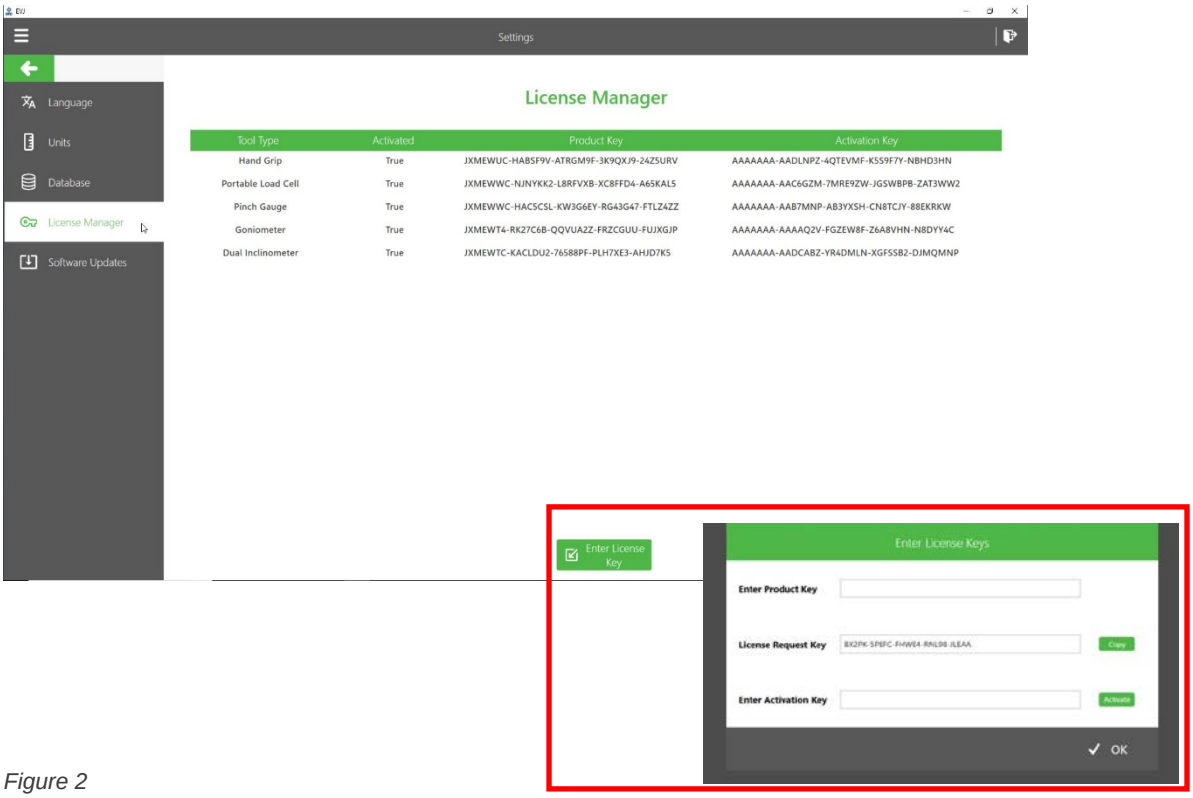


Figure 2

Once you receive the necessary Product Key and Activation Key from BTE Customer Service, return to License Manager, click the Enter License Key button, and enter the information into the appropriate fields. Upon entering the Activation Key, click the Activate button. Then click OK to close the pop-up window. The newly licensed tools should now be included in the list of activated tools.

Remember that it is necessary to calibrate and verify the tool(s) prior to first use. Refer to Section 2 – Hardware Setup for instructions.

E. Software Updates (and Version Information)

Information about your current Software Version and Build is noted here *(Figure 3)*. And when connected to internet, notification of available update can be viewed, and update performed using the Update button.

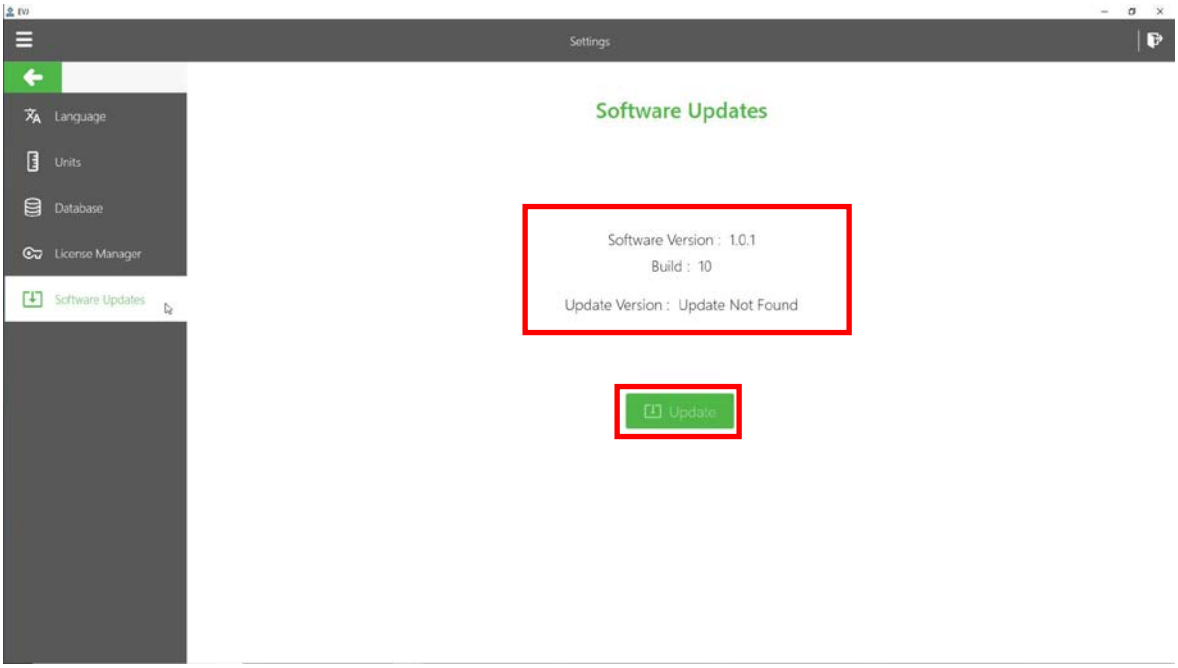


Figure 3

Section 8 – Troubleshooting and Maintenance

I. Troubleshooting

A. Bluetooth Hip Unit (BHU)

If the unit is not functioning:

1. Be sure unit is powered on. To power on, simply move the unit.
2. If no response to movement, insert freshly charged batteries. Have some standard AA batteries available in case there is an issue with the battery charger or life-end of the rechargeable batteries.
3. Verify the Bluetooth dongle/transmitter is plugged into the control module.
4. The BHU may have been dropped.

B. BTE Hand Grip

If the Hand Grip is not connecting or not reading any value :

Verify that:

1. The batteries in the BHU are charged and less than a year old.
2. The Bluetooth dongle/transmitter is plugged into the control module and BHU is powered on.
3. The Hand Grip, BHU, and RJ45 cable are not damaged, dirty at the connections, or have loose components.

Attempt the following:

1. Insert freshly charged batteries and ensure batteries in BHU are secure.
2. Try a different combination of batteries - if one of the batteries has gone bad, then the BHU will not work properly.
3. Attach a new RJ45 cable to the Hand Grip and BHU.

C. Pinch Gauge

If the Pinch Gauge is not connecting or not reading any value:

Verify that:

1. The batteries in the BHU are charged and less than a year old.
2. The Bluetooth dongle/transmitter is plugged into the control module and BHU is powered on.
3. The Pinch Gauge, BHU, and RJ45 cable are not damaged, dirty at the connections, or have loose components.

Attempt the following:

1. Insert freshly charged batteries and ensure batteries in BHU are secure.
2. Try a different combination of batteries - if one of the batteries has gone bad, then the BHU will not work properly.
3. Attach a new RJ45 cable to the Pinch Gauge and BHU.

D. Portable Load Cell (PLC)

If the PLC is not connecting or not reading any value:

Verify that:

1. The batteries in the BHU are charged and less than a year old.

2. The Bluetooth dongle/transmitter is plugged into the control module and BHU is powered on.
3. The PLC, BHU, and RJ45 cable are not damaged, dirty at the connections, or have loose components.

Attempt the following:

1. Insert freshly charged batteries and ensure batteries in BHU are secure.
2. Try a different combination of batteries - if one of the batteries has gone bad, then the BHU will not work properly.
3. Attach a new RJ45 cable to the PLC and BHU.

E. Dual Inclinometer

If the Dual Inclinometer is not connecting or not reading any value:

Verify that:

1. The batteries in the BHU are charged and less than a year old.
2. The Bluetooth dongle/transmitter is plugged into the control module and BHU is powered on.
3. The Dual Inclinometer, BHU, and RJ45 cable are not damaged, dirty at the connections, or have loose components.

Attempt the following:

1. Insert freshly charged batteries and ensure batteries in BHU are secure.
2. Try a different combination of batteries - if one of the batteries has gone bad, then the BHU will not work properly.
3. Attach a new RJ45 cable to the Dual Inclinometer and BHU.
4. Detach and reattach the link cable from both the Master side and the Remote side.

F. Goniometer

If the Goniometer is not connecting or not reading any value:

Verify that:

1. The batteries in the BHU are charged and less than a year old.
2. The Bluetooth dongle/transmitter is plugged into the control module and BHU is powered on.
3. The Goniometer, BHU, and RJ45 cable are not damaged, dirty at the connections, or have loose components.

Attempt the following:

1. Insert freshly charged batteries and ensure batteries in BHU are secure.
2. Try a different combination of batteries - if one of the batteries has gone bad, then the BHU will not work properly.
3. Attach a new RJ45 cable to the Goniometer and BHU.
4. If the top housing of the Goniometer is not properly secured, the Goniometer may not read a change in angle. To check, do the following:

   Step 1. Attach the long arm to the top of the Goniometer.

   Step 2. Place the Goniometer in a horizontal position and position the arms parallel to the floor.

   Step 3 Let go of the top arm - if it falls freely, then the top rotation housing screw needs to be tightened.

Step 4. Use a 5/64” Allen key, which is supplied with the system (this is the smallest Allen key in the set), to tighten the top set screw.

G. Heart Rate System

For Troubleshooting and Maintenance of the Heart Rate System, please refer to the included manufacturer’s information.

WARNING

The HR watch and USB dongle contain strong magnets that can affect pacemakers and implantable cardioverter-defibrillators (ICDs). Consult doctor or device manufacturer before using the watch.

II. Technical Support Information

To contact the HR System, refer to the information in the HR System packaging.

To contact BTE Technologies:

By Telephone: 1-800-331-8845 (U.S. & Canada)

1-410-850-0333 (Domestic & International)

By Email: Customer_Service@btetechnologies.com

III. General Maintenance and Care

A. Control Module Care

Since control modules are sensitive to extremes of temperature, do not place equipment close to a direct source of heat or cold (for example, in direct sunlight, next to a radiator, or next to an air conditioner).

Do not install any additional software onto the control module. The BTE Technologies Evaluator, Model EVJ system is in constant communication with the control module, so a “clean”, dedicated control module is crucial to the integrity of this communication system.

If your control module was purchased through BTE and unapproved software has been installed, the control module will not be covered under the BTE warranty.

1. Anti-Virus Software

The BTE warranty is void if the product malfunctions as a result of software virus.

Anti-virus software is installed on the control module. If the control module is connected to the internet, the software must be updated regularly to protect the control module against viruses. In addition, the software license must be renewed each year.

If the anti-virus software is not approved by your IT department, contact BTE before making any changes.

2. Control Module Maintenance

Using proper Windows shut-down procedures, shut down the control module every night to keep it running smoothly during testing.

B. Tools and Attachments

Regularly wipe down the tools and attachments with an alcohol-based solvent.

Periodically inspect the tools and attachments for any unusual wear or damage.

C. BHU

Replace the rechargeable batteries every 6 months if used frequently and every year if used occasionally. Keep some standard AA batteries available in case you experience any issues with the rechargeable batteries or the charger itself.

D. Cables

Periodically inspect the entire length of the cables used to attach the tools to the BHU. Inspect the connector ends since they can be damaged. Replace any cables that are damaged or do not seem to allow for proper communication.

E. Batteries

The provided rechargeable batteries are not charged prior to shipping; therefore, be sure to fully charge the batteries before using the system.

When fully charged, the batteries should power the BHU for up to 5 hours of continuous testing. This will vary depending on how much battery capacity is available and which tools are being used (e.g. the Dual Inclinometer and Goniometer use more battery power than the Hand Grip, Pinch Gauge, and Portable Load Cell).

The amount of charging time depends on the remaining capacity of the battery in addition to the charge rate set on the charger. Refer to the battery charger manual for information on the estimated charge time. Whenever possible, only charge the batteries after they have been drained. Short-charging batteries can degrade them over time and shorten their life expectancy.

IV. Strongly Recommended Additional Purchases

In addition to the equipment shipped to you from BTE Technologies, the purchase of the following items from a local supplier is strongly recommended:

- For adequate protection of your client data, USB flash drives or a USB external hard drive for backing up and archiving copies of client data.
- Disinfectant wipes to clean the commonly used surfaces on the tools and accessories.
- Standard AA batteries for backup in case there are any issues with the rechargeable ones.

Appendix A

EMC Guide

Safety with Regard to Electromagnetic Disturbances

- Electromagnetic environment of intended use:
  1) Professional healthcare facility such as a hospital or large clinic
  2) Small clinic that could be located in a residential or office area
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- WARNING: Use of accessories, transducers and cables other than those specified or provided by BTE could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EvalTech/Evaluator, including cables specified by BTE. Otherwise, degradation of the performance of this equipment could result.
- NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- Emissions and immunity tests compliance information:
  - Emissions class: Class A
  - The equipment is compliant with the following standards:
    - **IEC 60601-1-2:2014**, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
    - **CISPR 11:2010**, Limits and methods of measurement of radio disturbance; Characteristics of industrial, scientific and medical radio frequency equipment
    - **IEC 61000-4-2:2008**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 2: Electrostatic discharge immunity test
    - **IEC 61000-4-3:2010**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio-frequency, electromagnetic field immunity test
    - **IEC 61000-4-4:2012**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 4: Electrical fast transient/burst immunity test
    - **IEC 61000-4-5:2005**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 5: Surge immunity test
    - **IEC 61000-4-6:2013**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 6: Conducted immunity test
    - **IEC 61000-4-8:2009**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 8: Power frequency magnetic field immunity test

- **IEC 61000-4-11:2004**, Electromagnetic Compatibility (EMC) - Part 4: Testing and measurement techniques - Section 11: Voltage dips and interruptions immunity test
- **IEC 61000-3-2:2014**, Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16A per phase)
- **IEC 61000-3-3:2013**, Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16A per phase and not subject to conditional connection

- There are no deviations from the listed collateral standards.
- No precautions are needed for the expected service life to maintain the device basic safety with regard to electromagnetic disturbances.
- RF transmitters and receivers incorporated in the device operate in the following frequencies:
    - Bluetooth Hip Unit (BHU): 2.4 GHz (BHU can be incorporated in the system instead of the Portable Dock.) The Effective Radiated Power (ERP) is equal to 2mW.
    - Heart rate monitor; The Effective Radiated Power (ERP) is equal to 2.8Mw.
    - Bluetooth heart rate monitor: 2.4 GHz; The Effective Radiated Power (ERP) is equal to 1mW.