MCU™

Multi-Cervical Unit

User's Manual

Original Instructions

Printed in U.S.A.

This manual supports the BTE Technologies MCU 2

40040005 Rev. E, CO 5618

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 – Regulatory and Safety Information

I. Mandatory Action, Cautions and Warnings 11
II. Electromagnetic Interference 12
III. Operating Voltage 12
IV. Applied Parts 13
V. Servicing 13
VI. Connections 13
VII. Environmental Conditions 13
VIII. Equipment Marking 14
A. Explanation of Symbols and Certification Markings 14
B. Safety and Regulatory Marking on Equipment 14
C. Marking on Equipment Packaging 15
IX. Product Description, Use, and Applications Specifications 15
X. Components Designated as Repairable by Service Personnel 18
XI. Basic Safety Testing 18
XII. Environmental Protection 18
XIII. Performance Characteristics 18
XIV. Information Regarding EC Declaration of Conformity 19
XV. Notice to Customers Located in the European Union 19
XVI. Instructions for Incorporating MCU into IT Network 20

Section 2 - Introduction to the MCU 2

I. Introduction to the MCU 2 23
II. MCU 2 Components 23
A. Multi-Cervical Unit 23
B. Calibration Tools 25
C. Control Module and Cart 25
III. Assembly Instructions 26
A. Setting Up the MCU Station 27
B. Setting Up the Control Module and Cart 30
IV. Calibration and Verification 31
A. Performing the Calibration 32
B. Performing the Verification 36

C. Calibration Reports 37
V. Strongly Recommended Additional Purchases 39
VI. Control Module Care 39

Section 3 - Software Overview

I. Software Navigation 43
A. Color Scheme 43
B. Buttons and Icons 43
C. Input Controls 44
II. Primary Access Points 45
A. Hamburger Menu 45
B. Client Options 46
C. Log Out/Shut Down Control Module 47

Section 4 - Software Setup

I. Software Setup 51
A. Global Settings 53
B. User Management 54
C. Master Data 59

Section 5 - Client Management

I. Adding New Client 65
II. Choosing Existing Client 66
III. Client Overview 66
A. Edit Client information 67
B. Assign and Manage Tests/Exercises (using pre-programmed) 67
C. Reports 71
D. Forms 72
E. History 72

Section 6 - Test Administration

I. Pre-programmed Tests 77
A. Self Reports 77
B. Range of Motion (ROM) 77
C. Strength Tests: 77

D. BTE Assessment Template 78
II. Hardware Setup and Client Positioning for ROM and Strength Tests 79
A. ROM Testing 79
B. Isometric Strength Testing 86
III. Test Execution 100
A. Completing Self-Reports 102
B. Performing ROM Tests 102

Section 7 - Exercise

I. Assign Default Exercises 127
II. Exercise Execution 129
III. Perform Exercises 131
IV. Exercise Reports 135
V. Change Default Exercise Settings 142
VI. Manage Exercises 144

Section 8 - Global Management

I. Global Settings (remaining items) 149
A. Backup Reminder 149
B. LDAP Settings 150
C. Threshold 151
D. HL7 Protocol 152
E. System 153
F. Comparative Data 153
II. Reports / Forms 157
III. Database Management 157
A. Backup Database 157
B. Restore Database 158
C. Change Database 159
D. Export Data 159

Appendix A - EMC Guidelines 165

Section 1 – Regulatory and Safety Information

I. **Mandatory Action, Cautions and Warnings** 11

II. **Electromagnetic Interference** 12

III. **Operating Voltage** 12

IV. **Applied Parts** 13

V. **Servicing** 13

VI. **Connections** 13

VII. **Environmental Conditions** 13

VIII. **Equipment Marking** 14

A. Explanation of Symbols and Certification Markings 14

B. Safety and Regulatory Marking on Equipment 14

C. Marking on Equipment Packaging 15

IX. **Product Description, Use, and Applications Specifications** 15

X. **Components Designated as Repairable by Service Personnel** 18

XI. **Basic Safety Testing** 18

XII. **Environmental Protection** 18

XIII. **Performance Characteristics** 18

XIV. **Information Regarding EC Declaration of Conformity** 19

XV. **Notice to Customers Located in the European Union** 19

XVI. **Instructions for Incorporating MCU into IT Network** 20

I. Mandatory Action, Cautions and Warnings

Mandatory Action

Follow instructions for use.

Cautions

To avoid fall injuries, do not unbuckle client until chair is in position for safe egress.

Do not insert hand into path of halo parts.

Do not place hand in weight stack.

Do not position the equipment to make it difficult to disconnect the MCU column and chair power cord

To avoid monitor screen damage, use only cleaners identified in the maintenance section

Warnings

To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.

Do not modify this equipment without authorization of the manufacturer.

Do not operate the system with the transport casters attached.

To avoid neck injury, ensure that the correct pin is used for weight selection.

An additional multiple socket outlet or extension cord shall not be connected to the MCU system.

To avoid the risk of injury, do not place foot on the frame base between the chair and column.

Only MCU control module, printer, and monitor may be safely attached to the multiple socket outlet

Connecting electrical equipment in the multiple socket outlet effectively leads to creating a medical electrical system and the result can be a reduced level of safety.

The multiple socket outlet located inside the MCU control module cart column base is used to connect the system control module, printer, and monitor. The multiple socket outlet shall only be used for supplying power to the intended electrical equipment that is part of the medical electrical system. If other electrical equipment is connected, electrical current drawn by the system could exceed the maximum allowed current tripping the circuit breaker. This could make the equipment non-operational and delay treatment benefits for the client.

The responsible organization (e.g. the customer) must refer to the standard IEC 60601-1, third edition, for the requirements that are applicable to a medical electrical system (ME System).

The appliance (power) inlet located on the back side of the MCU column near the floor can be used to disconnect the equipment from a supply main. The MCU should not be located where access to the inlet is blocked.

II. Electromagnetic Interference

The MCU 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.

III. Operating Voltage

The MCU has two components: the control module cart and the base unit. The control module cart is capable of operating at the following voltages and frequencies which are factory set and noted on the external transformer case:

100V~ 50/60Hz

120V~ 60Hz

200V~ 50/60Hz

230V~ 50Hz

The base unit is capable of operating at the following voltages and frequencies which are set at the factory:

120V~ 50/60Hz

230V~ 50Hz

IV. Applied Parts

MCU applied parts include head braces (load cells) and the chair. The parts are designed as Type B Applied Parts.

V. Servicing

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

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

VI. Connections

Hosting Device	Port	Connected Device
Control Module	USB	Keyboard
		Mouse -or- pointing device
		Printer
		USB Powered Speakers
		BTE Hub
	VGA video output	LCD -or- LED Monitor
BTE Hub	SMA Connector	Wired connection to base unit
Base Unit	RJ45 Connector SMA Connector	Load cell attachments Wired connection to BTE hub

VII. Environmental Conditions

Permissible Environmental Operating Conditions:

Ambient temperature: +10° C to +40° C

Relative humidity: 30% to 75%

Atmospheric pressure: 700 hPa to 1060 hPa

The MCU sound pressure level does not exceed 70dbA at the workstation.

VIII. Equipment Marking

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	
General Warning Sign		Pinch Point Label	
Follow Instructions for Use		Crush Zone Label	
Type B Applied Part		Protective Earth	
“ON” (Power)		Alternating Current	
“OFF” (Power)		Do Not Forklift (or similar label)	
Do Not Use Blades to Open (or similar label)		Safety Certification	

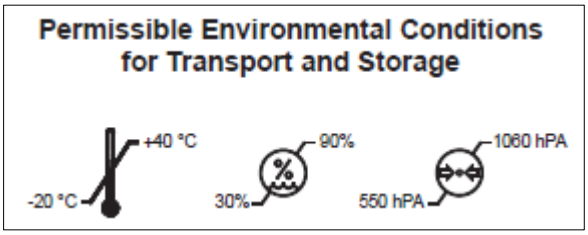
B. Safety and Regulatory Marking on Equipment

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Only MCU control module, printer, and monitor may be safely attached to the multiple socket outlet.

EC REP REF SN SGS C US 710101 CE (where applicable)

C. Marking on Equipment Packaging



IX. Product Description, Use, and Applications Specifications

Device: MCU Multi-Cervical Unit

Model: MCU 2

Short Description

A rehabilitation device for neck strengthening exercises, as well as measurement of cervical spine range of motion and strength. Neck musculoskeletal measurements can be taken for flexion, extension, lateral flexion, rotation, and for combined planes.

General Description

MCU Multi-Cervical Unit is used for cervical musculoskeletal measurement and treatment. Applications include chronic neck pain, whiplash and associated disorders, and neck weakness. The device is intended to measure deficits in strength and motion, increase strength and range of motion, and to track client progress through the process.

The active range of motion of the neck and the isometric strength of neck muscles can be measured in the following directions: flexion, extension, lateral flexion, rotation, and in combined planes.

Intended Use (Intended Purpose)

MCU is an exercise and measurement device that is intended for use in physical rehabilitation. The system offers a means to provide isometric and dynamic resistance for the physical rehabilitation of clients with injuries that affect the cervical spine musculature. MCU is used to improve the range of motion, muscle strength and muscle endurance of the targeted muscles.

The system measures force output (in terms of maximum isometric contraction) and range of motion of clients using the device. The information gathered by the computerized data collection systems on the device is used in the documentation of client progress from one treatment session to the next, as visual performance feedback, and to measure and compare the symmetry of strength and range of motion of the neck.

Application Specification

Intended Medical Indication

The system is intended for cervical exercise and to measure cervical strength and range of motion.

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. Contraindications include the following:

- cervical spinal cord injury
- healing fractures
- neural torticollis
- cervical malignancies
- spinal malignancies (unless medically cleared)
- pregnancies in the final trimester

Intended Client Population

General Population; anyone whose muscle strength or range of motion (ROM) needs to be measured. The device can be used with clients that weight up to 158 kg (350 lbs.). Clinical judgment is required to determine whether client should perform assessments.

Intended Anatomical Applicability

Measurement of the cervical musculoskeletal system

Intended User Profile

Medical healthcare professionals

Intended Conditions of Use

Office or clinic setting

Frequency of Use

There is no frequency of use restrictions for this device.

Use of Energy Source

An electric power source is required to move chair during setup, for system communication, and computing purposes.

Transfer of Energy to Client

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

Operating Principle

Client is seated with their head positioned in a halo. The halo can rotate about the vertical axis and horizontal axis. The client is asked to move their head in the axis through available or unrestricted range of motion. A load cell measures the force applied while potentiometers measure the distance moved. The data is reported to the operator for analysis.

The MCU provides rehabilitation of the neck muscles through the use of a weight stack that resists the movement of the halo. Various weights can be applied allowing the operator to increase or decrease force. A progressive resistive exercise program used to strengthen the neck muscles can be entered into the software and progress monitored.

Essential Performance

The device does not have any essential performance characteristics.

Essential Functions

Measurement – Provides charts and graphs with sufficient data for an operator to measure the neck strength and range of motion of a client;

Exercise – Permits the client to perform neck strengthening exercises;

Reports – Allows the operator to view and print reports on the client's progress;

Frequently Used Functions

The frequently used functions of the device will be the client record to evaluate strength and range of motion. Also, the clinician may assign one or more exercises to the client to increase strength and motion of the cervical spine.

X. Components Designated as Repairable by Service Personnel

There are no components on which preventative inspection and maintenance shall be performed by service personnel. Components will be replaced if needed in accordance with BTE service policy. In addition, documentation and instructions for any in-field repairs to be conducted by service personnel will be provided.

XI. Basic Safety Testing

Check monthly all the cables to ensure they are secure and in good working condition.

XII. 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.

XIII. Performance Characteristics

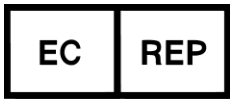
Load cells maximum is 50 lbs. with accuracy of +/-0.2% over the range.

The accuracy of potentiometers for rotation and flexion are not given in absolute values. What is defined is that the repeating of the measurement should provide a result within 2% of the initial reading. Rotation and flexion ranges are each +/-90 degrees.

XIV. Information Regarding EC Declaration of Conformity

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

The following information applies to the product:

Name and contact information of the manufacturer	 BTE Technologies 7455-L New Ridge Road Hanover, MD 21076, USA Telephone: (410) 850-0333 www.btetechnologies.com
Product identification	Product Name: MCU Multi-Cervical Unit Model: MCU 2
Medical device class	Class I
Route to compliance	Annex VII of the Medical Devices Directive
Intended use	System used for cervical neck assessment and rehabilitation
Contact information of the manufacturer's authorized representative operating in the European Community	 Emergo Europe Authorized Representative in Europe Prinsessegracht 20 The Hague 2514 AP The Netherlands Email: EmergoEurope@ul.com
CE marking	 The CE marking is placed on the device, where applicable.

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

XV. 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 Customer Service is your point of contact for technical support.

XVI. Instructions for Incorporating MCU 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 or a medical electrical system equipment

Your MCU 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 module.

Connection of the MCU to an IT network that includes other equipment could result in previously unidentified risks to clients, 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

Section 2 – Introduction to the MCU 2

I. Introduction to the MCU 2 23

II. MCU 2 Components 23

A. Multi-Cervical Unit 23

B. Calibration Tools 25

C. Control Module and Cart 25

III. Assembly Instructions 26

A. Setting Up the MCU Station 27

B. Setting Up the Control Module and Cart 30

1. Control Module 30
2. Printer 30
3. Mouse 30
4. Hub 30
5. Isolation Transformer 31

IV. Calibration and Verification 31

A. Performing the Calibration 32

B. Performing the Verification 36

C. Calibration Reports 37

V. Strongly Recommended Additional Purchases 39

VI. Control Module Care 39

I. Introduction to the MCU 2

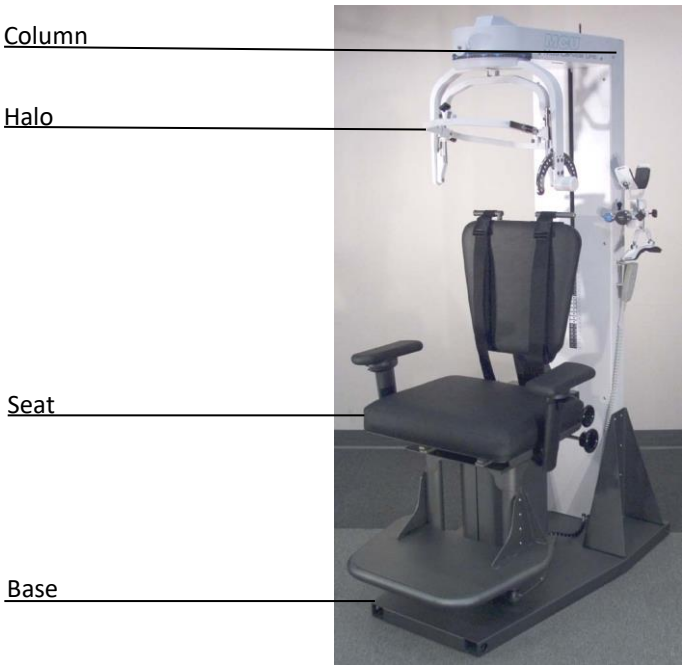
The MCU 2™ User's Manual will review the basic components of the system. Once you are familiar with the components, you can explore the techniques and protocols for performing a range of motion and isometric strength cervical assessment as well as isotonic exercise. This manual will also review the different types of reports that are automatically generated using the information acquired throughout the assessment.

II. MCU 2 Components

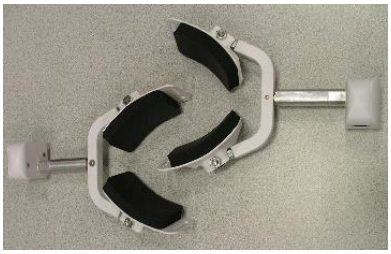
The MCU consists of the base, column with weight stack, seat, halo, weight stack pins, ROM stop, 2 head braces, 3 Velcro straps, and 4 RJ45 cables (2 short and 2 long (Figure 1-1).

DO NOT CHANGE OR MODIFY ANY COMPONENTS
Any changes or modifications not expressly approved by BTE Technologies could void the user's authority to operate the equipment.

A. Multi-Cervical Unit



Head Braces



Velcro Straps

ROM Stops

Weight Stack Pins

RJ45 Cables

B. Calibration Tools

The MCU 2 calibration kit consists of one calibration block, one 10 lb. weight, and one 15 lb. weight.

C. Control Module and Cart

The Control Module equipment consists of a Cart, Printer, Isolation Transformer, Hub, and Direct Connect Cable.

Cart and Printer

Isolation Transformer

Hub

Direct Connect Cable

III. Assembly Instructions

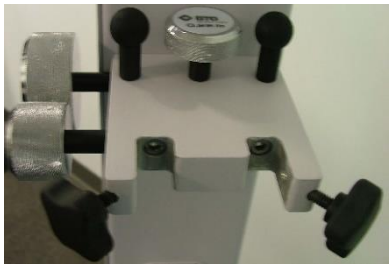
Once the MCU Unit and cart have been unpacked, you are ready to start assembling the unit.

A. Setting Up the MCU Station

The MCU is shipped on casters to provide maximum protection in transit and ease of installation. The caster assemblies also provide adjustable ground clearance. The system is shipped in the highest position to clear ramps, curbs, and thresholds, but it can also be lowered to pass under low doorways.

Step 1. Move the MCU™ to the location you wish it to be used. Using a 3/4” wrench, lower each caster a small amount until the MCU base is resting on the ground. Once the base is on the ground, remove the casters.

Step 2. Locate the weight stack pins and ROM stop pin and place them in the corresponding holes on the calibration plate.



Step 3. Locate the head braces (also known as load cells) and secure them to the calibration plate.

Step 4. Locate the Velcro straps and RJ45 cables. These may be placed on the control module cart.

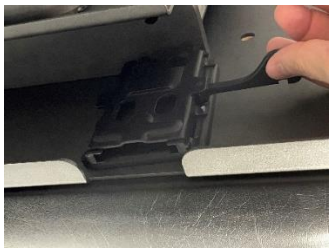
Step 5. Locate the calibration weights and calibration block and place them in the triangular bracket on the base.

Step 6. Locate the Direct Connect Cable and then locate the large hole on the top back of the MCU Unit. Insert the cable through this hole and secure it to the PCB.

Step 7. Locate the arm rests (note which is labeled left and which is labeled right) and attach them to the seat on the appropriate sides. Note that the armrest is inserted below the plastic piece that is within the bracket.

Attachment point on armrest

Press lever towards center of chair



Insert Arm Rest into Bracket

Insert arm rest fully

Press the lever to the outside of the chair until it parallel with the arm rest bracket

Step 8. Plug the power cord, which is located at the bottom back of the MCU, into the designated wall outlet. Hold your hand above the back of the MCU, next to the cable, and verify a light shines on your hand; this confirms the PCB is receiving power.


B. Setting Up the Control Module and Cart

1. Control Module

Remove the Control Module from its box and place it on the top shelf of the cart. Plug in the power cord and Hub.

2. Printer

Remove the printer from its box and place it on the 2nd shelf of the cart. Following the instructions within the printer box, insert the ink cartridges and plug in the power cord and USB cable. Once the control module is running and the printer is turned on, print a test page.

3. Mouse

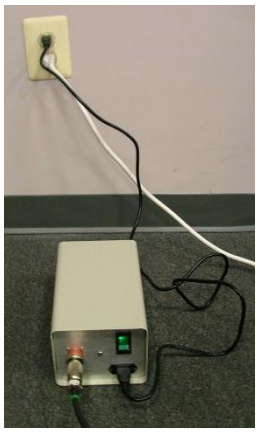
Remove the mouse from the box and plug it in to the control module. Place the mouse on the auxiliary shelf of the cart.

4. Hub

Place the hub it on the 1St or 2nd shelf of the control module cart. Note that there are magnets inside of the Hub which are intended to keep the Hub stable on the shelf. Secure the cable (from Step 6 of 'Setting Up the MCU Unit') to the Hub. Plug the USB cable into the Control Module.

5. Isolation Transformer

Locate the isolation transformer and its power cord and place it next to the designated wall outlet. Attach the control module cart cable, which is located at the bottom back of the cart, to the isolation transformer. Plug one end of the isolation transformer power cord into the isolation transformer and the other end into the designated wall outlet. Turn on the isolation transformer via the green switch.



The use of extension cords is not recommended. If an extension cord cannot be avoided, use no less than 14-gauge wire. Keep the cord as short as possible, and use only hospital approved plugs. The extension cord MUST complete the ground from the MCU power supply cord to the wall outlet.

IV. Calibration and Verification

The calibration and verification processes are performed to ensure the accuracy of the head brace, load cell readings, and readings from potentiometers located in the halo and seat. Prior to first use, the unit must be calibrated and verified. Afterwards, it is recommended to verify daily and to recalibrate when verification is unsuccessful. Reminders may be set in the software for calibrations and verifications.

To calibrate and verify the head brace load cells and halo and seat potentiometers, instructions provided in the software will walk you through the process. The software will indicate whether the load cell and potentiometer readings passed or failed calibration and/or verification.

Should calibration and/or verification of head brace load cells fail:

- check that correct weight is being used and
- check that the RJ45 cable is connected to the correct load cell
- remove weight and check that head brace is positioned correctly in the calibration block. Then proceed through same process shown on screen.

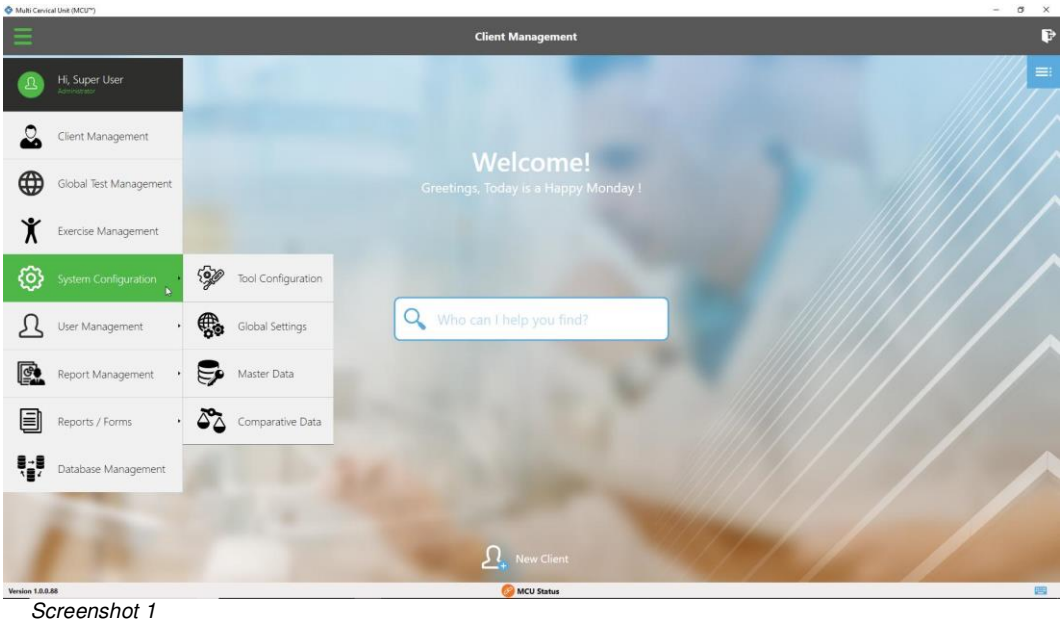
Should calibration and/or verification of the halo and seat potentiometers fail:

- check that the Hub is plugged in to the Control Module
- be sure positions of the chair were correct

- be sure movements of the halo were in correct directions and to the degree

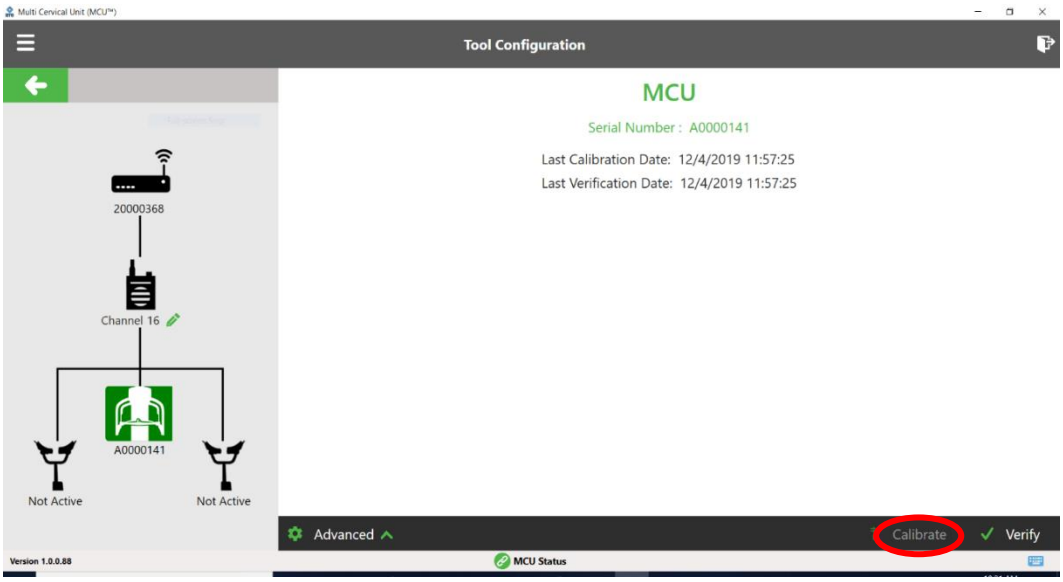
A. Performing the Calibration

Power on the isolation transformer which will power up the control module. The system will load up to the MCU kiosk. To login, enter the default username ‘bte’ and password ‘7455’. From the Client Management window, open the hamburger menu, select System Configuration and Tool Configuration all of which are designated in *Screenshot 1*.



Screenshot 1

The MCU™ Tool Configuration screen will appear. On the left are icons for the following components: hub, halo, and load cells. They will be labeled inactive or active depending on their state – active (green) indicates power on and connected/communicating. The screen will indicate the last date of successful calibration and verification when you click on the icon for the “MCU” or the “Load Cell” (*Screenshot 2*). If Calibration is necessary, the “Calibrate” text will be available.



Screenshot 2

Step 1. Secure the rod of the head brace you wish to calibrate to the calibration plate (Figure 5-1). Make sure the RJ45 cable is plugged into the head brace and to the port directly above the halo on the underside of the MCU (Figure 5-2)

Figure 5-1

Figure 5-2

Step 2. Place the calibration block on the head brace (Figure 5-5).

Figure 5-3

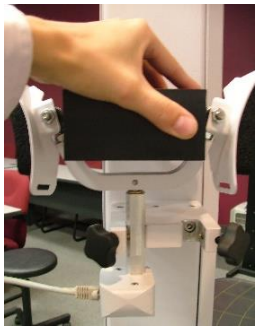


Figure 5-4

Figure 5-5

Step 3. Place the calibration weight(s) on the calibration block (Figure 5-6). Enter the amount of weight you are using to calibrate, remembering to add the weight of the calibration block, in the calibration screen.

Verify that neither the calibration block nor the U-bracket of the head brace are touching the calibration plate.

Figure 5-6

Step 4. Remove the calibration weights from the calibration block before proceeding with the rest of the calibration.

Step 5. If it is not already, set the halo rotation to 0 degrees (Figure 5-7).

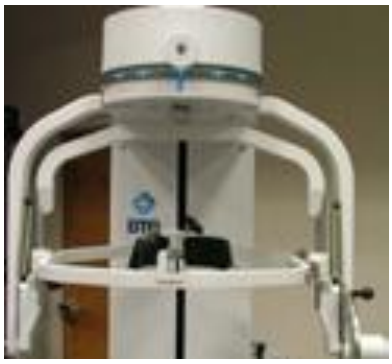


Figure 5-7

Step 6. Unlock the rotation pin, set the halo rotation to 90 degrees LEFT (which means the halo is rotated to the right), and then lock the rotation pin (Figure 5-8). Click OK on the calibration screen.

Figure 5-8

Step 7. Unlock the rotation pin, rotate the halo back to 0 degrees, and then lock the rotation pin.

Step 8. If it is not already, set the halo flexion/extension angle to 0 degrees and insert the ROM stop pin (Figure 5-9).

Figure 5-9

Step 9. Remove the ROM stop pin, set the halo flexion/extension angle to 70 degrees flexion, and then insert the ROM stop pin (Figure 5-10.1 and 5-10.2).

Figure 5-10.1

Figure 5-10.2

Step 10. Remove the ROM stop pin, set the halo flexion/extension angle back to 0 degrees, and insert the ROM stop pin.

Step 11. If it is not already, lower the seat height to its lowest position.

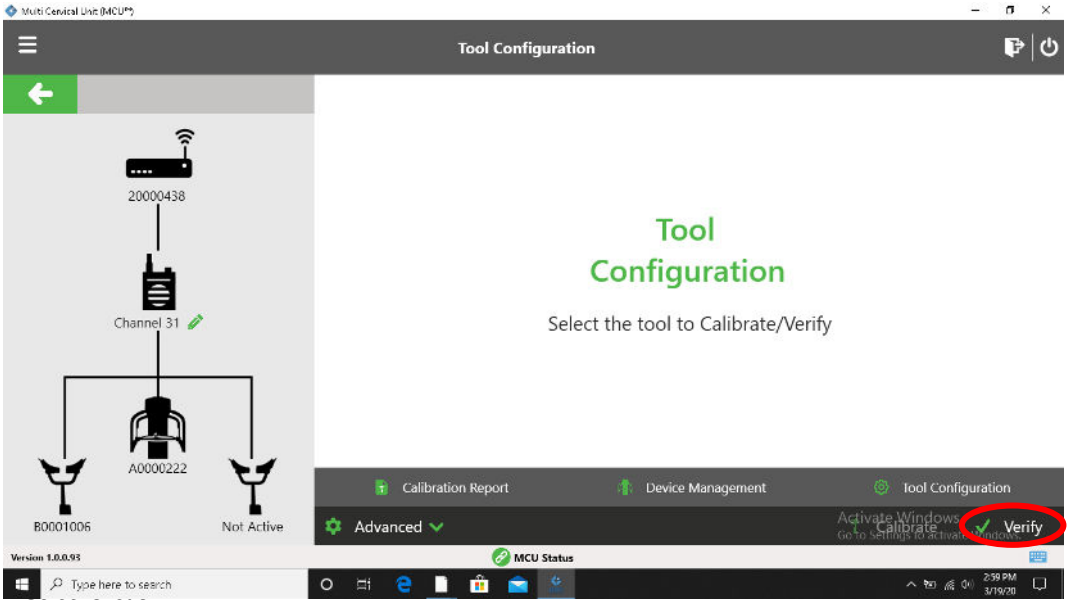
Step 12. Make sure the seat height is at its lowest position, and then raise the seat height to its highest position (Figure 5-11).

Figure 5-11

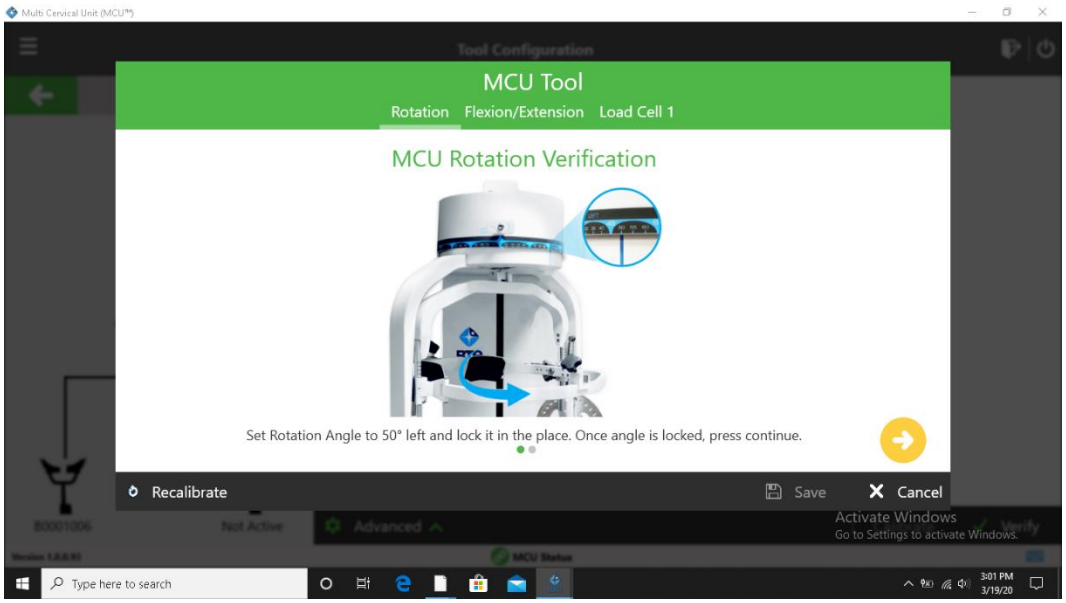
Step 13. Once the device has been successfully calibrated a screen will appear requesting the name of the individual who just completed the calibration.

B. Performing the Verification

It is recommended that the accuracy of the device be verified after calibration. The Verification option can be accessed under the Hamburger menu. Select System Configuration and Tool Configuration (*Screenshot 1*). The Verify Check is on the bottom right hand side. You will be able to verify the Rotation angle, Flexion/Extension Angle and the Load Cell (*Screenshot 3*).

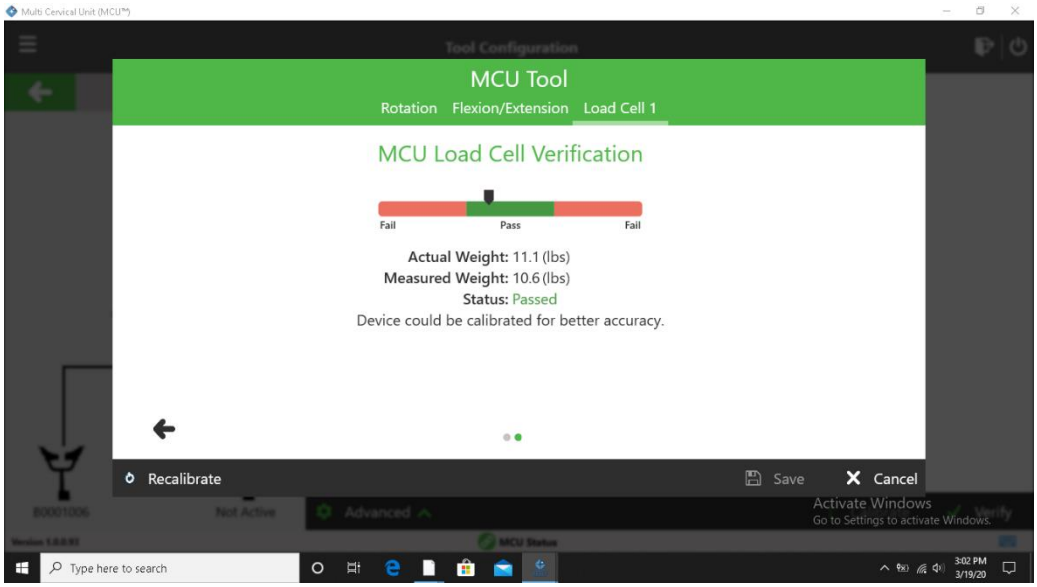


The MCU™ verification screen will appear-(Screenshot 4).



Screenshot 4

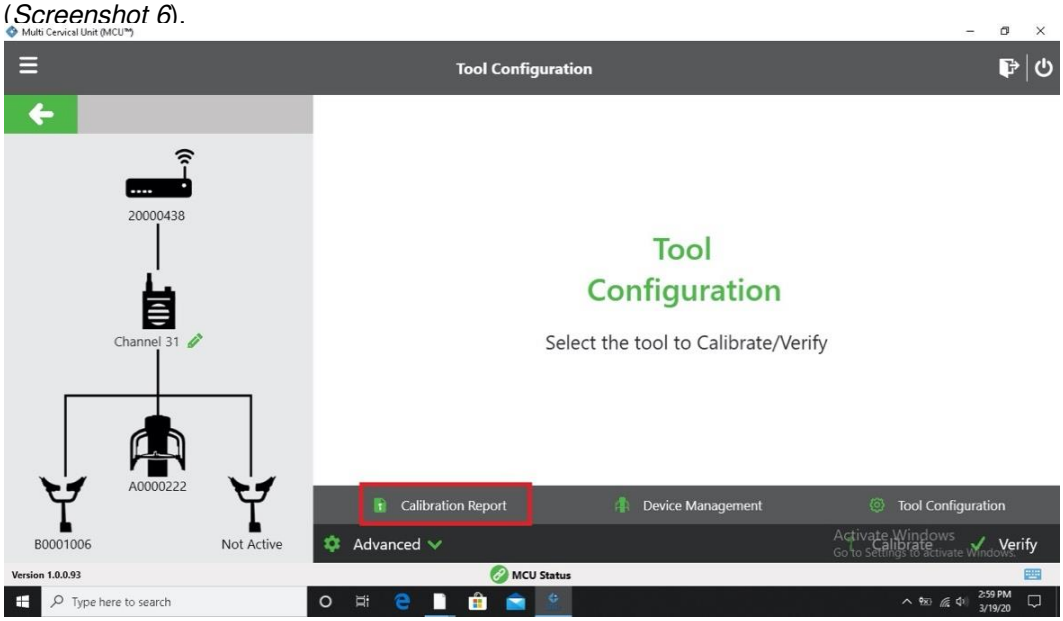
The verification tools and process are essentially the same as calibration. Follow the prompts on the screen and select “Save” when those positions have been verified successfully. (*Screenshot 5*)



Screenshot 5

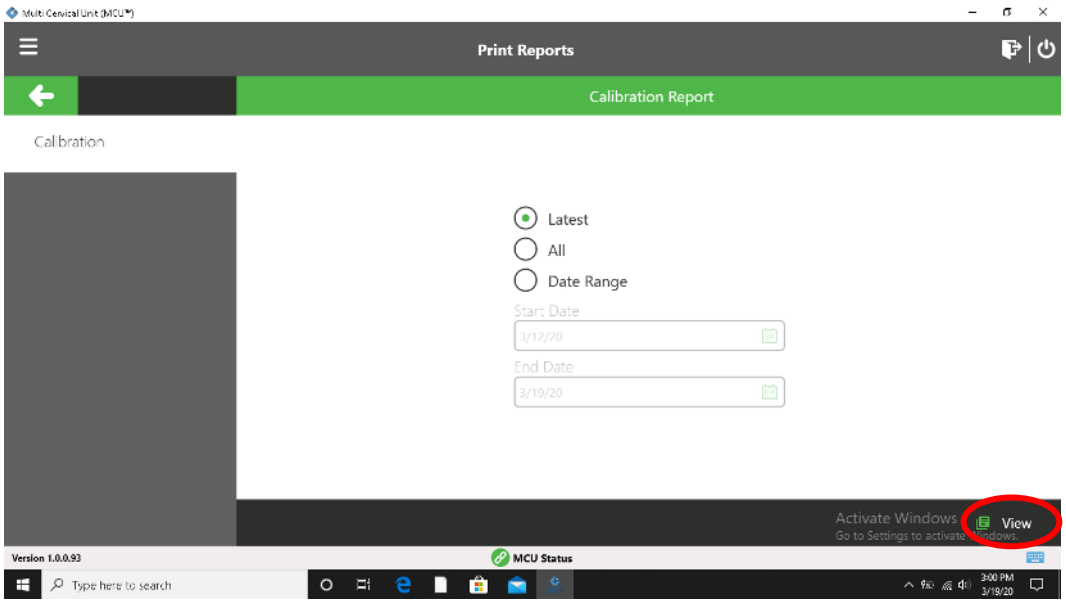
C. Calibration Reports

To print or view the calibration and verification reports, go to System Configuration and Tool Configuration. You can find the calibration report under the Advanced Options on the bottom of the tool configuration page. Click Advanced and then Calibration Report (*Screenshot 6*).



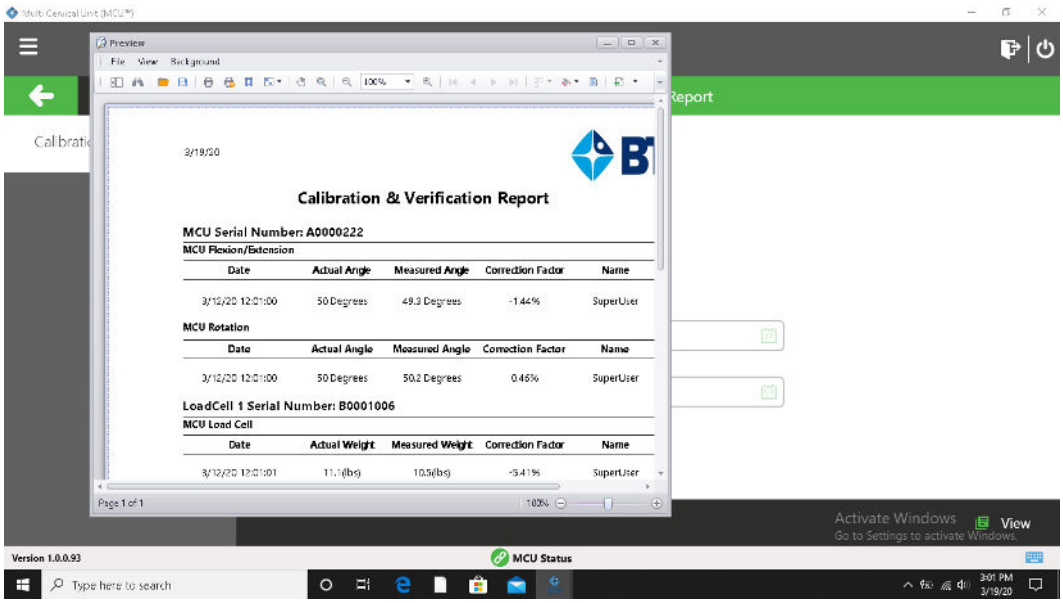
Screenshot 6

From there, you can choose to create a calibration report based on the most recent calibration, all calibrations, or those within a specific date range. When the desired option is selected, click on the View option in the bottom right (*Screenshot 7*).



Screenshot 7

The calibration report will be generated, and you will be able to save or print the report. Reports include the position in which the calibration was performed, the Serial Number of the load cell, the date of the calibration, actual vs measured angle, correction factor, and name of the person who performed the calibration/verification (*Screenshot 8*).



Screenshot 8

V. 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:

- a USB drive for backing up and archiving copies of client data.
- an Uninterruptible Power Supply (UPS) unit providing at least 14 amps as a safeguard against the permanent loss of client information due to a power surge or electrical power failure.
- disinfectant wipes to clean the commonly used surfaces on the machine and components.

IMPORTANT
In case of a malfunction, your control module can be repaired or replaced, but your client data can only be restored from copies kept on “back-up“ USB drive (See Section 2 - General Information).

VI. Control Module Care

IMPORTANT
Handle your control module with extreme care. A drop or bump, even from a height of 3 - 4 inches, may cause serious damage, which is not covered by the warranty.

A Control Module’s hard disk is vulnerable to loss of data and “corruption” of data (may not function correctly when you attempt to retrieve client information) from a sudden change in the level of electrical power. In the event of a power failure, the UPS battery will generate electricity long enough to allow you to shut down the system without damage to your client data.

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 an air conditioner).

Do not install any additional software onto the control module. The BTE Technologies MCU system is in contact communication, so a “clean”, dedicated system is crucial to the integrity of this communication. Lastly, your control module will not be covered under the warranty if any unapproved software has been installed.

Section 3 - Overview of Software

I. Software Navigation 43

A. Color Scheme 43
B. Buttons and Icons 43
C. Input Controls 44

II. Primary Access Points 45

A. Hamburger Menu 45
B. Client Options 46
C. Log Out/Shut Down Control Module 47

I. Software Navigation

The user interface of the MCU 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, exercise, 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.

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 / Manage
	Cancel and Close		Proceed
	Go Back		Logout
	Hamburger Menu		List
	Client		Tests

Global Reports

Client Reports

Range of Motion

Strength

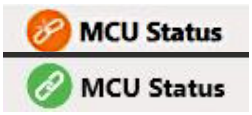
Exercise

Self-Reports

Forms

Settings

State of Communication of Tools



Red = No Communication

Green = Communicating

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

C. Input Controls

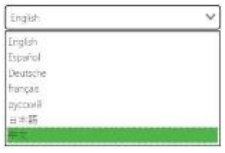
Input Controls used in the software include:

Checkbox – Click to select and deselect

Keyboard

Toggle on

Toggle off



Dropdown List – Choose from pre-populated options

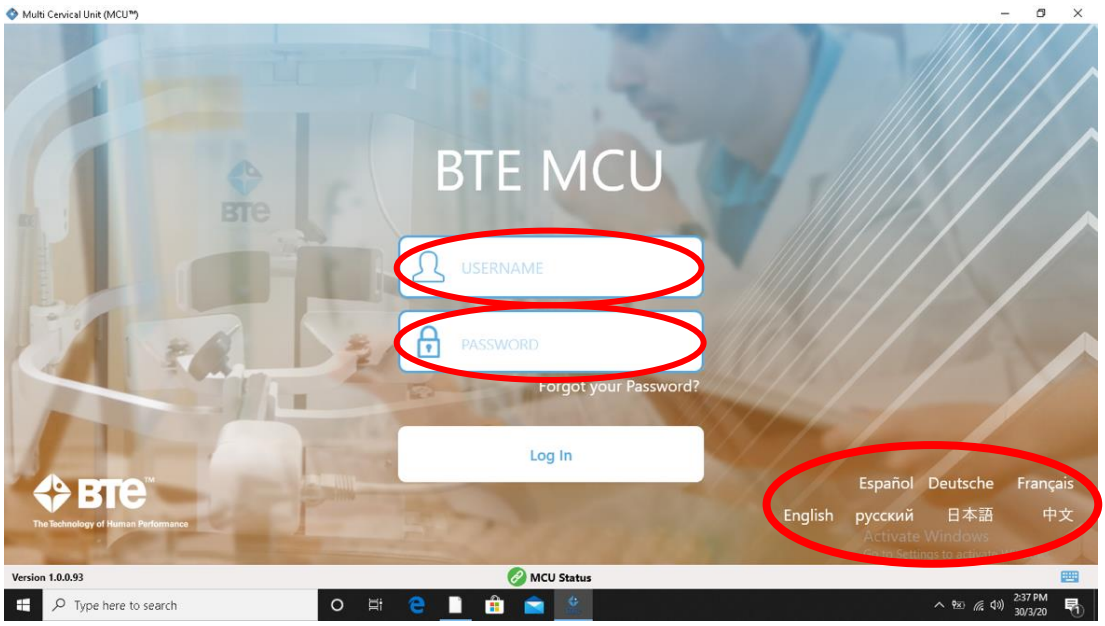
Radio Button – Click to choose option, function

Text Field – Place cursor in field and enter information

II. Primary Access Points

After turning on your control module, the system opens the MCU in 'kiosk' mode. From here, you can change the default language to that of your choosing by selecting the desired option from the bottom right. (*Screenshot 1*).

To enter the software, enter your username and password. The default username is "bte" and the password is "7455." (*Screenshot 1)*. It is recommended that each user create their own login credentials and profile which will be discussed later.

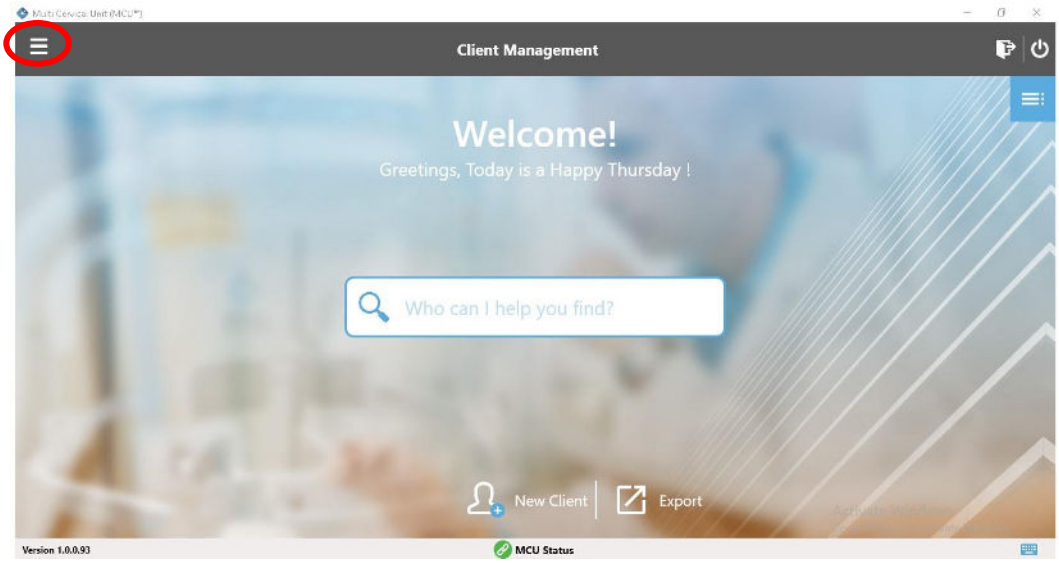


Screenshot 1

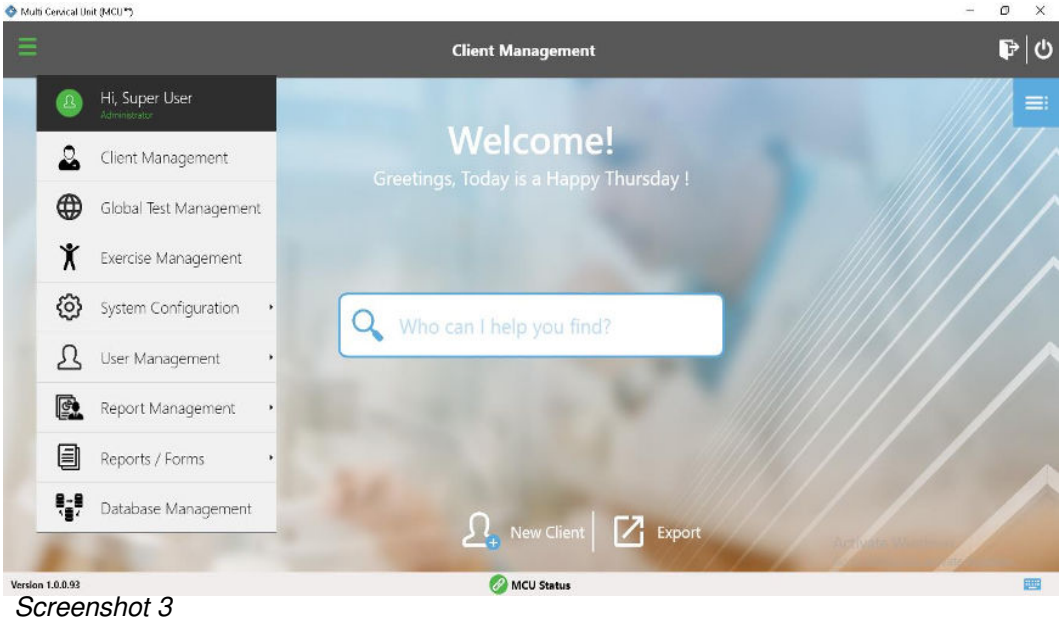
The Client Management window serves as the 'home page' of the software (*Screenshot 2*). The two primary access points for the software are available here. They are the Hamburger Menu located in the upper left corner and the Client List located in the upper right corner of the window.

A. Hamburger Menu

The Hamburger Menu provides access to the administrative options in the software (Screenshot *2 & 3)*.



Screenshot 2

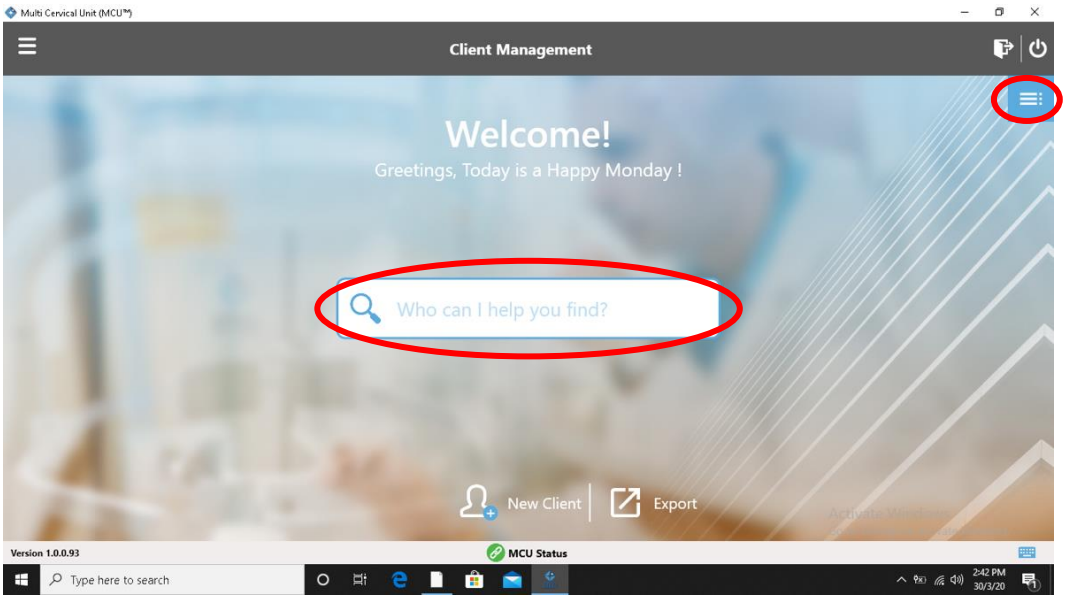


Screenshot 3

B. Client Options

There are several options that provide access to client information.

Access to Clients includes:



Screenshot 4

Choose existing client using the List

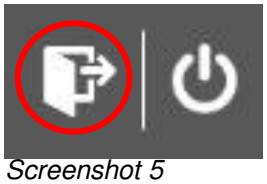
Add new client

Choose existing client using Search

These options will be further discussed in Section 4.

C. Log Out/Shut Down Control Module

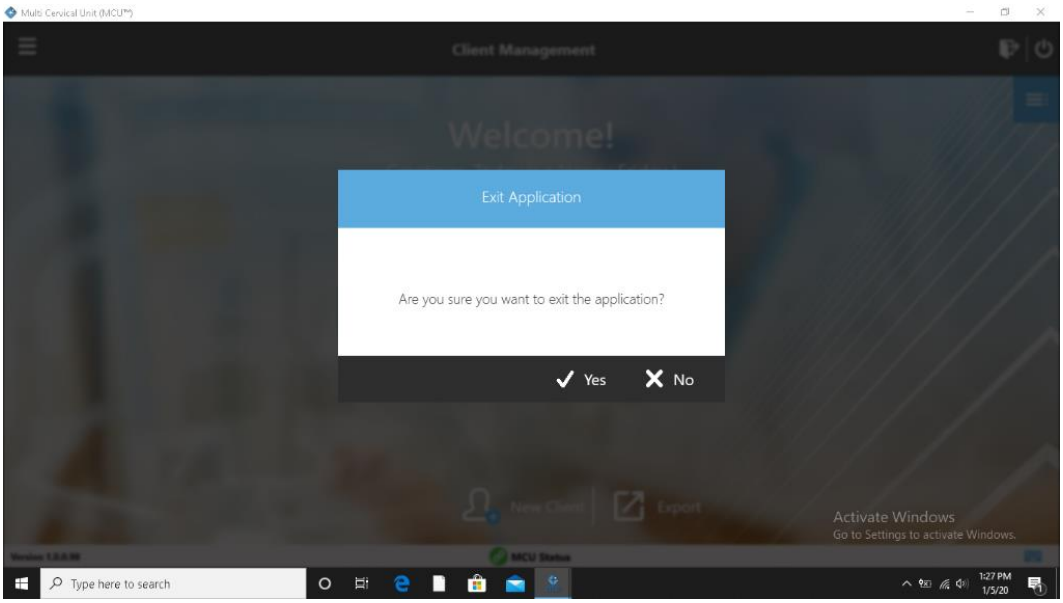
To log out of the software, use the log out icon in the upper right-hand corner of the screen (*Screenshot 5*).



Screenshot 5

When shutting down the control module, it is HIGHLY RECOMMENDED that you do not turn off the power supply on the transformer while the control module is still on. First, power down the control module (*Screenshot 6*). A message will appear asking if you would like to exit the application (*Screenshot 7*). When the screen goes black, it is safe to power off the transformer.

Screenshot 6



Screenshot 7

When turning the transformer back on, the MCU kiosk will load.

Section 4 – Software Setup

I. Software Setup 51

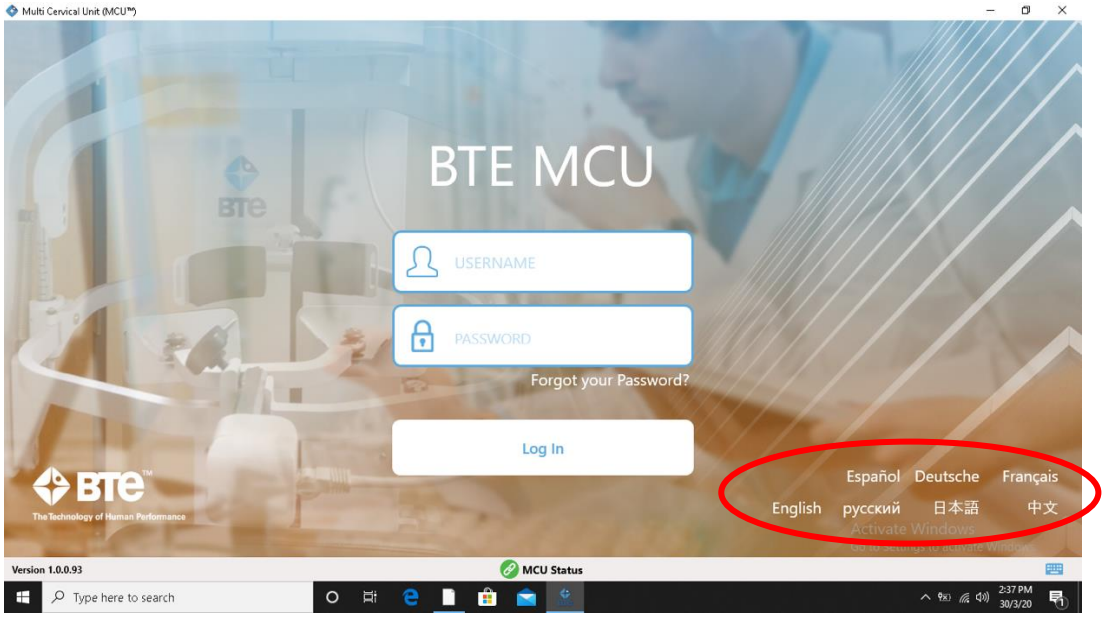
A. Global Settings 53
B. User Management 54
1. Manage Role 56
2. Manage Clinic 58
C. Master Data 59

I. Software Setup

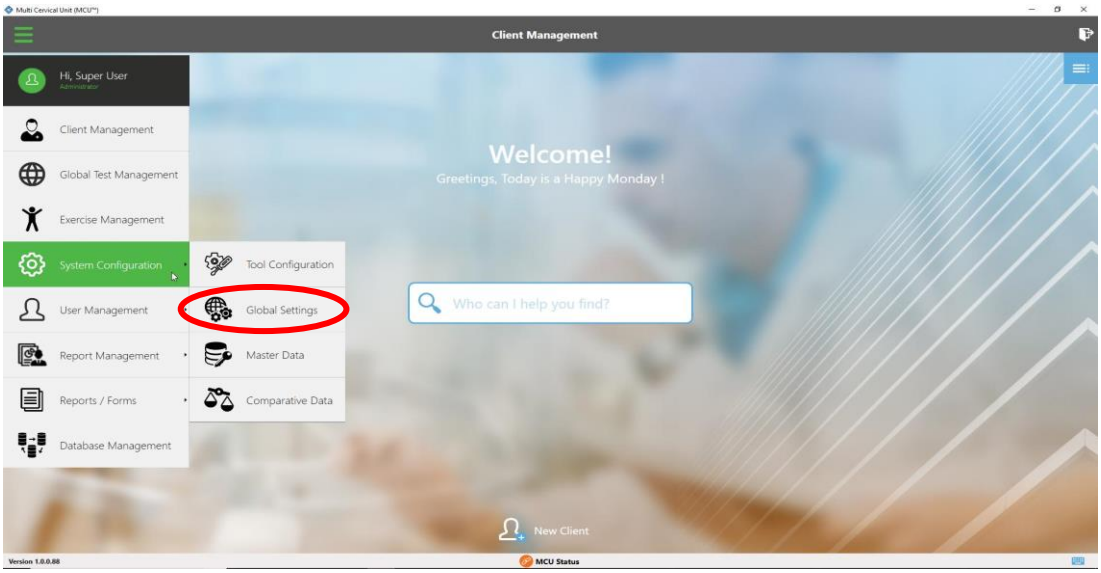
In preparation for using the software, there are several recommendations to offer. First, review the settings for language and the units of measure for the software to ensure they are appropriate for you.

The language can be changed from the login screen (Screenshot 1). If not done so at this point, it can also be changed from the Client Management screen.

Step 1. Open the Hamburger Menu and select System Configuration. (Screenshot 2).

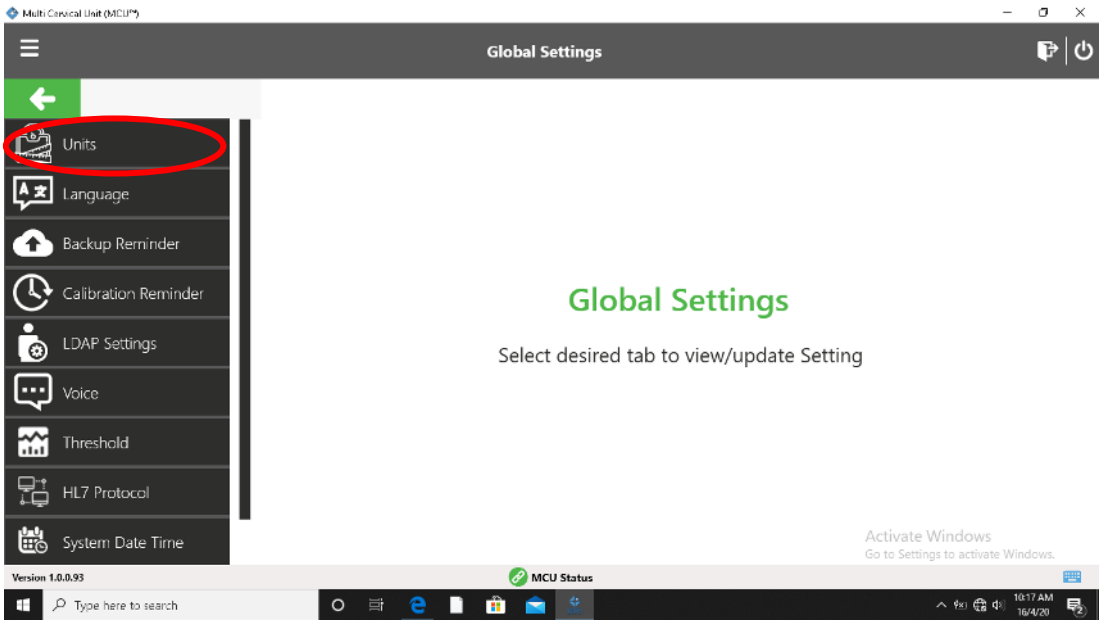


Screenshot 1

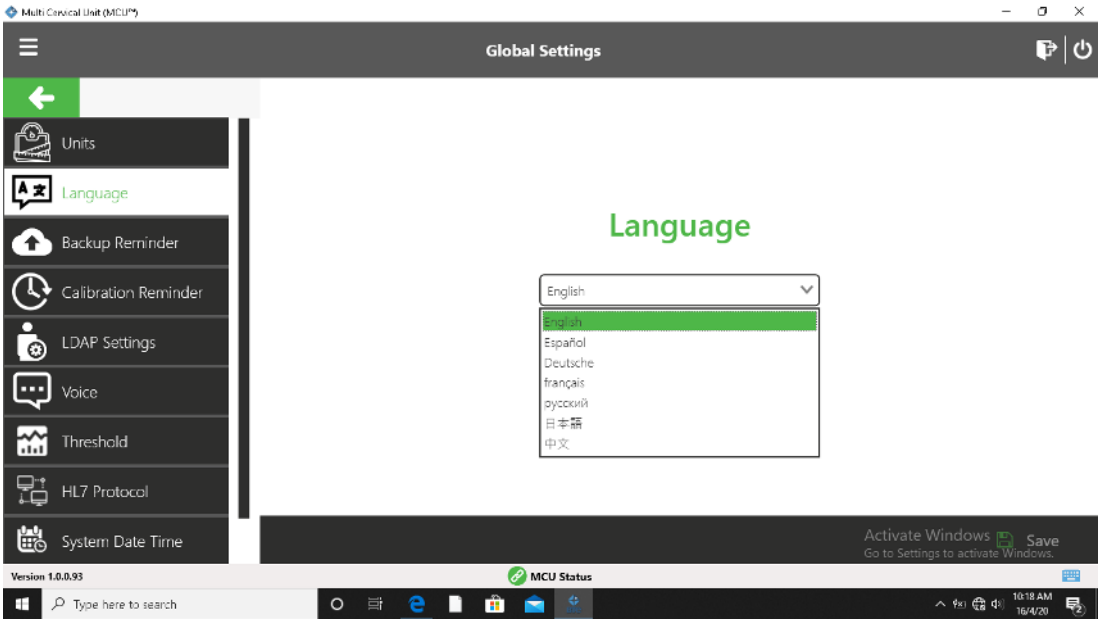


Screenshot 2

Step 2. From the Global Settings page, the Language can be found on the left side (*Screenshot 3*). Click and see the list of available languages. Save when finished (*Screenshot 4*).



Screenshot 3

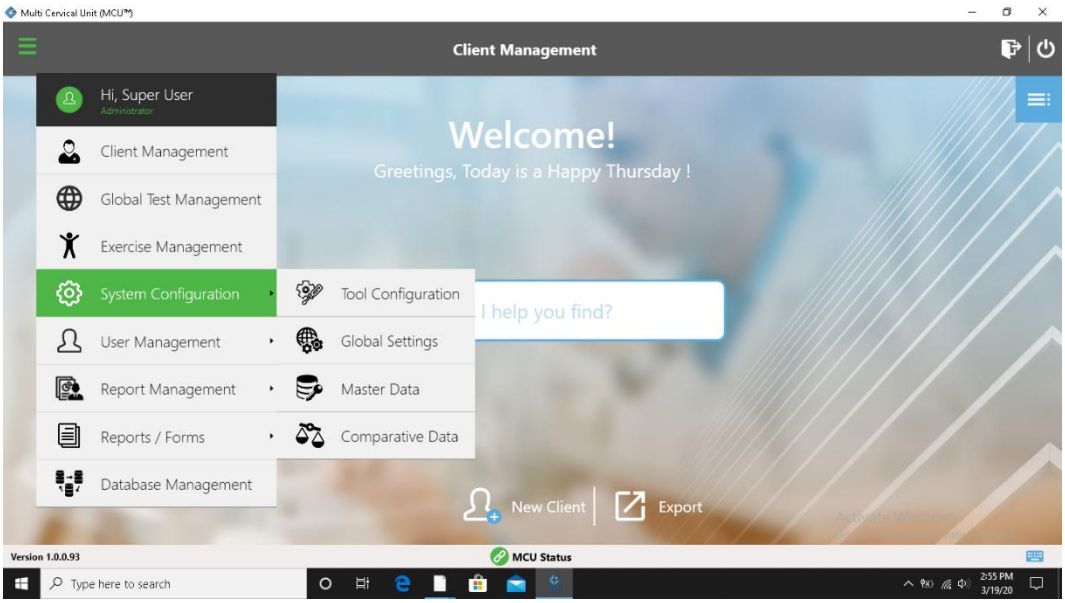


Screenshot 4

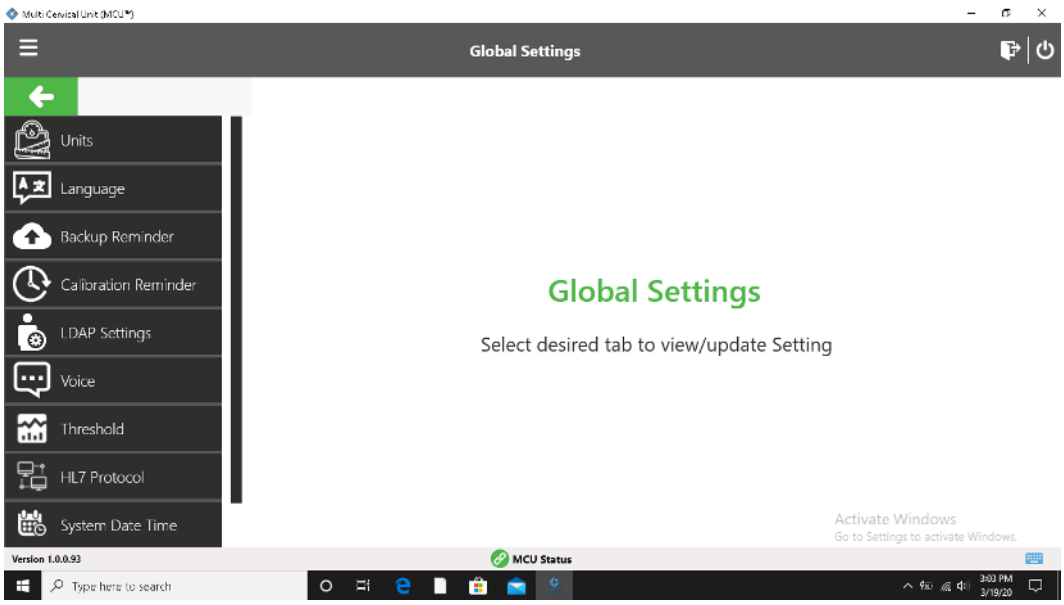
A. Global Settings

Here, you will be able to make system wide changes to the functionality of the software (*Screenshot 5*). Among items in this section are the ability to: change units, the language, set a backup reminder, set a calibration reminder, change LDAP settings, change the system voice, adjust the force and angle thresholds, connect to your EMR (HL7), and change the system date and time.

Select the desired option and enter the necessary changes. Be sure and select 'Save' once finished.



Screenshot 5

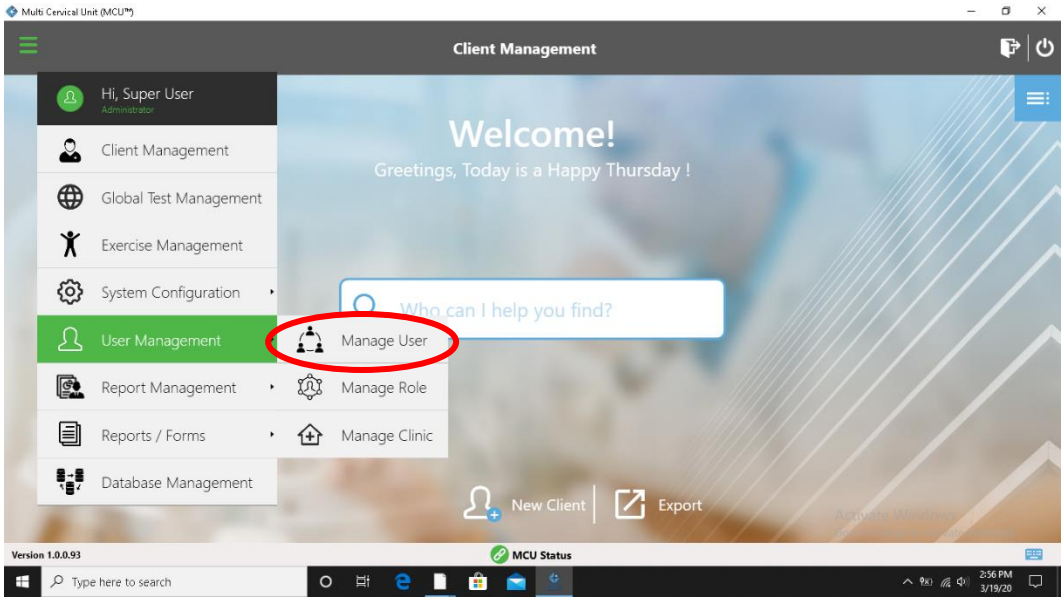


Screenshot 6

B. User Management

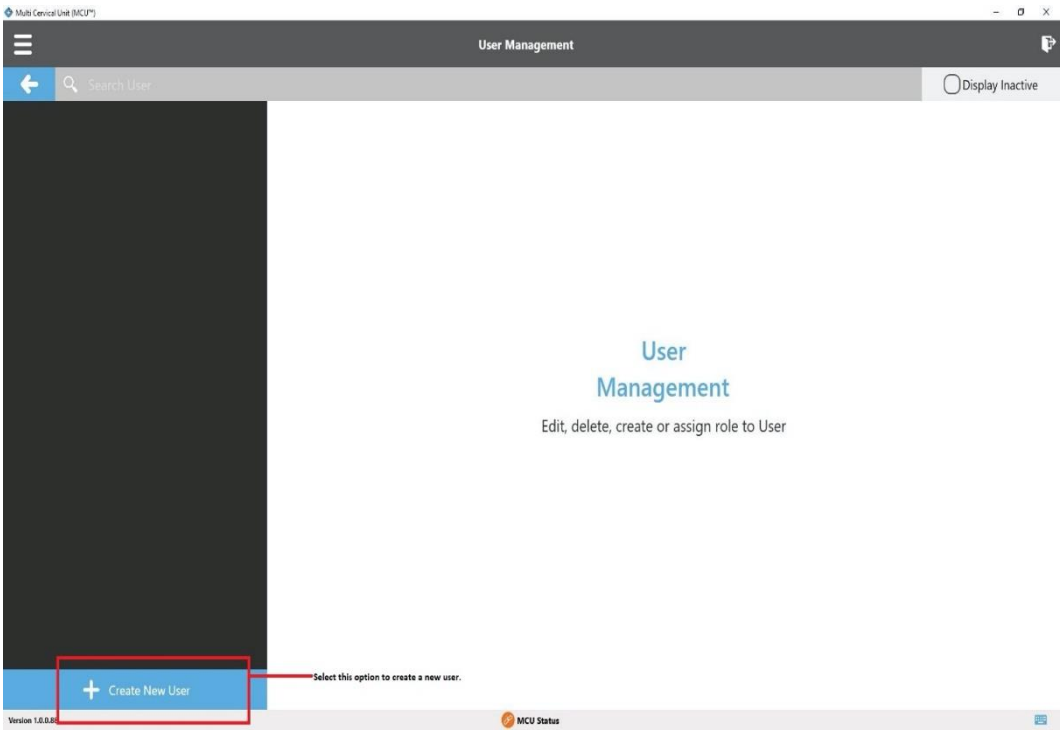
Should you decide that all users of the equipment have dedicated usernames and passwords rather than use the factory supplied username and password, User Management provides the tools to do so. Additionally, the access those users have to the functions of the software and clinic information that can appear on reports are addressed here.

Open the Hamburger Menu and choose User Management. Click that item to access the three available options: Manage User, Manage Role, and Manage Clinic *(Screenshot 7)*.



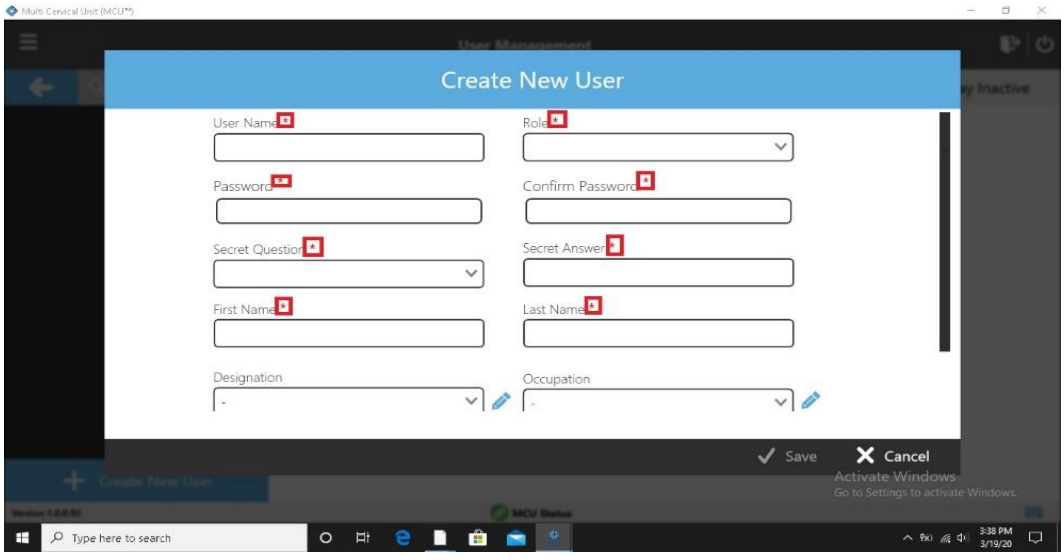
Screenshot 7

If there are existing users, those names will appear on the left-hand side of the User Management page. Otherwise, the black section will remain blank. For creating a new user, select the “Create New User” option at the bottom (*Screenshot 8*).



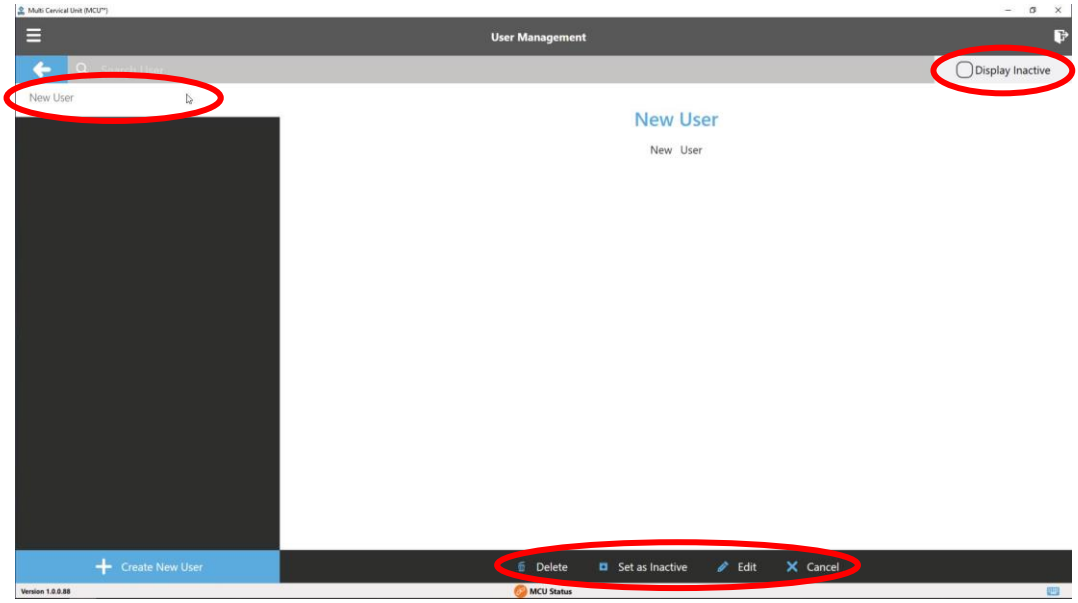
Screenshot 8

The fields with a red * are required. Among the necessary information in this section are a username, role, password, confirm password, secret question, secret answer, first name, and last name. The other options are designation, occupation, registration number, and email address (Screenshot 9).



Screenshot 9

Edit, delete an existing user



Screenshot 10

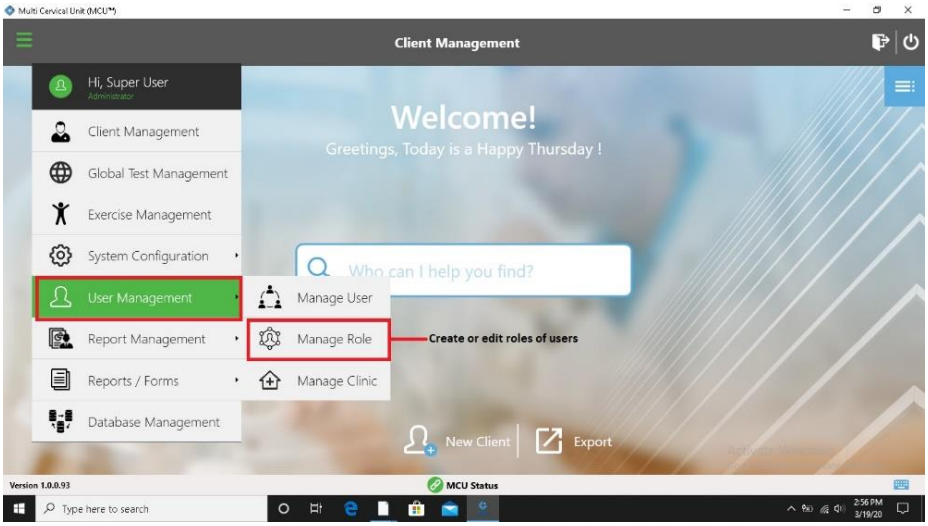
After entering a new user, their name will be visible on the left side of the User Management page (Screenshot 10). You now have several options available for this user profile. You may delete a user, you may choose to set that user as Inactive, or change the user info. Setting as inactive will remove the name from the list but not from the software. To review the inactive list, check the Display Inactive option in the top right. From the Inactive List, a user can be “set as active”, returning their name to the active user list.

1. Manage Role

Role Management allows you to create roles that will define the level of access a user can have within the software. Roles may be position based (i.e. Therapist, Assistant, Tech) or possibly based on use of equipment (Assessment, Treatment/Exercise, Calibration/Verification Only, etc.).

Permissions can be defined for each of the primary areas found in the hamburger menu.

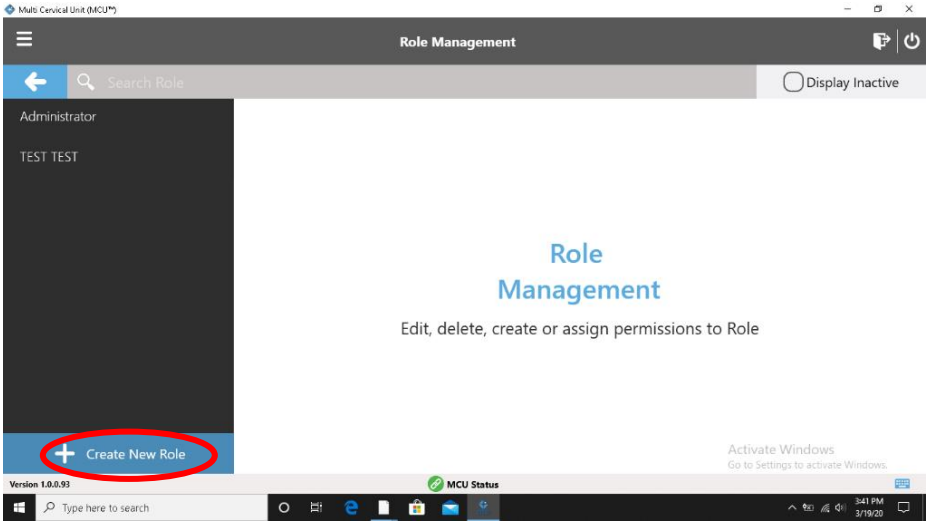
Note: the software ships with the role of Administrator. The Administrator has permission to access all areas and all functions available within the software.



Screenshot 11

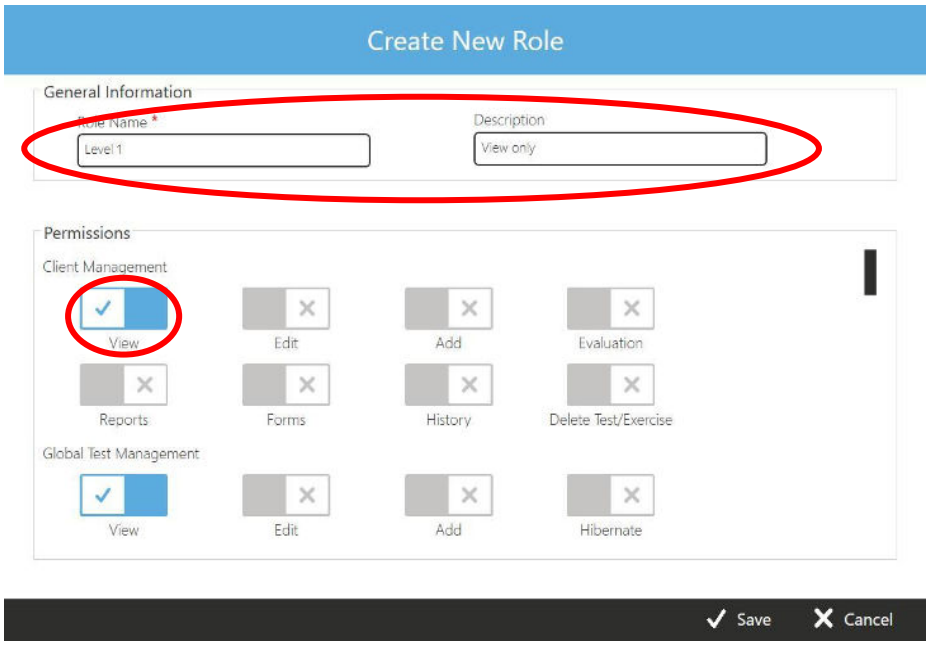
Step 1. From the Hamburger Menu, choose “User Management” and “Manage Role” to create new roles or modify existing roles (*Screenshot 11*). You will see existing Roles in the left hand portion of the screen.

Step 2. To create a new role, select that option at the bottom left (*Screenshot 12*)



Screenshot 12

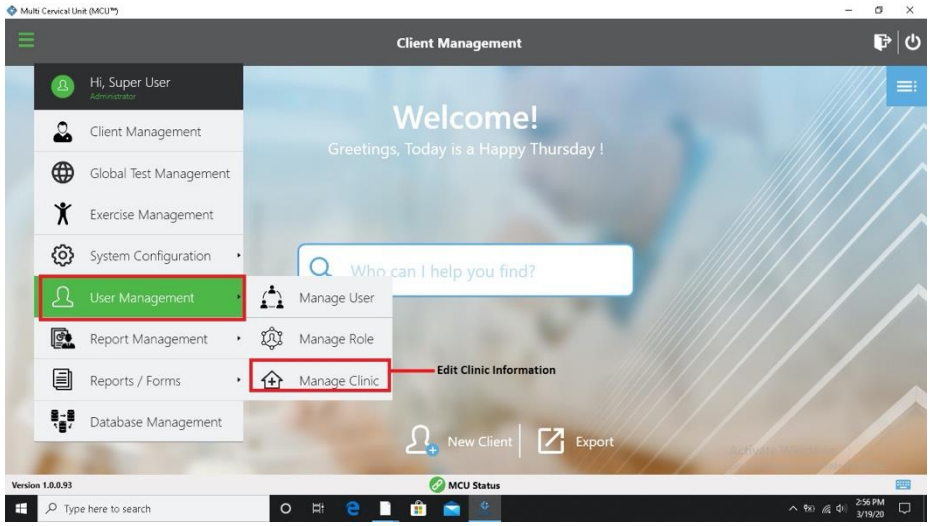
Step 3. The Role Name is required. From there, you can choose the permissions for that role. You can give access to an individual for various aspects within the software. A blue check box means that this user will have full access of that option within the software (Screenshot 13).



Screenshot 13

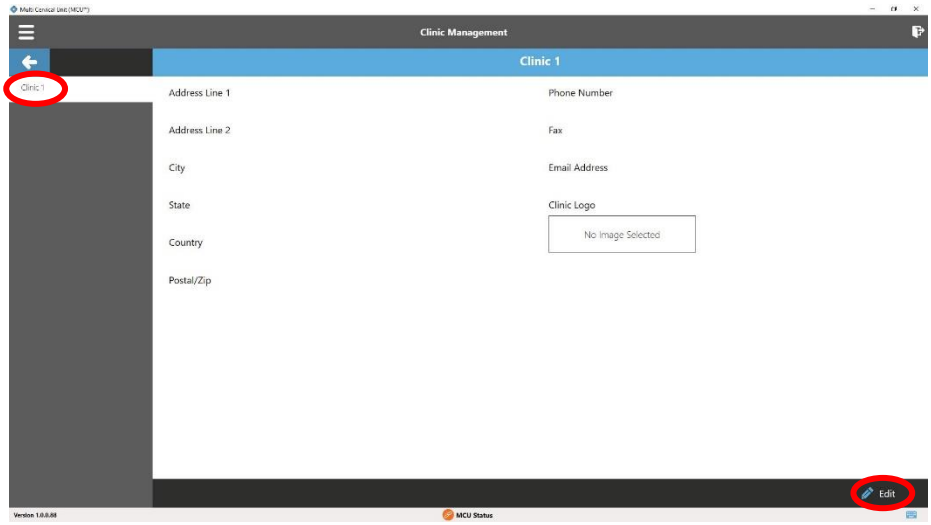
2. Manage Clinic

Manage Clinic allows you to enter your clinic's information including name, address, phone and fax numbers, email address, and clinic logo. From the Hamburger Menu and User Management select the "Manage Clinic" option (*Screenshot 14*).



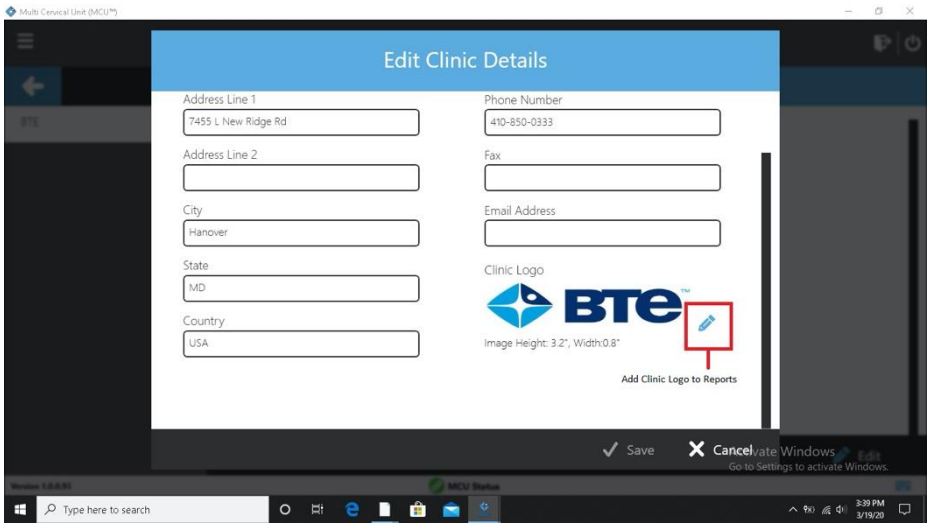
Screenshot 14

Edit the clinic information by selecting the "Edit" icon on the bottom right (*Screenshot 15*).



Screenshot 15

Fill in the information as you would like it to look on the final report. You can also choose to put your clinic logo on to the report by selecting the small pencil icon towards the bottom (Screenshot 16). Clicking this option will open a Desktop window. It is preferred to put your clinic logo on a thumb drive and to pull that image from that location. Be sure and save the clinic info.

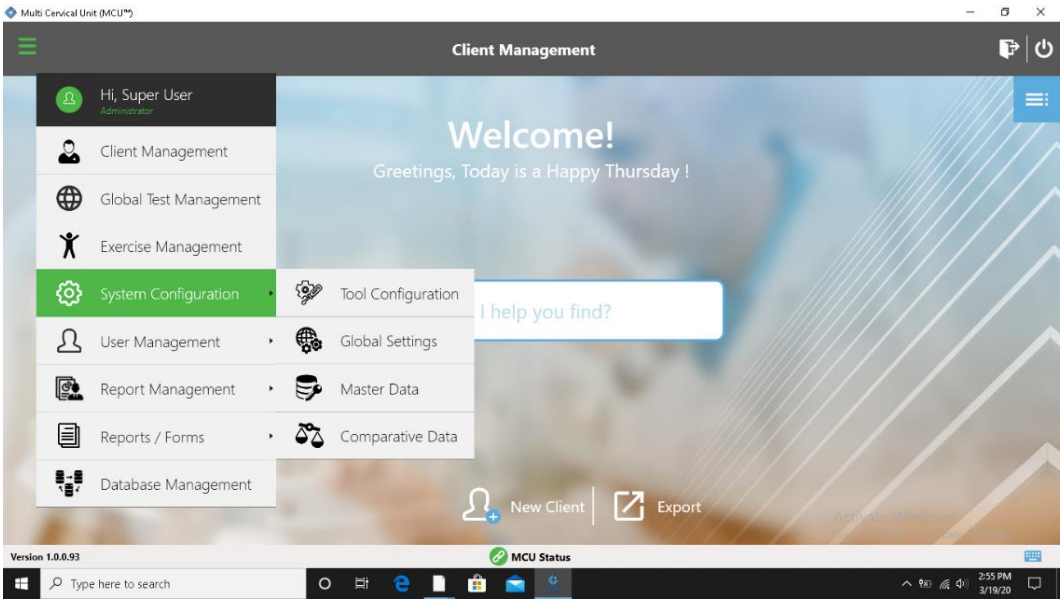


Screenshot 16

C. Master Data

Within the Global Settings and System Configuration, click on Master Data to edit City, State, Country, Designation, Occupation, Race. These items will be included within the client or user information.

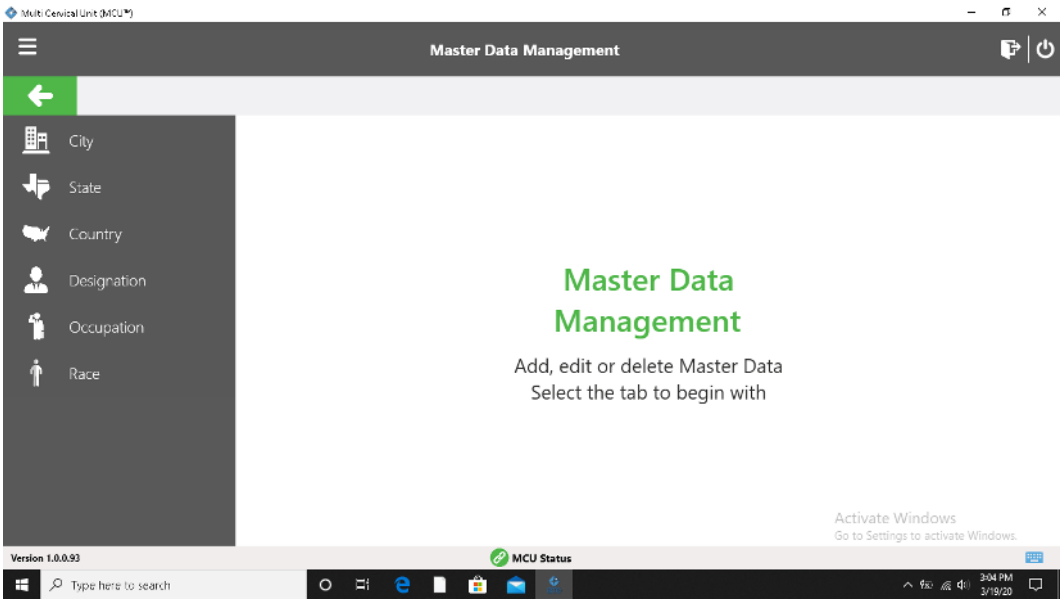
From the Hamburger Menu, select System Configuration, then Master Data (*Screenshot 17*).



Screenshot 17

Choose an item in the list (City, State, Country, Designation, Occupation, and/or Race).

To add an additional selection to that item's list, first select the category (Screenshot 18)



Screenshot 18

Select the "New" icon from the bottom of the page (Screenshot 19)

Screenshot 19

Enter the item to be added to the list

Confirm details and select “Save.” Also, you can select “Discard” to remove the item.

Repeat this process for each field. These items will be available for client or user records.

Section 5 – Client Management

I. Adding New Client 65

II. Choosing Existing Client 66

III. Client Overview 66

A. Edit Client information 67

B. Assign and Manage Tests/Exercises (using pre-programmed) 67

1. Assign Tests 67

2. Assign Exercises 70

A. Reports 71

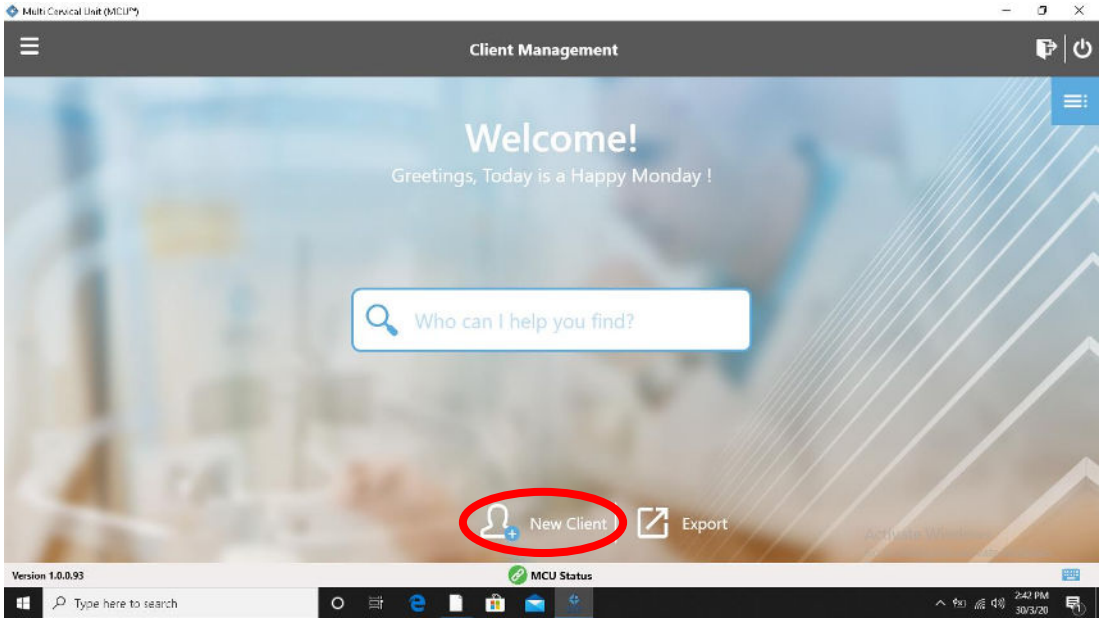
B. Forms 72

C. History 72

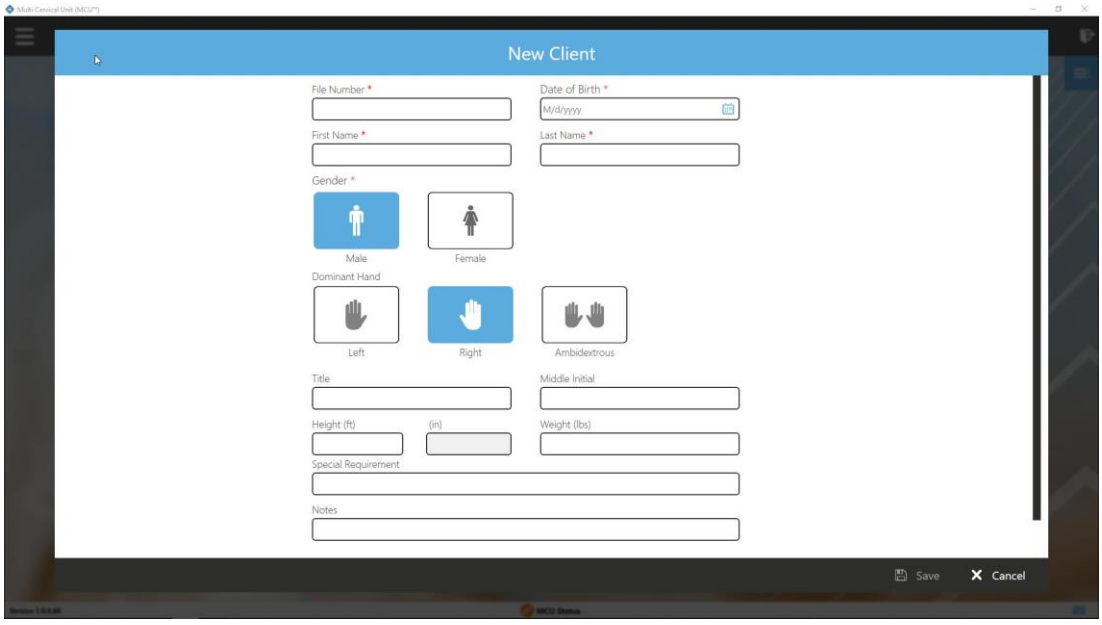
I. Adding New Client

This section provides you with the information needed to enter a new client into the software, assign tests and exercises, review test and exercise data, and generate reports and forms.

From the Client Management Home Page, click the Add New Client button at the bottom of the Client Management window (Screenshot 1). The New Client window will open (Screenshot 2).



Screenshot 1



Screenshot 2

The information with a red * next to it is required. (File Number, Date of Birth, First Name, Last Name, Gender). Additional information can be entered at the bottom of the New Client page.

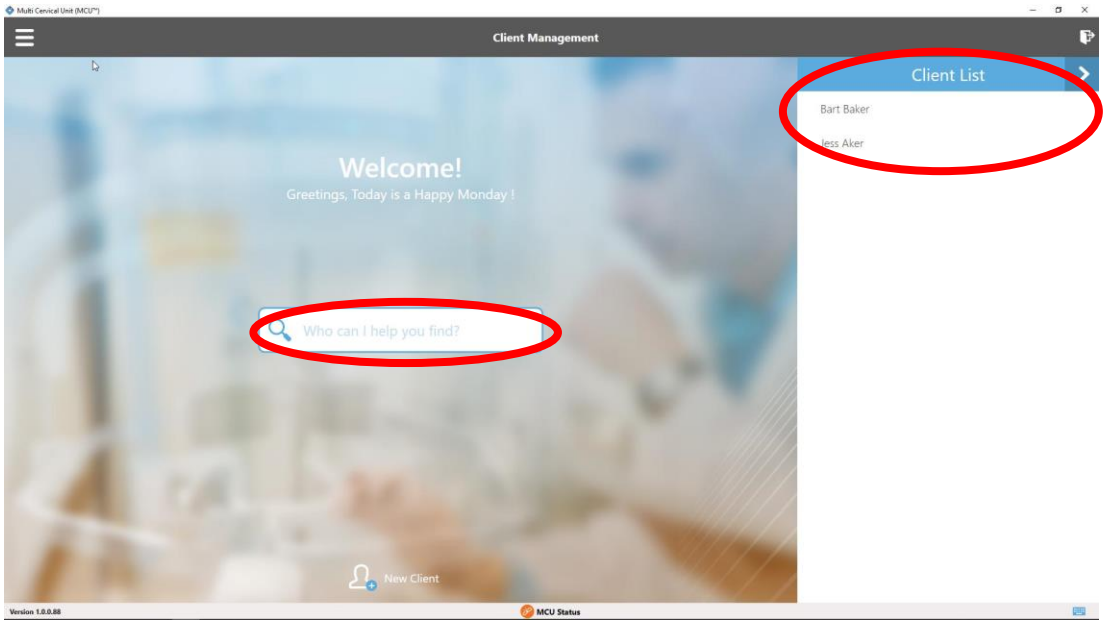
Once you have reviewed the information entered, click to save. Cancel will result in loss of entered information.

II. Choosing Existing Client

There are two options available to retrieve an existing client: *(Screenshot 3):*

Client List – click on Client List icon located in upper right area of Client Management window; scroll the list and select name

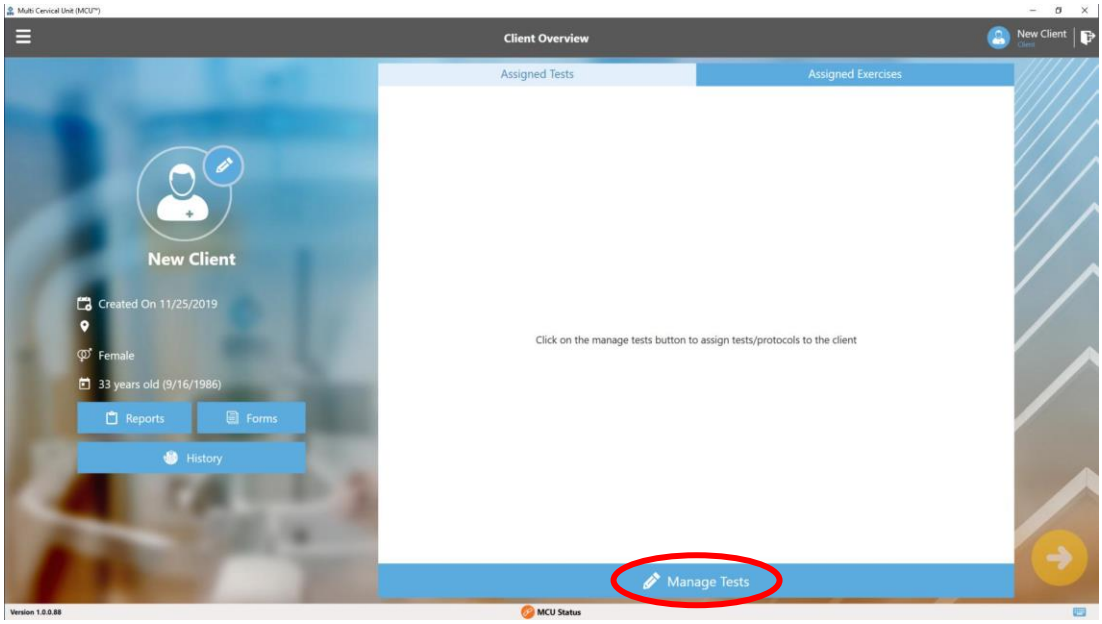
Search option – enter client's name into search field and select it from the list presented



Screenshot 3

III. Client Overview

After saving the New Client information or selecting an existing client, the software will advance to the Client Overview window *(Screenshot 4)*. Here you can edit the previously entered client information using the pencil icon next to the client avatar, assign and manage protocols, tests, and exercises for the client, access questionnaires (Forms), review test and exercise data (History), and view and print reports.



Screenshot 4

A. Edit Client information

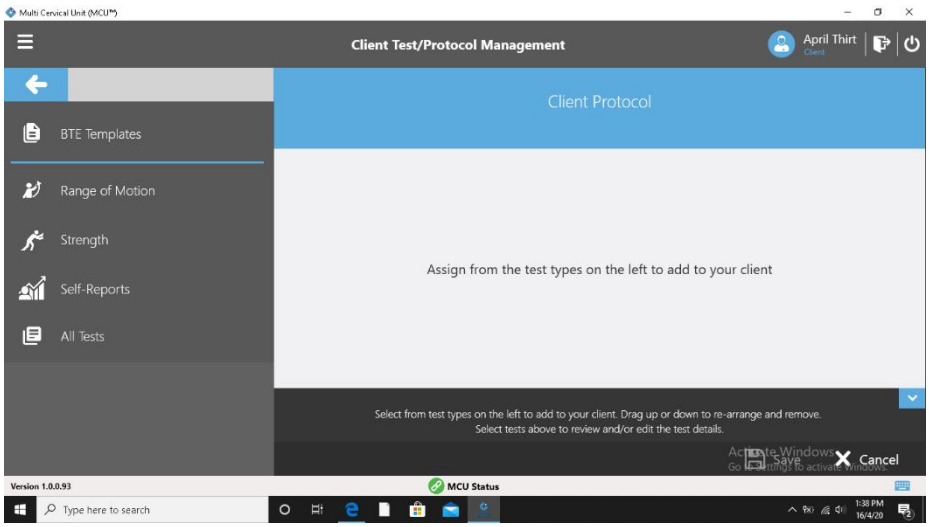
To edit or complete remaining text fields, click on the pencil icon located to the right of the client's name, make edits and/or complete the information, and then review and save.

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

The Client Management window is used to assign and manage tests and/or exercises. You can return to this list in order to include additional tests or exercises at any time.

1. Assign Tests

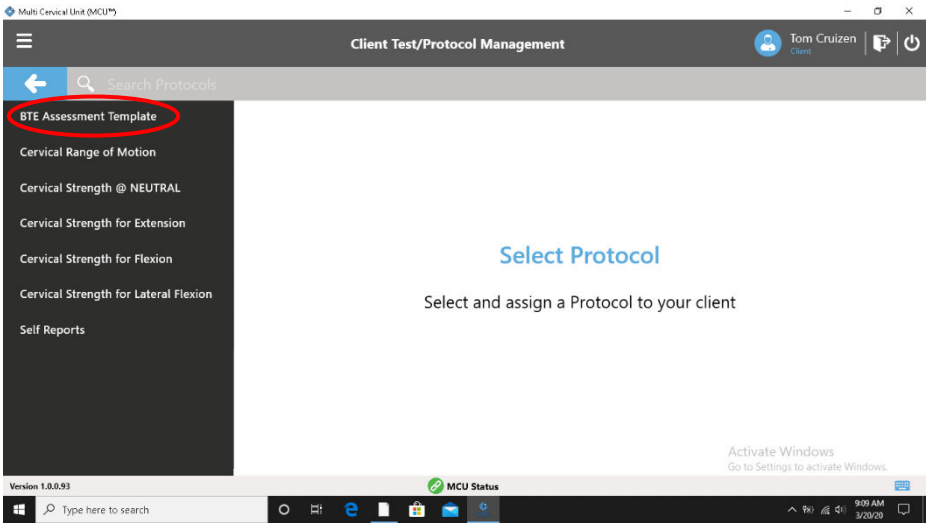
To assign tests, first highlight "Assigned Tests" on the top of the page. Click on the "Manage Tests" button at the bottom *(Screenshot 4)*. This will provide access to Client Test/Protocol Management window.
Select Range of Motion, Strength, Self-Reports, and/or All Tests to choose individuals tests you wish to assign to the client's list of tests *(Screenshot 5)*. Use of the "BTE Templates" is a time efficient method of assigning tests commonly used.



Screenshot 5

To assign a template to a client list, choose “BTE Templates” from the Client Test/Protocol Management main page (*Screenshot 5*).

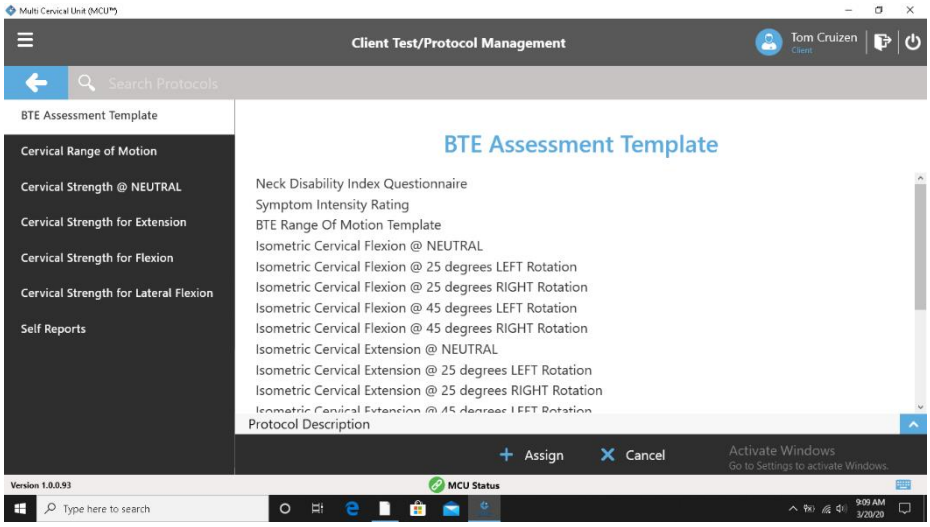
The BTE Assessment Template and other pre-assigned templates are also visible (*Screenshot 6*). The BTE Assessment Template consists of all range of motion and isometric strength assessments. If you will perform all measurements, assign this template to the client and save time.



Screenshot 6

Choose the template or the desired tests for this selected client.

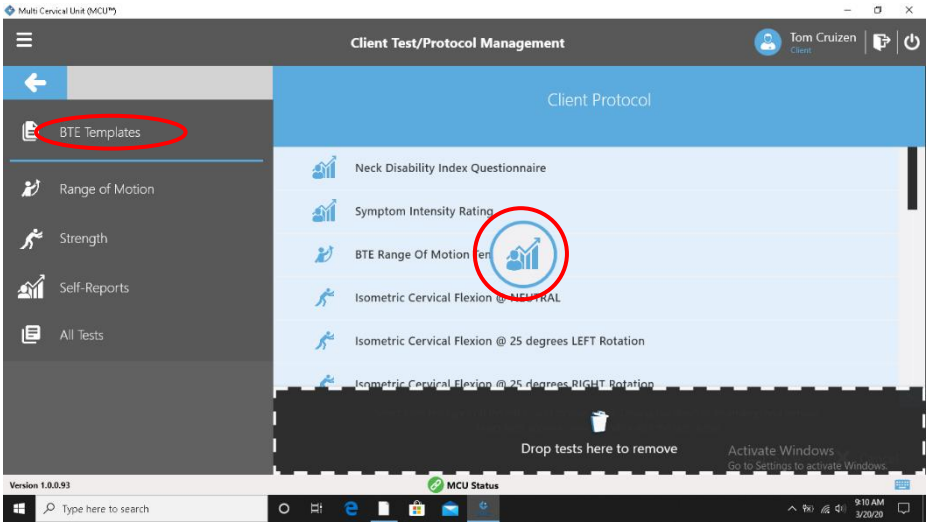
When selected, the lists of tests will be displayed in the center of the screen. Chose ‘Assign’ to add to client. (*Screenshot 7)*



Screenshot 7

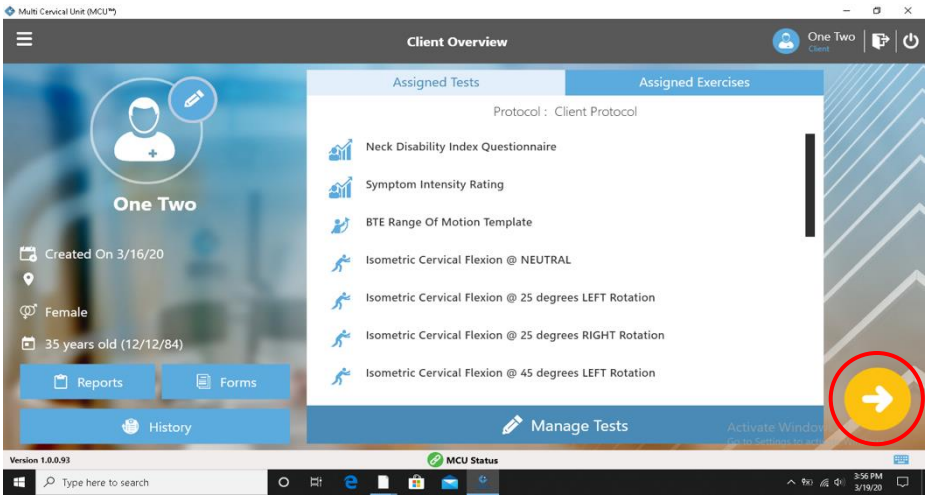
You will return to the Client Test/Protocol Management page.

If you would like to modify the order of the tests or to remove them entirely from that client, click and hold the test. An icon will become visible which indicates that you can drag the test to the desired spot in the list. You can also drag it to the bottom and dump it in the bottom bar to remove. Be sure and select 'Save' once all changes are made (*Screenshot 8).*



Screenshot 8

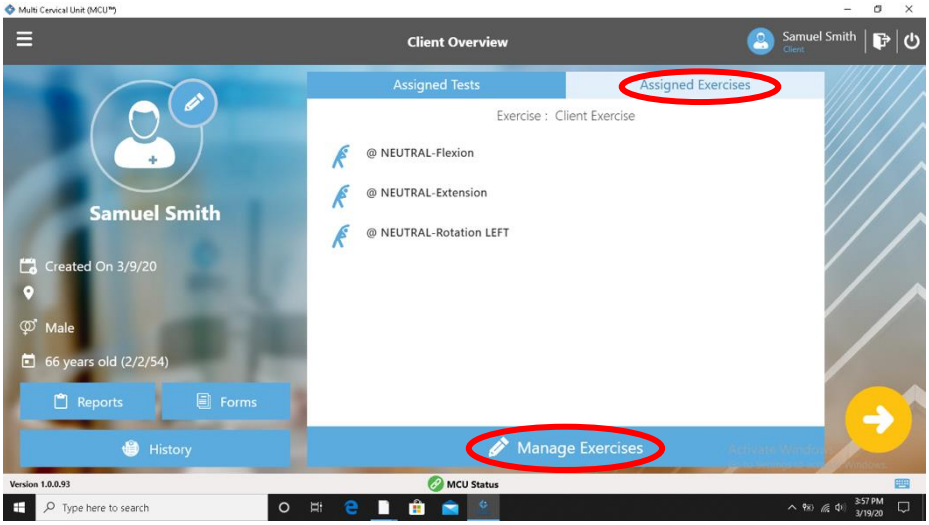
Once you have the final list, click Save. If you are ready to proceed with testing, do so by clicking the Proceed arrow *(Screenshot 9)*. Section 6 addresses Test Execution.



Screenshot 9

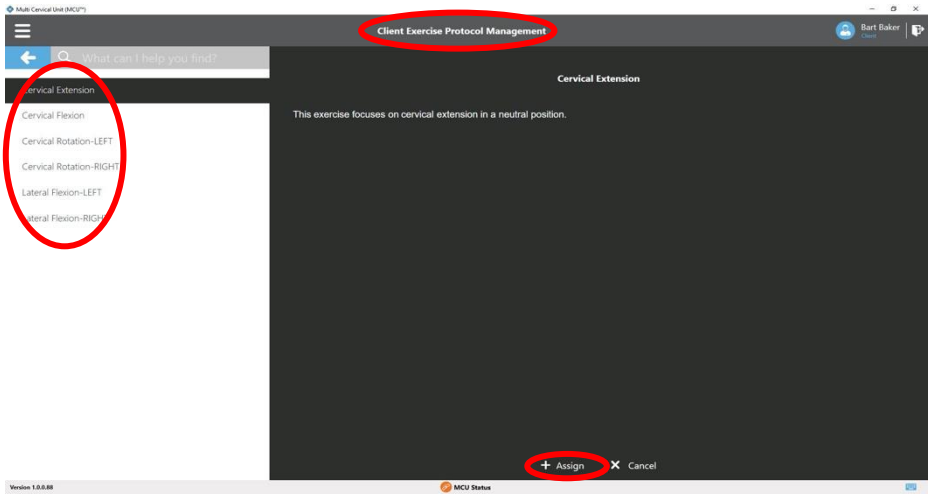
2. Assign Exercises

To assign exercises to a client, the steps are similar to those for assigning tests. To review, from the Client Overview window, click the “Assigned Exercises” tab followed by Manage Exercises (*Screenshot 10*).



Screenshot 10

Select exercises from the list on the left of the Client Exercise Protocol Management window and assign to the client list *(Screenshot 11)*.



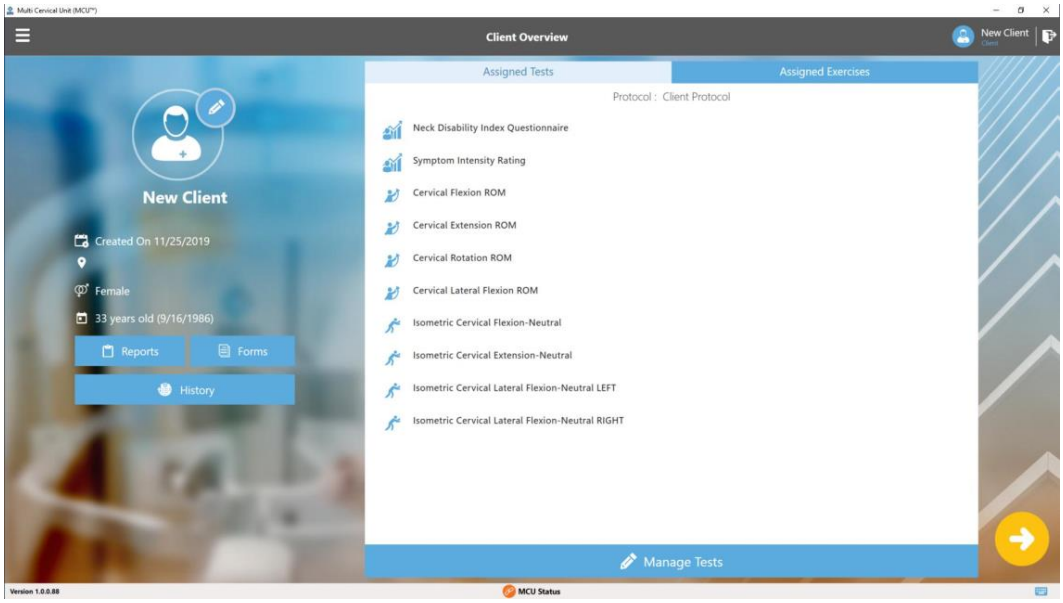
Screenshot 11

Upon completing selections, review list, reorder exercises as preferred, and then save to list. If you are ready to proceed with exercise, do so by clicking the Proceed arrow.

Section 7 will address Exercise execution.

C. Reports

The remaining icons/buttons on the Client Overview window are Reports, Forms, and History (Screenshot 12). Specific to Reports, 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.).



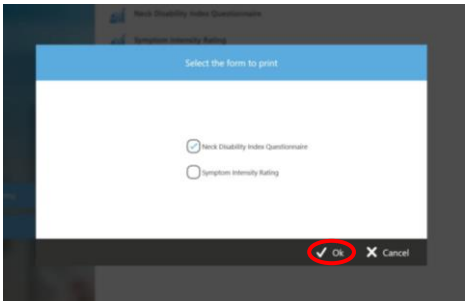
Screenshot 12

Detailed information about Reports is provided in Section 6 – Test Execution and Section 7 –Exercises.

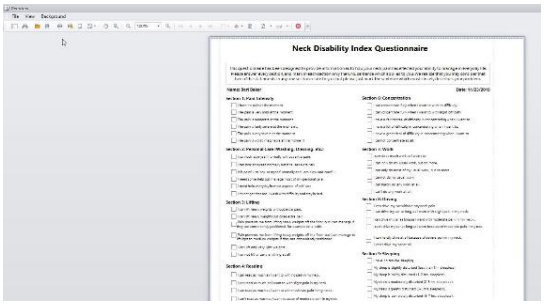
D. Forms

Forms relate to available questionnaires or Self-Reports such as the Neck Disability Index (NDI) and Symptom Intensity Rating (SIR). Each can be completed within the software or they can be printed.

To print a blank form for a client to complete, choose “Forms” *(Screenshot 12)*, select the form to be printed *(Screenshot 13)*, and then click “OK.” A preview of the form opens and provides access to Print button *(Screenshot 14)*.



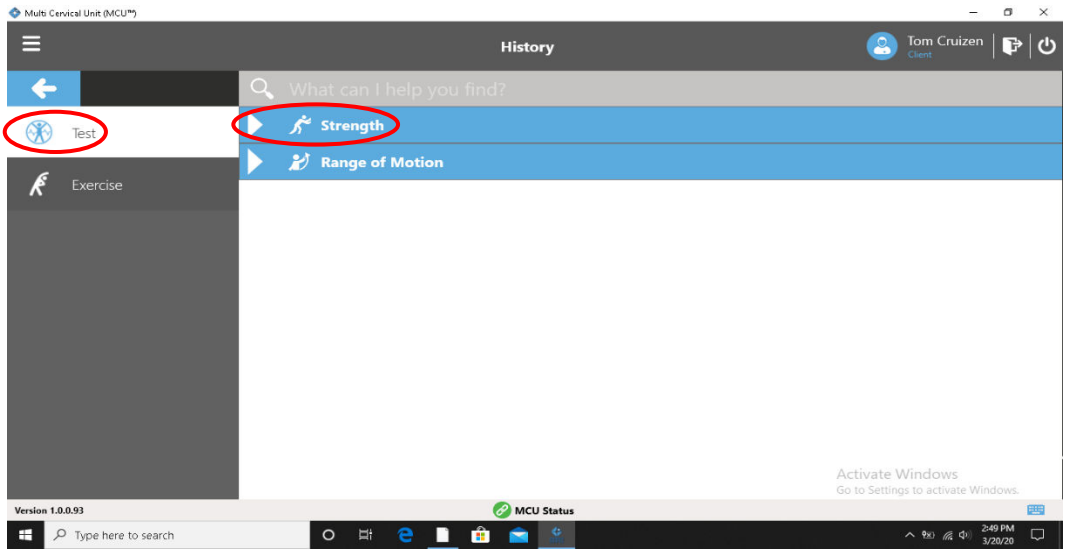
Screenshot 13



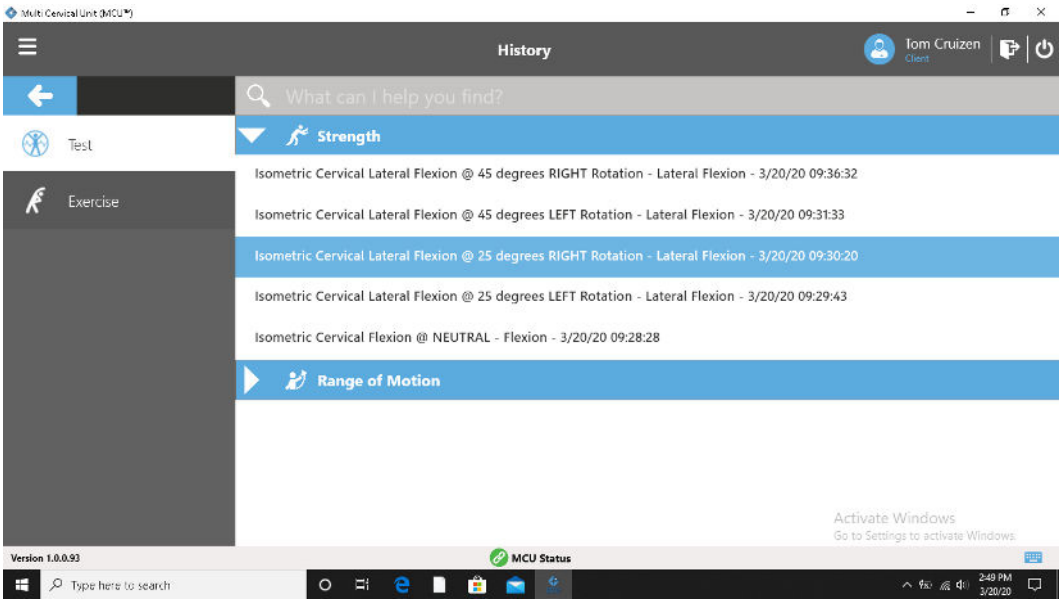
Screenshot 14

E. History

To review saved test and exercise data, use the History option *(Screenshot 12)*. Choose from Test or Exercise to access a list of all saved items *(Screenshot 15 & 16)*. Select self-report, test, or exercise from list to view.

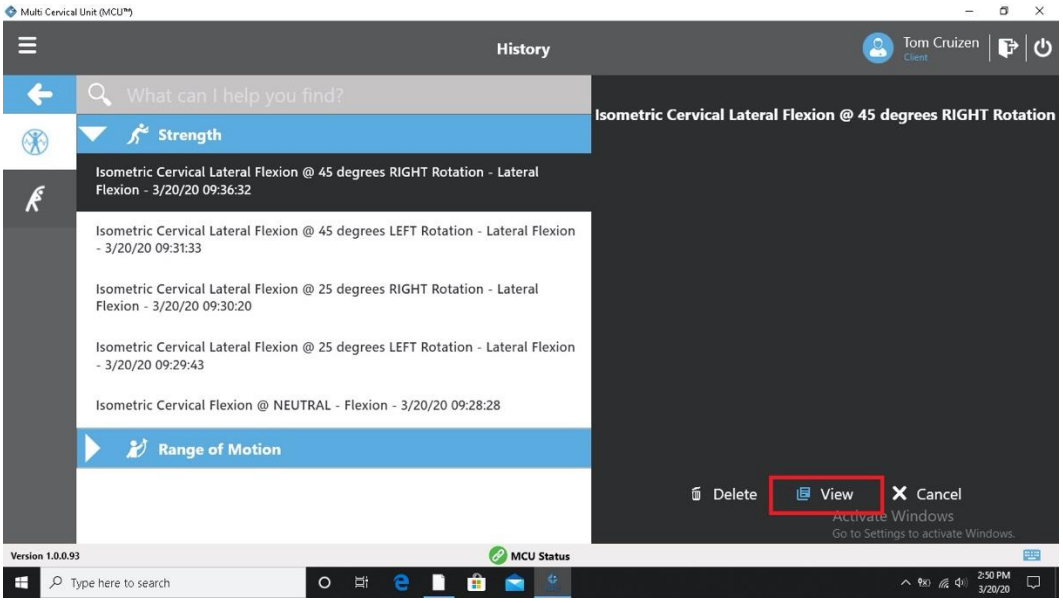


Screenshot 15



Screenshot 16

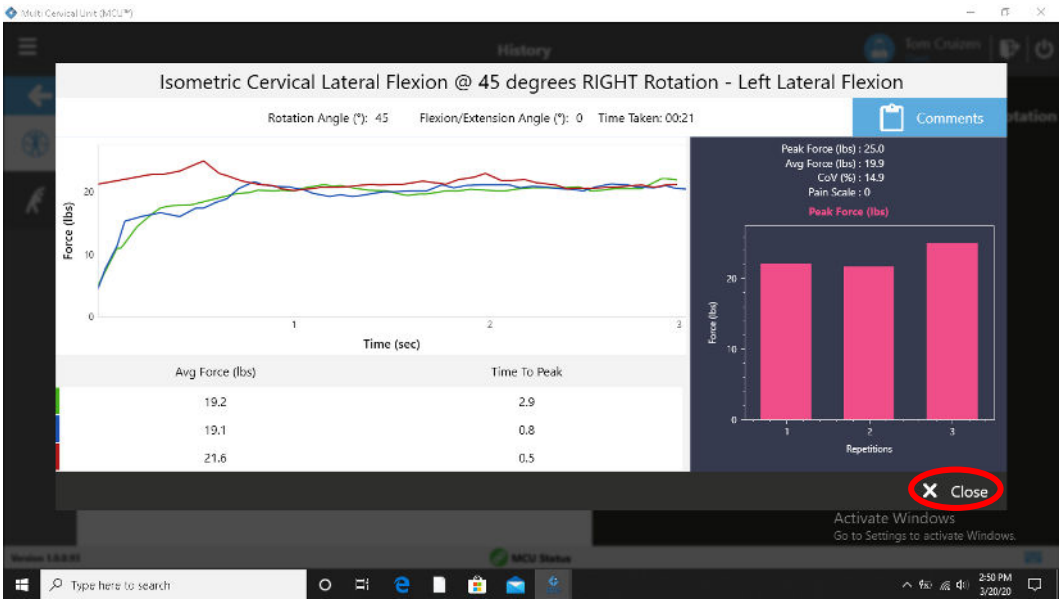
In addition to viewing (*Screenshot 17 & 18*), you also have the option to delete items available here (*Screenshot 15)*.



Screenshot 17

You can view the data from the chosen test. Also, if comments were entered, those will be visible when selecting the “Comments” box in the top right (*Screenshot 18*).

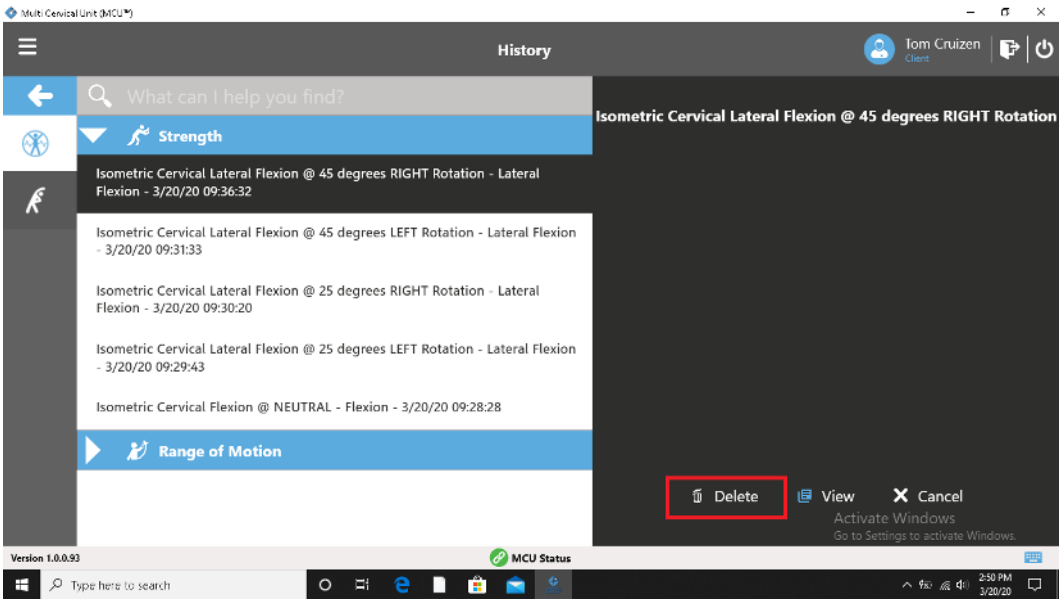
Select “Close” from the bottom right when done reviewing the chosen test.



Screenshot 18

From the “History” page, it is also possible to Delete a test.

Highlight the ROM or Strength test, and then select “Delete.” A message box will ask if you are sure you want to delete this item. Note that saved data will be lost if “Yes” is selected (Screenshot 19).



Screenshot 19

Section 6 – Test Administration

I. Pre-programmed Tests 77
A. Self Reports 77
1. Individual Self-Reports 77
2. Self-Reports Protocol 77
B. Range of Motion (ROM) 77
1. BTE Range of Motion Template 77
C. Strength Tests 77
1. Individual Isometric Tests 77
2. Isometric Strength Protocols: 78
D. BTE Assessment Template 78
II. Hardware Setup and Client Positioning for ROM and Strength Tests 79
A. ROM Testing 79
1. General Setup for ROM Testing 79
2. Test-Specific Setup for ROM 81
B. Isometric Strength Testing 86
1. Positioning the Client for Neutral Cervical Isometric Strength Protocols 86
2. Positioning the Client for 25 Degree Cervical Isometric Strength Protocols 91
3. Positioning the Client for 45 Degree Cervical Isometric Strength Protocols 95
III. Test Execution 100
A. Completing Self-Reports 102
B. Performing ROM Tests 102
1. ROM Test Execution 104
2. To Re-Do a Repetition 106
3. Test Termination 106
4. Performing Isometric Strength Tests 107
5. Strength Tests 109
6. Complete Testing and Reporting 114

I. Pre-programmed Tests

This section addresses aspects of test administration. Included are a review of available pre-programmed tests, the required hardware setup and client positioning for the pre-programmed tests, test execution, and test reporting.

The following lists offer a review of the pre-programmed tests included in the software.

A. Self Reports

1. Individual Self-Reports

Neck Disability Index
Symptom Intensity Rating

2. Self-Reports Protocol

Neck Disability Index
Symptom Intensity Rating

B. Range of Motion (ROM)

1. BTE Range of Motion Template:

Cervical Flexion ROM
Cervical Extension ROM
Cervical Left Lateral Flexion ROM
Cervical Right Lateral Flexion ROM
Cervical Left Rotation ROM
Cervical Right Rotation ROM

C. Strength Tests:

1. Individual Isometric Tests:

Isometric Cervical Flexion - Neutral
Isometric Cervical Extension - Neutral
Isometric Cervical Left Lateral Flexion - Neutral
Isometric Cervical Right Lateral Flexion - Neutral
Isometric Cervical Flexion – 25 degrees Left Rotation
Isometric Cervical Flexion – 25 degrees Right Rotation
Isometric Cervical Extension – 25 degrees Left Rotation
Isometric Cervical Extension - 25 degrees Right Rotation
Isometric Cervical Lateral Flexion - 25 degrees Left Rotation
Isometric Cervical Lateral Flexion - 25 degrees Right Rotation
Isometric Cervical Flexion – 45 degrees Left Rotation
Isometric Cervical Flexion – 45 degrees Right Rotation
Isometric Cervical Extension – 45 degrees Left Rotation
Isometric Cervical Extension - 45 degrees Right Rotation

Isometric Cervical Lateral Flexion - 45 degrees Left Rotation
Isometric Cervical Lateral Flexion - 45 degrees Right Rotation

2. Isometric Strength Protocols:

a. Cervical Strength @ Neutral

Isometric Cervical Flexion - Neutral
Isometric Cervical Extension - Neutral
Isometric Cervical Left Lateral Flexion - Neutral
Isometric Cervical Right Lateral Flexion – Neutral

b. Cervical Strength for Extension

Isometric Cervical Extension – Neutral
Isometric Cervical Extension – 25 degrees LEFT Rotation
Isometric Cervical Extension – 25 degrees RIGHT Rotation
Isometric Cervical Extension - 45 degrees LEFT Rotation
Isometric Cervical Extension - 45 degrees RIGHT Rotation

c. Cervical Strength for Flexion

Isometric Cervical Flexion – Neutral
Isometric Cervical Flexion – 25 degrees LEFT Rotation
Isometric Cervical Flexion – 25 degrees RIGHT Rotation
Isometric Cervical Flexion - 45 degrees LEFT Rotation
Isometric Cervical Flexion - 45 degrees RIGHT Rotation

d. Cervical Strength for Lateral Flexion

Isometric Cervical LEFT Lateral Flexion @ Neutral
Isometric Cervical RIGHT Lateral Flexion @ Neutral
Isometric Cervical Lateral Flexion @ 25 degrees LEFT Rotation
Isometric Cervical Lateral Flexion @ 25 degrees RIGHT Rotation
Isometric Cervical Lateral Flexion @ 45 degrees LEFT Rotation
Isometric Cervical Lateral Flexion @ 45 degrees RIGHT Rotation

D. BTE Assessment Template

Neck Disability Index

Symptom Intensity Rating

BTE Range of Motion Template

Cervical Flexion ROM
Cervical Extension ROM
Cervical Left Lateral Flexion ROM
Cervical Right Lateral Flexion ROM
Cervical Left Rotation ROM
Cervical Right Rotation ROM

Isometric Cervical Flexion – Neutral

Isometric Cervical Flexion – 25 degrees Left Rotation
Isometric Cervical Flexion – 25 degrees Right Rotation
Isometric Cervical Flexion – 45 degrees Left Rotation
Isometric Cervical Flexion – 45 degrees Right Rotation
Isometric Cervical Extension – Neutral
Isometric Cervical Extension – 25 degrees Left Rotation
Isometric Cervical Extension – 25 degrees Right Rotation
Isometric Cervical Extension – 45 degrees Left Rotation
Isometric Cervical Extension – 45 degrees Right Rotation
Isometric Cervical Left Lateral Flexion – Neutral
Isometric Cervical Right Lateral Flexion – Neutral
Isometric Cervical Lateral Flexion – 25 degrees Left Rotation
Isometric Cervical Lateral Flexion – 25 degrees Right Rotation
Isometric Cervical Lateral Flexion – 45 degrees Left Rotation
Isometric Cervical Lateral Flexion – 45 degrees Right Rotation

II. Hardware Setup and Client Positioning for ROM and Strength Tests

A. ROM Testing

In order to prepare for cervical ROM testing, it is extremely important to understand how to properly position the client; this will prevent any injury during testing. The following 7 steps are required prior to each type of ROM testing. Outlined after these 7 steps are the subsequent steps, which vary according to the test being performed.

1. General Setup for ROM Testing

Step 1. Insert the range of motion stop pin in the zero degree position on the halo (*Figure 1*).

Figure 1

Step 2. Lower the chair to its lowest position.

Step 3. Using the latch on the right side, open the halo (*Figure 2.1 and 2.2).*

Figure 2.1

Figure 2.2

Step 4. Ask the client to sit in the chair.

Step 5. Adjust the height of the seat (Figure 3.1), the position of the seat (Figure 3.2), the height of the back of the chair (Figure 3.2), and the arm rests (Figure 3.3) to accommodate the client's size, height, and posture. Set the halo height to 3 as a starting position (Figure 3.4).

Figure 3.1

Figure 3.2

Figure 3.3

Figure 3.4

Step 6. Secure the client with the waist strap and shoulder straps (Figure 4.1 and 4.2).

Figure 4.1

Figure 4.2

Step 7. Close and lock the halo (*Figure 5*).

Figure 5

2. Test-Specific Setup for ROM

a. Positioning the Client for a ROM Flexion or Extension Test

Step 8. For a flexion test, insert both of the head braces in the halo. For an extension test, insert the rear head brace with a Velcro strap attached. Note that the bottom of the back brace should be located at the external occipital protuberance (Figure 6.1, 6.2,

Figure 6.1

Figure 6.2

Figure 6.2

Step 9. Set the halo to 15 degrees below the horizontal (Figure 7).

Fig. 7

Step 10. Position the head brace(s) against the client's head, but do not secure his/her head in place.

Step 11. Make fine adjustments to the seat and halo such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 11.1 and 11.2*).

Figure 11.1

Figure 11.2

Step 12. Firmly secure the client with the head brace(s) and Velcro strap (if performing an extension test).

Step 13. Remove the range of motion stop pin before performing the test (*Figure 12.1 and 12.2*).

Figure 12.1 (flexion)

Figure 12.2 (extension

b. Positioning the Client for a ROM Left/Right Rotation Test

Complete Steps 1-7 for General Setup for ROM Testing

Step 8. Insert both of the head braces in the halo (*Figure 13*).

Figure 13

Step 9. Set the halo to 0 degrees with respect to the horizontal and 10 degrees flexion (*Figure 14.1 and 14.2*).

Figure 14.1

Figure 14.2

Step 10. Position the head brace(s) against the client's head, but do not secure his/her head in place.

Step 11. Make fine adjustments to the seat such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 15.1 and 15.2*).

Figure 15.1

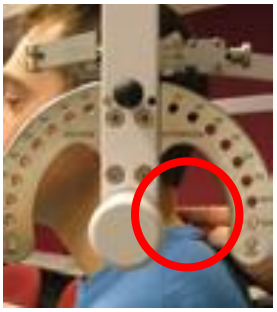


Figure 15.2 (C5-C6)

Step 12. Firmly secure the client's head with the head brace(s).

Step 13. While holding onto the side of the halo, unlock the rotation pin (*Figure 16.1*), which is located at the top middle of the halo, before performing the test (*Figure 16.2, final set up*).

Figure 16.1

Figure 16.2

c. Positioning the Client for a ROM Lateral Flexion Test

Complete Steps 1-7 for General Setup for ROM Testing

Step 8. Unlock the rotation pin and rotate the halo to 90 degrees right rotation. Reinsert the rotation pin to lock halo in place (*Figure 17*, Halo @ 90° R Rotation).

Figure 17

Step 9. Insert both of the head braces in the halo (*Figure 18*).

Figure 18

Step 10. Set the halo to 0 degrees with respect to the horizontal (*Figure 19.1*). Make sure the flexion/extension angle is set to 0 degrees (*Figure 19.2*).

Figure 19.1

Figure 19.2

Step 11. Position the head braces against the client's head, but do not secure his/her head in place.

Step 12. Make fine adjustments to the seat such that C5/C6 of the client's spine is aligned with the pivot point of the halo (Figure 20).

Figure 20

Step 13. Firmly secure the client's head with the head brace(s).

Step 14. Remove the range of motion stop pin before performing the test (Figure 21.1 and 21.2).

Figure 21.1

Figure 21.2

B. Isometric Strength Testing

1. Positioning the Client for Neutral Cervical Isometric Strength Protocols

In order to prepare for cervical strength testing, it is extremely important to understand how to properly position the client; this will prevent any injury during testing. The following steps are required prior to each type of strength testing. Outlined after these steps are the subsequent steps, which vary according to the test being performed.

a. General Setup for Neutral Testing

Step 1. Insert the range of motion stop pin in the zero-degree position on the halo (*Figure 22*).

Figure 22

Step 2. Lower the chair to its lowest position.

Step 3. Using the latch on the right side, open the halo (*Figure 23.1 and 23.2*).

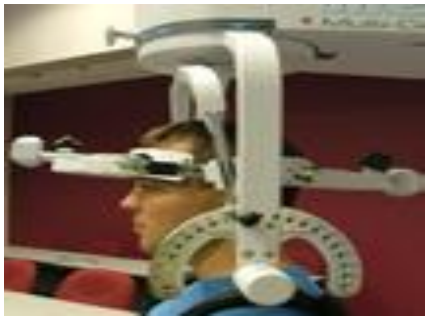


Figure 23.1

Figure 23.2

Step 4. Ask the client to sit in the chair.

Step 5. Adjust the height of the seat, the position of the seat (*Figure 24.1*), the position of the back of the chair, the height of the back of the chair, and the arm rests to accommodate the client's size, height, and posture. Set the halo height to 3 as a starting position (*Figure 24.2*).


Figure 24.1

Step 6. Secure the client with the waist strap and shoulder straps.

Step 7. Close and lock the halo (*Figure 25*).

Figure 25

b. Positioning the Client for a Neutral Isometric Flexion or Extension Test

Step 8. For a flexion test (*Figure 26.1),* insert the front head brace in the halo. For an extension test (*Figure 26.2*), insert the rear head brace. Note that the bottom of the back brace should be located at the external occipital protuberance.

Figure 26.1 (flexion)

Figure 26.2 (extension)

Step 9. Set the halo to 15 degrees below the horizontal (*Figure 27*).

Figure 27

Step 10. Position the head brace against the client's head, but do not secure his/her head in place.

Step 11. Make fine adjustments to the seat and halo such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 28.1 and 28.2*).

Figure 28.1

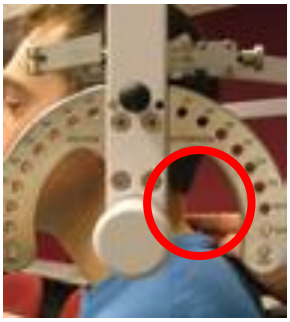


Figure 28.2

Step 12. Firmly secure the client's head with the head brace (*Figure 29.1 for flexion and 29.2 for extension).*

Figure 29.1

Figure 29.2

Step 13. Attach the RJ45 cable to the head brace being used and the RJ45 jack that is closest to the front of the unit at the top of the MCU (*Figure 30*).

Figure 30

c. Positioning the Client for a Neutral Isometric Lateral Flexion Test

Complete Steps 1-7 for General Setup for Neutral Testing

Step 8. Unlock the rotation pin and rotate the halo to 90 degrees right rotation. Reinsert the rotation pin to lock halo in place (*Figure 31*).

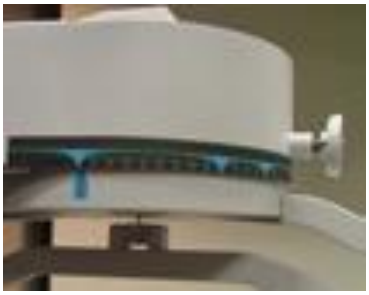


Figure 31

Step 9. Attach the head brace to the halo on the side being tested (*Figure 32*).

Figure 32

Step 10. Set the halo to 0 degrees with respect to the horizontal. Make sure the flexion/extension angle is set to 0 degrees (*Figure 33.1*) and insert the locking pin (*Figure 33.2*).

Figure 33.1

Figure 33.2

Step 11. Position the head brace against the client's head, but do not secure his/her head in place.

Step 12. Make fine adjustments to the seat such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 34.1 and 34.2*).

Figure 34.1

Figure 34.2

Step 13. Firmly secure the client's head with the head brace.

Step 14. Attach the RJ45 cable to the head brace being used and the RJ45 jack that is closest to the front of the unit at the top of the MCU (*Figure 35.1 and 35.2*).

Figure 35.1

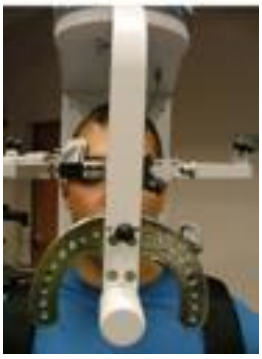


Figure 35.2

2. Positioning the Client for 25 Degree Cervical Isometric Strength Protocols

In order to prepare for cervical strength testing, it is extremely important to understand how to properly position the client; this will prevent any injury during testing. The following 7 steps are required prior to each type of strength testing. Outlined after these 7 steps are the subsequent steps, which vary according to the test being performed.

> Locate the rotation labels to the left and right of the rotation lock pin. The label to the right of the lock pin says “Rotation Left” and the label to the left of the lock pin says “Rotation Right”. The left and right direction refer to the client’s point of view. Any reference in the manual to left or right will correspond to the label and therefore the client.

a. General Setup for 25 Degree Testing

Step 1. Insert the range of motion stop pin in the zero-degree position on the halo (*Figure 36*).

Figure 36

Step 2. Lower the chair to its lowest position.

Step 3. Using the latch on the right side, open the halo (*Figure 37.1 and 37.2*).

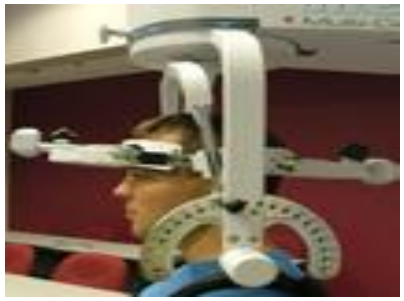


Figure 37.1

Figure 37.2

Step 4. Ask the client to sit in the chair.

Step 5. Adjust the height of the seat, the position of the seat, the position of the back of the chair, the height of the back of the chair, and the arm rests to accommodate the client’s size, height, and posture.

Step 6. Secure the client with the waist strap and shoulder straps

Step 7. Close and lock the halo (*Figure 38*).

Figure 38

b. Positioning the Client for a 25 Degree Isometric Flexion or Extension Test

Step 8. For a flexion test, insert the front head brace in the halo. For an extension test, insert the back head brace. Note that the bottom of the back brace should be located at the external occipital protuberance (*Figure 39.1 and 39.2*).

Figure 39.1

Figure 39.2

Step 9. Set the halo to 15 degrees below the horizontal (Figure 40).

Figure 40

Step 10. Position the head brace against the client's head, but do not secure his/her head in place.

Step 11. Make fine adjustments to the seat and halo such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 41-1 and 41-2*).

Figure 41-1

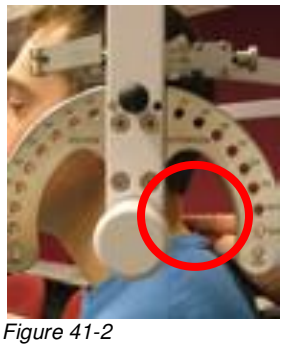


Figure 41-2

Step 12. Firmly secure the client's head with the head brace.

Step 13. While holding onto the side of the halo, unlock the rotation pin (*Figure 42-1*), which is located at the top middle of the halo. If you are testing the client's left side, rotate the halo to 25 degrees right rotation and then lock the rotation pin. Rotate the halo to 25 degrees left rotation to test the client's right side (*Figure 42-2, 25° LEFT*).

Figure 42-1

Figure 42-2 (25° LEFT)

Step 14. Attach the RJ45 cable to the head brace being used and the RJ45 jack that is closest to the front of the unit at the top of the MCU (*Figure 43-1, 43-2, and 43-3*).

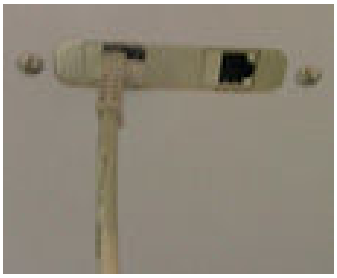


Figure 43-1

Figure 43-2

Figure 43-3

c. Positioning the Client for a 25 Degree Isometric Lateral Flexion Test

Complete Steps 1-7 for General Setup for 25 Degree Testing

Step 8. Unlock the rotation pin, which is located at the top middle of the halo. If you are testing the client's left side, rotate the halo 25 degrees toward the right, and then lock the rotation pin. Rotate the halo 25 degrees toward the left when testing the client's right side (*Figure 44*).

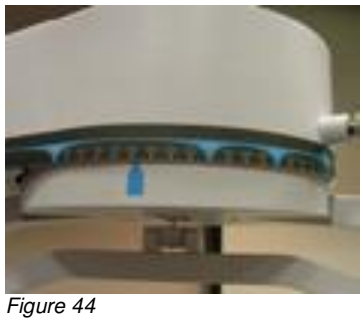


Figure 44

Step 9. Attach the head brace to the halo on the side being tested (*Figure 45*).

Figure 45

Step 10. Set the halo to 0 degrees with respect to the horizontal (*Figure 46-1*). Make sure the flexion/extension angle is set to 0 degrees (*Figure 46-2*).

Figure 46-1

Figure 46-2

Step 11. Position the head brace against the client's head, but do not secure his/her head in place.

Step 12. Make fine adjustments to the seat such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 47-1 and 47-2*).

Figure 47-1

Figure 47.2

Step 13. Firmly secure the client's head with the head brace.

Step 14. Attach the RJ45 cable to the head brace being used and the RJ45 jack that is closest to the front of the unit at the top of the MCU (*Figure 48-1 and 48-2*).

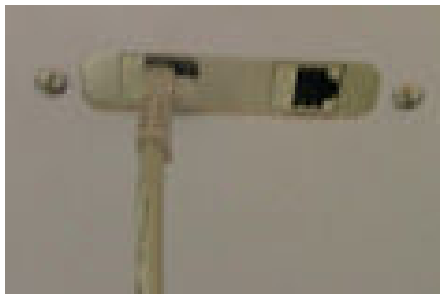


Figure 48-1

Figure 48-2 (Testing RIGHT side) @ 25° LEFT head rotation

3. Positioning the Client for 45 Degree Cervical Isometric Strength Protocols

In order to prepare for cervical strength testing, it is extremely important to understand how to properly position the client; this will prevent any injury during testing. The following 7 steps are required prior to each type of strength testing. Outlined after these 7 steps are the subsequent steps, which vary according to the test being performed.

a. General Setup for 45 Degree Testing

Step 1. Insert the range of motion stop pin in the zero degree position on the halo (*Figure 49*).

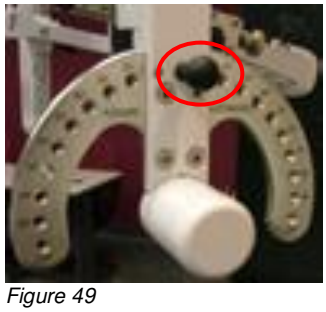


Figure 49

Step 2. Lower the chair to its lowest position.

Step 3. Using the latch on the right side, open the halo (*Figure 50-1 and 50-2*).

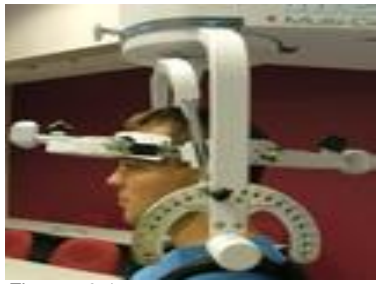


Figure 50-1

Figure 50-2

Step 4. Ask the client to sit in the chair.

Step 5. Adjust the height of the seat, the position of the seat, the position of the back of the chair, the height of the back of the chair, and the arm rests to accommodate the client's size, height, and posture.

Step 6. Secure the client with the waist strap and shoulder straps

Step 7. Close and lock the halo (*Figure 51*).

Figure 51

b. Positioning the Client for 45 Degree Isometric Flexion or Extension Test

Step 8. For a flexion test (*Figure 52-1*), insert the front head brace in the halo. For an extension test, insert the back head brace (*52-2*). Note that the bottom of the back brace should be located at the external occipital protuberance.


Figure 52-1


Figure 52-2

Step 9. Set the halo to 15 degrees below the horizontal (*Figure 53*).


Figure 53

Step 10. Position the head brace against the client's head, but do not secure his/her head in place.

Step 11. Make fine adjustments to the seat and halo such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 54-1 and 54-2*).


Figure 54-1

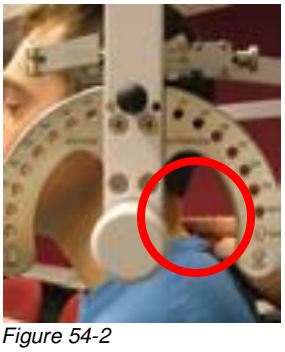


Figure 54-2

Step 12. Firmly secure the client's head with the head brace.

Step 13. While holding onto the side of the halo, unlock the rotation pin (*Figure 55-1*), which is located at the top middle of the halo. If you are testing the client's left side, rotate the halo to 45 degrees right rotation and then lock the rotation pin. Rotate the halo to 45 degrees left rotation to test the client's right side (*Figure 55-2*).


Figure 55-1


Figure 55-2

Step 14. Attach the RJ45 cable (*Figure 56-1*) to the head brace being used and the RJ45 jack that is closest to the front of the unit at the top of the MCU (*Figure 56-2 and 56-3 for final set up*).

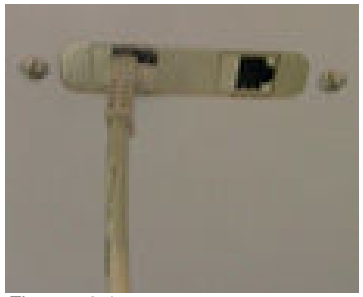


Figure 56-1


Figure 56-2 (Flex)


Figure 56-3 Ext)

c. Positioning the Client for 45 Degree Isometric Lateral Flexion Test

Complete Steps 1-7 for General Setup for 45 Degree Testing

Step 8. Unlock the rotation pin, which is located at the top middle of the halo. If you are testing the client's right side, rotate the halo 45 degrees toward the right, and then lock the rotation pin. Note that the figures show a setup for testing the client's right side (*Figure 57*).

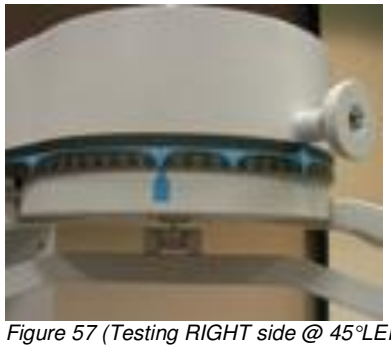


Figure 57 (Testing RIGHT side @ 45°LEFT Rotation)

Step 9. Attach the head brace to the halo on the side being tested (*Figure 58*).

Figure 58

Step 10. Set the halo to 0 degrees with respect to the horizontal (*Figure 59-1*). Make sure the flexion/extension angle is set to 0 degrees as well (*Figure 59-2*).

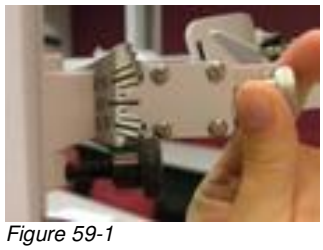


Figure 59-1

Figure 59-2

Step 11. Position the head brace against the client's head, but do not secure his/her head in place.

Step 12. Make fine adjustments to the seat such that C5/C6 of the client's spine is aligned with the pivot point of the halo (*Figure 60-1 and 60-2*).

Figure 60-1

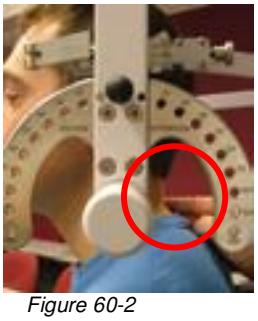


Figure 60-2

Step 13. Firmly secure the client's head with the head brace.

Step 14. Attach the RJ45 cable to the head brace being used and the RJ45 jack that is closest to the front of the unit at the top of the MCU (Figure 61-1 and 61-2).

Figure 61-1

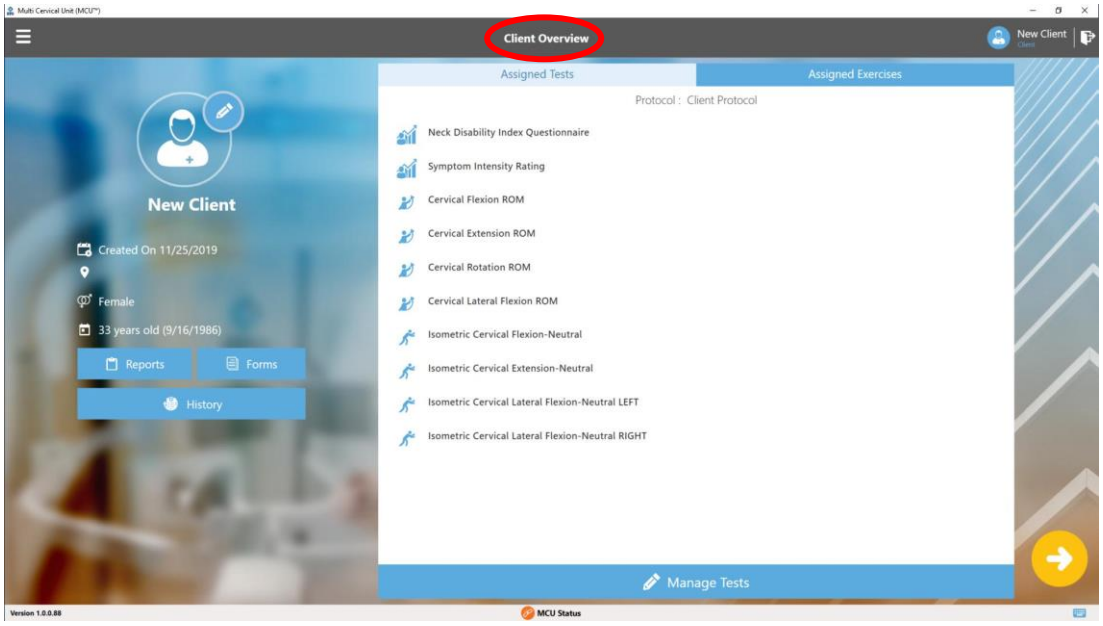
Figure 61-2 (RIGHT side) @ 45°LEFT head Rotation

III. Test Execution

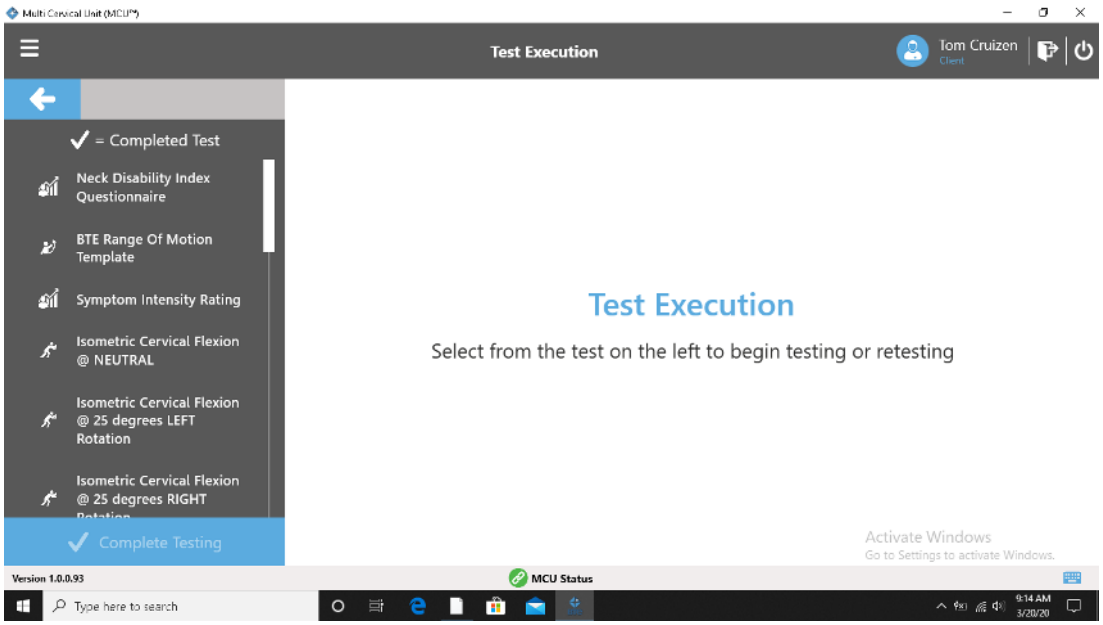
Please be aware that the information being presented here assumes that users possess the clinical knowledgeable necessary to measure spinal range of motion. This includes alignment of the measurement device in relation to associated anatomical landmarks, positioning of client, etc.

If you have not already selected client, do so from the Client Management window. The Client Overview window opens upon client selection. It is assumed you have already assigned tests and/or protocols to the client. If you have not, refer to Section 5 – Client Management, III. Client Overview, B.

Assign and Manage Tests/Exercises. At the Client Overview window, click the Proceed button to enter the Test Execution page *(Screenshot 1 and 2)*.



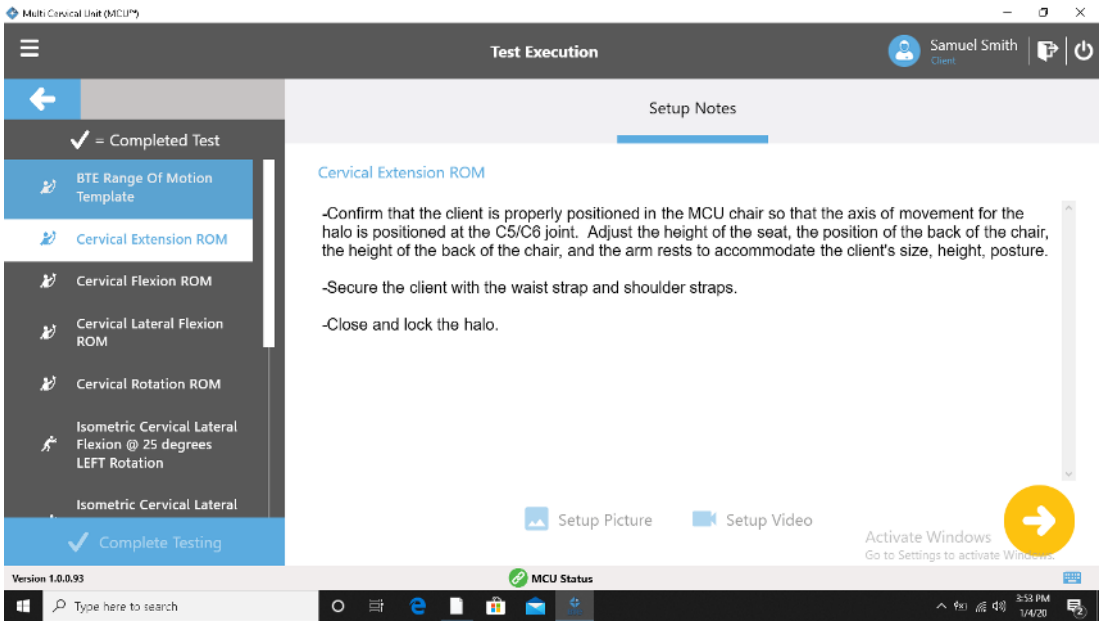
Screenshot 1



Screenshot 2

The Test execution window reflects the client's test(s) list to the left side of the window.

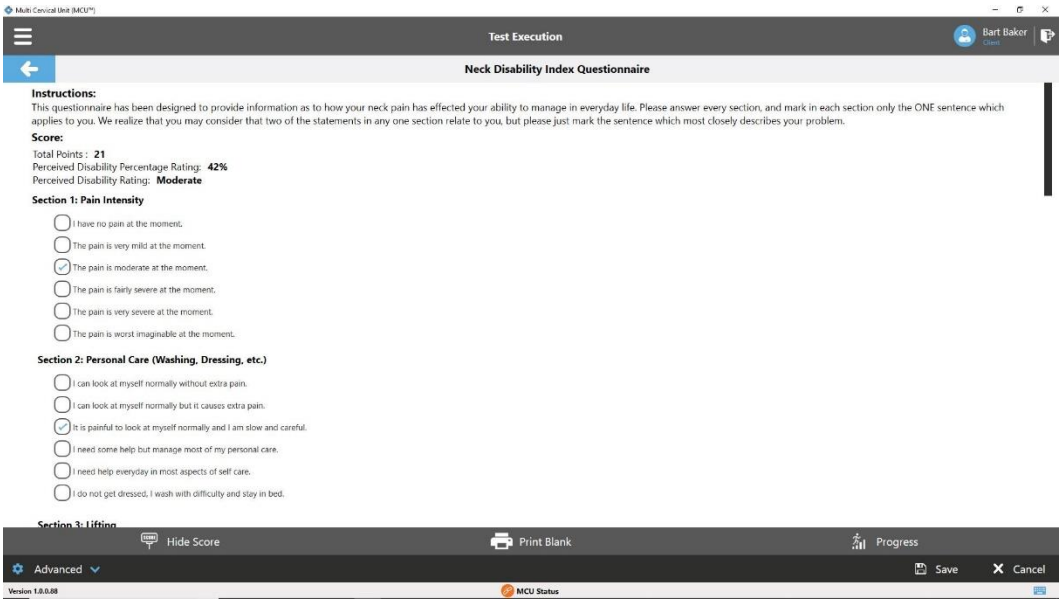
Select the test to be performed first *(Screenshot 3)*. Doing so will allow you to review the Setup Notes for the selected test. These may include setup notes related to hardware, client positioning instructions, and/or test instructions to be read to the client. Once you are ready to start the test, click the Proceed button (lower right corner of window).



Screenshot 3

A. Completing Self-Reports

On the Test Execution page, choose the Self Report desired. In this example, the Neck Disability Index (NDI) was chosen. When clicking proceed, you will be taken to the digital NDI form (*Screenshot 4*). The clinician or the client can fill in this form OR the form can be printed. When complete, "SAVE" the test on the bottom right. A checkmark will be visible on the first Test Execution page next to the NDI indicating that the test has been performed and data saved.

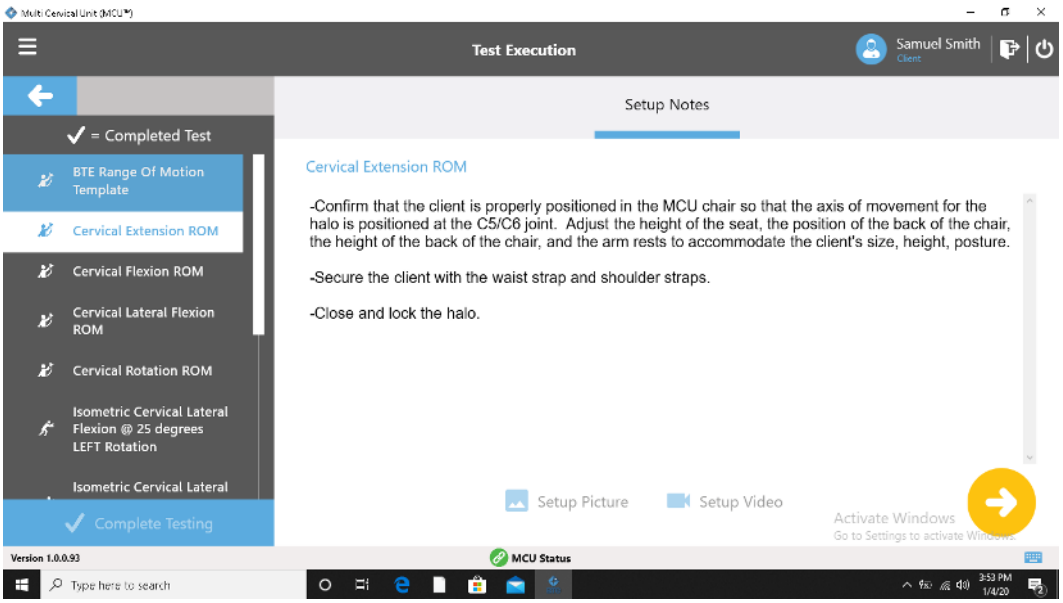


Screenshot 4

B. Performing ROM Tests

The ROM tests measure the client's range of motion with respect to the various cervical muscle groups (flexors, extensors, lateral flexors, and rotators).

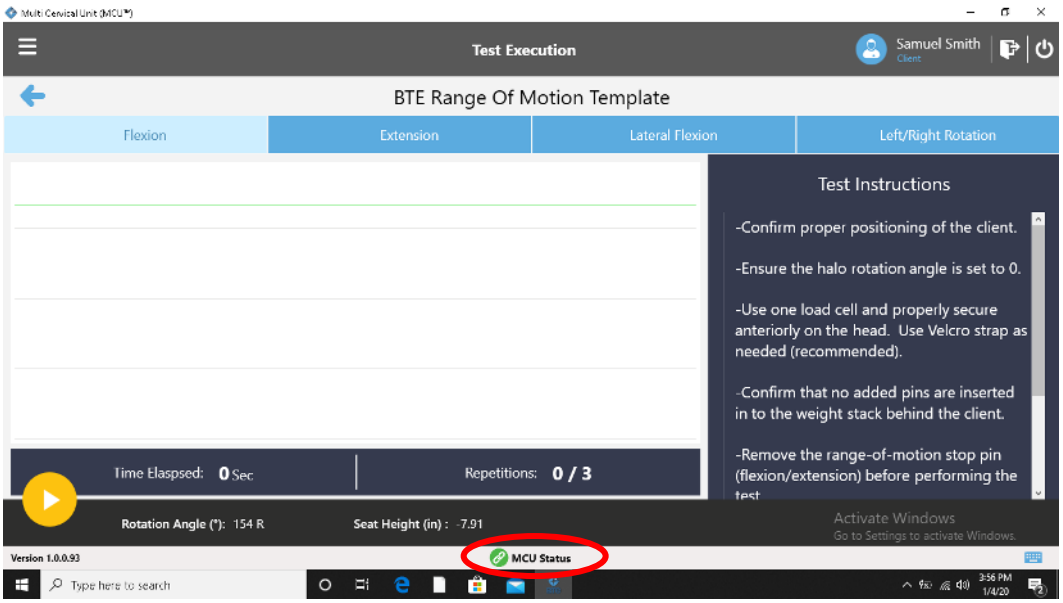
From the client's list of tests, select the BTE Range of Motion Template. Doing so will provide the Setup Notes for the selected test(s) (*Screenshot 5)*.



Screenshot 5

Position the hardware and the client according to the instructions. When ready, click the Proceed button.

From the test execution screen, choose the appropriate tab reflecting the desired test movement (*Screenshot 6, Flexion is selected*).



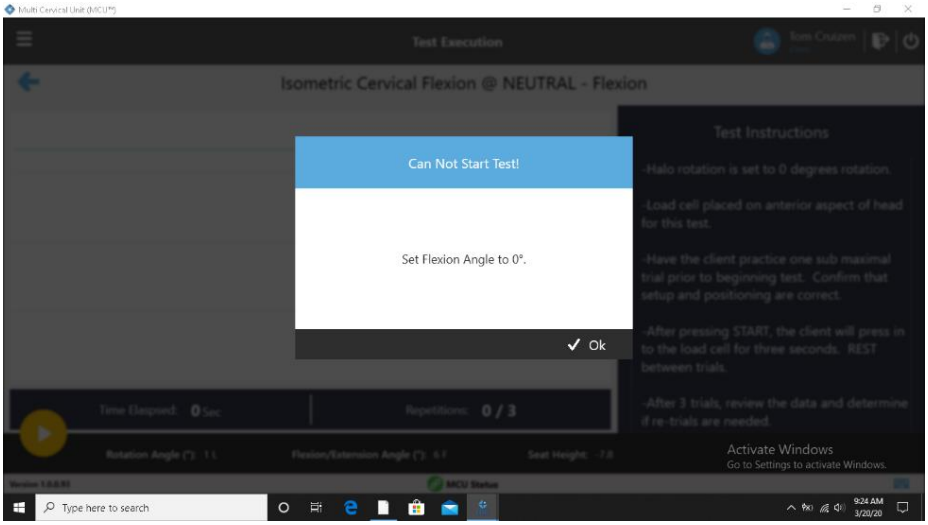
Screenshot 6

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 orange

1. ROM Test Execution

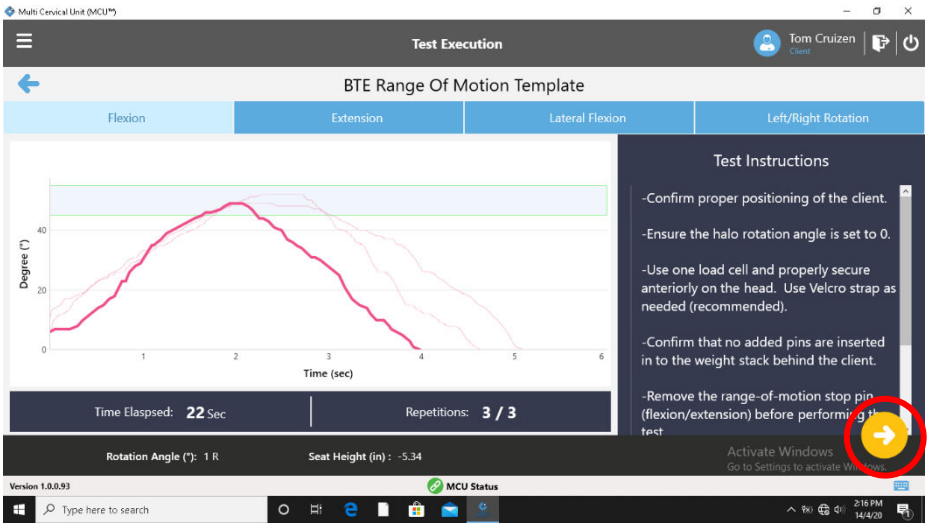
To perform a ROM test, select the first movement to be performed if not already designated and then click the yellow Proceed button on the bottom left *(Screenshot 6)*.

Confirm that the flexion/extension angle and rotation angle are correct. The real time rotation reading is present on the bottom left of the screen next to the Proceed button (*Screenshot 6*) If the setup is incorrect, a window will appear with a reminder of setting the proper position (*Screenshot 7*). Confirm halo positioning and select OK.



Screenshot 7

Begin test. A line will move across representing the real time degree of movement (Y axis) and the time to complete the repetition (X axis). The client will need to return to the zero position in order for the next trial data to be collected. Instruct the client to move to their full end range of motion and then smoothly back to the start.

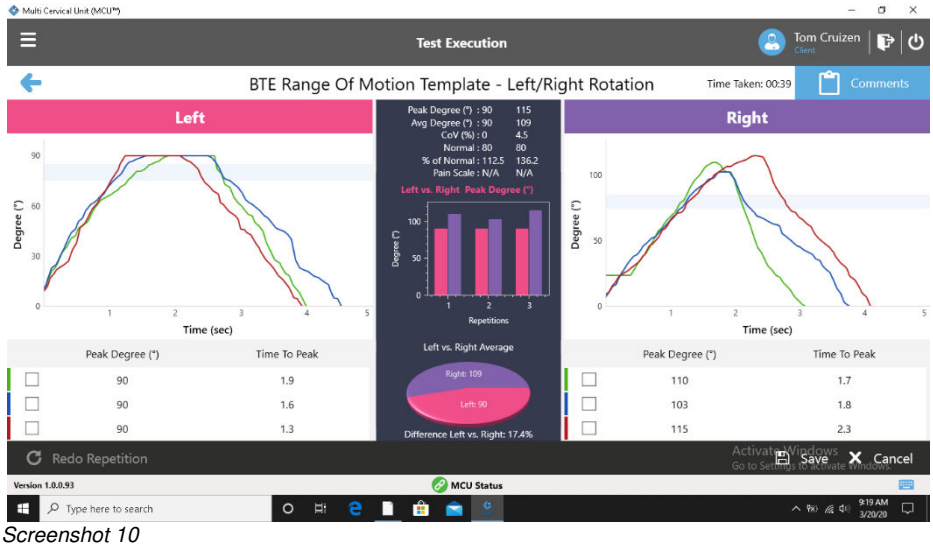


Screenshot 8

After the set number of trials are completed, choose the proceed arrow on the right side of the screen to review the data.

From the review screen, you will see information specific to each repetition. Also, you will see the cumulative info on the right side of the screen for a flexion/extension test (*Screenshot 9*). If you have performed a Left vs Right Rotation or Left vs Right Lateral Flexion test, the side to side comparison data will be visible in the middle of the screen. (*Screenshot 10*)

Screenshot 9

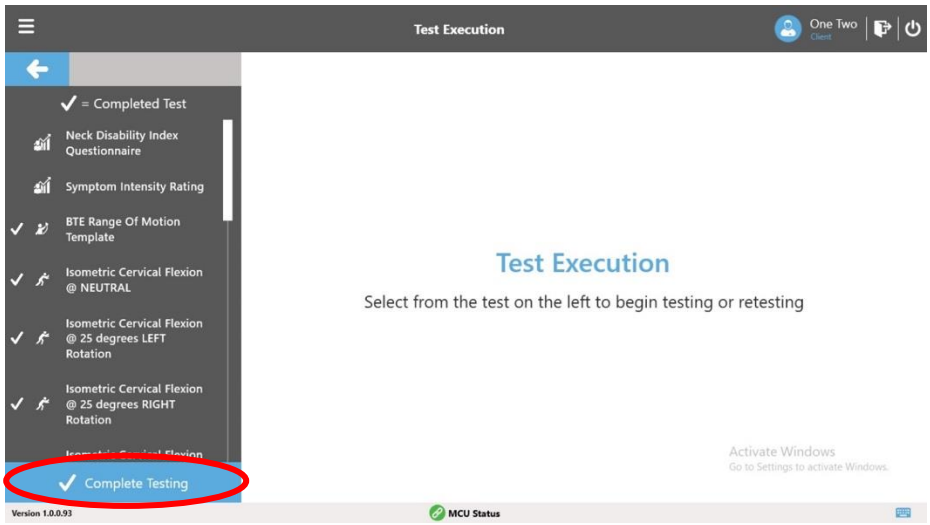


Screenshot 10

If the data is acceptable and you would like to save the data, simply choose 'Save' on the bottom right of the screen.

Continue to perform each Range of Motion movement on the Test Execution page. After completing all repetitions for all movements, click the Proceed and Save button.

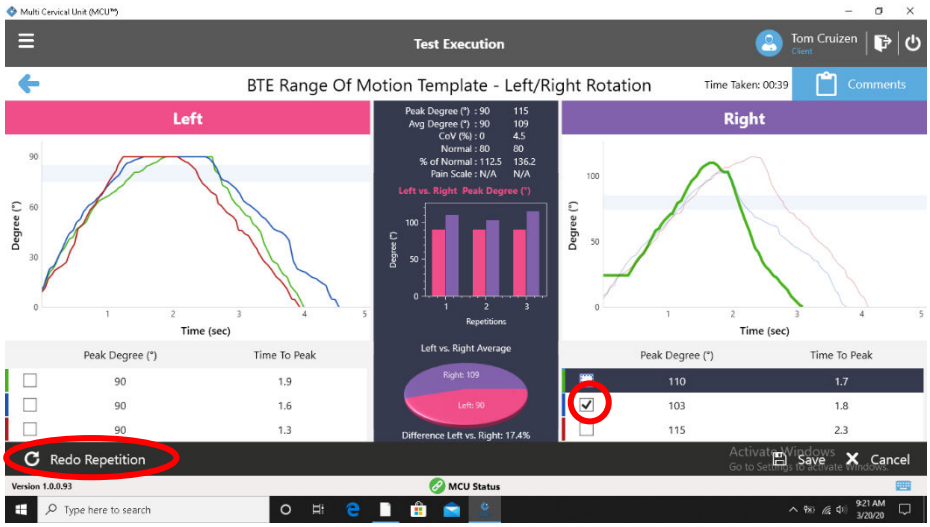
You will be taken back to the Test Execution page (Screenshot 11). If you have completed all desired tests, choose 'Complete Testing' at the bottom left of the screen to end the session and be taken back to the client profile.



Screenshot 11

2. To Re-Do a Repetition

If a repetition needs to be redone, click the box to the left of repetition to be redone *(Screenshot 12)*. The Redo Repetition icon (lower left corner of Test Results window) becomes active.



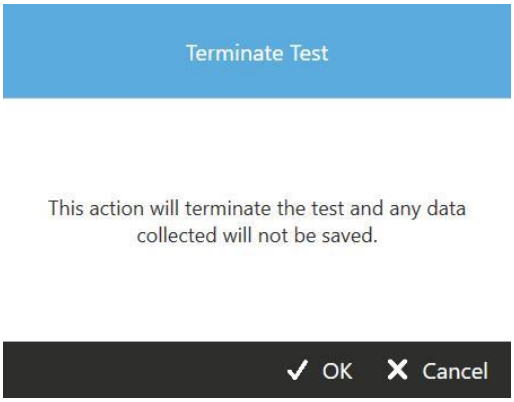
Screenshot 12

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.

3. 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” *(Screenshot 13)*. Clicking OK to stop the test will lead to a second pop-up altering

you to loss of any data already collected. Cancel will return you to the test in order to complete the test.



Screenshot 13

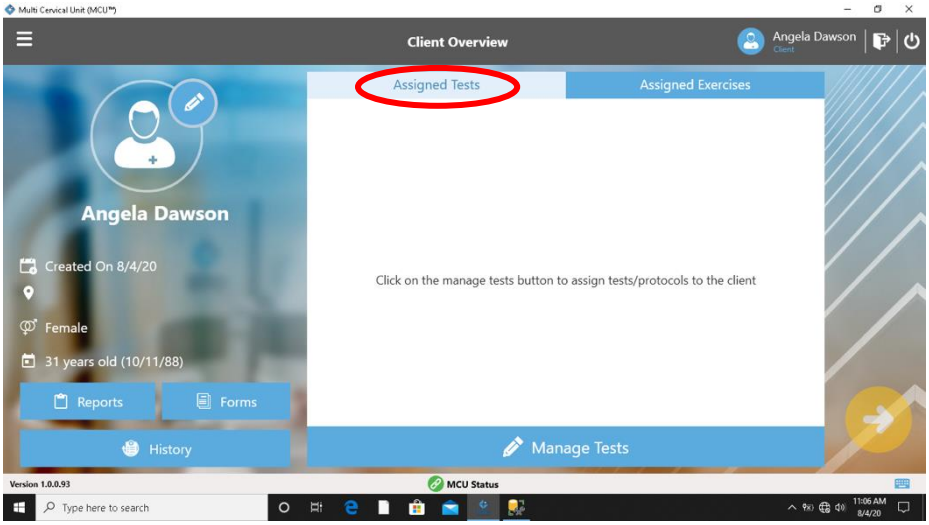
4. Performing Isometric Strength Tests

Utilizing the Cervical Strength Templates

You can choose to perform individual isometric tests in neutral or rotated positions. You can also utilize the BTE Assessment Template that includes all range of motion and isometric tests (in neutral and rotated positions) as well as the NDI and SIR questionnaires.

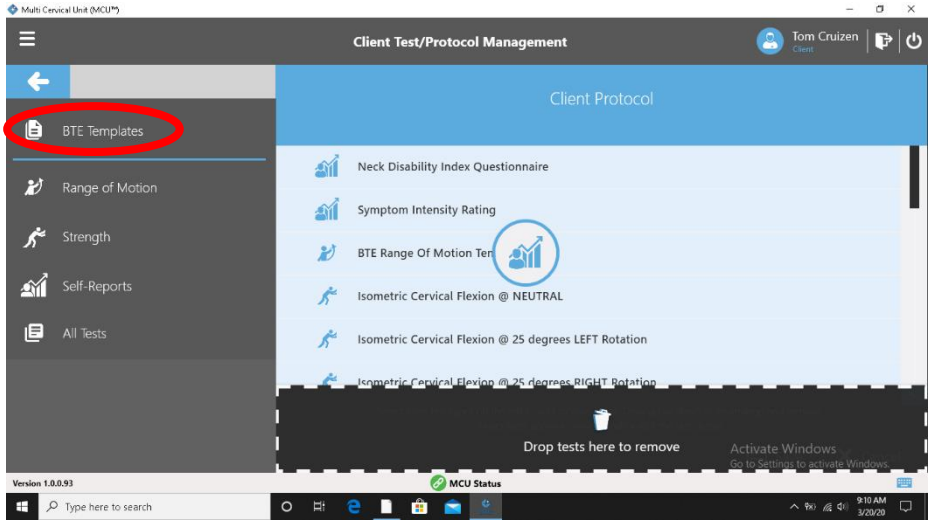
Accessing the Cervical Strength Tests

After a client has been created or selected, you will be taken to the Client Overview page where you can assign tests or exercises. Click on "Assigned Tests" and then Manage Tests (*Screenshot 14*).



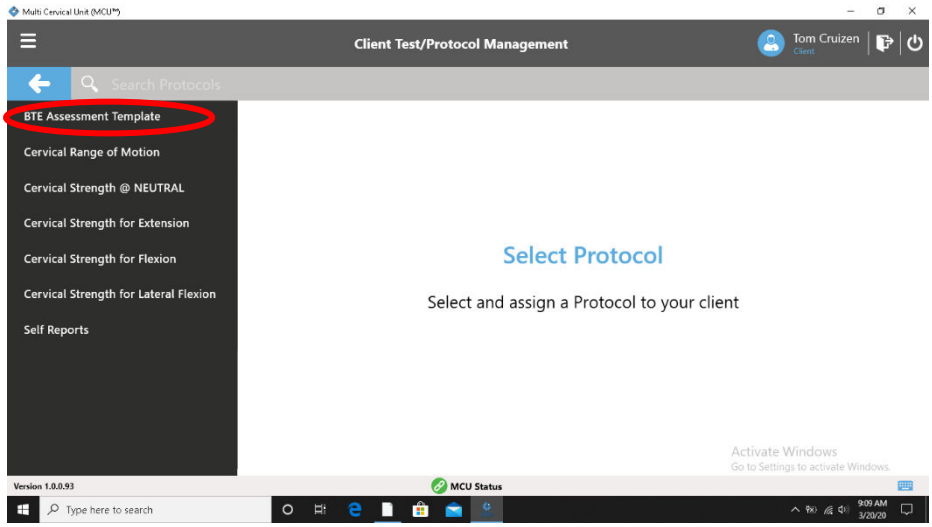
Screenshot 14

Choose "BTE Templates" from Client Test/Protocol Management (*Screenshot 15*).

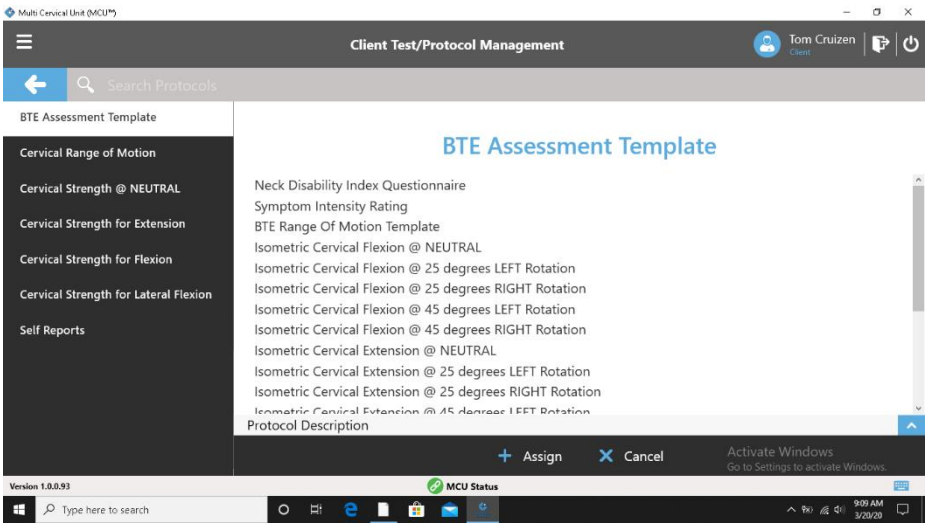


Screenshot 15

Access the pre-programmed Strength protocols by selecting “BTE Assessment Template” from the list on the left (*Screenshot 16*).



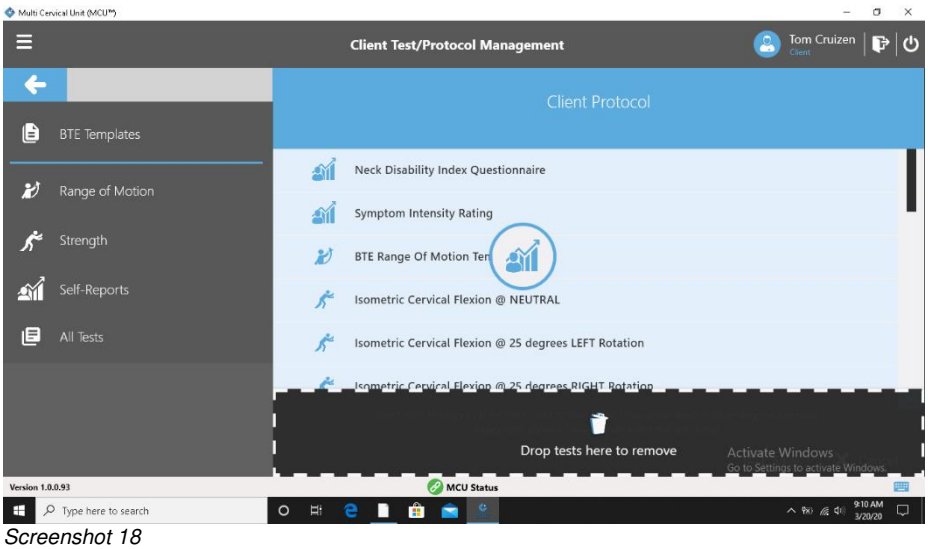
Screenshot 16



Screenshot 17

The list/order of tests is now visible. Assign this to the client.

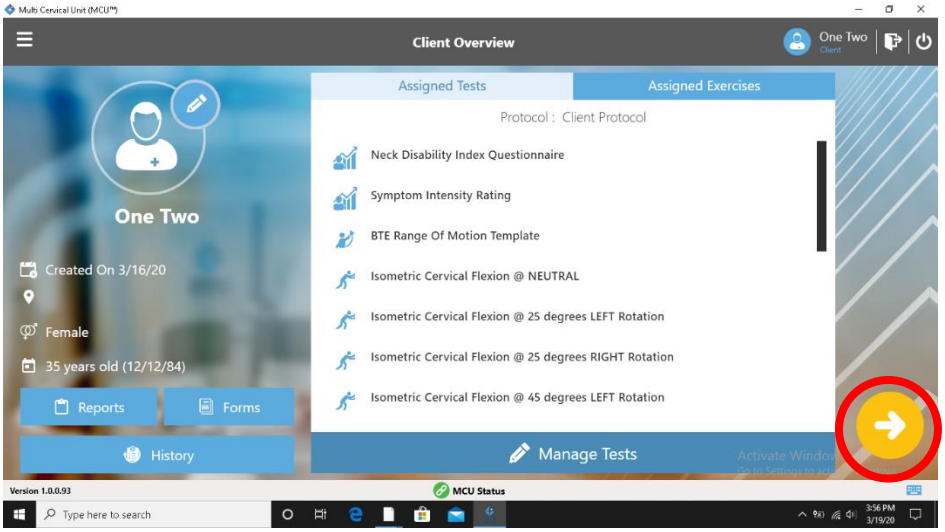
You will be taken back to the Client Test/Protocol Management page where you will be able to change the order of tests, delete tests, or Save the test to the client (Screenshot 18).



Screenshot 18

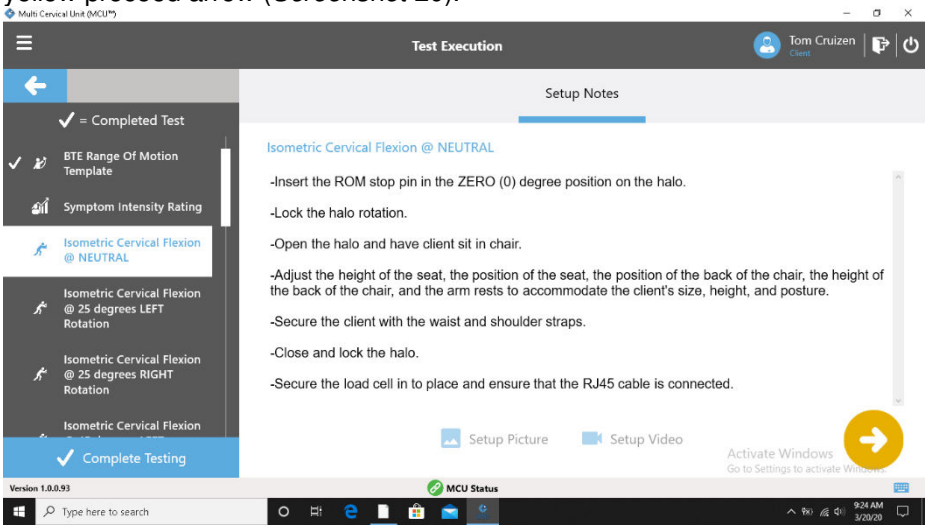
5. Strength Tests

To perform a strength test, confirm that you have one of the isometric tests assigned to the client. Select the yellow proceed arrow from the Client Overview page (*Screenshot 19*).



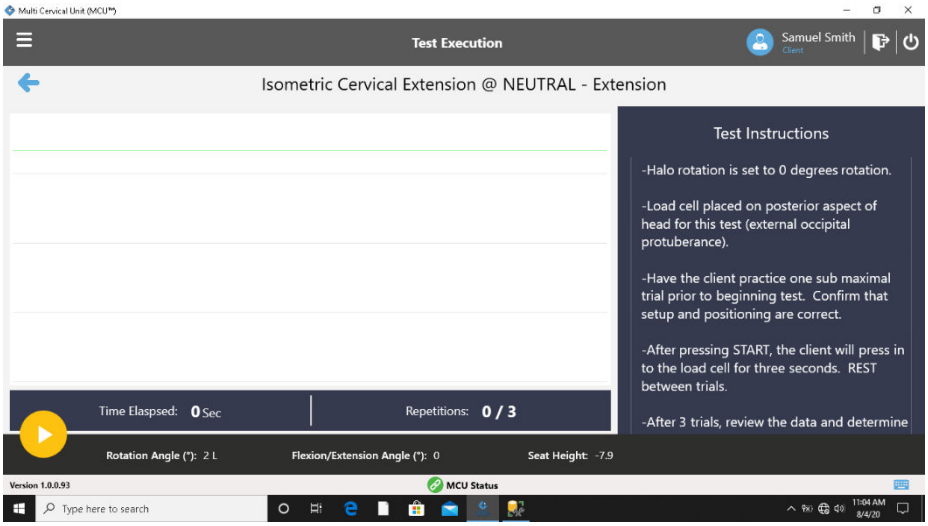
Screenshot 19

From the Test Execution Page, scroll down to the desired isometric test and click on the test. When doing so, the Setup Notes for that test will be visible. Set the halo and position the client accordingly for the selected test and then choose the yellow proceed arrow (*Screenshot 20*).



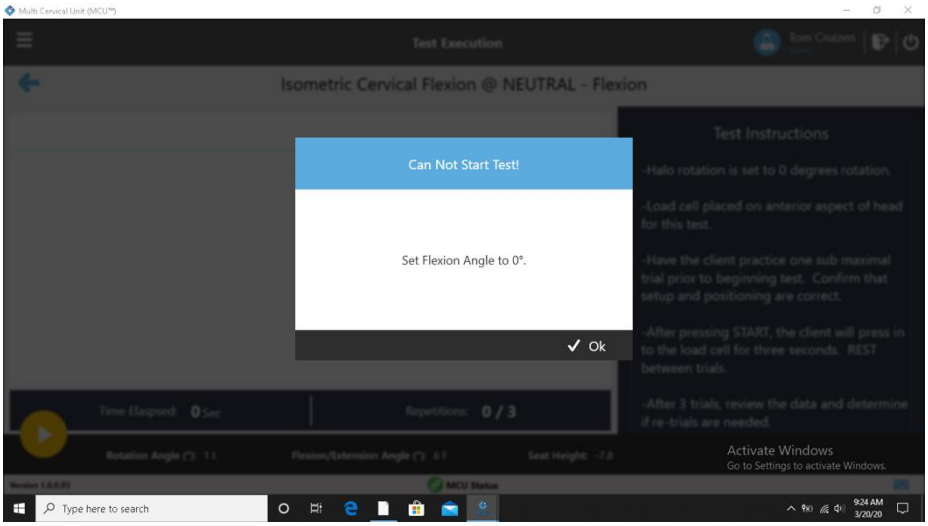
Screenshot 20

On the Test Execution page, you will see the name of the test (position included) as well as the Test Instructions. On the bottom of the page will be the reading of the 'Rotation Angle' of the Halo as well as the 'Flexion/Extension Angle' and 'Seat Height.' Press the yellow proceed button on the bottom left to begin the test (*Screenshot 21*).



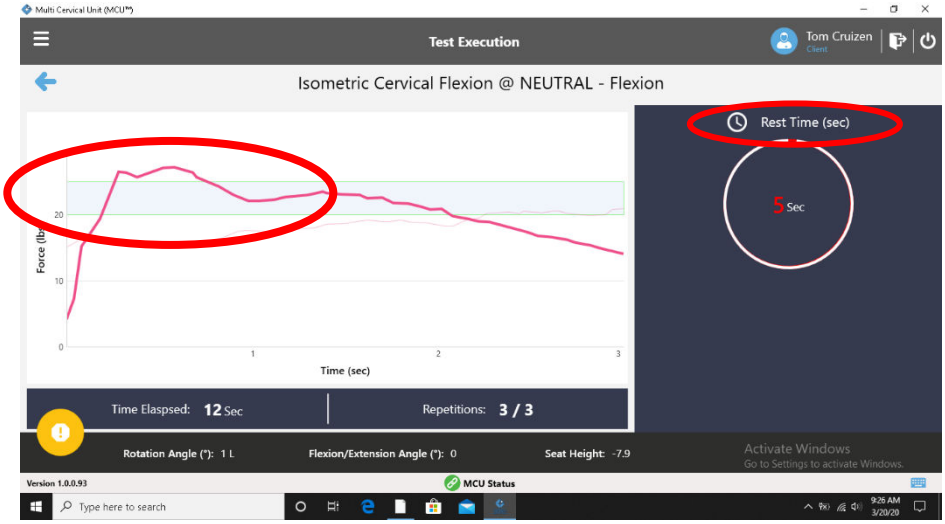
Screenshot 21

If the Halo is not set up correctly, a message will pop up with a reminder of the proper halo position (rotation and flexion/extension angle). Make the necessary adjustments and select 'ok' and you will hear a voice prompting the client to "Start Test Now." (*Screenshot 22*)



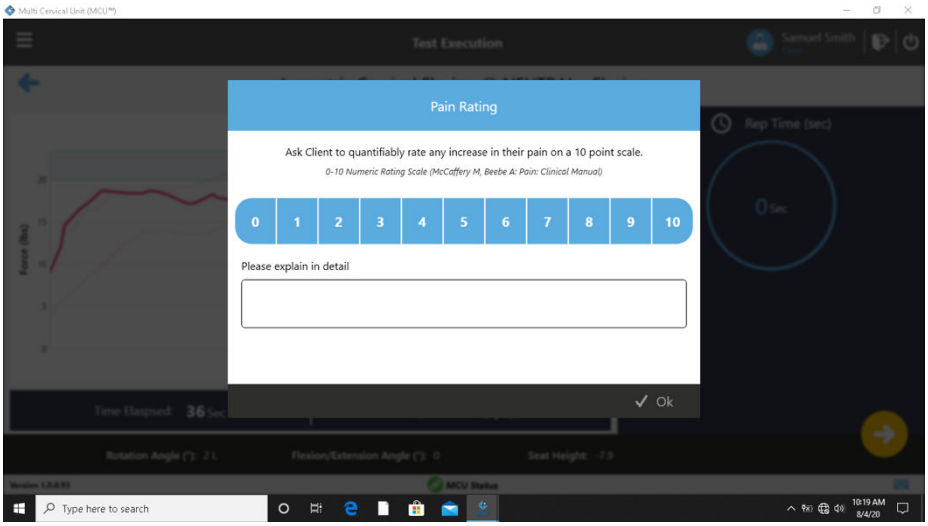
Screenshot 22

Instruct the client to begin pressing against the load cell in the correct manner until the trial is completed. There will be a voice prompt beginning the rest period and a countdown clock will be visible. On the x axis, you will see the time of the repetition while the y-axis displays the demonstrated force. There is also a horizontal gray window outlined in green indicating the normative data associated with that particular test (*Screenshot 23*).



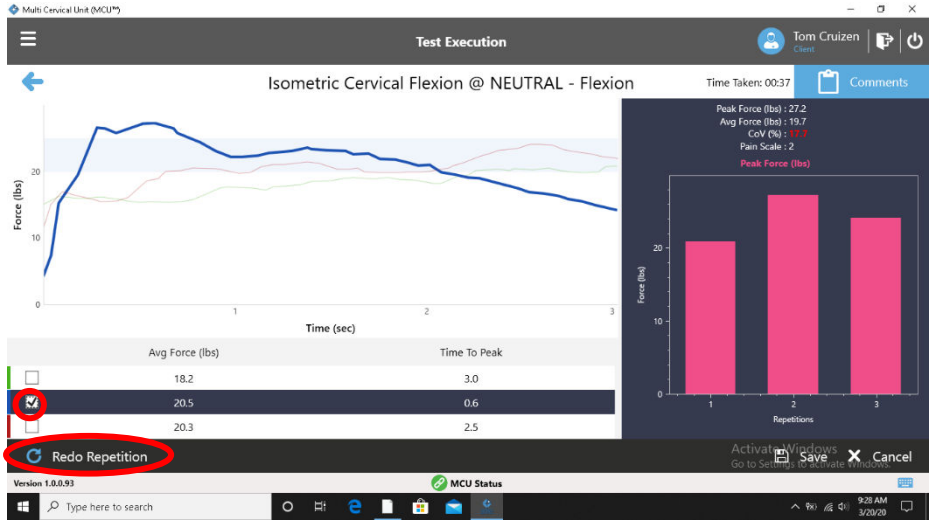
Screenshot 23

After completing the assigned number of trials, a pain scale will show up on the screen. Choose the appropriate pain rating and enter a comment as needed. Select the 'OK' on the bottom right side of the window. (*Screenshot 24*).



Screenshot 24

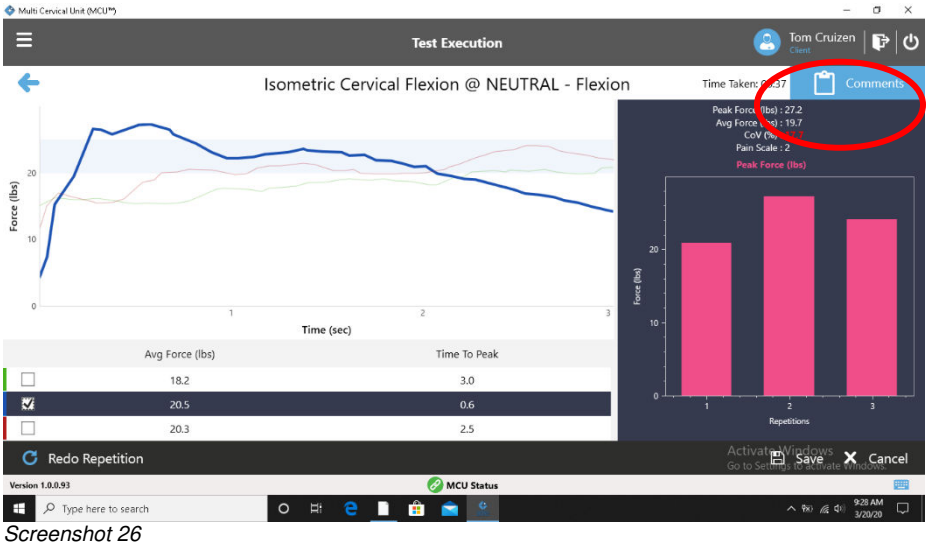
You will now be able to review the results of those trials. Clicking on an individual trial will highlight the data for just that trial. Review the results (Peak Force, Average Force, CoV, Pain Scale) and determine if it is necessary to Redo a Repetition (*Screenshot 25*).



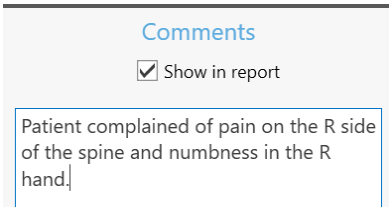
Screenshot 25

If you would like to do Redo a trial, select which trial and then "Redo Repetition." You will be taken back to the test execution page. Press the yellow proceed/start button on the left side and perform trial.

You now may want to enter comments related to the test. These comments can be referred to at a later date when reviewing the test "History" (more on that later). When reviewing the test data, the "Comments" box is in the upper right hand corner. Click on it to open a text box and enter necessary data. (*Screenshot 26 and 27*).



Screenshot 26

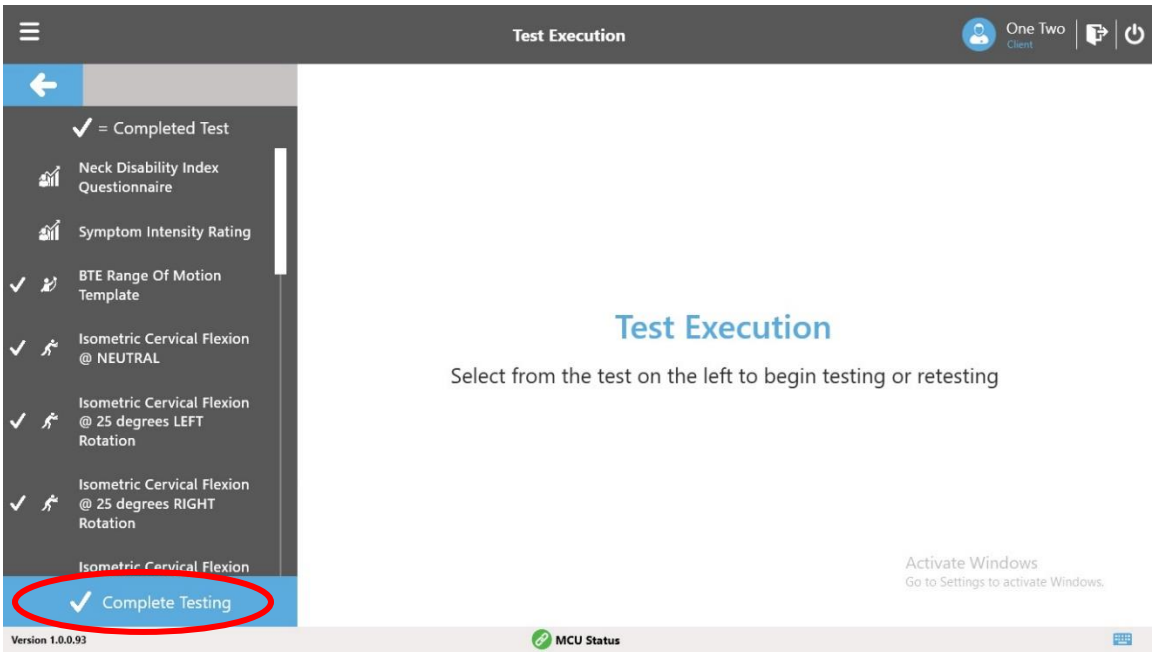


Screenshot 27

When you have determined that you have completed testing and entered the necessary comments for that position, choose “Save.”

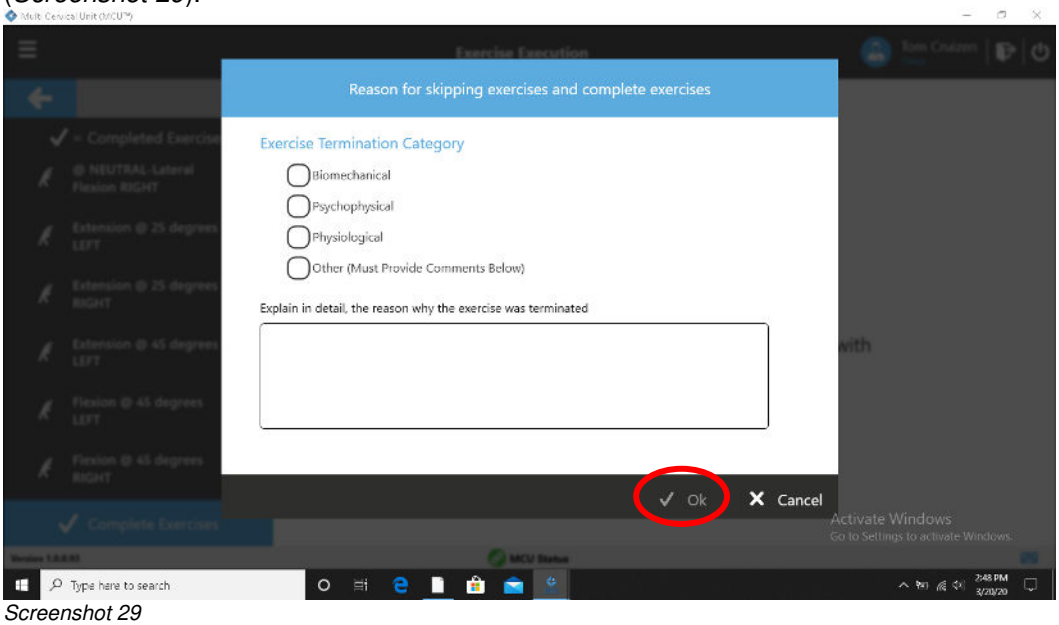
6. Complete Testing and Reporting

Once you have completed the test session, click on the Complete Testing button located at the lower left corner of the Test Execution window *(Screenshot 28)*. Doing so without completing all the tests will prompt a screen asking you to choose a reason for skipping tests.



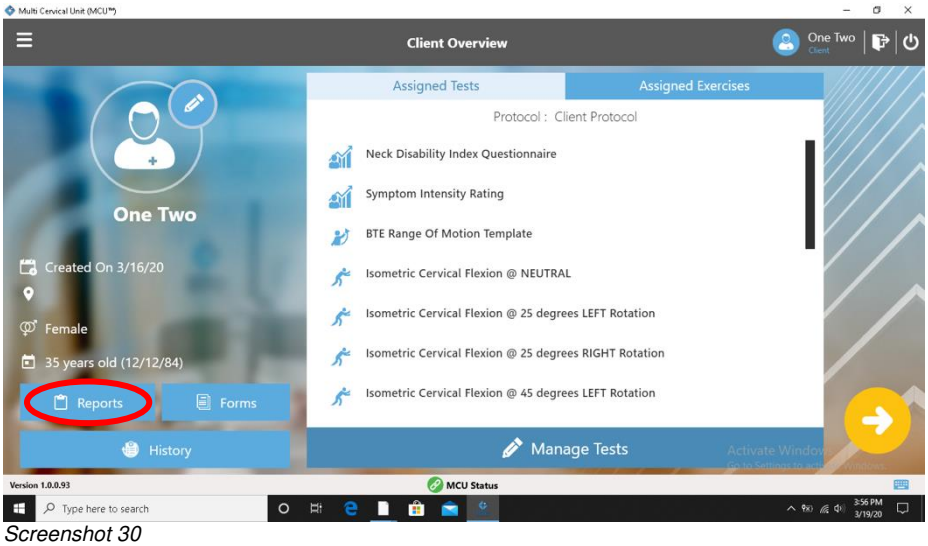
Screenshot 28

Choose the reason. If no reason is needed, select “Other” and then “OK” (*Screenshot 29*).



Screenshot 29

Now, you are back to the Client Overview screen. From here, you will be able to review the previously saved tests under “History.” Also, you can use the “Forms” option to print out or complete the questionnaires. Finally, the “Reports” option is available. (*Screenshot 30*).



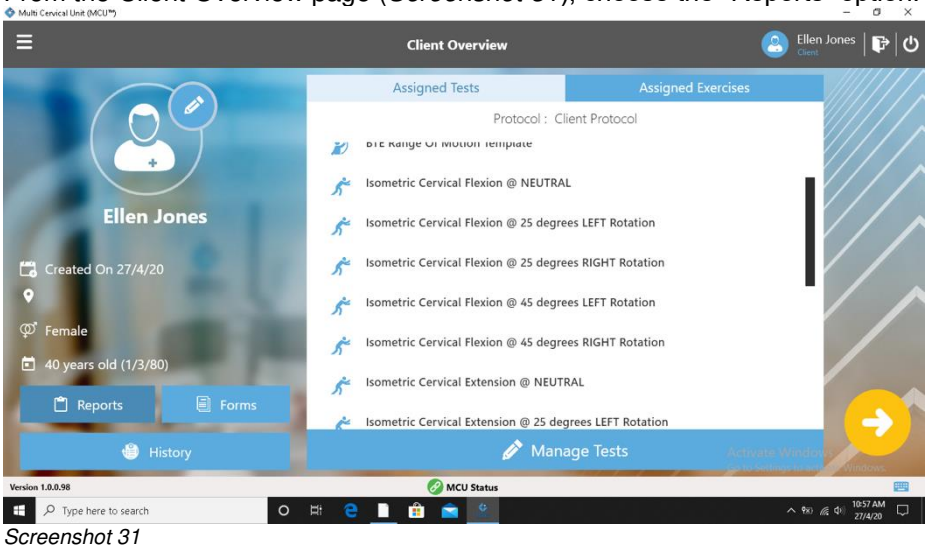
Screenshot 30

Evaluation Reports

There are two primary reports available. For one evaluation, you can choose the Evaluation Summary. And, if there are multiple evaluations where you would like to compare the results, you can choose a Progress Report.

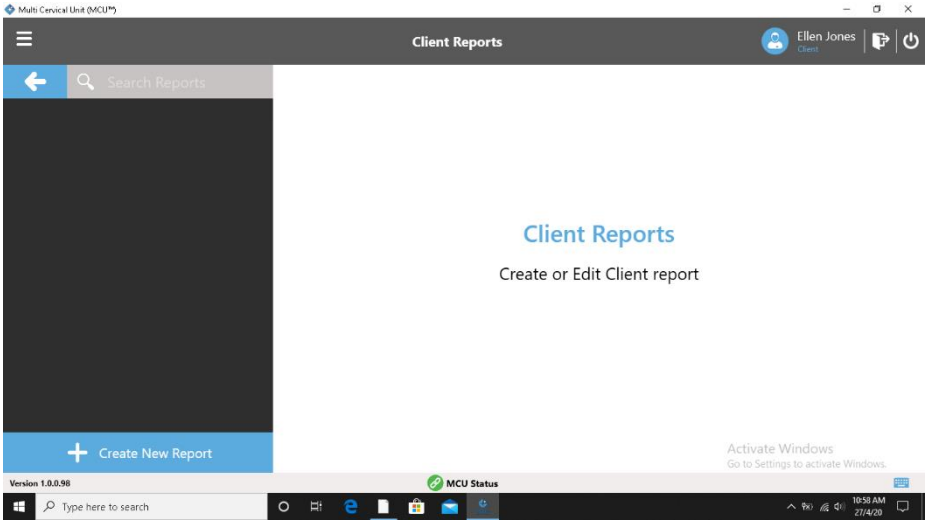
Evaluation Summary

From the Client Overview page (*Screenshot 31*), choose the “Reports” option.



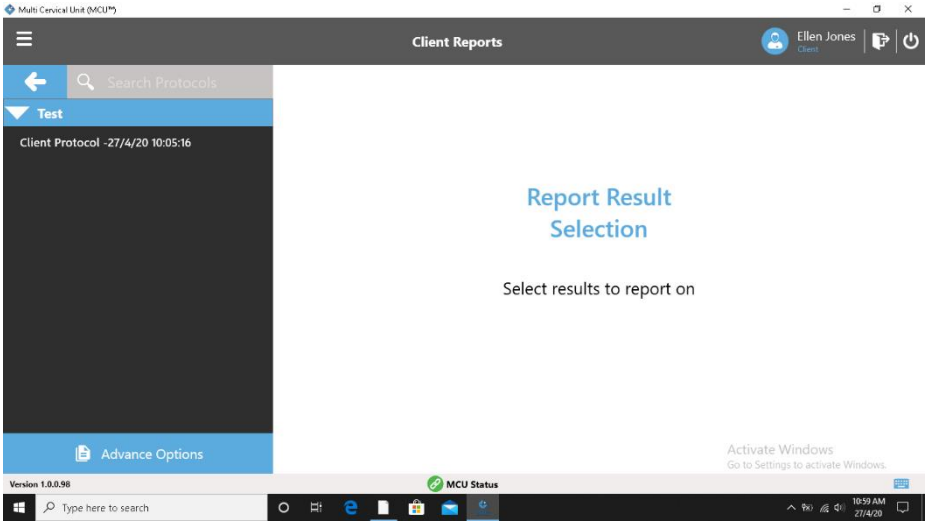
Screenshot 31

You will now see the “Client Reports” section (*Screenshot 32*). Choose to “Create New Report.”



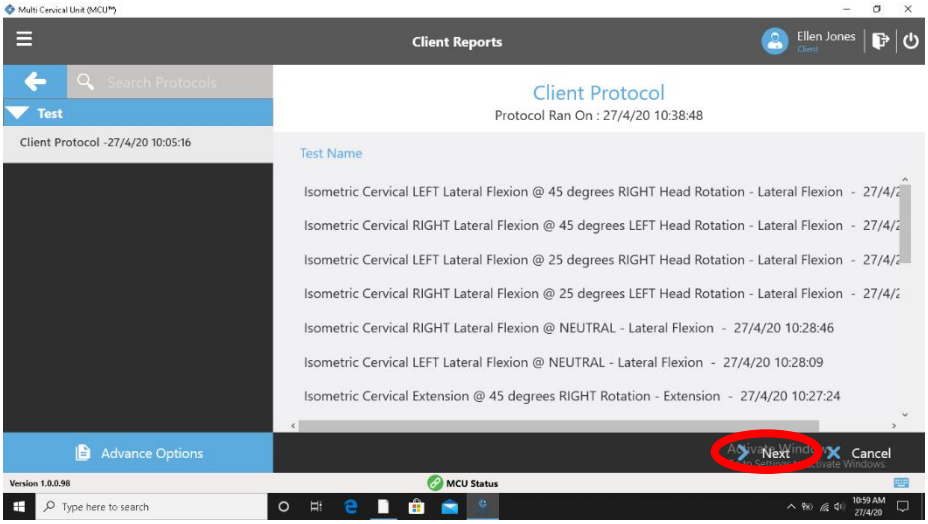
Screenshot 32

You will see a date visible under “Test.” This shows each time a client protocol was completed. Select the date (*Screenshot 33*).



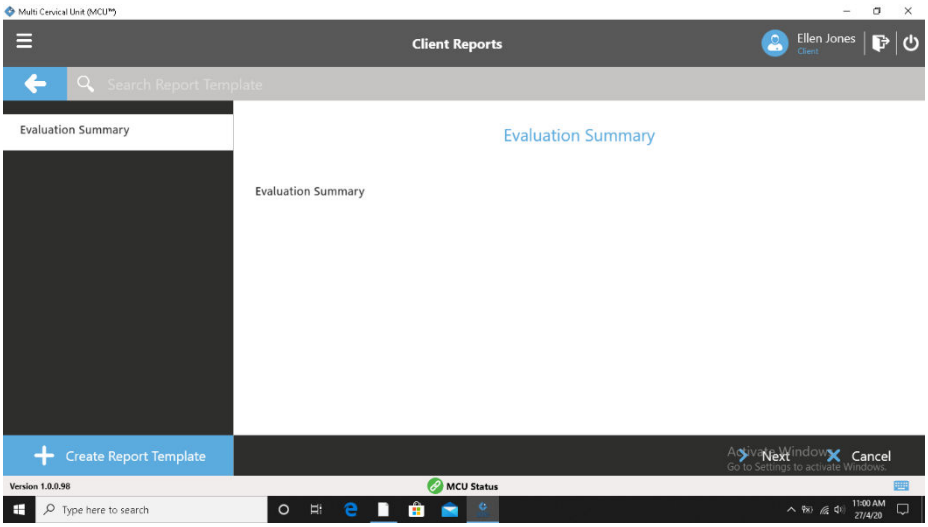
Screenshot 33

Select the date/time. You will see the lists of saved tests on the screen (*Screenshot 34*) and choose “Next.”



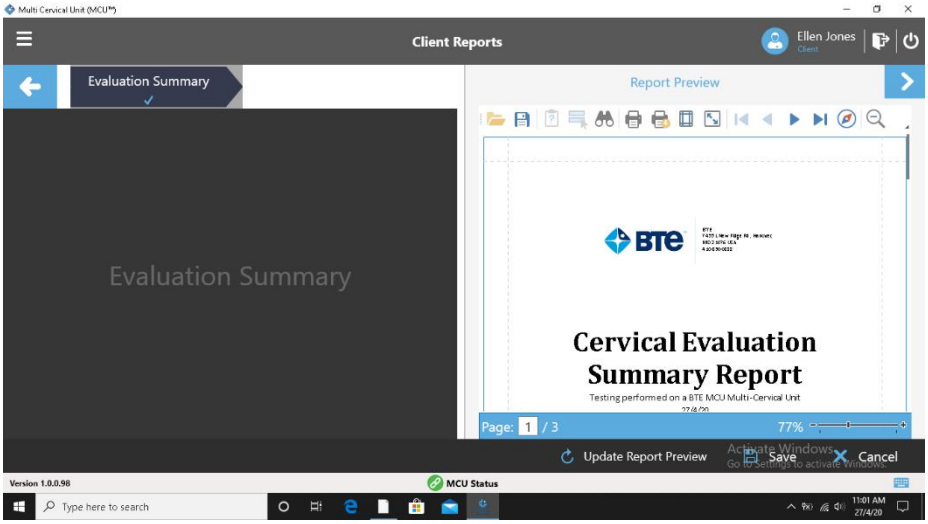
Screenshot 34

After selecting “Next,” you will now click “Evaluation Summary.” Choose this option and select “Next” again (*Screenshot 35*).



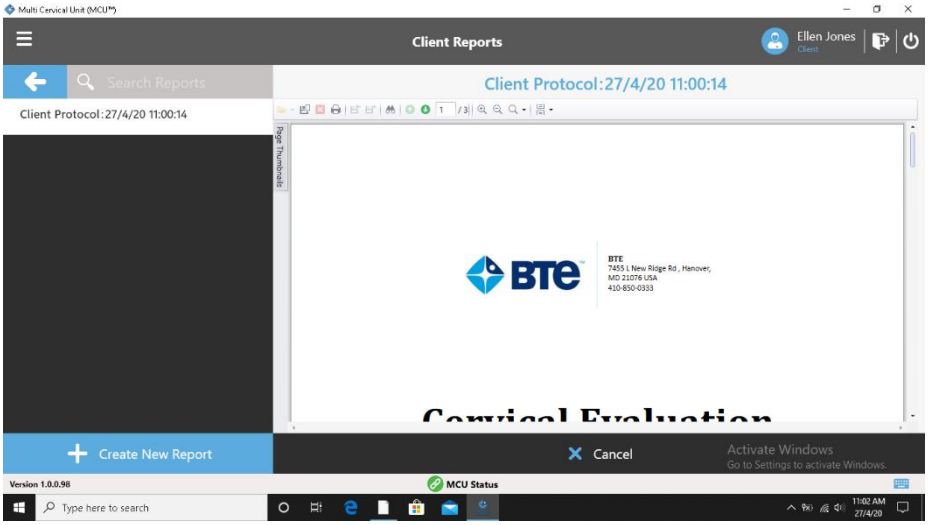
Screenshot 35

The “Cervical Evaluation Summary Report” is visible. You can view the report and enlarge the display. Also, you will be able to save the report for viewing at a later time (*Screenshot 36*).



Screenshot 36

A saved Client Report (*Screenshot37*)



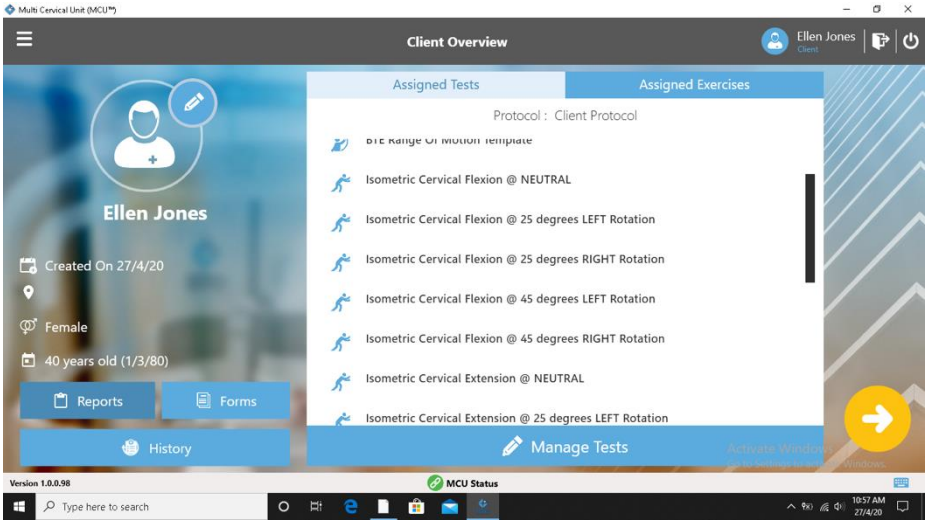
Screenshot 37

At any time, this report can be viewed/generated from the Client Overview page.

Evaluation Progress Report

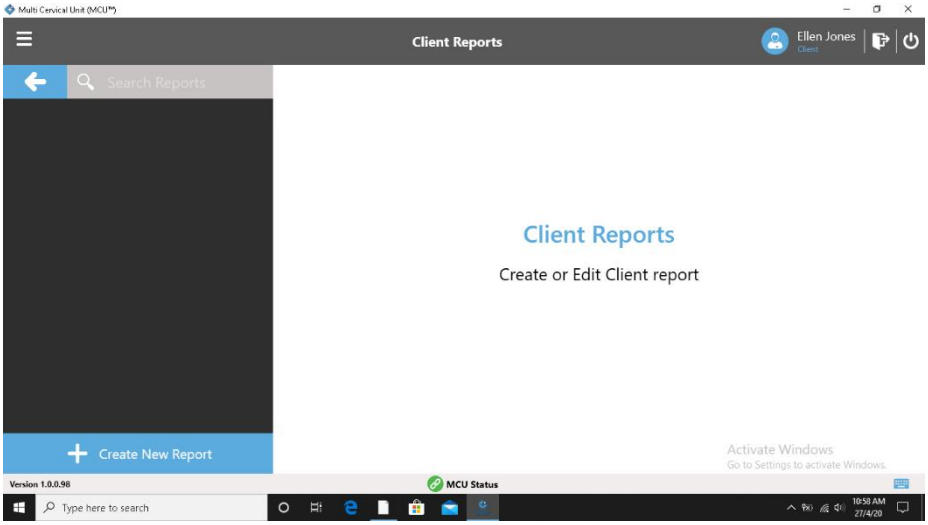
This report allows you to show changes from one evaluation to the next.

Begin at the Client Overview Page (Screenshot 38).



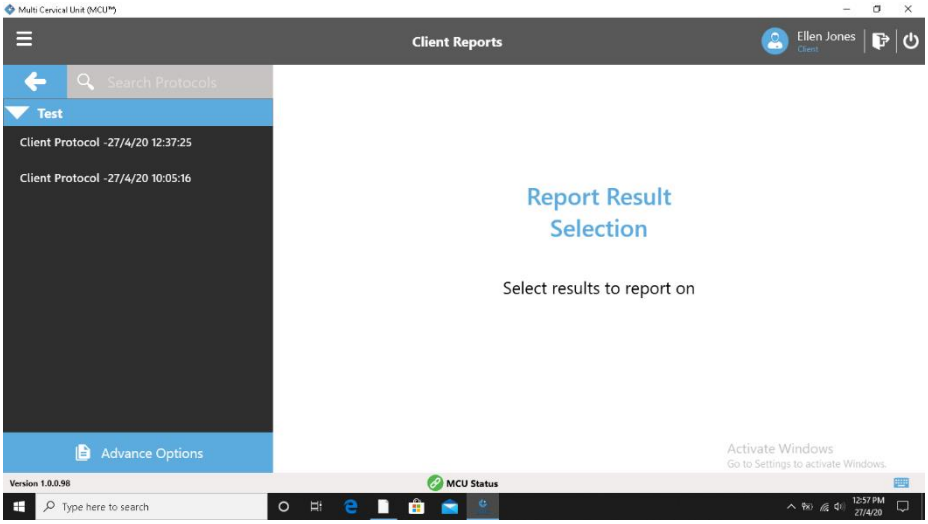
Screenshot 38

Create a new report (*Screenshot 39*).



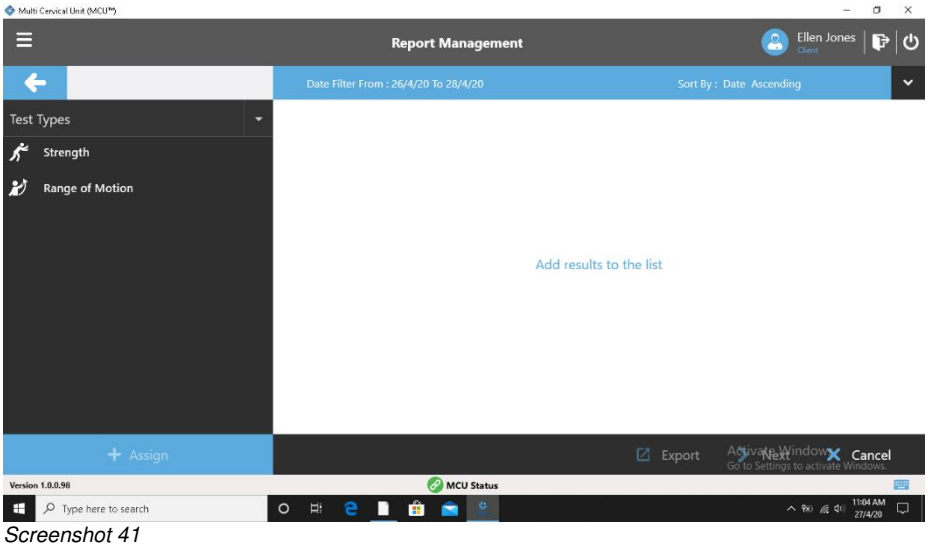
Screenshot 39

Multiple test protocols will be visible. Choose “Advanced Options” from the bottom left (*Screenshot 40*)



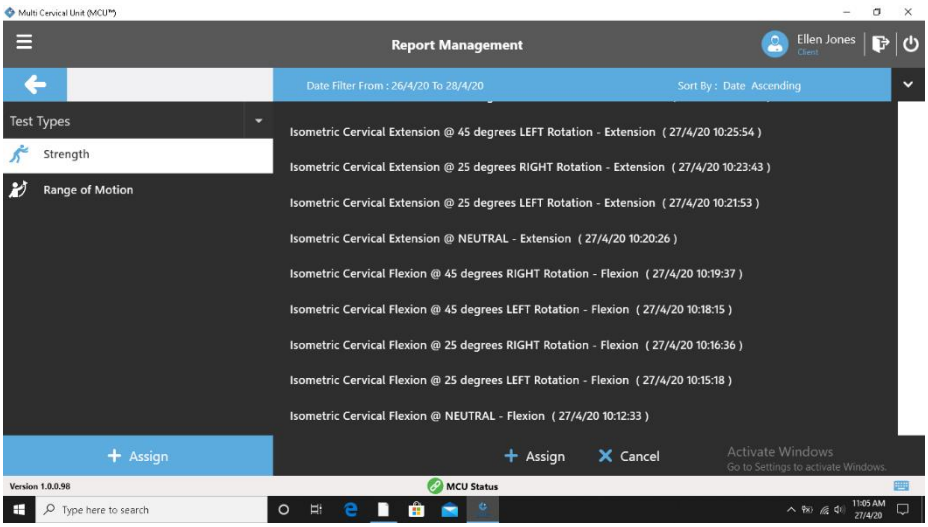
Screenshot 40

Strength and Range of Motion Test types are available on the left (Screenshot 41).



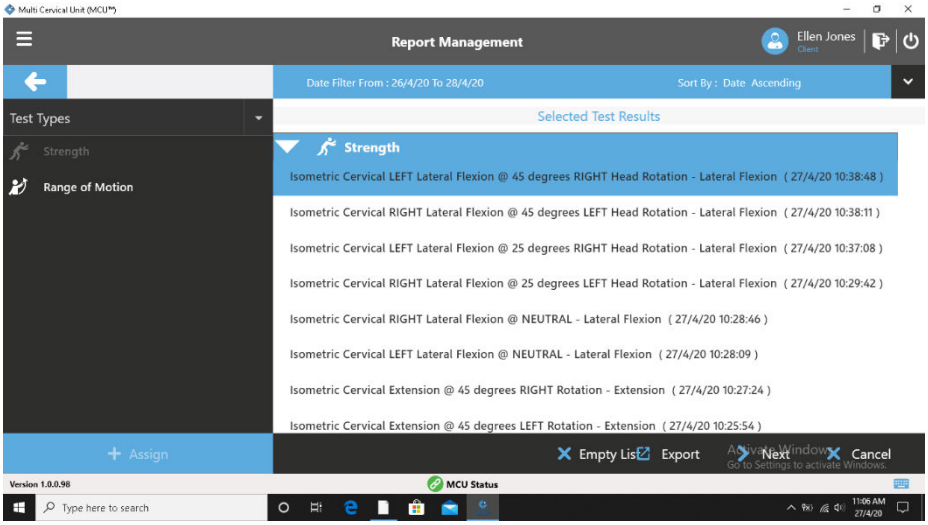
Screenshot 41

Choose “Strength” to “Assign” all the strength tests. If you would also like to include the progress report for Range of Motion, also choose that option and “Assign.” You can choose to include ALL strength and ALL range of motion tests by selecting the “Assign” option on the bottom left. Or, you could choose individual tests and then assign those by using the “Assign” option in the bottom center (Screenshot 42).



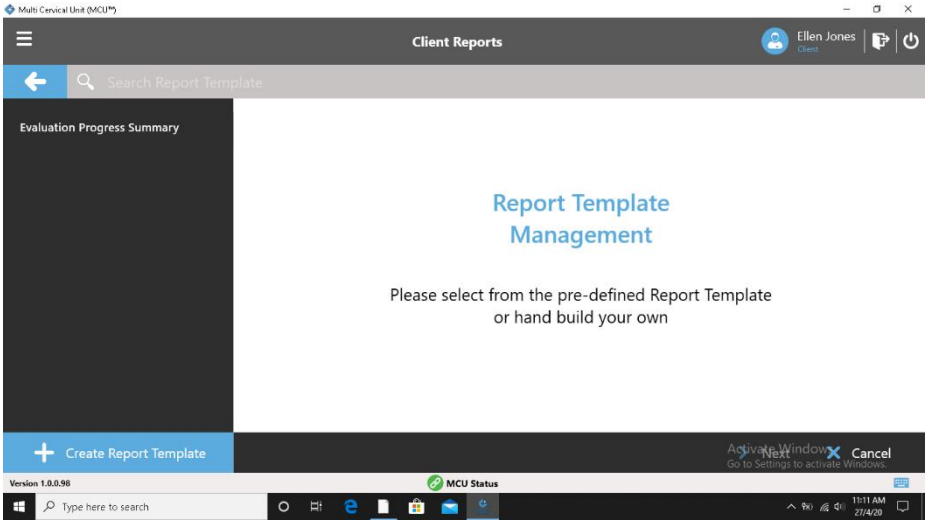
Screenshot 42

Next, you will see all the tests that are included in this report. Select “Next” (Screenshot 43).



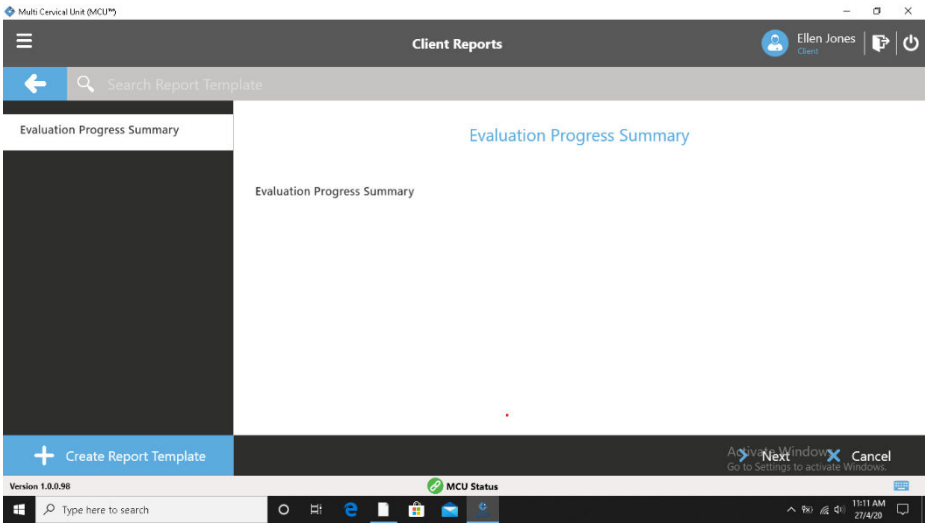
Screenshot 43

Select “Evaluation Progress Summary from the upper left (Screenshot 44).



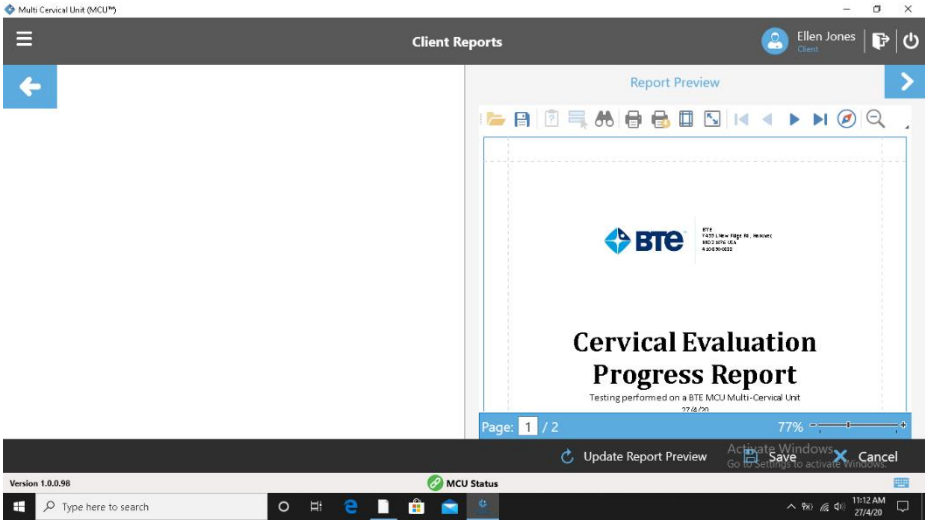
Screenshot 44

Select Evaluation Progress Summary once more from the center of the page and click “Next” (Screenshot 45).



Screenshot 45

You have now created a “Cervical Evaluation Progress Report” and you can now print the report or save it to the client profile. (Screenshot 46)



Screenshot 46

Section 7 – Exercise

I. Assign Default Exercises 127
II. Exercise Execution 129
III. Perform Exercises 131
IV. Exercise Reports 135
V. Change Default Exercise Settings 142
VI. Manage Exercises 144

I. Assign Default Exercises

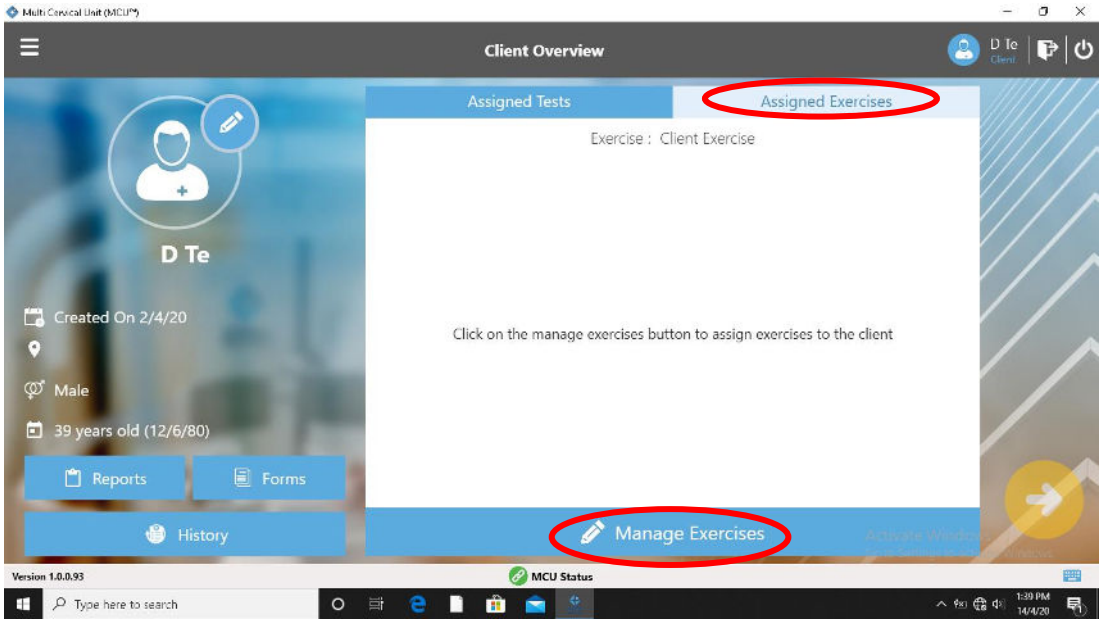
Please be aware that the information being presented here assumes that users possess the clinical knowledgeable necessary to measure spinal range of motion. This includes alignment of the client in relation to associated anatomical landmarks, positioning of client, etc.

The MCU offers both assessment and exercise options. When an assessment has been performed, you will be able to use that range of motion and isometric data to assist in determining the appropriate degree of motion and level of resistance for that client.

*****NOTE that there is no isometric assessment for rotation for safety purposes. However, you are able to dynamically exercise in rotation. You will need to choose the starting pin position and targeted ROM for left or right rotation.**

After a client has been selected, you will be taken to the "Client Overview" page. From here, click on "Assigned Exercises" to choose the exercise(s) that you would like to perform with your client.

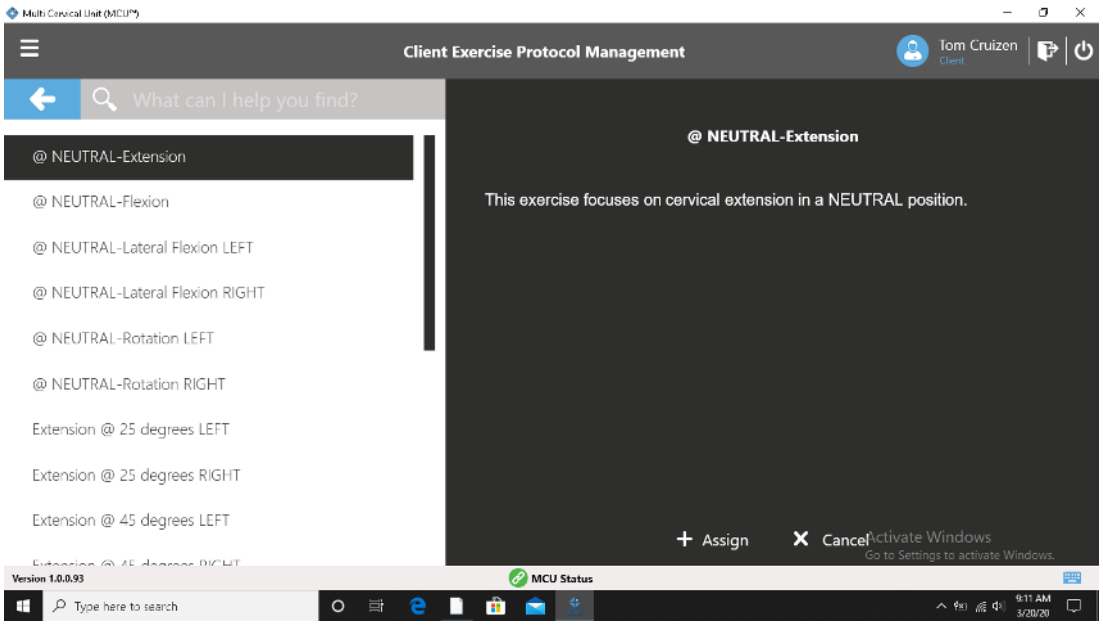
Choose "Manage Exercises." (Screenshot 1).



Screenshot 1

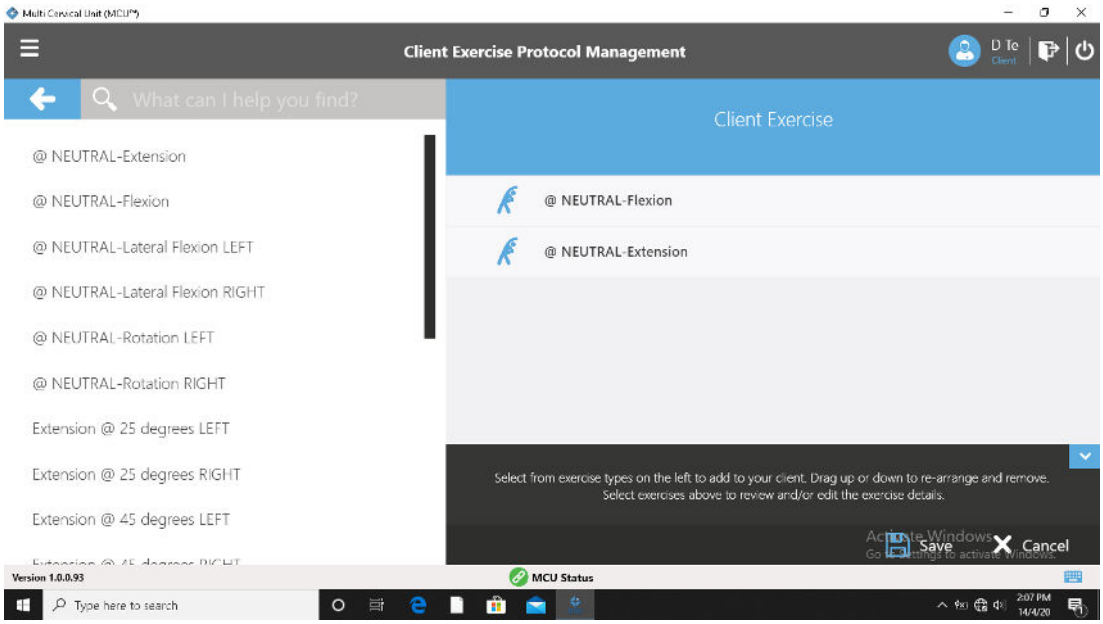
Next, you will be taken to the "Client Exercise Protocol Management." You will see a list of default exercises on the left.

Choose an exercise you would like to perform with your client and then "Assign."(*Screenshot 2*) You will need to repeat this step for each additional exercise you would like included.



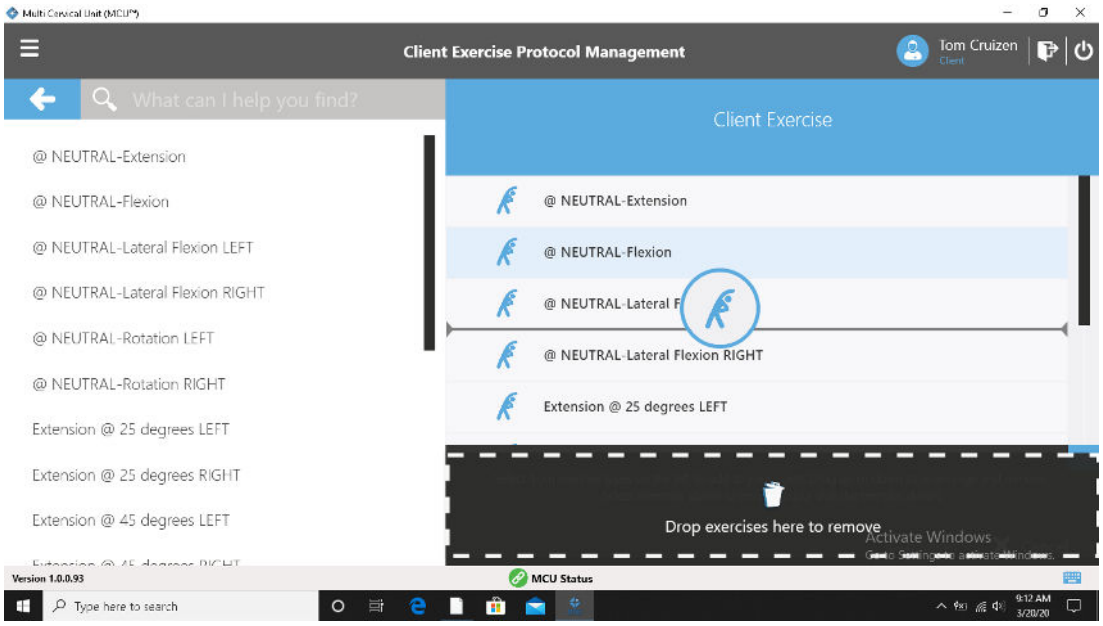
Screenshot 2

After each exercise has been assigned, the “Client Exercise” page will be displayed (*Screenshot 3*).



Screenshot 3

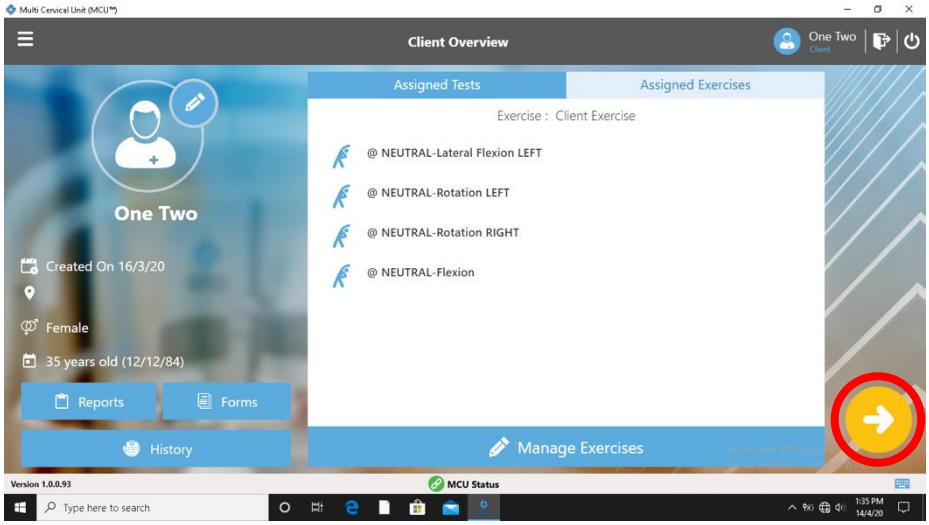
From here, you can move the order of exercises by clicking the exercise and dragging it up or down the list. You can also click the exercise and drag it to the bottom of the page to the “Drop exercise here to remove” section (*Screenshot 4*)



Screenshot 4

When happy with the chosen exercises and the order, click “Save” to return to the “Client Overview” page. The exercises selected will now be visible.

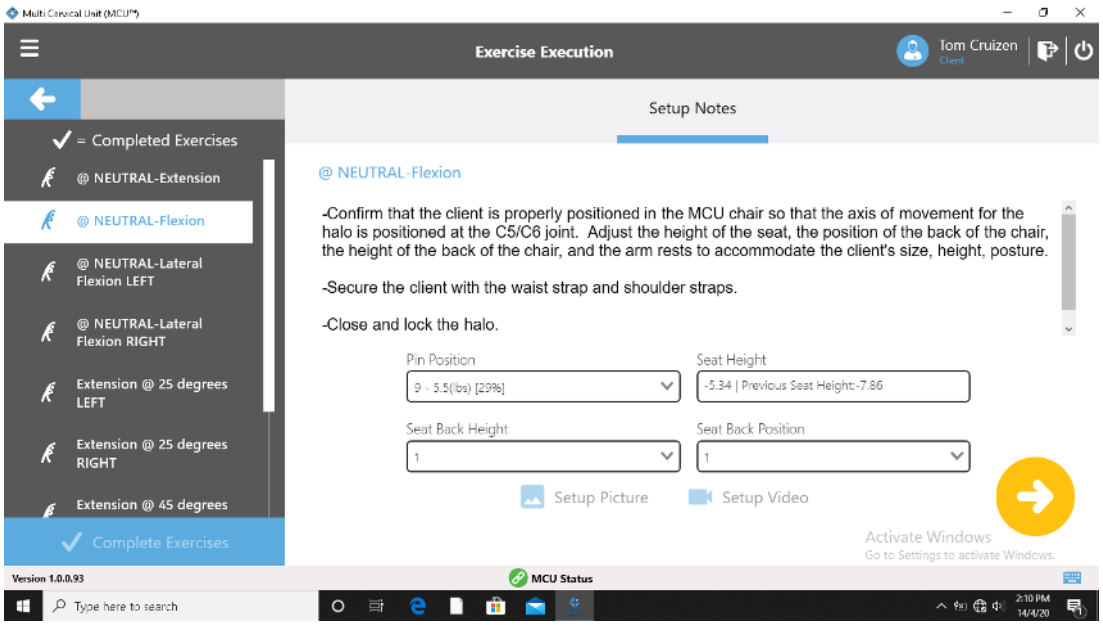
Clicking on the yellow proceed button will take you to the “Exercise Execution” page. (*Screenshot 5*)



Screenshot 5

II. Exercise Execution

On the exercise execution page, clicking on the exercise will display the setup information for that specific exercise. Here you will see the setup details for the MCU and halo. Also, you will see the recommended pin position, and a place to enter the seat back height and seat back position for future reference. Finally, the real time seat height position is visible. (*Screenshot 6*)



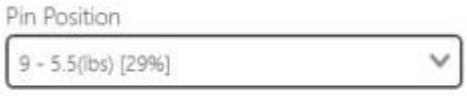
Screenshot 6

Recommended Pin Position

If the selected client has previously performed an isometric assessment for this movement, the Pin Position will be pre-selected to be 30% of that isometric max. This is a global setting that can be easily changed for the system or even for each client and will be discussed in greater detail later.

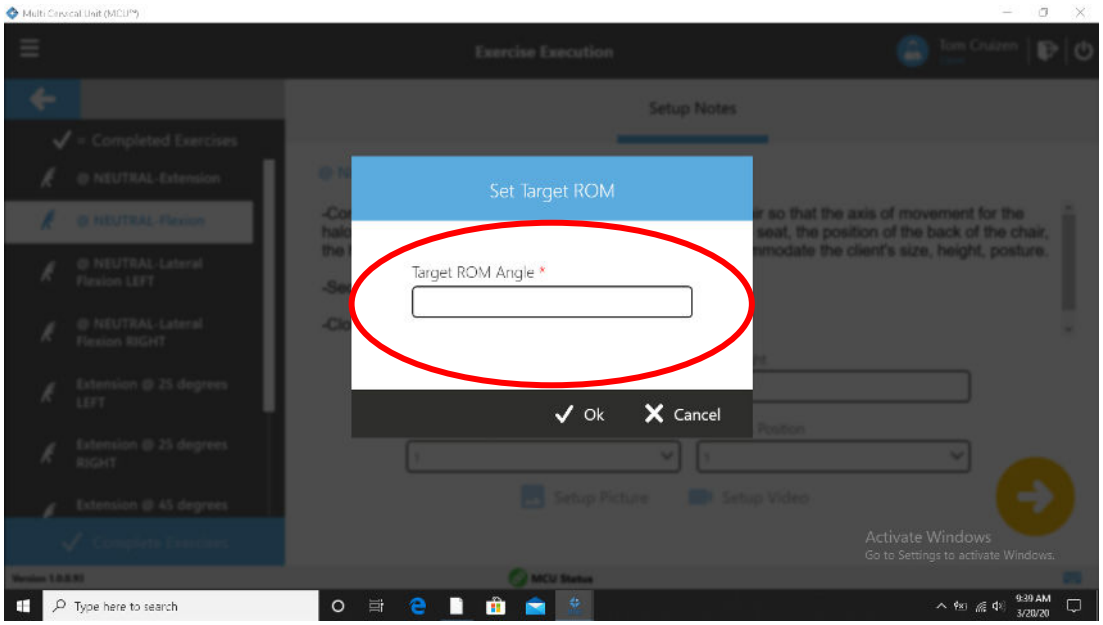
The displayed pin position under “Setup Notes” will show the recommended pin position, the weight used in that position, and the percentage of isometric max (*Screenshot 7*). Use the dropdown menu to choose a higher or lower pin position/weight for that specific exercise. –

Choose the yellow proceed arrow when ready to begin exercise.



Screenshot 7

After pressing the yellow proceed arrow, you will see the “Set Target ROM” screen (*Screenshot 8*). Here you will determine the target Range of Motion angle. This is the minimum angle where the client will receive credit for the repetition. Setting this angle will also provide a visual display and audible tone for this set angle. If a range of motion assessment was performed for this movement, there will be a minimum angle already recommended. If there is no associated data for this movement, the field will be blank. Enter the desired target angle and select “OK.”



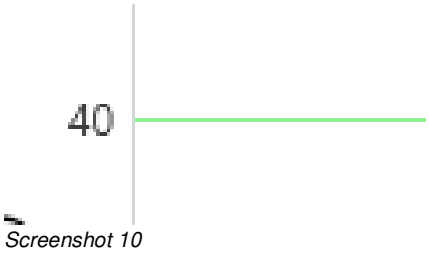
Screenshot 8

III. Perform Exercises

You are now in the Exercise Execution page (*Screenshot 9*). Here, you will see the title of the exercise. Also, you will see the exercise instructions on the right side of the screen. Confirm the client is properly set up prior to pressing the yellow proceed arrow on the bottom left of the screen. When pressing this arrow, the control module will give you an audible voice stating to "Begin exercise now."

Instruct the client to move smoothly thru range and to go until they hear the "*DING"* sound which reflects their achieving the targeted range of motion. This targeted angle is also visible with a horizontal green line (*Screenshot 9 & 10*).

Screenshot 9

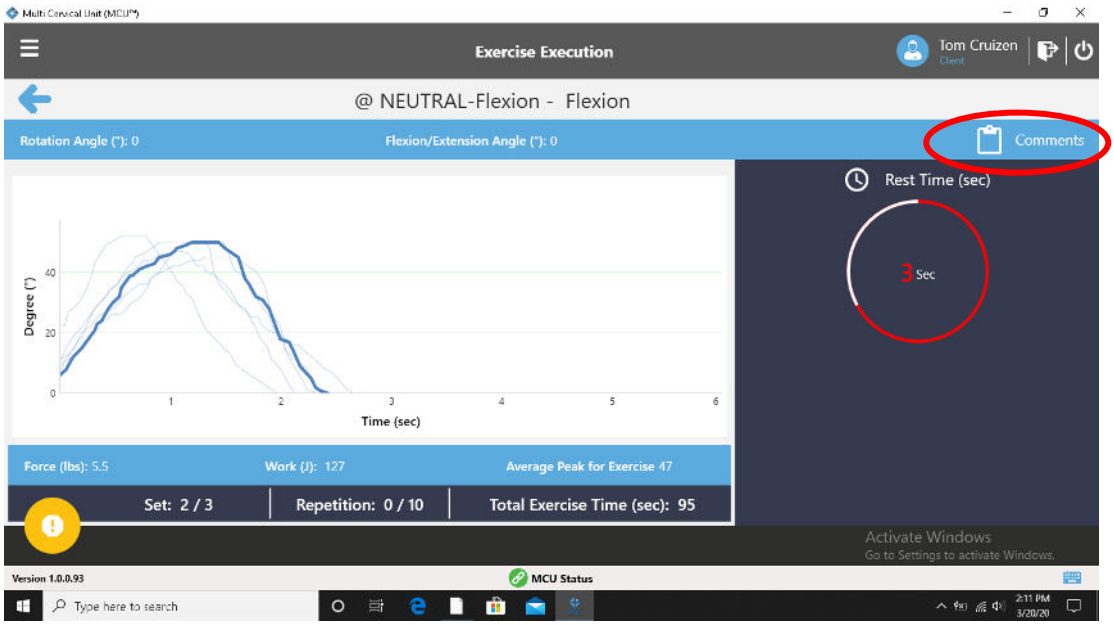


Screenshot 10

On the bottom of the exercise execution page you will find the Force, Work (Force X Distance), Average Peak for Exercise, the current set information, repetition information and the total time to perform the exercise.

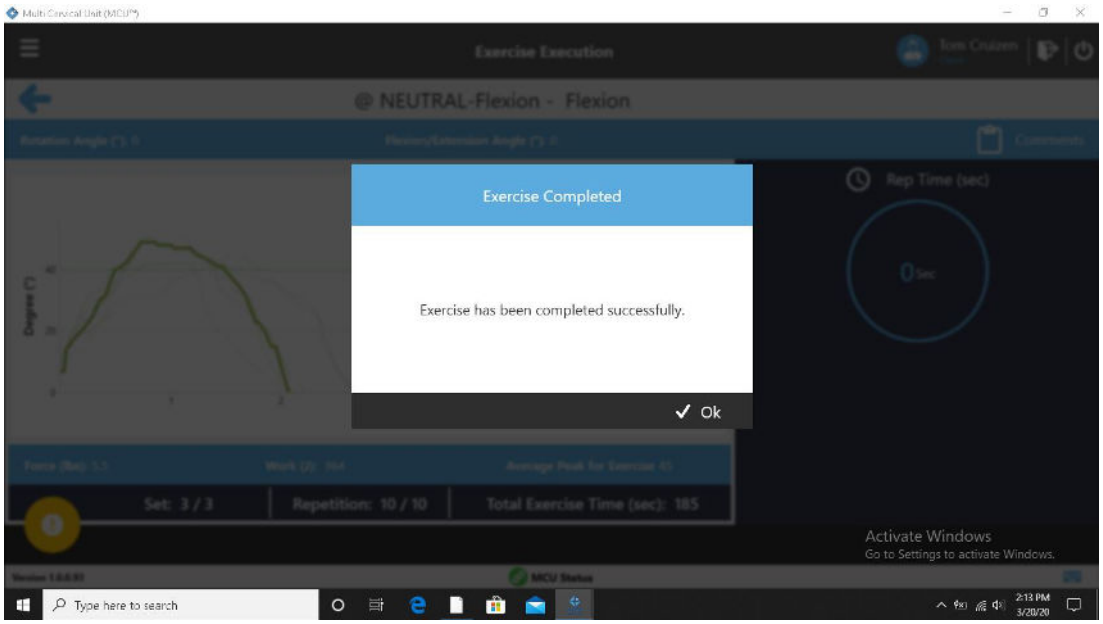
A client is ONLY given credit for those repetitions that achieve the targeted range of motion. There will be a "*Ding"* sound each time a person achieves the target. Also, be certain that the client goes back to the neutral or zero position prior to beginning the next repetition. Follow the repetition number on the screen and listen to the verbal prompts for when to rest prior to the next set.

At the end of the set, there will be a rest period. This time can be adjusted in the global exercise settings (you can also adjust sets and repetitions in default settings). During the rest period, you will see the count down on the right side of the screen. You can also review the consistency of the repetitions in the middle of the screen. (*Screenshot 11*)



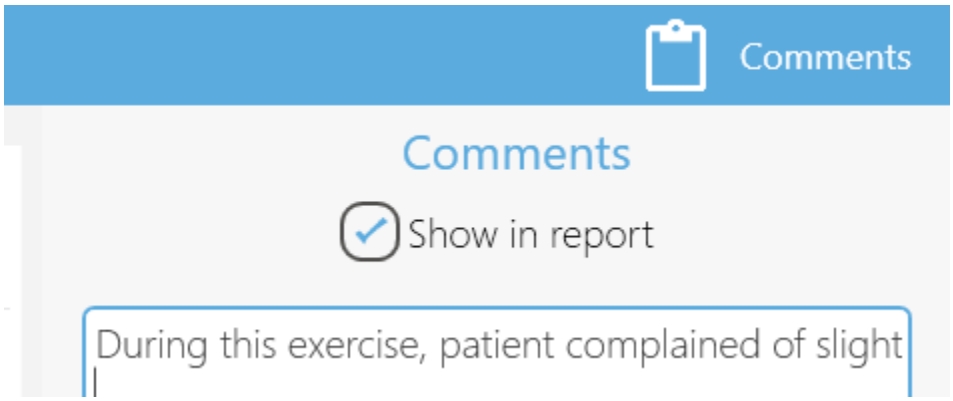
Screenshot 11

After the last set, a message will appear informing you that this exercise has been completed. When selecting "OK," (*Screenshot 12*) there will be a voice that says "Exercise Completed."



Screenshot 12

Before exiting the exercise, you have the ability to enter comments on that particular exercise. Select the "Comments" box (*Screenshot 11*). Enter the comment, if necessary, (*Screenshot 13*) and when done, click the comments icon again to hide the dialog box.

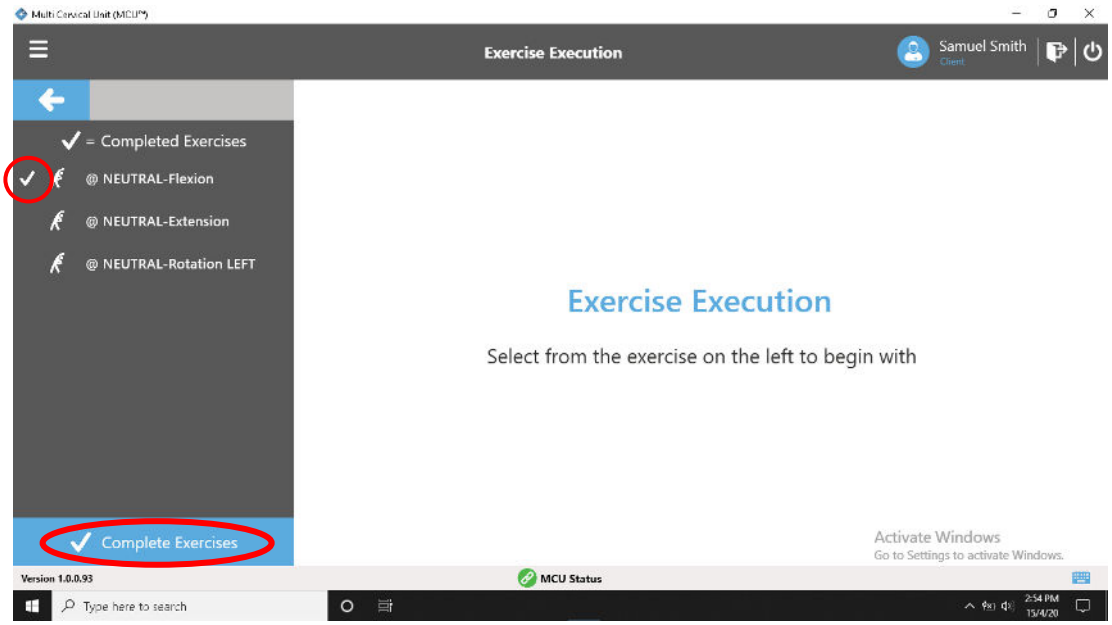


Screenshot 13

Selecting the Yellow Proceed Arrow will take you back to the "Exercise Execution" page. A check mark will now be placed next to the completed exercise(s) Select which exercise to do next and repeat the same process as above (*Screenshot 14*).

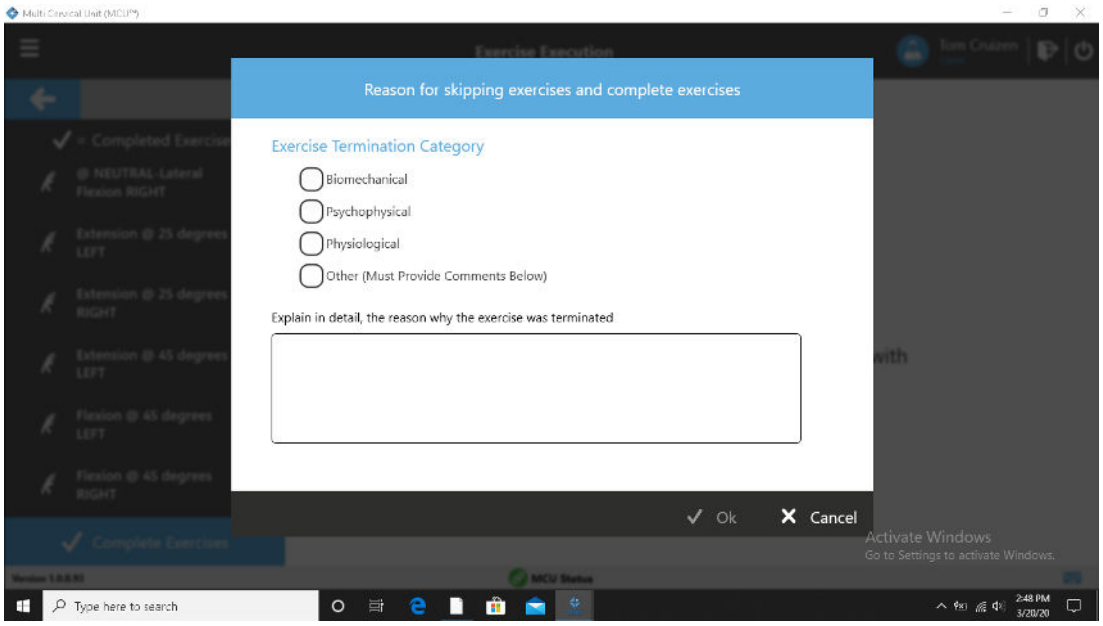
NOTE: At any point you can terminate the exercises by selecting the icon on the bottom left portion of the exercise screen. Determine whether or not you would like to save the data before proceeding. You will leave the exercise screen and be returned to the "Exercise Execution" page.

Now, you are back at the list of exercises. If you are finished with all the exercises for this session, choose the "Completed Exercises" option (*Screenshot 14*).



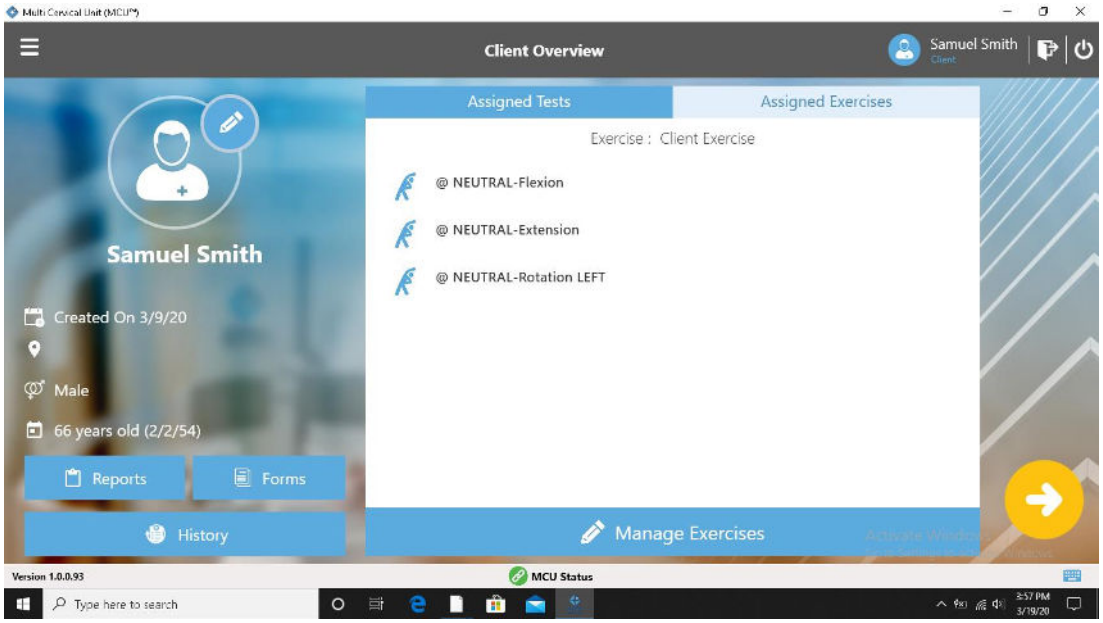
Screenshot 14

If you have not completed all the exercises on the list, you will be asked to provide a reason for skipping those exercises (*Screenshot 15*). Choose the reason that best fits or the other option if no additional explanation is needed.



Screenshot 15

You have now completed the exercises with this client and you are back at the Client Overview page. You can choose to generate a report or view other information related to that client (*Screenshot 16*).



Screenshot 16

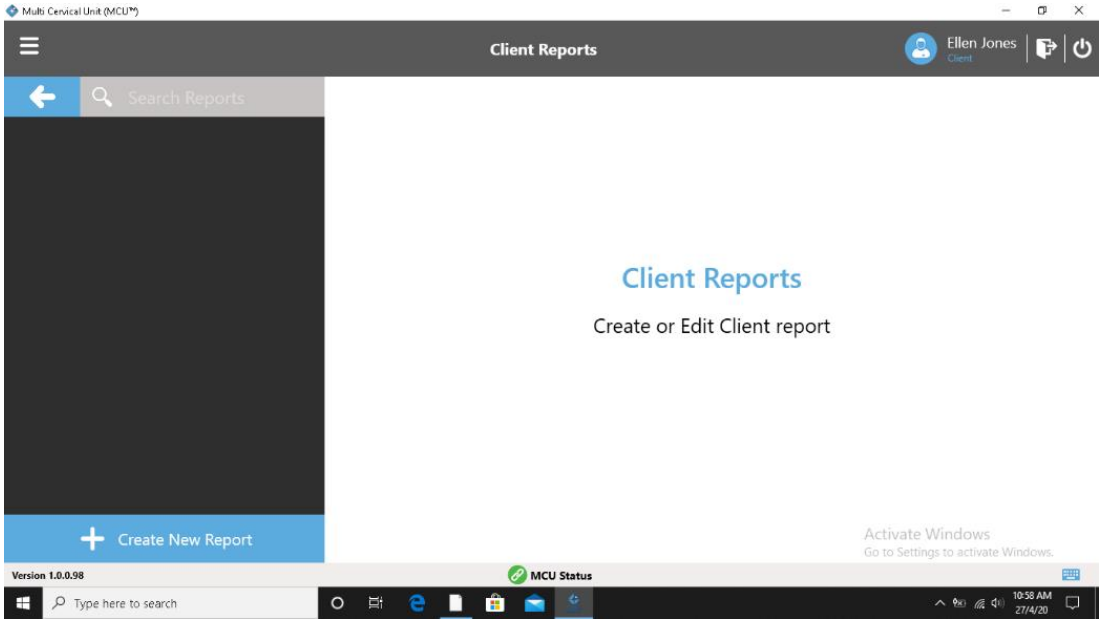
IV. Exercise Reports

There are two types of reports available for exercises. A summary report is available to provide details of each exercise(s) for a given day. You also have the ability to generate a progress report of exercise(s) that covers the duration of treatment.

Summary Report (Session Report)

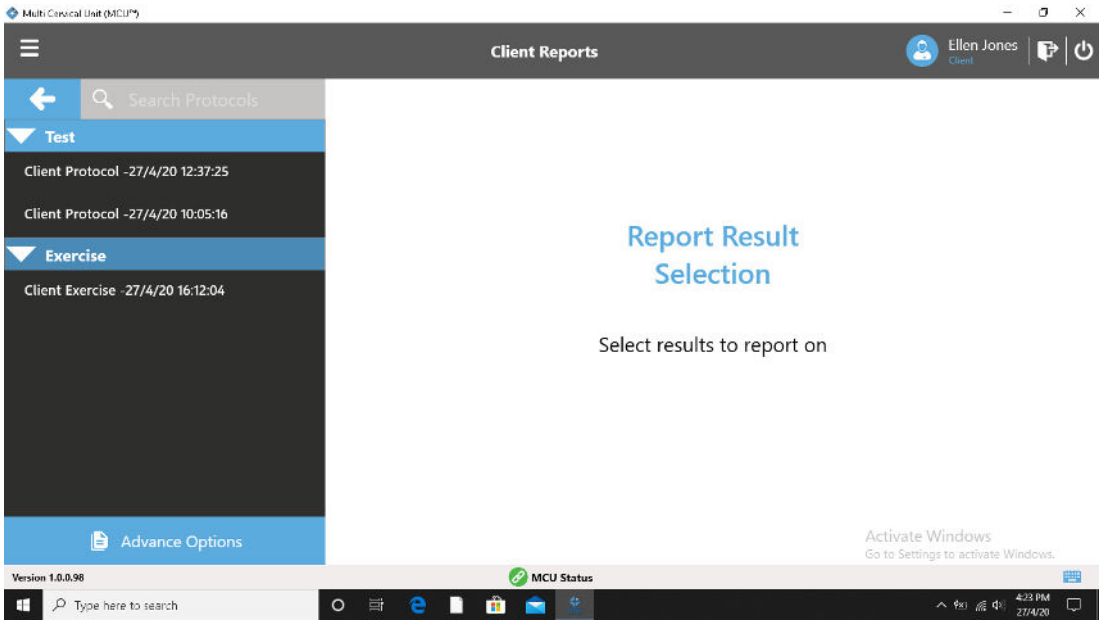
From the client overview page, select the “Assigned Exercises Tab” to view the exercises for that client.

Select “Create New Report” from the Client Report page (*Screenshot 17*).



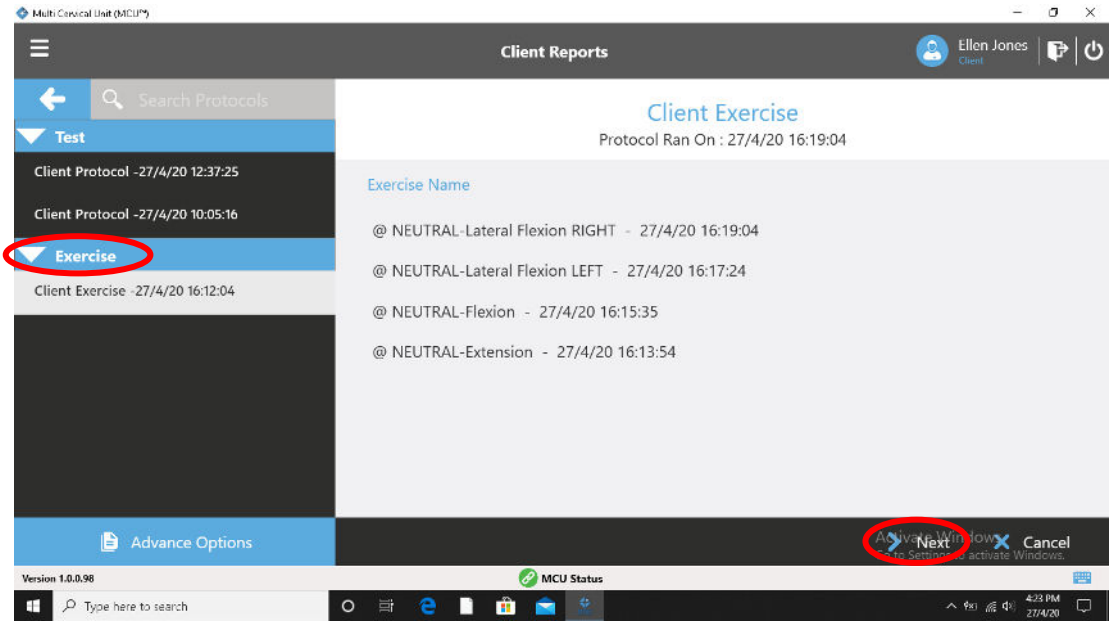
Screenshot 17

You will see “Test” and “Exercise” drop down menus on the left side of the screen. Select the “Exercise Option” and highlight that date of completed exercises (*Screenshot 18*).



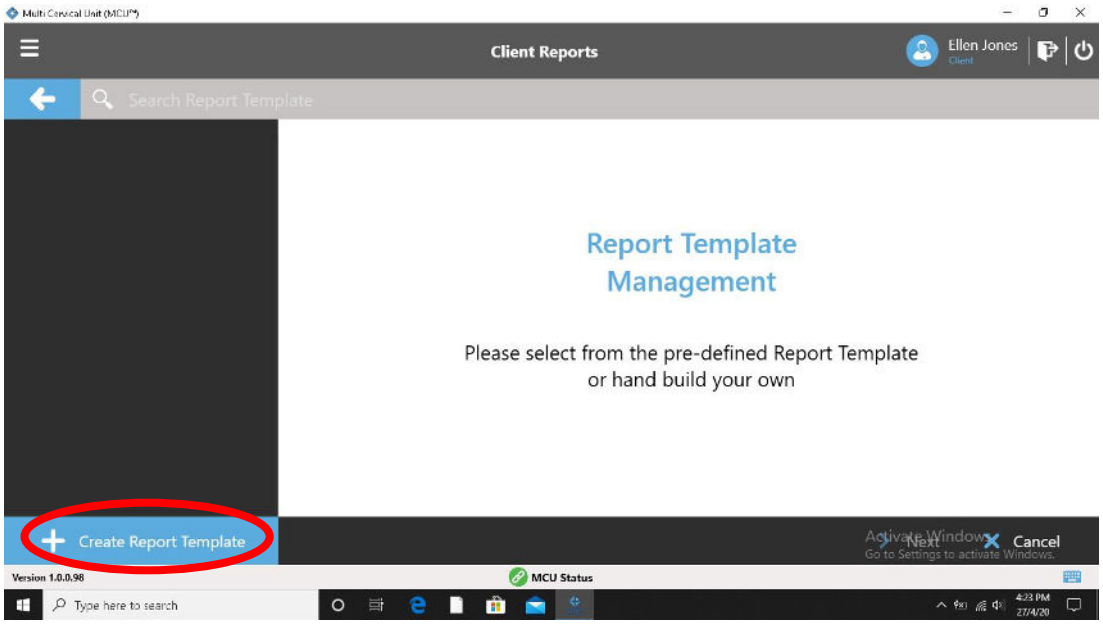
Screenshot 18

The list of exercises with saved data are visible after selecting Exercise. Select “Next” (S*creenshot 19*).



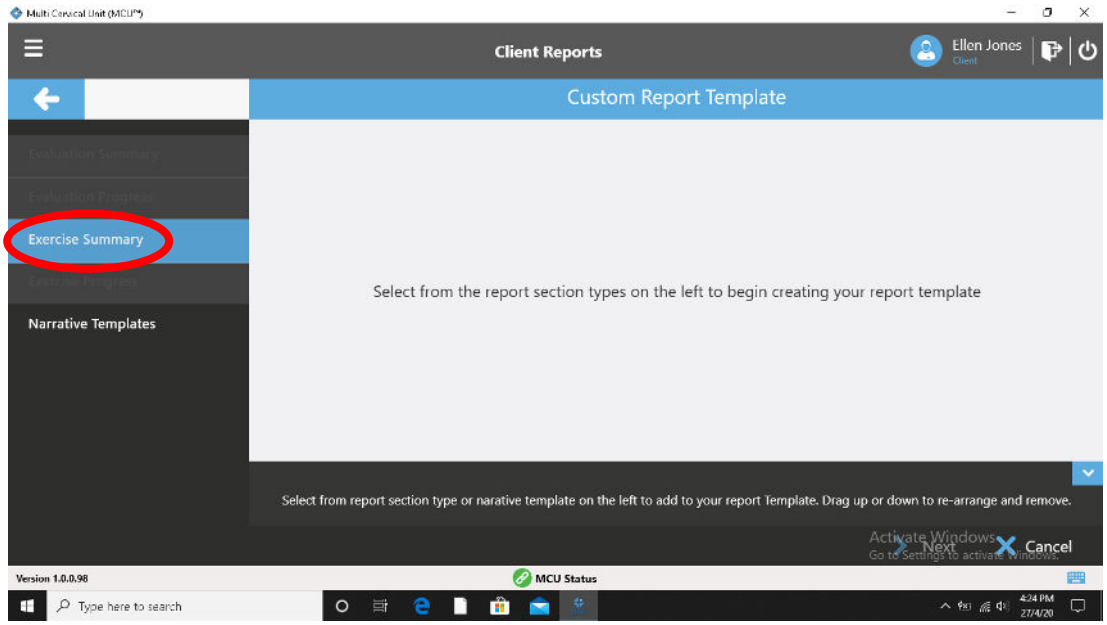
Screenshot 19

Select the “Create Report Template” option (*Screenshot 20*).



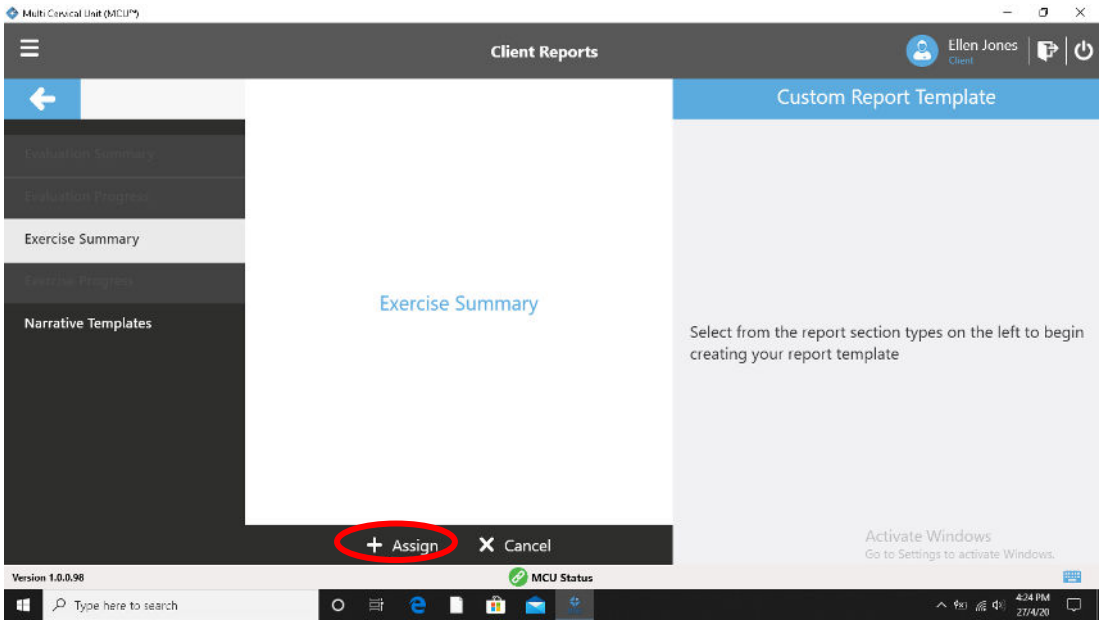
Screenshot 20

Select “Exercise Summary” (*Screenshot 21*).



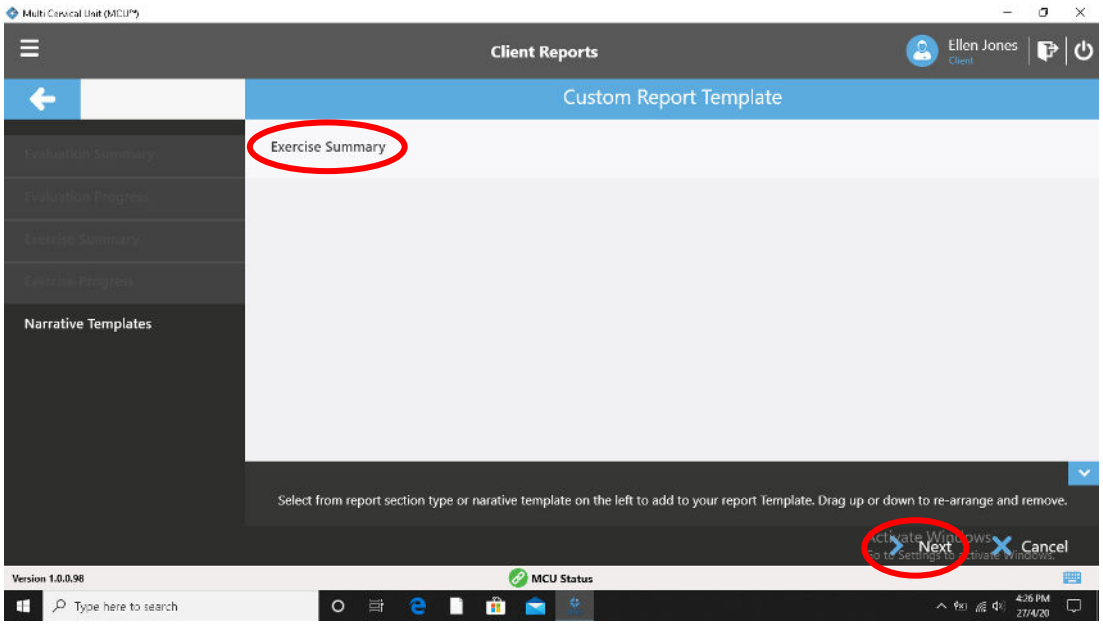
Screenshot 21

Select “Assign” (*Screenshot 22*).



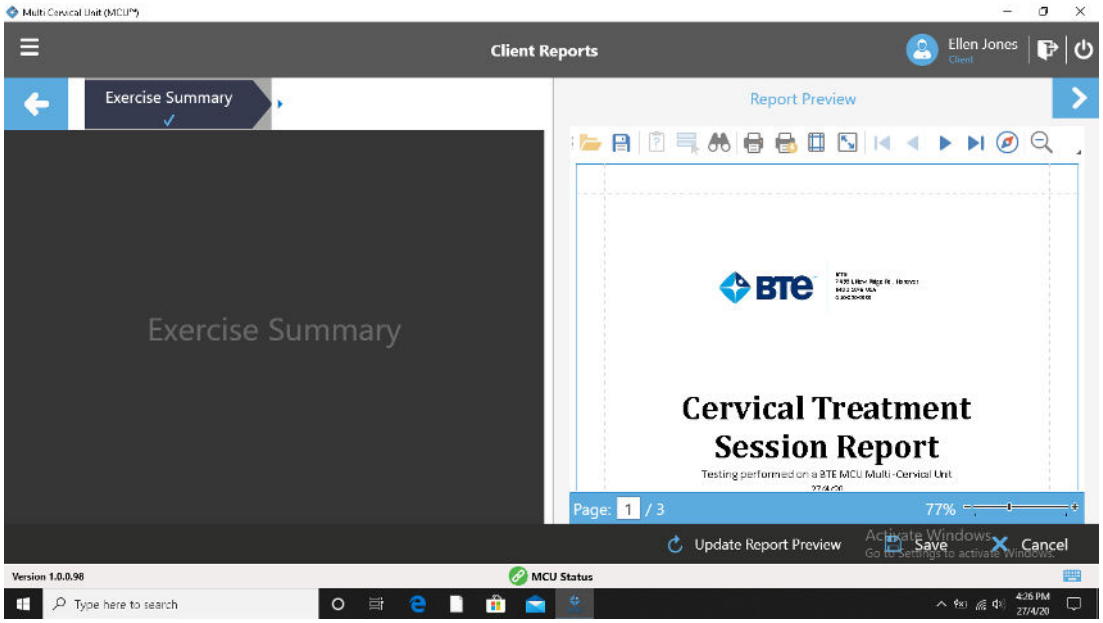
Screenshot 22

Select “Exercise Summary” and then “Next” from the bottom right (*Screenshot 23*).



Screenshot 23

You have now generated a Cervical Treatment Session Report (*Screenshot 24*).



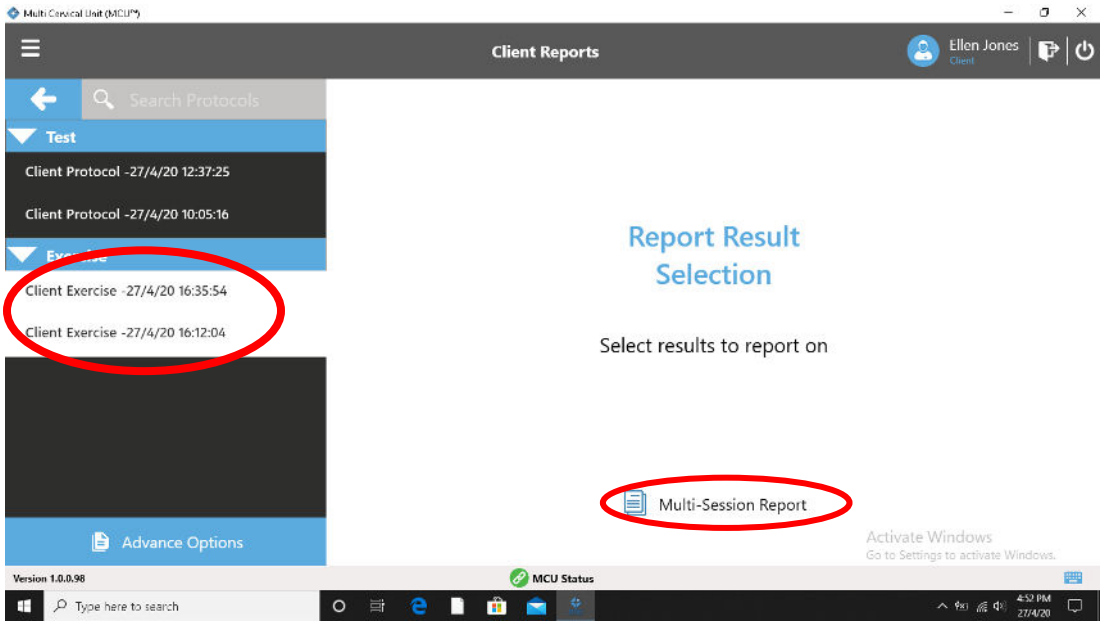
Screenshot 24

Print the session report or save it for future viewing.

Exercise Progress Report

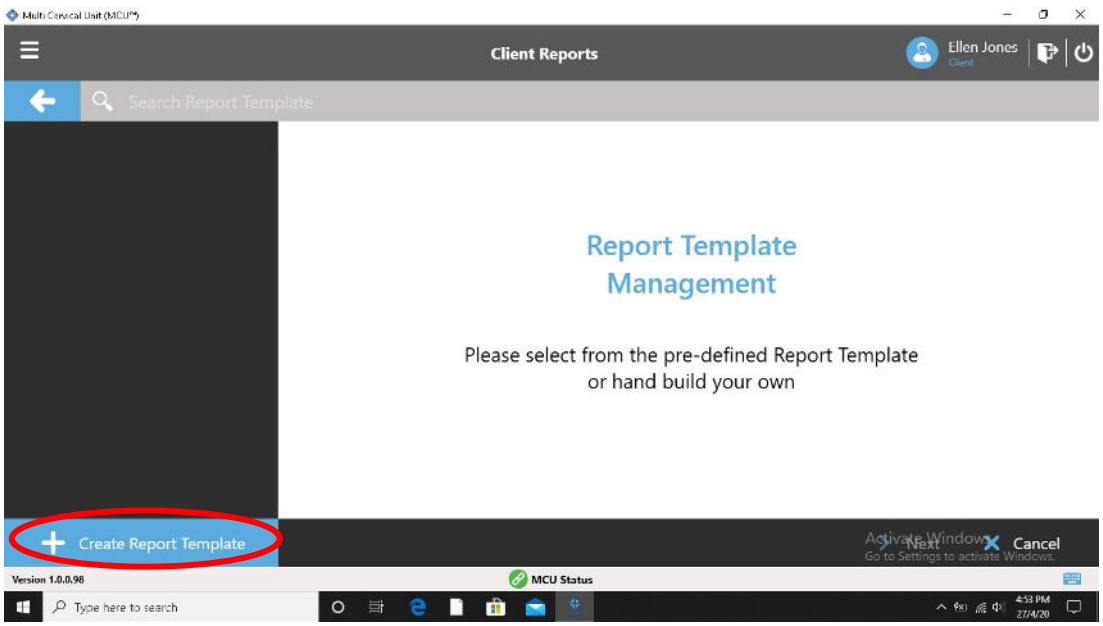
Begin at the Client Management Page and choose “Reports” and Create New Report as you did for a session report (*Screenshot 25*).

When multiple exercise days are visible, you can generate a Progress Report. Select all exercise dates and sessions that you want displayed in the report (*Screenshot 25*). Select “Multi Session Report” at this time.



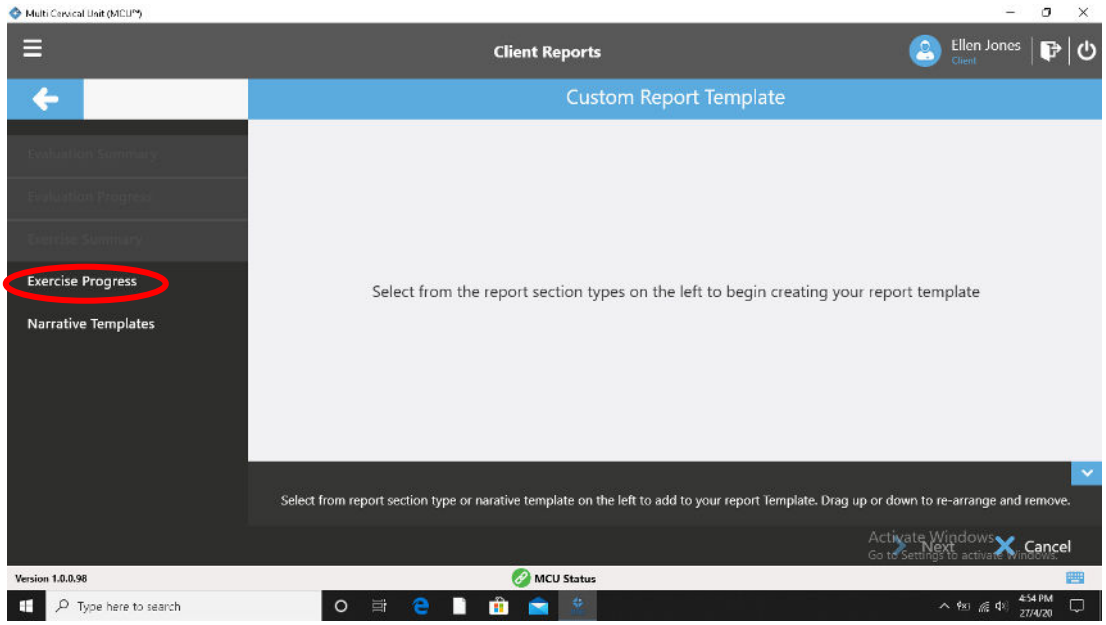
Screenshot 25

Select “Create Report Template” (*Screenshot 26*) from the bottom left.



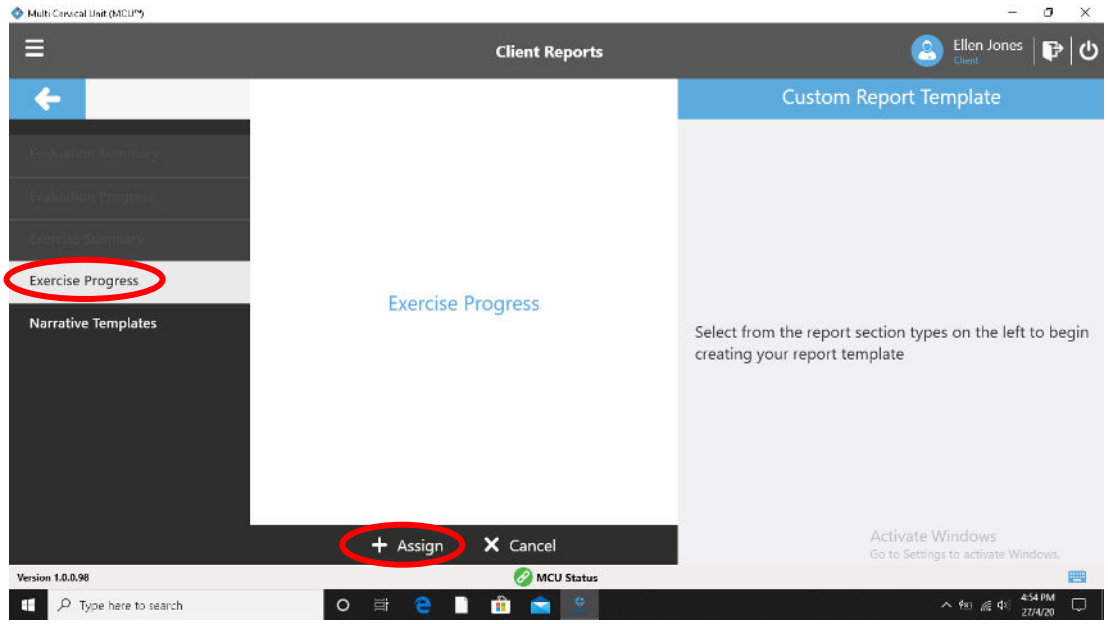
Screenshot 26

Choose the “Exercise Progress” option (*Screenshot 27*).



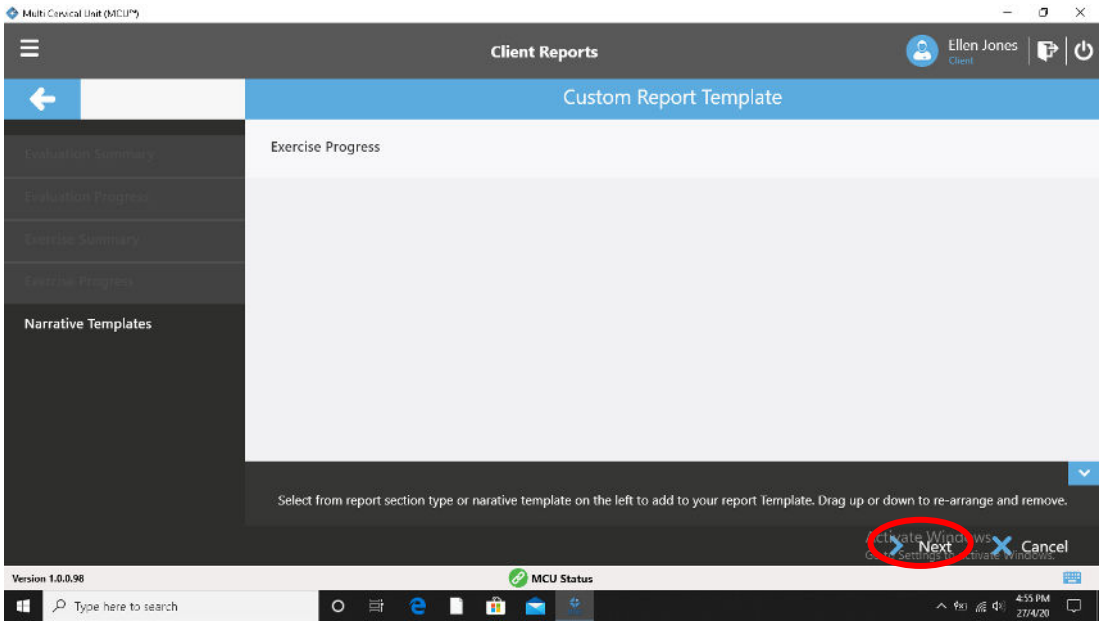
Screenshot 27

Choose “Assign” from the middle of the page (*Screenshot 28*).



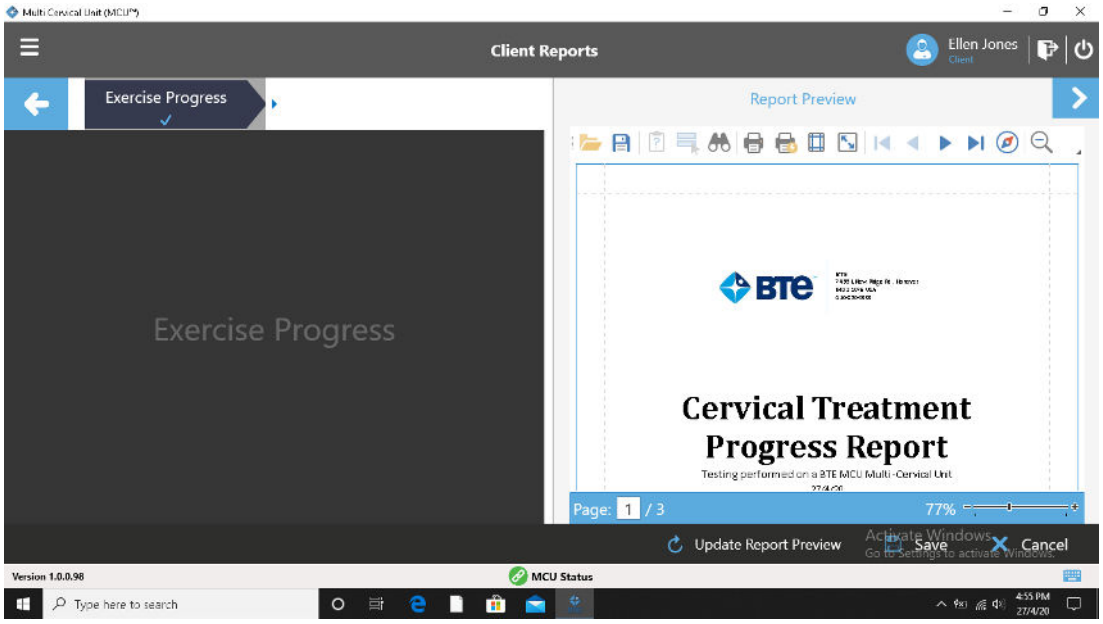
Screenshot 28

Select “Exercise Progress” and “Next” (Screenshot 29).



Screenshot 29

You have now generated a “Cervical Treatment Progress Report” where you can view progress between each exercise from the first treatment to the most recent treatment (*Screenshot 30*).

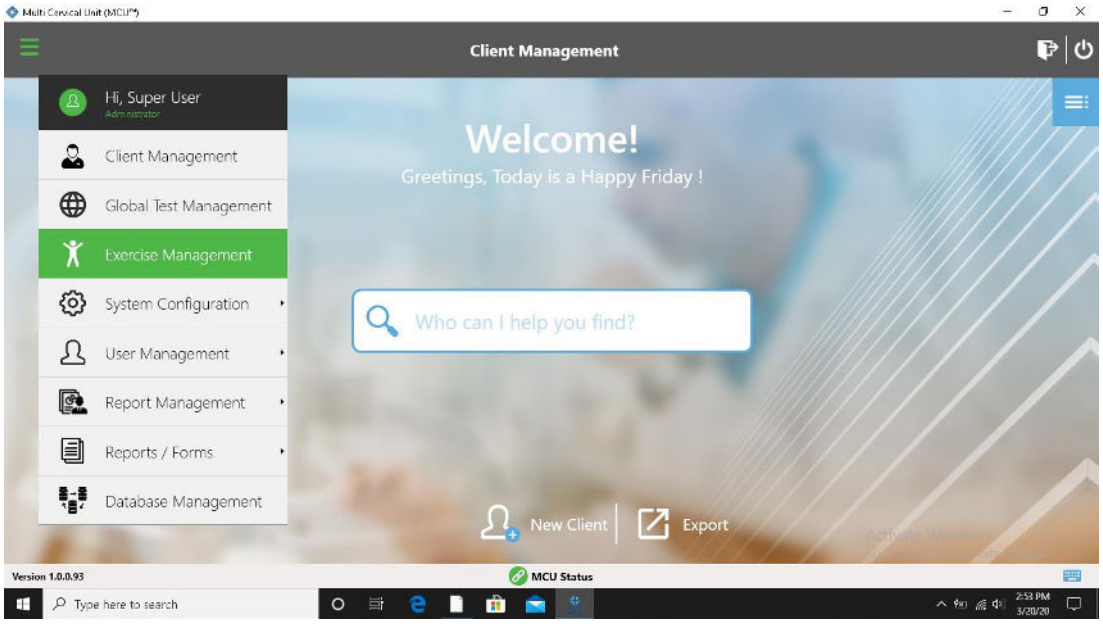


Screenshot 30

V. Change Default Exercise Settings

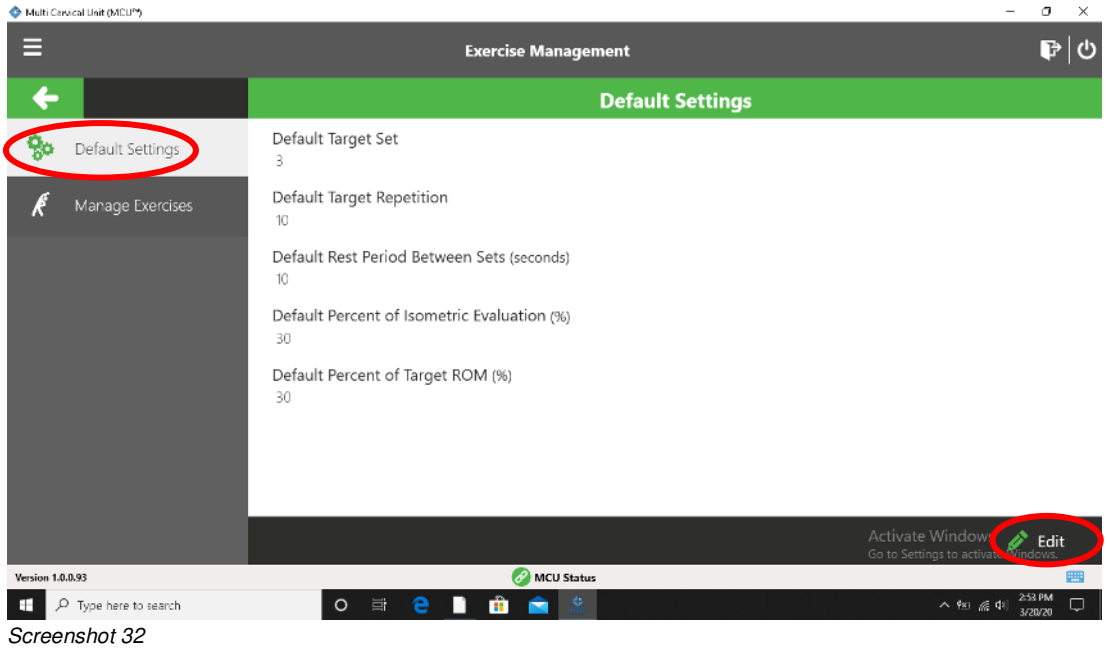
Within the exercise execution, there are default settings for sets, repetitions, % of isometric assessment, and % of ROM assessment. The number of sets and reps are global settings that are the same for every client. This is easily changeable.

From the upper left Hamburger Menu, choose the “Exercise Management” option (Screenshot 31).



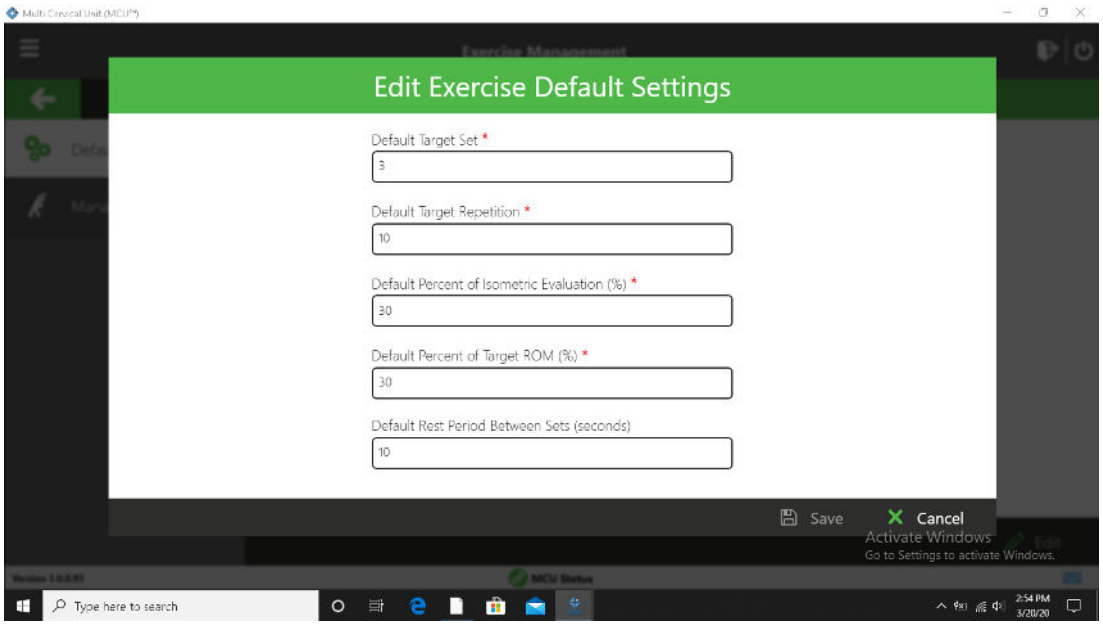
Screenshot 31

On the upper left hand portion of the screen, choose the “Default Settings” option where you can see the current global settings (*Screenshot 32*). Choose “Edit” from the bottom right to change these default settings.



Screenshot 32

Edit the Exercise Default Settings (*Screenshot 33*) and choose “Save” when finished. You have now changed the global exercise settings.

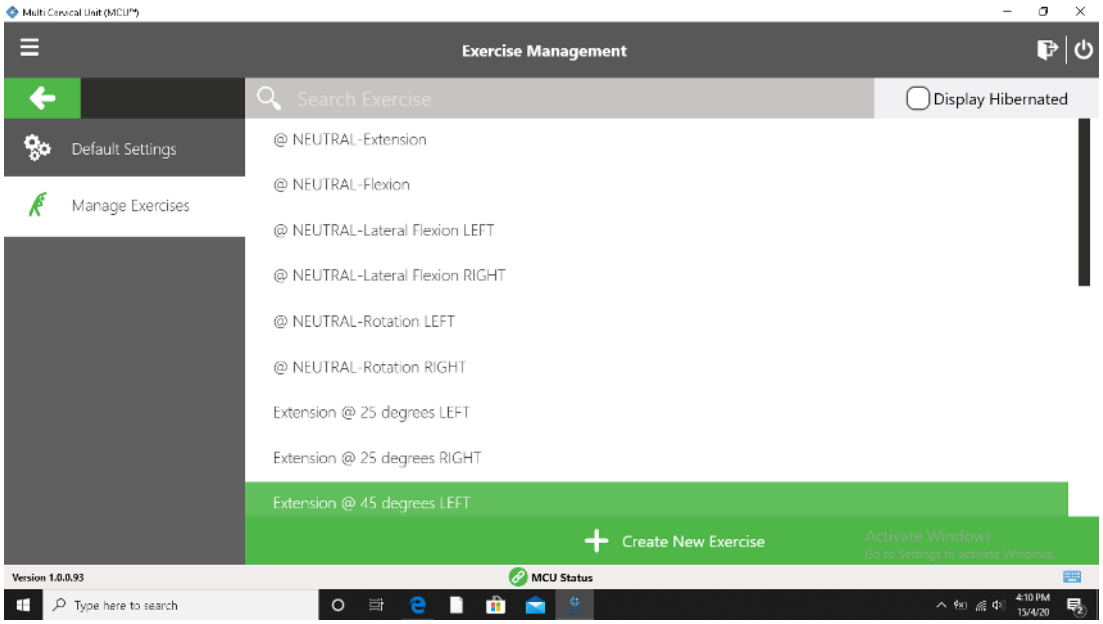


Screenshot 33

VI. Manage Exercises

You have the ability to add new exercises or to edit the setup information for existing exercises. On the main Client Management page Hamburger Menu, choose the “Exercise Management” option (Screenshot 31).

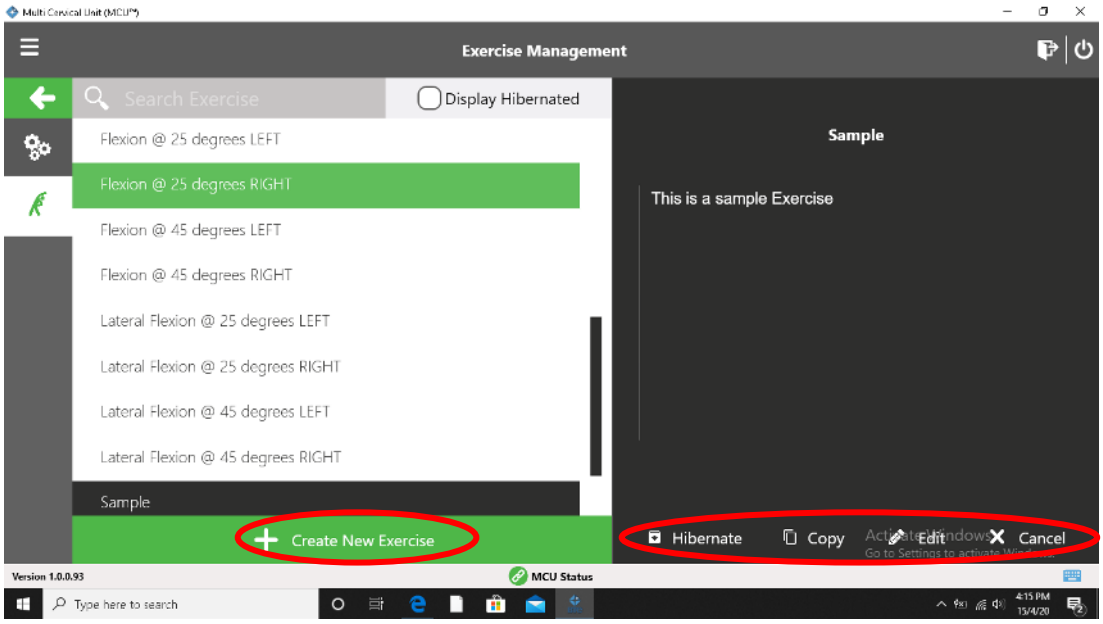
Select “Manage Exercises” from the upper left hand portion of the screen (Screenshot 34). In the center, you will see the current list of exercises sorted by the halo position and the movement.



Screenshot 34

If you click on a specific exercise, you can choose to Hibernate, Copy, or Edit each exercise.

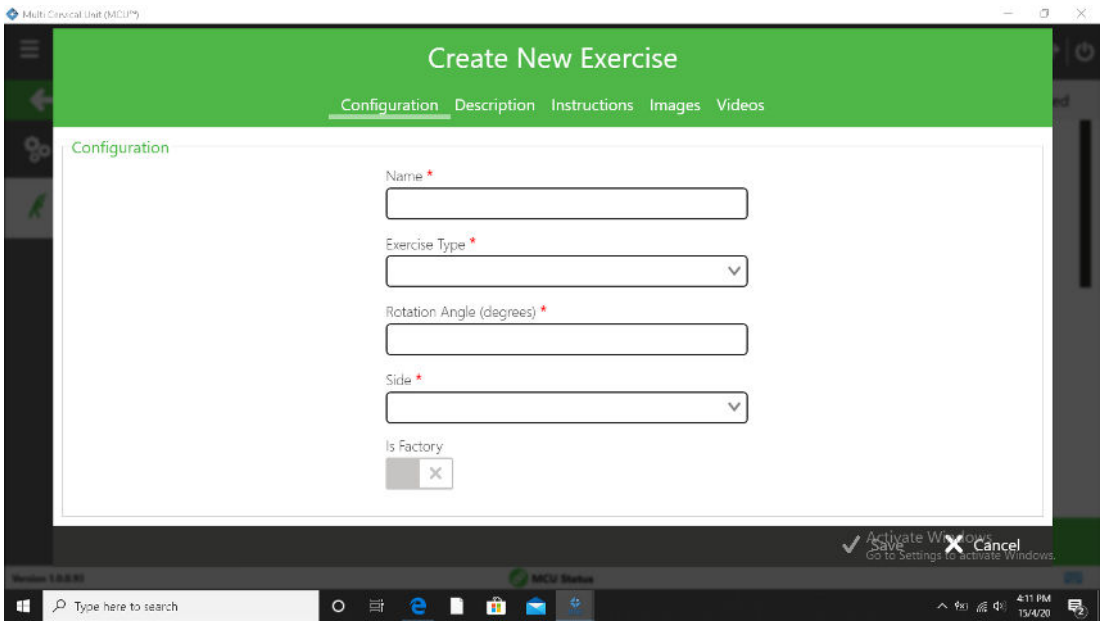
-To view the description and setup information, choose edit (*Screenshot 35*). To Create a New Exercise, choose that option at the bottom.



Screenshot 35

Creating a New Exercise

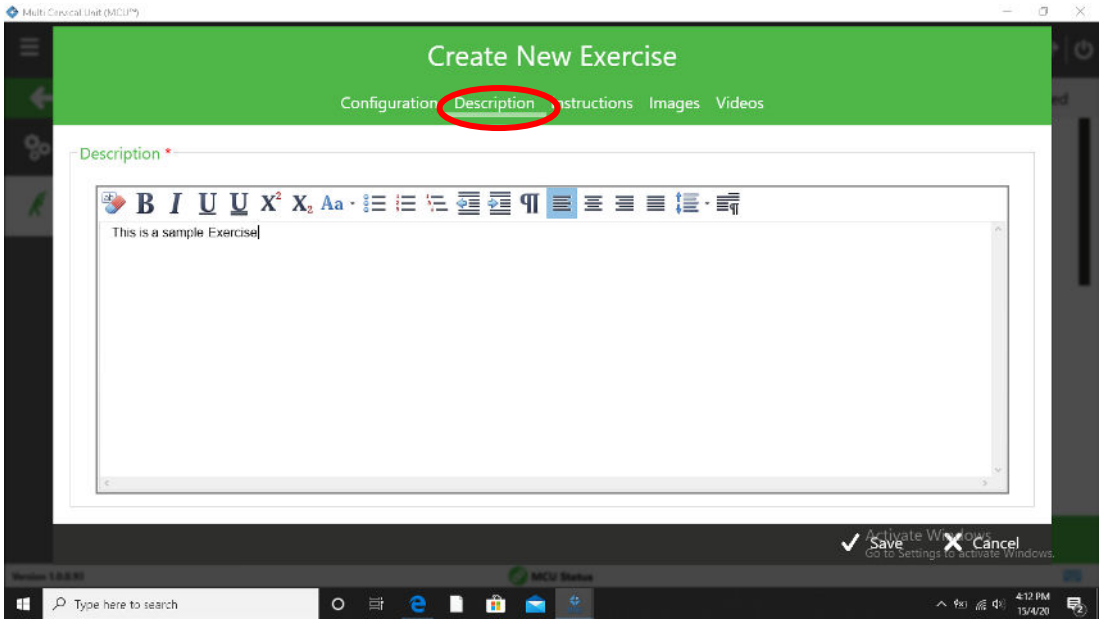
From the Exercise Management page, select “Create New Exercise” (Screenshot 35). You will be taken to the configuration page where you will enter the name of the exercise, exercise type (Flexion, Extension, Lateral Flexion, Rotation), Rotation Angle (degree of the halo), and the Side in which the halo is rotated (Screenshot 36).



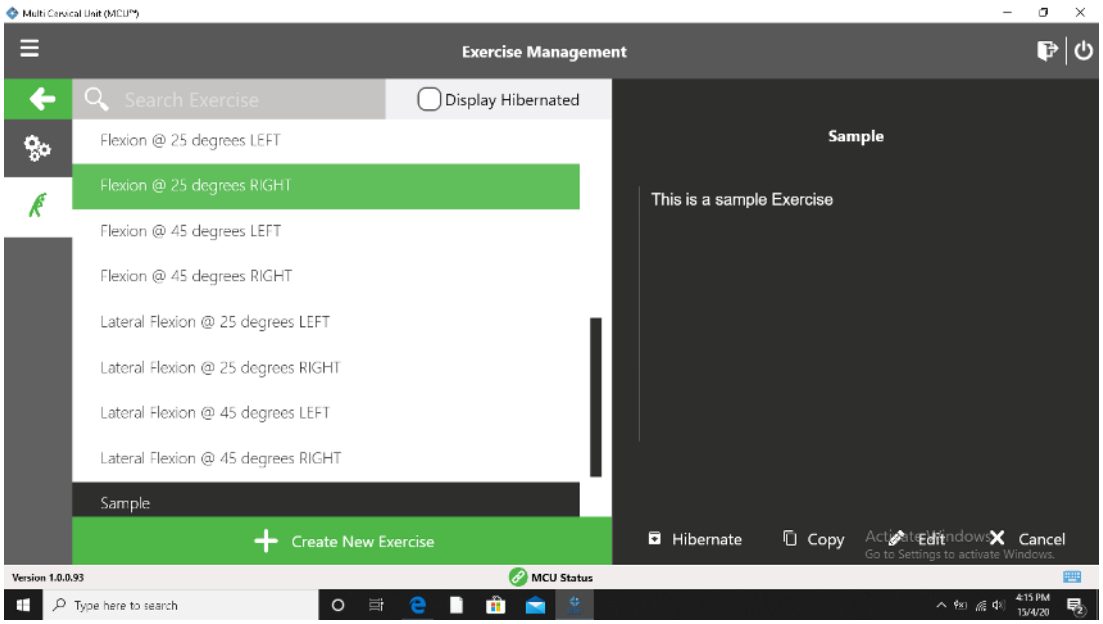
Screenshot 36

Next, describe the exercise. This will be visible on the Exercise Management page (*Screenshot 37*). Enter the setup instructions for the exercise that will be visible.

Select “Save” and you have now completed creating a new exercise (*Screenshot 38*) which can be assigned to any client moving forward.



Screenshot 37



Screenshot 38

You have now created a new exercise that can be assigned to any client.

Section 8 - Global Management

I. Global Settings (remaining items) 149

A. Backup Reminder 149
B. LDAP Settings 150
C. Threshold 151
D. HL7 Protocol 152
E. System 153
F. Comparative Data 153
1. Create NEW comparative data 153
2. EDIT an item in an existing list 156
3. DELETE an item in an existing list 156

II. Reports / Forms 157

III. Database Management 157

A. Backup Database 157
B. Restore Database 158
C. Change Database 159
D. Export Data 159

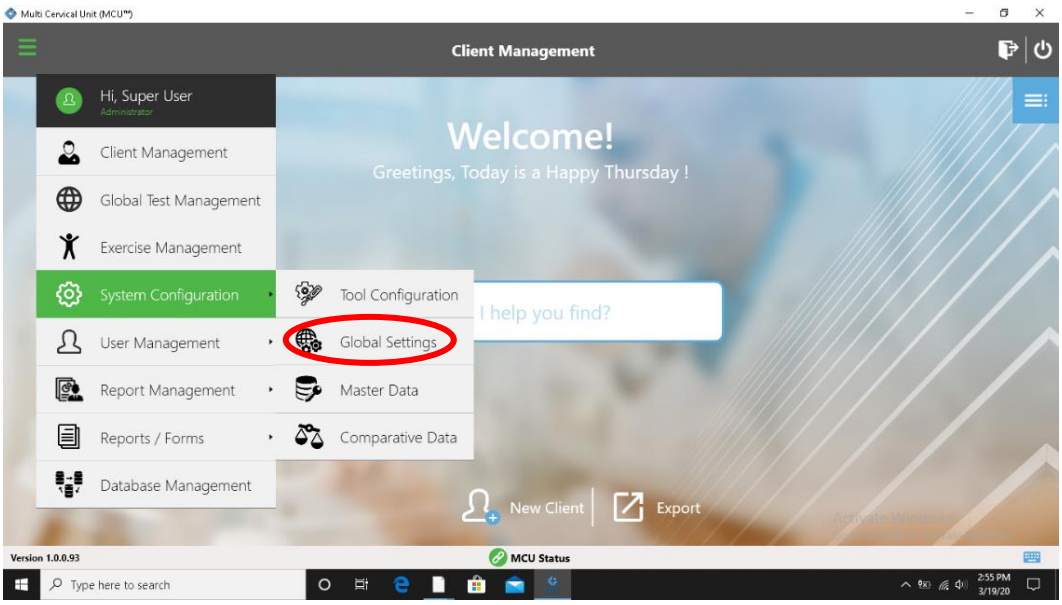
I. Global Settings (remaining items)

A. Backup Reminder

The Backup Reminder is a feature that prompts a user to back up the database to a USB drive on a regularly scheduled basis. BTE recommends backup of the database at the end of each day's use.

To set that schedule, do the following:

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings (*Screenshot 1*).

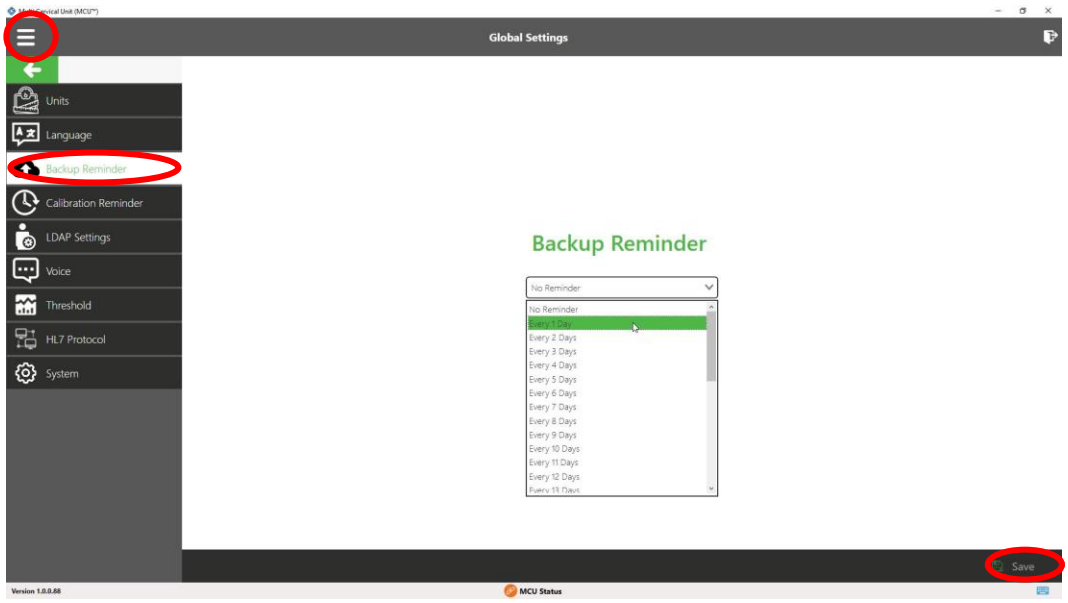


Screenshot 1

Step 2. Select Backup Reminder (*Screenshot 2*).

Step 3. Open the dropdown list and select a timeframe from the list. (*Screenshot 2*).

Step 4. Click the Save button.



Screenshot 2

B. LDAP Settings

Lightweight Directory Access Portal or LDAP is a client-server protocol for accessing directory services. It runs over TCP/IO or other connection-oriented transfer services. LDAP is used for user authentication and authorization. It also stores your credentials in a network security system and retrieves it with your password, giving you access to the services. To enable the use of LDAP for login, proceed as defined below (*Screenshot 3*).

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings.

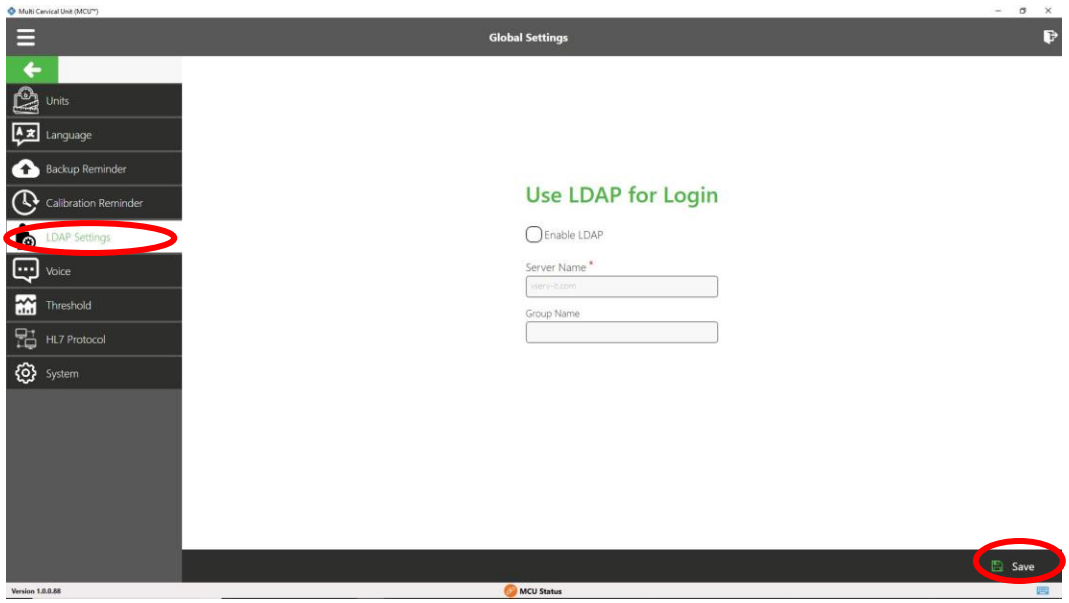
Step 2. Select LDAP Settings.

Step 3. Click in box next to Enable LDAP.

Step 4. Enter Server Name

Step 5. Enter Group Name

Step 6. Review the information entered and then click the SAVE button.



Screenshot 3

C. Threshold

This Threshold setting of degrees is specific to exercise using the weight stack. The number of degrees set here defines deviation arc of motion while performing repetitions of each exercise. To define the threshold, address these steps: (*Screenshot* 4)

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings.

Step 2. Select Threshold.

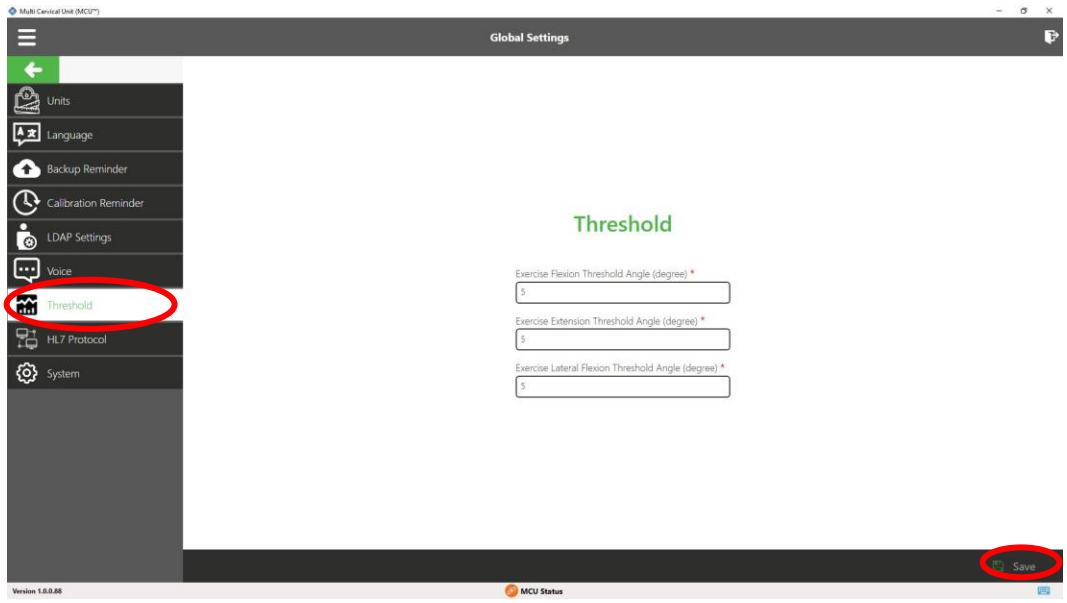
Step 3. A default value of 5 degrees is suggested for each angle, but a different value may be entered for the 3 movements.

Exercise Flexion Threshold Angle (degrees)*

Exercise Extension Threshold Angle (degrees)*

Exercise Lateral Flexion Threshold Angle (degrees)*

Step 4. Review the information entered, the click the Save button.



Screenshot 4

D. HL7 Protocol

Health Level Seven or HL7 refers to a set of international standards, formats, and definitions for exchanging and developing electronic health records (EHRs). To enable HL7 within the MCU software, follow these steps: Note that items with asterisk are mandatory (*Screenshot* 5)

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings.

Step 2. Select HL7 Protocol.

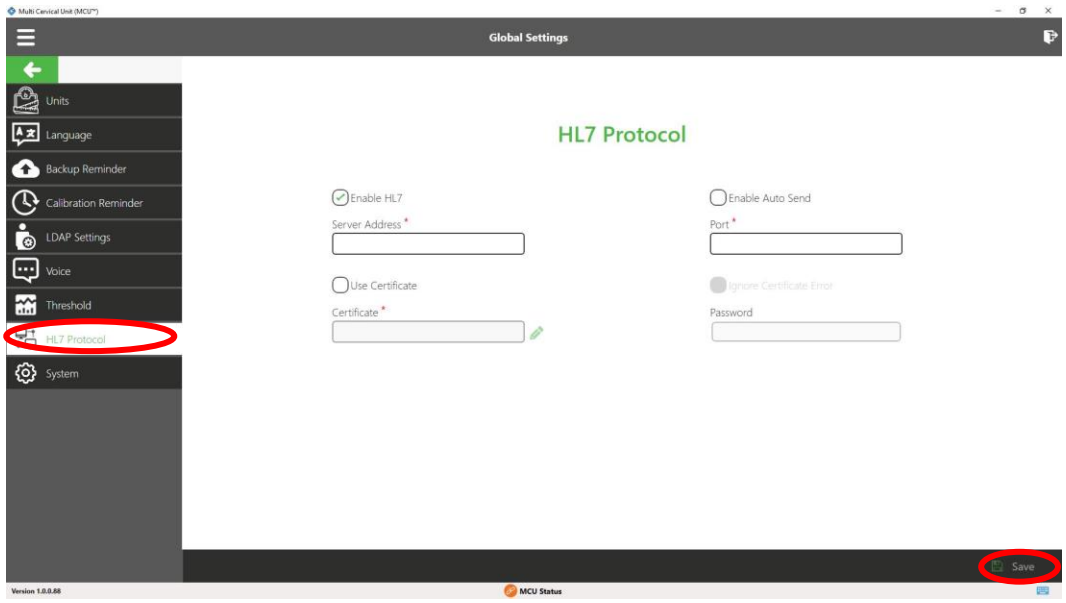
Step 3. Click the button next to Enable HL7 and enter your Server Address* in the text field below.

Step 4. Click the button next to Enable Auto Send (optional). If checked, you must then enter the Port*.

Step 5. Click the button next to Use Certificate (optional). If checked, click the Edit icon next to the Certificate* text field. This allows you to search and select the folder and drive. Click OK after making selection on each page of File Explorer.

Step 6. Click the button next to Ignore Certification Error. Enter the Password.

Step 7. Review the information and then click the Save button.



Screenshot 5

E. System

System is only chosen when directed so by BTE personnel. as it is used for diagnostic purposes only. **Do not change any values on this screen**.

F. Comparative Data

Comparative Data Management allows the user to create, edit, copy, and deactivate comparative or normative data associated with range of motion and isometric strength testing. Already included in the MCU software are data for Range of Motion and Strength:

1. Create NEW comparative data

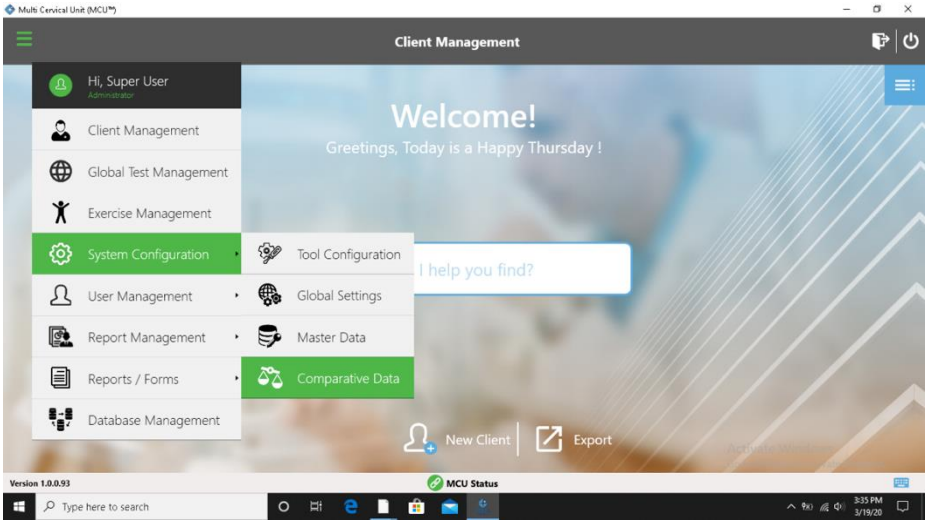
To add comparative/normative data from a published research article or other source, follow these instructions:

Step 1. From the Hamburger Menu, select System Configuration.

Step 2. Choose Comparative Data (*Screenshot 6*).

Step 3. Select either Range of Motion or Strength.

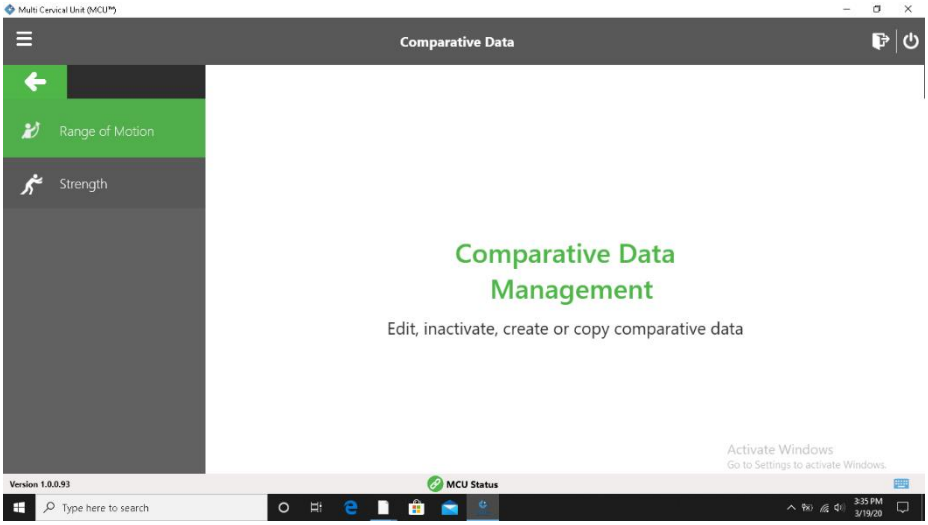
Step 4. Click on the Create New Comparative Data button.



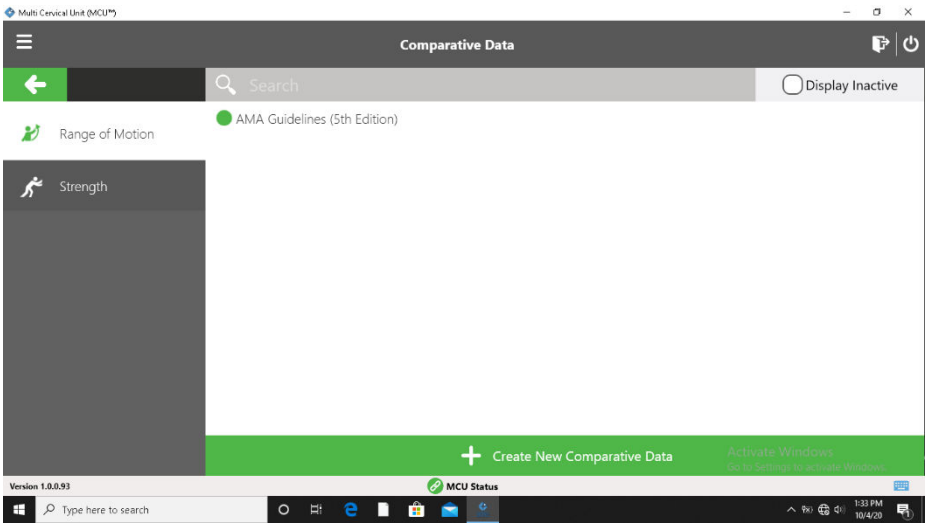
Screenshot 6

If Range of Motion is chosen (Screenshot 7-9)

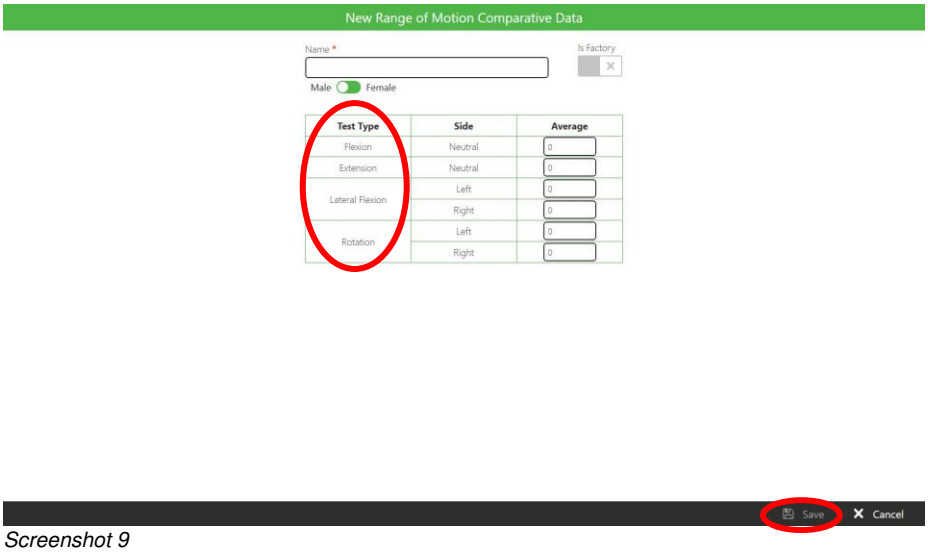
- enter the reference information (article, book, etc.)
- move toggle switch to male or female
- enter the average ROM data into the table provided
- review the data and then click Save button



Screenshot 7



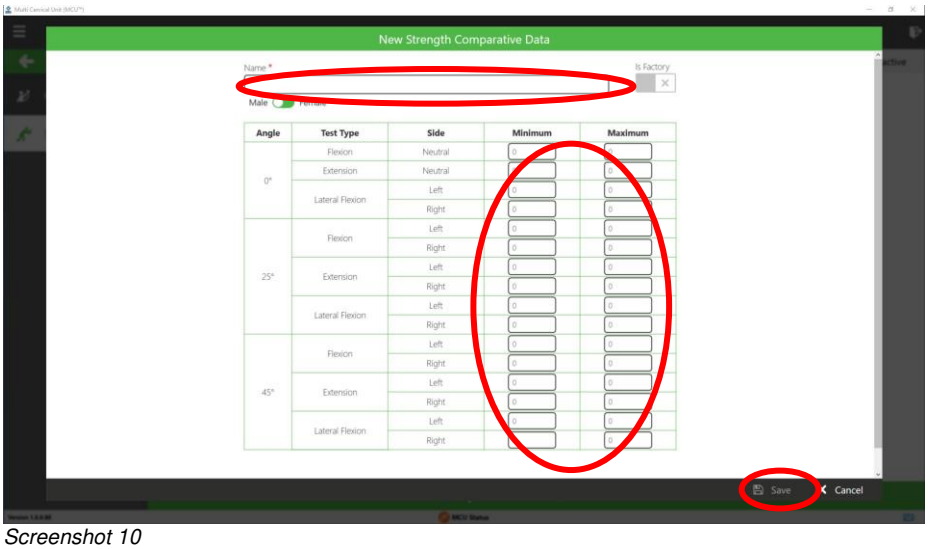
Screenshot 8



Screenshot 9

If Strength is chosen

- follow the same steps for range of motion, but choose strength instead.
- enter the reference information (article, book, etc.)
- move toggle switch to male or female
- enter the average isometric strength data into the table provided (Screenshot 10)
- review the data and then click Save button



Screenshot 10

2. EDIT an item in an existing list

Step 1. From the Hamburger Menu, select System Configuration.

Step 2. Then choose Comparative Data.

Step 3. Choose either Range of Motion or Strength.

Step 4. Click on the Edit icon at the bottom of the window.

Step 5. Select the item to be edited.

Step 6. Review change(s) and then click Save. Discard will remove the item (Screenshot 11).

3. DELETE an item in an existing list

Step 1. From the Hamburger Menu, select System Configuration.

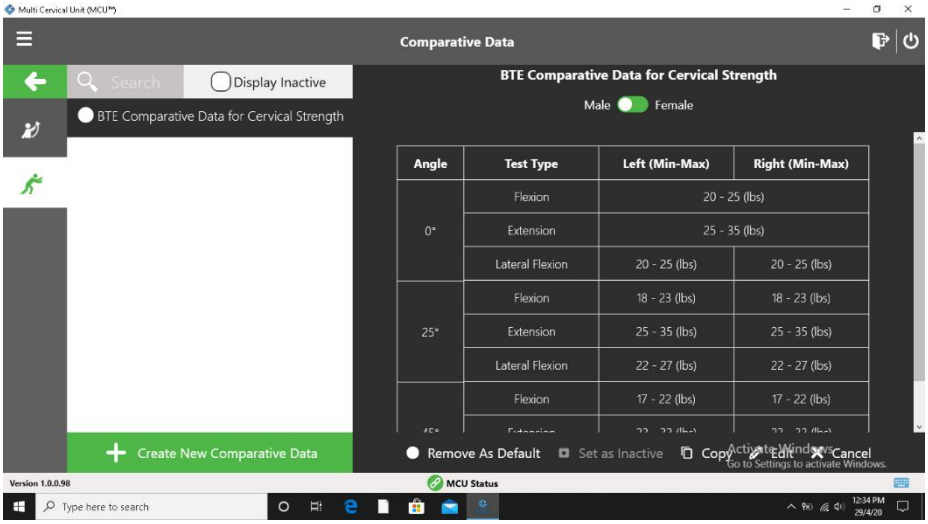
Step 2. Then choose Comparative Data.

Step 3. Choose either Range of Motion or Strength.

Step 4. Click on the Delete icon at the bottom of the window.

Step 5. Select the item to be deleted from list.

Step 6. Confirm that you want to delete this item by clicking Yes (Screenshot 11)



Screenshot 11

II. Reports / Forms

This menu item provides you with the ability to print Reports and blank forms (Neck Disability Index and Symptom Intensity Rating).

Access to both Calibration Reports and Client Reports is offered here.

III. Database Management

Database Management allows you to back up your current database, restore a database, and change from one database to another.

A. Backup Database

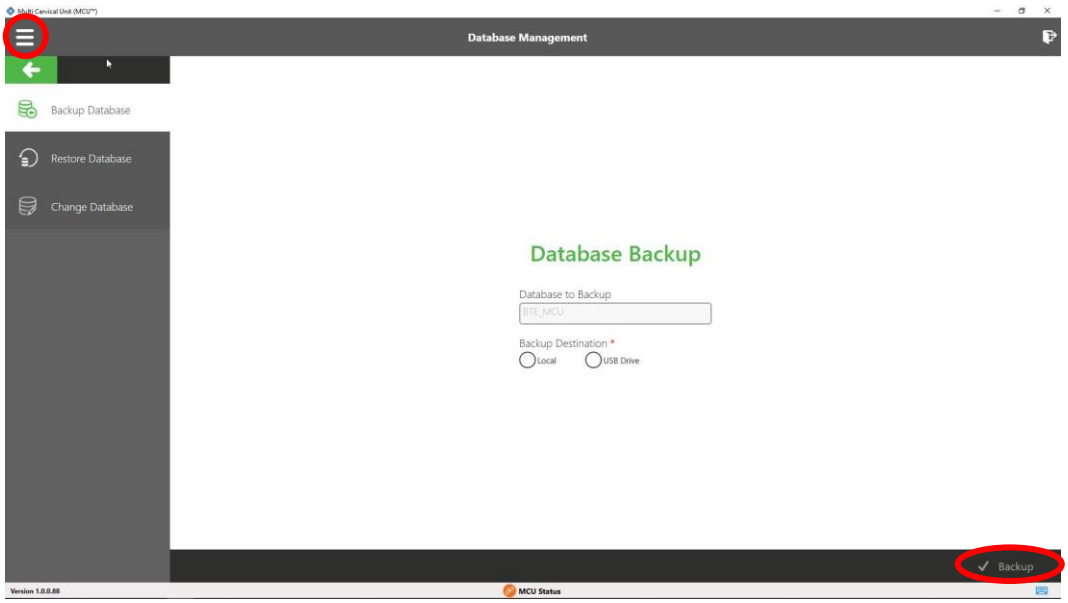
Backup Database is a process used to protect and restore a database. A duplicate of the database is made in case the primary database is corrupted, crashes, or is lost. It is highly recommended that you back up your database at the end of each day in order to avoid loss of data due to database issues or hard drive issues.

The MCU software provides two locations for data backup; local and to a USB drive. The local option makes a copy that resides on the control module. To back up the database, follow these steps:

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings.

Step 2. Click on Backup Database.

Step 3. The name of the current database should be identified in the text field labeled Database to Backup. Simply choose the backup destination, Local or USB Drive, and click the Backup button. A popup window will confirm that a backup copy has been made (*Screenshot 12*).



Screenshot 12

B. Restore Database

Restore Database is a process of copying a database from another location back to the original location in the MCU software. This copy process is used should the original database be damaged or lost. To restore the database, follow these steps: (Screenshot 13)

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings.

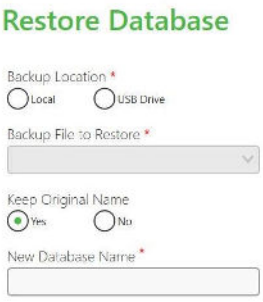
Step 2. Click on Restore Database.

Step 3. Select the location from which the copy will be retrieved – Local or USB Drive.

Step 4. Select the name of the database to be restored from the dropdown list.

Step 5. Address the question of maintaining the original file name or renaming it.

Step 6. Review the information, then click the Restore button.



Screenshot 13

C. Change Database

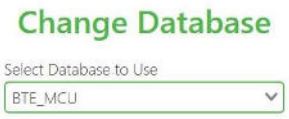
Change Database allows you to change from one database to another should you have multiple working databases. To change databases, follow these steps: (*Screenshot 14*)

Step 1. From the Hamburger Menu, select System Configuration, then Global Settings.

Step 2. Click on Change Database.

Step 3. Select the name of the database to be used from the dropdown list.

Step 4. Click the Change button.

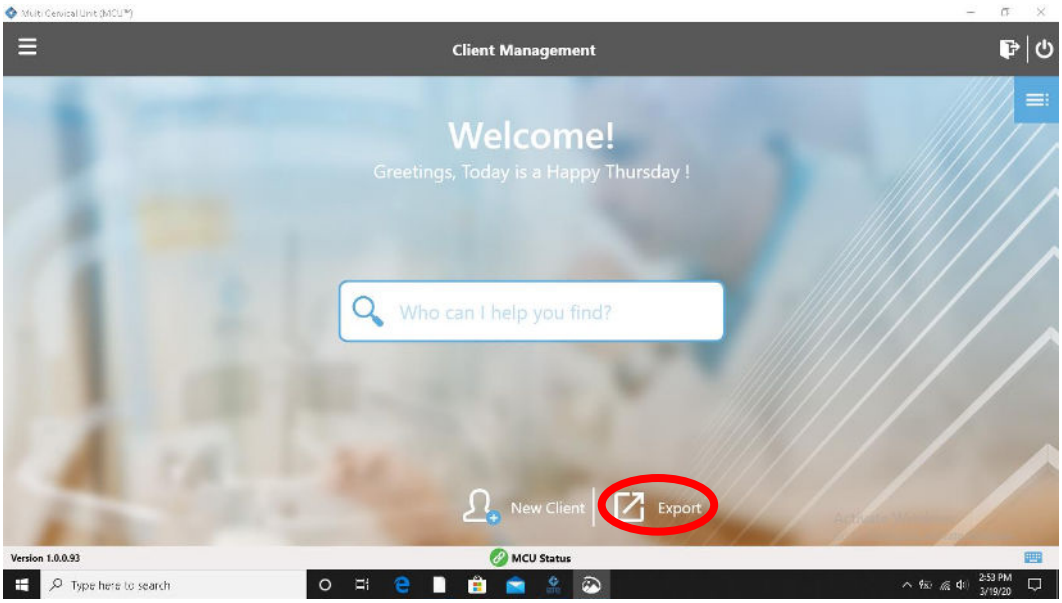


Screenshot 14

D. Export Data

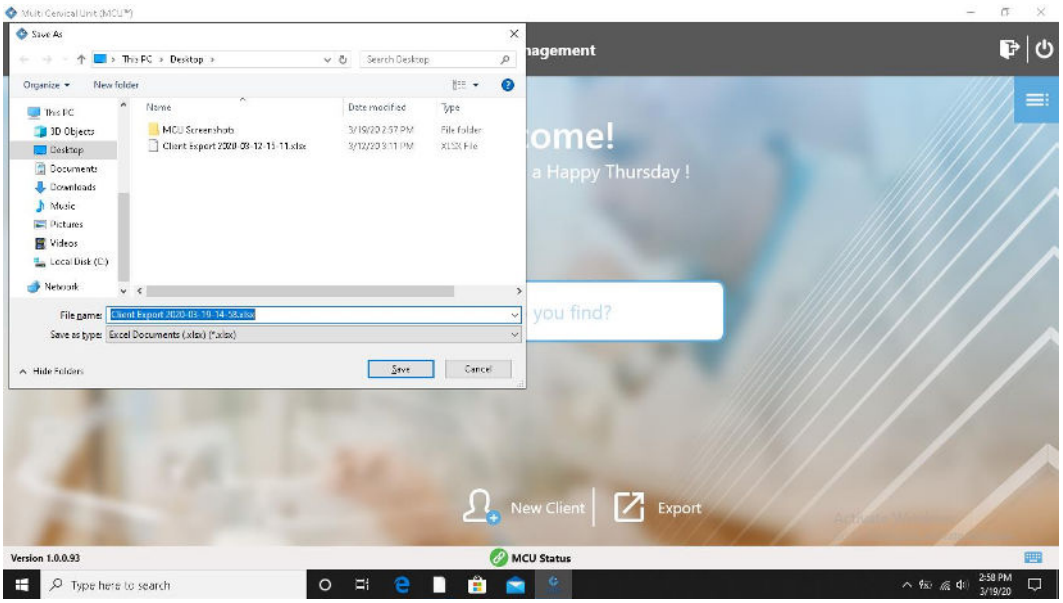
Client data can be exported directly from the main kiosk page (*Screenshot 15*).

Click on the “Export” icon (*Screenshot 15*).



Screenshot 15

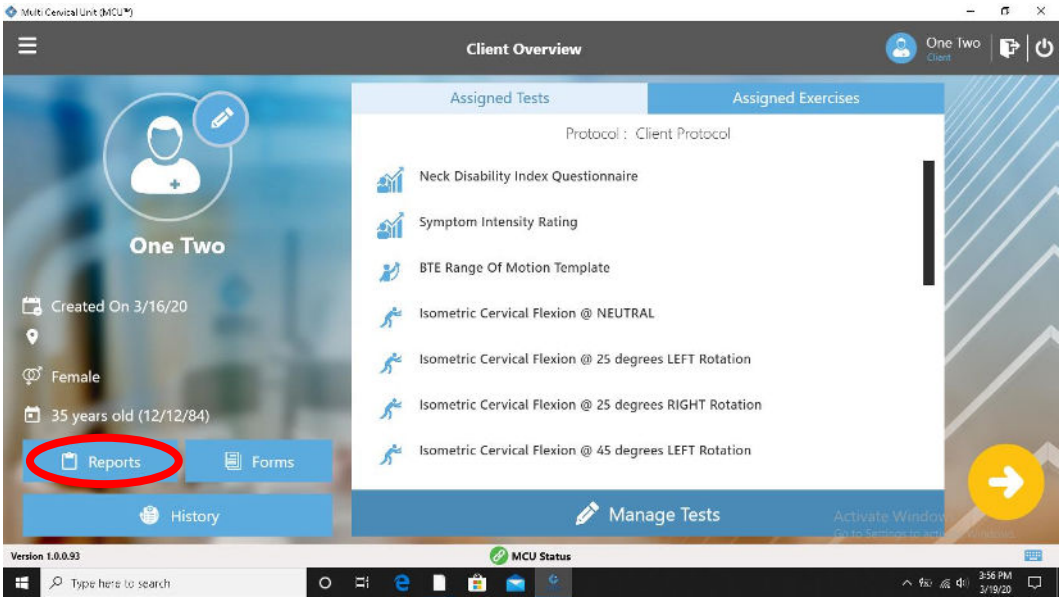
Choose the location in which to save the data.



Screenshot 16

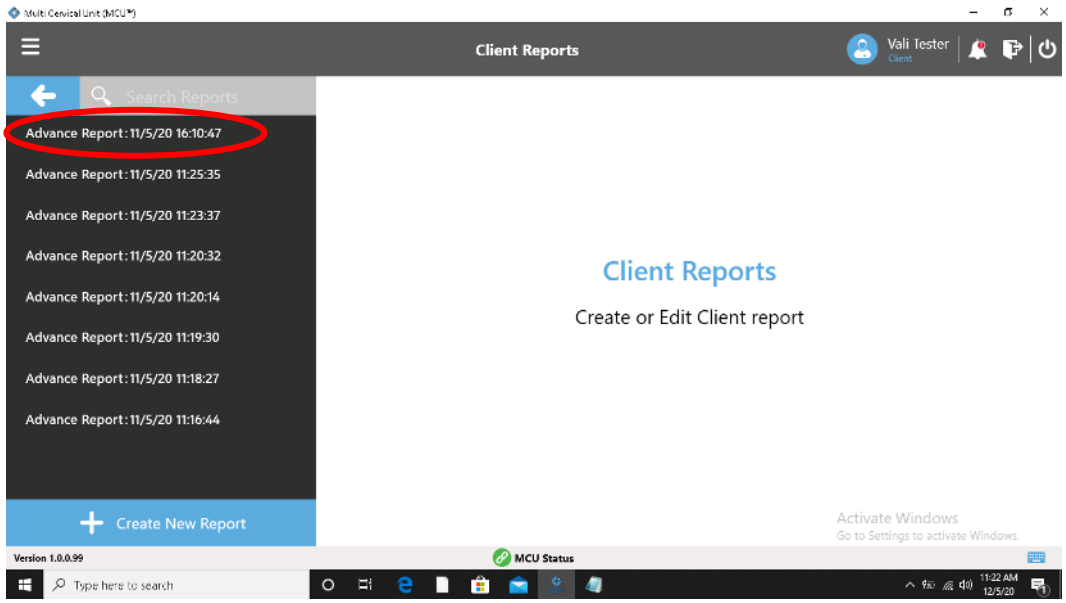
To export raw data exclusively from an individual client, you will need to first select the client.

From the Client Overview page, choose Reports (Screenshot 17).



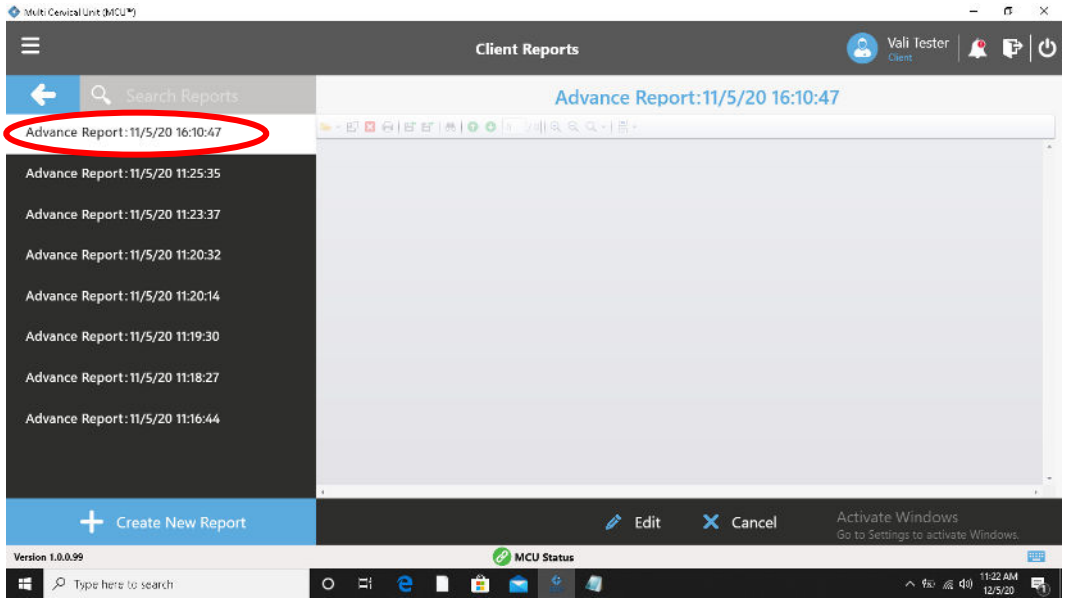
Screenshot 17

If you have already saved a report to the system, choose a report from the left of the page that contains the data you would like to export (*Screenshot 18*).



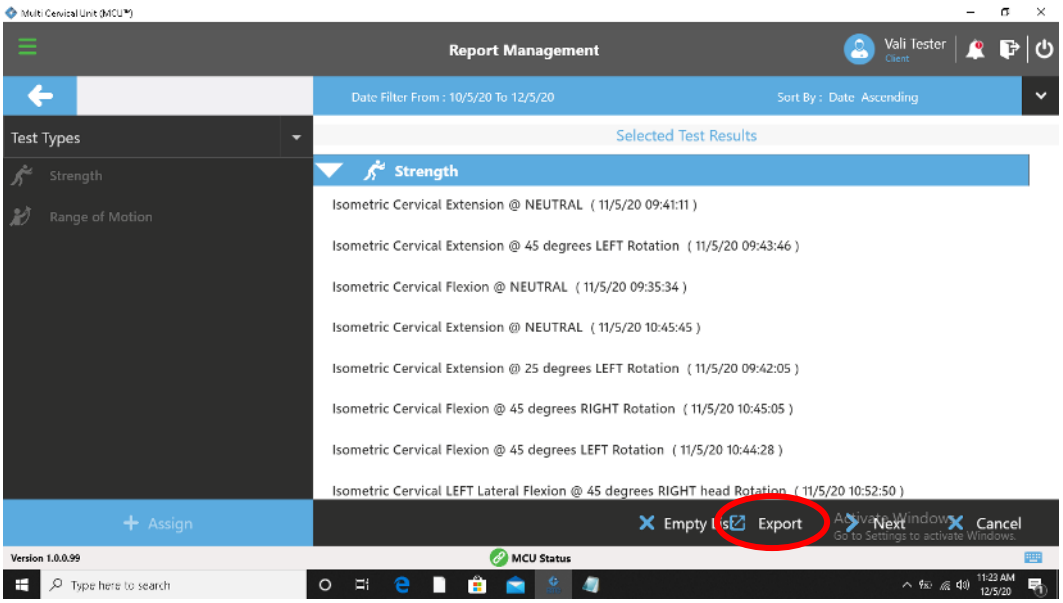
Screenshot 18

Choose “Edit” (Screenshot 19).



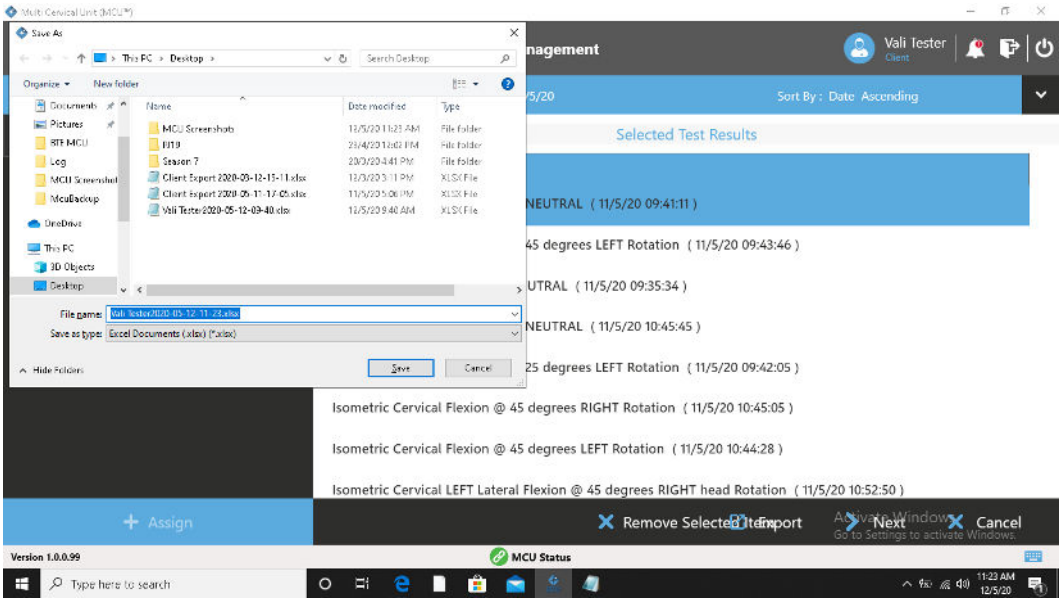
Screenshot 19

You will see the selected tests in the middle of the page. Click Export (*Screenshot 20*).



Screenshot 20

Choose where to save the file (*Screenshot 21*).

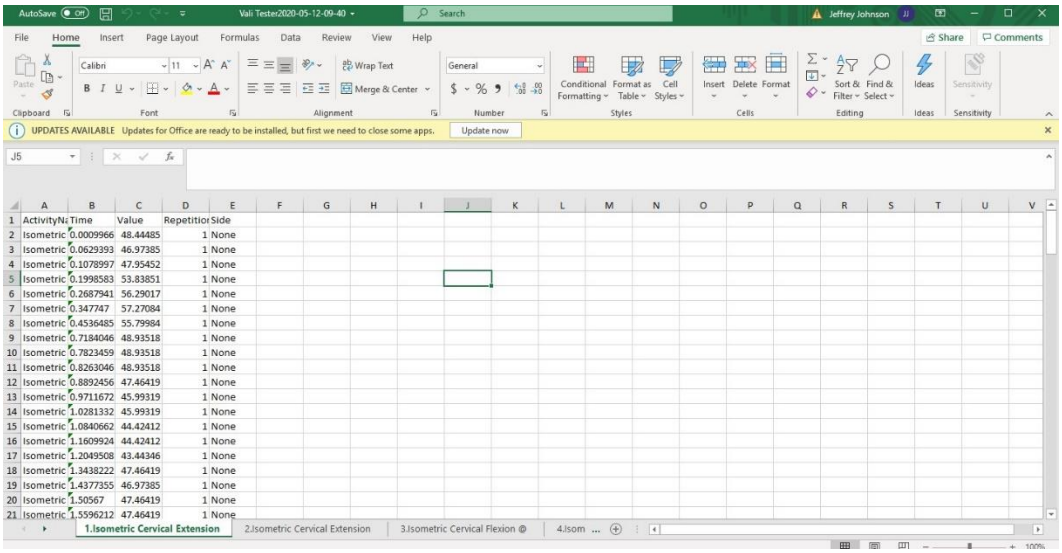


Screenshot 21

The exported document is in Excel format. Each tab represents one specific movement (Screenshot 22).

Column A is the name of the test
Column B is the time where that value was taken
Column C is the isometric force value
Column D is the repetition
Column E is the side

On the bottom of the excel file are different spreadsheets for each motion with saved data. To view the data, click on the desired spreadsheet.



	A	B	C	D	E
1	ActivityNa	Time	Value	Repetitior	Side
2	Isometric	0.0009966	48.44485	1	None
3	Isometric	0.0629393	46.97385	1	None
4	Isometric	0.1078997	47.95452	1	None
5	Isometric	0.1998583	53.83851	1	None
6	Isometric	0.2687941	56.29017	1	None
7	Isometric	0.347747	57.27084	1	None
8	Isometric	0.4536485	55.79984	1	None
9	Isometric	0.7184046	48.93518	1	None
10	Isometric	0.7823459	48.93518	1	None
11	Isometric	0.8263046	48.93518	1	None
12	Isometric	0.8892456	47.46419	1	None
13	Isometric	0.9711672	45.99319	1	None
14	Isometric	1.0281332	45.99319	1	None
15	Isometric	1.0840662	44.42412	1	None
16	Isometric	1.1609924	44.42412	1	None
17	Isometric	1.2049508	43.44346	1	None
18	Isometric	1.3438222	47.46419	1	None
19	Isometric	1.4377355	46.97385	1	None
20	Isometric	1.50567	47.46419	1	None
21	Isometric	1.5596212	47.46419	1	None

Screenshot 22

Appendix A - EMC Guidelines

Guidance and manufacturer's declaration – electromagnetic emissions

MCU is intended for use in the electromagnetic environment specified below. The customer or the user of MCU should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	MCU uses RF energy only for its internal function. The RF emissions from the MCU are very low and not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	MCU is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/flicker emissions 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

MCU is intended for use in the electromagnetic environment specified below. The customer or the user of MCU should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be non-conductive.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV	± 2 kV	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	

Power Frequency, Magnetic Fields IEC 61000-4-8	3A/m	3A/m	

Guidance and manufacturer's declaration – electromagnetic immunity

MCU is intended for use in the electromagnetic environment specified below. The customer or the user of MCU should assure that it is used in such an environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U T (>95 % dip in U T) for 10mS 40 % U T (60 % dip in U T) for 100mS 70 % U T (30 % dip in U T) for 500mS **<5 % U T** **(>95 % dip in U T)** **for 5 s**	<5 % U T (>95 % dip in U T) for 10mS 40 % U T (60 % dip in U T) for 100mS 70 % U T (30 % dip in U T) for 500mS **<5 % U T** **(>95 % dip in U T)** **for 5 s**