OPERATOR'S GUIDE

The PROMETHEUS GROUP®

CMT

PATHWAY® CTS 1500

Pelvic Muscle Rehabilitation System
(Part #CTS-1500B, Part #CTS-1500)

CONTACT INFORMATION

The Prometheus Group®

One Washington Street, Suite 3171 Dover, New Hampshire 03820 U.S.A.

For assistance, please call your local sales representative, distributor, or The Prometheus Group® at:

CUSTOMER SERVICE

Business Hours: M-F, 9 AM – 5 PM EST

Toll Free: (800) 442-2325

Local: (603) 749-0733

Email: info@theprogrp.com

Fax: (603) 749-0511

theprogrp.com | info@theprogrp.com

TECHNICAL SUPPORT

Business Hours: M-F, 8:30 AM – 5 PM EST

Toll Free: (800) 272-8492

Local: (603) 749-0733

Email: support@theprogrp.com

After Hours Technical Support

M-F, 5 PM – 8 PM EST

(603) 343-8000

Copyright © 2013 The Prometheus Group®. All rights reserved. This document contains confidential and proprietary information that is the property of The Prometheus Group®, Inc. and is protected by the copyright laws of the United States, international copyright treaties, and all other applicable national laws. Any unauthorized use, reproduction or transfer of any information in this document is strictly prohibited. This document contains information regarding technology that is protected under one or more United States patents and other pending United States and foreign patents. The Prometheus Group® logo, Pathway® logo, combinations thereof, are registered trademarks of The Prometheus Group®, Inc., One Washington Street, Suite 3171, Dover, NH 03820. All other brand and product names are used for identification only and are the property of their respective holders. Specifications are subject to change without notice. Printed in the U.S.A.

52_055PTiEN

TECHNICAL SUPPORT CONTACT INFORMATION:

Toll-Free: (800) 272-8492
Local: (603) 749-0733
Fax: (603) 749-0511
Email: Support@theprogrp.com

Our support team is available
M-F, 8:30 AM - 5:00 PM EST.

There is never a charge for Telephone Technical Support.

After Hours Technical Support:
M-F, 5:00 PM - 8:00 PM EST
(603) 343-8000

Dear Valued Customer,

On behalf of The Prometheus Group®, we would like to personally thank you for your recent purchase.

The Prometheus Group® is recognized for providing exceptional products, outstanding customer service, and unparalleled technical support.

Because our goal is to build a long-term partnership with your company, our dedicated team is here to make sure you get the most from your investment.

Feel free to contact our technical support team to answer any questions that you may have concerning the installation or operation of your equipment. Our products are user friendly, and most training and questions can be handled effectively over the phone. The technical support line may be used as an invaluable tool at your convenience.

We value our relationship and look forward to working with you and your company for years to come.

Respectfully,
The Prometheus Group® Technical Support Team

52_006gEN

One Washington Street, Suite 3171, Dover, NH 03820
info@theprogrp.com | theprogrp.com | Phone: (800) 442-2325 | Fax: (603) 749-0511

TABLE OF CONTENTS

NOMENCLATURE **5**

SERVICE INFORMATION **7**

INDICATIONS FOR USE **7**

CONTRAINDICATIONS **7**

CAUTIONS **8**

WARNINGS AND PROHIBITIONS **9**

SYSTEM CONTENTS FOR PATHWAY® CTS 1500 PELVIC MUSCLE REHABILITATION (PART #CTS-1500B) **11**

SYSTEM CONTENTS FOR PATHWAY® CTS 1500 PELVIC MUSCLE REHABILITATION (PART #CTS-1500) **13**

CHAPTER 1: PHYSICAL/MECHANICAL OVERVIEW **14**

Pathway® CTS 1500 Control Module (Front and Back Panels) *14*

Connecting the Pathway® CTS 1500 Control Module *14*

Powering the Pathway® CTS 1500 Control Module *14*

Pathway® CTS 1500 Control Module Connections *15*

CHAPTER 1: PHYSICAL/MECHANICAL OVERVIEW **16**

EMG A/STIM Channel *16*

Pathway® Rectal Intracavity Sensor Orientation *17*

EMG B Channel *19*

CHAPTER 2: SOFTWARE SETUP **20**

The Initial Software Startup Process *20*

The First Time Startup Opening Screen *20*

CHAPTER 2: SOFTWARE SETUP **24**

Create An Associate *24*

Create A Location *25*

Create Unique Identifiers *27*

CHAPTER 3: CTS 1500 TOOLS **29**

Introduction *29*

Create/Edit/View Associates *31*

Create/Edit/View Locations *33*

CHAPTER 4: STUDY CREATION **36**

Create a New Patient *36*

Select an Existing Patient *38*

Create a Patient Visit *39*

Attachments *40*

CHAPTER 5: LAUNCH CTS 1500 EMG/STIM TREATMENT **43**

CHAPTER 6: A 2EMGS, ENDURANCE **47**

CHAPTER 7: H STIM, 50Hz, 5ON10OFF, 15MIN **52**

CHAPTER 8: DIAGNOSIS AND PLAN OF CARE **56**

CHAPTER 9: SESSION EVALUATION **58**

CHAPTER 10: EXERCISE PRESCRIPTION **60**

CHAPTER 11: OPENING DOCUMENTS **62**

CHAPTER 12: REVIEW CURRENT VISIT **65**

CHAPTER 13: REVIEW PREVIOUS VISITS **66**

CHAPTER 14: COMPARE **67**

CHAPTER 15: REVIEW PATIENTS BY DATE **72**

CHAPTER 16: ACTIVE TREATMENT SCREEN CHANGES ADDENDUM **74**

CHAPTER 17: UTILITIES **84**

CHAPTER 18: DELETE PROTOCOL **85**

TROUBLESHOOTING **86**

CLEANING AND DISINFECTING **87**

DISPOSAL OF EQUIPMENT, ACCESSORIES, AND WASTE PRODUCTS **93**

PATHWAY CTS 1500 PELVIC MUSCLE REHABILITATION SYSTEM (Part #CTS-1500B) SPECIFICATIONS **94**

TO ORDER ACCESSORIES **96**

SOFTWARE LICENSE AGREEMENT **97**

THE PROMETHEUS GROUP® STANDARD PRODUCT WARRANTY AGREEMENT **98**

NOMENCLATURE

Warnings and Safety Information

Meaning of Signal Words and Symbols

In this operator's guide, the signal words such as **WARNING**, **CAUTION**, and **NOTE** are used regarding safety and important instructions. All users of the **Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500)** must understand the meaning of these signal words. The following symbols may appear in, on, or with products manufactured or distributed by The Prometheus Group®, not all symbols are applicable to all products.

	WARNING: A hazard to a person - a potential danger to the operator or patient such as electrical shock or some other potential danger.
	CAUTION: A hazard to a piece of equipment or property – for example, potential for an electrical short, water damage, or some other danger to the equipment but not the operator or patient. Can also be a reference to HIPAA or another medical legal requirement.
	Type BF Equipment (B = body, F = floating applied part).
	ATTENTION, refer to user manual.
	GENERAL PROHIBITION: To signify a prohibited action.
	Consult Instructions for Use.
	Follow operating instructions. Refer to instruction manual/booklet.
	Manufacturer; May be combined with Date of Manufacture (Year-Month-Day)
	Date of Manufacture (Year-Month-Day)
	Do NOT re-use, Single Use, Use Only Once.
SN	**Serial Number**
REF	**Catalogue Number**
LOT	**Batch or Lot Code**
QTY	**Quantity**
EC REP	**Authorized Representative in the European Community**
CE	**CE Mark- European Compliance**
	TUV Rheinland of North America, Inc, cTUVus Certification

NOMENCLATURE

	Use by date
	Do not use if package is damaged.
	Contains or presence of natural rubber latex.
	Non-sterile
	Sterile
	Sterilized using ethylene oxide.
	Keep away from sunlight.
	Temperature Limits (Upper and Lower)
	Keep Dry
	Prescription only; May also appear as Rx only.
	Stand-by
	Non-ionizing electromagnetic radiation
	For Indoor use only
	Alternating Current
	Direct current
	Class II equipment
	Waste electrical and electronic equipment. Do NOT Dispose of in a landfill or with municipal or household waste. Dispose of in accordance to local regulations.
	Flow Direction
	Do not allow fingers to come into contact with moving parts.
	Load rating (system components) Please refer to the label for appropriate load.

SERVICE INFORMATION

⚠	**CAUTION: There are no serviceable parts within the Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B or Part #CTS-1500) system. The user should not attempt to service the system beyond that described in the Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B or Part #CTS-1500) system Operator's Guide. Refer all other servicing to The Prometheus Group® qualified Technical Support personnel. Please call (800) 272-8492 or e-mail support@theprogrp.com.**
⚠	**The Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B or Part #CTS-1500) system should be serviced by The Prometheus Group® qualified Technical Support personnel when:** • **Any cable, cord, or plug has been damaged.** • **The system does not appear to operate normally or exhibits a marked change in performance.** • **The instrument has been dropped, or the casing is damaged.** • **Fluid has been spilled on the module, or it has been immersed, and it appears that fluid has entered the housing.**

INDICATIONS FOR USE

The **Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B or Part #CTS-1500) system** is indicated for the following uses:

Muscle Activity Measurement

- Muscle re-education, strengthening, endurance building, and relaxation of skeletal muscles, specifically the pelvic floor muscles.
- Assessment of pelvic floor dysfunctions, monitoring the muscle activity associated with the performance of Kegel exercises.
- Assessment of conditions including stress incontinence, mixed incontinence, and urge incontinence.

CONTRAINDICATIONS

The **Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B or Part #CTS-1500)** is contra-indicated for the following uses:

- Active Infection or Genital Disease
- Severe Pelvic Pain
- Pregnancy
- Postpartum or Post-Surgical (6 weeks)
- Atrophic Vaginitis
- Dyspareunia
- Menstrual Period
- Pacemaker or Cardiac Arrhythmia
- Presence of Any Known Malignancy
- History of Severe Urine Retention
- Prolapse
- Diminished Sensory Perception
- Not for Use with infants (0-2 Years)

CAUTIONS

⚠	**The system should be treated as a medical device and not utilized with entertainment/music software or applications.**
⚠	**Do not stack or locate the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) too close to other equipment.**
⚠	**Frequency band of the equipment transceivers are as follows: 2.402 GHz – 2.4835 GHz ISM Band.**
⚠	**The Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) may be interfered with by other equipment.**
⚠	**The Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) is designed for use with the accessories and cables listed on page 96. The use of accessories or cables other than those listed on page 96 could result in increased emissions or decreased immunity.**
⚠	**Portable and mobile RF communications equipment can affect the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500)**
⚠	**The minimum patient physiological amplitude for sEMG is 1 uV.**
⚠	**Use only the approved power supplies provided with Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500)**
⚠	**Prior to using this system, be sure to read the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) Operator's Guide for installation, maintenance, cleaning, technical data, service, and warranty information.**
⚠	**Federal law (USA) restricts these systems for sale by or on the order of a licensed medical practitioner, licensed by law in the state in which they practice.**
⚠	**Skin irritation may develop beneath or around electrode sites.**
⚠	**HIPAA requires safeguards to protect patient privacy. Connecting these systems to a network is done at your own risk.**
⚠	**Detachable Power Supplies are only available from The Prometheus Group®.**

WARNINGS AND PROHIBITIONS

	The Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) IS NOT intended for use with anesthetic gases mixed with air, oxygen, or nitrous oxide. Danger of electrical ignition.
	Be sure to read this operator's manual before using this Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500).
	Use by improperly trained personnel or non-licensed healthcare professionals may cause damage to the equipment or harm to the patient.
	Use only electrodes and accessories from The Prometheus Group® with the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500). Any other electrodes or accessories may not be compatible with the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) and will void the system's warranty.
	DO NOT immerse or spill any part of Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) in any fluid.
	Ensure all wheels are locked during testing procedures to prevent injury to the patient. Do not lean on the equipment or hang excessive weighted objects on the cart other than the standard accessories provided by The Prometheus Group®.
	To reduce the risk of electrical shock, DO NOT connect any preamplifier, lead wire, electrode, or any other component to a wall outlet.
	DO NOT leave accessory cables attached when the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) system is not in use.
	To reduce the risk of electrical shock, DO NOT open the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) control module housing. Refer all servicing to The Prometheus Group® qualified Technical Support personnel.
	DO NOT prematurely unpack electrodes as prolonged exposure to air may cause the electrode adhesive to dry out.
	DO NOT use electrodes or other consumables with an expired shelf-life.
	DO NOT clean and re-use single use consumables.

WARNINGS AND PROHIBITIONS

	Disassembly of equipment by anyone other than The Prometheus Group® qualified Technical Support personnel will void the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) system warranty.
	To avoid risk of electrical shock, this equipment MUST only be connected to a supply mains with protective earth.
	Move the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) with caution to avoid tipping which could result in damage to the systems and/or harm the user or patient.
	DO NOT use the Pathway® CTS 1500 Pelvic Muscle Rehabilitation system (Part #CTS-1500B or Part #CTS-1500) prior to receiving clinical training.
	To reduce the risk of electrical shock, DO NOT use the equipment if any of the power supplies or line cords show signs of damage.

SYSTEM CONTENTS FOR PATHWAY® CTS 1500 PELVIC MUSCLE REHABILITATION (PART #CTS-1500B)

Before using the **Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B or Part #CTS-1500) system** for the first time, carefully open the box and confirm that all equipment and accessories listed below are included and agree with the packing list or invoice.

If there are questions about the contents, or you wish to order additional supplies, please call Customer Service, Toll-Free: (800) 442-2325 or Fax: (603) 749-0511. Customer Service Representatives are available between 8:30 AM and 5:00 PM EST.

The Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B) system contains the following items:

(1) Notebook Computer

(1) Wireless Mouse

(1) Color Printer

(1) USB Serial Interface Cable

(1) Pathway® CTS 1500 Pelvic Muscle Rehabilitation System USB Flash Drive Software Program

(1) Pathway® CTS 1500 Pelvic Muscle Rehabilitation System Operator's Guide

The Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B) system provides:

(1) Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG

(1) Channel of Accessory Muscle sEMG

(1) Channel of Vaginal and Rectal Electrical Stimulation

SYSTEM CONTENTS FOR PATHWAY® CTS 1500 PELVIC MUSCLE REHABILITATION (PART #CTS-1500B)

Starter Accessory Package

(4) - Disposable Lead Wire Electrodes Sample Packets, Square Electrode, 24" Lead Wire, .060 Female Pin (Part #7400)

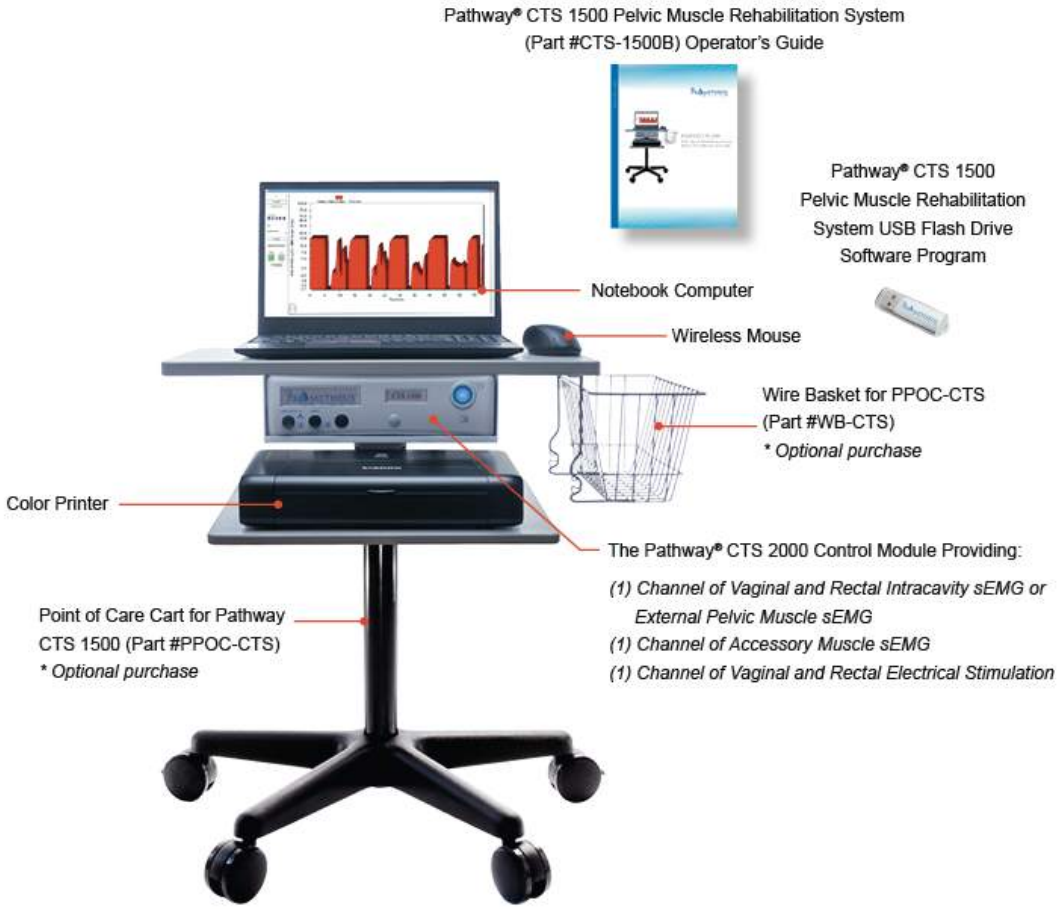
(4) – Pathway® Electrodes Sample Packets, (Rectangular, 3 Snaps in a Row Style) (Part #6750)

(1) – Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300)

(1) – Ch B Extended Pathway® Preamplifier, White, 10' (Part #2583E)

(4) – Pathway® Vaginal sEMG/Stimulation Sensor (Part #6330)

(2) – Pathway® Rectal sEMG/Stimulation Sensor (Part #6340)



SYSTEM CONTENTS FOR PATHWAY® CTS 1500 PELVIC MUSCLE REHABILITATION (PART #CTS-1500)

The Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500) system contains the following items:

(1) USB Serial Interface Cable

(1) Pathway® CTS 1500 Pelvic Muscle Rehabilitation System USB Flash Drive Software Program

(1) Pathway® CTS 1500 Pelvic Muscle Rehabilitation System Operator's Guide

The Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500) system module provides:

(1) Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG

(1) Channel of Accessory Muscle sEMG

(1) Channel of Vaginal and Rectal Electrical Stimulation

Starter Accessory Package

(4) - Disposable Lead Wire Electrodes Sample Packets, Square Electrode, 24" Lead Wire, .060 Female Pin (Part #7400)

(4) – Pathway® Electrodes Sample Packets, (Rectangular, 3 Snaps in a Row Style) (Part #6750)

(1) – Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300)

(1) – Ch B Extended Pathway® Preamplifier, White, 10' (Part #2583E)

(4) – Pathway® Vaginal sEMG/Stimulation Sensor (Part #6330)

(2) – Pathway® Rectal sEMG/Stimulation Sensor (Part #6340)

Pathway® CTS 1500 Control Module (Front and Back Panels)

Connecting the Pathway® CTS 1500 Control Module

1. Connect the USB cable to the USB Cable Interface
2. Connect the other end of the USB Cable to the Notebook Computer.

Powering the Pathway® CTS 1500 Control Module

1. Connect the Power Supply to the 12VDC Power Input.
2. Ensure the Line Power Cord is connected to the Power Supply.
3. Connect the Line Power Cord to an electrical wall outlet.
4. Turn the **Pathway® CTS 1500 Control Module ON** by pressing the blue **On/Off Power Button** on the front panel.
5. When the Pathway® CTS 1500 Control Module is **ON**, the **On/Off Power Button** will illuminate. This indicates that the Pathway® CTS 1500 Control Module is ready for operation. If the **On/Off Power Button** does not illuminate, press the **On/Off Power Button** again (turning it **OFF**) and follow these trouble-shooting steps:

    A. Be sure the Power Supply is firmly connected to the 12VDC Power Input.
    B. Be sure the Line Power Cord is plugged firmly into the Power Supply.
    C. Be sure the Line Power Cord is connected to an electrical outlet and the electrical outlet is operational.
    D. Be sure the green light on the Power Supply is illuminated.

6. Press the **Pathway® CTS 1500** Control Module **On/Off Power Button**.

Pathway® CTS 1500 Control Module Connections

The **Pathway® CTS 1500 Control Module** pictured above has a total of three connectors.

EMG A / STIM: One Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG, One Channel of Vaginal and Rectal Electrical Stimulation.

EMG B: One Channel of Accessory Muscle sEMG

(EMG A/STIM Channel):

Cable Connections for Vaginal and Rectal Intracavity sEMG and Stimulation: *Connecting the* ***Pathway® Vaginal and Rectal Intracavity sEMG and Stimulation Sensor(s)*** *to the* ***EMG A/STIM Input*** *of the* ***Pathway® CTS 1500 Control Module.***

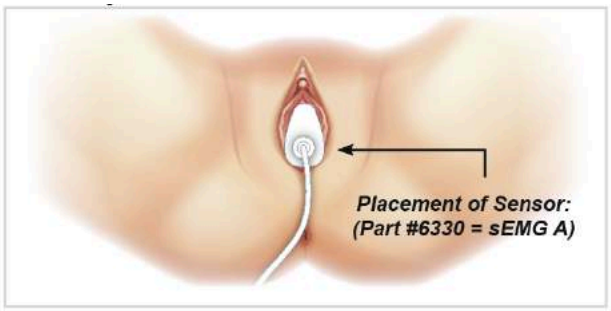
Sensor Connections to (EMG A/STM input): To connect the Pathway® Vaginal and Rectal Intracavity Sensor(s) (Part #6330 or Part #6340) into the EMG A/STM input of the Pathway® CTS 1500 Control Module, insert the Pathway® Intracavity Sensor(s) (Part #6330 or Part #6340) sensor plug end (male six-pin mini din connector) with flat side up, noting the notched top of the connector input (also flat side up), and push the sensor plug end straight into the Pathway® CTS 1500 Control Module to make the male/female connection. **Push firmly and do not twist**.

Lubrication: Refer to the ***"Directions for Use"*** section of the Pathway® Sensor packaging product insert for lubrication instructions.

Pathway® Vaginal sEMG/Stimulation Sensor Placement (Part #6330): For proper orientation of the sensing surfaces, insert the Pathway® Vaginal sEMG/Stimulation Sensor (Part #6330) into the vagina so the sensor base rests up against the labia and the tab is pointed up toward the pubis. *(See Figure 1 below).*

Pathway® Vaginal and Rectal Intracavity sEMG and Stimulation Sensor Orientations

Figure 1. Pathway® Vaginal sEMG/ Stimulation Sensor Placement (Female)



Pathway® Vaginal sEMG/Stimulation Sensor (Part #6330)

The two active **(ACT)** sensing surfaces are located at 10 and 2 o'clock.
The single ground **(GND)** sensing surface is located at 6 o'clock.

NOTE: ALL PROMETHEUS GROUP® SENSORS ARE RESTRICTED TO SINGLE PATIENT USE ONLY.

NOTE: For complete information regarding the Pathway® Vaginal sEMG/Stimulation Sensor (Part #6330), or the Pathway® Rectal sEMG/Stimulation Sensor (Part #6340), refer to the product packaging insert which includes:

- Cautions
- Cleaning
- Directions for Use
- Indications for Use
- Contraindications for Use
- Warranty Information

Additional cleaning instructions can also be found on page 87 at the back of this Operator's Guide.

Pathway® Rectal Intracavity Sensor Orientation

Pathway® Rectal sEMG/Stimulation Sensor (Part #6340) Placement: For proper orientation of the sensing surfaces, insert the Pathway® Rectal sEMG/Stimulation Sensor (Part #6340) into the rectum so the sensor base rests up against the anus and the longer tab labeled "FRONT" is pointed up toward the pubis. *(See Figures 2 and 2A below).*

Figure 2. Pathway® Rectal sEMG/Stimulation Sensor Placement (Female)

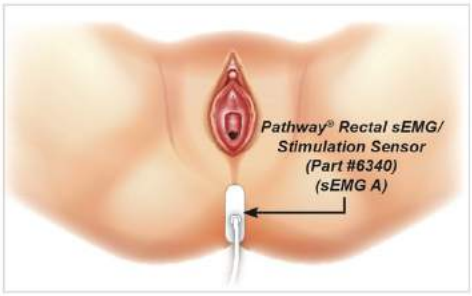
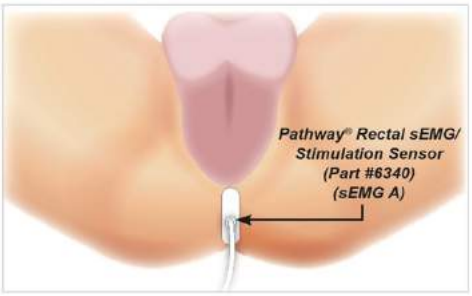


Figure 2A. Pathway® Rectal sEMG/Stimulation Sensor Placement (Male)



Pathway® Rectal sEMG/Stimulation Sensor (Part #6340)

The two active **(ACT)** sensing surfaces are located at 10 and 2 o'clock.
The single ground **(GND)** sensing surface is located at 6 o'clock.

NOTE: ALL PROMETHEUS GROUP® SENSORS ARE RESTRICTED TO SINGLE PATIENT USE ONLY.

NOTE: For complete information regarding the Pathway® Rectal sEMG/Stimulation Sensor (Part #6340), refer to the product packaging insert which includes:

- Cautions
- Cleaning
- Directions for Use
- Indications for Use
- Contraindications for Use
- Warranty Information

Additional cleaning instructions can also be found on page 87 at the back of this Operator's Guide.

(EMG A/STIM Channel):

Cable Connections for External Pelvic Muscle: *Connecting the* ***Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300)*** *to the* ***EMG A/STIM Input*** *of the* ***Pathway® CTS 1500 Control Module.***

To obtain best sEMG results the following steps should be taken:

Connecting Disposable Lead Wire Electrodes (Part #7400) to the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300): Insert the Disposable Lead Wire Electrodes (Part #7400) into the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300) ensuring the two red (active) lead wires and the single green (ground) lead wire are inserted completely and match the color on the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300).

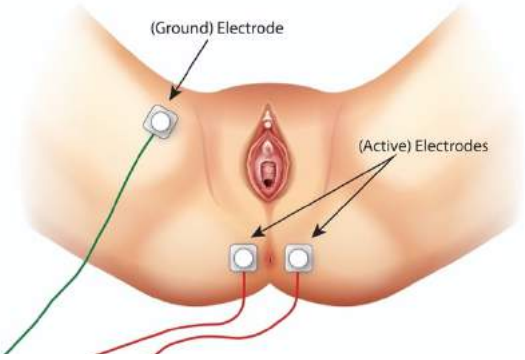
Connecting the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300) to the EMG A/STIM Channel of the Pathway® CTS 1500 Control Module: Insert the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300) plug end (male six-pin mini din connector) with flat side up, noting the notched top of the connector input (also flat side up), and push the plug end straight into the Pathway® CTS 1500 Control Module to make the male/female connection. **Push firmly and do not twist**.

Skin Preparation: Gently wipe down the area around the perineum using a moist, disposable, towelette and allow area to dry completely.

Disposable Lead Wire Electrode Preparation: With the Disposable Lead Wire Electrodes (Part #7400) attached to the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300), carefully remove the mylar backing being cautious to keep the hydrogel adhesive intact on the back of the electrodes. Remove the Disposable Lead Wire Electrodes (Part #7400) individually.

Pathway® Surface Electrodes (External Pelvic Floor) Orientations

Figure 3. Pathway® Disposable Lead Wire Electrode Placement (Female)



Pathway® Disposable Lead Wire Electrodes (Part #7400)

The two active (ACT) surface electrodes are located at 3 and 9 o'clock. The single ground (GND) surface electrode is placed on the leg adductor.

NOTE: Cleaning instructions for the Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300) can be found on page 88 at the back of this Operator's Guide.

(EMG B Channel)

Cable Connections for External Accessory Muscle: *Connecting the* ***Ch B Extended Pathway® Preamplifier*** *to the* ***EMG B input*** *of the* ***Pathway® CTS 1500 Control Module.***

To obtain best sEMG results the following steps should be taken:

Connecting Pathway® Electrode(s) to the Ch B Extended Pathway® Preamplifier: The Ch B Extended Pathway® Preamplifier (Part #2583E) have three female snap on electrode positions: two labeled (**ACT)** for active electrodes and one (**GND)** for the ground electrode. Verify the male tabs of the Pathway® Electrodes (Part #6750) are snapped into the corresponding female snaps of the Pathway® Preamplifier (Part #2583).

Connecting the Ch B Extended Pathway® Preamplifier to the Pathway® CTS 1500 Control Module: With the Pathway® Electrodes (Part #6750) attached to the Ch B Extended Pathway Preamplifier, plug the Ch B Extended Pathway® Preamplifier (Part #2583E) into the EMG B Channel input of the Pathway® CTS 1500 Control Module.

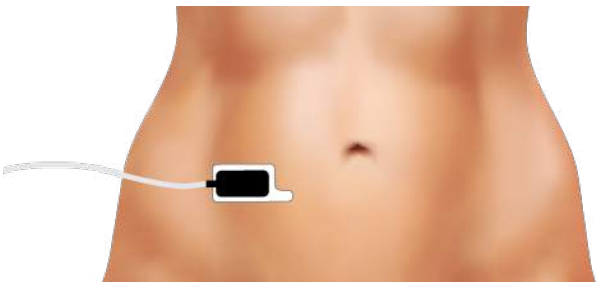
Skin Preparation: Prepare the skin with an alcohol pad to avoid high impedance artifact. Wipe dry with a tissue or cloth.

Pathway® Electrode Preparation: With the Pathway® Electrode (Part #6750) attached to the Ch B Extended Pathway® Preamplifier (Part #2583E), use the white tab on the Pathway® Electrode (Part #6750), to carefully remove the mylar backing being cautious to keep the hydrogel adhesive strips intact on the surface of the electrode.

Pathway® Electrode Placement: Place the two active (**ACT**) electrodes over the bulk of the muscle. Make sure the length of the Pathway® Electrode (Part #6750) is placed parallel with the muscle fibers as shown in Figure 4 below.

Pathway® Surface Electrodes (Accessory Muscle) Orientation

Figure 4. Pathway® Electrode (Part #6750) Placement



NOTE: Accessory muscles such as Abdominals, Leg Adductors, and Gluteals are commonly monitored by placing the active electrodes over the bulk of the muscle.

NOTE: Cleaning instructions for the Ch B Extended Pathway® Preamplifier, White, 10' (Part #2583E) can be found on page 88 at the back of this Operator's Guide.

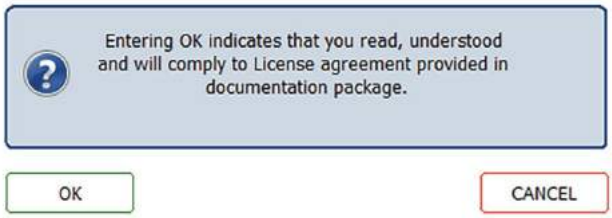
Ch B Extended Pathway® Preamplifier, White, 10' (Part #2583E)	Pathway® Electrode (Rectangular, 3 Snaps in a Row Style) (Part #6750)

The Initial Software Startup Process

The **Pathway® CTS 1500 Pelvic Muscle Rehabilitation (Part #CTS-1500B)** software comes preloaded on the **Notebook Computer** supplied with the system. Before operating the system for the first time, the software must be configured by entering the **Associate** or **Associates** who will have access to the program and the level of access, the **Location** or **Locations** (if there are multiple clinics) of the practice, and how patients will be identified.

To begin, double click the **Pathway® CTS 1500** icon on the Windows Desktop.

Read the **Software License Agreement** on **page 97** in this **Operator's Guide.** Click **OK.**

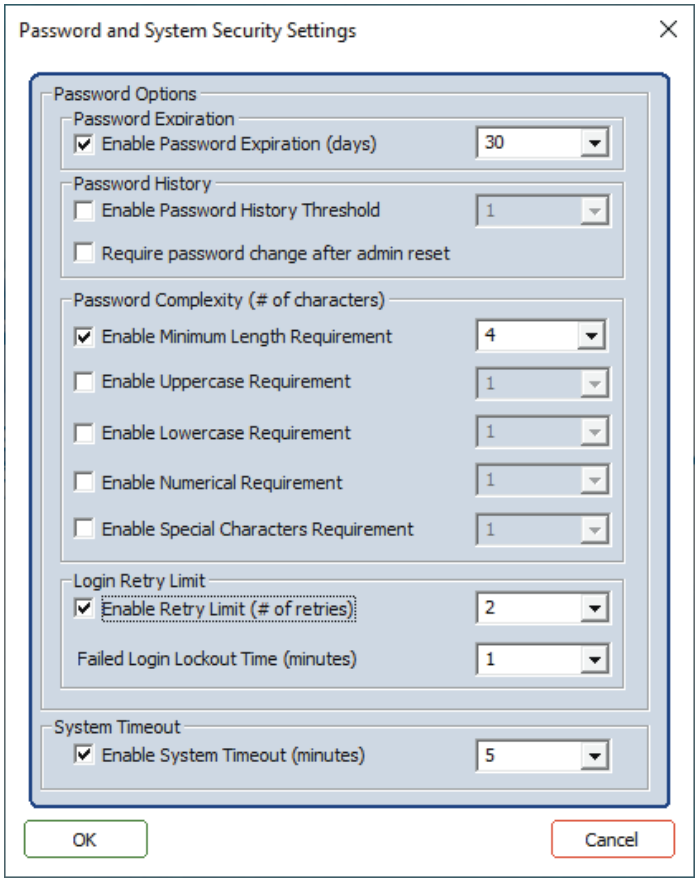


The First Time Startup Opening Screen

1. **Welcome to the first time startup wizard** window will appear. Click **Next.**

2. **Setup Password and System Security Settings** will appear. Click Next.

Setup Password and System Security Settings



Password Expiration: *When enabled, sets the number of days after which the password will expire.*

- Enable Password Expiration (**days**): Minimum (**30**), Maximum (**180**)

Password History: *When enabled, sets the number of previous passwords that cannot be re-used and for the Admin Reset, if enabled, will require the user to change the default password that was set by the Administrator.*

- Enable Password History Threshold: **Minimum** (1), **Maximum** (8)
- Require Password Change After Admin Reset: **Checked** (Yes), **Unchecked** (No)

Password Complexity (# of characters): *When enabled, defines the complexity of all passwords.*

- Enable Minimum Length Requirement: **Minimum** (4), **Maximum** (14)
- Enable Uppercase Requirement: **Minimum** (1), **Maximum** (3)
- Enable Lowercase Requirement: **Minimum** (1), **Maximum** (3)
- Enable Numerical Requirement: **Minimum** (1), **Maximum** (3)
- Enable Special Character Requirement: **Minimum** (1), **Maximum** (3)

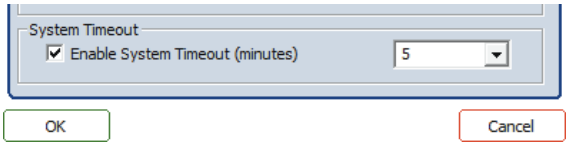
Login Retry Limit: *When enabled, provides added security for failed login attempts including a system lockout caused by failed login attempts.*

- Enable Retry Limit **(# of retries)**: **Minimum** (2), **Maximum** (10)
- Failed Login Lockout Time **(minutes)**: **Minimum** (1), **Maximum** (15)

System Timeout: *When enabled, this will lock the system after a period of inactivity and requests a Username and Password.*

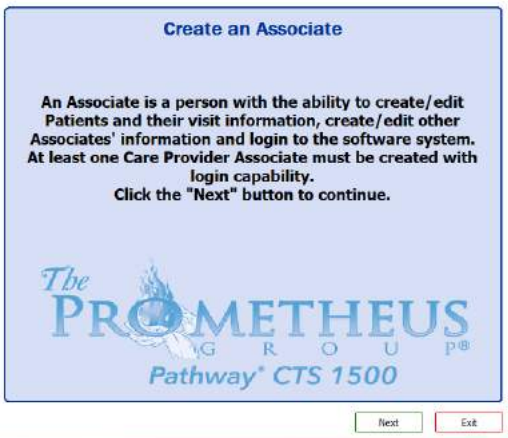
- Enable System Timeout **(minutes)**: **Minimum** (5), **Maximum** (60)

Use the appropriate check boxes and drop-down menus to configure a unique password combination.



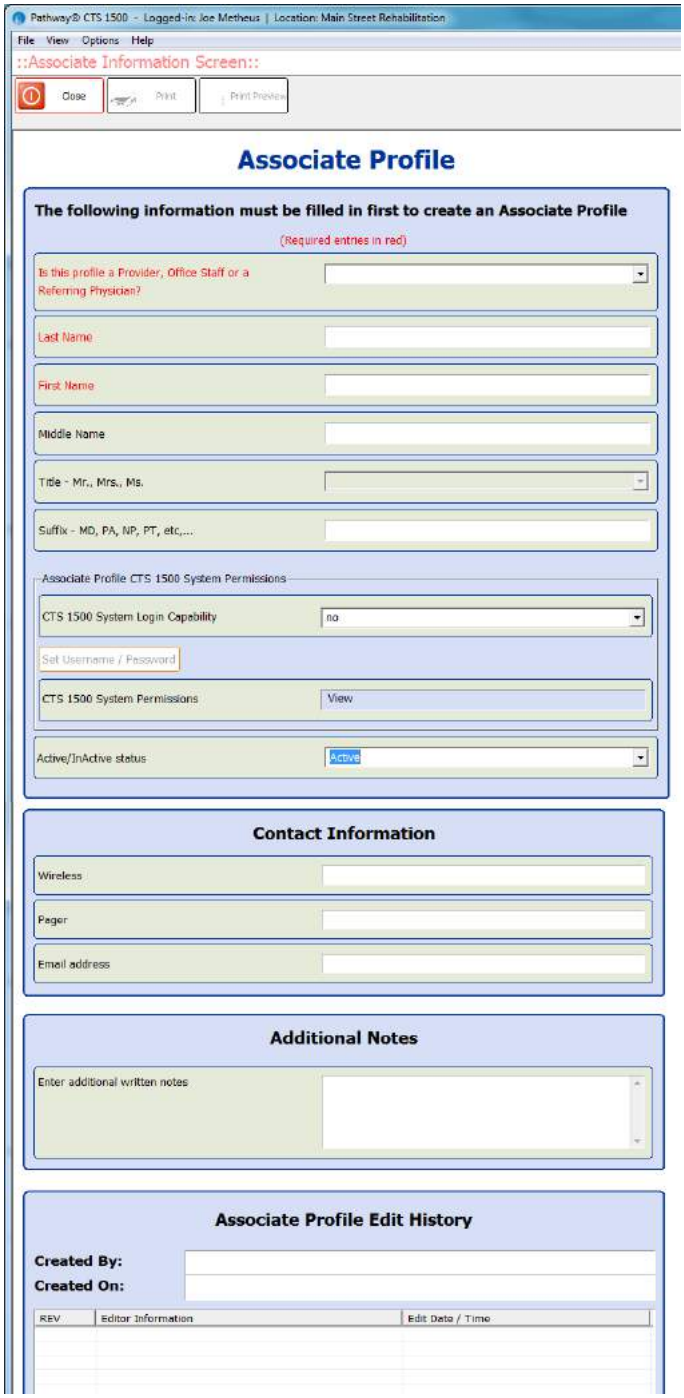
Click **OK** once all settings have been configured.

Create An Associate



1. **Create an Associate** will appear. This is to create an associate with login permissions. Additional associates can be added later. Click **Next**.

2. **Associate Profile** will appear.

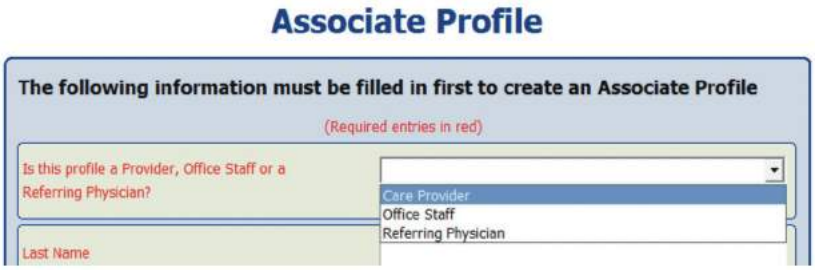


3. Click on the fill-in boxes and key in the information. **All red entry fields must be completed** to satisfy the minimum description requirements. All black entry fields are optional.

Create An Associate

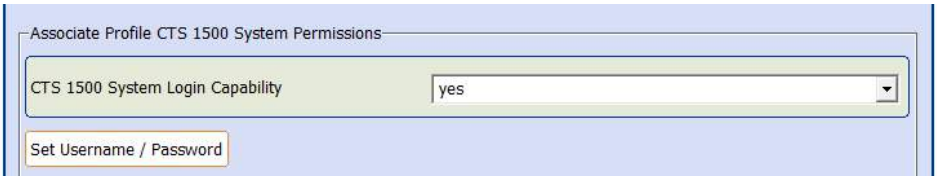
1. In the entry field, **Is this profile a Provider, Office Staff, or a Referring Physician? (**and other similar entry fields with drop-down lists), click on the drop-down arrow to open the list of options. Click on the appropriate option. Note that only a **Care Provider** or **Office Staff** may have login privileges.

> **NOTE:** The initial Associate Profile **MUST** be a **Care Provider**.

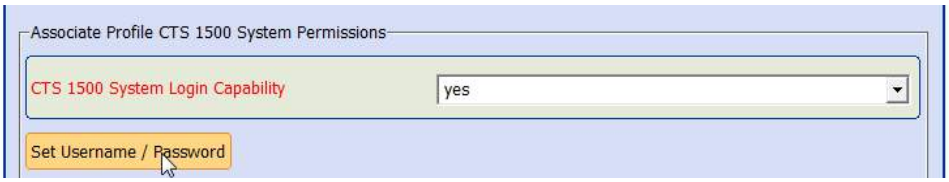


2. Select **Yes** for **CTS 1500 System login capability.**

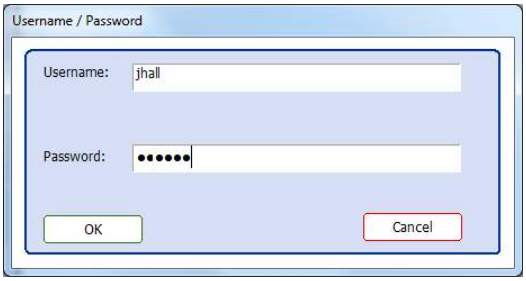
> **NOTE:** The initial Associate **MUST** be given **CTS 1500 System login capability** and **MUST** be given a **Username** and **Password**. The program will not proceed until these steps are taken. The system will automatically assign Admin status to this initial Associate.



3. Click **Set Username/Password.**

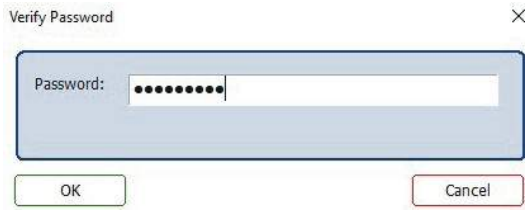


4. Enter the information and click **OK.**



Create An Associate

5. **Verify Password** will appear. Re-enter the password and click **OK**. If the password is not entered exactly as before, the program will prompt for the password to be re-entered correctly.



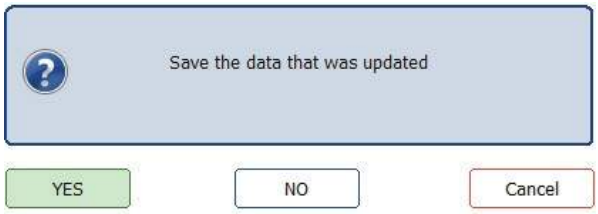
> **NOTE:** It is strongly recommended that the **Username** and **Password** be recorded in a secure location for future reference.

6. OPTIONAL: Additional Associate information may be entered into **Contact Information** and **Additional Notes**. This, and other optional information, can be added later.

7. OPTIONAL: **Associate Profile Edit History** contains profile edit data. This data may be needed for compliance with HIPAA and other legal requirements.

8. There is now enough required information in the **Associate Profile** to satisfy the minimal associate description. Click **Close** to exit.

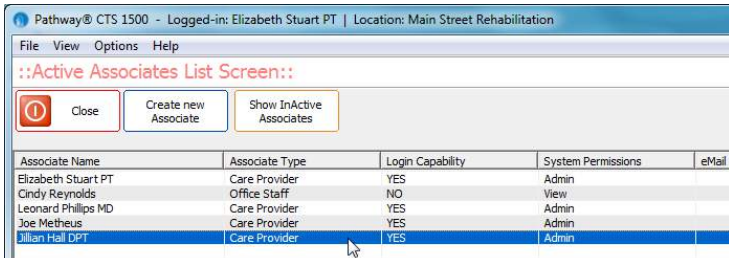
9. **Save the data that was updated** will appear. Click **YES**.



Create An Associate

10. **Saving Associate Data** will appear.

11. **Associates List Screen** will appear. The associate just entered is listed. Additional associates may be entered at this time but are not required, click **Close** to continue the Initial Startup Process.

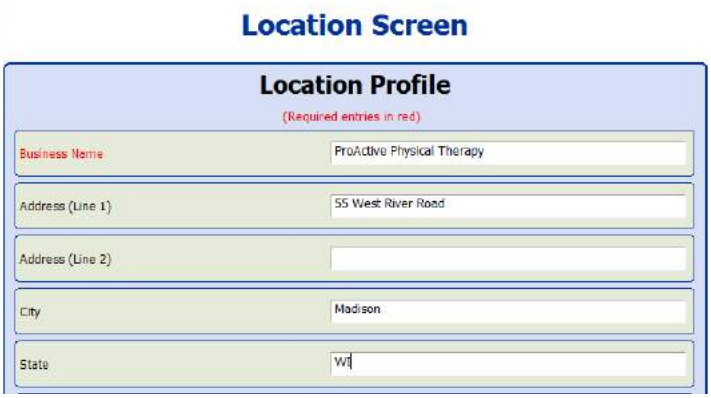


Create A Location

1. **Create a Location** will appear. The purpose of this is to create a place of service. Additional locations, if necessary, can be added later. Click **Next**.

Create A Location

NOTE: The red entry field **Business Name MUST** be filled in. While additional information may be entered later, entering the address and phone number of this location now will complete the header section of the documents.



2. There is now enough required information in the **Location Profile** to satisfy the minimal location description. Click **Close**.

3. **Save the data that was updated** will appear. Click **YES.**

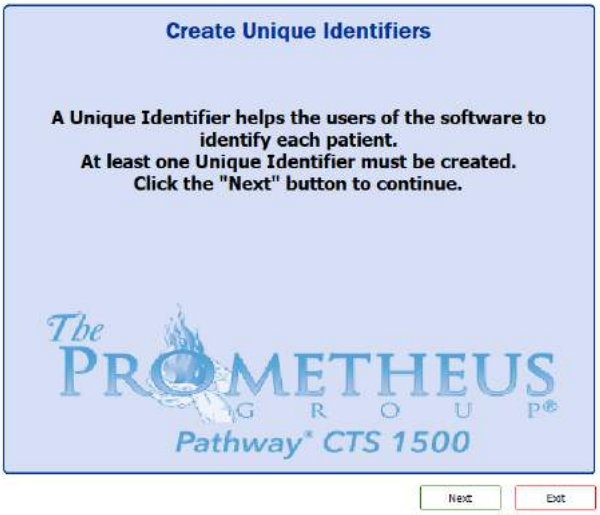
4. **Saving Location Data** will appear.

Create A Location

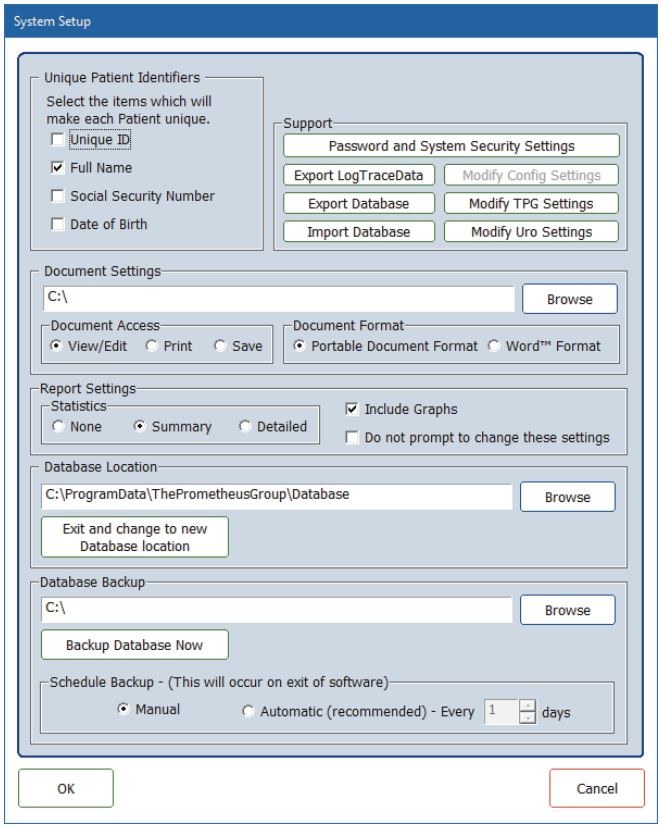
5. **Location List Screen** will appear. Note that the location just entered is listed. Additional locations may be entered at this time but are not required. Click **Close** to continue the Initial Startup Process.

6. There is now enough required information in the Location Profile to satisfy the minimal location description. Click **Close**.

Create Unique Identifiers



1. **Create Unique Identifiers** will appear. This is the method by which patients will be identified in the patient database. This feature ensures that the practice is compliant with HIPAA requirements for patient privacy. Click **Next**.

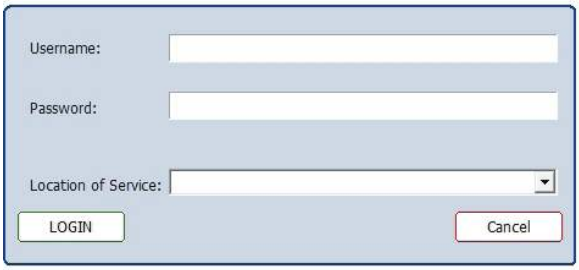


2. Click on the appropriate box or boxes to choose one or more **Unique Patient Identifiers**. Clicking on a box with a check mark (√) removes the check mark and that method of identifying the patient. The example shows **Full Name** checked. Click **OK**.

Create Unique Identifiers

Congratulations!!! will appear. The Initial Startup Process is now complete. Click **Next**.

3. **LOGIN** will appear. Enter the **Username** and **Password** to use the program now. Click the drop-down arrow to select the **Location of Service**. Click on the correct **Location of Service**. Click **LOGIN.**
   Click **Cancel** to exit the program.



Introduction

1. Input the **Username** and **Password** and select the **Location of Service** entered during the Initial Startup Process. Click **LOGIN**.

2. The **Pathway® CTS 1500** Software has two main components:

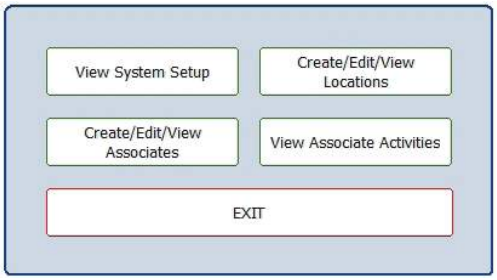
   A). Administrative functions, which are accessed from the opening screen by clicking **Tools:**

   B). Clinical functions, including patient studies, treatments, and documents, which are accessed by clicking **Start Here:**

NOTE: Access to Tools is restricted to Administrators only and is used to **View System Setup, Create/Edit/View Associates, Create/Edit/View Locations**, or **View Associate Activities**. If not adding or changing these, proceed directly to the clinical functions **Start Here**.

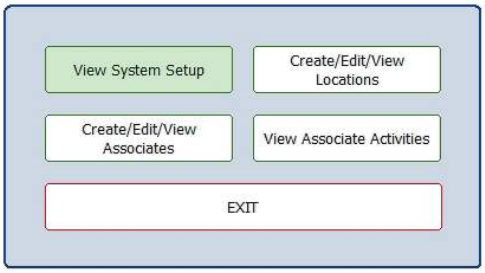
3. Click **Tools:**

4. The **Tools** window will appear:

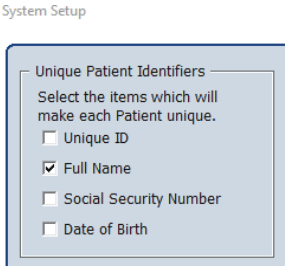


Introduction

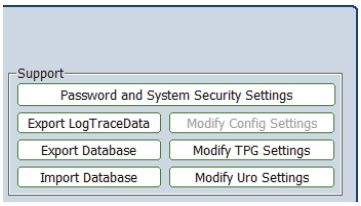
5. Click **View System Setup**:



6. **System Setup** will appear:

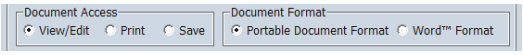


Unique Patient Identifiers: Select from the four options. **Unique ID** will provide the option to enter any sequence of letters and numbers while **Full Name, Social Security Number** and **Date of Birth** will use the patient's existing information.

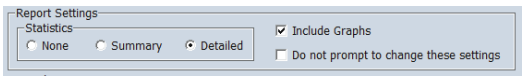


Support: Password and System Security Settings. (Refer to **page 21**). Also, Technical support functions used by The Prometheus Group® when accessing the system remotely. These functions are used to troubleshoot and resolve software issues and potentially diagnose hardware problems.

Document Settings: Default settings where documents will be saved. Allows selection of a specific folder on the computer or network location where documents will be saved when **Save** is selected during the **View/Print/Save Documents** process.



Document Access: Default settings for Documents.

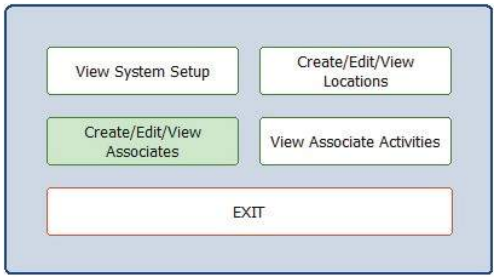


Report Settings: Default settings for Reports.

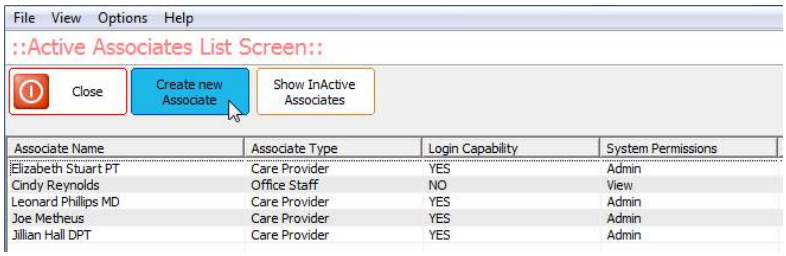
Upon completion of changes to the **System Setup** options, click **OK** to save changes. Clicking **Cancel** will remove any changes made during this visit and exit back to **Tools.**

Create/Edit/View Associates

1. Click **Create/Edit/View Associates.**



2. **Associates List Screen** will appear. Click **Create New Associate**.

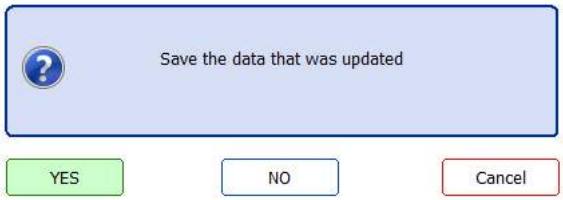


3. **Associate Profile** will appear. Complete as instructed in the Initial Startup Process.

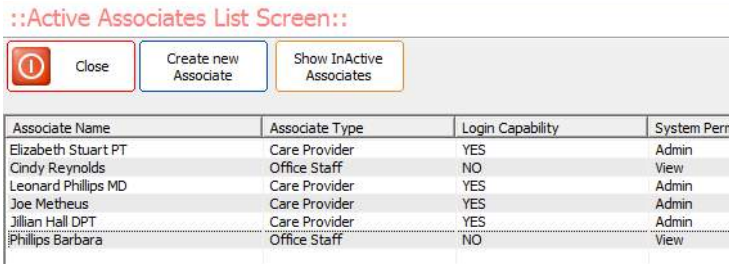
4. Click **Close** on the **Associate Profile** when complete.

Create/Edit/View Associates

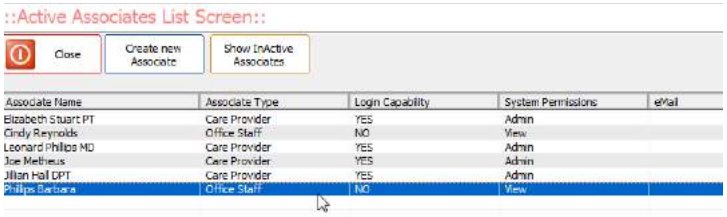
5. Click **YES** to **Save the data that was updated.**



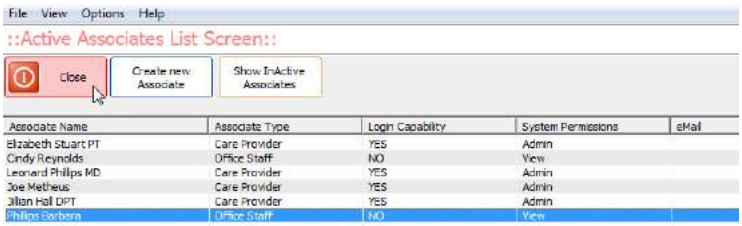
6. **Associates List Screen** will appear with the new entry.



7. To view and/or edit an associate profile, double click an associate name. Associate profile will appear with the information available for viewing/editing. Click **Close** when viewing/editing is complete.
Click **YES** on **Save the data that was updated**.

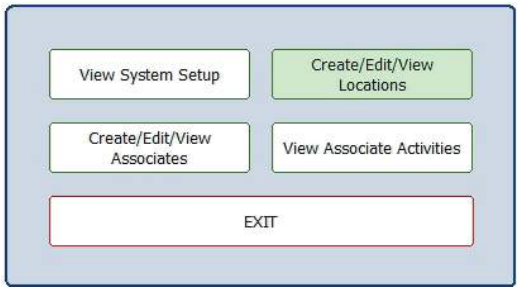


8. Click **Close** on the **Associate List Screen** when creating/editing/viewing associates is complete.

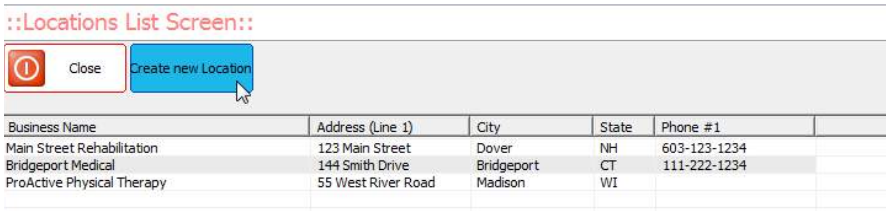


Create/Edit/View Locations

1. Click **Create/Edit/View Locations:**



2. **Locations List Screen** will appear. Click **Create new Location:**

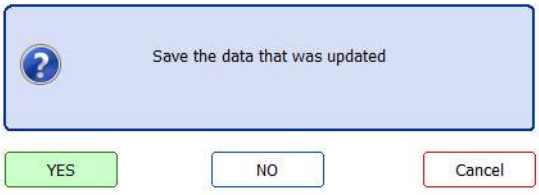


Create/Edit/View Locations

3. **Location Screen** will appear. Complete as instructed in the **Initial Startup Process**.

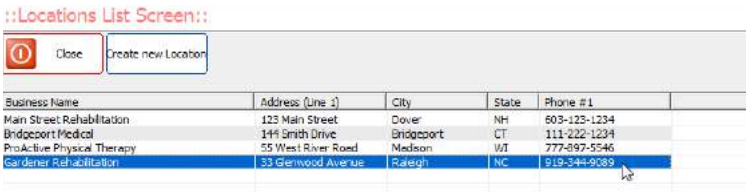
4. Click **Close** on the **Location Screen** when complete.

5. Click **YES** on the **Save the data that was updated.**



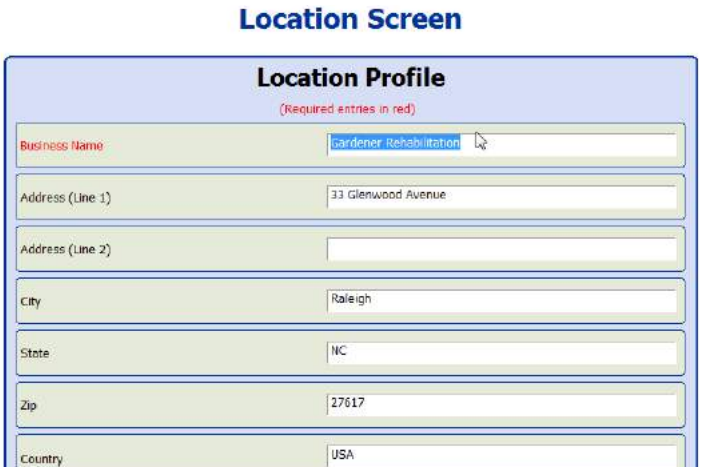
Create/Edit/View Locations

7. **Locations List Screen** will appear with the new entry.



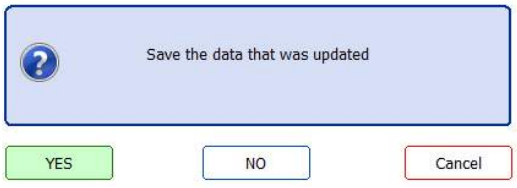
8. To view and/or edit a location on the **Locations List Screen**, double click the **Business Name**.

9. **Location screen** will appear with the information available for viewing/editing.



10. Click **Close** when viewing/editing is complete.

11. Click **YES** on **Save the data that was updated.**



Create a New Patient

1. Click **Create New Patient** to establish a new patient record. Go to the next section, **Select an Existing Patient** to access an existing patient.

2. Enter the patient data. Red entries **MUST** be completed. The provider selected should be the patient's primary provider. Click **Add New Provider** and create an **Associate Profile** if the provider does **NOT** appear on the list. Click **Save New Patient**. The **Patient Selection Screen** is now populated with the information.

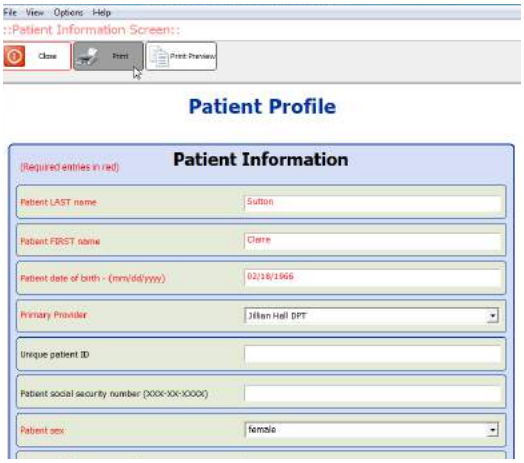
> **NOTE:** Red entries will vary depending on what is specified as **Unique Patient Identifiers.** In the example below, **Full Name** was specified and **Unique ID, Social Security Number** and **Date of Birth** were **NOT** specified.

3. Click **Create New Patient** and repeat Step 2 to create additional new patients.

Create a New Patient

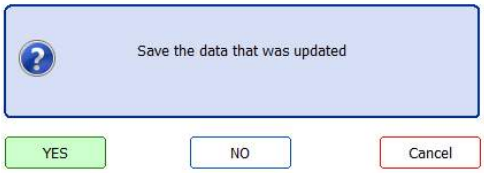
4. To edit/review patient information click **Edit/Review Additional Patient Information**. The **Patient Information Screen** will open.

5. Patient information can be edited/reviewed as necessary. Click **Print** and **Print Preview** to print the patient information.



6. Click **Close** when complete.

7. **Save the data that was updated** will appear. Click **YES** to exit and save the changes. Click **NO** to exit without saving the changes. Click **Cancel** to make additional changes. Click **YES**.



Create a New Patient

8. **Saving Patient Data** will appear.

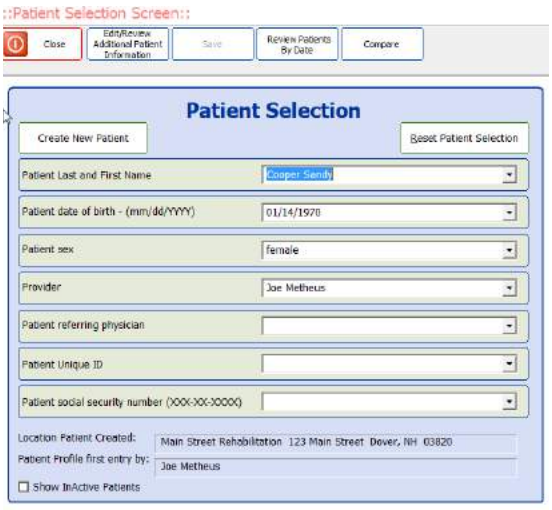
Select an Existing Patient

Selecting an **Existing Patient** in the **Patient Selection** Window can be done one of two ways:

1. In the **Patient Last** and **First Name** field, click the drop-down arrow and select the patient using the scroll bar or,

2. Key in the **Patient Last** and **First Name**. Note, if you have multiple patients with the same last name, key in the **Patient's First Name** to find the appropriate patient.

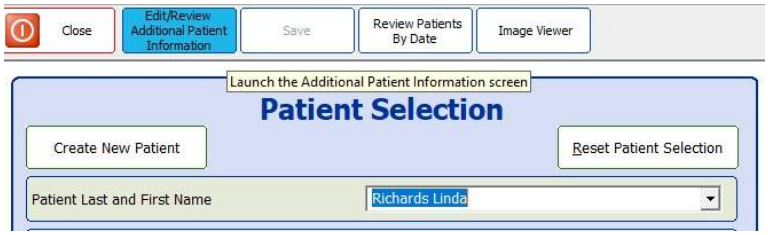
3. **Patient Selection** will automatically populate the patient's information.



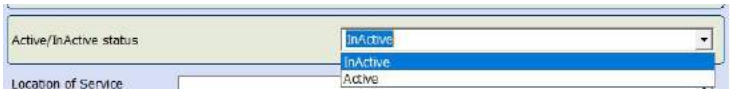
4. Click **Reset Patient Selection** to choose a different patient.

Select an Existing Patient

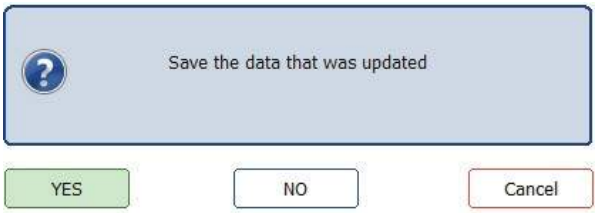
5. To place a patient on the **InActive** list, populate the **Patient Selection** screen with the patient and click **Edit/Review Additional Patient Information**.



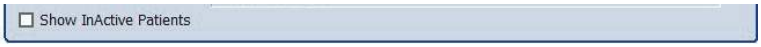
6. Click the drop-down arrow in the **Active/InActive** Status box and click **InActive**.



7. Click **Close. Save the data that was updated** will appear. Click **YES**.

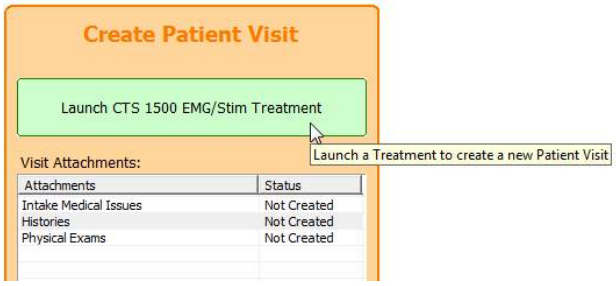


8. Check the **Show InActive Patients** box on the **Patient Selection** screen to show the inactive patient list. Follow the same steps as # 5 above to return a patient to the active list. Click **Active** in the **Active/InActive Status** box. Click **Close. Save the data that was updated** will appear. Click **YES**.



Create a Patient Visit

Once a patient is selected, **Create Patient Visit** is active, and **Launch CTS 1500 EMG/Stim Treatment** or **Attachments** can be selected.

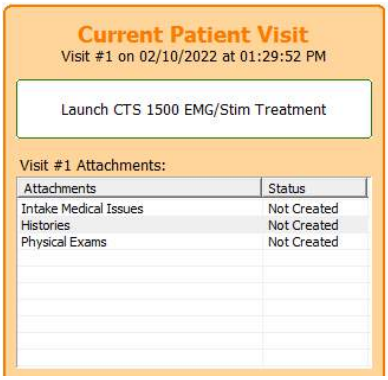


Attachments

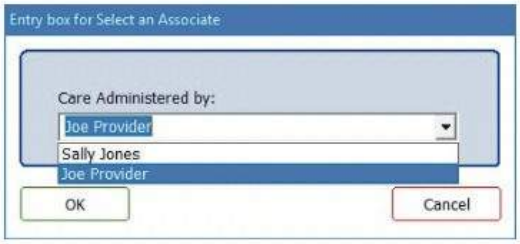
Four Attachments are available: **Intake Medical Issues**, **Histories**, **Physical Exams** and **Procedures**.

Intake Medical Issues.

1. Double click Intake Medical Issues.



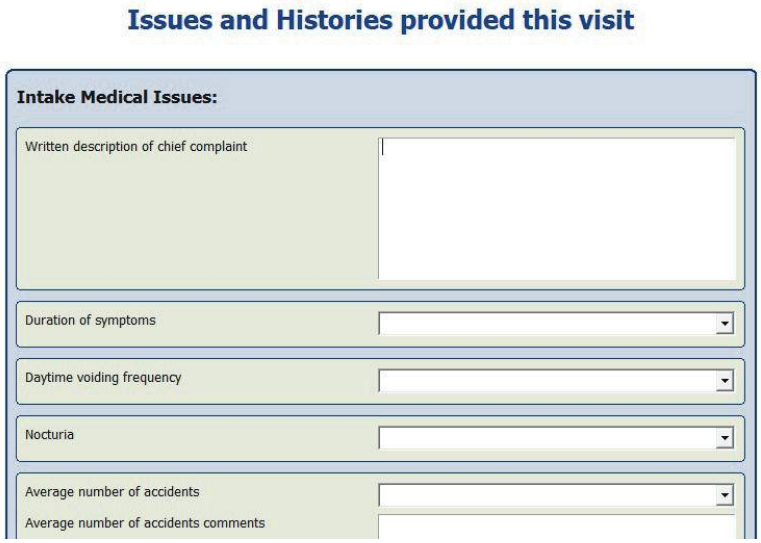
2. **Entry box for Select an Associate** will appear. Click the drop-down arrow to expand the list. Click the correct associate. Click **OK.**



NOTE: Be sure to select the associate who is actually administering the patient care.

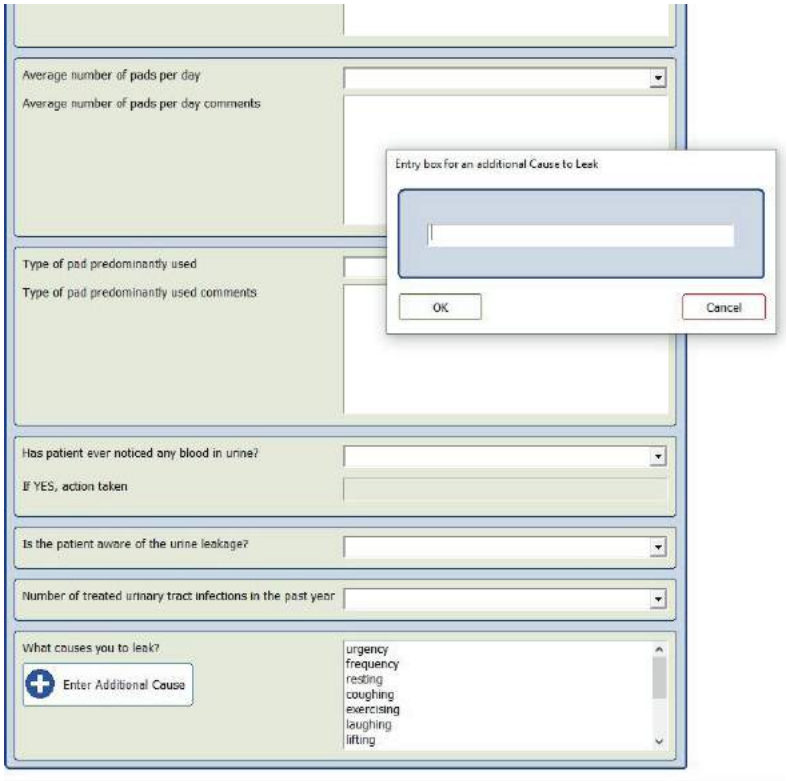
3. **Creating Patient Visit** will appear.

4. **Issues and Histories provided this visit** will appear. Enter the **Written description of chief complaint** by keying in the window. Complete the remainder by clicking on the drop-down arrow and clicking an option.
   Add **comments** by keying in the selected window.



5. In the **What causes you to leak?** section use the scroll bar to access additional causes Click on the cause(s) to select. Click on the selected cause(s) to deselect.

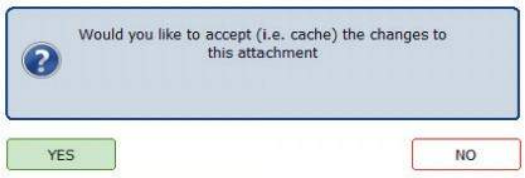
6. Click **Enter Additional Cause** and key in if the cause does not appear on the list. Click **OK.**



Attachments

7. Click **Close**.

8. Click **Yes.**

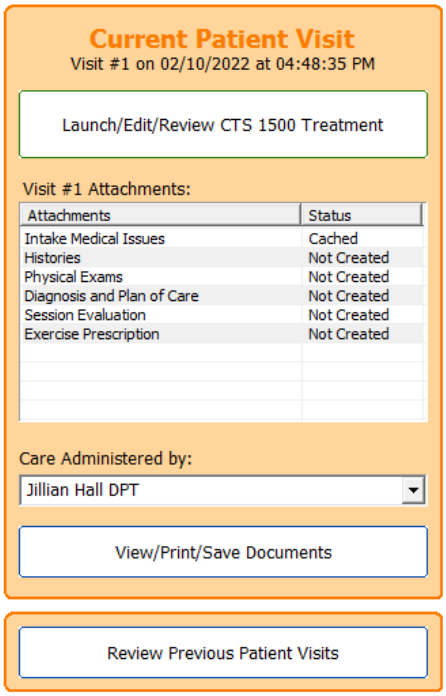


9. When the **Patient Selection Screen** reappears:

   i. **Create Patient Visit** becomes **Current Patient Visit** with a visit number, date, and time.

   ii. The status of **Intake Medical Issues** is now **Cached** (saved in memory).

   iii. A **Care Administered by** box appears with the associate selected when accessing **Intake Medical Issues**

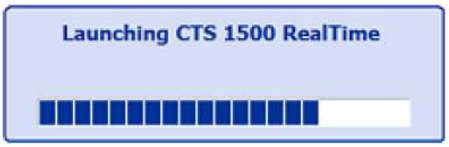


NOTE: Once **Intake Medical Issues** is completed, future patient visits will become **Current Medical Issues**. **Attachments** can be completed prior to or after Launch **CTS 1500 EMG/Stim Treatment** or at a future time.

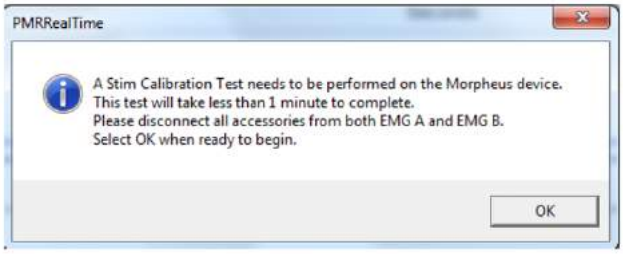
Launching Treatment

1. Click **Launch CTS 1500 EMG/Stim Treatment**

2. Save the data that was updated will appear. Click Yes. **Intake Medical Issues** will move from a **Cached** to a **Created** status.
3. **Launching CTS 1500 RealTime** will appear.

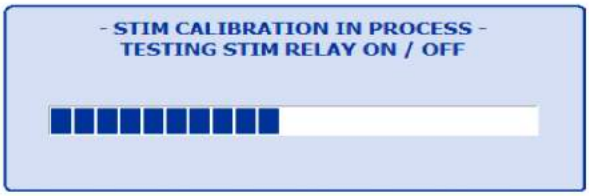


4. An automatic **Stimulation Calibration Test** is performed for the first launch of each day. Click **OK**.

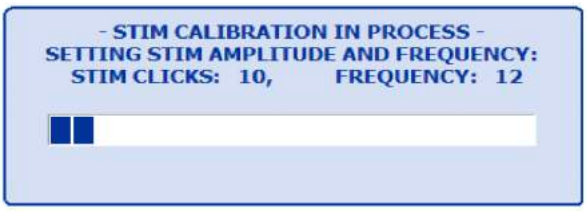


Launching Treatment

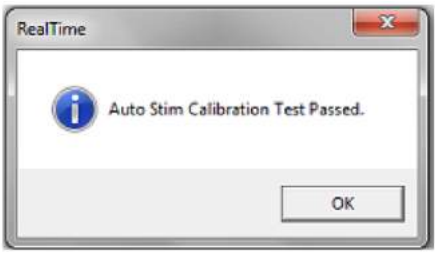
5. **STIM CALIBRATION IN PROCESS – TESTING STIM RELAY ON / OFF** will appear.



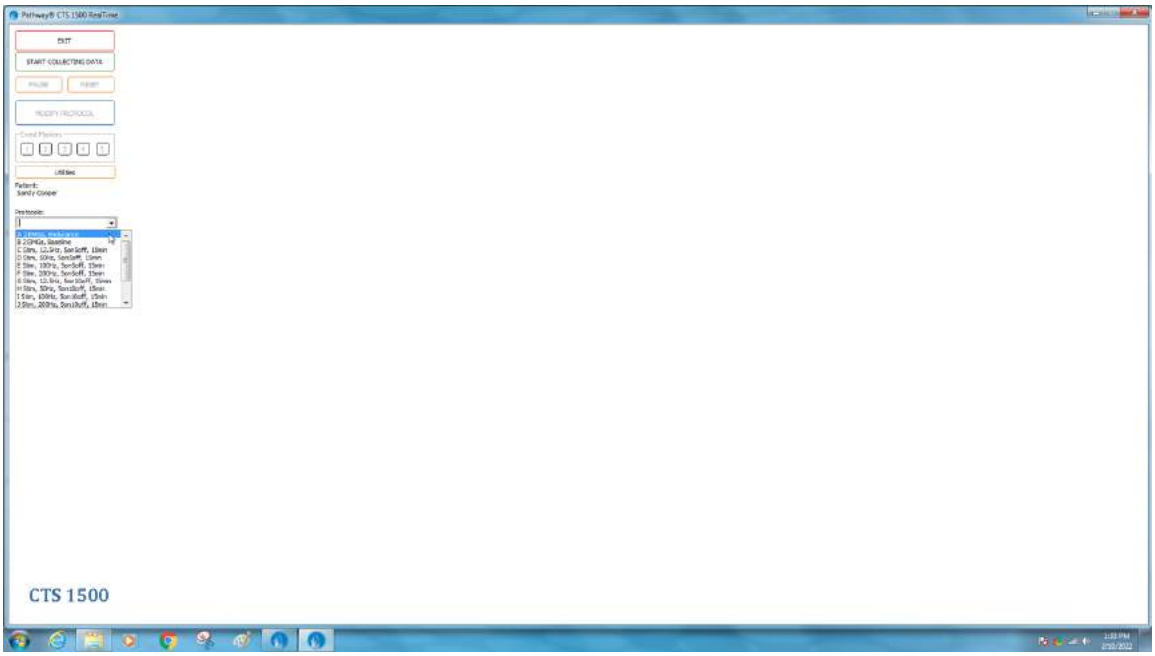
6. Followed by **STIM CALIBRATION IN PROCESS – SETTING STIM AMPLITUDE AND FREQUENCY:**



7. Once the stimulation values are calibrated **Auto CALIBRATION TEST PASSED** will appear. Click **OK**.



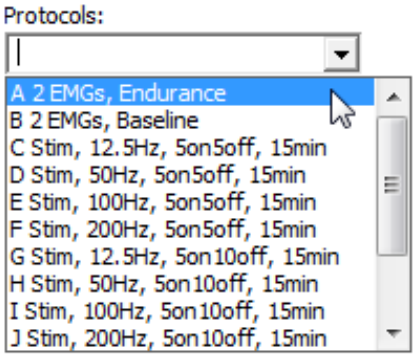
8. **CTS 1500 RealTime** will appear.



Protocols

9. Click the drop-down list arrow under **Treatment Protocols**.

10. Fourteen **Treatment Protocols** are available:



A 2 EMGs, Endurance provides two EMG channels integrated into a dual screen display acquiring data from **EMG A/STIM and EMG B**. **Endurance** describes a work (contract)/rest (relax) protocol for a specific number of trials (repetitions). This protocol has default values of 10 seconds work, 10 seconds rest and 20 trials.

B 2 EMGs, Baseline provides two EMG channels integrated into a dual screen display acquiring data from **EMG A/STIM and EMG B**. **Baseline** describes a continuous (non-work/rest) protocol.

C Stim, 12.5Hz, 5on5off, 15min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **12.5Hz** denotes the frequency of stimulation. **5on5off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

D Stim, 50Hz, 5on5off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **50Hz** denotes the frequency of stimulation. **5on5off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

E Stim, 100Hz, 5on5off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **100Hz** denotes the frequency of stimulation. **5on5off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

F Stim, 200Hz, 5on5off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **200Hz** denotes the frequency of stimulation. **5on5off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

G Stim, 12.5Hz, 5on10off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **12.5Hz** denotes the frequency of stimulation. **5on10off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

H Stim, 50Hz, 5on10off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **50Hz** denotes the frequency of stimulation. **5on10off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

Protocols

I Stim,100Hz, 5on10off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **100Hz** denotes the frequency of stimulation. **5on10off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

J Stim, 200Hz, 5on10off, 15 min provides synchronous EMG and stimulation integrated into a single screen display acquiring data from the **EMG A/Stim**. **200Hz** denotes the frequency of stimulation. **5on10off** denotes the stimulation on and off time in seconds. EMG is provided during the stimulation off time to measure muscle strength, fatigue, or awareness. **15min** denotes the total treatment time of 15 minutes.

K Stim,12.5Hz, Continuous, 15 min provides stimulation on a single screen display acquiring data from the **EMG A/Stim**. **12.5Hz** denotes the frequency of stimulation. **Continuous** denotes continuous stimulation. **15min** denotes the total treatment time of 15 minutes.

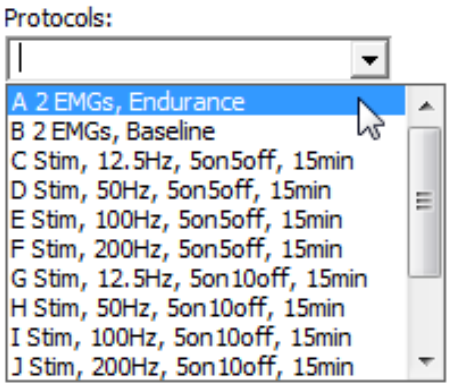
L Stim, 50Hz, Continuous, 15 min provides stimulation on a single screen display acquiring data from the **EMG A/Stim**. **50Hz** denotes the frequency of stimulation. **Continuous** denotes continuous stimulation. **15min** denotes the total treatment time of 15 minutes.

M Stim, 100Hz, Continuous, 15 min provides stimulation on a single screen display acquiring data from the **EMG A/Stim**. **100Hz** denotes the frequency of stimulation. **Continuous** denotes continuous stimulation. **15min** denotes the total treatment time of 15 minutes.

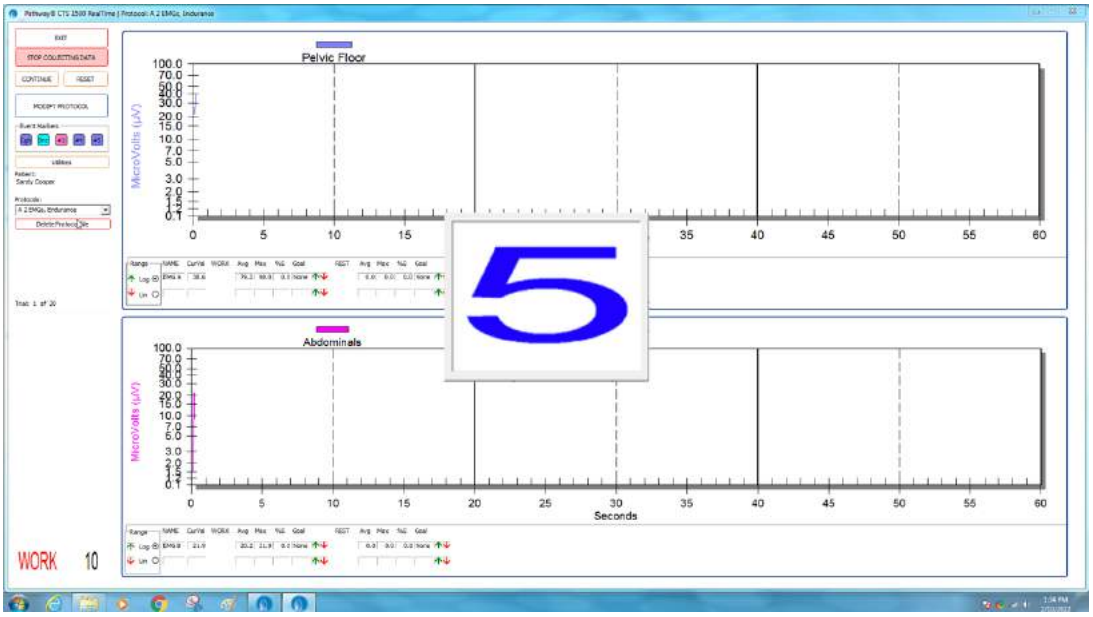
N Stim, 200Hz, Continuous, 15 min provides stimulation on a single screen display acquiring data from the **EMG A/Stim**. **200Hz** denotes the frequency of stimulation. **Continuous** denotes continuous stimulation. **15min** denotes the total treatment time of 15 minutes.

A 2EMGs, Endurance

1. Click **A 2EMGs, Endurance**.



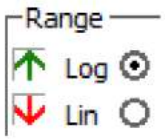
2. The screen will be active and begin data collection. A 5 second countdown will start followed by the first 10 second work interval. Click **PAUSE** to freeze the display (**PAUSE** will now read **CONTINUE**). Click **CONTINUE** to resume the display. Click **RESET** to restart the display. Click **STOP COLLECTING DATA** to stop a treatment.



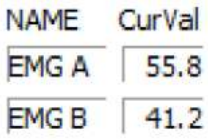
3. The top graph displays the **EMG A** channel and the bottom graph the **EMG B** channel. The **EMG A** channel measures the muscle activity of the **Pelvic Floor** in µV (microvolts), and the **EMG B** channel measures the activity of the accessory muscle (in this example **Abdominals**) in µV.

A 2EMGs, Endurance

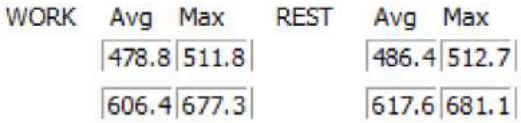
4. The total µ**V Range** for **EMG A** and **EMG B** is **0.1-1000** µ**V** with a display default range of **0.1-100** µ**V**. If a **Range** change is required, click the **Up** Arrow in the **Range** box to increase, the **Down** Arrow to decrease.



5. To the right of the **Range** box, the current value (**CurVal**) in µ**V** for each channel is displayed.



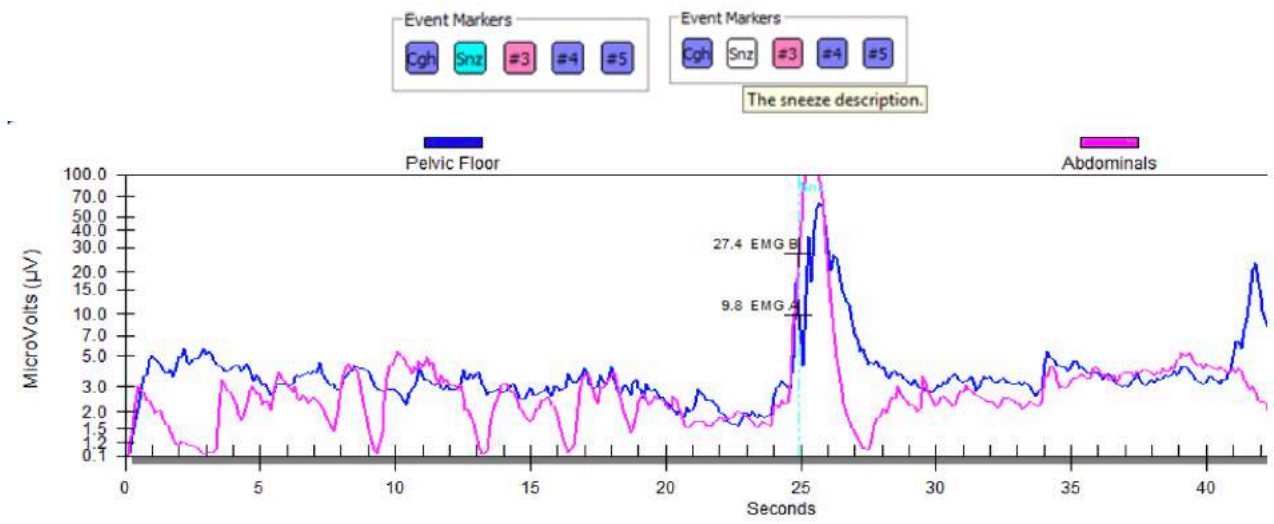
6. To the right of the **CurVal**, a work/rest protocol activates both the **WORK** and **REST** average (**Avg**) and maximum (**Max**) µV display.



7. To the right of **Avg** and **Max** are **%S** and **Goal** columns. A treatment goal can be established in µ**V** for each channel and, in this case, for **BOTH WORK** and **REST** intervals. The treatment goal will appear as a line on the graph. The **%S** will track the percentage success in attaining the treatment goal and the **Goal** column will display whether the treatment goal is to contract **AbvTn** (above) the goal or relax **BlwTn** (below). Successfully meeting a goal triggers audio feedback**.** If more than one goal is set, the audio feedback will be matrixed so that all goals must be met simultaneously**.** Click the **Up** and **Down Arrows** to move the goal line.

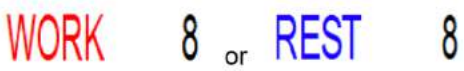
A 2EMGs, Endurance

8. **Event Markers** mark anomalies such as the patient coughing, sneezing, or moving. Click on an event marker. This will place a marker line on the graph. In this example, **Snz** (Sneeze) is selected.



9. The current **Trial** number is displayed. The total number of trials is 20.

10. A work/rest protocol activates a **WORK** and **REST** countdown as well as audio cues delineating the beginning of a work or rest interval.



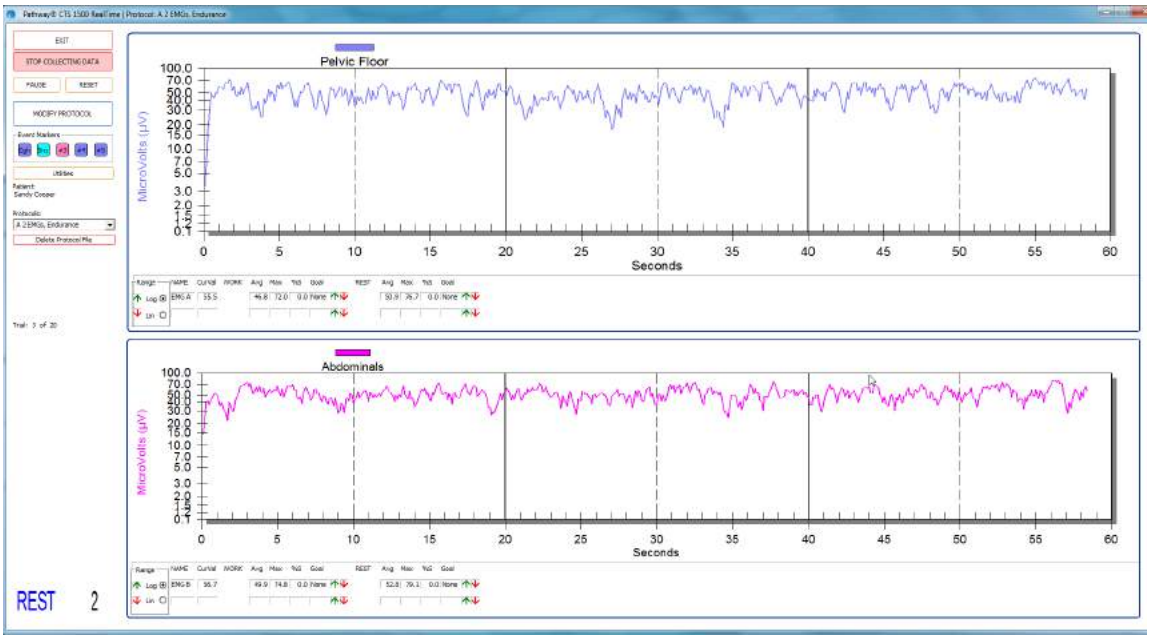
11. Click **STOP COLLECTING DATA** at any time to truncate the treatment.

A 2EMGs, Endurance

12. The treatment will automatically end once 20 trials are complete. Click **STOP COLLECTING DATA**.

13. **End Session and Save Data?** Select **YES**, **NO** or **CANCEL** will appear.

14. Click **Yes** and a **Review Screen** will appear.

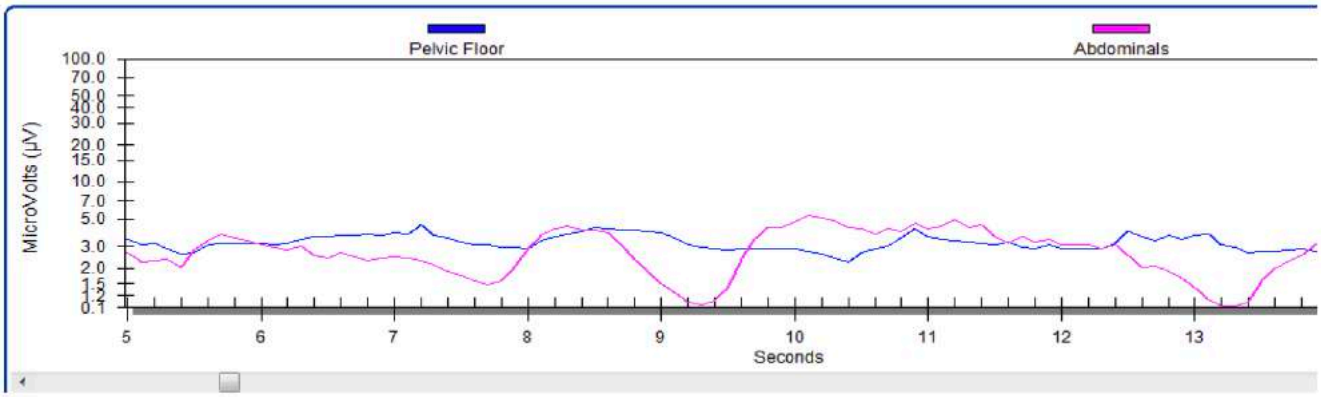


15. **Zoom** is available to magnify a portion of the graph display.

16. Place the cursor on the graph at the beginning point (must be just past the 0 ordinate). Hold down the left mouse button. The cursor will change to a magnifying glass. Drag the magnifying glass to the desired right most position. Release. The selected portion of the graph will fill the window. Repeat to expand this area further.

A 2EMGs, Endurance

17. A scroll bar now appears at the bottom of the graph. The entire treatment may be viewed in the zoomed mode by using the scroll bar.

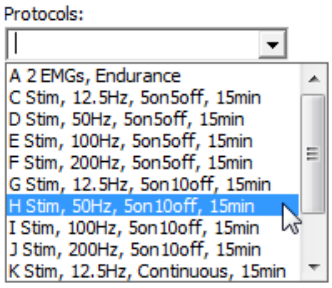


18. To add an **Event Marker,** click the desired marker. The cursor inside the graph will change to a pointing finger with the marker line. Move the pointing finger to the desired marker location and double click.
19. To move an **Event Marker**, place the cursor over the marker line. The cursor will change to a pointing finger. Double Click. The line will change from a solid to a dotted line. Move the pointing finger and the marker line will also move. Move the pointing finger to the desired marker location and double click.
20. To delete an **Event Marker,** double click the marker line then press the **Delete** key on the keyboard.
21. Click **Undo Zoom** to return the graph to the original view.
22. Click **PRINT DISPLAY** if a printed screen copy is needed.

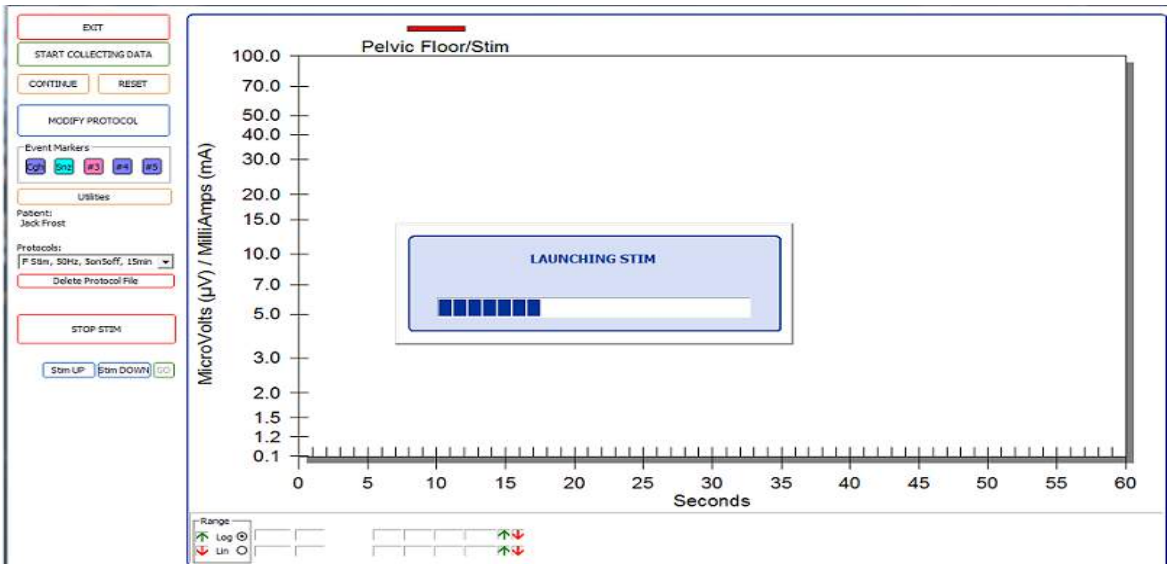
23. While in the review window another treatment may be launched. The user may launch, complete, save, review, and edit up to **SIX** treatments of any combination within a single session.

H Stim, 50Hz, 5on10off, 15min

1. Click **H Stim, 50Hz, 5on10off, 15min**



2. **LAUNCHING STIM** will appear.



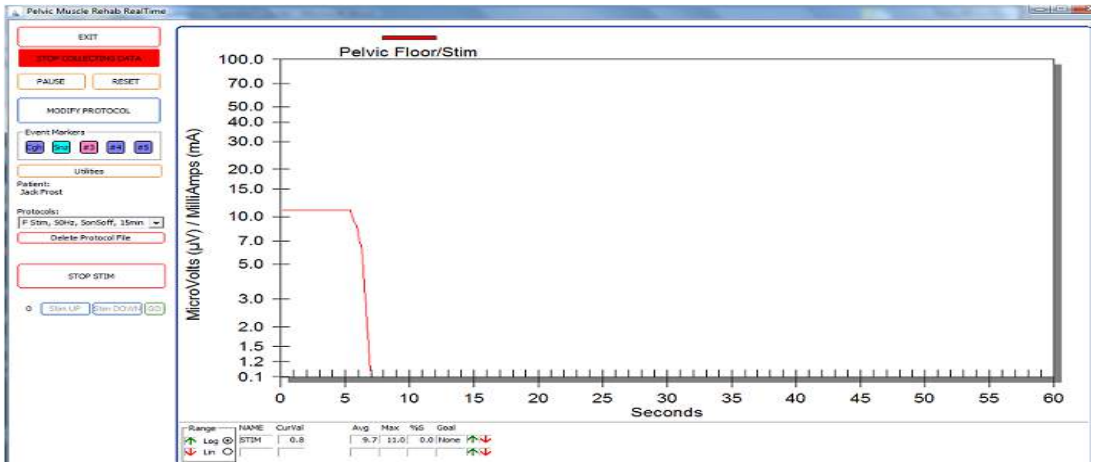
3. The screen will be active and begin data collection.

4. Click **Stim UP** until the required level of stimulation amplitude is reached. Note the level on the amplitude counter. Each click increases the stimulation amplitude **one MilliAmp** (mA). **Stim DOWN** functions the same to decrease the stimulation amplitude.

5. Once the required stimulation amplitude is reached, click **GO**.

H Stim, 50Hz, 5on10off, 15min

6. The 15 minute stimulation session will begin.



7. Click **PAUSE** to freeze the display (**PAUSE** will now read **CONTINUE**). Stimulation will stop. Click **CONTINUE** to resume the display. Stimulation will resume. Click **RESET** to restart the display. Stimulation will restart.

8. The stimulation amplitude can be adjusted during the treatment. **Stim UP** and **Stim DOWN** will be active only when stimulation has reached the peak amplitude set by clicking **GO.** During ramp up, ramp down and EMG**, Stim UP** and **Stim DOWN** are **NOT** active.
9. Click **STOP STIM** at any time to truncate the stimulation treatment.

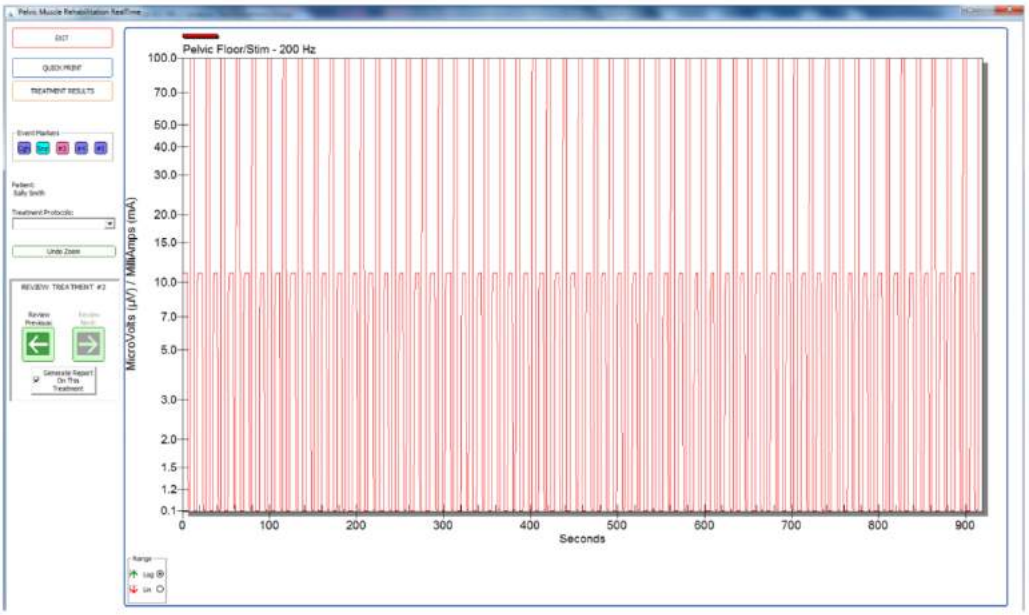
9. EMG will remain active on the display. **STOP STIM** now becomes **START STIM**. Click **START STIM** to start a new treatment or **STOP COLLECTING DATA** to end the treatment.

10. Whether the treatment is truncated or runs the full 15 minutes, stimulation will stop, and **EMG** will remain active on the display. Click **STOP COLLECTING DATA** to end the treatment.

H Stim, 50Hz, 5on10off, 15min

12. **End Session and Save Data?** Select **YES**, **NO** or **CANCEL** will appear.

13. Click **Yes** and a review screen will appear.



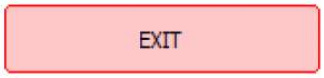
14. Now that two treatments are saved, the previous treatment may be reviewed by clicking on the **Review Previous** green arrow. A **Review Next** green arrow is provided as well. In the **REVIEW TREATMENT** area, the **Generate Report On This Treatment** has a check mark. Click the check mark to remove this treatment from inclusion in generated documents. Click to restore the check mark.

15. The **Zoom**, **Undo Zoom** and **Event Markers** functions are active for each treatment.

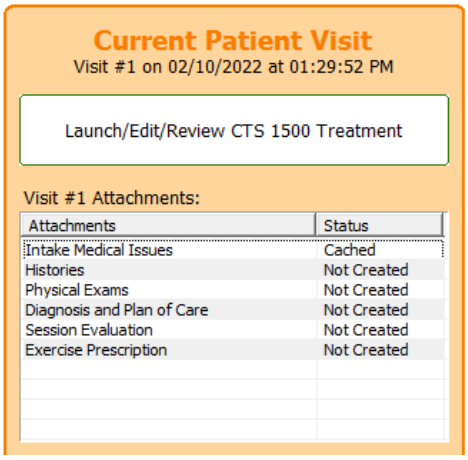
16. Click **PRINT DISPLAY** if a printed screen copy is needed.

H Stim, 50Hz, 5on10off, 15min

17. Click **Exit** once all treatments and changes are complete.

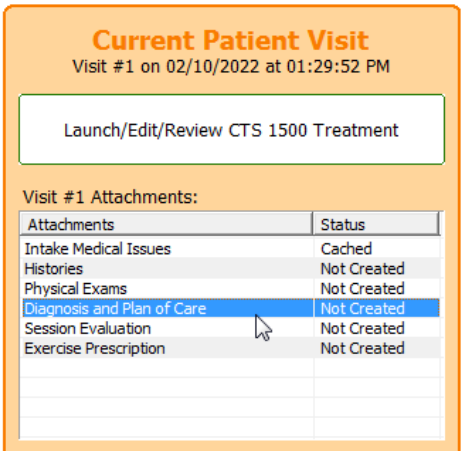


18. **Patient Selection Screen** will appear. In **Current Patient Visit, Diagnosis and Plan of Care**, **Session Evaluation** and **Exercise Prescription** attachments have been added.



Diagnosis and Plan of Care

1. Double click **Diagnosis and Plan of Care**.



Diagnosis and Plan of Care

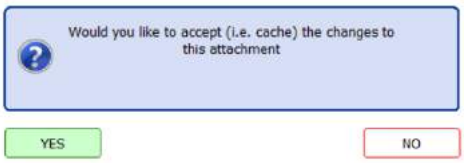
2. **Procedures Administered this Visit** will open. Complete **Diagnosis** by clicking the appropriate option(s). Use the scroll bar if necessary. Click on a selected option(s) to deselect.

3. **Plan of Care: Enter Additional patient notes for follow-up visit** allows the input of commonly used terms or phrases which, after entered and clicked on, appear in **Additional patient notes for follow-up visit** for further editing.

4. **Additional patient notes for follow-up visit** terms and phrases automatically carry forward for use with all subsequent treatments.

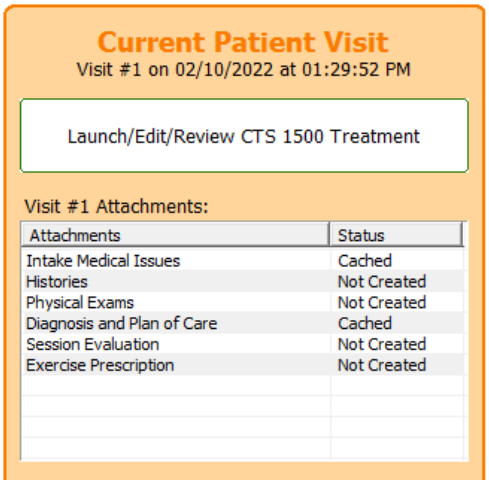
5. Click **Close**.

6. Click **YES**.



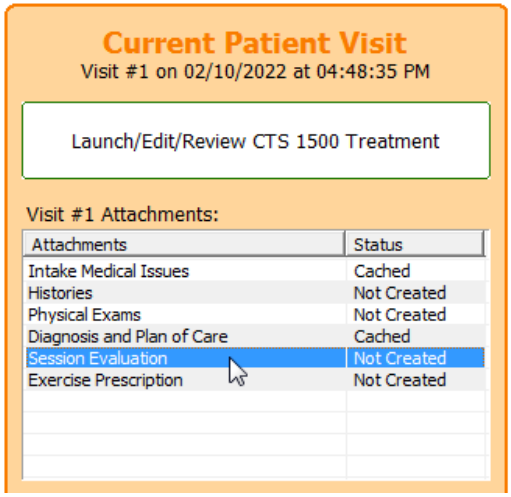
Diagnosis and Plan of Care

7. **Diagnosis and Plan of Care** is now **Cached**.



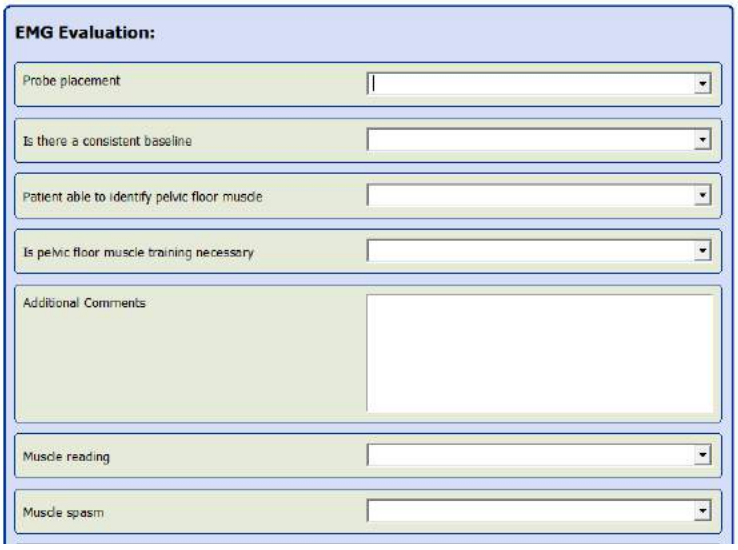
Session Evaluation

1. Double click **Session Evaluation**.



2. **Procedures Administered this Visit** will open.

3. Complete **EMG Evaluation** by selecting from drop-down menus**. Additional Comments** allows the input of commonly used terms or phrases which, after entered and clicked on, appear in the **Additional Comments** for further editing.

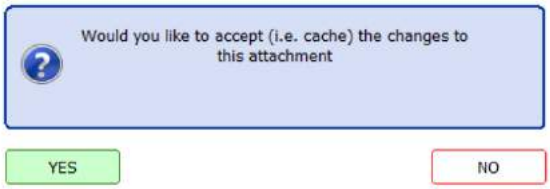


Session Evaluation

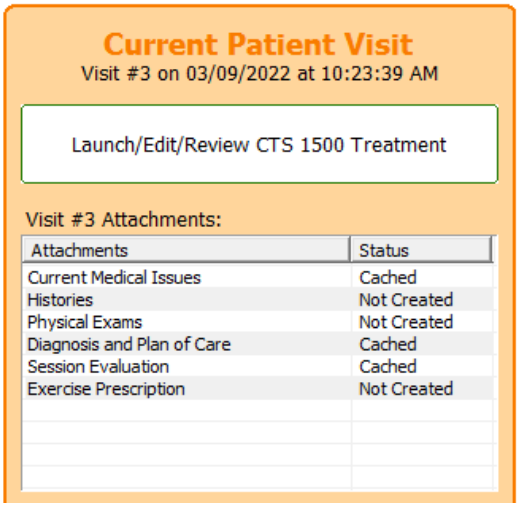
4. **Additional Comments** terms and phrases automatically carry forward for use with all subsequent treatments.

5. Click **Close**.

6. Click **YES**.

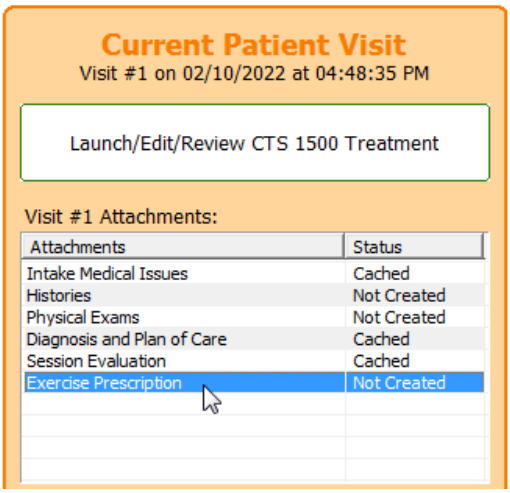


7. **Session Evaluation** is now **Cached**.



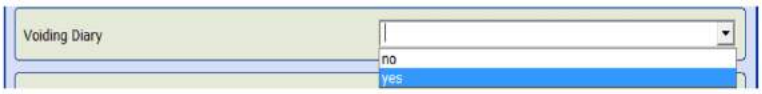
Exercise Prescription

1. Double click **Exercise Prescription**.



2. **Procedures Administered this Visit** will open.
3. Complete the **Exercise Prescription** from drop-down menus and input boxes.

4. If a **Voiding Diary** is required select **yes**.



Exercise Prescription

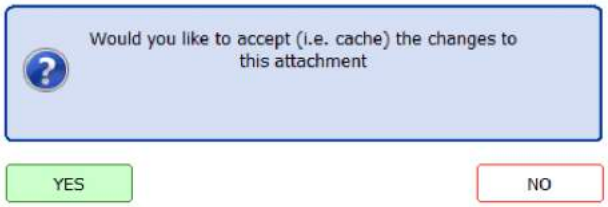
5. **Additional Comments** allows the input of commonly used terms or phrases which, after entered and clicked on, appear in the **Additional Comments** for further editing.

6. **Additional Comments** terms and phrases automatically carry forward for use with all subsequent treatments.

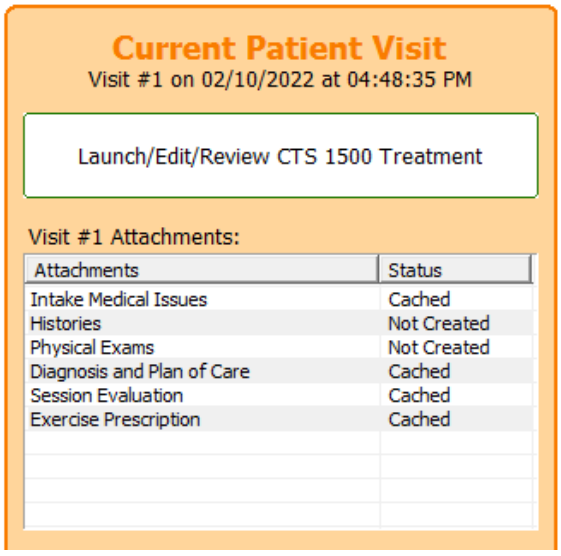
> **NOTE:** For comparison and progress tracking, the **previous Exercise Prescription** will show in red on the **Exercise Prescription** screen.

7. Click **Close**.

8. Click **YES**.

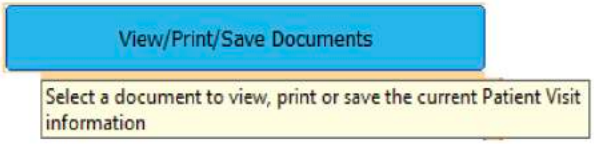


9. **Exercise Prescription** is now **Cached.**

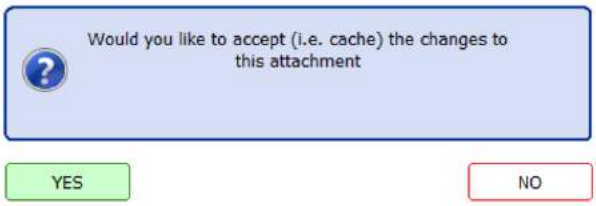


Opening Documents

1. The program automatically compiles patient and provider information, **Attachments,** and treatment results to generate documents in Adobe® Acrobat® **PDF** or **Word™ (Editable)** file format. **Documents** can be viewed, edited, printed, and saved to another location. To open **Documents**, click **View/Print/Save Documents**.

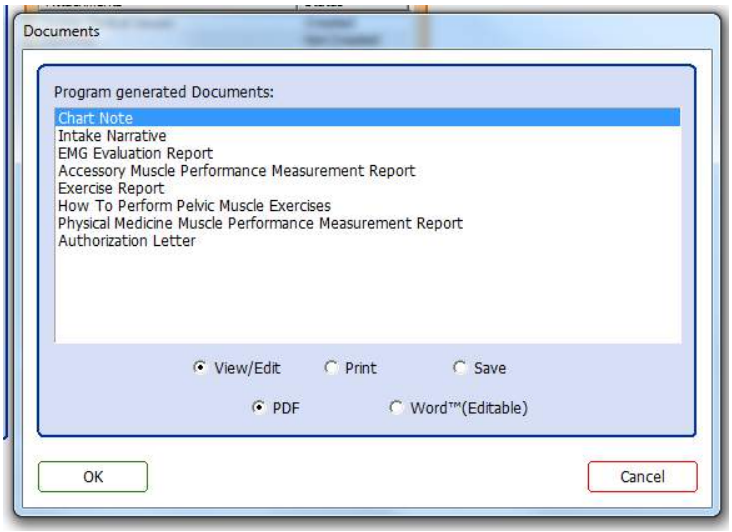


2. **Save the data that was updated** will appear. Click **YES**. This will move all **Attachments** from a **Cached** to a **Created** status.



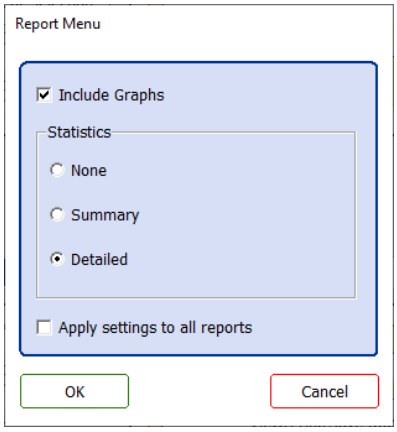
3. A **Documents** window will appear. Choose **View/Edit, Print** or **Save** in a **PDF** or **Word™ (Editable)** format**.** Only the **Word™ (Editable)** format will activate the **Edit** function for the **View/Edit** option**.** A comprehensive list of **Documents** include: **Chart Note, Intake Narrative, EMG Evaluation Report, Accessory Muscle Performance Measurement Report, Exercise Report, How To Perform Pelvic Muscle Exercises, Physical Medicine Muscle Performance Measurement Report, Pelvic Floor Muscle Stimulation Report, Authorization Letter, Referral Letter** and **Conclusion of Treatment Referral Letter.** A single **Document** or **Documents** in any combination can be accessed by clicking on the individual **Documents**. The selected **Document(s)** will be highlighted. To deselect click on the highlighted **Document(s).**

4. In this example **Chart Note**, **View/Edit** and **PDF** are selected. Click **OK**.



Opening Documents

6. **Report Menu** will appear. Click on the provided options. Click **OK**.



7. **Processing Chart Note** will appear.

Opening Documents

8. The **Chart Note** will be generated. To print, click on the **printer icon** on the top toolbar or click **File** on the top toolbar and click **Print**. The **Chart Note** can also be printed directly from **Program generated Documents**.

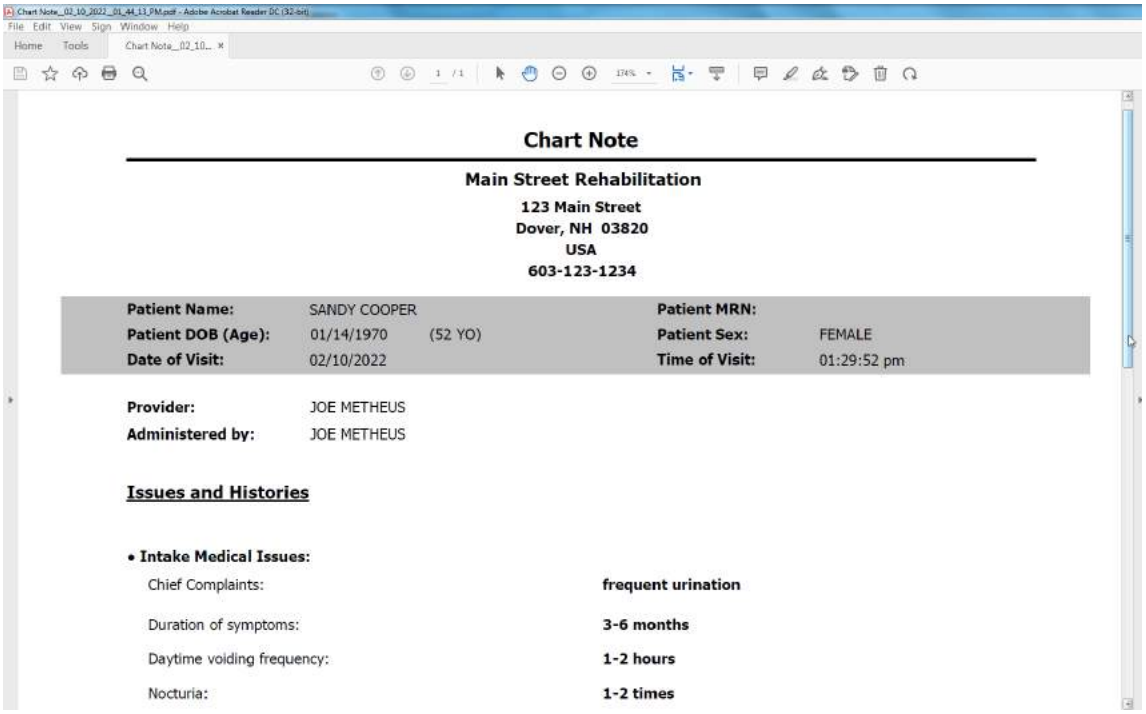


Chart Note

Main Street Rehabilitation
123 Main Street
Dover, NH 03820
USA
603-123-1234

Patient Name:	SANDY COOPER	**Patient MRN:**	
Patient DOB (Age):	01/14/1970 (52 YO)	**Patient Sex:**	FEMALE
Date of Visit:	02/10/2022	**Time of Visit:**	01:29:52 pm

Provider: JOE METHEUS
Administered by: JOE METHEUS

Issues and Histories

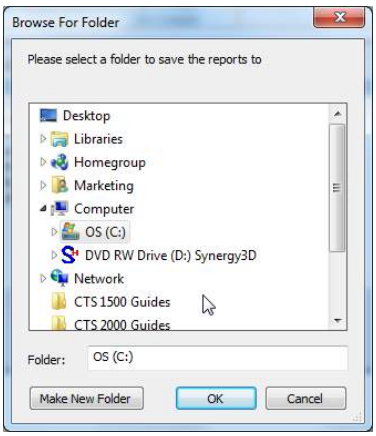
- **Intake Medical Issues:**

Chief Complaints:	**frequent urination**
Duration of symptoms:	**3-6 months**
Daytime voiding frequency:	**1-2 hours**
Nocturia:	**1-2 times**

NOTE: Exit the **PDF** document by clicking on the in the upper right-hand corner of the screen.

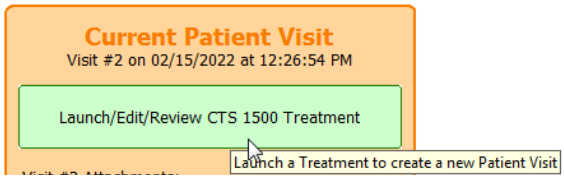
9. All the information imputed in the **Attachments** is included in a comprehensive format on selected **Documents** along with the graph and statistical information gathered during the session.

10. Clicking **Save** from **Program generated Documents** brings up **Browse for Folder** to **Save** and **transfer documents** to another location.

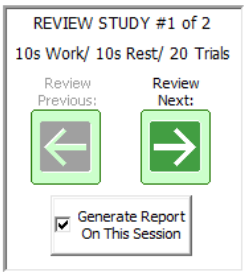


Review Current Visit

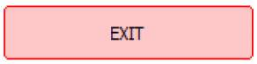
1. Click **Launch/Edit/Review CTS 1500 Treatment.**



2. If there are multiple treatments, toggle between treatments to review or edit by selecting **Review Previous** or **Review Next**. All treatments, whether **Generate Report On This Treatment** is checked or not, are shown for edit/review. Full review screen edit capabilities are active.



3. Click **Exit** when the review/edit of these treatments is complete. **Patient Selection Screen** will appear.

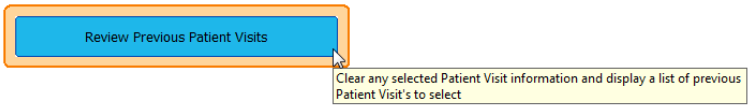


4. **Attachments** can be created, edited, and added to the current session. To create or edit an attachment double click on that attachment. Enter the needed information. Refer to the **Attachments** section for further information.

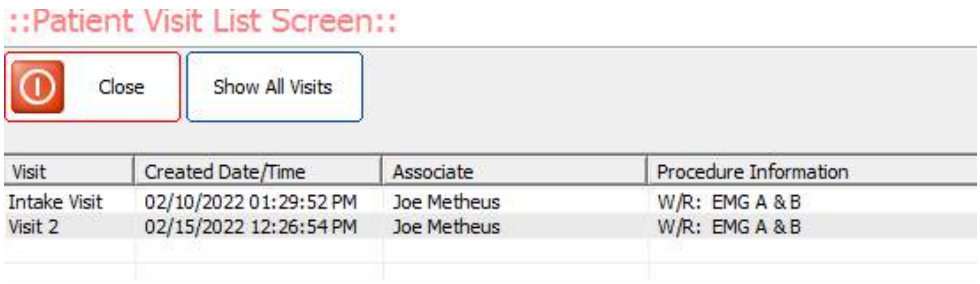
5. Click **Close**. Select **Yes** to accept or **No** to **NOT** accept the changes/additions made.

Review Previous Visits

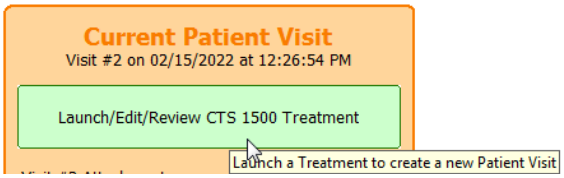
1. Click **Review Previous Visits**.



2. **Patient Visit List Screen** will appear. To review a specific visit, double click on that visit. The **Patient Selection Screen:** will appear.



3. Click **Launch/Edit/Review CTS 1500 Treatment**



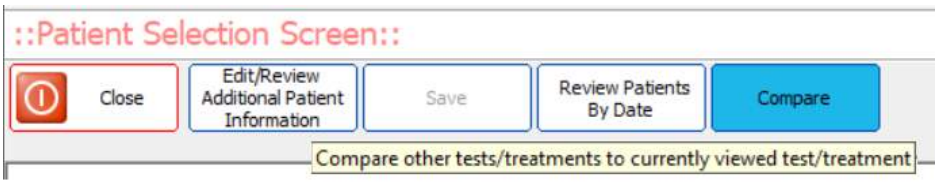
4. Follow the steps outlined in **Review Current Visit**.

Compare

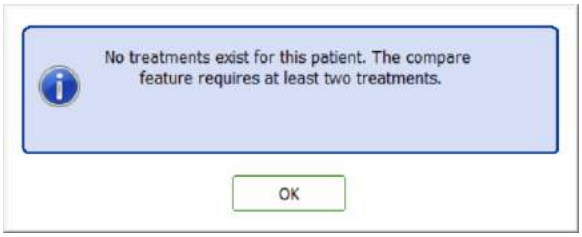
The **Compare Reports** feature allows users to compare up to four treatments against one baseline/benchmark treatment.

To begin comparing treatments for a patient:

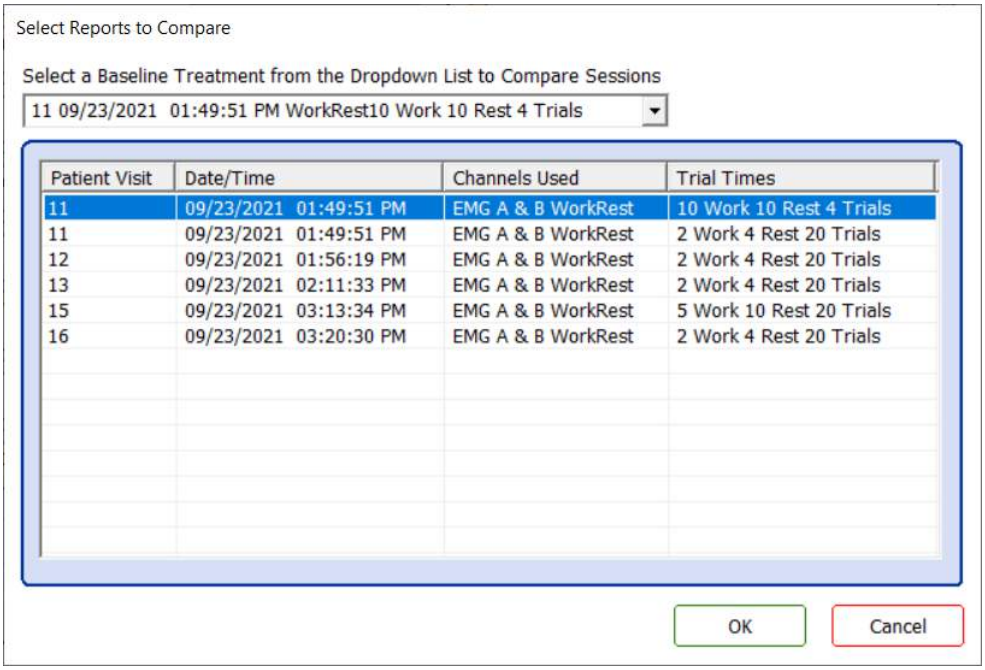
1. Select the **Patient** from the **Patient Selection** screen.
2. Select the **Compare** button from the menu bar to launch the Compare Reports dialog.



3. If the currently selected patient does not have any saved treatments, the software will present the following warning:



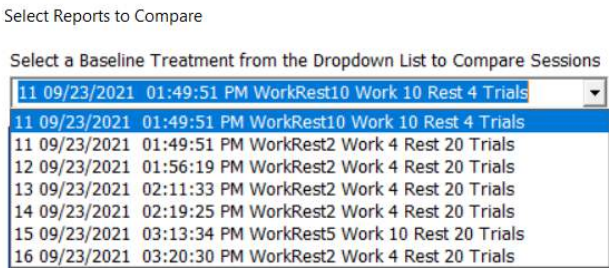
4. If two or more treatments are available, the **Compare Reports** launches with the intake or first visit pre-selected as the baseline in the dropdown and all other associated treatments in the listing panel:



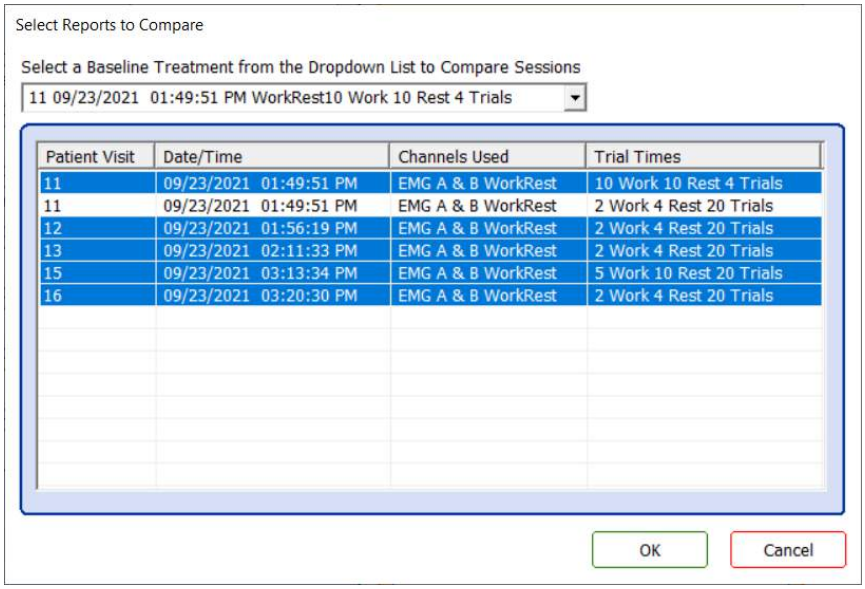
Note: If a treatment or patient visit is already loaded in the **Current Patient Visit** area, this said treatment will automatically be selected as the baseline treatment upon launching the **Compare Reports** dialog.

Compare

5. To Select another **Baseline** treatment, click the arrow next to the dropdown and all matching treatments will be listed in the listing panel:

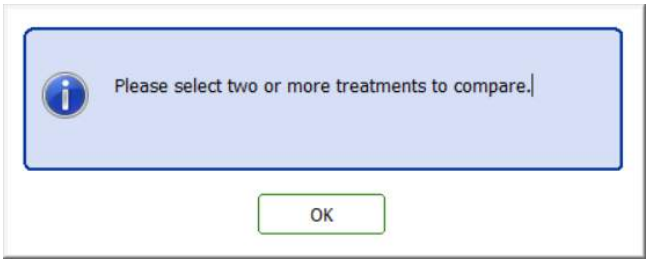


6. Select up to four additional treatments to **Compare** using a single left mouse click:



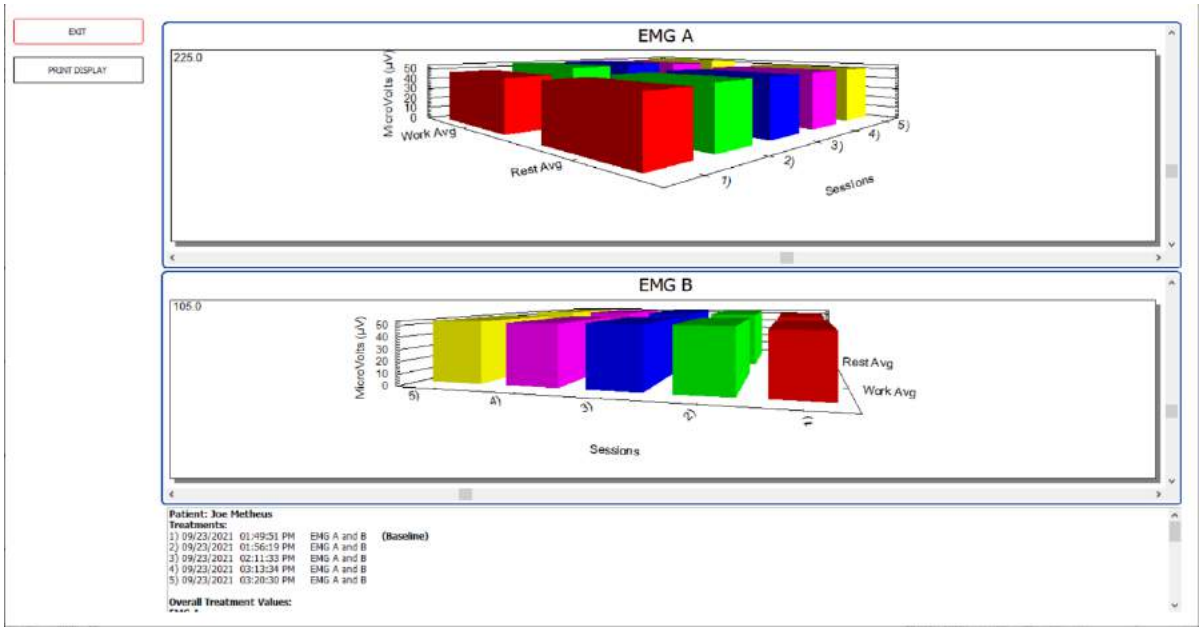
Note: To deselect a treatment, simply left click on the highlighted treatment once.

7. If less than two treatments are selected prior to clicking the **OK** button, the software presents the following warning:

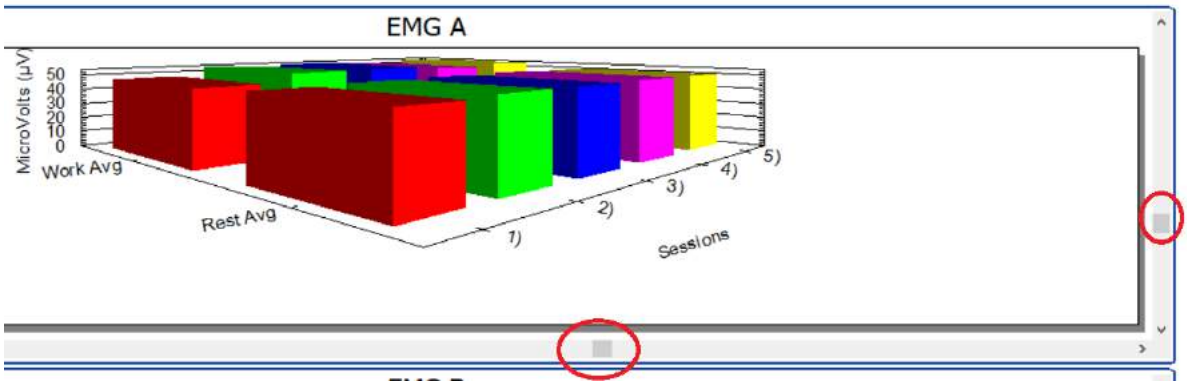


Compare

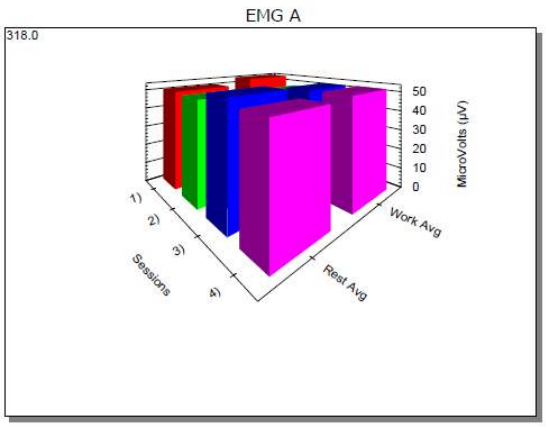
8. Once the desired treatments to be compared are selected, click **OK** to launch the compare graph:

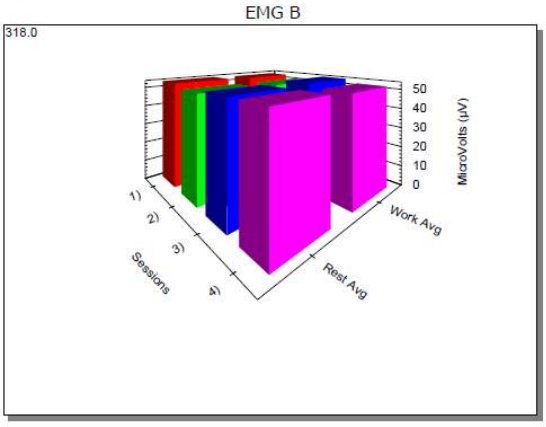


9. Use the vertical and horizontal scroll bars to adjust the graph:



10. Click **PRINT** to print a separate copy of the Compared graph channels.



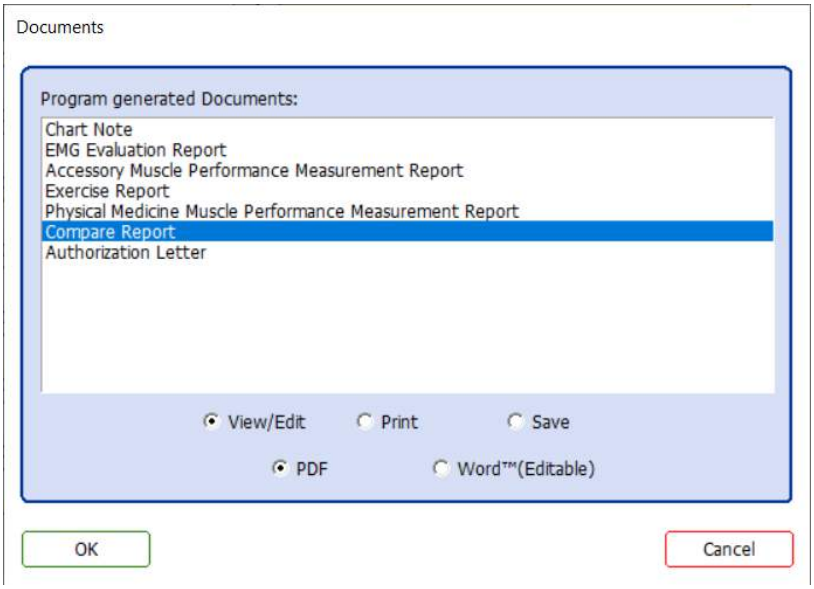


Compare

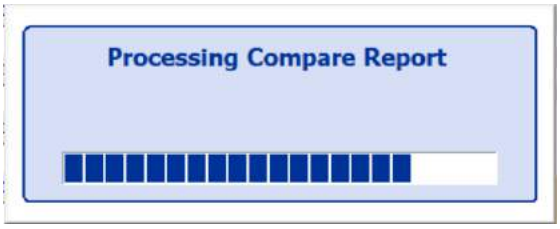
11. Click **EXIT** to return to the **Patient Selection Screen.**

12. To Print the **Compare Report**, click **View/Print/Save Documents**

13. Select **Compare Report** from the list of available report templates.



14. Click **OK** to begin processing the compare report.



Compare

15. The printed report will include the compared graphs and statistics as seen below.

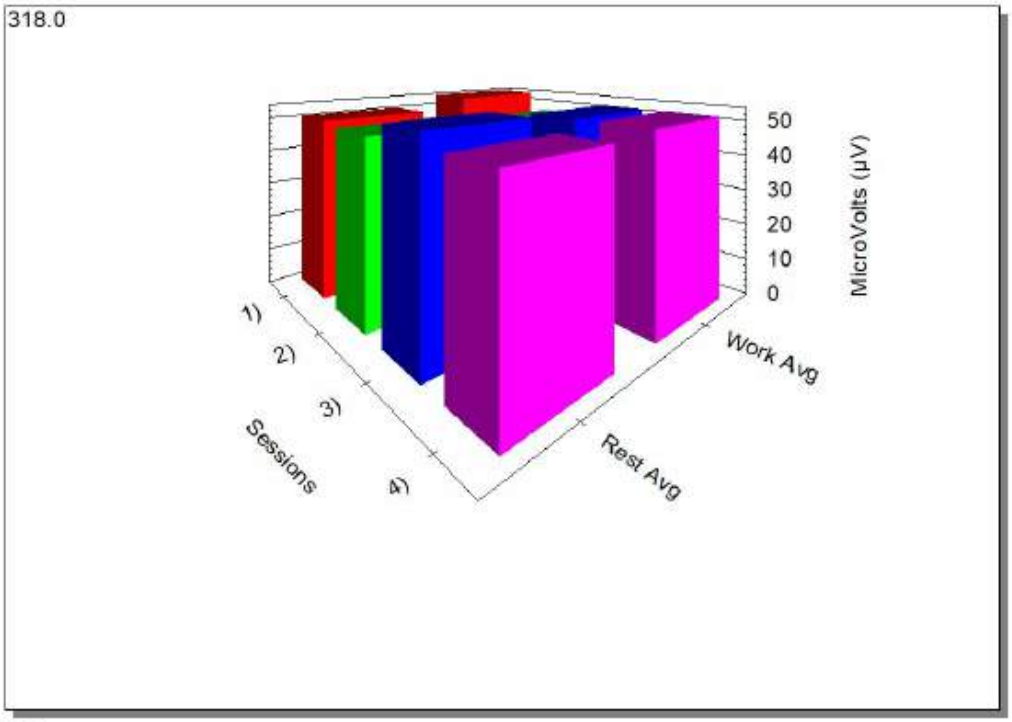
Compare Report

The Prometheus Group

Patient Name:	JOE METHEUS	**Patient MRN:**	
Patient DOB (Age):	06/15/1961 (60 YO)	**Patient Sex:**	MALE
Date of Visit:	09/23/2021	**Time of Visit:**	02:11:33 pm

Provider: JOE PROVIDER B.S. RN
Administered by: JOE PROVIDER B.S. RN

EMG A

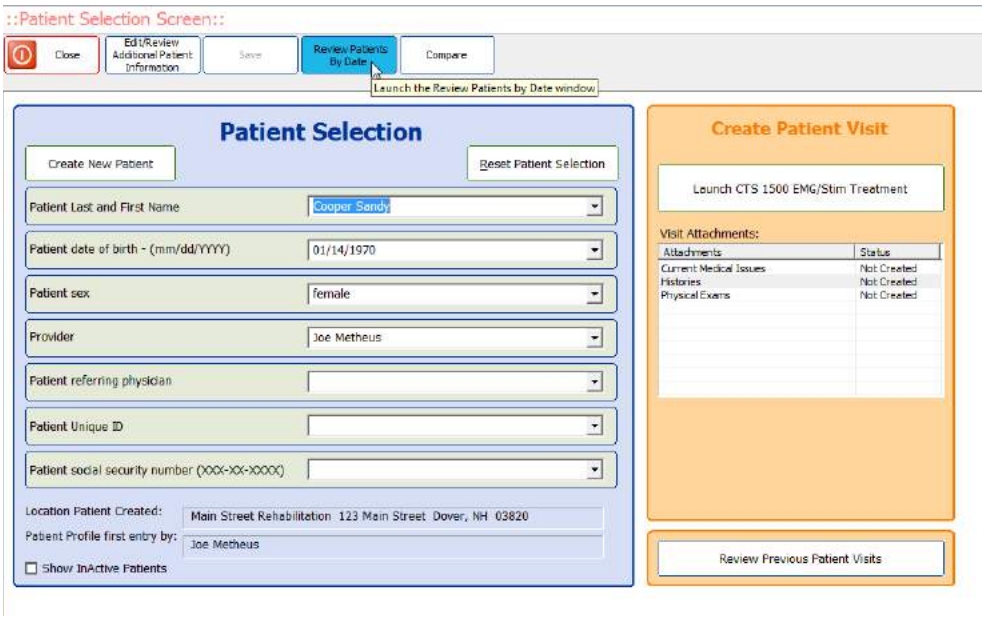


EMG A

Treatment	Average(µV)	Minimum(µV)	Maximum(µV)	W-R Rise(µV)	% Success
1) Work	53.4	16.5	76.7	3.2	N/A
1) Rest	50.1	17.4	81.9		N/A
2) Work	47.4	16.5	71.1	-1.8	N/A
2) Rest	49.2	18.1	81.0		N/A
3) Work	51.2	18.9	86.2	-2.2	N/A
3) Rest	53.4	25.0	88.2		N/A
4) Work	51.6	21.7	83.1	1.4	N/A
4) Rest	50.2	16.5	88.2		N/A

Review Patients By Date

1. Click **Review Patients By Date**.



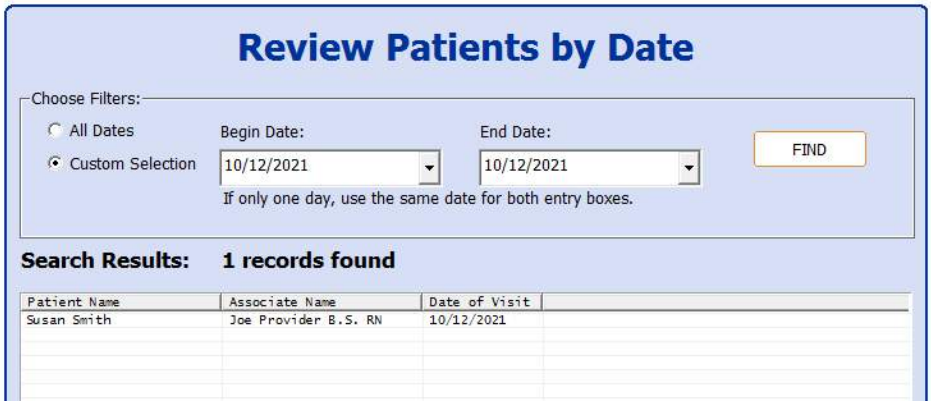
2. Click **All Dates** or **Custom Selection**. **Custom Selection** activates **Begin Date** and **End Date** calendars.

3. Click **Find**.

4. Search Results will be populated.

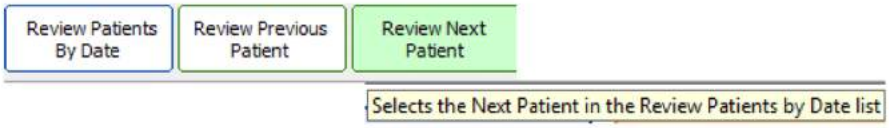
Review Patients By Date

5. **Search Results** can be sorted. Clicking **Patient Name** and **Associate Name** will organize these categories in alphabetical order. Clicking **Date of Visit** will organize by either ascending or descending date.



6. Double click on a record, launch the edit/review from the **Patient Selection Screen** with the same capabilities as described in the **Review Current Visit** section. The edit/review functions depend on the modality selected.

> **NOTE:** Two new buttons appear beside **Review Patients By Date: Review Previous Patient** and **Review Next Patient**.

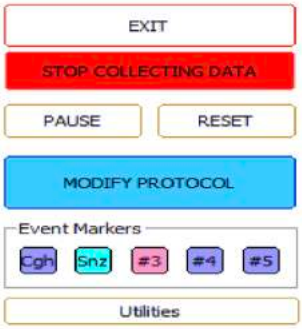


7. Clicking **Review Previous Patient** or **Review Next Patient** will advance to the previous or next patient record.

> **NOTE: Create New Visit** appears when accessing either **Review Previous Visits** or **Review Patients By Date** for other than the current date.

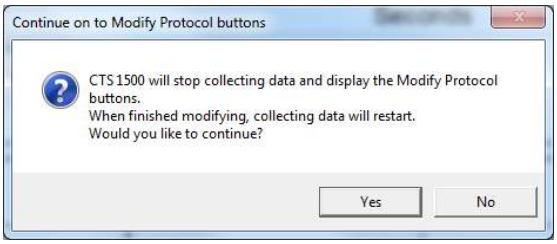
Modify Protocol

1. Click on the protocol to modify from the **Treatment Protocols** list. Click **MODIFY PROTOCOL** once the display becomes active.



> **NOTE:** Always select the correct protocol as a template/starting point (i.e. **Work/Rest**, **Resting/Baseline**, **On/Off Stim** or **Continuous Stim Protocol**). Once all changes have been made, **Rename** and **Save** the newly created **Protocol**. If the protocol name is **NOT Renamed** the **original protocol will be overwritten** with any and all changes made.

2. **Continue on to Modify Protocol** buttons will appear. Click **YES**.



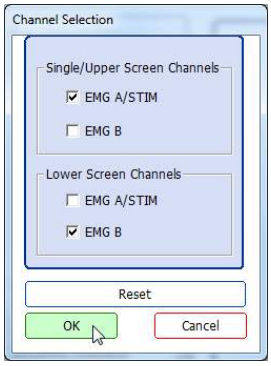
3. The modify protocol **Menu** will appear.

> **NOTE: Stim Menu** will only show if a stim protocol is selected. If a stim protocol is selected **Stop Stim MUST** be clicked before clicking **Modify Protocol**.

Channels

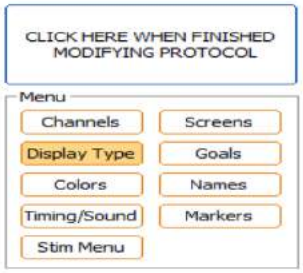
1. Click **Channels**.

2. **Channel Selection** will appear. Select which **Channel(s)** appear on the graph and on which screen (if Dual Screen) by clicking in the appropriate box. Deselect a Channel by clicking the check mark. Click **OK**.

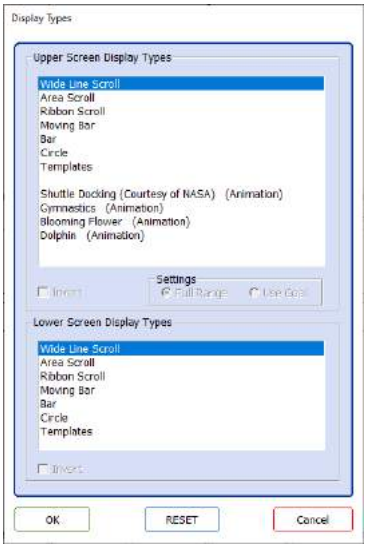


Display Type

1. Click **Display Type**.

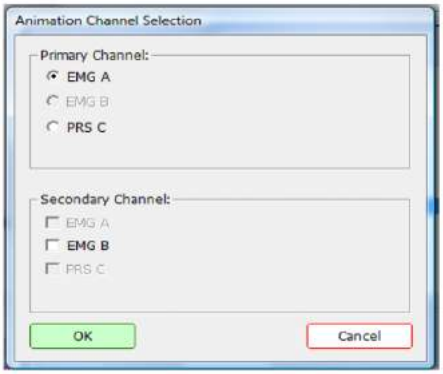


2. Click on a **Display Type**. Click **OK**.

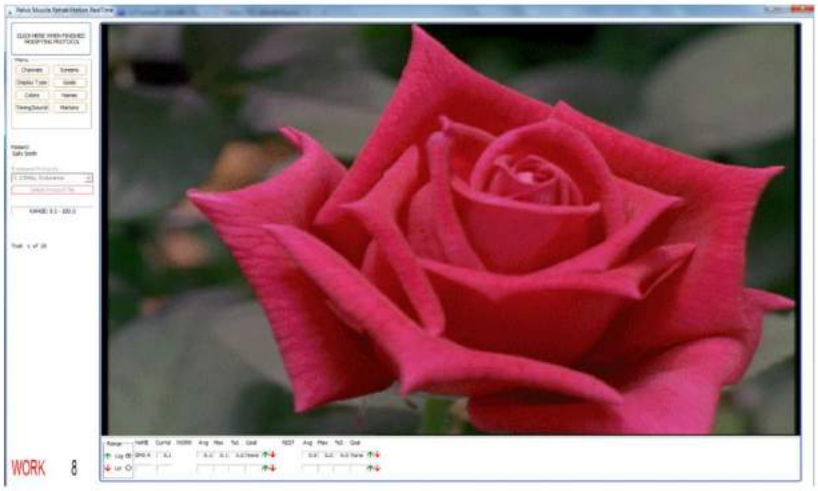


Display Type

3. If an **Animation** display is selected, **Animation Channel Selection** will appear. **Primary Channel** will control the **Animation**. **Secondary Channel** will display statistics only. Click **OK**.



NOTE: Animations only run on a **Single Screen**.

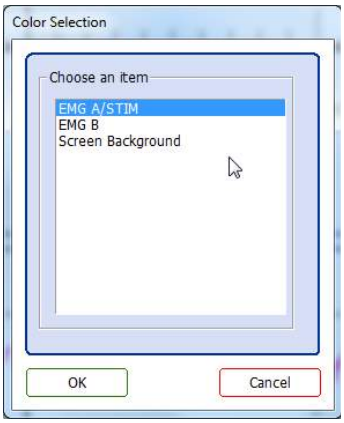


Colors

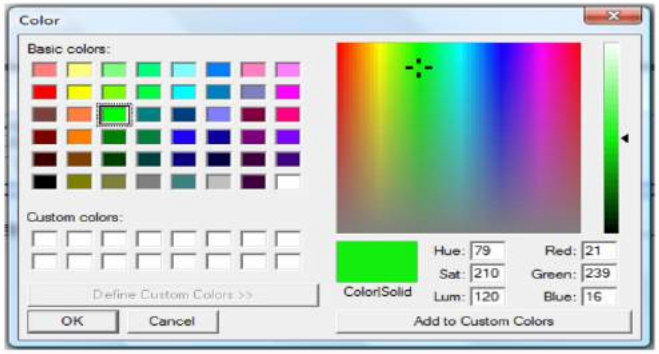
1. Click **Colors**.

Colors

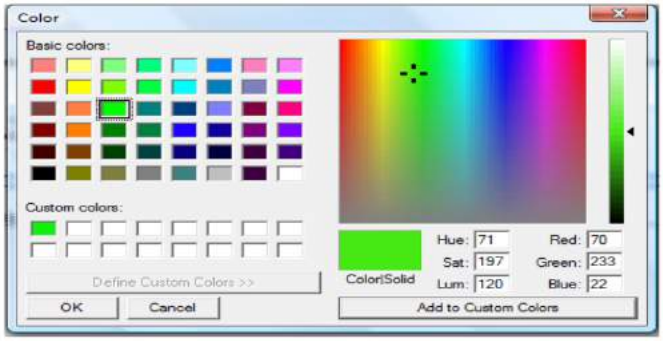
2. **Color Selection** will appear. Click **EMG A/STIM.** Click **EMG B**, or the **Screen Background** to modify its color. Click **OK**.



3. Color will appear. Set **EMG A/Stim** to be a basic color by clicking on one of the **Basic colors**. Select a **Custom color** by clicking and holding on the bull's-eye in the color spectrum window. Drag the bull's eye over the color spectrum until the desired color appears in **Color|Solid**. Both **Basic colors** and **Custom colors** can be adjusted lighter or darker. Click, hold, and drag the color saturation bar up or down. To add an adjusted color to **Custom colors**, click **Add to Custom Colors**.



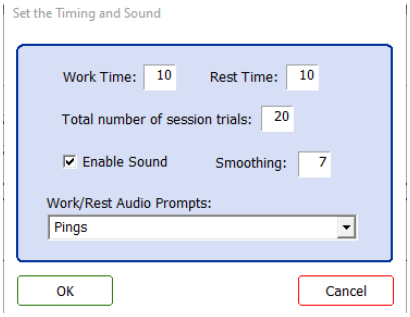
4. The new color will appear in **Custom colors**. Click **OK**.



Timing/Sound

1. Click **Timing/Sound**.

2. **Set the Timing and Sound** will appear.

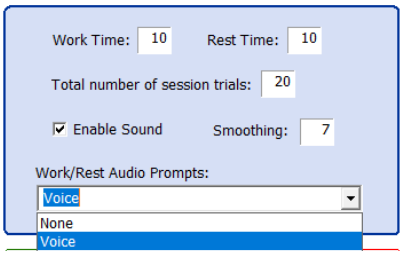


> **NOTE: Set the Timing and Sound** only appears when modifying a work/rest protocol.

3. Change the **Work Time:** and **Rest Time:** in seconds by clicking in the cell, highlighting the existing time, and keying in the new time.
4. Change the **Total number of session trials:** in the same manner.
5. To **Enable Sound,** place a check mark in the cell. To disable, click on the check mark.
6. Change **EMG Smoothing:** by clicking in the cell and keying in the value desired. An integer between **0-15 MUST** be entered.

> **NOTE:** It has been determined that a setting of **7** yields the best performance numbers and has therefore been set as the default value.

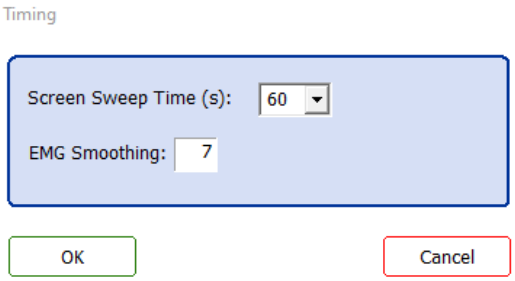
7. Click the drop-down arrow to change **Work/Rest Audio Prompts:** The default option is **Pings**. Click the option desired.



8. Click **OK**.

Timing/Sound

9. A protocol without **Work/Rest** will display **Timing**.



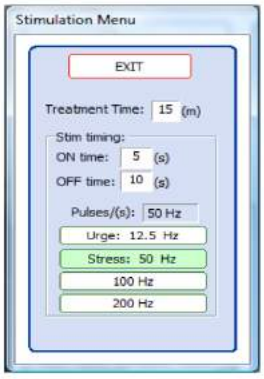
11. Click the drop-down arrow to change **Screen Sweep Time (s):** in seconds. Click the sweep time required.
12. Change **EMG Smoothing** as outlined above.
13. Click **OK**.

Stim Menu

> **NOTE:** The **Stim Menu** button is only available in the **Modify Protocol Menu** when a **Stimulation Protocol** has been selected.

1. Click **Stim Menu**.

2. **Stimulation Menu** will appear.



3. Change **Treatment Time:** in minutes by clicking in the cell, highlighting the existing time, and keying in the new time.
4. Change **Stim timing:** in seconds (both **ON time:** and **OFF time:**) by clicking in the cell, highlighting the existing time, and keying in the new time.

> **NOTE:** The **ON time:** - **OFF time:** fields are disabled when modifying a **Continuous** stim protocol.

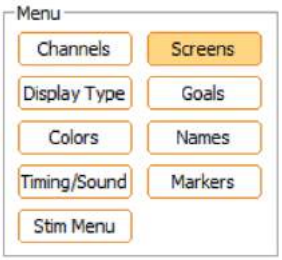
Stim Menu

5. Change the **Pulses/(s):** (**Hz**) by clicking on the frequency required.

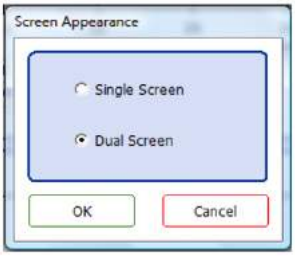
6. Click **Exit**.

Screens

1. Click **Screens**.

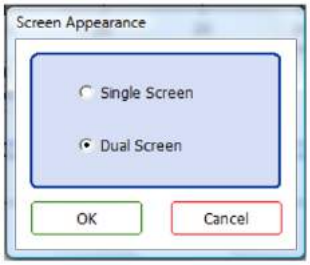


2. **Screen Appearance** will appear.



Screens

3. Select either **Single Screen** or **Dual Screen** and click **OK**.



Goals

1. Click **Goals**.

2. **Channel Goal Selections** will appear.

Goals

3. An **Above Tone WORK** goal has been selected for **EMG A (Pelvic Floor)** in the example below. Notice the goal line in the work time intervals. The line color matches the color of **EMG A**. The default value for a goal is **10.0 µV**.

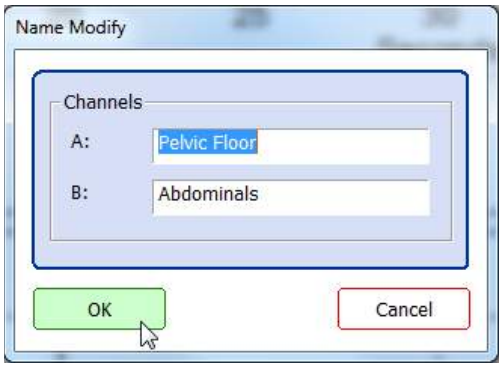
4. **WORK Goal** for **EMG A** now shows an **AbvTn** (Above Tone) goal. To increase the **µV** goal click the **green up arrow**. To decrease the **µV** goal click the **red down arrow**. Goal changes are in **1 µV** increments above **10 µV**. Goal changes are in **0.1 µV** increments below **10 µV**.

5. Click **OK**.

Names

1. Click **Names**.

2. **Name Modify** will appear. To modify a name, click on the appropriate cell and key in the new name. Click **OK**.

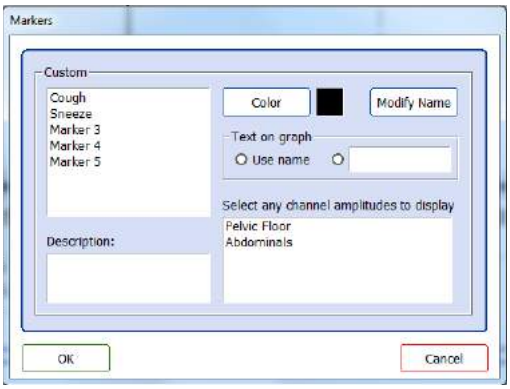


Markers

1. Click **Markers**.

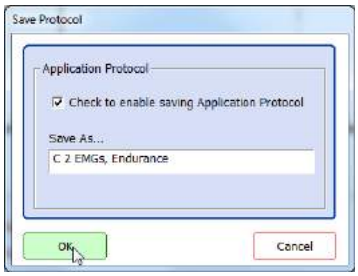
2. **Markers** will appear.

3. Click the **Cough** marker.



4. Click **Color**. **Cough** color can now be changed from **Colors**.
5. The marker name can be changed. Click on a marker name and click **Modify Name**. Key in the change.
6. The **Text on graph** can be changed. Click on a marker name. Click **Use name** and key in a maximum of **3** letters.
7. The marker **Description:** can be changed. Click on the marker name and key in the **Description:** box.
8. **Select any channel amplitudes to display** determines which channels will display amplitudes when a marker is placed. Click a highlighted channel to deselect.
9. Click **OK**.
10. Click, **CLICK HERE WHEN FINISHED MODIFYING PROTOCOL**.

10. **Save Protocol** will appear. Place a check in the box **Check to enable saving Application Protocol**. Remember to change the name in **Save As…** to save as a new protocol. If the protocol name is **<u>NOT</u>** changed the **original <u>protocol will be overwritten</u>** with any and all changes made.



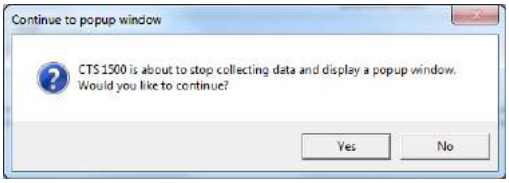
12. Click **OK**.

Utilities

NOTE: The **Launch CTS 1500 EMG/Stim** is set to **Live** mode by default. There is a **Simulation** mode which will run the session with preloaded data for demonstration purposes. This is a limited feature set not meant for clinical use.

1. To select **Simulation Mode,** click **Utilities**.

2. A popup window will appear stating the **CTS 1500 is about to stop collecting data and display a popup window. Would you like to continue?** Click **Yes**.



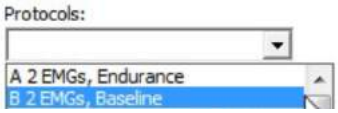
3. **Utilities** will appear.

4. If **Simulation** is selected, **Simulation Mode** will flash in the lower left-hand corner of the treatment screen.

SIMULATION MODE

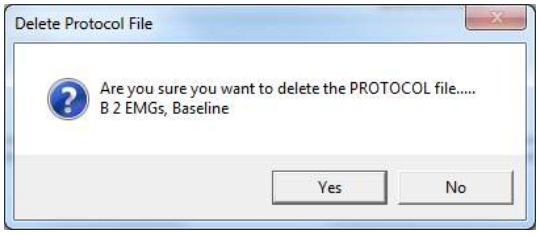
Delete Protocol

1. Click on the protocol to **Delete** from the **Treatment Protocols:** drop-down menu.



2. Click **Delete Protocol File**.

3. **Delete Protocol File will appear asking: Are you sure you want to delete the PROTOCOL file….**



NOTE: Once the **Yes** button in **Delete Protocol File** has been selected, **the Treatment Protocol** will be **DELETED**.

4. Click **Yes** to **Delete**.

High Baseline, Unresponsive and Unstable sEMG Readings

1. Refer to **page 18** Skin Preparation—lack of skin preparation will increase electrode impedance resulting in high baseline readings.
2. Refer to **page 18** Disposable Lead Wire Electrodes placement—ensure that the active electrodes are placed at 10 and 4 o'clock around the perineum or anus. Overlapping electrodes (ex. 3 and 3 o'clock) could result in unresponsive readings.
3. Make sure that none of the electrodes have lifted off of the skin surface. A floating electrode will result in unstable readings.
4. Make sure the Ch A 10' Interface Cable for Disposable Lead Wire Electrodes is firmly attached to the EMG A/STIM input jack.
5. Gently wiggle the interface between the Disposable Lead Wire Electrodes and the Ch A 10' Interface Cable for Disposable Lead Wire Electrodes for all three contacts. Determine which contact causes the readings to change and firmly reseat this contact.
6. Verify the Ch A 10' Interface Cable for Disposable Lead Wire Electrodes is not physically damaged.
7. An ungrounded or improperly grounded power exam table can produce high baseline readings. Disconnect the power once the patient is situated.
8. Check surroundings for other devices connected to wall outlets or power strips. Disconnect one device at a time and observe baseline readings.
9. The close proximity of cell phones can elevate baseline readings.
10. Using the criteria above perform a simple forearm test prior to the study:

    A. With arm laying on desk palm side up prep the skin with an alcohol pad. Place one of the electrodes in the center of the forearm, then place the second and third electrode alongside the first parallel to the muscle fiber of the arm.

    B. Hang arm loosely at side and observe the reading. The reading should be <3uV.

    C. Contract and relax the forearm muscle and observe the graph response. The graph should respond without delay to the contraction and return to a baseline level of <3uV.

Communication Error

1. Software reports a **Communication Error** when a study is launched.

    A. Verify the **Pathway® CTS 1500 Control Module** power is on. The blue **Power Indication Light** is illuminated.
    B. Verify the **USB Cable** is connected to the computer. Check for cable damage.

CLEANING AND DISINFECTING

SYSTEMS & DEVICES

EMYO® Series
Morpheus®
Pathway® CTS Systems
Pathway® NMR Series
Pathway® DUO
Pathway® MR Series
Pathway® TR Series
Pathway® STM-10
WiFLOW®
QuickScan®

Use a damp, soft, non-abrasive cloth. When disinfection is required, a cloth wipe using isopropyl alcohol, chlorine bleach in water (no stronger than a 1:10 ratio mixture), or a 2% glutaraldehyde solution (such as Cidex) is recommended.
After cleaning, wipe with water using a clean, damp cloth, and then a clean dry cloth.

- **Do Not** immerse the module or device in liquid, as immersion will damage the internal electronic components.
- **Do Not** soak or clean the module or device with harsh chemicals such as acetone.
- **Do Not** expose the metal components (pins, snaps, sockets, etc.) to isopropyl alcohol, chlorine bleach, or glutaraldehyde solution.

> **NOTE:** A good quality rubbing alcohol may be used to remove stains or adhesives that stick to the carry pouch of the hand-held devices.

ACCESSORIES

Intracavity Sensors
Pathway® Rectal sEMG/Stimulation Sensor (Part #6340)
Pathway® Rectal Silicon Pressure Sensor (Part #6425)
Pathway® Vaginal sEMG/Stimulation Sensor (Part #6330)
Pathway® Vaginal/Rectal sEMG Sensor (Part #6320)

Clean the sensor before the first use and immediately after each subsequent use. Wash hands with soap, then apply the same lather to the sensor and wash it thoroughly. Completely rinse your hands and the sensor of all soap residue, wipe the sensor dry with a clean cloth or paper towel. Allow to air-dry, and store sensor in its original packaging.

- **Do Not** use abrasive cleaners.
- **Do Not** expose to high temperatures.
- **Do Not** submerge in water.
- **Do Not** get the sensor plug or cable wet.
- **Do Not** sterilize.

> **NOTE:** Sensors are Single Patient Multi-Use. For complete information regarding the Pathway® Sensors, refer to the product insert included with the sensor packaging.

ACCESSORIES (CONTINUED)

Accessory Cables & Lead Wires
24" Electrode Lead Wire Set (Part #5328)
6' Electrode Lead Wire Set (Part #5338)
Adapter for 7400 Disposable Lead Wire Electrodes (Part #7100)
Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7300)
Ch B 10' Interface Cable for 7400 Disposable Lead Wire Electrodes (Part #7350)
Ch B Extended Pathway® Preamplifier (Part #2583E)
Pathway® Preamplifier 5' (Part #2583)
Ruggedized Pathway® Preamplifier Cable (Part #2583RUG)
10' Yoke Assembly Cable (Part #7808)
24" Abdominal Air-Charged Reusable Cable (Part #1010)
24" Urethral Air-Charged Reusable Cable (Part #1020)
24" Vesical Air-Charged Reusable Cable (Part #1030)
24" Abdominal Water Perfused Reusable Cable (Part #8010)
24" Urethral Water Perfused Reusable Cable (Part #8020)
24" Vesical Water Perfused Reusable Cable (Part #8030)
24" Posterior Quadrant Air-Charged Reusable Cable (Part #4010)
24" Anterior Quadrant Air-Charged Reusable Cable (Part #4020)
24" Left Quadrant Air-Charged Reusable Cable (Part #4030)
24" Right Quadrant Air-Charged Reusable Cable (Part #4040)

Use a damp, cloth wipe with alcohol-free hand soap or USP green soap tincture. When disinfection is required, a cloth wipe using isopropyl alcohol, chlorine bleach in water (no stronger than a 1:10 ratio mixture), or a 2% glutaraldehyde solution (such as Cidex) is recommended. After cleaning and disinfection, wipe with water using a clean damp cloth and then a clean dry cloth.

- **Do Not** expose the metal components (pins, snaps, sockets, etc.) to isopropyl alcohol, chlorine bleach, or glutaraldehyde solution.

> **NOTE:** Prometheus Group® accessory cables and lead wires are reusable and are provided non-sterile. For complete information regarding accessory cables and lead wires, refer to the product insert included with the packaging.

COMPUTER EQUIPMENT

To Clean the Monitor:
Gently wipe the display with a dry, lint-free, soft cloth.
If a stain, smudge, or other blemish remains, moisten the cloth with water or a 50-50 mixture of isopropyl alcohol and water (distilled or deionized) and squeeze out excess liquid. Allow to air-dry.

To Clean the Keyboard:
Lightly absorb isopropyl alcohol on a lint-free, soft cloth, and squeeze out excess liquid. Wipe the keyboard surface, making sure liquid does not drip on or between the keys. Allow to air-dry.

To Clean the Exterior of the Computer:
Gently wipe the exterior surfaces of the computer with a damp, lint-free, soft cloth using a mild cleaning solution (non-ammonia based, and non-abrasive). Rinse the cloth with water and squeeze out excess liquid. Re-wipe the surface to remove any left-over cleaner. Allow to air-dry.

COMPUTER EQUIPMENT (CONTINUED)

Disinfecting the Monitor, Keyboard, and Computer

1. Commercial Disinfection:
   - 1.1 Squeeze out excess liquid from the wipe or disinfecting cloth.
   - 1.2 Gently wipe all the system components.
   - 1.3 Be careful not to drip on or between the keys on the keyboard. Do not wipe any connector pins.
   - 1.4 After disinfecting, follow the cleaning procedure from the supplier to minimize chemical buildup of disinfectant residue.
   - 1.5 Allow all system components to air-dry prior to use.

2. Chemical Disinfection: Compositions vary greatly, and some may impact cosmetic appearance[1] and system functionality[2].

3. Recommendations:
   - 3.1 Hydrogen peroxide wipes (such as Virox Accel wipes w/ a maximum of 0.5% hydrogen peroxide)
   - 3.2 Alcohol based wipes (such as PDI Germicidal or B.Braun Meliseptol Wipes sensitive)
   - 3.3 Wipe away residual solvent after the prescribed contact time, then wipe the surface again with a dry, lint-free, soft cloth.
   - 3.4 Do not use wipes containing sodium hypochlorite (bleach).

[1] *Cosmetic appearance could include discoloration, residual material build-up, and paint bubbling.*

[2] *System functionality could include (but is not limited to) corrosion and function failure of electrical parts.*

NOTE:

- Prior to cleaning, remove media from the drives and turn off all connected devices and the computer.
- Disconnect all power sources such as batteries or power cords from electrical outlets, and disconnect all cables connected to the computer.
- Never spray or pour any liquid directly on the monitor or the keyboard.
- Use a can of compressed air to remove any crumbs and dust from beneath the keys. **Do not** use an air compressor.
- Anti-static screen cleaning cloths, Kim Wipes, and some types of lens cleaning wipes are acceptable alternatives for a lint-free, soft cloth.
- Isopropyl alcohol is a flammable liquid. **Do not** use near an exposed flame or when the system power is on.

EQUIPMENT

Point of Care Cart

Use a damp, soft, non-abrasive cloth. When disinfection is required, a cloth wipe using isopropyl alcohol, chlorine bleach in water (no stronger than a 1:10 ratio mixture), or a 2% glutaraldehyde solution (such as Cidex) is recommended.
After cleaning, wipe with water using a clean, damp cloth, and then a clean dry cloth.

- **Do Not** immerse, soak, or clean with harsh chemicals such as acetone.
- **Do Not** expose the metal components (pins, sockets, etc.) to isopropyl alcohol, chlorine bleach, or glutaraldehyde solution.

IV Pole

Use a damp, soft, non-abrasive cloth and gently wipe using a mild non-abrasive detergent (household cleaner, soapy water, or hospital grade disinfectant). Rinse the cloth with water and squeeze out excess liquid. Re-wipe the surface to remove any left-over cleaner. Allow to air-dry.

- **Do Not** wash under water pressure, steam clean, or use cleansers that could damage the IV Pole's finish.

Isolation Transformer

Use a damp, soft, lint-free cloth. Do not use a cleaning agent.

- **Do not** expose to humidity, rain, or excessive heat.

Wireless Uroflowmetry Load Cell
Use a damp, soft, non-abrasive cloth. When disinfection is required, a cloth wipe using isopropyl alcohol, chlorine bleach in water (no stronger than a 1:10 ratio mixture), or a 2% glutaraldehyde solution (such as Cidex) is recommended. After cleaning, wipe with water using a clean, damp cloth, and then a clean dry cloth.

- **Do Not** expose the metal components (pins, snaps, sockets, etc.) to isopropyl alcohol, chlorine bleach, or glutaraldehyde solution.
- **Do Not** immerse, soak, or clean with harsh chemicals such as acetone.

2000ml Pitcher (Part #ML)
Remove the pitcher from the Wireless Uroflowmetry Load Cell and dispose of any waste properly. Completely rinse with soap and water or a mild detergent (household cleaner, soapy water, or hospital grade disinfectant) solution and wipe dry with a clean paper towel or cloth. Return the pitcher to the Wireless Uroflowmetry Load Cell.

Uroflowmetry Funnel (Part #UFN)
Use a damp, soft, non-abrasive cloth and gently wipe using a mild non-abrasive detergent (household cleaner, soapy water, or hospital grade disinfectant). Rinse the cloth with water and squeeze out any excess liquid.
Re-wipe the surface to remove any left-over cleaner, and wipe dry with a clean paper towel or cloth.

Uroflowmetry Stand (Part #US)
Use a damp, soft, non-abrasive cloth. When disinfection is required, a cloth wipe using isopropyl alcohol, chlorine bleach in water (no stronger than a 1:10 ratio mixture), or a 2% glutaraldehyde solution (such as Cidex) is recommended. After cleaning, wipe with water using a clean, damp cloth, and then a clean dry cloth.

- **Do Not** immerse, soak, or clean with harsh chemicals such as acetone.

Commode (Part #CM)
Bucket:
Dispose of any waste properly. Completely rinse with soap and water. Using a disinfectant wipe (such as Clorox®), wipe down the inside and outside. Rinse with warm water, and wipe dry with a clean paper towel or cloth. Spray an aerosol disinfectant (such as Lysol®) into the commode bucket and return it to the commode.

Commode Frame:
Use a disinfectant wipe (such as Clorox®) to clean the exterior surfaces. Use a clean dry cloth to wipe away any disinfectant residue. Repeat this step with a new disinfectant wipe and clean the top and underside of the lid. Using a clean paper towel or cloth, wipe any remaining residue from the commode lid.

NOTE:
- Wear protective gloves when performing the cleaning process.
- 2000ml Pitcher/Uroflowmetry Funnel are reusable, however, it may discolor over time and may need to be replaced.

CLEANING AND DISINFECTING

ULTRASOUND TRANSDUCERS

Pathway® GP-C01 3.5-7.5MHz Curved Array Ultrasound Imaging Transducer
Pathway® SP-L01 5-10MHz Linear Array Ultrasound Imaging Transducer
Morpheus® GP-C01 3.5-7.5MHz Curved Array Ultrasound Imaging Transducer
QuickScan® 3.5 MHz Bladder Ultrasound Imaging Transducer

To Clean and Disinfect the Transducers:

⚠	**WARNING: Always disconnect the transducer from the computer before performing maintenance or cleaning.**
⚠	**WARNING: Always follow the manufacturer's instructions when cleaning and disinfecting transducers.**
⚠	**WARNING: Do not use a surgeon's brush when cleaning transducers. Even the use of soft brushes can damage the transducer.**

Transducer Cleaning
The USB Ultrasound Transducer is capable of withstanding, without damage or deterioration of the safety provisions, the cleaning and/or disinfecting process specified.

1. Wear protective gloves when performing the cleaning process.
2. Disconnect the transducer from the computer.
3. Remove any sheaths.
4. Discard sheaths (sheaths are a single-use item) in a biohazard container.
5. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any particulate matter or body fluids that remain on the transducer or cable.
6. To remove remaining particulates, rinse with water up to the USB cable connection of the transducer.
7. Wipe with a dry cloth; or wipe with a water-dampened cloth to remove soap residue, and then wipe with a dry cloth.
8. Or, as an option, use PDI Sani-Cloth AF3 Germicidal Disposable Wipes.

Transducer Disinfecting
A 10^6 reduction in pathogens should be reached following the disinfecting procedures and using the following recommended solutions. The following disinfectants are recommended because of both biological effectiveness (as qualified though the FDA 510(k) process), and compatibility with the transducer material.

Solutions	Country	Type	Active Ingredient	FDA 510(k)
Cidex®	USA	Liquid	Glutaraldehyde	K924434
Cidex Plus®	USA	Liquid	Glutaraldehyde	K923744
Sporicidin®	USA	Liquid	Phenol	K904581
Revital- Ox™ Resert® HLD	USA	Liquid	Hydrogen Peroxide	K080420

1. Wear protective gloves when performing the disinfecting procedure.
2. Check the expiration date on the solution that is being used.
3. Use only solutions that are within the expiration date.

CLEANING AND DISINFECTING

⚠	**WARNING: The level of disinfection required for a device is dictated by the type of tissue it will contact during use. To avoid infection, ensure the disinfectant type is appropriate for the equipment. For information, see the disinfectant label instructions and the recommendations of the Association of Professional in Infection Control and Epidemiology (APIC) and the U.S. Food and Drug Administration (FDA).** **For additional guidance on disinfection levels and tissue contact please consult: The Centers for Disease Control: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf** **The Joint Commission: https://www.jointcommission.org/**
⚠	**WARNING: Using a non-recommended disinfection solution, incorrect solution strength, or immersing the transducer deeper or for a period longer than recommended by disinfectant manufacturer can damage or discolor the transducer and will void the transducer warranty.**
⚠	**WARNING: Disinfect transducers using only liquid solutions. Using autoclave, gas (EtO), heat or radiation to sterilize or other non-approved methods will permanently damage the transducer and void the warranty.**

1. Examine the transducer for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, abandon disinfection, discontinue use of the transducer, and contact the Technical Support Team.
2. Mix the disinfecting solution that is compatible with the transducer according to label instructions for solution strength. A disinfectant qualified by the FDA 510(k) process is recommended.
3. Immerse the transducer up to the cable in the disinfecting solution for the recommended length of time per the manufacturer. **Do Not** immerse any part of the transducer's cable or cable connector.
4. Using the instructions on the disinfectant or sterilization label, rinse the transducer up to the cable connector, and then air dry or towel dry with a clean cloth.

In conjunction with the supplied recommended cleaning instructions, The Prometheus Group® recommends following guidance from the Centers for Disease Control (CDC) and The Joint Commission in regard to the level of sterilization required.

The CDC and The Joint Commission recommend the use of the Spaulding Classification which defines the minimum level of disinfection or sterilization that should be utilized according to the risk of infection that is associated with a medical device.

Patient Contact	Device Classification	Minimum Disinfection Level	Examples
Intact Skin	Non-Critical	Low Level or Intermediate Level Disinfection	stethoscopes, blood pressure cuffs, crutches, and computers
Mucous Membranes or non-intact skin	Semi-Critical	High Level Disinfection	esophageal manometry probes, cystoscopes, anorectal manometry catheters, endocavitary ultrasound probes
Sterile Areas of the body (i.e.: Vascular System)	Critical	Sterilization	cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities

The Centers for Disease Control: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf
The Joint Commission: https://www.jointcommission.org/-/media/enterprise/tjc/tjc-documents/to-delete-documents/private-for-hidden-content/tjc_hld_boosterpakpdf.pdf?db=web&hash=5805EEA1131DAB35E767E906F1A0DF15

Intact Skin: is skin that has not been opened by cuts, abrasions, dermatitis, chapped skin, etc.
Non-intact skin: Areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin, etc.

DISPOSAL OF EQUIPMENT, ACCESSORIES, AND WASTE PRODUCTS

- After use, discard the contaminated, plastic, single-use disposables, and any packaging according to your institution's standard operating procedures on medical waste handling.
- For end-of-life product, waste electrical and electronic equipment should be collected separately and returned to the designated local recycling service.
- For end of battery life, disposal must be handled according to local regulations.
- Packaging waste should be collected separately for available national packaging collection and recycling services.

PATHWAY CTS 1500 PELVIC MUSCLE REHABILITATION SYSTEM (Part #CTS-1500B) SPECIFICATIONS

Pathway® CTS 1500 Module:

Width:	29.2 cm (11.5 in)
Height:	8.4 cm (3.3 in)
Length:	25 cm (9.9 in)
Weight:	2 kg (4.5 lbs)
Input Voltage:	12 VDC
Input Current:	7.08 A

Electromyography:

Number of Channels:	2
Range:	1 - 800 µV
Accuracy:	2% ± 2 Microvolts (Less than 500 Microvolts)
Sampling Rate:	10 Hz
Display:	Linear or Logarithmic
Signal Processing:	True RMS Conversion 20 to 500 Hz Bandpass 60 Hz Notch Filter Input Common Mode Rejection greater than 100dB Input Noise Level of less than 1 µV Internal Active Electrode Preamplifier on both channels Active Electrode Impedance of 10 gigohms

Stimulation:

Number of Channels:	1
Range:	1 - 100 Milliamps (mA)
Frequency:	12.5/50/100/200 Hz
Signal:	Biphasic
Pulse Width:	300 microseconds (µs)
Charge Per Pulse:	28 microcoulombs

PC Notebook:

Windows 10 Professional	
Architecture:	64 Bit Operating System
Display Resolution:	1920 x 1080
Processor:	Intel i5 or Higher
RAM:	8 GB RAM or 16 GB to support optional Game Animation Option
Hard Drive:	256 GB (to allow for database expansion)
HDMI Port Availability	
Minimum of 2 USB 2.0 Ports	
Bluetooth Functionality	

The Prometheus Group® recommends a grounded power supply.

*Note: Specifications subject to change without notification.

PATHWAY CTS 1500 PELVIC MUSCLE REHABILITATION SYSTEM (Part #CTS-1500B) SPECIFICATIONS

PC Notebook (Continued):

Patient Data Storage:	> 500 Patient Records
Battery:	40 Whr Rechargeable Battery providing 4+ hours of use
Display:	15.6 in
Width:	37.6 cm (14.8 in)
Height:	26.7 cm (10.5 in)
Depth:	25.9 cm (10.2 in)
Weight:	2.3 kg (5 lbs)

Color Printer:

Pages per minute:	21 pages Black 17 pages Color
Paper Feeder:	100 Sheets
Width:	44.5 cm (17.5 in)
Height:	11.9 cm (4.7 in)
Depth:	33.5 cm (13.2 in)
Weight:	5.6 kg (12.3 lb)

Operating Conditions:

Ambient Temperature:	10°C to 35°C (50°F to 95°F)
Relative Humidity:	20% to 80% no condensing
Atmospheric Pressure:	700 hPa to 1060 hPa

Storage/Transportation Conditions:

Ambient Temperature:	-10°C to 50°C (14°F to 122°F)
Relative Humidity:	20% to 80% no condensing
Atmospheric Pressure:	700 hPa to 1060 hPa

Warranty:

CTS 1500 Module:	1 Year Parts and Labor
PC Notebook:	1 Year Parts and Labor
Color Printer:	1 Year Parts and Labor

Standards and Approvals:

ISO 13485:2016

TO ORDER ACCESSORIES

To re-order accessories and consumables for any **Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B or Part #CTS-1500)** please call your local distributor or The Prometheus Group® sales office at (800) 442-2325, or **email orders@theprogrp.com**.

Part Number:	**Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B)**
7400	Disposable Lead Wire Electrodes, Bag of 75 / 25 Patients, Square Electrode, 24” Lead Wire, .060 Female Pin
6750	Pathway® Electrodes Sample Packets, (Rectangular, 3 Snaps in a Row Style)
7300	Ch A 10’ Interface Cable for 7400 Disposable Lead Wire Electrodes
2583E	Ch B Extended Pathway® Preamplifier, White, 10’
6330	Pathway® Vaginal sEMG/Stimulation Sensor
6340	Pathway® Rectal sEMG/Stimulation Sensor

SOFTWARE LICENSE AGREEMENT

The Prometheus Group® grants to the purchaser of the **Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B or Part #CTS-1500) software** the right to use one copy of **Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B or Part #CTS-1500) software** on one computer within one business entity. **Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B or Part #CTS-1500) software** cannot be shared among or between multiple business entities; for example, a satellite clinic affiliated with a hospital operating as a separate business entity. Each business entity is required to have its own original copy of the **Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B or Part #CTS-1500) software**

THE PROMETHEUS GROUP® STANDARD PRODUCT WARRANTY AGREEMENT

1.1 Contact Information. Email: support@theprogrp.com or call The Prometheus Group® at (800) 442-2325.

1.2 The Prometheus Group® warrants Equipment of its own manufacture to be free from defects in material and workmanship for one (1) year from the date of shipment to the original Customer, subject to the terms, conditions, limitations and exclusions specified herein.

1.2.1 Service. The Prometheus Group® Technical Support Team will provide, for the term of this Warranty, repair of defective The Prometheus Group® Equipment. This Warranty will include all parts and labor charges. The Customer must obtain a Return Material Authorization (RMA) number and must return the defective Equipment at the Customer's expense. The Prometheus Group® may, at its sole option, repair and return the Equipment or provide replacement Equipment. Should The Prometheus Group® elect to provide replacement Equipment, the remainder of the Warranty is automatically transferred to the replacement Equipment. The Prometheus Group® will return, at its own expense, the repaired or replacement Equipment.

1.2.2 Exclusions. The following conditions are excluded from service:

1.2.2.1 Repair of damage or malfunction of The Prometheus Group® Equipment due to abuse, accident, modification or other cause other than normal use, including but not limited to operator error, failure of other Customer supplied equipment and equipment operation in excess of design specifications.

1.2.2.2 Use of accessories, consumables and components not supplied or approved by The Prometheus Group®.

1.2.2.3 Equipment loss due to fire, flood, robbery, burglary, theft, vandalism, radioactive contamination, or other natural disasters or Acts of God.

1.2.2.4 Replacement of batteries, accessories and consumables such as electrodes.

1.2.2.5 Commercial equipment manufactured by others, such as computers and printers. Any service required must be obtained from the manufacturer.

1.3 Optional Extended Warranty. This Warranty may be extended by written Agreement and acceptance by The Prometheus Group® and Customer. The cost for the Extended Warranty will be the price in effect at the time the Extended Warranty is put in force. The Prometheus Group® shall waive any inspection and conditional repair requirements for uninterrupted Warranty extensions.

1.4 Limitation of Remedy. The Prometheus Group® shall not be held liable for any damages caused by the delay in furnishing Warranty services or other performance under this Warranty. The Warranty expressed in 1.2.1 represents the sole and exclusive remedy for any Warranty claims under expressed or implied Warranties, including without limitation any Warranty of merchantability or fitness. This Warranty specifically limits the liability of The Prometheus Group®, including liability for negligence claims by Customers and disclaiming any other claims of non-performance by The Prometheus Group®. In no event shall The Prometheus Group® be held liable for any incidental or consequential damages of any kind.

1.5 Assignment. This Warranty will not be assigned by the Customer without prior written consent of The Prometheus Group®. The Warranty will be binding on all of the parties and their successors and assigns.