# PATHWAY® CTS 1500 CONTINENCE EVALUATION and TRAINING SYSTEM OPERATOR'S GUIDE



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#### **NOMENCLATURE**

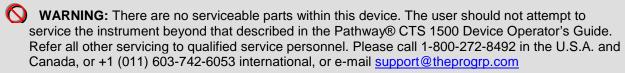
In this Operator's Guide, NOTES, CAUTIONS, and WARNINGS are included, which have the following implications:

NOTE: A procedural emphasis - usually something regarding preparation for a process or a reminder that some bit of information recorded here will be used later for another purpose

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.

WARNING: A hazard to a person - a potential danger to the operator or patient such as electrical shock or some other potential danger.

#### SERVICE INFORMATION





The instrument should be serviced by qualified service personnel when:

- Any cable, cord, or plug has been damaged.
- The instrument 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 instrument, or it has been immersed, and it appears that fluid has entered the housing.

#### TECHNICAL SUPPORT

To contact THE PROMETHEUS® GROUP Technical Support for assistance: Telephone: 800-272-8492 U.S.A. and Canada; +1 (011) 603-742-6053 international; e-mail: support@theprogrp.com.



#### INDICATIONS FOR USE

#### **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.

#### CONTRA-INDICATIONS FOR USE

- · 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

#### **Warnings**

⚠ This device is not intended for use with anesthetic gases mixed with air, oxygen or nitrous oxide. Danger of electrical ignition. Use only electrodes from THE PROMETHEUS® GROUP with the Pathway® CTS 1500. Any other electrodes may not be compatible with the Pathway® CTS 1500. Do **NOT** immerse any part of this system in any fluid. 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 electrodes attached when device is not in use. To reduce the risk of electrical shock, Do **NOT** open the instrument's housing. Refer servicing to qualified personnel only. Disassembly of equipment by unauthorized personnel will void the instrument's warranty. The following practices may be dangerous and void any guarantee(s) and obligations for THE PROMETHEUS® GROUP: (1) The device is not used according to the enclosed manuals and other accompanying documentation; (2) The device is modified by persons other than THE PROMETHEUS® GROUP Service Technicians; (3) Do not use accessories, consumables and components not supplied or approved by THE PROMETHEUS® GROUP. Discontinue use if bleeding develops. Be sure stimulation is off while inserting or removing sensors/electrodes.



Skin irritation may develop beneath or around electrode sites.

#### **Cautions**

Prior to using this device, be sure to read the CTS 1500 Device Operator's Guide for installation, maintenance, cleaning, technical data, service, and warranty information.

Federal law (USA) restricts this device for sale by or on the order of a licensed medical practitioners, licensed by law in the state in which they practice.



Use only the approved power supply supplied with this device.



Be sure that USB Serial Interface Cable is no longer than 3 meters.

HIPAA requires safeguards to protect patient privacy. Connecting this system to a network is done at your own risk.

#### **EQUIPMENT & ACCESSORIES**

Before setting up the Pathway® CTS 1500 system for the first time, carefully open the packing cartons and confirm that all Pathway® CTS 1500 equipment and accessories listed below are included and agree with the packing list/invoice. If there are questions about the contents or you wish to order additional supplies, call Customer Service, Toll-Free: **1.**800.442.2325 in the U.S.A. and Canada, +1 (011) 603.749.0733 international, or Fax: 1.603.749.0511. Customer Service Representatives are on duty between 9:00 a.m. and 5:00 p.m., Eastern Standard Time.

#### **CONTENTS**

#### Pathway® CTS 1500 Continence Evaluation and Training System

One Pathway® CTS 1500 Module consisting of two channels of EMG and one channel of electrical stimulation with Pathway® CTS 1500 Software.

Includes: One Notebook Computer with Operator's Guide, Color Printer with Operator's Guide, Power Supply, USB Serial Interface Cable, Pathway® CTS 1500 Operator's Guide.

#### **Starter Accessory Package:**

Part Number	(Quantity)	Description
7400	(4)	Disposable Lead Wire Electrodes Sample Packets
6750	(4)	Pathway® Electrodes Sample Packets
7300	(1)	Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes
2583E	(1)	Ch B Extended Pathway® Preamplifier
6330	(4)	Pathway® Vaginal EMG/Stimulation Sensor
6340	(2)	Pathway® Rectal EMG/Stimulation Sensor
Suppo	ort Services:	

(1) Unlimited hardware and software telephone Technical Support

**NOTE:** P.O./Quote dictates what accessories are included; The Packing slip/Invoice is generated from the P.O./Quote.



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## CHAPTER 1: PHYSICAL-MECHANICAL OVERVIEW & SETUP

#### The Pathway® CTS 1500 Module



Figure 1 Figure 2



Figure 3 Figure 4

**Figure 1.** Complete Pathway® CTS 1500 system with optional Point of Care Cart. **Figure 2 Top.** Front panel of Pathway® CTS 1500 Module. Input EMG A/Stim for Part Numbers 7300, 6330 and 6340. EMG B for Part Number 2583E. Large, illuminated blue On/Off Power Button. **Figure 2 Bottom**. Left-12V DC Power Input. Center-blank panel. Right-USB Cable Interface. The Pathway® CTS 1500 Module is powered by an external medical grade power supply. Units for use in the U.S.A. are configured for 115-120 V, 60 Hz AC. **Figure 3**. Part Number 7300. **Figure 4** Part Number 2583E

**NOTE:** Before using the Pathway®CTS 1500 system, the Pathway® CTS 1500 software <u>MUST</u> be configured and patient information entered into the system. See **Chapter 2: Pathway® CTS 1500 SOFTWARE SETUP** for software configuration and **Chapter 3: USING Pathway® CTS 1500 SOFTWARE** for entering patient information.

#### CONNECTING THE PATHWAY® CTS 1500 MODULE

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



#### POWERING THE PATHWAY® CTS 1500 MODULE

- 1. Connect the Power Supply to the 12VDC Power Input.
- 2. Connect the Line Power Cord to the Power Supply.
- 3. Connect the Line Power Cord to an electrical wall outlet.

**NOTE**: It is recommended that the Line Power Cord be connected **DIRECTLY** to an available wall outlet and **NOT** a power strip. Nongrounded power strips can creat electrical interference with the Pathway® CTS 1500 Module operation. If necessary, use a heavy duty extension cord with multiple outlets.

- 4. Turn the Pathway® CTS 1500 Module ON by pressing the blue On/Off Power Button on the front panel.
- 5. When the Pathway® CTS 1500 Module is ON, the On/Off Power Button will illuminate. This indicates that the Pathway® CTS 1500 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 Module On/Off Power Button.

**NOTE:** If the Pathway® CTS 1500 Module still does not turn on, contact THE PROMETHEUS® GROUP Technical Support for further assistance. *Telephone:* 800.272.8492 U.S.A. and Canada; +1 (011) 603.742.6053 international; e-mail: support@theprogrp.com.

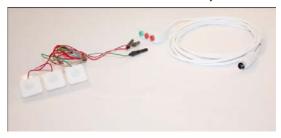


#### EMG A/STIM CHANNEL

 Pelvic Muscle EMG and Stimulation channel. Input for the intracavity #6330 Pathway® Vaginal EMG/Stimulation Sensor, the intracavity #6340 Pathway® Rectal EMG/Stimulation Sensor or the external pelvic muscle EMG #7300 Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes. Make certain orientation of the connector matches the input jack (flat side of connector facing up), push firmly (do <u>NOT</u> twist). Refer to the instructions for use, cleaning and care enclosed with each sensor or cable.



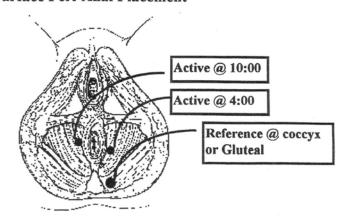
#6330 Pathway® Vaginal EMG/Stimulation Sensor #6340 Pathway Rectal EMG/Stimulation Sensor



#7300 Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes and #7400 Disposable Lead Wire Electrodes

2. Match the colors of the #7300 Ch A 10' Interface Cable for 7400 Disposable Lead Wire Electrodes to the #7400 Disposable Lead Wire Electrodes and push the pins completely into the sockets. The two red lead wires, referred to as the "Active" electrodes, will be placed at a 10:00 and 4:00 o'clock position perianally. The green lead wire, referred to as the "Reference" or "Ground" electrode will be placed in a neutral location such as the Coccyx or Gluteal muscle.

#### **Surface Peri-Anal Placement**



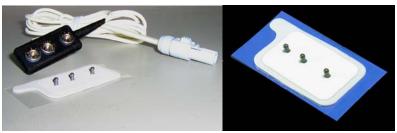
Positioning the #7400 Disposable Lead Wire Electrodes on the pelvic muscle.



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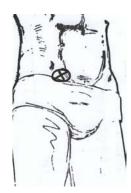
#### **EMG B CHANNEL**

1. Accessory muscle EMG channel. Input for #2583E Ch B Extended Pathway® Preamplier.



#2583E Ch B Extended Pathway® Preamplifier and #6750 Pathway® Electrode

2. Attach a #6750 Pathway® Electrode to the #2583E Ch B Extended Pathway® Preamplifier. Align the snaps correctly and snap together. EMG B Channel will be used for measurement of the accessory muscle. Place the #6750 Pathway® Electrode on the right abdominals, to avoid the descending aorta, just above the pubic hairline.



Positioning the #6750 Pathway® Electrodes on the accessory muscle.

**NOTE:** Accessory Muscles such as Abdominals, Leg Adductors and Gluteals are commonly monitored by placing the active electrodes over the bulk of the muscle. Prepare the skin with an alcohol pad to avoid high impedance artifact. Wipe dry with a tissue or cloth.

**NOTE:** Use only accessories, consumables and components <u>supplied or approved</u> by THE PROMETHEUS® GROUP. Using off brand items may result in inaccurate readings, misdiagnosis, or possible damage to the unit and void the unit's warranty.



## <u>CHAPTER 2:</u> PATHWAY® CTS 1500 SOFTWARE SETUP

**For general assistance**, contact THE PROMETHEUS® GROUP Technical Support: Telephone: 800-272-8492 U.S.A. and Canada; +1 (011) 603-742-6053 international; e-mail: <a href="mailto:support@theprogrp.com">support@theprogrp.com</a>.

#### **Initial Startup Process**

The Pathway® CTS 1500 Software comes preloaded on the Notebook Computer supplied with the system. Before operating the system for the first time, the software <u>MUST</u> 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 start, double click the CTS 1500 icon on the Windows Desktop.

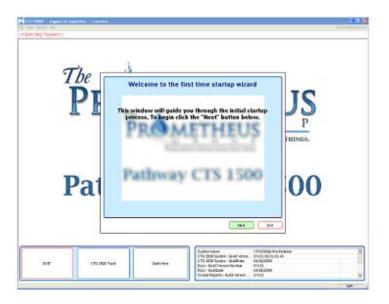
Read the Software License Agreement on Page 71 of this guide. Click OK.





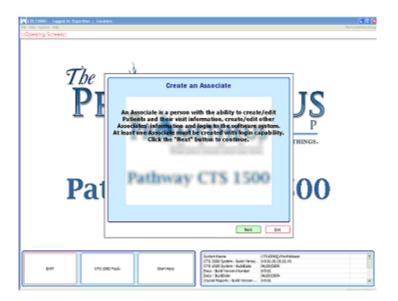
#### THE FIRST TIME STARTUP OPENING SCREEN

Click Next.



#### **C**REATE AN **A**SSOCIATE

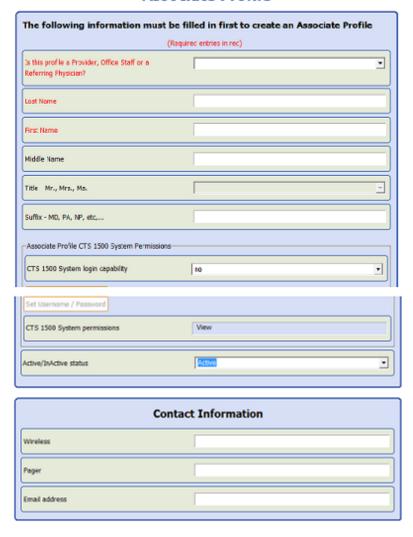
1. **Create an Associate** will appear. This is to create an associate with login permissions. Additional associates can be added later. Click **Next**.



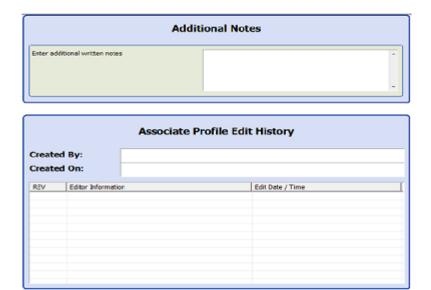


#### 2. Associate Profile will appear.

#### **Associate Profile**



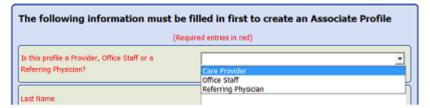




3. Click on the fill-in boxes and key in the information. All red entry fields must be completed to satisfy the minimum description requirements. All black entry fields are optional.

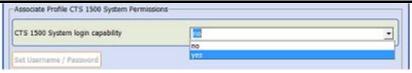
In the entry field, **Is this profile a Provider**, **Office Staff or a Referring Physician?** and other similar entry fields with drop down lists, click on the drop down arrow to open the list of options. Click on the appropriate option. Note that only a **Care Provider** or **Office Staff** may have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

#### **Associate Profile**



4. Select Yes for CTS 1500 System login capability.

**NOTE:** This initial Associate <u>MUST</u> be given CTS 1500 System login capability and <u>MUST</u> 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.



5. Click Set Username/Password.

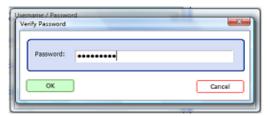


6. Enter the information and click OK.





7. **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.

- 8. OPTIONAL: Additional Associate information may be entered into **Contact Information** and **Additional Notes**. This, and other optional information, can be added later.
- 9. OPTIONAL: **Associate Profile Edit History** contains profile edit data. This data may be needed for compliance with HIPAA and other legal requirements.
- 10. There is now enough required information in the **Associate Profile** to satisfy the minimal associate description. Click the **Close** button to exit.



11. Save the data that was updated will appear. Click YES.



12. Saving Associate Data will appear.



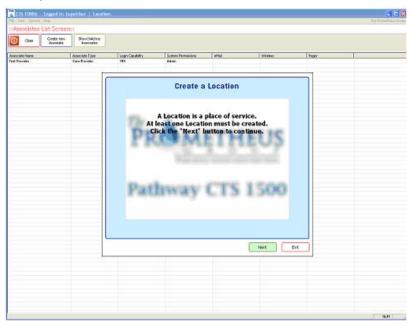
13. **Associates List Screen** will appear. The Associate just entered is listed. Additional associates may be entered at this time but are not required, click **Close** to continue the Initial Startup Process.





#### **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**.



**NOTE:** The red entry field **Business Name** <u>MUST</u> 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.

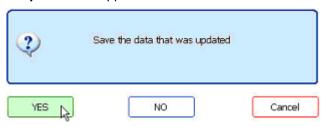




2. There is now enough required information in the **Location Profile** to satisfy the minimal location description. Click **Close**.



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



4. Saving Location Data will appear.



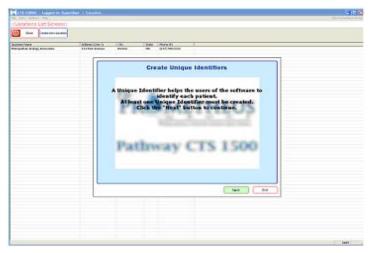
5. **Locations List Screen** will appear. Note that the Location just entered is listed. Additional Locations may be entered at this time but are not required. Click **Close** to continue the Initial Startup Process.



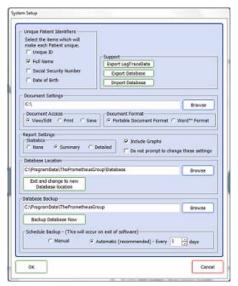


#### **CREATE UNIQUE IDENTIFIERS**

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.** 



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





4. 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.



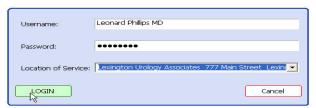
#### CHAPTER 3: CTS 1500 TOOLS

#### Introduction

1. Launch the Pathway® CTS 1500 Software by double clicking on the CTS 1500 icon on the Windows Desktop.



After the Pathway® CTS 15000 Software loads, the login window will appear. Input the Username
and Password and select the Location of Service entered during the Initial Startup Process. Click
LOGIN.

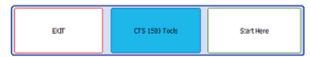


3. The Pathway® CTS 1500 software has two main components:



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 a. Administrative functions, which are accessed from the Opening Screen by clicking CTS 1500 Tools.



 b. Clinical functions, including patient treatments and documents, which are accessed by clicking Start Here.

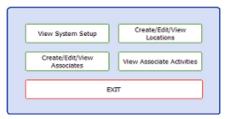


**NOTE:** Access to the **CTS 1500 Tools** section is restricted to Administrators only and is used to **Create/Edit/View Associates** and **Locations**, change **Unique Patient Identifiers**, or **View Associate Activities**. If not adding or changing these proceed directly to the clinical functions **Start Here.** 

4. Click CTS 1500 Tools.

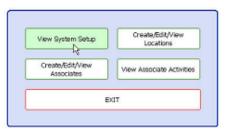


5. The CTS 1500 Tools window will appear.



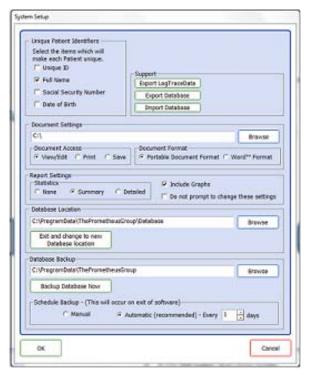
#### VIEW SYSTEM SETUP

1. Click View System Setup.



2. System Setup will appear.

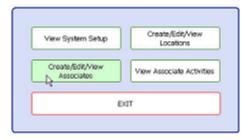




- a. Unique Patient identifiers. Select from the four options. Unique ID will provide the option to enter any sequence of letters and numbers while Full Name, Social Security Number and Date of Birth will use the patient's existing information.
- b. Database Location. A default location for the database is automatically provided. Click Browse to change the location of the database. A Windows Browse window will appear allowing for navigation to the location on the computer or network where the database is to be located. Follow standard Microsoft<sup>®</sup> procedure to create a new folder at the location, and then click Exit and change to new Database location to enable the CTS 1500 software to automatically navigate to the location selected.
- c. **Database Backup**. Select a location for the database backup file; for example, on a LAN or WAN server. Click **Backup Database Now** to perform an immediate backup of the database manually. The database backup schedule may be set to **Manual** (user maintained) or **Automatic** (software maintained with user prompts) backup by clicking on the appropriate button. The daily interval between automatic backups may be set by using the up/down arrows next to the entry box to increase or decrease the interval. <u>Automatic backups on a daily basis are recommended</u>. Upon completion of changes to the **System Setup** options, click **OK** to save changes. Clicking **Cancel** will delete any changes and exit to **CTS 1500 Tools**.

#### **CREATE/EDIT/VIEW ASSOCIATES**

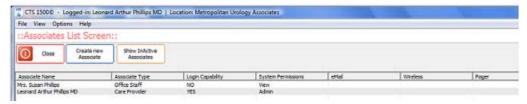
Click Create/Edit/View Associates.





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2. Associates List Screen will appear.

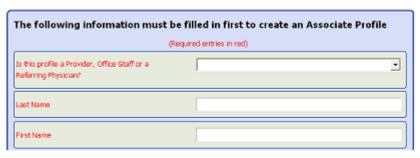


3. Click Create new Associate.



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

#### **Associate Profile**



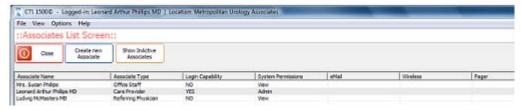
5. Click Close on the Associate Profile when complete.



6. Click YES on Save the data that was updated.

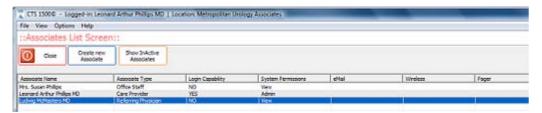


7. **Associates List Screen** will appear with the new entry.

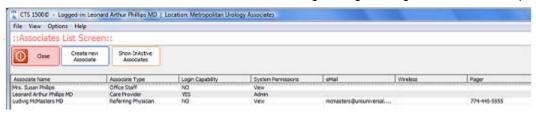


8. To view and/or edit an associate profile, double click an associate name. **Associate Profile** will appear with the information available for viewing/editing. Click **Close** when viewing/editing is complete. Click **YES** on **Save the data that was updated**.



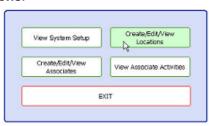


9. Click Close on the Associate List Screen when creating/editing/viewing associates is complete.

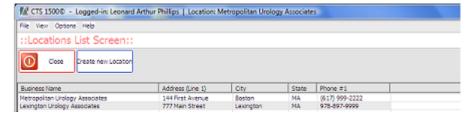


#### CREATE/EDIT/VIEW LOCATIONS

Click Create/Edit/View Locations.



2. Locations List Screen will appear.



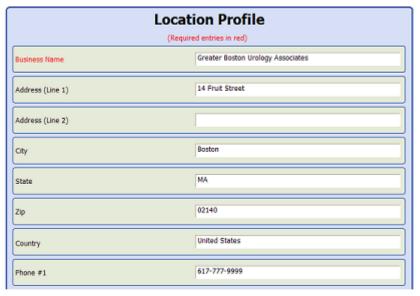
3. Click Create new Location.



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



#### **Location Screen**



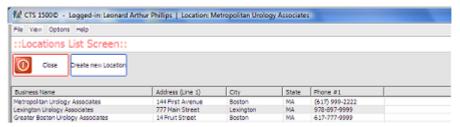
5. Click Close on the Location Screen when complete.



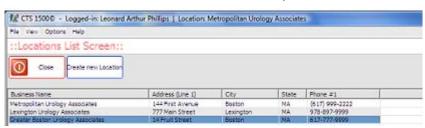
6. Click YES on the Save the data that was updated.



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



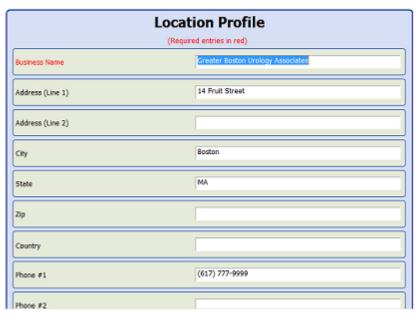
8. To view and/or edit a location on the **Locations List Screen**, double click on the **Business Name**.





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

#### **Location Screen**



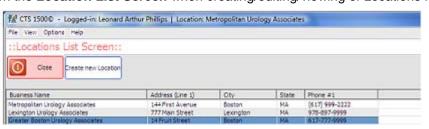
10. Click Close when viewing/editing is complete.



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



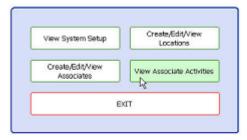
12. Click Close on the Location List Screen when creating/editing/viewing of Locations is complete.



#### VIEW ASSOCIATE ACTIVITIES

1. Click View Associate Activities.





2. View Associate Activities will appear.

#### View Associate Activities



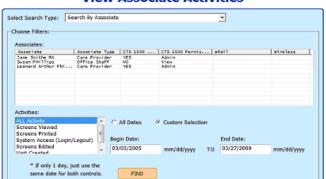
3. **Select Search Type** is used to **Search by Associate** or **Search by Patient**. Click the drop down arrow to expand the list and click an option.



4. A list of associates or patients will appear. Double click on the associate or patient name. **Activities** will then populate with options depending on whether an Associate or Patient is selected and also the



Associate's permissions. Click on an option. In the example shown below, **Search by Associate**, Leonard Phillips MD, and **ALL Activity** is selected. Additionally, **Custom Selection** is selected and 03/03/2005 is keyed into **Begin Date** and 03/27/2009 is keyed into **End Date**. **All Dates** will return all activities for an associate or patient since the profile was created. **Custom Selection** can be used to narrow the scope of the search. Click **FIND**.

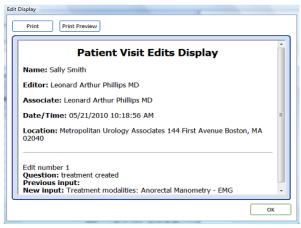


#### **View Associate Activities**

5. The search found 265 records for Leonard Phillips MD for the time period. The **Search Results** listbox displays 28 records within the window. To view additional records use the scroll bar at the right of the window:



6. Double clicking on a record displaying **EDIT** in the **Activity** column will open **Patient Visit Edits Display** showing the addition or edit that was made to that record. Click **Print Preview** to preview the information in Adobe Reader. Click **Print** to print the information. Click **OK** to close.



7. Click **Print** on **View Associate Activity Screen** to print the entire list of activities. Click **Print Preview** to preview the information in Adobe Reader.

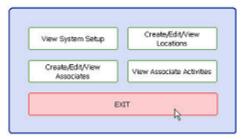




8. Click Close.



9. Click **EXIT** on the **CTS 1500 Tools** window to return to the Opening Screen.



#### **Pelvic Muscle Rehabilitation**

On the Pathway® CTS 1500 opening screen click Start Here.



#### **CREATE A PATIENT**



1. Click **Create New Patient** to establish a new patient record. Go to the following section **SELECT AN EXISTING PATIENT** (page 29) to select an existing patient.



2. Enter the patient data. Red entries <u>MUST</u> be completed. The <u>Provider</u> selected should be the patient's primary provider. Create an <u>Associate Profile</u> if the provider does <u>NOT</u> appear on the list. Click <u>Save New Patient</u>. The <u>Patient Selection Screen</u> 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.
- 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**.



8. Saving Patient Data will appear



#### **SELECT AN EXISTING PATIENT**

Click the drop down arrow in the Patient Last and First Name line. Use the scroll bar to browse the
list and click on the patient or key in the patient's last name in the Patient Last and First Name
window. Key in the last name and then the first name if there is more than one patient with the same
last name.



2. Patient Selection will automatically populate with the patient's information.





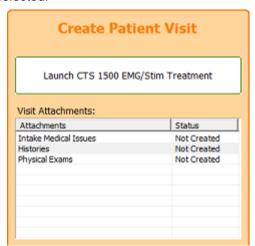
3. Click Reset Patient Selection to choose a different patient.

Reset Patient Selection

4. To place a patient on the inactive list, populate the Patient Selection screen with the patient and click Edit/Review Additional Patient Information. Click the drop down arrow in the Active/InActive Status box and click InActive. Click the Show InActive Patients box on the Patient Selection screen to show the inactive patient list. Follow the same steps from the inactive patient list to return a patient to the active list clicking Active in the Active/InActive Status box.

#### CREATE A PATIENT VISIT

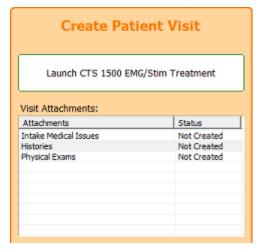
Once a patient is selected **Create Patient Visit** is active and **Attachments** or **Launch CTS 1500 EMG/Stim Treatment** can be selected.



#### **ATTACHMENTS**



1. Three Attachments are available: Intake Medical Issues, Histories and Physical Exams.



#### 2. Intake Medical Issues

- a. Double click Intake Medical Issues.
- b. **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 <u>select the associate</u> who is actually administering the patient care.



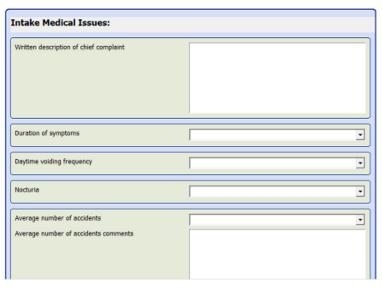
3. Creating Patient Visit will appear.



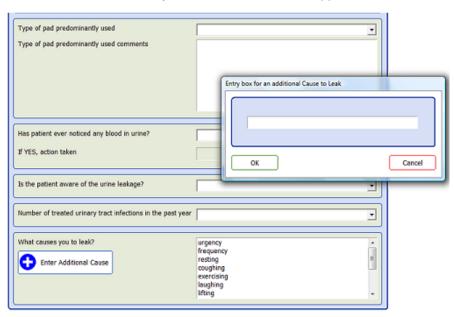


4. **Issues and Histories provided this visit** will appear. Enter the **Written description of chief complaint** by keying in the window. Complete the remainder by clicking on the drop down arrow and clicking an option. Add **comments** by keying in the selected window.

#### Issues and Histories provided this visit



- 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.

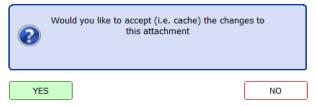


7. Click Close.

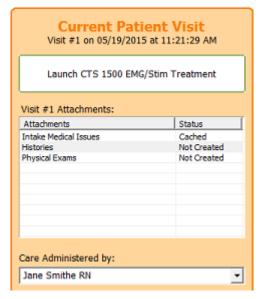




8. Click Yes.



- 9. When the **Patient Selection Screen** reappears.
  - a. Create Patient Visit becomes Current Patient Visit with a visit number, date and time.
  - b. The status of Intake Medical Issues is now Cached (saved in memory).
  - c. A Care Administered by box appears with the associate selected when accessing Intake Medical Issues

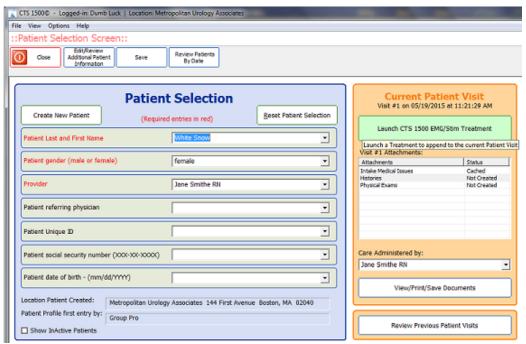


**NOTE:** Once **Intake Medical Issues** is completed, future patient visits will become **Current Medical Issues**.

Attachments can be completed <u>prior</u> to or <u>after</u> Launch CTS 1500 EMG/Stim Treatment or at a future time.

#### LAUNCH CTS 1500 EMG/STIM

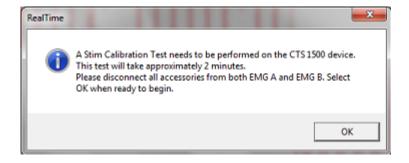
1. Click Launch CTS 1500 EMG/Stim Treatment.



- 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.

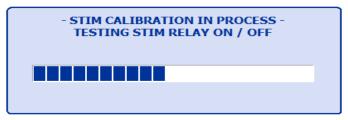


- 4. An automatic **Stimulation Calibration Test** is performed for the first launch of each day.
- 5. Click OK.

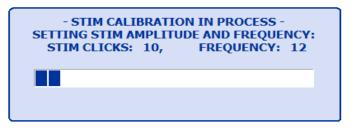




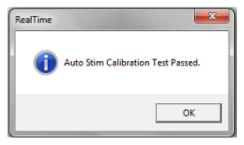
6. STIM CALIBRATION IN PROCESS - TESTING STIM RELAY ON / OFF will appear.



7. Followed by STIM CALIBRATION IN PROCESS – SETTING STIM AMPLITUDE AND FREQUENCY.



Once the stimulation values are calibrated Auto Stim Calibration Test Passed will appear. Click OK.



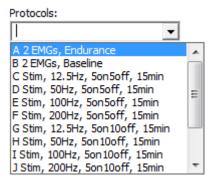
9. CTS 1500 RealTime will appear.



10. Click the drop down list arrow under **Protocols**.



11. Fourteen **Protocols** are available.



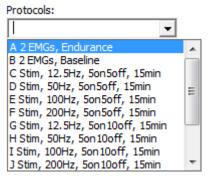
- A 2 EMGs, Endurance provides two EMG channels integrated into a dual screen display acquiring data from EMG A/STIM and EMG B. Endurance describes a work (contract)/rest (relax) protocol for a specific number of trials (repetitions). This protocol has default values of 10 seconds work, 10 seconds rest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



- 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

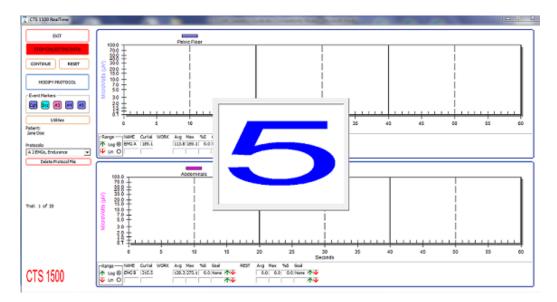
1. Click A 2EMGs, Endurance



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  $\mu V$  (microvolts) and the **EMG B** channel measures the activity of the accessory muscle (in this example **Abdominals**) in  $\mu V$ .
- 4. The total  $\mu V$  Range for EMG A and EMG B is .1-1000 $\mu V$  with a display default range of .1-100 $\mu V$ . 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 μV for each channel is displayed.

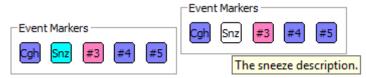
6. To the right of the **CurVal**, a work/rest protocol activates both the **WORK** and **REST** average (**Avg**) and maximum (**Max**)  $\mu$ V display.

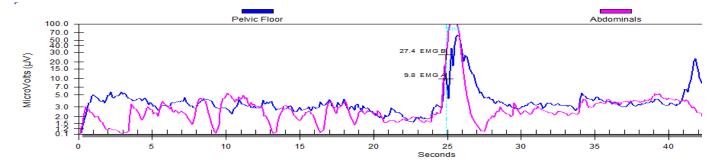
7. To the right of Avg and Max are %S and Goal columns. A treatment goal can be established in μV for each channel and, in this case, for BOTH WORK and REST intervals. The treatment goal will appear as a line on the graph. The %S will track the percentage success in attaining the treatment goal and the 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.





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.

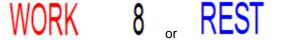




9. The current **Trial** number is displayed. The total number of trials is 20.

Trial: 1 of 20

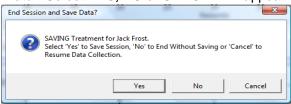
10. A work/rest protocol activates a **WORK** and **REST** countdown as well as audio cues delineating the beginning of a work or rest interval.



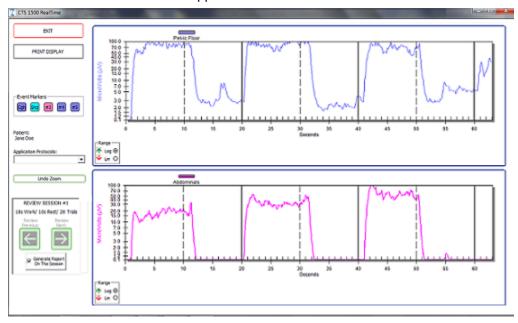
11. Click **STOP COLLECTING DATA** at any time to truncate the treatment.



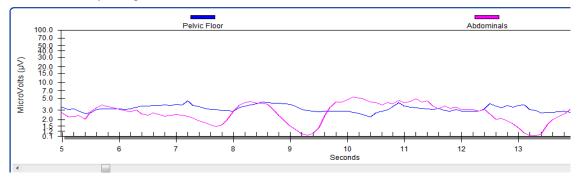
- 12. The treatment will automatically end once 20 trials are complete. Click STOP COLLECTING DATA.
- 13. End Session and Save Data? Select YES, NO or CANCEL will appear.



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.
- 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.

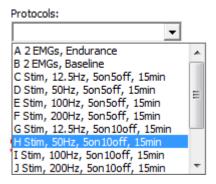


23. While in the review window another treatment may be launched. The user may launch, complete, save, review and edit up to **SIX** treatments of any combination within a single session.

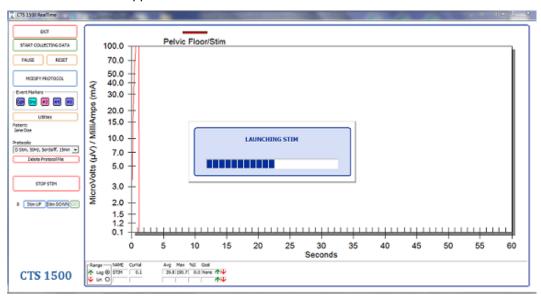
Protocols:	
	▾

### H Stim, 50Hz, 5on10off, 15min

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



2. LAUNCHING STIM will appear.



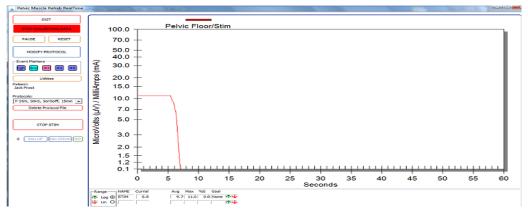
- 3. The screen will be active and begin data collection.
- 4. Click **Stim UP** until the required level of stimulation amplitude is reached. Note the level on the amplitude counter. Each click increases the stimulation amplitude one MilliAmp (mA). **Stim DOWN** functions the same to decrease the stimulation amplitude.



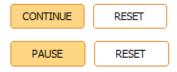
5. Once the required stimulation amplitude is reached, click GO.



6. The 15 minute stimulation session will begin.



 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.



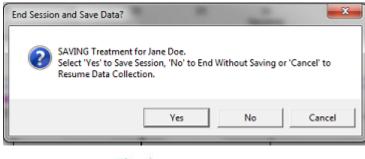
- 8. The stimulation amplitude can be adjusted during the treatment. **Stim UP** and **Stim DOWN** will be active only when stimulation has reached the peak amplitude set by clicking **GO**. During ramp up, ramp down and EMG, **Stim UP** and **Stim DOWN** are NOT active.
- 9. Click **STOP STIM** at any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



10. 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.



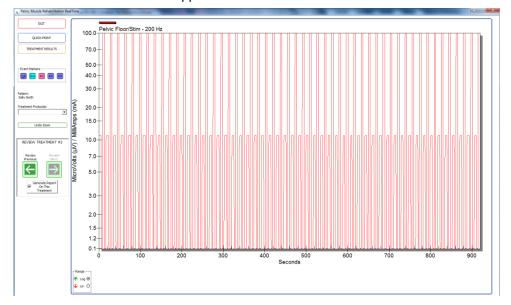
- 11. Whether the treatment is truncated or runs the full 15 minutes, stimulation will stop and EMG will remain active on the display. Click **STOP COLLECTING DATA** to end the treatment.
- 12. End Session and Save Data? Select YES, NO or CANCEL will appear.





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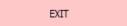
14. Now that two treatments are saved, the previous treatment may be reviewed by clicking on the **Review Previous** green arrow. A **Review Next** green arrow is provided as well. In the **REVIEW SESSION** area the **Generate Report On This Session** has a check mark. Click the check mark to remove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



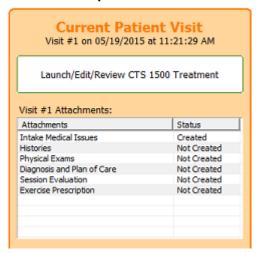
- 15. The zoom, **Undo Zoom** and **Event Markers** functions are active for each treatment.
- 16. Click **PRINT DISPLAY** if a printed screen copy is needed.

PRINT DISPLAY

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

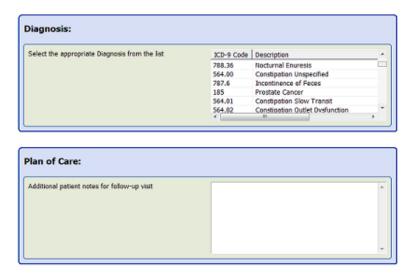
1. Double click Diagnosis and Plan of Care.





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.

#### **Procedures Administered this Visit**



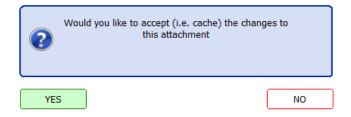
3. Plan of Care: Additional patient notes for follow-up visit allows the input of commonly used terms or phrases which, after entered and clicked on, appear in Additional patient notes for follow-up visit for further editing.



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

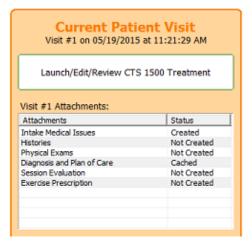


6. Click YES.



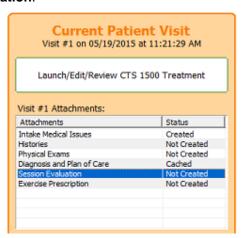


7. Diagnosis and Plan of Care is now Cached.



## **SESSION EVALUATION**

1. Double click Session Evaluation.

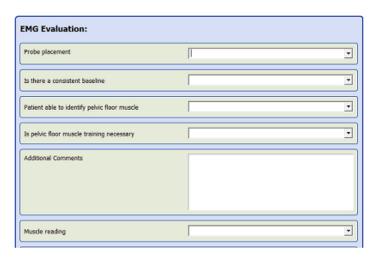


2. Procedures Administered this Visit will open.



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.

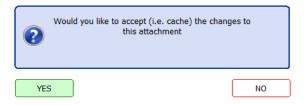
#### **Procedures Administered this Visit**



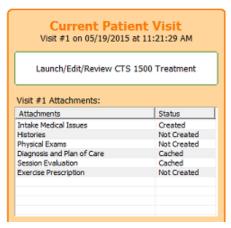
- 4. **Additional Comments** terms and phrases automatically carry forward for use with all subsequent treatments.
- 5. Click Close.



6. Click YES.



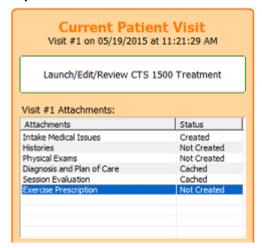
7. Session Evaluation is now Cached.





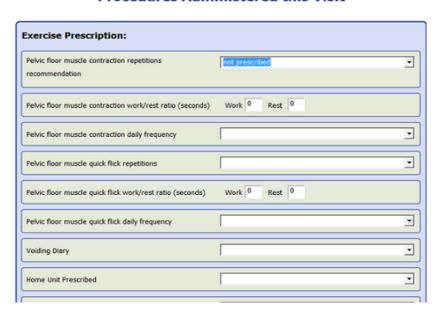
#### **EXERCISE PRESCRIPTION**

1. Double click Exercise Prescription.

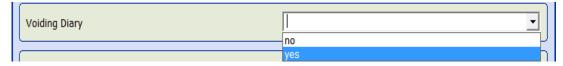


- 2. Procedures Administered this Visit will open.
- 3. Complete the **Exercise Prescription** from drop down menus and input boxes.

#### **Procedures Administered this Visit**

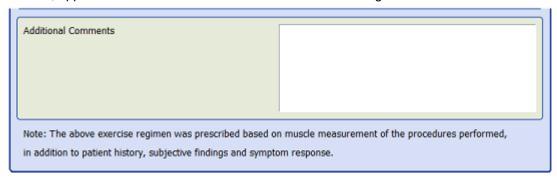


4. If a Voiding Diary is required select yes.





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.



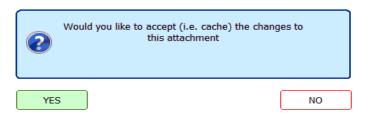
6. **Additional Comments** terms and phrases automatically carry forward for use with all subsequent treatments.

**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.



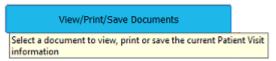
9. Exercise Prescription is now Cached.





#### **Opening Documents**

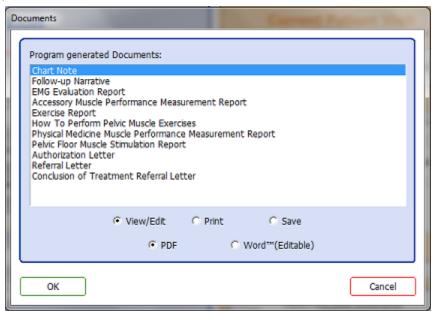
The program automatically compiles patient and provider information, Attachments and treatment results to generate documents in Adobe<sup>®</sup> Acrobat<sup>®</sup> PDF or Word<sup>™</sup> (Editable) file format.
 Documents can be viewed, edited, printed and saved to another location. To open Documents,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



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

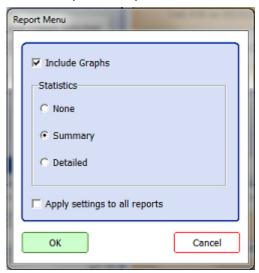


- 3. A Documents window will appear. Choose View/Edit, Print or Save in a PDF or Word™ (Editable) format. Only the Word™ (Editable) format will activate the Edit function for the View/Edit option. A comprehensive list of Documents include: Chart Note, Intake Narrative, EMG Evaluation Report, Accessory 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.





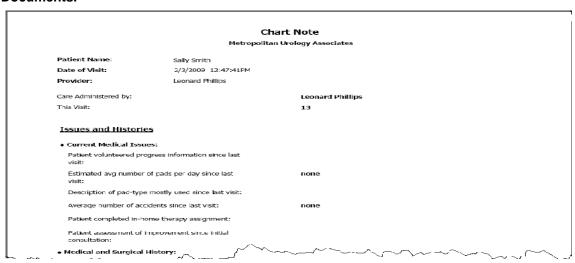
5. Report Menu will appear. Click on the provided options. Click OK.



6. Processing Chart Note will appear.



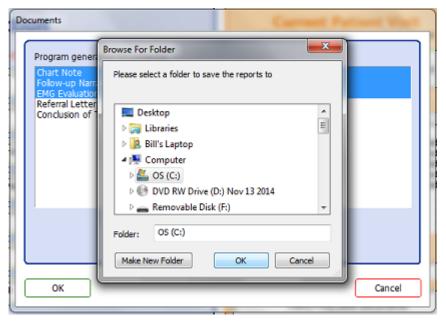
7. The **Chart Note** will be generated. To print, click on the printer icon on the top toolbar or click **File** on the top toolbar and click **Print.** The **Chart Note** can also be printed directly from **Program generated Documents.** 



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



- 8. 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.
- 9. 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.

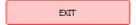


2. If there are multiple treatments, toggle between treatments to review or edit by selecting **Review**Previous or Review Next. All treatments, whether Generate Report On This Treatment is checked or not, are shown for edit/review. Full review screen edit capabilities are active

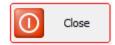


3. Click **Exit** when the review/edit of these treatments is complete. **Patient Selection Screen** will appear.





- 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.

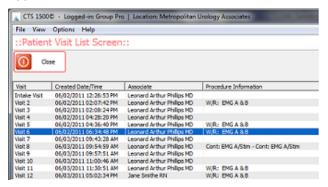


#### **Review Previous Visits**

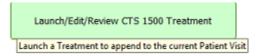
1. Click Review Previous Visits.



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.

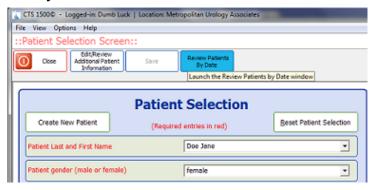


4. Follow the steps outlined in Review Current Visit.

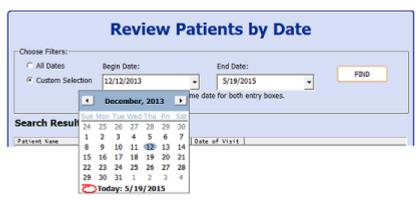


#### **Review Patients By Date**

1. Click Review Patients By Date.



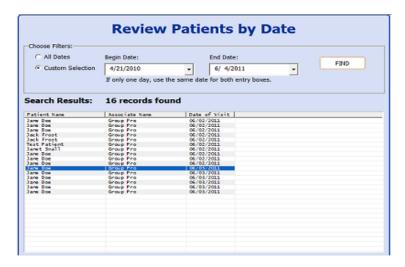
Click All Dates or Custom Selection. Custom Selection activates Begin Date and End Date calendars.



3. Click **Find. Search Results** will be populated.



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.



5. 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.

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



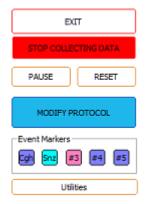
6. Clicking **Review Previous Patient** or **Review Next Patient** will advance to the previous or next patient record.

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

# **Active Treatment Screen Changes Addendum Modify Protocol**

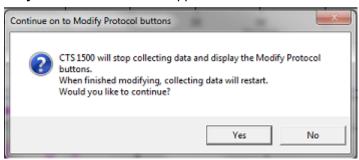
1. Click on the protocol to modify from the **Treatment Protocols** list. Click **MODIFY PROTOCOL** once the display becomes active.





**NOTE:** Always select the correct protocol as a template/starting point (ie. **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 <u>will be overwritten</u> 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 <u>only show</u> if a stim protocol <u>is selected.</u> If a stim protocol <u>is selected</u> Stop Stim <u>MUST</u> 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**.



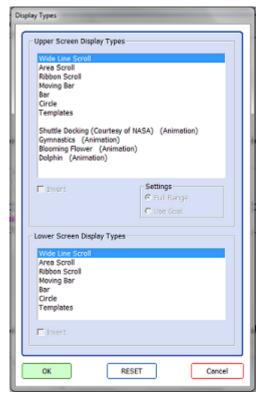
## **DISPLAY TYPE**

1. Click Display Type.



2. Click on a Display Type. Click OK.





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.





#### **C**OLORS

1. Click Colors.



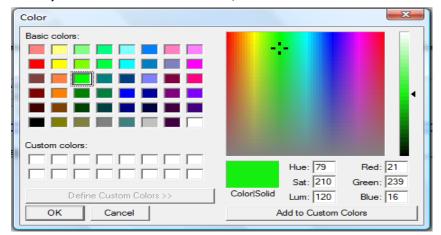
2. Color Selection will appear. Click EMG A/STIM. Click EMG B, or the Screen Background to modify its color. Click OK.



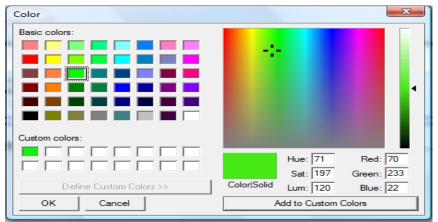
3. Color will appear. Set EMG A/Stim to be a basic color by clicking on one of the Basic colors. Select a Custom color by clicking and holding on the bull's-eye in the color spectrum window. Drag the bull's eye over the color spectrum until the desired color appears in Color|Solid. Both Basic and



**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**.

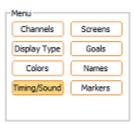


4. The new color will appear in Custom colors. Click OK.



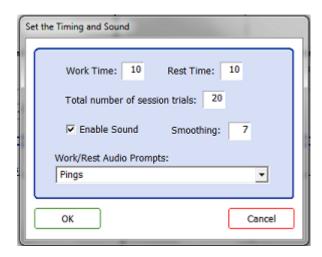
## TIMING/SOUND

1. Click Timing/Sound.



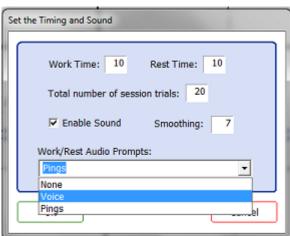
2. Set the Timing and Sound will appear.





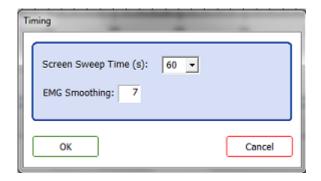
NOTE: Set the Timing and Sound only appears when modifying a work/rest protocol.

- 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 **3** 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.
- 9. A protocol without work/rest will display Timing.





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

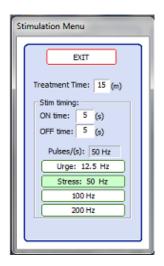
# STIM MENU

**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.

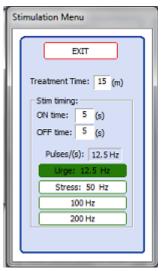




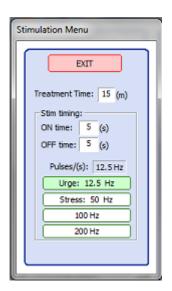
- 3. Change **Treatment Time**: in minutes by clicking in the cell, highlighting the existing time and keying in the new time.
- 4. Change **Stim Timing:** in seconds (both **ON time:** and **OFF time:**) by clicking in the cell, highlighting the existing time and keying in the new time.

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

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



6. Click Exit.



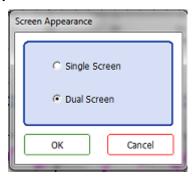


# **S**CREENS

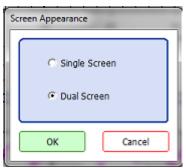
1. Click Screens.



2. Screen Appearance will appear.



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



#### GOALS

1. Click Goals.





2. Channel Goal Selections will appear.



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**  $\mu$ **V**.



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

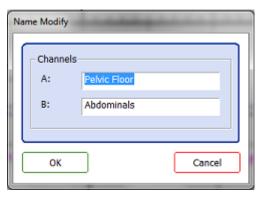


# **N**AMES

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**

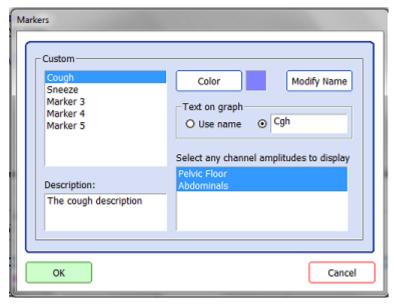
1. Click Markers.



2. Markers will appear.



3. Click the Cough marker.

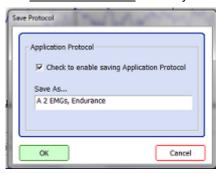


- 4. Click Color. Cough color can now be changed from Colors.
- 5. The marker name can be changed. Click on a marker name and click **Modify Name**. Key in the change.
- 6. The **Text on graph** can be changed. Click on a marker name. Click **Use name** and key in a maximum of **3** letters.
- 7. The 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.





11. **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 **NOT** changed the original protocol will be overwritten with any and all changes made. Click **OK**.



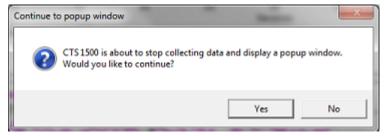
#### **Utilities**

**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.

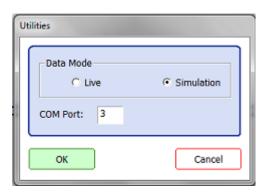
1. To select Simulation mode click Utilities.



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.

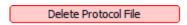
## SIMULATION MODE

#### **Delete Protocol**

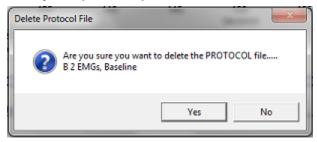
1. Click on the protocol to **Delete** from the **Protocols** drop down menu.



2. Click Delete Protocol File.



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



Note: Once the Yes button in Delete Protocol File <u>has been selected</u> the Treatment Protocol <u>will be</u> deleted.

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



## Pathway® CTS 1500 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:  $1 - 800 \,\mu\text{V}$ 

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 microculombs

PC:

Notebook:

Display: 15.6 in
Resolution: 1366 X 768
Processor: 1.8 GHz Dual Core

RAM: 4 GB RAM Hard Drive: 500 GB

Patient Data Storage: > 500 Patient Records

Battery: 40 Whr Rechargeable Battery providing 4+ hours of use

 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: 1 Year Parts and Labor Color Printer: 1 Year Parts and Labor 2 Year Parts 2

Standards and Approvals: ISO 13485:2003

# **SOFTWARE LICENSE AGREEMENT**

THE PROMETHEUS® GROUP grants to the purchaser of the Pathway® CTS 1500 Software the right to use one copy of Pathway® CTS 1500 Software on one computer within one business entity. Pathway® 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 Software.



## STANDARD WARRANTY SERVICE AGREEMENT

THE PROMETHEUS® GROUP warrants equipment of its own manufacture to be free from defects in material and workmanship as follows:

One (1) year from the date of shipment to the original purchaser, subject to the terms, conditions, limitations, and exclusions specified herein.

- 1. Service: THE PROMETHEUS® GROUP of New Hampshire, Ltd., hereafter "THE PROMETHEUS® GROUP", shall provide, for the term of this warranty, repair of defective Prometheus® Group units. This warranty shall include all parts and labor charges. The purchaser must obtain a Return Authorization Number and must return the defective unit, at the purchaser's own expense to THE PROMETHEUS® GROUP. THE PROMETHEUS® GROUP may, at its option, repair and return the unit or provide a replacement unit. Should THE PROMETHEUS® GROUP elect to provide a replacement unit, then this warranty is automatically transferred to the replacement unit. THE PROMETHEUS® GROUP shall return, at THE PROMETHEUS® GROUP'S own expense, the repaired or replacement Prometheus® Group unit.
- 2. Exclusions: The following conditions are excluded from service under this warranty:
  - A. Preventative maintenance. Preventative maintenance, defined as maintenance performed for the purpose of preventing a malfunction, is excluded from service under this warranty.
  - B. Repair of damage or malfunction of Prometheus® Group equipment resulting from abuse, accident, modification, usage of accessories, consumables and components not supplied or approved by THE PROMETHEUS® GROUP, or other cause other than normal usage, including but not limited to operator error, failure of other user-supplied equipment, and equipment operation in excess of design specifications is excluded from service under this warranty.
  - C. Loss due to fire, flood, robbery, burglary, theft, vandalism, radioactive contamination, or other natural disasters or Acts of God is excluded from service under this warranty
  - D. Replacement of batteries, accessories and expendables such as electrodes, are excluded from service under this warranty.
  - E. Commercial Equipment made by others, such as computers and printers.

**NOTE:** THE PROMETHEUS® GROUP provides no warranty on these items, and any service required must be obtained from the original manufacturer.

- 3. Optional Warranty Extension: This warranty may be renewed or extended by written agreement and acceptance of both parties. The price for such extension shall be the price in effect at the time the extension is put in force. THE PROMETHEUS® GROUP shall waive any inspection and conditional repair requirements for uninterrupted warranty extensions.
- 4. Limitation of Remedy: THE PROMETHEUS® GROUP shall not be liable for any damages caused by the delay in furnishing warranty services or other performance under this warranty. The service warranty expressed in paragraph 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 users 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.
- 5. Assignment: This warranty shall not be assigned by the purchaser without prior written consent of THE PROMETHEUS® GROUP. The warranty shall be binding upon all of the parties and their successors and assigns.

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