2020

TECHNICAL RESOURCE GUIDE

A Comprehensive Reference for Prometheus Products and Technology Platforms.

The **PROMETHEUS** GROUP®

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

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Software Controlled Product Descriptions

All of the software applications offered by The Prometheus Group® are HIPAA compliant and include database encryption with automatic or manual backups, multi-level password protection, provider and administrative access controls, unique patient identifiers and audit management.

Telesis® Software for the Pathway® MR Series (Part #9250): Telesis® Software utilizes a USB Serial Interface to the Pathway® MR Series Systems providing One or Two Channels of sEMG. Telesis® Software includes multiple display options, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

Telesis® ST Software for the Pathway® MR Series (Part #9250ST): Telesis® ST Software utilizes a USB Serial Interface to the Pathway® MR Series Systems providing One or Two Channels of sEMG. Telesis® ST Software includes multiple display options and application and modified protocols. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system

EMYO® 100B and 200B (Part #EM100B-N and #EM200B-N): EMYO® 100B or 200B Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the EMYO® 100B or 200B Modules providing One or Two Channels of sEMG. EMYO® 100B or 200B Software Program includes game displays on a separate 24" HDMI Monitor, multiple display options, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

EMYO® 100U and 200U (Part #EM100U-N and #EM200U-N): EMYO® 100U or 200U Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the EMYO® 100U or 200U Modules and the Uroflowmetry Load Cell providing One Channel of External Pelvic Muscle sEMG or One Channel of External Pelvic Muscle sEMG and One Channel of Accessory Muscle sEMG plus one Channel of Uroflowmetry Volume and one Channel of Uroflowmetry Rate. EMYO® 100U or 200U Software Program includes application and modified protocols, automated marker placement, three nomograms, calculated sEMG Lag Time and Post Void Residual and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

EMYO® 100UB and 200UB (Part #EM100UB-N and #EM200UB-N): EMYO® 100UB or 200UB Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the EMYO® 100UB or 200UB Modules and the Uroflowmetry Load Cell providing One Channel of External Pelvic Muscle sEMG or One Channel of External Pelvic Muscle sEMG and One Channel of Accessory Muscle sEMG plus one Channel of Uroflowmetry Volume and one Channel of Uroflowmetry Rate. EMYO® 100UB or 200UB Software Program includes game displays on a separate 24" HDMI Monitor, multiple display options, application and modified protocols, automated marker placement, three nomograms, calculated sEMG Lag Time and Post Void Residual and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

EMYO® 100S and 200S (Part #EM100S-N and #EM200S-N): EMYO® 100S or 200S Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the EMYO® 100S or 200S Modules providing One or Two Channels of sEMG. EMYO® 100S or 200S Software Program includes game displays on a separate 24" HDMI Monitor, multiple display options and application and modified protocols. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

Pathway® CTS 2000 Pelvic Muscle Rehabilitation System (Part #CTS-2000B): Pathway® CTS 2000 Pelvic Muscle Rehabilitation System Software Program utilizes a USB Serial Interface to the Pathway® CTS 2000 Pelvic Muscle Rehabilitation System Module providing one Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG, One Channel of Vaginal and Rectal Electrical Stimulation and One Channel of Rectal Pressure Manometry. Pathway® CTS 2000 Pelvic Muscle Rehabilitation System Software Program includes multiple display options, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

Pathway® CTS 1500 Pelvic Muscle Rehabilitation System (Part #CTS-1500B): Pathway® CTS 1500 Pelvic Muscle Rehabilitation System Software Program utilizes a USB Serial Interface to the Pathway® CTS 1500 Pelvic Muscle Rehabilitation System Module providing one Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG and One Channel of Vaginal and Rectal Electrical Stimulation. Pathway® CTS 1500 Pelvic Muscle Rehabilitation System Software Program includes multiple display options, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

Pathway® Musculoskeletal Ultrasound Imaging (Part #MSK-S-T): Pathway® Musculoskeletal Ultrasound Imaging Software Program utilizes a USB Serial Interface to the SP-LO1 5-10MHz Linear Array Ultrasound Imaging Transducer. Pathway® Musculoskeletal Ultrasound Imaging Software Program includes image quality controls, Preset protocols, measurements, single image and Cine (video) storage and review, image overlay and comparisons, annotated attachment and chart note. Chart note reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system. Single images and Cine (video) can be transferred to an electronic medical record (EMR) System.

Pathway® Ultrasound Imaging System for Lumbopelvic Rehabilitation (Part #TUI-S-T): Pathway® Ultrasound Imaging System for Lumbopelvic Rehabilitation Software Program utilizes a USB Serial Interface to the GP-CO1 3.5-7.5MHz Curved Array Ultrasound Imaging Transducer. Pathway® Ultrasound Imaging System for Lumbopelvic Rehabilitation Software Program includes image quality controls, Preset protocols, measurements, single image and Cine (video) storage and review, image overlay and comparisons, annotated attachment and chart note. Chart note reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system. Single images and Cine (video) can be transferred to an electronic medical record (EMR) System.

WiFLOW® Uroflowmetry (Part #WLC-T): WiFLOW® Uroflowmetry Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the Uroflowmetry Load Cell providing one Channel of Uroflowmetry Volume and one Channel of Uroflowmetry Rate. WiFLOW® Uroflowmetry Software

Program includes automated marker placement, three nomograms, calculated Post Void Residual and printout.

Morpheus® Control Module (Part #MOR0118): Morpheus® Control Module utilizes a USB Serial Interface providing Two Channels of sEMG, One Channel of Rectal Pressure Manometry, One Channel of Electrical Stimulation and Four Channels of Pressure Manometry. Morpheus® Control Module **REQUIRED** for Pelvic Muscle Rehabilitation (Part #PMR), Two Channel EMG with Stimulation (Part #EMG/S), Anorectal Manometry with Paradoxical EMG (Part #ARM), Urodynamics (Part #CURO), Advanced Urodynamics (Part #MORADV) and Video Urodynamics (Part #MORVID). Options:

1. **Pelvic Muscle Rehabilitation (Part #PMR):** Morpheus® Pelvic Muscle Rehabilitation Software Program provides one Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG, One Channel of Vaginal and Rectal Electrical Stimulation and One Channel of Rectal Pressure Manometry. Morpheus® Pelvic Muscle Rehabilitation Software Program includes multiple display options, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.
   a. **Game Option (Part #ANOP):** Morpheus® Game Software Program option provides game displays on a separate 24" HDMI Monitor.
2. **Two Channel sEMG with Stimulation (Part #EMG/S:** Morpheus® Two Channel sEMG with Stimulation Software Program provides one Channel of Vaginal and Rectal Intracavity sEMG or External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG and One Channel of Vaginal and Rectal Electrical Stimulation. Morpheus® Two Channel sEMG with Stimulation Software Program includes multiple display options, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.
3. **Anorectal Manometry with Paradoxical sEMG (Part #ARM):** Morpheus® Anorectal Manometry with Paradoxical sEMG Software Program provides Four Channels of Directional Anorectal Manometry, One Channel of Compliance Balloon Pressure and One Channel of External Pelvic Muscle or Intracavity Rectal sEMG. Morpheus® Anorectal Manometry with Paradoxical sEMG Software Program includes free style or structured depth study with rest, squeeze and push measurements, RAIR study, capacity study and expulsion study, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.
4. **Urodynamics (Part #CURO):** Morpheus® Urodynamics Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the Uroflowmetry Load Cell and Integrated Digitally Controlled Infusion Pump providing One Channel of Abdominal Pressure, One Channel of Bladder Pressure, One Channel of Urethral Pressure, Two Channels of Calculated Pressure, One Channel of External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG , One Channel of Flow and Volume , One Channel of Infusion Pump Volume, Three Calculated Nomograms, Automatic Post Void Residual Calculations, Bladder Outlet Obstruction Calculation and Urethral Pressure Profile Calculations. Morpheus® Urodynamics Software Program includes application protocols for complex urodynamics, uroflowmetry, sEMG/Uroflowmetry, modified protocols and integrated attachments. Chart note and narrative reports are generated in a

Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

5. **Advanced Urodynamics (Part #MORADV):** Morpheus® Advanced Urodynamics Software Program utilizes a 27" Curved 4K UHD Monitor with Split Screen Display, Turbo Speed Industrial Grade Computer with HD Mirroring and Automatic High Speed Backup, wireless Bluetooth connection or USB Serial Interface to the Uroflowmetry Load Cell and Integrated Digitally Controlled Infusion Pump providing One Channel of Abdominal Pressure, One Channel of Bladder Pressure, One Channel of Urethral Pressure, Two Channels of Calculated Pressure, One Channel of External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG, One Channel of Flow and Volume, One Channel of Infusion Pump Volume, Three Calculated Nomograms, Automatic Post Void Residual Calculations, Bladder Outlet Obstruction Calculation and Urethral Pressure Profile Calculations. Morpheus® Advanced Urodynamics Software Program includes application protocols for complex urodynamics, uroflowmetry, sEMG/Uroflowmetry, modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

6. **Video Urodynamics (Part #MORVID):** Morpheus® Video Urodynamics Software Program utilizes a 34" Curved 4K UHD Monitor with Split Screen Display, Turbo Speed Industrial Grade Computer with HD Mirroring and Automatic High-Speed Backup, Digital Image Capture Board with Real Time Video Streaming. wireless Bluetooth connection or USB Serial Interface to the Uroflowmetry Load Cell and Integrated Digitally Controlled Infusion Pump providing One Channel of Abdominal Pressure, One Channel of Bladder Pressure, One Channel of Urethral Pressure, Two Channels of Calculated Pressure, One Channel of External Pelvic Muscle sEMG, One Channel of Accessory Muscle sEMG, One Channel of Flow and Volume, One Channel of Infusion Pump Volume, Three Calculated Nomograms, Automatic Post Void Residual Calculations, Bladder Outlet Obstruction Calculation, Urethral Pressure Profile Calculations, Unique Split Screen Video and Urodynamics Display, Automatic Communication with Imaging Equipment, Real Time Audio/Video Streaming and Auto Mirroring with Auto Capture . Morpheus® Video Urodynamics Software Program includes application protocols for complex urodynamics, uroflowmetry, sEMG/Uroflowmetry, modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

7. **360◦ Endocavity Ultrasound Imaging (Part #RTCU-S-8):** Morpheus® 360◦ Endocavity Ultrasound Imaging Software Program utilizes a USB Serial Interface to the 360◦ ER 12MHz Endocavity Ultrasound Transducer. Morpheus® 360◦ Endocavity Ultrasound Imaging Software Program includes image quality controls, Preset protocols, measurements, single image and Cine (video) storage and review, image overlay and comparisons, annotated attachment and chart note. Chart note reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system. Single images and Cine (video) can be transferred to an electronic medical record (EMR) System.

8. **Transperineal Ultrasound Imaging (Part #RTTU-S-8):** Morpheus® Transperineal Ultrasound Imaging Software Program utilizes a USB Serial Interface to the GP-CO1 3.5-7.5MHz Curved Array Ultrasound Imaging Transducer. Morpheus® Transperineal Ultrasound Imaging Software Program includes image quality controls, Preset protocols, measurements, single image and Cine (video) storage and review, image overlay and comparisons, annotated attachment and chart note. Chart note reports are generated in a Portable Document Format (PDF) or a Microsoft

Word Document and can be transferred to an electronic medical record (EMR) system. Single images and Cine (video) can be transferred to an electronic medical record (EMR) System.

9. **Morpheus Uroflowmetry (Part #URO-S-N):** Morpheus® Uroflowmetry Software Program utilizes a wireless Bluetooth connection or USB Serial Interface to the Uroflowmetry Load Cell providing one Channel of Uroflowmetry Volume and one Channel of Uroflowmetry Rate. Morpheus® Uroflowmetry Software Program includes automated marker placement, three nomograms, calculated Post Void Residual, application and modified protocols and integrated attachments. Chart note and narrative reports are generated in a Portable Document Format (PDF) or a Microsoft Word Document and can be transferred to an electronic medical record (EMR) system.

Product Chart Computer Configurations

Computer / Software	Turbo Speed Industrial Grade Computer	High Resolution All-in-One Touchscreen Computer	Notebook Computer	Touchscreen Tablet Computer	24" HDMI Monitor
Telesis® and Telesis® ST Software (Part #9250 and #9250ST))			X		
EMYO® Series (Part #EM100 and #EM200, B, U, UB, S-N)			X		
Pathway® CTS 2000 (Part #CTS-2000B)			X		
Pathway® CTS 1500 (Part #CTS-1500B)			X		
Pathway® Musculoskeletal Ultrasound Imaging (Part #MSK-S-T)				X	
Pathway® Ultrasound Imaging System for Lumbopelvic Rehabilitation (Part #TUI-S-T)				X	
WiFLOW® Uroflowmetry (Part #WLC-T)				X	
Pelvic Muscle Rehabilitation (Part #PMR)		X			
Game Option (Part #ANOP)					X

Computer / Software	Turbo Speed Industrial Grade Computer	High Resolution All-in-One Touchscreen Computer	Notebook Computer	Touchscreen Tablet Computer	24" HDMI Monitor
Two Channel sEMG with Stimulation (Part #EMG/S)		X			
Anorectal Manometry with Paradoxical sEMG (Part #ARM)		X			
Urodynamics (Part #CURO)		X			
Advanced Urodynamics (Part #MORADV)	X				
Video Urodynamics (Part #MORVID)	X				
360◦ Endocavity Ultrasound Imaging (Part #RTCU-S-8)		X			
Transperineal Ultrasound Imaging (Part #RTTU-S-8)		X			
Morpheus® Uroflowmetry (Part #URO-S-N)			X		

NOTE: Computers are configured as a medical device and **SHOULD NOT** be treated as a personal computer. Any modifications made to the computers are done so at your own risk.

Computer Specifications:

Turbo Speed Industrial Grade Computer

- Processor: Intel Core i7-8700T (Coffee Lake) 2.4 GHz – 35W
- Memory 32 GB (2x16 SO-DIMM DDR4 2133)
- Primary Storage: 1 TB M.2 SSD
- Additional Storage: 1 TB 2.5" SSD
- Wireless Connectivity: Wi-Fi/BT Atheros Dual-Band 2x2 802.11a/b/g/n (DHXA-222)
- Antennas: 2 x Wi-Fi Dual-Band Terminal PIFA Antenna, 161mm (6.34")
- Add-on Module: ASRock Nuvoton TPM 2.0 Module
- AC Adapter: Power Adapter DC 19 V, 4.73 A, 90 W
- Operating System: Windows 10 IoT Enterprise 2019 LTSC High End (i7, Xeon) – 64 Bit

High Resolution All-In-One Touchscreen Computer

- Operating System: Windows 10 Professional
- Architecture: 64 Bit Operating System
- Display Resolution: 1920 x 1080
- Processor: Intel i5 or Higher
- RAM: 8 GB RAM or 16GB to support optional Game Animation Option
- Hard Drive: 500 GB (to allow for database expansion)
- HDMI Port Availability
- Minimum of 3 USB 2.0 Ports
- Bluetooth Functionality

Notebook Computer

- Operating System: Windows 10 Professional
- Architecture: 64 Bit Operating System
- Display Resolution: 1920 x 1080
- Processor: Intel i5 or Higher
- RAM: RAM: 8 GB RAM or 16GB to support optional Game Animation Option
- Hard Drive: 500 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.

Touchscreen Tablet Computer

- Operating System: Windows 10 Professional
- Architecture: 64 Bit Operating System
- Display Resolution: 1920 x 1200
- Processor: Intel i5 or Higher
- RAM: 4 GB RAM
- Hard Drive: 256 GB (to allow for database expansion)
- Minimum of 1 USB 2.0 Ports
- Minimum of 1 USB 3.0 Type C
- Bluetooth Functionality

24" HDMI Monitor Specifications:

- Device Type: LED-Backlit LCD Monitor
- Screen Size: 24"
- Aspect Ratio: Widescreen (16:9)
- Native Resolution: Full HD (1080p) 1920 x 1080 at 60 Hz or greater
- Color Support: 16.7 Million Colors
- Input Connectors
    - HDMI (MHL), DisplayPort, Mini DisplayPort
    - USB 2.0 or greater Required if used with a Wireless video adapter (Screenbeam™ Mini 2 Wireless Display Receiver)

Data Storage Charts

Data Storage Type	Estimated Size	Unit
Raw Session Data and Log Files	1,000	KB
ARM Depth Study Graph Image Sm (15min)	800	KB
ARM Depth Study Graph Image Lrg (15min)	1,000	KB
ARM RAIR Status Graph Image Sm (5min)	400	KB
ARM RAIR Status Graph Image Lrg (5min)	500	KB
EMG STIM Graph Image (15min)	200	KB
EMG Baseline Graph Image (5min, 2ch)	2,000	KB
EMG Endurance Graph Image (5min, 20trials, 2ch)	1,000	KB
Ultrasound Image	300	KB
Ultrasound Cine Video (5sec,64fps, uncompressed)	8,200	KB
Ultrasound Cine Video (5sec,128fps, uncompressed)	16,400	KB
Ultrasound Cine Video (5sec,256fps, uncompressed)	32,800	KB
Ultrasound Cine Video (5sec,512fps, uncompressed)	65,600	KB
Ultrasound Cine Video (5sec,1024fps, uncompressed)	131,200	KB
Ultrasound Cine Video (5sec,64fps, compressed-2:1)	4,100	KB
Ultrasound Cine Video (5sec,128fps, compressed-2:1)	8,200	KB
Ultrasound Cine Video (5sec,256fps, compressed-2:1)	16,400	KB
Ultrasound Cine Video (5sec,512fps, compressed-2:1)	32,800	KB
Ultrasound Cine Video (5sec,1024fps, compressed-2:1)	65,600	KB
Ultrasound Cine Video (5sec,64fps, compressed-3:1)	2,800	KB
Ultrasound Cine Video (5sec,128fps, compressed-3:1)	5,600	KB
Ultrasound Cine Video (5sec,256fps, compressed-3:1)	11,200	KB
Ultrasound Cine Video (5sec,512fps, compressed-3:1)	22,400	KB
Ultrasound Cine Video (5sec,1024fps, compressed-3:1)	44,800	KB
Ultrasound Cine Video (5sec,64fps, compressed-4:1)	2,100	KB
Ultrasound Cine Video (5sec,128fps, compressed-4:1)	4,200	KB
Ultrasound Cine Video (5sec,256fps, compressed-4:1)	8,400	KB
Ultrasound Cine Video (5sec,512fps, compressed-4:1)	16,800	KB
Ultrasound Cine Video (5sec,1024fps, compressed-4:1)	33,600	KB
Uroflow Flow/Volume Graph Image (1min)	150	KB
Uroflow Nomogram Graph Image (3)	400	KB
Urodynamics Cystometry Filling Graph Image Sm (15min)	800	KB
Urodynamics Cystometry Filling Graph Image Lrg (15min)	1,000	KB
Urodynamics Cystometry Voiding Graph Image Sm (5min)	400	KB
Urodynamics Cystometry Voiding Graph Image Lrg (5min)	500	KB
Urodynamics Cystometry Nomograms Graph Image (3)	400	KB
Urodynamics Cystometry Urethral Pressure Graph Image (4)	200	KB
Video Urodynamics Snapshot X-ray Image	4,000	KB
Video Urodynamics Snapshot Graph Image	100	KB

Data Storage Type	Estimated Size	Unit
Video Urodynamics Burst Graph Image (5sec)	200	KB
Video Urodynamics Burst X-ray Video Thumbnail Image	300	KB
Video Uro Burst X-ray Video (5sec,8fps,32bit, uncompressed)	192,000	KB
Video Uro Burst X-ray Video (5sec,8fps,24bit, uncompressed)	145,000	KB
Video Uro Burst X-ray Video (5sec,8fps,16bit, uncompressed)	96,000	KB
Video Uro Burst X-ray Video (5sec,8fps,32bit, compressed-Intel IYUV Codec)	72,000	KB
Video Uro Burst X-ray Video (5sec,8fps,24bit, compressed-DV Video Encoder)	5,000	KB
Video Uro Burst X-ray Video (5sec,8fps,16bit, compressed-Intel IYUV Codec)	72,000	KB
Video Uro Burst X-ray Video (5sec,32fps,32bit, uncompressed)	765,000	KB
Video Uro Burst X-ray Video (5sec,32fps,24bit, uncompressed)	573,000	KB
Video Uro Burst X-ray Video (5sec,32fps,16bit, uncompressed)	382,000	KB
Video Uro Burst X-ray Video (5sec,32fps,32bit, compressed-Intel IYUV Codec)	286,000	KB
Video Uro Burst X-ray Video (5sec,32fps,24bit, compressed-DV Video Encoder)	19,000	KB
Video Uro Burst X-ray Video (5sec,32fps,16bit, compressed-Intel IYUV Codec)	286,000	KB

Example Study Calculations

Example of a 20-min Video Cystometry Study with 3 (5sec,8fps,24bit) bursts, 11 snapshots:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	Urodynamics Cystometry Filling Graph Image Sm (15min)	800	KB
1	Urodynamics Cystometry Filling Graph Image Lrg (15min)	1,000	KB
1	Urodynamics Cystometry Voiding Graph Image Sm (5min)	400	KB
1	Urodynamics Cystometry Voiding Graph Image Lrg (5min)	500	KB
1	Urodynamics Cystometry Nomograms Graph Image	400	KB
1	Urodynamics Cystometry Urethral Pressure Graph Image	200	KB
11	Video Urodynamics Snapshot X-ray Image	44,000	KB
11	Video Urodynamics Snapshot Graph Image	1,100	KB
3	Video Urodynamics Burst Graph Image (5sec)	600	KB
3	Video Uro Burst X-ray Video Thumbnail Image	900	KB
3	Video Uro Burst X-ray Video (5sec,8fps,24bit, uncompressed)	435,000	KB
3	Video Uro Burst X-ray Video (5sec,8fps,24bit, compressed-DV Video Encoder)	15,000	KB
Estimated storage for a single video study w/ 3 uncompressed video files		**485,900**	**KB**
Estimated storage for a single video study w/ 3 compressed video files		**65,900**	**KB**

Example of a 20-min Standard Cystometry Study with Filling/Voiding phases:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	Urodynamics Cystometry Filling Graph Image Sm (15min)	800	KB
1	Urodynamics Cystometry Filling Graph Image Lrg (15min)	1,000	KB
1	Urodynamics Cystometry Voiding Graph Image Sm (5min)	400	KB
1	Urodynamics Cystometry Voiding Graph Image Lrg (5min)	500	KB
1	Urodynamics Cystometry Nomograms Graph Image	400	KB
1	Urodynamics Cystometry Urethral Pressure Graph Image	200	KB
Estimated storage for a single cystometry study		**4,300**	**KB**

Example of a 1-min Video Uroflow Study with 1 (5sec,8fps,24bit) bursts, 2 snapshots:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	Uroflow Flow/Volume Graph Image (1min)	150	KB
1	Uroflow Nomogram Graph Image (3)	400	KB
2	Video Urodynamics Snapshot X-ray Image	8,000	KB
2	Video Urodynamics Snapshot Graph Image	200	KB
1	Video Urodynamics Burst Graph Image (5sec)	200	KB
1	Video Uro Burst X-ray Video Thumbnail Image	300	KB
1	Video Uro Burst X-ray Video (5sec,8fps,24bit, uncompressed)	145,000	KB
1	Video Uro Burst X-ray Video (5sec,8fps,24bit, compressed-DV Video Encoder)	5,000	KB
Estimated storage for a single video uroflow study w/ 3 uncompressed video files		**155,250**	**KB**
Estimated storage for a single video uroflow study w/ 3 compressed video files		**15,250**	**KB**

Example of a 1-min Standard Uroflow (Flow/Volume) Study:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	Uroflow Flow/Volume Graph Image (1min)	150	KB
1	Uroflow Nomogram Graph Image (3)	400	KB
Estimated storage for a single uroflow study		**1,550**	**KB**

Example of a 20-min Anorectal Manometry Study (6-1cm depth & RAIR study):

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	ARM Depth Study Graph Image Sm (15min)	800	KB
1	ARM Depth Study Graph Image Lrg (15min)	1,000	KB
1	ARM RAIR Status Graph Image Sm (5min)	400	KB
1	ARM RAIR Status Graph Image Lrg (5min)	500	KB
Estimated storage for a single uroflow study		**3,700**	**KB**

Example of an Ultrasound Study with 3 (5sec,64fps) cine, 10 annotated images:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
10	Ultrasound Image	3,000	KB
3	Ultrasound Cine Video (5sec,64fps, uncompressed)	24,600	KB
3	Ultrasound Cine Video (5sec,64fps, compressed-2:1)	12,300	KB
Estimated storage for an ultrasound study w/ 3 uncompressed video files		**28,600**	**KB**
Estimated storage for an ultrasound study w/ 3 compressed video files		**16,300**	**KB**

Example of a 15-min EMG/STIM Study:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	EMG STIM Graph Image (15min)	200	KB
Estimated storage for a single EMG STIM study		**1,200**	**KB**

Example of a 5-min EMG Baseline Study with 2 EMG Channels:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	EMG Baseline Graph Image (5min, 2ch)	2,000	KB
Estimated storage for a single EMG Baseline study		**3,000**	**KB**

Example for a 5-min EMG Endurance or Work/Rest Study:

Qty	Data Storage Type	Estimated Size	Unit
1	Raw Session Data and Log Files	1,000	KB
1	EMG Endurance Graph Image (5min, 20trials, 2ch)	1,000	KB
Estimated storage for a single EMG Endurance study		**2,000**	**KB**

Cautions

<u>DO NOT</u> do the following with The Prometheus Group® supplied computer and software:

- Modify the pre-set computer settings
    - o Modifications to these settings are done so at your own risk
- Enable Windows Updates.
    - o The computer is shipped with Windows Updates disabled. Enabling Windows Updates can cause the software to malfunction. Enabling Windows Updates is done so at your own risk.
- Leave the computer running twenty-fours a day, seven days a week.
    - o This will not allow the computer to remove temporary or cached files. These files take up computer resources and may degrade performance.
- Operate other software applications while using The Prometheus Group® software.
    - o This could redistribute the allocation of resources on the computer to focus on a secondary application(s) and not The Prometheus Group® software causing performance issues.
- Exit or minimize The Prometheus Group® software while performing any study or treatment.

Configuring a User Supplied Computer

If using a computer supplied by The Prometheus Group® proceed to the Initial Software Startup Process on Page 31.

Computer Preparation

Prior to installing The Prometheus Group® software, configure the following settings on the computer. A Windows administrator account is required.

Changing the User Account Control (UAC) Settings

1. Select the **Start** Option on the bottom left corner of the Desktop Screen

2. Navigate to **Windows System** and select **Control Panel**
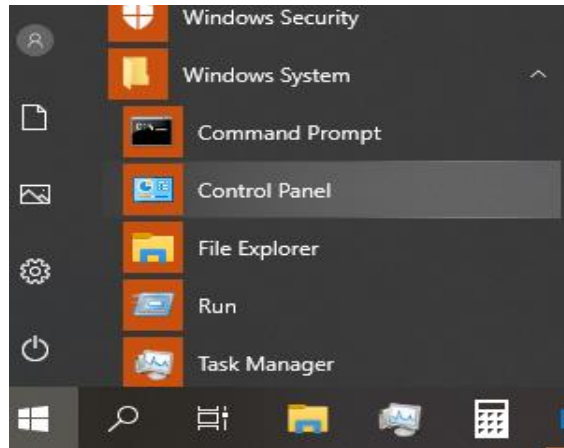
3. Select **System and Security**
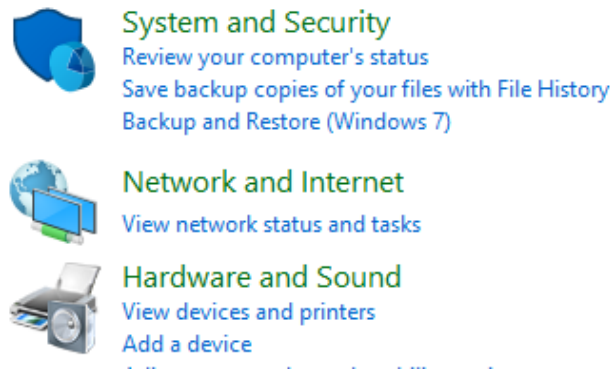
4. Select **Change User Account Control Settings** from the **Security and Maintenance** section.
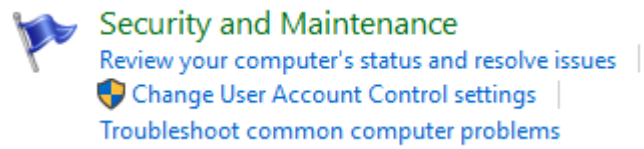
5. Using the slide bar to set the **User Account Control Settings** to **Never Notify**.

6. Click **Ok**.

7. Close out of the **Control Panel.**

User Account Control Settings

Choose when to be notified about changes to your computer

User Account Control helps prevent potentially harmful programs from making changes to your computer.
Tell me more about User Account Control settings

Always notify

Never notify me when:

- Apps try to install software or make changes to my computer
- I make changes to Windows settings

ⓘ Not recommended.

Never notify

OK   Cancel

8. Restart the computer using the **Windows Start** button.

Documents

Sleep

Shut down

Restart

Power
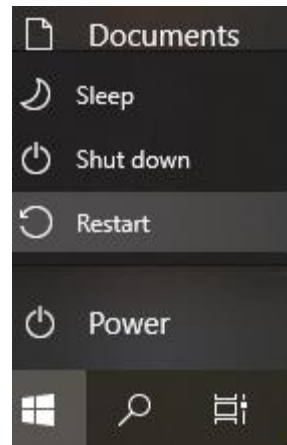
Suspension of Anti-Virus and Encryption Services

Anti-Virus and Encryption should be suspended for the software installation. Full disk encryption products will not have to be suspended but Window's Bit Locker File Encryption and other file encryption software may block system files from being installed. Many Anti-Virus software programs have also been known to block the installation of software files.   All services can be reset to active after completing the software installation.

Disabling Driver Signature Enforcement

For Windows 10 Operating Systems only. Complete this process prior to software installation to prevent device driver installation problems for the Pathway® MR Series, The Pathway® CTS 2000, and The Pathway® CTS 1500 purchased prior to October 2018.

1. Click on the
   Windows Start
   button on the
   Desktop Screen.
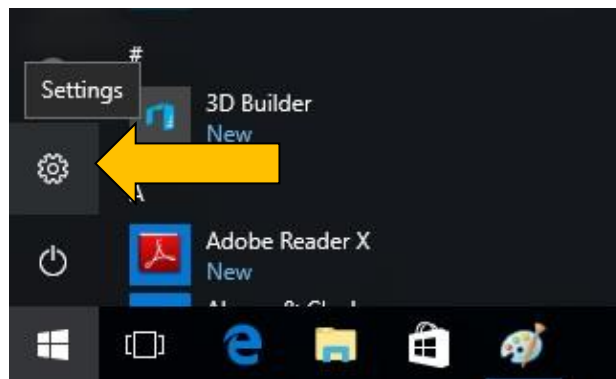
2. Click **Settings**.

3. Click **Update &**
   Security from the
   Settings Menu.
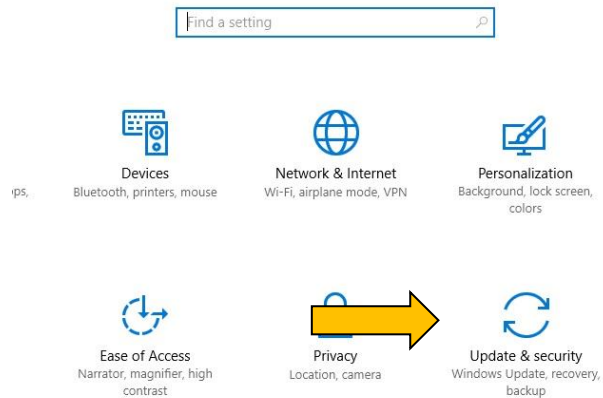
4. Click on **Recovery.**
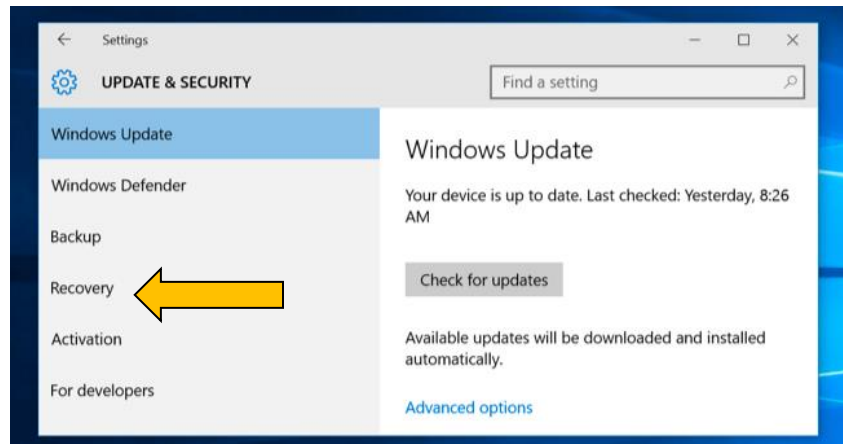
5. Click **Restart Now** under the **Advanced startup** option

6. Click on **Troubleshoot** on the **Choose an option** menu
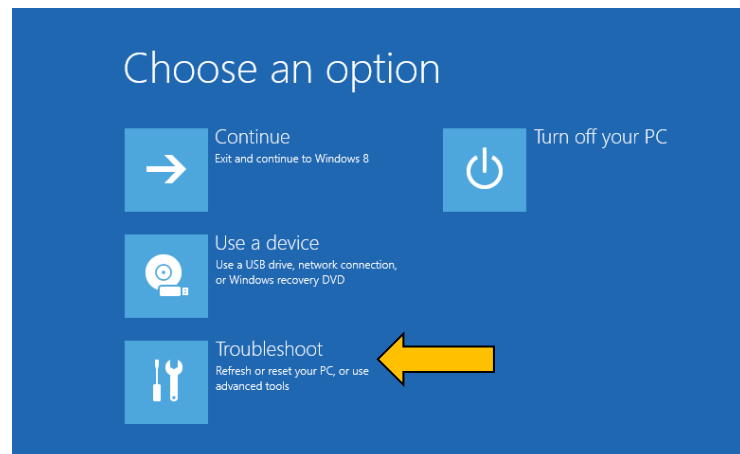
7. Click on **Advanced Options** on the **Troubleshoot** menu.
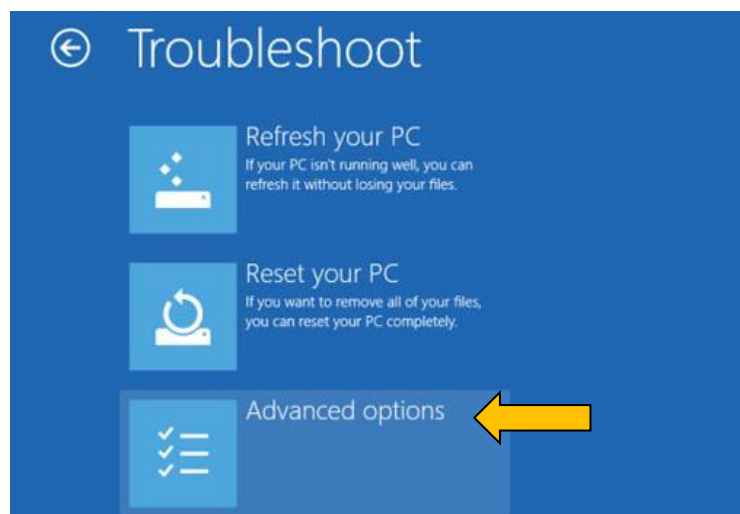
8. Click on **Startup Settings** on the **Advanced options** menu.
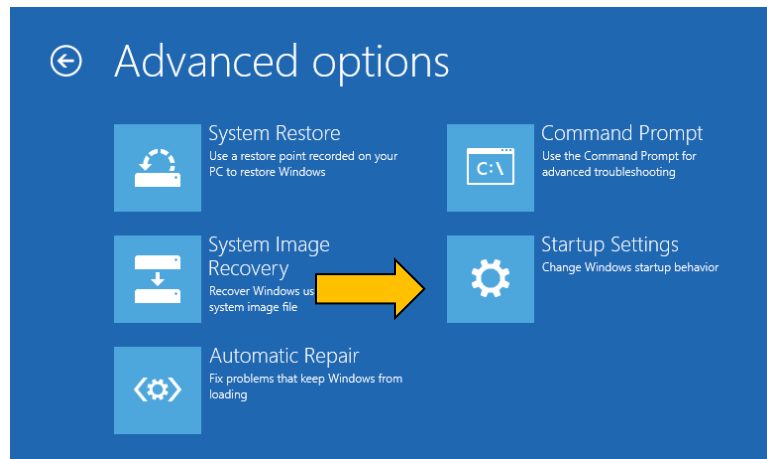
9. Click **Restart** on the **Startup Settings** menu.
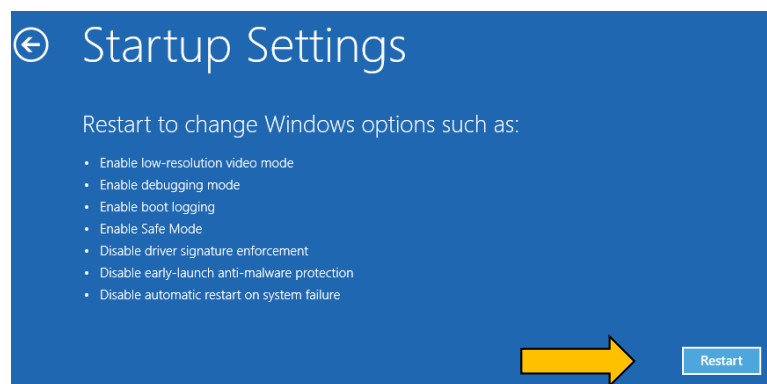
10. The computer will restart and a new **Startup Settings** menu will appear. Press **7** on the keyboard to select **Disable driver signature enforcement.**
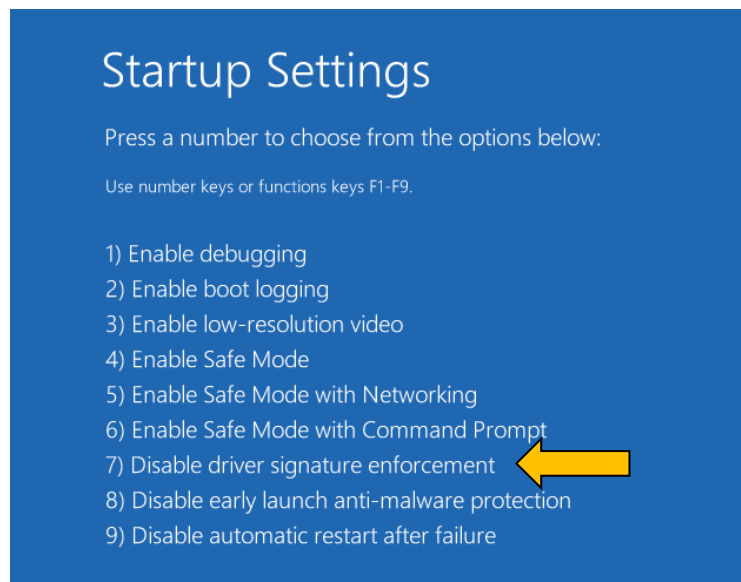
11. Windows will restart automatically, login if necessary.

Software Installation

Software media is provided on a USB Flash Drive. Please ensure that a Windows administrator account with software installation capability is being used.

1. Insert the provided USB Flash Drive into an available USB Port on the Computer.

2. If a pop-up window does not appear navigate to **File Explorer**. If a pop-up window appears proceed to **Step. 5**

3. Navigate to the device's software and click to open. In this example **CTS 1500** software is used.
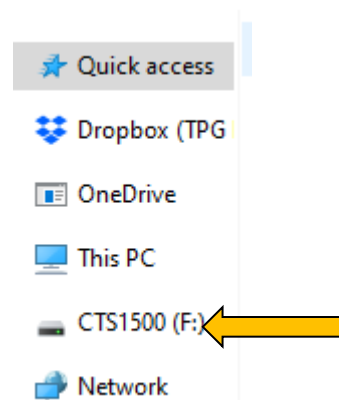
4. Double click on the file **Setup.bat**

5. The **InstallShield Wizard** will appear. Please follow the on-screen prompt. Click **OK** when ready to proceed.
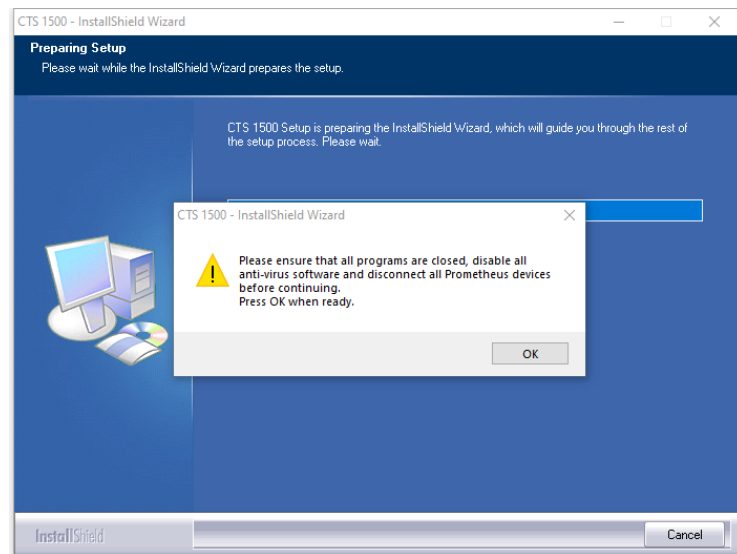
6. Click **Next** and follow the on-screen prompts.
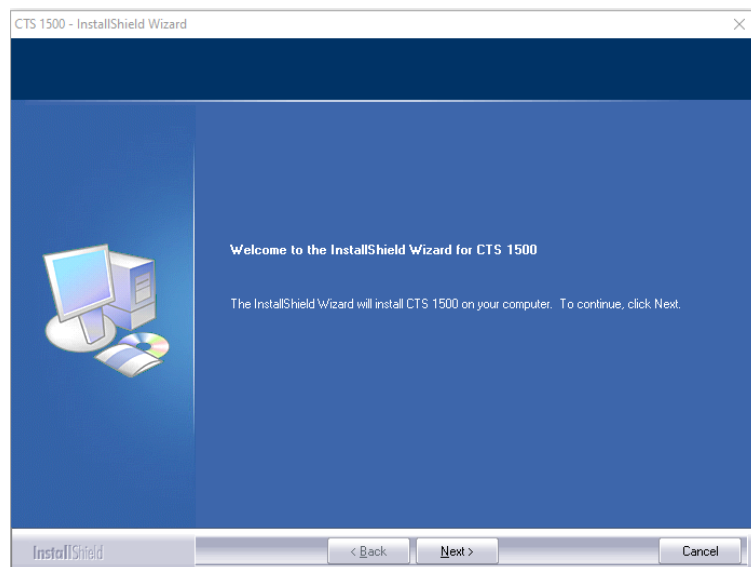
7. **License Agreement** Please read the software license agreement.

8. If the license terms are accepted, click in the accept box.

9. Click **Next**.
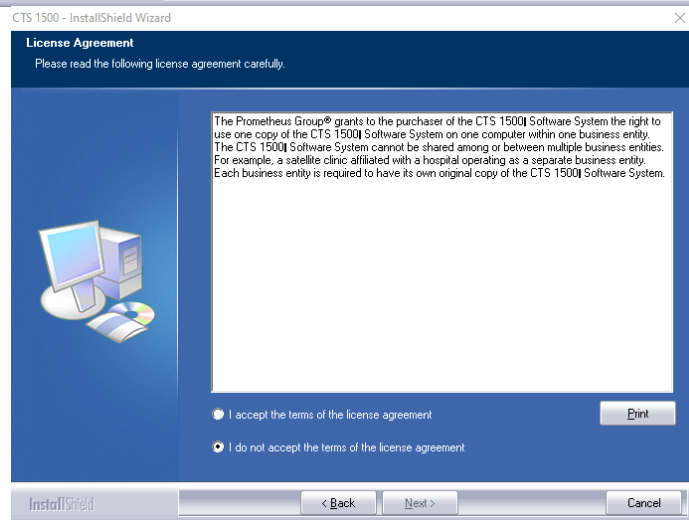
10. Click **Install.**
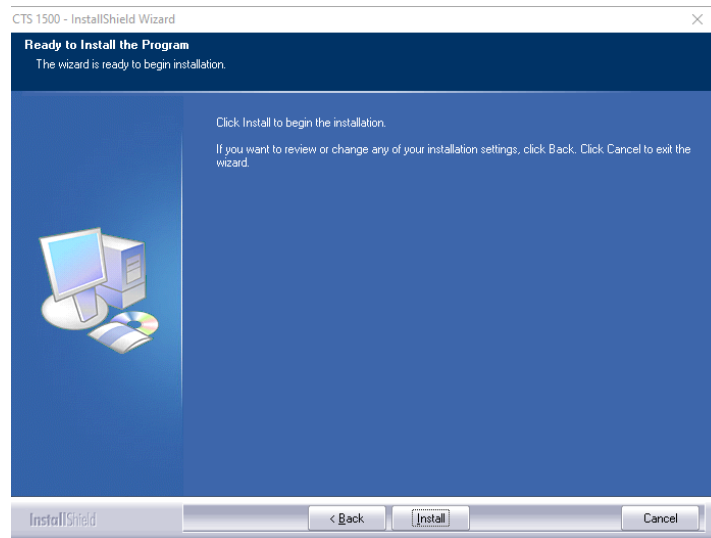
11. If using a device requiring the **Disabling of Driver Signature Enforcement <u>DO NOT</u>** restart the computer and complete the **Driver Installation for USB Devices** by following the steps below. If using a device that does not require this process proceed to **Device Communication Types.**
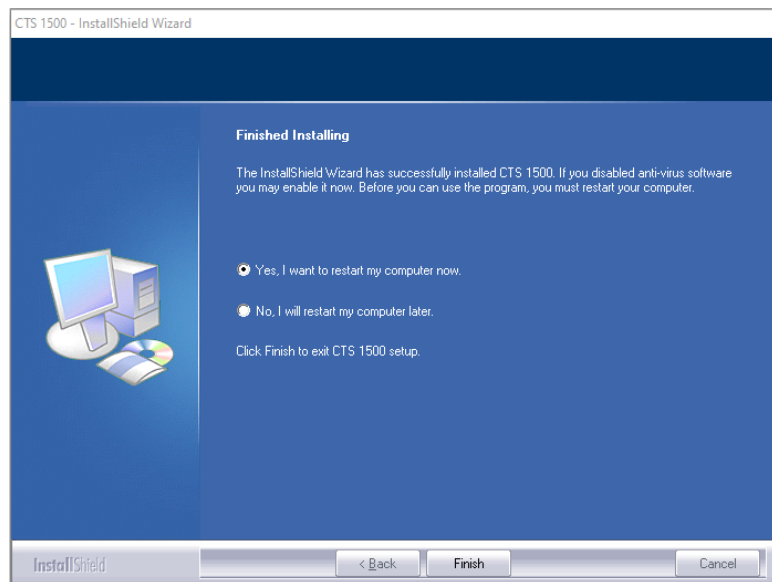
Driver Installation for USB Devices

<u>For Windows 10 Operating Systems ONLY</u>. **Complete this process after the software installation to prevent device driver installation problems for The Pathway® MR Series, The Pathway® CTS 2000, and The Pathway® CTS 1500 <u>purchased prior to October 2018 ONLY</u>.**

1. Navigate to **File Explorer** and click on the folder.

2. Navigate to the following file path: **C:\Program Files (x86)\The Prometheus Group\Drivers**

3. Right click on **unsigned.zip** and select **Copy**.
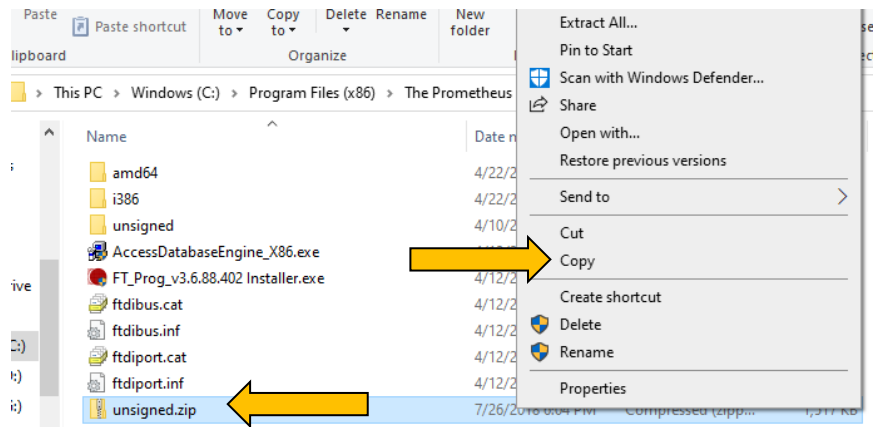
4. Minimize the **File Explorer** to return to the desktop**.**
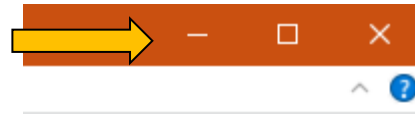
5. Right Click in a blank area on the desktop and select **Paste**
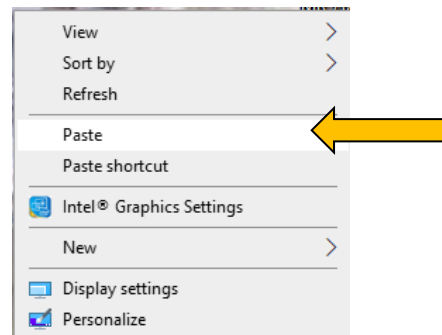
6. Right click on the **unsigned.zip** file and select **Extract All.**
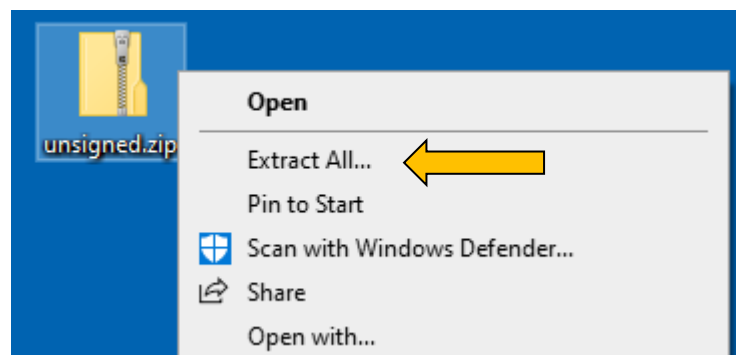
7. Use the **Browse** button to select the **Desktop.**
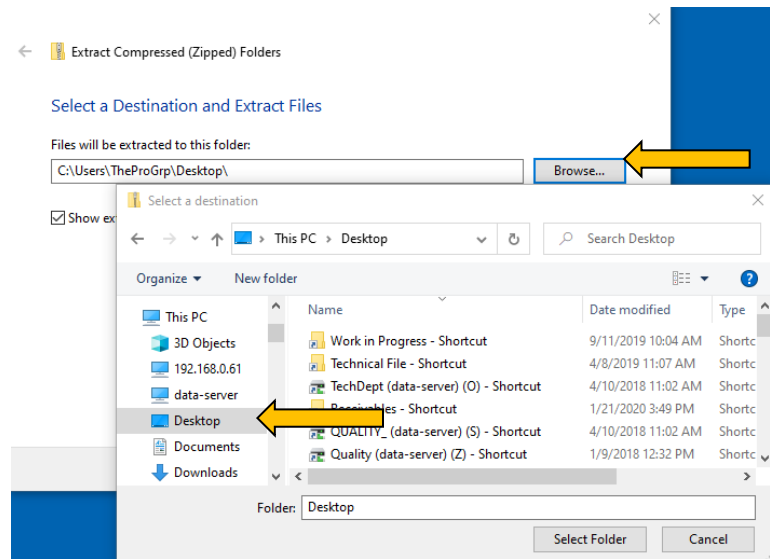
8. Click on **New Folder** and name it **unsigned.** This is done to keep all the files together.

9. Ensure that the **unsigned** folder is selected and click **Select Folder**.

Extract Compressed (Zipped) Folders

Select a Destination and Extract Files

Files will be extracted to this folder:

C:\Users\TheProGrp\Desktop\unsigned   Browse...

☑ Show extracted files when complete
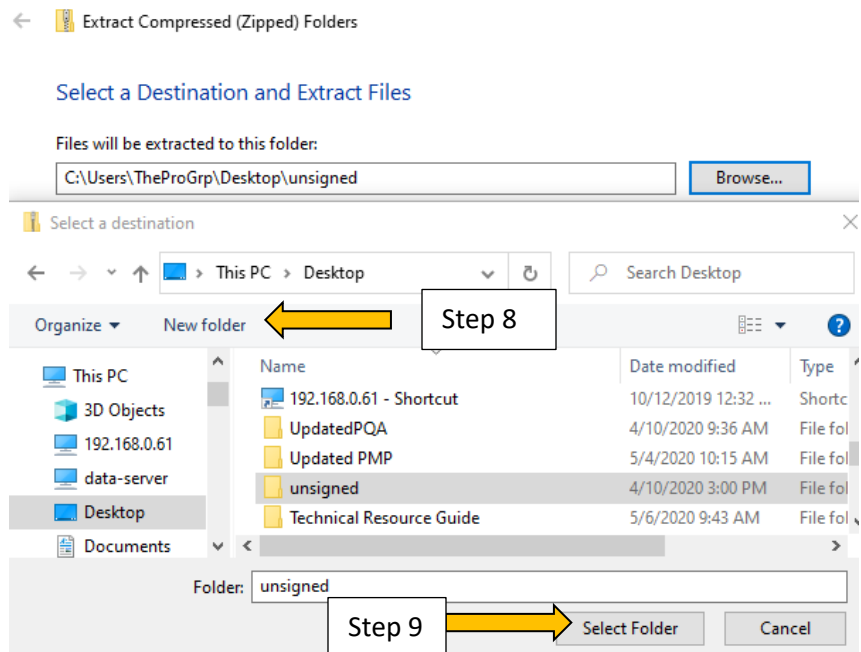
10. Click on **Extract**.

Extract   Cancel
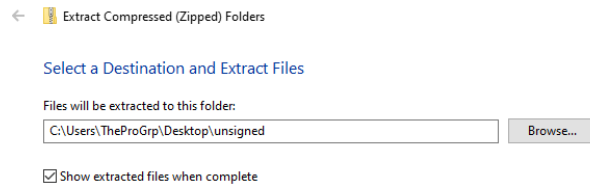
11. Right click on the newly created **unsigned** folder and select **Copy.**
    NOTE: Do not select the **.zip** file.

CTS 1500   Firefox

unsigned.zip   unsigned
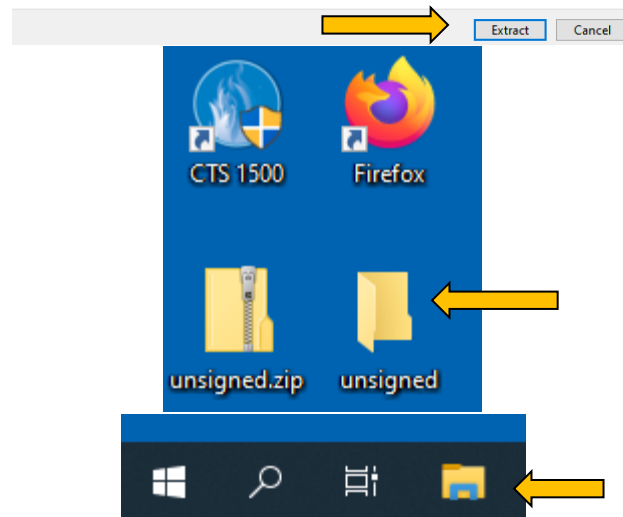
12. Return to the minimized **File Explorer** on the taskbar and maximize the screen.

> This PC > Windows (C:) > Program Files (x86) > The Prometheus Group > Drivers

Name	Date modified	Type
amd64	4/22/2020 10:39 AM	File folder
i386	4/22/2020 10:40 AM	File folder
AccessDatabaseEngine_X86.exe	4/12/2020 9:09 PM	Application
FT_Prog_v3.6.88.402 Installer.exe	4/12/2020 9:09 PM	Application
ftdibus.cat	4/12/2020 9:09 PM	Security Catalog
ftdibus.inf	4/12/2020 9:09 PM	Setup Information
ftdiport.cat	4/12/2020 9:09 PM	Security Catalog
ftdiport.inf	4/12/2020 9:09 PM	Setup Information
unsigned.zip	7/26/2018 6:04 PM	Compressed (zipp...

13. Right click in a blank area and select **Paste**

View
Sort by
Group by
Refresh

Customize this folder...

Paste
Paste shortcut

Give access to

New

Properties

23
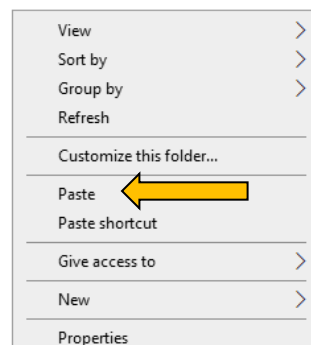
14. Ensure that there is now a folder named **unsigned.**

15. Close the **File Explorer** Window and return to the desktop.

Name	Date modified	Type	Size
amd64	4/10/2020 12:27 PM	File folder	
i386	4/10/2020 12:25 PM	File folder	
unsigned	4/10/2020 2:29 PM	File folder	
DPInst.exe	10/20/2017 12:14 ...	Application	664 KB
FT_Prog_v3.6.88.402 Installer.exe	6/22/2018 2:16 PM	Application	1,548 KB
ftdibus.cat	6/22/2018 2:16 PM	Security Catalog	19 KB
ftdibus.inf	6/22/2018 2:16 PM	Setup Information	26 KB
ftdiport.cat	6/22/2018 2:16 PM	Security Catalog	18 KB
ftdiport.inf	6/22/2018 2:16 PM	Setup Information	17 KB
unsigned.zip	7/26/2018 5:04 PM	Compressed (zipp...	1,517 KB

16. Right click on the **Windows Start** button.

17. Click on **Device Manager**.

18. Connect the Pathway® device to the computer with the supplied USB cable.

Programs and Features
Mobility Center
Power Options
Event Viewer
System
Device Manager
Disk Management
Computer Management
Command Prompt
Command Prompt (Admin)

Task Manager
Control Panel
File Explorer
Search
Run

Desktop

Select Device Manager Here
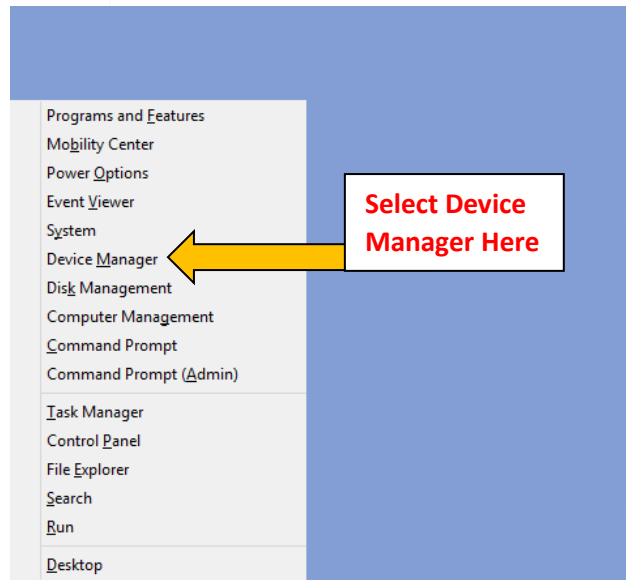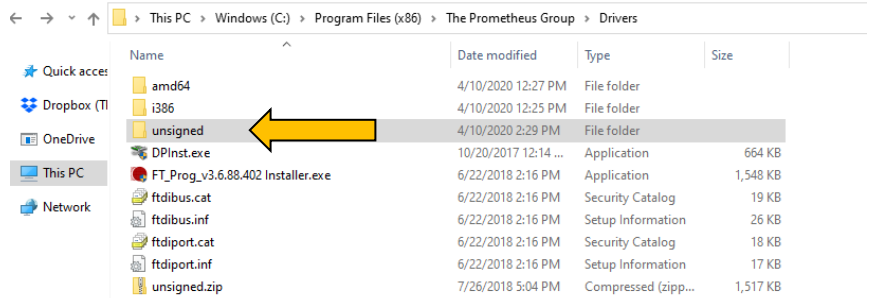
19. Right click on the **USB Serial Port** listed under **Other Devices** on the **Device Manager** menu.

20. Click on **Update Driver Software…**

Device Manager

File   Action   View   Help

▷ IDE ATA/ATAPI controllers
▷ Imaging devices
▷ Keyboards
▷ Mice and other pointing devices
▷ Monitors
▷ Network adapters
▲ Other devices
    USB Serial Port
▷ Print queues
▷ Processors
▷ Sound, video a
▷ Storage contro
▷ System devices
▲ Universal Serial
    CTS2000 US
    Generic USB Hub
    Generic USB Hub
    Intel(R) 7 Series/C216 Chipset Family USB Enhanced Host Controller - 1E2D
    Intel(R) 7 Series/C216 Chipset Family USB Enhanced Host Controller - 1E26
    Intel(R) USB 3.0 eXtensible Host Controller - 0100 (Microsoft)
    Realtek USB 2.0 Card Reader
    USB Composite Device

Update Driver Software…
Disable
Uninstall

Scan for hardware changes

Properties

Step 20

21. Click **Browse my computer for driver software** on the **Update Drivers** menu.
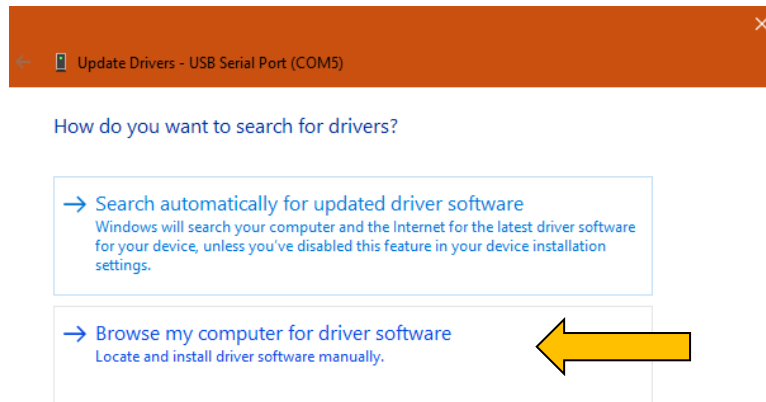
22. Click on **Browse.** Navigate to the **C:\Program Files (x86)\The Prometheus group\Drivers\unsigned** folder and select **OK**

23. Click **Next** on the **Update Drivers** window.
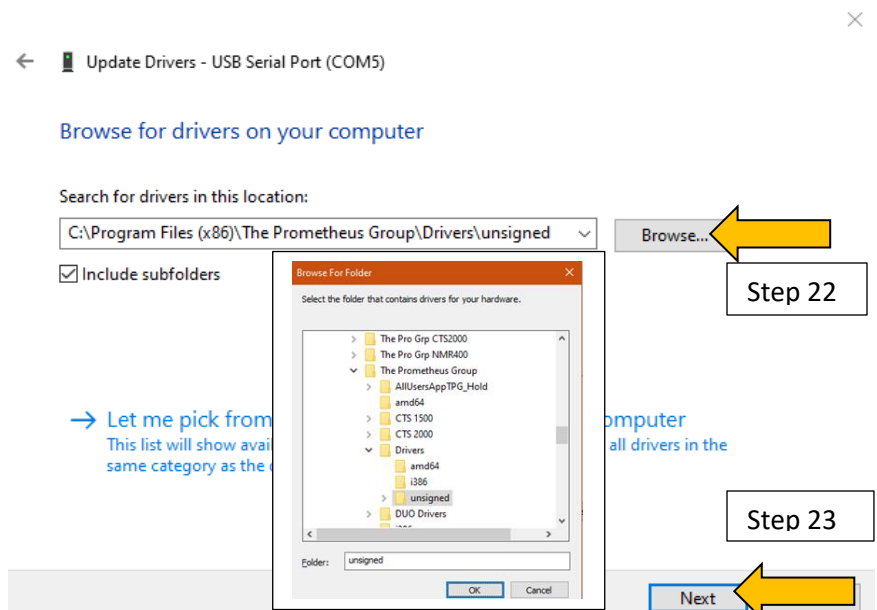
24. Click on **Install this driver software anyway** on the **Windows Security** menu.

25. If prompted a second time, click on the **Install this driver software anyway.**

26. Click on **Close** once installation has completed.

27. Repeat **Steps 19** through **Step 26** if any additional devices still appear in **Other Devices.**

28. Upon completion of driver installations, restart the computer**.**
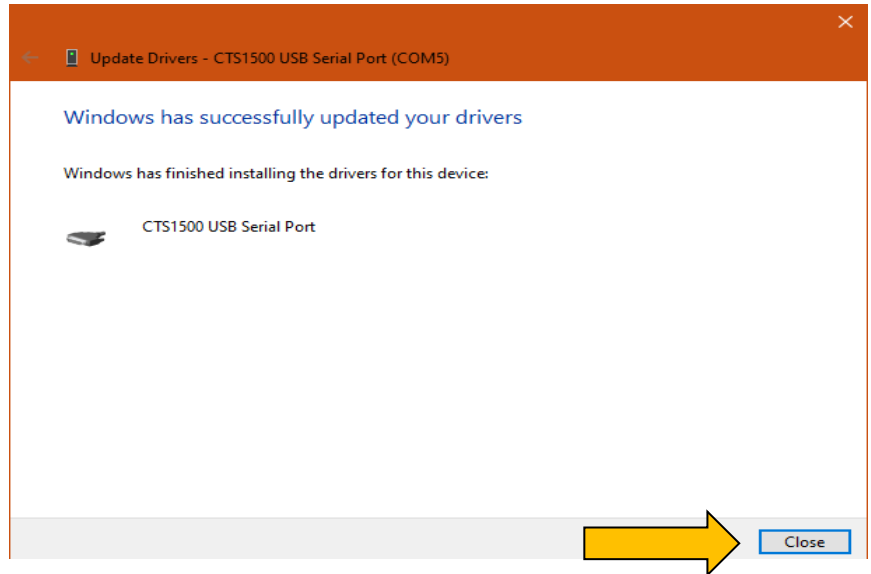
Device Communication Types

9-Pin Serial Device Communication

Some legacy Pathway® devices may come equipped with a 9-Pin Serial Port, such as the Pathway® MR-Series devices and the Pathway® CTS 2000. In order to use these devices, the computer must have a 9-Pin Serial Port. If not, a 9-Pin Serial to USB Adapter must be used. The Prometheus Group® supplies the Tripp-Lite Keyspan USA-19HS Serial to USB Adapter due to its data transmission rates and low voltage levels. The Tripp-Lite Keyspan USA-19HS Serial to USB Adapter is packaged with its own software installation CD and installation instructions. If the computer does not have a disc drive the software may be downloaded from https://www.tripplite.com/support/USA19HS . Upon completion of the software installation use a 9-Pin Serial Cable to connect the Tripp-Lite Keyspan to the device and then connect the Tripp-Lite Keyspan to an available USB Port on the computer using the included USB cable.

9-Pin Serial Port   Tripp-Lite Keyspan   9-Pin Serial Cable

Bluetooth Device Communication

The EMYO® Series and the Uroflowmetry Load Cell offer wireless connectivity through Bluetooth communication. For wireless communication, these devices will need to be paired with the computer.

1. Power on the device to be paired using the On/Off button.

2. Click the Bluetooth option on the computer task bar. **NOTE:** May need to click on **Show Hidden Icons.**
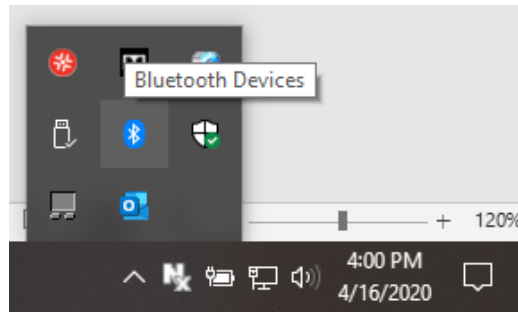
3. Click the **Add a Bluetooth Device** from the **Bluetooth Menu.**
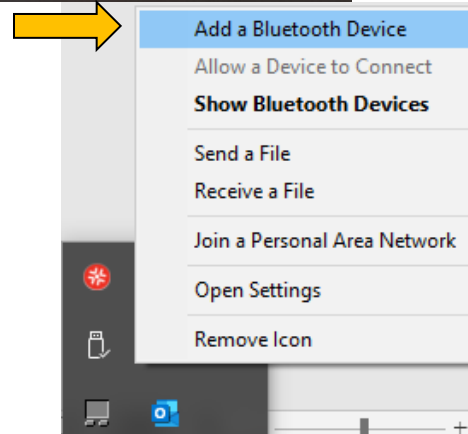
4. Click **Add Bluetooth or other device** from the **Settings** menu.
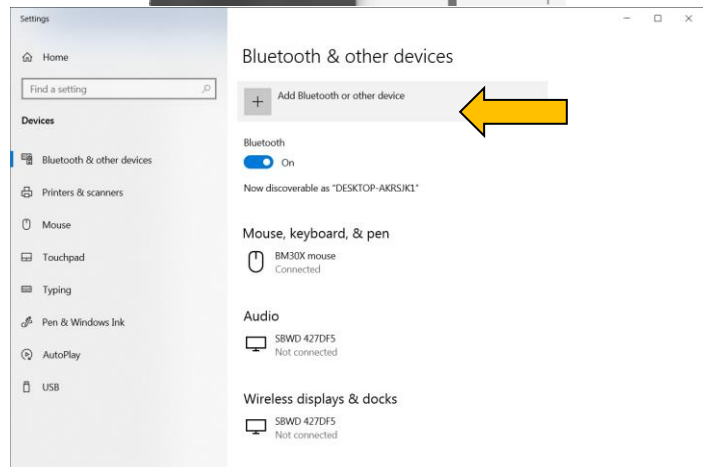
5. Click on **Bluetooth** on the **Add a device** menu.
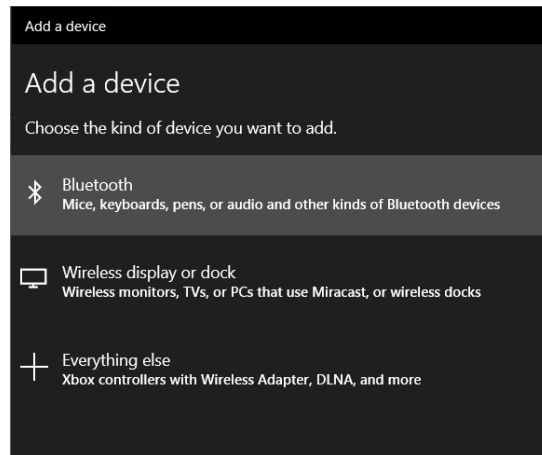
6. Click on the device to be paired from the **Add a device** menu. An EMYO® is used in the example.

NOTE: The serial number of the device appears in the description. EMY or EMS_X00_XXXXXXXX = EMYO®
LoadCell_WLC_XXXXX = Uroflowmetry Load Cell

7. Enter the PIN **PATHWAY** in **all capital letters** in the data entry block provided and then click **Connect.**
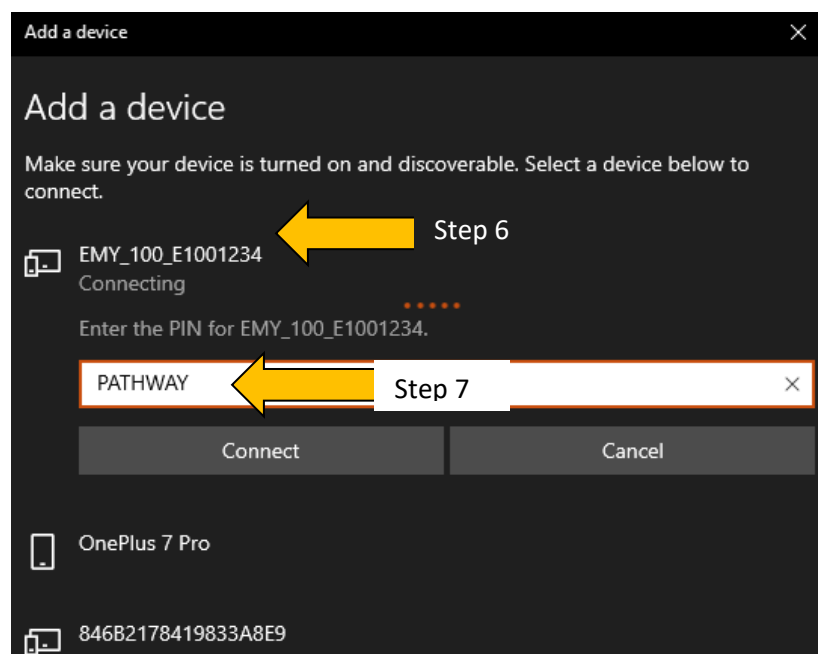
8. The device will indicate paired, click on **Done.**
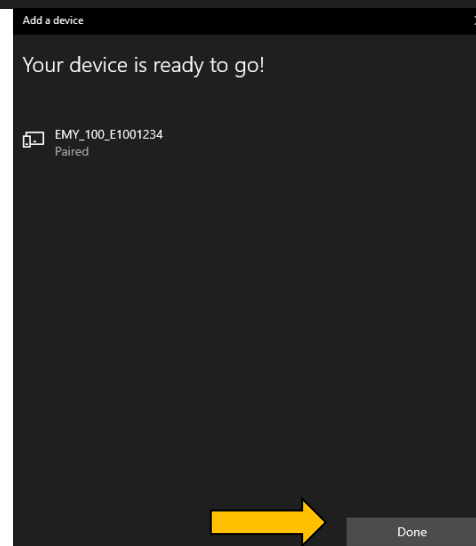
9. The device will show as paired in the list of **Other devices** in the **Bluetooth and other devices** menu.

10. Close the **Settings** menu by clicking the **X** in the upper right corner.
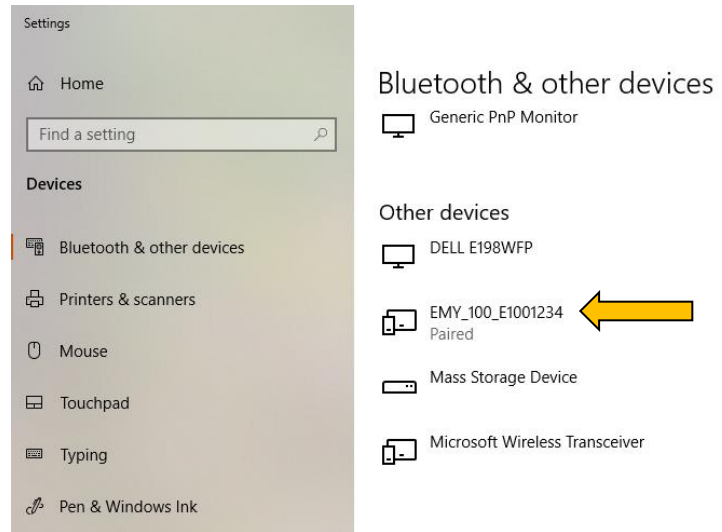
USB Serial Interface Communication

All software controlled modules have a USB Serial Interface communication port. Once the software has been installed, connect the provided USB Serial Interface cable to the device and the computer. For the EMYO® Series and the Uroflowmetry Load Cell, this connection will automatically replace the wireless Bluetooth connection. To return to the wireless Bluetooth connection disconnect the USB Serial Interface cable from the module and the computer.

NOTE: Make sure the USB Serial Interface cable is correctly oriented. Incorrect orientation can damage both the device and computer.

HDMI Monitor Setup

1. To display games for the EMYO® 100 and 200 B, UB, S and the Game Option of Morpheus® Pelvic Muscle Rehabilitation, the HDMI Monitor must be set to the extended display mode.
2. Connect the HDMI Monitor to the computer using one of the following options:
     a. Wireless – may require wireless adapter (ex: Screenbeam™ Mini 2 Wireless Display Receiver)
     b. Hardwire – HDMI or dataport cable
3. Right click on the computer desktop

4. Click on **Display Setting.**
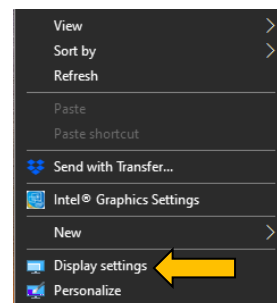
5. The HDMI Monitor will be connected and
   appear as the number **2** display,
   duplicating the computer screen (number **1**
   display).
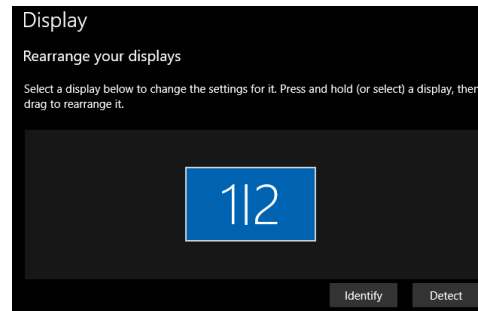
6. Scroll down the **Display Setting** screen to
   Multiple Displays.

7. To utilize Game Displays, click on the drop-
   down box then click on **Extend these
   displays.**
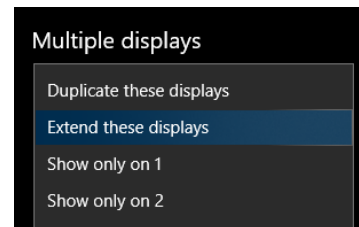
8. Click on **Keep Changes.**
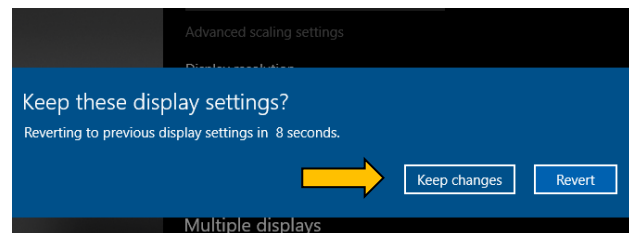
9. Scroll to the top of the **Display** screen. The
   HDMI Monitor now appears as the number
   2 display, separate from the number **1**
   display.
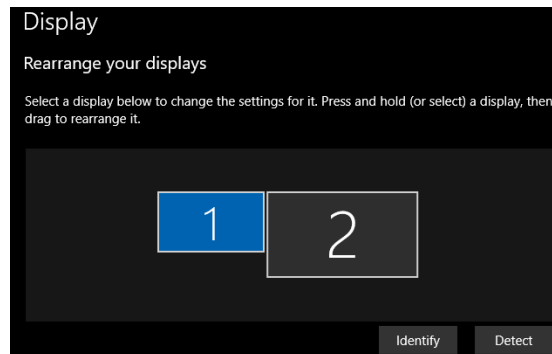
10. The number **2** HDMI Monitor <u>**MUST**</u> be located to the left of number **1** for the game displays to be active. **Rearrange your displays** by clicking and dragging the number **2** to the left of the number **1.** Release the mouse button.
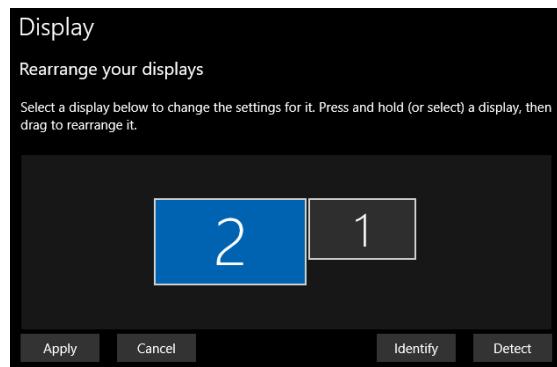
11. Click **Apply.**

12. Click the red **X** in the top right corner of the **Display Settings** screen to exit.

Reset Anti-Virus and Encryption

Upon completion of software and driver installation as well as device pairing the computer can be restarted and Anti-Virus and Encryption can be put reset to active status.

The Initial Software Startup Process

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.

1. Double click on the icon on the desktop. In this example the **EMYO®200** is used.

2. Read the **Software License Agreement** on Page 69. Click **OK**.
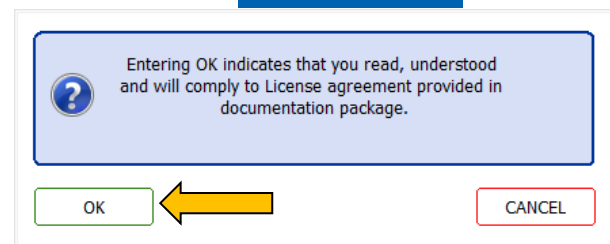
Setup Password and System Security Settings

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

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

Password Expiration: S*ets the number of days after which the password will expire*
- **Enable Password Expiration** (**days**): **Minimum** (30), **Maximum** (180)

Password History: S*ets the number of previous passwords that cannot be re-used and the **admin reset** will require the user with administrative permissions to change the default password.*
- **Enable Password History Threshold**: **Minimum** (1), **Maximum** (8)
- **Require password change after admin reset**: **Checked** (Yes), **Unchecked** (No)

Password Complexity (# of characters): D*efines 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: P*rovides 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: T*his will lock the system after a period of inactivity requesting a Username and Password.*
- **Enable System Timeout (minutes)**: **Minimum** (5), **Maximum** (60)

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

4. Click **OK** to accept changes or to continue.

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 (see above)

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.

4. 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.**

5. Select **Yes** for **EMYO® System login capability.**

> **NOTE:** The initial Associate **MUST** be given **Software 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 adminstrator permissions to the initial Associate.

6. Click **Set Username/Password.**

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

8. **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.

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

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

11. There is now enough required information in the **Associate Profile** to satisfy the minimal associate description. Click **Close** to exit.
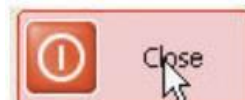
12. **Save the data that was updated** will appear. Click **YES**.

13. **Saving Associate Data** will appear.

14. **Active 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 Software 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.**

::Location Information Screen::

Close

Location Screen

Location Profile
(Required entries in red)

Business Name	Smith Rehabilitation Services
Address (Line 1)	144 First Street
Address (Line 2)	Suite 104
City	Boston
State	MA
Zip	02640
Country	United States
Phone #1	(617) 123-4567

2. 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.

3. 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. **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 Software Startup Process.

::Locations List Screen::

Business Name	Address (Line 1)	City	State	Phone #1
Smith Rehabilitation Services	144 First Street	Boston	MA	(617) 123-4567

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**.

> **NOTE**: A minimum of one **Unique Patient Identifiers** must be selected. Any combination of **Unique Patient Identifiers** may be used. Note that adding or changing **Unique Patient Identifiers** may require an update to existing patient information.

3. **Congratulations!!!** will appear. The initial software setup has been completed. Click **Next.**
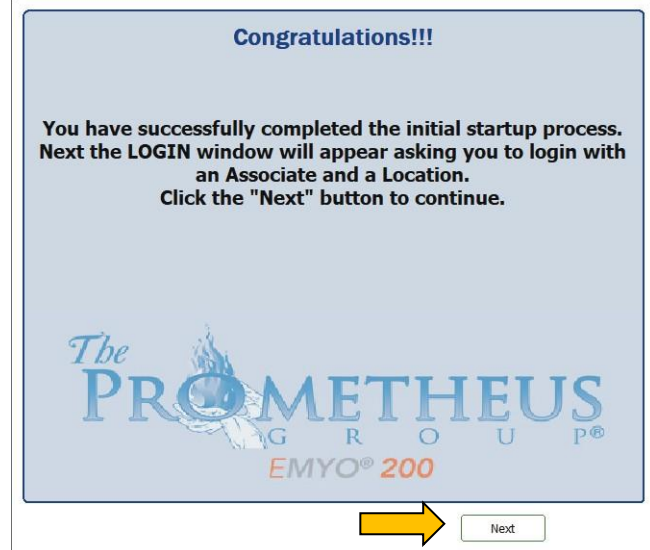
4. **LOGIN** will appear. Enter the **Username** and **Password** to use the program now. Click the drop-down arrow to select the **Location of Service**. Click on the correct **Location of Service**. Click **LOGIN**. Click **Cancel** to exit the program.

Tools

Access to **Tools** is restricted to users with administrative permissions only and is used to **View System Setup, Create/Edit/View Locations, Create/Edit/View Associates,** or to **View Associate Activities.**

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

2. Click **Tools**.

3. The **Tools** window will appear.
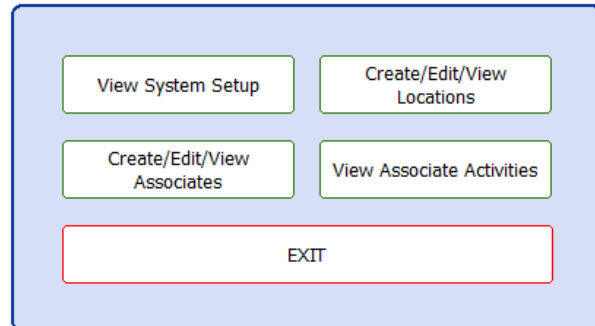
View System Setup

1. Click **View System Setup**

2. **System Setup** will appear:
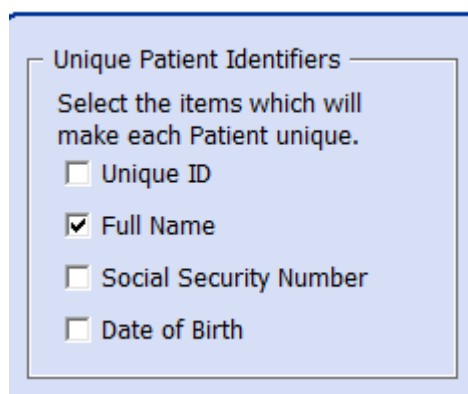
Unique Patient Identifiers

1. **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.
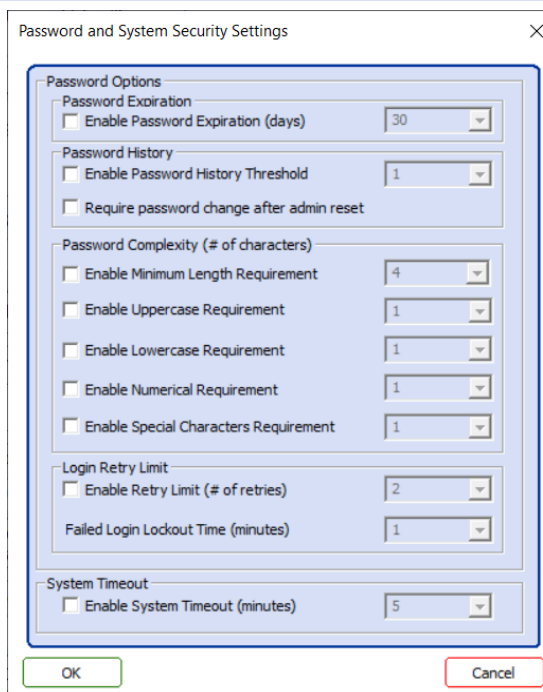
Support

1. Click **Password and System Security Settings** to change the password requirements and/or security settings inputted in the Initial Software Startup Process.

2. 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. These settings should **NOT** be modified.

Export LogTraceData	Modify Config Settings
Export Database	Modify TPG Settings
Import Database	Modify Uro Settings
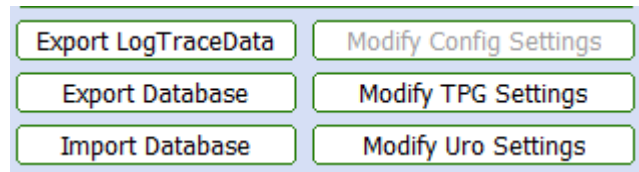
The Prometheus Group® offers unlimited hardware and software support through the Technical Support Team, which can be contacted at 1-800-272-8492 in the U.S. and Canada or +1 (011) 603-742-6053 International Monday through Friday 8:30am to 5pm Eastern Standard Time. In addition to telephone support the Technical Support Team may also utilize a HIPAA Compliant remote support tool, TeamViewer. To obtain the client copy of TeamViewer please use this link: https://get.teamviewer.com/theprogrp . For additional details regarding the compliance and security of TeamViewer please use this link: https://www.teamviewer.com/en-us/trust-center/compliance/ . **NOTE:** TeamViewer is a registered trademark of **TeamViewer GmbH.**

The Pathway® CTS 2000 Pelvic Muscle Rehabilitation System and select options of the Morpheus® system offer one day on-site Clinical Training. This training encompasses clinical equipment operation, equipment settings, interpretation, protocols and mentoring with staff personnel.

Document Settings
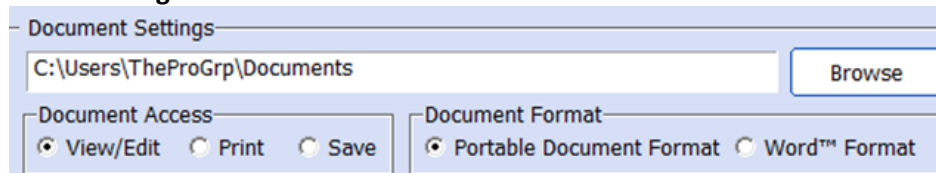
1. Documents are saved to the local hard drive (C:\) by default. To save to a network/data server click **Browse.**
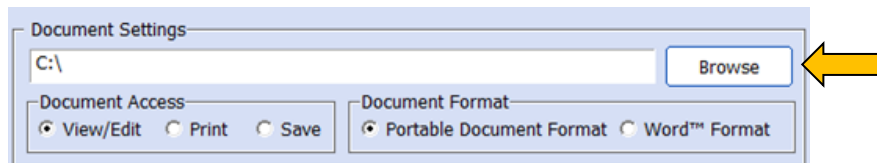
2. Select a new location from the **Browse For Folder** file directory.

3. Click **OK.**
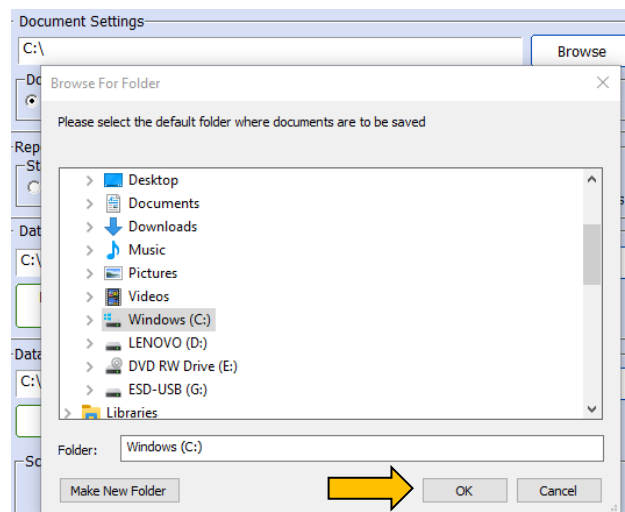
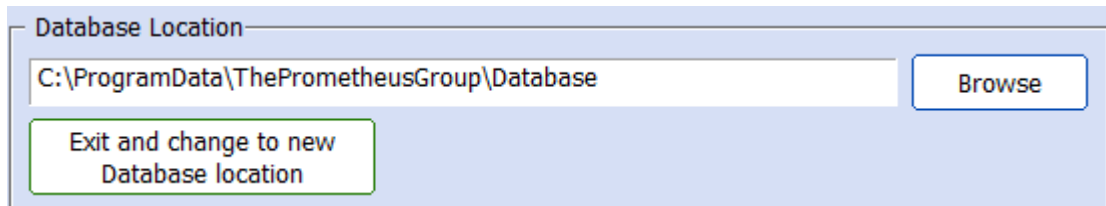4. The **Document Settings** will now reflect the new location.

5. **Document Access, Document Format,** and **Report Settings** are configured by the **Care Provider**. Refer to the Operator's Guide for details.
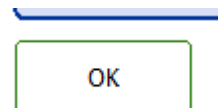
Database Location

The Prometheus Group® Software uses a password protected and encrypted Microsoft Office Access 2007 ACCDB File Format by the Microsoft Enhanced Cryptographic Provider 1.0 which utilizes the RC4 encryption algorithm and a 128-bit encryption key length. The latest Microsoft Office Access 2013 ACCDB File Format uses the Advanced Encryption Standard (AES) to provide encryption by default. This is a very strong encryption algorithm that has been approved by the National Security Agency for use with classified U.S. government information. This ACCD database format has been implemented with The Prometheus Group® Software version 3.1 and later. Earlier versions of The Prometheus Group® Software supports the Microsoft Office Access 2003 MDB File Format which is also password protected but only provides a 40-bit RC4 encryption algorithm. **Software solutions offered by The Prometheus Group® do NOT support SQL or ORACLE databases.**

NOTE: The Prometheus Group® does not store, maintain, or use patient information or the database that houses the patient information. Once the software is installed and configured, the facility is responsible for maintaining the patient information and database.

1. **Database Location** is saved to the Local Hard drive (C:\) by default. To save to a Network/Data Server click **Browse.**

2. Click **OK** on the **System Setup** window to move the database**.**
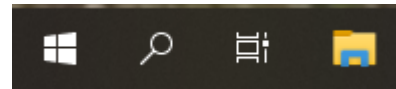
3. Click **Exit** on the **Tools** menu.
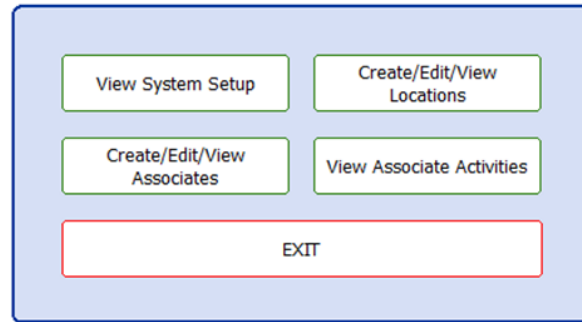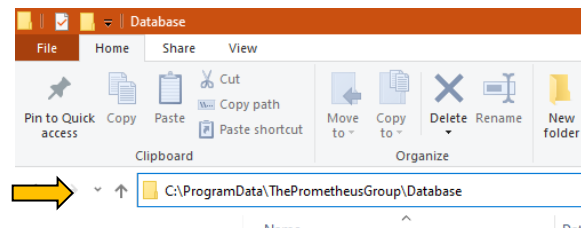
4. Minimize the software.
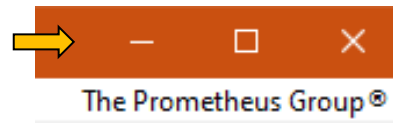
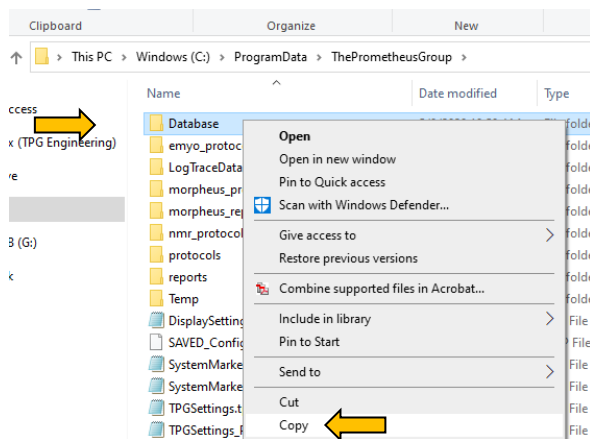5. From the desktop click on **File Explorer.**

6. Navigate to the **Database** location.
   Example:
   **C:\ProgramData\ThePrometheusGroup
   \Database**

7. Use the **Up Arrow** to return to the file
   folder that contains the **Database f**older**.**

8. Right click on the **Database** folder and
   select **Copy. NOTE: <u>DO NOT </u>**move the
   folder. Moving the folder will result in a
   database error.

9. Use **File Explorer** to navigate to the new
   location to store the **Database.** *Example:*
   C:\Users\ThePrometheusGroup
   NOTE: If moving the **Database** to a
   network/data server the user(s) **MUST** have
   Read/Write/Modify Permissions to the
   network/data server.

44
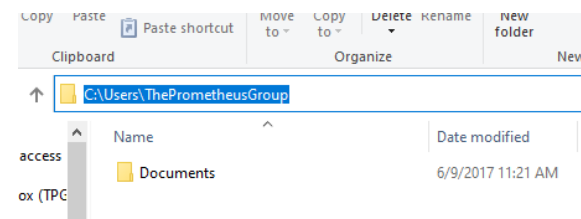
10. Right click in a blank space and select **Paste.**

11. Make sure that the **Database** folder now appears in the new location. Note the new file path.
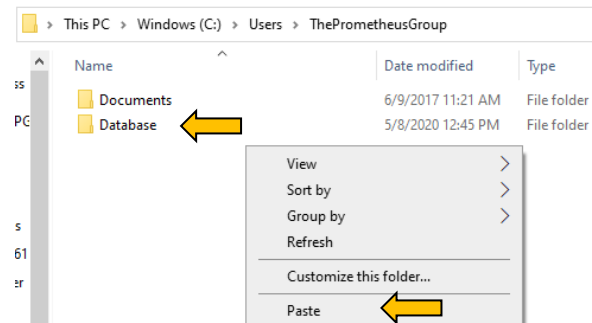
12. Minimize **File Explorer.**

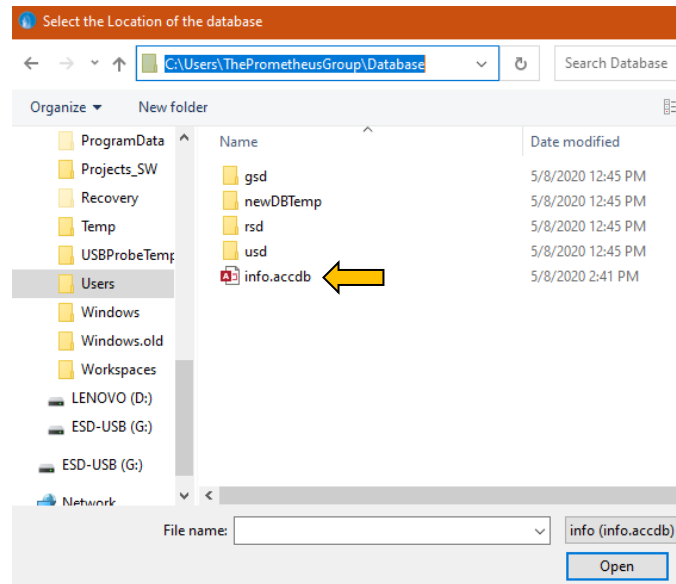13. Click on the software icon on the taskbar to return to the software.

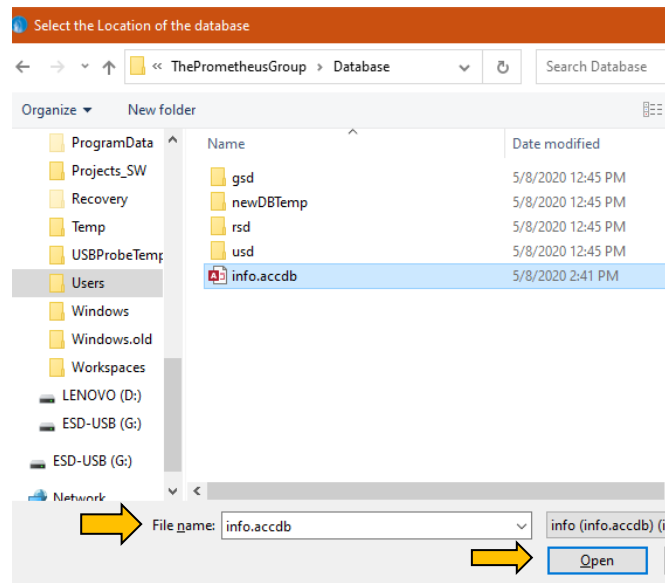14. Return to the **Database Location** within **System Setup**.
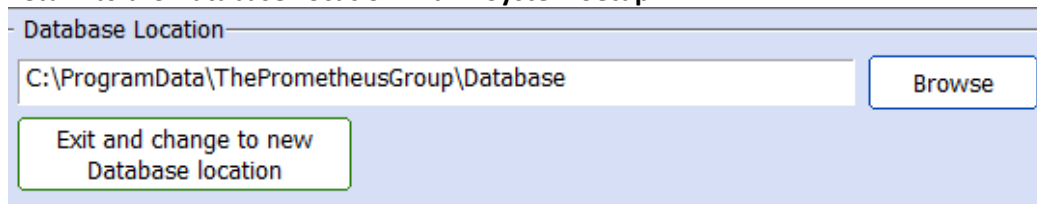
15. Click on the **Browse** button. **NOTE:** The current **Database location** will appear in the window.
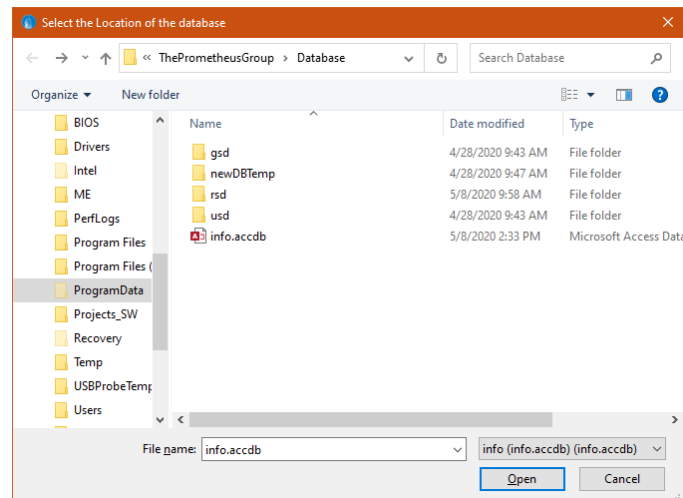
16. Navigate to the new database location that was set in step **11.**

17. Click on the **info.accdb** file **(info.mdb** for software versions prior to 3.1).

18. Make sure that the **info** file appears in the **File name** field and click **Open.**

19. From **System Setup make sure** that the **Database Location** now contains the new file path. If the file path is correct, click **Exit and change to new Database location.**
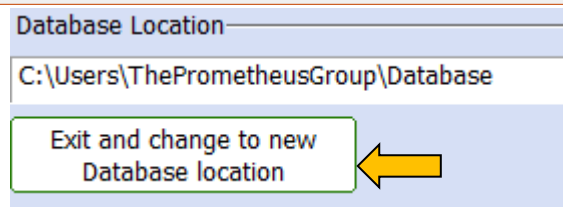
20. Click **YES** to change to the new **Database Location** or click **NO** to keep the original **Database Location.**
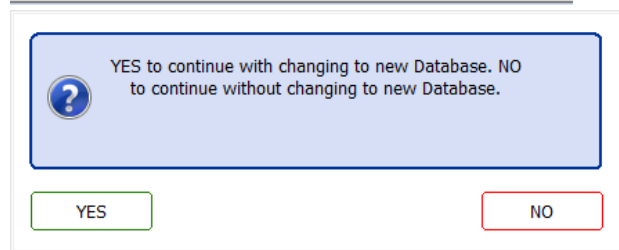
21. If **YES,** the following window will appear. Click **OK** to continue.

22. The software will close and return to the desktop.

The new Database configuration is complete. EMYO™ 200 will now exit. To continue, please re-launch program

OK

23. Double click on the software icon and login.

24. Click on **Tools.**

25. Click on **View System Setup.**

26. Verify the **Database Location** now contains the new file path.

Database Location

C:\Users\ThePrometheusGroup\Database   Browse

Exit and change to new Database location
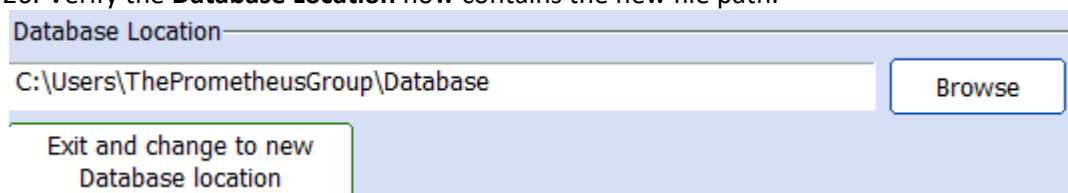
Database Backup

NOTE: The Prometheus Group® is not responsible for the loss of database files. The Prometheus Group® strongly recommends that the database files be backed up on a regular basis.

1. **Database Backup** is saved to the Local Hard drive (C:\) by default. To save to a network/data server click **Browse.**

Database Backup

C:\   Browse

Backup Database Now

Schedule Backup - (This will occur on exit of software)

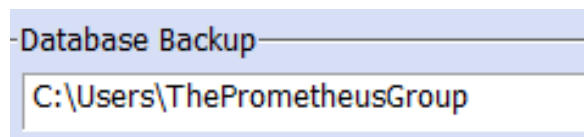◉ Manual   ◯ Automatic (recommended) - Every 1 days
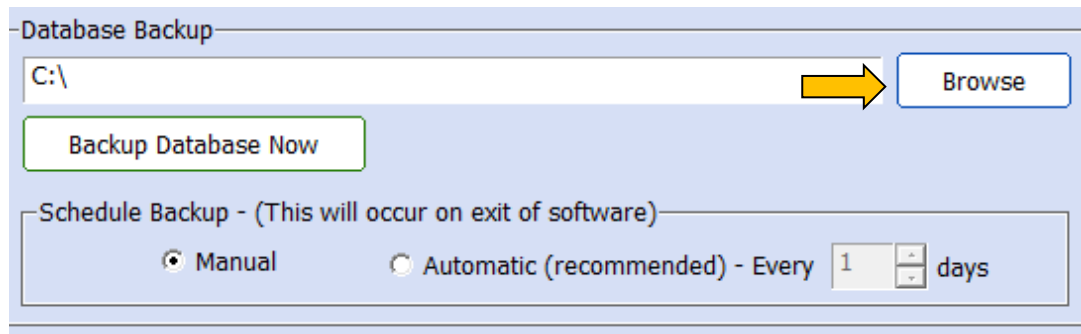
2. From the **Browse For Folder** window, navigate to the new location for the **Database Backup.**
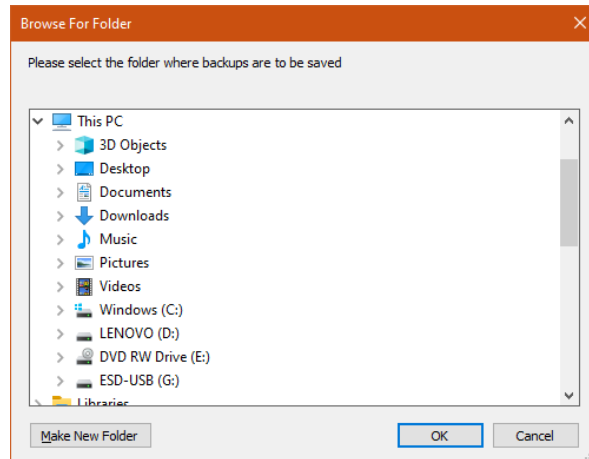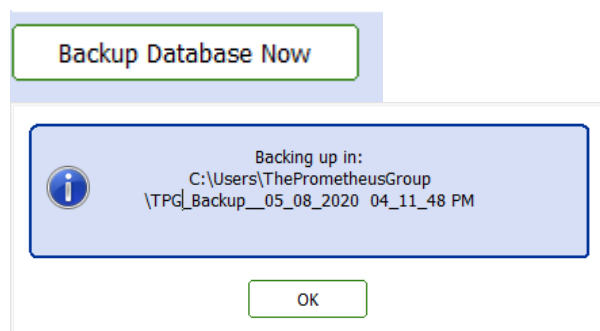

3. Once the new location folder is selected or created click **OK.**
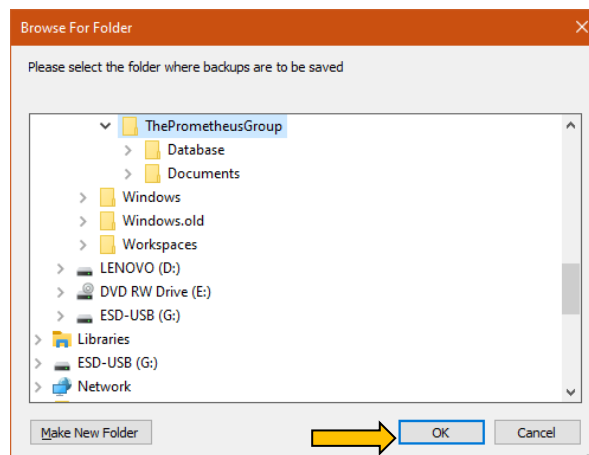
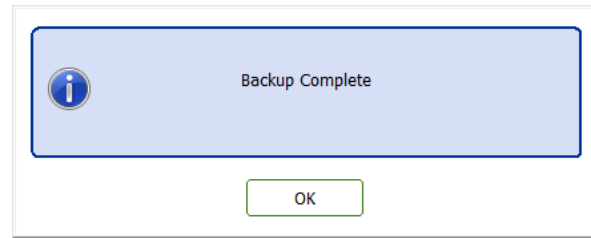4. Make sure that the **Database Backup** now has the new file path.

5. Clicking **Backup Database Now** will bring up a window showing the new file path, date and time of the backup.
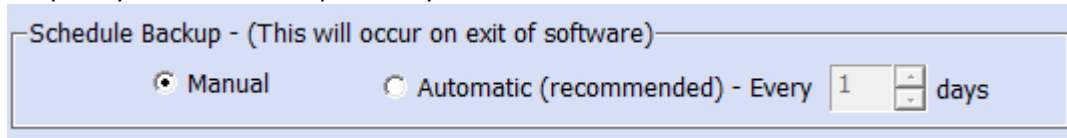
6. Click **OK** and the backup will begin.

Backup Complete

OK

7. Click **OK** to return to the **System Setup** window

8. **Schedule Backup** enables either a **Manual** or **Automatic** backup with the backup frequency. **Manual** backup is set by default.
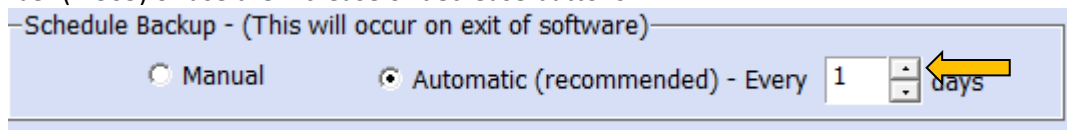

Schedule Backup - (This will occur on exit of software)

○ Manual   ○ Automatic (recommended) - Every 1 days

9. **Manual** backups require use of the **Backup Database Now** button.

Database Backup

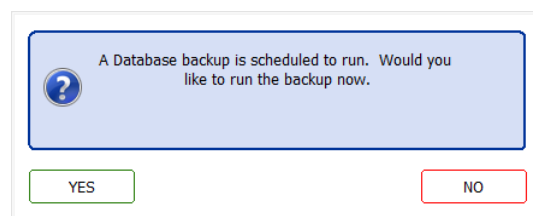C:\Users\ThePrometheusGroup

Backup Database Now
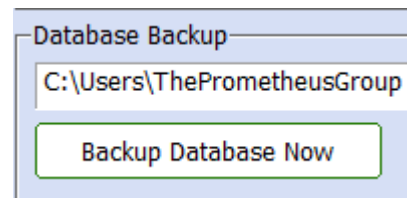
10. Click **Automatic** to deselect **Manual.**

11. **Automatic** backup can be set to run from **1 day** to **365 days.** Simply type in the number (1-365) or use the increase or decrease buttons.

Schedule Backup - (This will occur on exit of software)

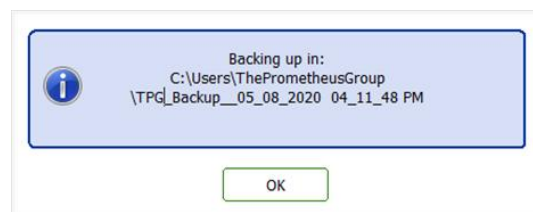○ Manual   ● Automatic (recommended) - Every 1 days

12. The **Automatic** backup will occur on exiting the software appear.

13. The **Care Provider** should be made aware of this setting and click **YES** when prompted.

A Database backup is scheduled to run. Would you like to run the backup now.

YES   NO

14. Click **OK** and the backup will begin.

Backing up in:
C:\Users\ThePrometheusGroup
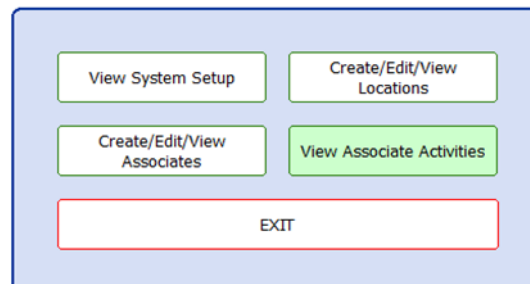\TPG_Backup__05_08_2020 04_11_48 PM

OK

15. Click **OK** to exit the software.
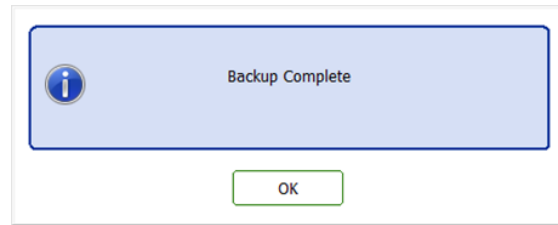
View Associate Activities

View Associate Activities can be utilized for audit purposes. This tool stores and displays records of the activities and edits performed on patients by each associate. **NOTE:** This feature is only accessible by users with administrative permissions.

1. Click **View Associate Activities.**

2. **View Associate Activities** will appear:

3. **Select Search Type** is used to **Search by Associate** or **Search by Patient**. Click the drop-down arrow 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. Click on an **Activities** option. In the example shown, **Search by Associate**, **Joe Provider B.S. RN**, and **ALL Activity** is selected. Additionally, a **Custom Selection** is chosen with a **Begin Date** of 03/27/2009 and an **End Date** of 05/11/2020. **All Dates** will compile 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**.

5. The search found 211 records for Joe Provider B.S. RN for the time period. The **Search Results** list box displays 28 records within the window. Use the scroll bar to view additional records.

6. Double clicking on a record displaying **EDIT** in the **Activity** column will open **Patient Profile 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 Activities** 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 **Tools** window to return to the Home Screen.
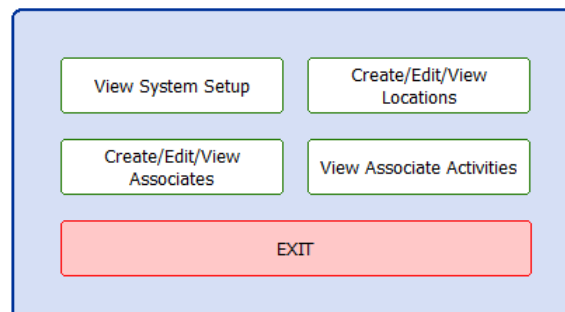
Additional Configuration Settings

Permissions Required to Operate the System

The software requires the Associate to have Full Control Permissions (Read/Write/Modify) to the following folders on the computer:

- C:\Program Files (x86)\The Prometheus Group
- C:\Program Data\ThePrometheusGroup

Full Control Permissions will also be required for the database location if it has been copied to a network/data server location. The network/data server location also needs to be mapped on the Associates computer.

Configuring Multiple Computers to a Networked Database

A database that has moved to a Network/Data Server location can be used by multiple Associates from multiple computers at any time.

To configure the additional computers, the software must be installed and the Initial Software Startup Process must be completed. To avoid the duplication of multiple **Associate Profiles** on each computer, it is recommended to create only one **Associate Profile** during the initial software startup process on each computer.

1. Open the software
2. Select the software **Tools** Button.
3. Select **View System Setup** button.
4. Navigate down to **Database Location** and select the **Browse** button.
5. Using the **Select the location of the database** window, navigate to the network location and select the **Database** folder.
   example: z:\Database
6. Select the **info.accdb** (**info.mdb** for software versions prior to 3.1)
7. The new file path should be the path to the new database location in the **View System Setup** windows
8. If it does show the correct path, click **Exit and change to new database location**
9. Click **YES** on the popup window asking to change the database location

10. The database location will change and the software will close.
11. Open the software and login using the credentials from the first computer that was setup for the networked database.

Final Preparation

Assist the Associates with configuring their own **Associate Profile** and login credentials where needed.

Frequently Asked Questions
Basic Organizational Questions

1. What is the full name and address for the company headquarters?
    A. The Prometheus Group®
        One Washington Street
        Suite 3171
        Dover, NH 03820

2. Does the facility hold any ISO Certifications?
    A. Yes, please contact support@theprogrp.com to request a copy of the current certificate(s).

3. Does your organization employ DMARC, DKIM, & SPF records for email security?
    A. No

4. Has your organization suffered a data breach within the last 3 years?
    A. No

5. Will your organization host, receive, process, transmit or remotely access (from The Prometheus Group® equipment) any facility data (PHI, PII, PCI, Employee, Financial….)?
    A. No, The Prometheus Group® does not store, maintain, or use any facility data, patient information or the database that houses the patient information. Once the software is installed and configured, the facility is responsible for maintaining the patient information.

Security Assessment

Scoping

1. Has your organization completed a Manufacturer Disclosure Statement for Medical Device Security (MDS²)?
    A. Yes, to request an MDS[2] contact The Prometheus Group® Technical Support Team via email at support@theprogrp.com or contact the Technical Support Team via phone at 1-800-272-8492 in the U.S. and Canada or +1 (011) 603-742-6053 International.

2. Does this device require internet connectivity?
    A. No, (TeamViewer is offered for remote access by the Technical Support Team for the user if needed but it is not a requirement).

3. What is the Operating System for the client device?
    A. Windows 10 Professional

4. Due to using Microsoft (MS) for your operations system (O/S), who within your company tests for new patches released by Microsoft every month? How often is this done? Where do you post the patches that have been tested and approved for installation?
    A. If computers are purchased through The Prometheus Group®, the operations system (O/S) are updated and verified on the date of shipment with the latest Microsoft (MS) updates and then the automatic update feature is disabled (set to manual).

5. Does the device have any external communication capability (e.g., network modem, etc.)?
    A. The device does not have any external communication capability.

6. Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)?
    A. Yes, depending on the computer Operating System.

7. Any encryption of data at rest/transmission?
    A. No data is transmitted but Windows Bit Locker can be used to encrypt data at rest.

8. List the manufacturer's stated maintenance requirements.
    A. See Page 69.

9. If a device is sent in for an evaluation, service/repair, functionality/calibration verification or preventive maintenance what type of service documentation would be included with the returned device?
    A. A Returned Materials Report would accompany the returned device stating: Facility name/address/contact, model of device, serial number of the device, date of the event, items received, complaint root cause, analysis/corrective action, ship to/bill to addresses, method of return shipping (i.e….ground, 2nd day, overnight), warranty status, purchase order number and signature of the technician who performed the service.

10. Are there any purchase restrictions on repair parts or PM kits?
    A. Not applicable, the device(s) are designed to be maintenance free and have no user adjustments.

11. Is the product capable of being scanned using well-known anti-virus systems for malicious code?
    A. Anti-virus can be used on the computer. It is recommended to suspend anti-virus during installation of the software.

12. Is the product able to be joined to a Windows Domain for authentication and Active Directory Authentication?
    A. Yes, but the software uses its own login and is not compatible with Active Directory Authentication.

13. Is the solution capable of utilizing LDAP/SAML authentication integrations?
    A. The computer system can be put in LDAP, however the software itself uses an integrated authentication and does not support Active Directory.

Development Security Operations
1. What is your software Engineering Capability Model (CMM) maturity level?
    1.1. The process is defined/confirmed as a standard business process. Feature Driven Development is also used.

2. Describe how secure programming and validation is built into your SDLC or software development process.
    2.1. The Prometheus Group® is an ISO 13485 registered company and has procedures in place for verification and validation activities.

3. Are web services used in this solution?
   3.1. No

4. Is any open source code used in this solution?
   4.1. No

5. Describe the change control process used for the production being assessed. Looking for separation of duties between code writing and elevation to production.
   5.1. The Prometheus Group® is an ISO 13485 registered company and has procedures in place for design controls, change controls, and verification and validation activities.

Cleaning and Disinfecting

Systems and Devices

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

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 EMG/Stimulation Sensor (Part #6340)
Pathway® Rectal Silicon Pressure Sensor (Part #6425)
Pathway® Vaginal EMG/Stimulation Sensor (Part #6330)
Pathway® Vaginal/Rectal EMG 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 it's 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.

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.

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.*

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
Morpheus® 360° ER 12MHz Endocavity 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.

⚠	**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).**
⚠	**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.

Software Troubleshooting

Database May Be Missing

A missing database prompt occurs when the database is created on the local C: Drive of a computer and the user does not have permission to use the software from its installed location. It may also occur when the database is moved to a network and the network location is not available. This means that the database cannot reach the specified path.
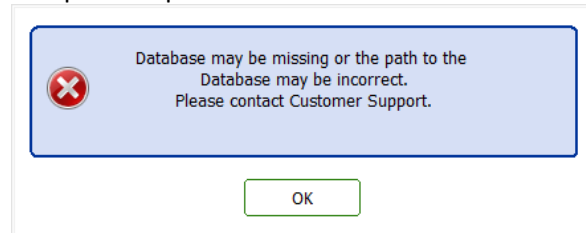

1. Verify network connectivity to ensure the network location is available to the user.
2. Verify the Windows user has Full Control permission to the software and the database location.
   Failure to have Full Control permission to the software and database will prevent the files from being read or a database location change to be applied.
   a. Software locations are:
      i. C:\Program Files (x86)\The Prometheus Group
      ii. C:\ProgramData\ThePrometheusGroup
3. For a network location, verify the software can navigate to the network database location using the **Browse** button in the software Tools\View System Setup\Database Location field.
   a. If a network database location cannot be located using **Browse**, the drive must be mapped to the user's computer to allow the software to see the database location.

System DSN Does Not Exist

This may occur in conjunction with the database may be missing error.

The user account does not have permission for the software to modify the Window's Registry or software configuration files to accept the database location change.
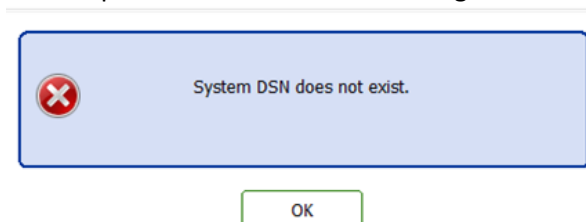
1. If the software continues to report a missing database or DSN error, edit the **Windows Registry** to include the correct file path to the database.
2. Right click on the **Windows Start** Button
3. Click on **Run**
4. Enter "**Regedit**" in the Open: text box
5. Click **OK**
6. Click **File** on the top menu bar
7. Click **Export** on the **File Menu**
8. Enter a file name in the text box provided. Example of a file name: Registry 3-27-2020
   Note: File is saved for a backup of the registry prior to making changes
9. Click **Save**

10. Navigate to
    **HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\ODBC\ODBC.INI\ThePrometheusGroupD
    B** in the left window
11. Right click in the right window
12. Click **New**
13. Click **String Value**
14. Name/rename the new **String Value "Defaultdir"**
15. Right click **DefaultDir**
16. Click **Modify**
17. Enter the correct path to the network database in the **Value Data** text box
    Example: T:\Telesis\Database. Click **OK**
18. Right **c**lick **DBQ**
19. Click **Modify**
20. Enter the correct file path to the database on the network in the **Value Data** text box including
    the database file name
        Example: T:\Telesis\Database\info.accdb
21. Exit the **Registry Editor** window
22. Restart the computer

Database May Be Corrupt

This means that the software's database has been corrupted and access to the database has been restricted. This will render the software unusable until the database corruption has been fixed.
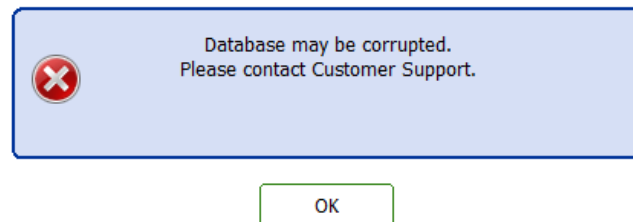
Database corruption may occur due to the following: 1) a virus or malware attack; 2) weak network connectivity; 3) incorrectly exiting the software or; 4) sudden system shutdown. Contact the Technical Support Team at The Prometheus Group® to assist with repairing the database at 1-800-272-8492 in the U.S. and Canada or +1 (011) 603-742-6053 International during 8:30am to 5pm Eastern Standard Time. The Technical Support Team will require a copy or access to the database. Once the database has been repaired, the Technical Support Team will remove all database files from their computers.

> **NOTE:** The Prometheus Group® does not store, maintain, or use patient information or the database that houses the patient information.

Communication Error

The software reports a **Communication Error** when real time is launched.

1. Verify the device is on.
2. If using a USB Serial Interface, verify that the USB Cable is connected to both the device and computer and that it is not damaged. For the Pathway® MR Series verify the red LED light is on.
3. For a wireless Bluetooth connection, verify that the device or devices are paired with the computer.
4. See also **COMPort v**erification.

COMPort Verification

If either of the two prompts appear when launching real time:

1. Verify the USB Serial Interface is connected to the device and the computer.

2. Right click on the **Start** button on the computer desktop

3. Select **Device Manager** from the list of options
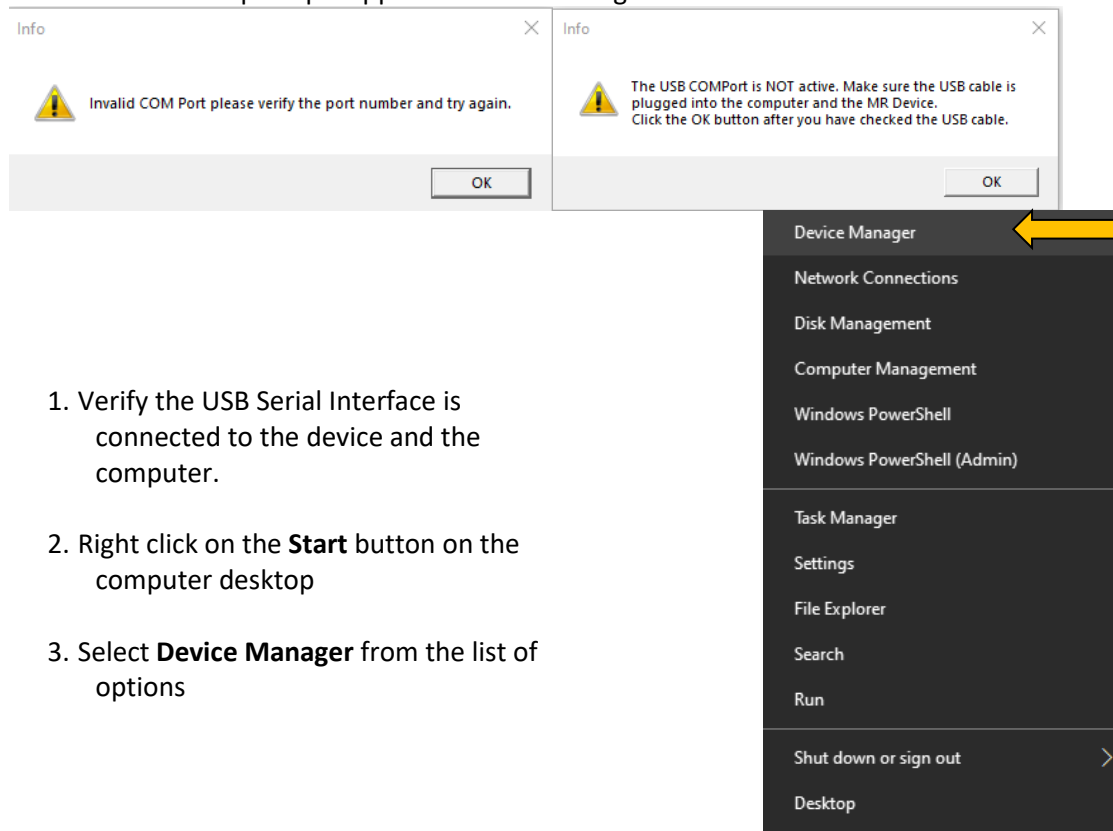
4. Click on the **>** s**y**mbol to the left of the **Ports (COM & LPT)** to open this section.
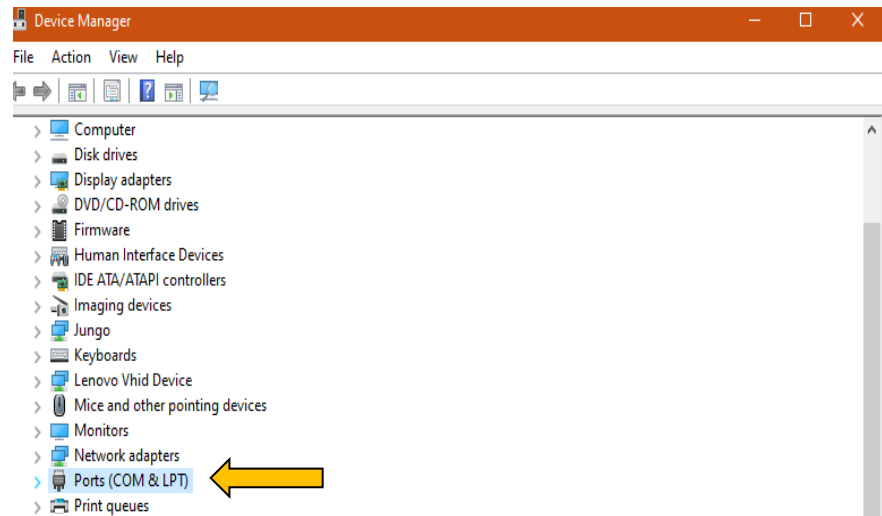
5. The devices connected will appear under the **"Ports (COM & LPT)"** . In the example to the right there are devices using the **Keyspan Adapter, USB Serial Port,** and **Bluetooth.** Note that **Bluetooth** utilizes two COM Ports. If a device has **Bluetooth** and **USB Serial Port** connection options, only one of these connection types may be used at a time.

6. If the device cannot be identified, unplug the USB Serial Interface from the device or the computer and see which device connection is removed. Reconnect and see which device connection is now added.

7. Make note of which **COM** number corresponds to the device connection.
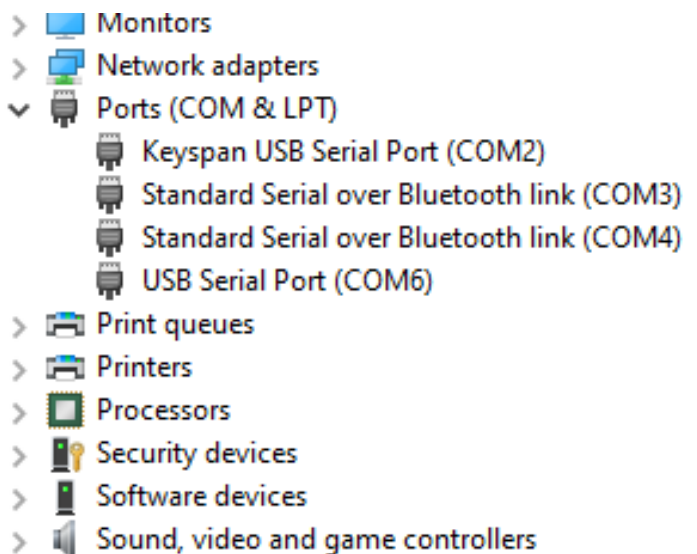
8. Change the **COM Port** number in the **Utilities** menu to the **COM** number from **Ports (COM & LPT).**

9. If using a device with a **9-Pin Serial Port** the **Device Connection Type** <u>MUST BE</u> set to **Serial.** If using a device with a **USB Serial Interface** the **Device Connection Type** <u>MUST BE</u> set to **USB.**

Start Collecting Data Does Not Function Or Cannot Save Data
(Telesis® and Telesis® ST Software)

1. Make sure a protocol is selected from the protocol list.

2. The software installation media includes a label with an **Unlock Keycode** and device serial number. Verify the device serial number (located inside the battery compartment) matches the media label.

3. If there are multiple Pathway® MR Series devices, locate and exchange the device that matches the media label or locate the media label that matches the device and change the **Unlock keycode** in **Utilities.**

Game Displays

(EMYO® Series and Morpheus® Pelvic Muscle Rehabilitation with Game Option)

1. **Games** do not show on the HDMI monitor.
   A. Make sure the monitor is on.
   B. Verify the Game has been selected prior to selecting a protocol.
   C. Verify the monitor is properly set up in the extended mode. See Page 29.

2. **Games** are displayed but there is no sound.
   A. Verify the computer volume is not muted and set to an audible level.
   B. Verify **Speakers** are selected and not **Digital** on the **Speaker Volume** menu

Definition of Symbols

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.

Symbol	Definition
⚠	**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**
⚠	**WARNING: A hazard to a person - a potential danger to the operator or patient such as electrical shock or some other potential danger**
🚫	**GENERAL PROHIBITION: To signify a prohibited action**
📖	**Consult Instructions for Use**
📖	**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**
⧖	**Use by date**
⊘	**Do not use if package is damaged**
LATEX	**Contains or presence of natural rubber latex**
NON STERILE	**Non-sterile**
STERILE	**Sterile**
STERILE EO	**Sterilized using ethylene oxide**
☼	**Keep away from sunlight**

Symbol	Definition
	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
	Type BF applied part
	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

Maintenance and Calibration

Pathway® Devices, EMYO® Series, and Morpheus®

These devices are designed to be maintenance free. There are no user serviceable parts. The Technical Support Team suggest an annual functionality and calibration check. This service is available at a nominal fee. If the device is within the warranty period and requires repair, the repair will be performed by The Technical Support Team according to the terms of the Standard or Extended Warranty Service Agreement. If the device is out of warranty and requires repair, the Technical Support Team will quote repair charges for approval prior to performing the work necessary to return the device to factory standards. Whether an annual checkup or repair, documentation of services performed will accompany the device. Please contact The Prometheus Group® Technical Support Team at 1-800-272-8492 in the U.S. and Canada or +1 (011) 603-742-6053 International for a Returned Materials Authorization Number (RMA) and proper shipping instructions.

Ultrasound Transducers

The transducer is designed to be maintenance free. There are no user serviceable parts. If the transducer is within the warranty period and requires repair, the repair will be performed by The Technical Support Team according to the terms of the Standard Warranty Service Agreement. Additional charges may occur for expedited shipping. If the device is out of warranty and requires repair, the Technical Support Team will quote repair charges including shipping fees for approval prior to performing the work necessary to return the device to factory standards. Documentation of services performed will accompany the repaired transducer. Please contact The Prometheus Group® Technical Support Team at 1-800-272-8492 in the U.S. and Canada or +1 (011) 603-742-6053 International for a Returned Materials Authorization Number (RMA) and proper shipping instructions.

Software License Agreement

The Prometheus Group® grants to the purchaser of The Prometheus Group® Software the right to use one copy of the Software on one computer within one business entity. The 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 Prometheus Group® Software.