

Owner’s Manual

Cath Ergometer

Owner \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Model \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Serial # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical Positioning, Inc.

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**MEDICAL POSITIONING, INC**

9732 Pflumm Road

Lenexa, KS 66215

**Cath Ergometer**

|  |  |
| --- | --- |
| **Attribute** | **Rating** |
| Voltage | 120 VAC |
| Amperage | 2.6 Amps |
| Cycle | 50/60 Hz |
| Duty Cycle | 10%, 1 min. on/9 min. off |
| Leakage Current | < 100 µA |

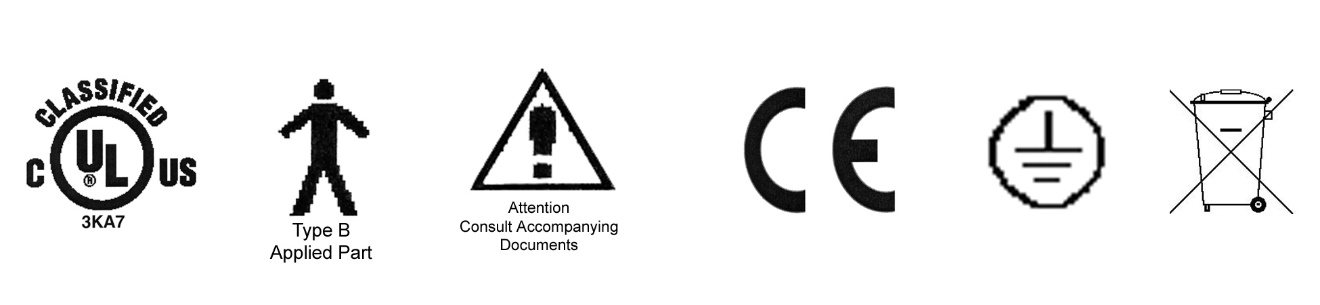
**UL 60601-1 CLASSIFICATIONS:**

* Class 1 Equipment
* Type B Applied Part
* Degree of Protection Against Ingress of Water / IPXO
* Equipment Not Suitable for Use in Flammable Anesthetic Mixture

All electrical circuitry is isolated from chassis.

Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked “Hospital Only” or “Hospital Grade”

The power cord is to be used for mains disconnection.



MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1 AND CAN/CSA C22.2 NO. 601.1

Transportation and storage:

Temperature range within -40 to 70 C

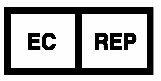
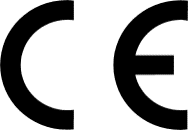
Relative humidity range within 10% to 100%

Atmospheric pressure range within 500 to 1080 hPa

# Symbols and Definitions

|  |  |
| --- | --- |
| TypeB  Type B Applied Part | Applied Part complying with specified requirements for protection against electric shock. Type B Applied Parts are those parts, which are usually Earth referenced. Type B are those parts not suitable for direct cardiac application |
| Attention  Attention | Attention, consult accompanying documents |
| earth  Protective Earth | Any terminal which is intended for connection to an external protective conductor for protection against electric shock in case of a fault |
| weee_symbol | This device contains materials that are potentially hazardous to the environment. In accordance with the DIRECTIVE 2002/96/EC OF THE EUROPEAN PARLIAMENT AND OF THE CONCIL on waste electrical and electronic equipment (WEEE), the Cath Ergometer electrical system and accessories should not be disposed as unsorted municipal waste. Consult your instructional policies and local regulations regarding disposal. Contact your Medical Positioning, Inc. Service Representative if additional disposal details are required. |

# European Union Representative



MDSS GmbH

Schiffgraben 41

30175 Hannover, Germany

# Precautions

Your Ergometer has been pre-assembled and tested to ensure operation on day one. Please closely inspect it when you receive it to ensure no damage has occurred during shipment. Because it is a complex piece of equipment, make note of the following precautions.

* WARNING, POTENTIAL FOR INJURY OR DEATH. Do not leave patient unattended while using the equipment.
* WARNING, POTENTIAL FOR INJURY OR DEATH. Do not modify this equipment without authorization of the manufacturer.
* WARNING, POTENTIAL FOR INJURY OR DEATH. Do not use in oxygen rich environment.
* **WARNING, POTENTIAL FOR INJURY OR DEATH. To reduce the risk of electrical shock, grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked “hospital only” or “hospital grade”.**
* **WARNING, POTENTIAL FOR INJURY OR DEATH. To reduce the risk of electrical shock, do not remove secured covers. Refer servicing to qualified personnel.**
* **WARNING, POTENTIAL FOR INJURY. To reduce the risk of a potential injury, always use two (2) people to install or remove the Ergometer. It has a weight that exceeds that for which a single individual can safely lift.**
* **WARNING, POTENTIAL FOR INJURY. Do not install or remove the Ergometer Controller while the equipment is in use.**
* **WARNING, POTENTIAL FOR INJURY. To reduce the potential for patient knee injury, position the ergometer so the patient’s knees remain slightly bent through all positions of pedal rotation.**
* WARNING, POTENTIAL FOR INJURY. Always read manufactures instructions and warnings before using any cleaning product or disinfectant.
* WARNING, POTENTIAL FOR INJURY OR DEATH. It is recommended that the product be cleaned between patients; please follow your facilities documented policy.
* **CAUTION, PRODUCT DAMAGE MAY RESULT. The ergometer control cable must be disconnected from the Ergometer Controller before you install or remove the Ergometer Controller. Failure to do so may result in Ergometer Controller damage.**
* **CAUTION, PRODUCT DAMAGE MAY RESULT. Proper alignment of the connector pins is critical. Failure to properly align the connector pins can result in damaging the connector.**
* **CAUTION, PRODUCT DAMAGE MAY RESULT. Always grasp the connector and not the cable.**
* **CAUTION, PRODUCT DAMAGE MAY RESULT. Do not over tighten the mounting screws. Over tightening may result in stripping threads.**
* **CAUTION, PRODUCT DAMAGE MAY RESULT. Do not use abrasives to clean surfaces.**

# Intended Use

The product is intended for use with ultrasound systems and ECG systems. The product is intended for the environment where physiologic monitoring equipment is used, and right heart cardiac catheterization procedures are performed in hospitals. The product is contraindicated for patients that cannot safely sit in a chair or lie on an elevated surface.

* **WARNING, POTENTIAL FOR INJURY OR DEATH. Do not leave patient unattended while using the equipment.**
* **WARNING, POTENTIAL FOR INJURY OR DEATH. Do not modify this equipment without authorization of the manufacturer.**
* **WARNING, POTENTIAL FOR INJURY OR DEATH. Do not use in oxygen rich environment.**

# Set Up

Your Ergometer has been shipped to you in “plug and play” condition. After unpacking the product, we recommend performing an initial test of your Ergometer to ensure that each function is in correct working order. After reviewing this manual you are ready to begin using your Ergometer.

# Operation

Your Ergometer is shipped assembled and ready for use. Each function has been pre-tested to ensure perfect working order on day one.

A **“Troubleshooting Guide”** is included in this manual to assist you in the event of a malfunction.

Ergometer

* **WARNING, POTENTIAL FOR INJURY. To reduce the risk of a potential injury, always use two (2) people to install or remove the Ergometer. It has a weight that exceeds that for which a single individual can safely lift.**

Ergometer Controller

The Ergometer Controller provides protocols (both pre-programmed and user programmable) to allow predetermined and precise exercise regimens to achieve desired levels of patient exercise. The Ergometer Controller will produce a cadence tone or a rhythmic beep to assist the patient to match his or her pedaling speed to the protocol. The patient’s performance through the stages of a protocol is also monitored and displayed. An additional timer automatically begins timing when the protocol ends to indicate post exercise time.

The Ergometer Controller and the protocols provide repeatable exercise sequences that are easy to set up and use. Any one of ten (10) pre-programmed protocols or four (4) protocols you design and program, can be selected. An additional manual protocol also allows you to choose and manually change or vary the ergometer resistance setting before and during exercise.

* **WARNING, POTENTIAL FOR INJURY. Do not install or remove the Ergometer Controller while the Ergometer is in use.**

**Mounting the Ergometer Controller**

| **STEP** | **ACTION** |
| --- | --- |
| 1 | Loosen (Rotate counterclockwise) the controller swivel mount tensioner and slide computer controller onto metal tube at the top of the ergometer. See Figure 1 |
| 2 | Position the controller so that it is facing the side you will be monitoring from. |
| 3 | Turn the controller swivel mount tensioner clockwise until the controller is secure. See Figure 1 |
| 4 | Holding the connector on the end of ergometer control cable (cable coming out of the top of the ergometer). Align the cable connector with the connector on the back of the Ergometer Controller. Push the cable connector firmly into place. See Figure 2 |
| 5 | Tighten the screw knobs of the connector to the computer controller. See Figure 2 |

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**Figure 1**

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**Figure 2**

* **CAUTION, PRODUCT DAMAGE MAY RESULT. The ergometer control cable must be disconnected from the Ergometer Controller before you install or remove the Ergometer Controller. Failure to do so may result in Ergometer Controller damage.**
* **CAUTION, PRODUCT DAMAGE MAY RESULT. Proper alignment of the connector pins is critical. Failure to properly align the connector pins can result in damaging the connector.**

**Removing the Ergometer Controller**

| **STEP** | **ACTION** |
| --- | --- |
| 1 | To remove the computer controller, disconnect the computer controller control cable by unscrewing the knobs. See Figure 2 |
| 2 | Grasping the connector, pull it out from the rear panel. See Figure 2 |
| 3 | Turn the swivel mount tensioner counterclockwise to loosen. Lift the computer controller off of the support tube. See Figure 1 |

* **CAUTION, PRODUCT DAMAGE MAY RESULT. Always grasp the connector and not the cable.**

**Ergometer Controller Operation**

The top portion of the Ergometer Controller front panel contains all the displays. The Patient Monitor band (green) is the first line of displays across the top of the front panel. They are used to show measured parameters. Below are the Program Presets (blue). They are used to show current protocol progress and programming information. Below the displays, the Ergometer Controller controls are used to setup, program, and operate the Ergometer Controller. The Operational Controls (green) on the left side are used to select protocols to control the operation of the Ergometer Controller. The programming Controls on the right side (blue) are used to create custom protocols or to control the manual operation of the ergometer.

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**Figure 3**

Please refer to Figure 3 for the display and controls described below.

| **Display** | **Description** |
| --- | --- |
| PATIENT RPMS | The patient’s pedaling rate is shown in revolutions per minute. |
| METS | Metabolic Equivalents – Multiples of resting oxygen uptake. This value is dependent upon the weight of the patient. METS as displayed on the Medical Positioning, Inc. Ergometer Controllers are based on a body weight of 154 lbs. (70 kb). If higher precision is desired, the value obtained can be corrected for the actual weight of the patient using the following calculations.  or |
| PROTOCOL NUMBER | The number from 1 to 15 is shown to indicate the selected protocol. |
| ELAPSED TIME | This display shows the total time the patient has pedaled in minutes and seconds since the protocol in use was started. |
| POST EXERCISE TIME | This display shows time in minutes and seconds beginning when the protocol ends or when the patient stops pedaling before a protocol is finished. The letters PROG will be shown in the display when a protocol is being programmed. |
| PEDAL RATE | This display shows the programmed pedal rate in revolutions per minute at which the patient should be pedaling for a given stage in a protocol. When programming a new protocol, this display shows the pedal rate being set for a stage of a protocol. The cadence tone is synchronized to 60 RPMs. |
| RESISTANCE | This display shows the resistance in watts that the ergometer is providing to oppose the patient’s pedaling while a protocol is in use. When programming a new protocol, this display also shows the resistance being set in a protocol stage. When previewing a protocol, it shows the resistance set for a stage of a protocol. |
| STAGE | This display shows the current stage of the protocol that is currently running. When programming a new protocol, this display shows the stage being programmed. When pre-viewing a protocol, it shows the stage of a protocol. |
| STAGE DURATION | This display shows the duration in minutes and seconds of the current protocol stage while a protocol is in use. This display serves as a timer and shows the time remaining in a given stage. The display counts down from the programmed stage time to zero during the progress of the stage. When programming a new protocol, this display also shows the duration being set in a protocol stage. When previewing a protocol; it shows the stage duration set for a stage of a protocol. |
| AUTO STOP | Displays “ON” or “NO” indicating if the automatic protocol stop feature is enabled (ON) or disabled (NO). See Setting Automatic Protocol Stop in this manual. |
| STAGE HOLD | Displays “ON” or “NO” indicating if the stage hold feature is enabled (ON) or disabled (NO). |

| **CONTROL** | **Description** |
| --- | --- |
| PROTOCOL-UP/DN | This control is used to select the protocol you wish to use or preview. Pressing the UP side moves to the next higher numbered protocol and pressing the DN side moves to the next lower numbered protocol. When UP or DN is pressed and held, the computer controller will scroll through the protocols. This control can be used any time the ergometer is turned on except when a protocol is in progress. |
| STAGE-UP/DN | This control is used to select the stage of the selected protocol you wish to use or preview. Pressing the UP side moves to the next higher numbered stage and pressing the DN side moves to the next lower numbered stage. This control can be used any time the ergometer is turned on. |
| TONE | This control is used to turn the cadence tone on or off. If the cadence tone is on, press this control to turn it off. If the cadence tone is off, press this control to turn it on. |
| AUTO STOP | This control is used to turn the automatic protocol stop on or off. See the setting Automatic protocol stop in this manual. |
| STAGE HOLD | This control is used to hold or “pause” a stage during a protocol. Pressing the “Program Stage” button while a protocol is running will place the protocol in a paused move. The total elapsed time will continue but the stage will not advance. Pressing it a second time will resume normal operation. You can confirm the status of this feature in the “Stage Hold” window of the controller. |
| START | This control is used to start the selected protocol. |
| STOP | This control is used to stop the selected protocol. Press this control a second time to place the computer controller in the Ready mode. During an exercise protocol, the controller will recognize the termination of exercise in one of two ways. If the stop button is pressed, pedaling resistance is eliminated and the post exercise timer begins. If the Auto Stop feature is enabled and the patient stops pedaling for ten seconds, this also signals the end of the procedure, the pedaling resistance is eliminated, and the post exercise timer begins. (The automatic protocol stop feature can be disabled. See ““Defaulting Automatic Protocol Stop” following this section.) With either stop condition, the STOP control must be pressed an additional time to return the controller to the Ready mode. |
| PROGRAM PROTOCOL/STAGE | This control is used in programming a protocol to select the number of the protocol that will be programmed. Continual pressing of the PROTOCOL side cycles through the programmable protocols (11-15) until the desired protocol number for programming is displayed. Pressing the STAGE side cycles to the next higher stage of the protocol that is being programmed. |
| TIME-UP/DN | This control is used to program the time in minutes and seconds for a protocol stage. Pressing the UP side will cycle to the next higher selection for time. Pressing the DN side will cycle to the next lower selection for time. Time is increased or decreased in 15 second increments. |
| WATTS UP/DN | This control is used to program the amount of resistance in Watts for a protocol stage. Pressing the UP side will cycle to the next higher selection for resistance. Pressing the DN side will cycle to the next lower selection for resistance. Watts are increased or decreased in 5 watt increments. |
| RPM UP/DN | This control is used to program the desired patient pedaling rate in revolutions per minute for a protocol stage. Pressing the UP side will cycle to the next higher selection for RPM. Pressing the DN side will cycle to the next lower selection for RPM. RPM is increased or decreased in 5 RPM increments. |
| VOLUME CONTROL | The speaker is located on the front of the patient coach. When the tone is on, the computer controller will beep at a rate that the patient can use to adjust his or her pedaling speed to the rate set for the protocol stage. The volume level of the cadence tone is controlled by turning the VOLUME CONTROL KNOB. Turn the VOLUME CONTROL KNOB in either direction as needed to increase or decrease the volume. You may also adjust the cover over the speaker to reduce the volume further. |

**Programming a Protocol**

Protocol numbers 1 through 10 are fixed and cannot be changed. Protocols 11 through 14 can be programmed or altered with up to 10 stages. Protocol 15 is a manual program where you can manually increase or decrease the ergometer resistance and/or leave it at the selected resistance level for as long as needed. Refer to Figure 3 for the location and description of displays and controls mentioned in the following procedure. A program that you create can be programmed. Use the following procedure to program a protocol.

| **STEP** | **ACTION** |
| --- | --- |
| 1 | If the Ergometer is unplugged from the power strip; plug it in to the respective outlet. Wait 10 seconds before proceeding to the next step. |
| 2 | Press the PROGRAM-PROTOCOL control. The computer controller will enter the Programming mode and PROG will be shown in the POST EXERCISE TIME display. The number 11 will be shown in the PROTOCOL NUMBER display and the number 1 will be shown in the STAGE display. |
| 3 | If you want to program or alter a protocol other than number 11, press the PROGRAM-PROTOCOL control as needed to show the protocol numbers 12 through 14 in the PROTOCOL NUMBER display. If you want to program or alter a stage other than number 1, press the PROGRAM-STAGE control to show the stage number that you wish to change in the STAGE display. |
| 4 | Press the TIME-UP/DN control to select the desired time for stage duration for the selected stage as shown in the STAGE DURATION display. |
| 5 | Press the WATTS-UP/DN control to select the desired amount of resistance for the selected stage as shown in the RESISTANCE display. |
| 6 | Press the RPM-UP/DN control to select the desired patient pedaling rate in revolutions per minute for the selected stage as shown in the PEDAL RATE display. |
| 7 | Press the PROGRAM STAGE control to program or alter the next stage of the protocol. Each time you press the PROGRAM STAGE control, the protocol program is saved for that stage. |
| 8 | Repeat steps 4 through 7 for all remaining stages to be programmed. |
| 9 | When all the stages have been programmed, press the PROGRAM STAGE control to save the last stage. The protocol program will be available for use. |
| 10 | To SAVE the protocol in permanent memory and exit the programming mode, press START. If you are not planning to use the protocol that you just programmed, you may press STOP after the protocol begins. Starting and running or starting and stopping a new protocol stores the protocol in memory. It will remain in memory until a new protocol is programmed in this channel. |
| 11 | To alter any or all stages of a previously programmed protocol, perform steps 1 through 10. |
| 12 | To program the manual protocol, protocol 15, perform step 1 and press the PROTOCOL-UP/DN control as needed to show the number 15 in the PROTOCOL NUMBER display. Press the WATTS-UP/DN control to show the desired amount of initial resistance in the RESISTANCE display. |
| 13 | Press the WATTS-UP/DN control at any time during the protocol to change the resistance as desired. |

**Utilizing a Protocol**

Any one of 15 protocols can be selected and used. Protocol numbers 1 through 10 contain fixed pre-programmed exercise steps. Protocols 11 through 14 can contain protocols that you have programmed (See “How to Program a Protocol”). Protocol 15 allows you to manually increase or decrease the ergometer resistance and leave it at the selected resistance level for as long as needed. Refer to Figure 3 for the location and description of displays and controls mentioned in the following procedure. Use the following procedure to set up, use, and/or stop a protocol. This procedure is to be followed after the patient has been positioned.

| **STEP** | **ACTION** |
| --- | --- |
| 1 | If the Ergometer is unplugged from the power strip; plug it in to the respective outlet. Allow 10 seconds for the computer to complete internal self-diagnostics before proceeding. If the power is already on, press the STOP control to place the computer in the Ready mode. The computer controller will then be ready to use the protocol that was last run, beginning with stage one. |
| 2 | Press the PROTOCOL-UP/DN control until the number of the desired protocol is shown in the PROTOCOL NUMBER display. This number is the exercise protocol that the patient will be using. If you will be using protocol 15, proceed to “Using Manual Protocol 15” further in this section. |
| 3 | If you prefer to begin a protocol at a stage other than stage one, you can start at another stage in the protocol by pressing the STAGE-UP/DN control until the number of the desired stage is shown in the STAGE indicator. |
| 4 | You can select to have the cadence tone be on or off during the protocol. Either before you start or during the exercise protocol, the cadence tone can be changed from ON to OFF or from OFF to ON by pressing the TONE control. You can adjust the volume of the tone by turning the VOLUME ADJUST KNOB clockwise or counterclockwise. |
| 5 | If you will be using the cadence tone, tell the patient that he or she will need to begin pedaling when the computer controller begins beeping and to pedal in rhythm with the beeps. (For example, if the patient has his or her right foot fully forward at the tone, the patient should complete one revolution of the pedals and have the same foot in the same position - fully forward - at the next tone.) If you have turned off the cadence tone, tell the patient to start pedaling when you press the START control and to begin pedaling faster or slower as needed to illuminate the green light in the center of the “Patient Assist”. If the protocol you will be using will change the pedaling rate, tell the patient that this will happen and that he or she will have to change how fast they are pedaling during the exercise protocol. |
| 6 | When you and the patient are ready to begin, press the START control and tell the patient to begin pedaling. |
| 7 | When the patient achieves double product range or target heart rate you can tell the patient to stop pedaling. If the AUTOMATIC PROTOCOL STOP (see SETTING AUTOMATIC PROTOCOL STOP later in this manual) is turned on, the protocol will stop automatically when pedal revolutions have stopped for 10 seconds. You can also stop the protocol at any time by pressing the STOP control. Note that if the patient stops pedaling before the protocol is finished and the AUTOMATIC PROTOCOL STOP is turned on, the Ergometer Controller will stop the protocol ten seconds after the pedals have stopped turning. Once an exercise protocol is stopped by either of the above methods, all of the information including the protocol elapsed time and stage duration elapsed time remain on the displays for patient charting. The information will remain on the display until the STOP button is pushed again. When a protocol is finished or has otherwise been stopped, the POSTEXERCISE TIME display will begin keeping track of the time since the protocol was stopped and will provide a series of audible tones every minute during post exercise. |
| 8 | To return the computer to the Ready mode, press the STOP control a second time after the protocol has stopped. The computer controller will then be ready to use the protocol that you just completed and the first stage will be selected. |
| 9 | If this or another protocol is to be set up and run, repeat steps 2 through 8. |

**Utilizing the Manual Protocol**

Protocol 15 is used if you want to manually set, adjust, or vary the resistance of the ergometer without having any automatic protocol steps running. This protocol is used to give the patient a fixed or variable resistance for an indefinite amount of time. The stage duration timer is not available while using protocol 15. Refer to Figure 3 for the location and description of indicators and controls mentioned in the following procedure. Use the following procedure for protocol 15.

| **STEP** | **ACTION** |
| --- | --- |
| 1 | If the Ergometer is unplugged from the power strip; plug it in to the respective outlet. Allow 10 seconds for the computer to complete internal self-diagnostics before proceeding. If the power is already on, press the STOP control to place the computer in the Ready mode. |
| 2 | Press the PROTOCOL-UP/DN control until the number 15 is shown in the PROTOCOL NUMBER display. |
| 3 | Select and program the pedal rate and watts of resistance at which you wish the test to begin. |
| 4 | When you and the patient are ready to begin, press the START control and tell the patient to begin pedaling. |
| 5 | At any time during the procedure you can change the resistance or pedal rate using the appropriate control. |
| 6 | When you and the patient are finished with the exercise, press the STOP control. |
| 7 | To return the computer to the Ready mode, press the STOP control again. |

**Setting Automatic Protocol Stop**

The Ergometer Controller allows you to automatically stop the protocol and start post exercise timing after the patient has ceased pedaling for 10 seconds. This feature allows you to ignore the controller and begin post exercise imaging.

When the controller goes into the post exercise timer mode, a brief burst of tones are sounded to alert both you and the patient to the end of the test. The post exercise timer display is in the center of the controller (see Figure 3). Once the post exercise timer has begun, the computer controller sounds a series of tones every minute. This tone is a reminder for other measurements such as post-test blood pressure.

Anytime the ergometer is turned on and before beginning a procedure, press the “Auto Stop” button. Confirm the status in the “Auto Stop” window of the controller (ON for enabled and NO for disabled).

Patient Coach

Please refer to Figure 4 for the display and controls described below.

| **CONTROL** | **Description** |
| --- | --- |
| PEDAL SPEED INDICATOR LIGHT | These lights indicate patient pedaling speed. The left amber light indicates patient is pedaling too slow, green light indicates correct speed, right amber light indicates patient is pedaling too fast. This feature allows you to use visual monitoring to judge patient progress in lieu of audio cadence. |
| VOLUME ADJUST KNOB | Rotate to adjust volume of cadence. Note: Cadence tone can be turned on or off using the TONE BUTTON on the ERGOMETER CONTROLLER. |

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**Figure 4**

**Mounting the Patient Coach**

| **STEP** | **ACTION** |
| --- | --- |
| 1 | Place the patient coach on top of the Ergometer Controller facing the patient’s head. The hook and loop fasteners on both units will secure them together. |
| 2 | Secure the RS232 type wiring connector to the back of the patient coach and the bottom of the Ergometer Controller. See Figure 5 |

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**Figure 5**

# Ergometer Quick Reference Guide

|  |
| --- |
| TO BEGIN   * Connect ergometer power cord to an approved electrical outlet, wait 10 seconds, then select exercise protocol. * Attach monitoring equipment: blood pressure cuff, ECG, pulse oximeter, etc. according to your lab’s protocol * Explain stress procedure to patient * Secure patient’s feet in ergometer pedal boots and adjust ergometer for proper bend in patient’s knee. It is important to do this just before you obtain your baseline intra-cardiac pressure measurements, so that patient’s legs are not elevated for a long period before beginning exercise. If there is a waiting period due to absence of physician or nurse, remove patient’s feet from boots until ready to begin. * Perform baseline intra-cardiac pressure data acquisition with the patient’s feet secured in the boots. It is important to have the same preload for baseline and exercise data acquisition. * Press computer START button and instruct patient to begin pedaling. * Encourage the patient throughout the exercise to pedal at a consistent speed, aided by the patient coach.   DATA ACQUISITION DURING EXERCISE   * Acquire intra-cardiac pressure data during any stage of exercise or at peak exercise. It is recommended to acquire data at the end of the stage for steady state circulatory physiology (for example, during the last minute of a 3-minute stage) or use STAGE HOLD at the end of a 2 minute stage. * If needed, you can STAGE HOLD or STAGE DOWN to keep the patient pedaling until you acquire all your measurements. * When all exercise data has been acquired, press STOP and instruct patient to stop pedaling. * Obtain post-test information per your protocol.   WHEN FINISHED   * Remove patient’s feet from ergometer pedal boots * Slide ergometer out away from patient * Transfer patient from procedure room per your lab’s protocol. |

Ergometer Storage Cart

The Ergometer may be used with an optional Ergometer Storage Cart for storing the Ergometer.

* **WARNING, POTENTIAL FOR INJURY. To reduce the risk of a potential injury, lock all casters before installing, adjusting, or removing the Ergometer.**
* **WARNING, POTENTIAL FOR INJURY. To reduce the risk of a potential injury, always use two (2) people to install or remove the Ergometer. It has a weight that exceeds that for which a single individual can safely lift.**

# Preventative Maintenance

* **WARNING, POTENTIAL FOR INJURY OR DEATH. Do not modify this equipment without authorization of the manufacturer.**

The following Preventative Maintenance should be performed at a minimum annually:

* Visually inspect all mechanical assemblies and moving parts on the product ensuring smooth, steady operation
* Visually inspect all fasteners (bolts, nuts, screws, etc.) to insure all are fully installed. Tighten as necessary.
* Visually inspect all electrical cables and wires for signs of abrasion or other damage. If damaged, replace.
* Visually inspect all electrical connections to insure they are fully and properly connected. Reconnect as necessary.

|  |  |
| --- | --- |
| weee_symbol | This device contains materials that are potentially hazardous to the environment. In accordance with the DIRECTIVE 2002/96/EC OF THE EUROPEAN PARLIAMENT AND OF THE CONCIL on waste electrical and electronic equipment (WEEE), the Ergometer’s electrical system and accessories should not be disposed as unsorted municipal waste. Consult your instructional policies and local regulations regarding disposal. Contact your Medical Positioning, Inc. Service Representative if additional disposal details are required. |

# Cleaning

* WARNING, POTENTIAL FOR INJURY. Always read manufactures instructions and warnings before using any cleaning product or disinfectant.

The plastic surfaces can be cleaned with normal cleaners and disinfectant.

* **CAUTION, PRODUCT DAMAGE MAY RESULT. Do not use abrasives to clean surfaces.**

The Ergometer and Ergometer Storage Cart can be cleaned as needed. The exposed surfaces of the computer and ergometer can be cleaned with normal cleaners and disinfectant. Do not spray cleaner or any liquid directly onto the ergometer or the computer controller.

| **STEP** | **ACTION** |
| --- | --- |
| 1 | Clean and/or disinfect the outer surfaces of the Ergometer, Ergometer Storage Cart, Ergometer Controller, and/or Patient Coach by applying cleaner or disinfectant to a clean cloth and wiping surfaces. Be sure to follow instructions provided with cleaner or disinfectant. |
| 2 | After cleaner and/or disinfectant has been applied, wipe surfaces clean with a damp cloth. |

# Troubleshooting Guide

A **“Troubleshooting Guide”** is included to instruct you in the event of a malfunction. If you are experiencing any of the following symptoms, this guide may help you quickly solve the problem. If, after consulting this guide, you are still unable to operate your product, please contact Medical Positioning at 1-800-593-3246. Please have the following information ready when you call:

1. Model Number or Name of Product
2. Date Received
3. Condition When Received
4. Symptom (or problem) Encountered & Result of Troubleshooting Procedure

**Complaint Reporting Procedure**

In the event of a product malfunction or patient injury, please immediately report the incident to:

Medical Positioning, Inc.

9732 Pflumm Road

Lenexa, KS 66215

[www.MedicalPositioning](http://www.MedicalPositioning).com

011-816-474-1555

800-593-3246 (ECHO)

| **SYMPTOM** | **PROBABLE CAUSE** | **SUGGESTION** |
| --- | --- | --- |
| Ergometer and Ergometer Controller Do Not Turn On | * Ergometer power cord is not completely plugged in at power strip | * Push ergometer power cord plug securely into power strip |
| * Power outlet receptacle not supplying 120 VAC power | * Check power availability or plug unit into another receptacle |
| Ergometer Controller Does Not Turn On | * Cable is loose or disconnected at Ergometer Controller | * Firmly push connector on to Ergometer Controller |
| Cannot Set or Program the Ergometer Controller | * Cable is loose or disconnected at Ergometer Controller | * Firmly push connector on to Ergometer Controller |
| * Ergometer power problem | * Refer to symptom “Ergometer and Ergometer Controller Do Not Turn On” |
| Patient Coach Does Not Turn On | * Cable is loose or disconnected at Ergometer Controller | * Firmly push connector on to Ergometer Controller |
| No Pedal Resistance | * Ergometer power problem | * Refer to symptom “Ergometer and Ergometer Controller Do Not Turn On” |

Troubleshooting Test: Ergometer/Ergometer Controller

An internal self-test is performed on the Ergometer Controller each time it is turned on. No further function testing is required for the Ergometer Controller. The ergometer function test consists of verifying that it is providing resistance to movement of the pedals.

**Tools Required:**  No tools are required to perform the ergometer function test.

| **STEP** | **ACTION** |
| --- | --- |
| 1 | Unplug the Ergometer from the wall outlet. Wait 5 seconds. |
| 2 | Before powering the unit again, press and hold the RPM-UP button. While you hold the RPM-UP button, have another person plug the unit into the wall outlet. |
| 3 | Release the RPM-UP button after the displays on the computer controller come on. |
| 5 | The automatic protocol stop will be disabled and remain disabled until the main power has been shut off. |
| 6 | Press the PROTOCOL-UP/DN control until the number 15 is displayed in the PROTOCOL NUMBER indicator. |
| 7 | Press the WATTS-UP/DN control until the number 25 is displayed in the RESISTANCE display. |
| 8 | While continuing to turn the pedals, press the WATTS-UP control until the number 40 is displayed in the RESISTANCE display. |
| 9 | Continue to rotate the ergometer pedals by hand and verify that there is more resistance to pedal movement than in step 7. |

# Warranty

Cath Ergometer

**2 YEAR WARRANTY**

**Warranty**

Medical Positioning, Inc. (“MPI”) warrants and represents that this product will be free from material and workmanship defects during the period indicated above (the “Warranty Period”), commencing with tender of delivery as defined in Uniform Commercial Code § 2-503, irrespective of any inspection period and provided that the product is maintained and operated in accordance with MPI’s specifications.

If the product fails due to a manufacturing defect, MPI will, at its sole expense and discretion, repair the product, authorize repairs to the product, or replace the product. MPI will ship any replacement products or parts using standard shipping rates; if the customer requires expedited shipping of replacement products or parts, the customer is responsible for paying shipping costs above standard rates.

Preventative maintenance and repairs due to damage by use, accident, improper care, negligence, or other non-defect related failures are not covered by this warranty. This warranty is void as to products that have been modified without the advance written permission of MPI.

OTHER THAN AS SET FORTH HEREIN, MPI MAKES NO WARRANTY WHATSOEVER, EITHER EXPRESSED OR IMPLIED, WITH RESPECT TO THIS PRODUCT. MPI SPECIFICALLY DISCLAIMS THE (a) IMPLIED WARRANTY OF MERCHANTABILITY; (b) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; AND (c) WARRANTY AGAINST INFRINGEMENT OF ANY PATENT, COPYRIGHT, TRADEMARK, TRADE SECRET OR OTHER PROPRIETARY RIGHTS OF A THIRD PARTY; WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.

This warranty is nontransferable. The remedies provided under this warranty are the customer’s sole and exclusive remedies. In no event will MPI be liable for any direct, indirect, special, incidental, consequential damages or lost profits or income whether based on contract, tort, or any other legal theory.

**Medical Positioning, Inc.**

9732 Pflumm Road

Lenexa, KS 66215

(816) 474-1555

(800) 593-3246

Fax (816) 474-7755

WAR069-B

# Return Policy

MPI accepts returns of unused products within 30 days from the date of delivery, irrespective of any inspection period. Returns are subject to a 30% restocking fee, any applicable duties or taxes and quality inspection. No product may be returned without prior written authorization from MPI. The customer is responsible for all shipping charges and any applicable duties or taxes incurred in connection with a return.

WAR093-A