

# W2 Family – Wrist CPM CE Marked 3<sup>rd</sup> Edition Instructions for Use



**QAL Medical<sup>®</sup>**  
**OrthoAgility<sup>®</sup>**

Customer Contact:  
**QAL Medical<sup>®</sup>, LLC**  
(A division of Quality Assembly and Logistics, LLC)  
3000 Woleske Road  
Marinette, Wisconsin 54143 USA  
Tel: 1-888-430-1625  
Email: [cpm-csr@qualityal.com](mailto:cpm-csr@qualityal.com)  
Website: [www.qalmedical.com](http://www.qalmedical.com)

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## **1 Intended Use**

### **1.1 Introduction**

The W2 Continuous Passive Motion (CPM) system is designed for the rehabilitation of the wrist.

The W2 Family of Wrist CPM devices has the following features:

- Full range of motion in flexion/extension, ulnar and radial deviation or a combination of the two
- Anatomical free-linkage movement with floating hand support that eliminates compression and distraction of radial carpal joint.
- Easy setup and alignment
- Two operating force settings
- No reassembly is required to change from flexion to deviation.
- Durable, compact and fully portable
- Lightweight and comfortable
- Reverse-on-load safety feature
- Rechargeable battery operation

### **1.2 Application**

A Continuous Passive Motion (CPM) device is best applied post-operatively per physician's prescription.

### **1.3 Clinical Advantages/Indications**

- Maintenance of range of motion
- Prevention of negative effects on immobilization

### **1.4 Use (Past and Present)**

Physicians have prescribed immediate post-operative CPM use for the following:

- General Wrist surgery
- Fracture rehabilitation
- Reconstructive surgery on bone, cartilage, tendons and ligaments
- Prolonged joint immobilization

### **1.5 Contraindications/Residual Risks**

Do not use the device if any of the following are present/known:

- Untreated or uncontrolled infection
- Unstable fractures
- Bleeding
- Nickel allergy/sensitivity
- Indoor use only
- Do not immerse in liquid

◆ **Note:** If signs of infection such as fever, redness, irritation, warmth, swelling, bleeding and/or increased pain are present, discontinue use of the CPM device and contact the patient's physician. Do not continue using the device until the physician has approved continuing use of the device.

## 1.6 Safety Features

Read manual before use and operating the device. We recommend that all clinicians and others responsible for the operation of this device become thoroughly familiar with its capabilities and proper operation procedures prior to actual patient use. Skill at measuring the patient and adjusting the device accordingly will come with experience and practice.

### Low Voltage

The power supply delivers less than 20 volts DC to the device. The W2 family of CPM medical devices will tolerate electrical supply variations that may be found in the home or hospital environments.

### Reverse-On-Load

The device is designed to automatically reverse direction if an obstruction occurs.

### Safety Considerations

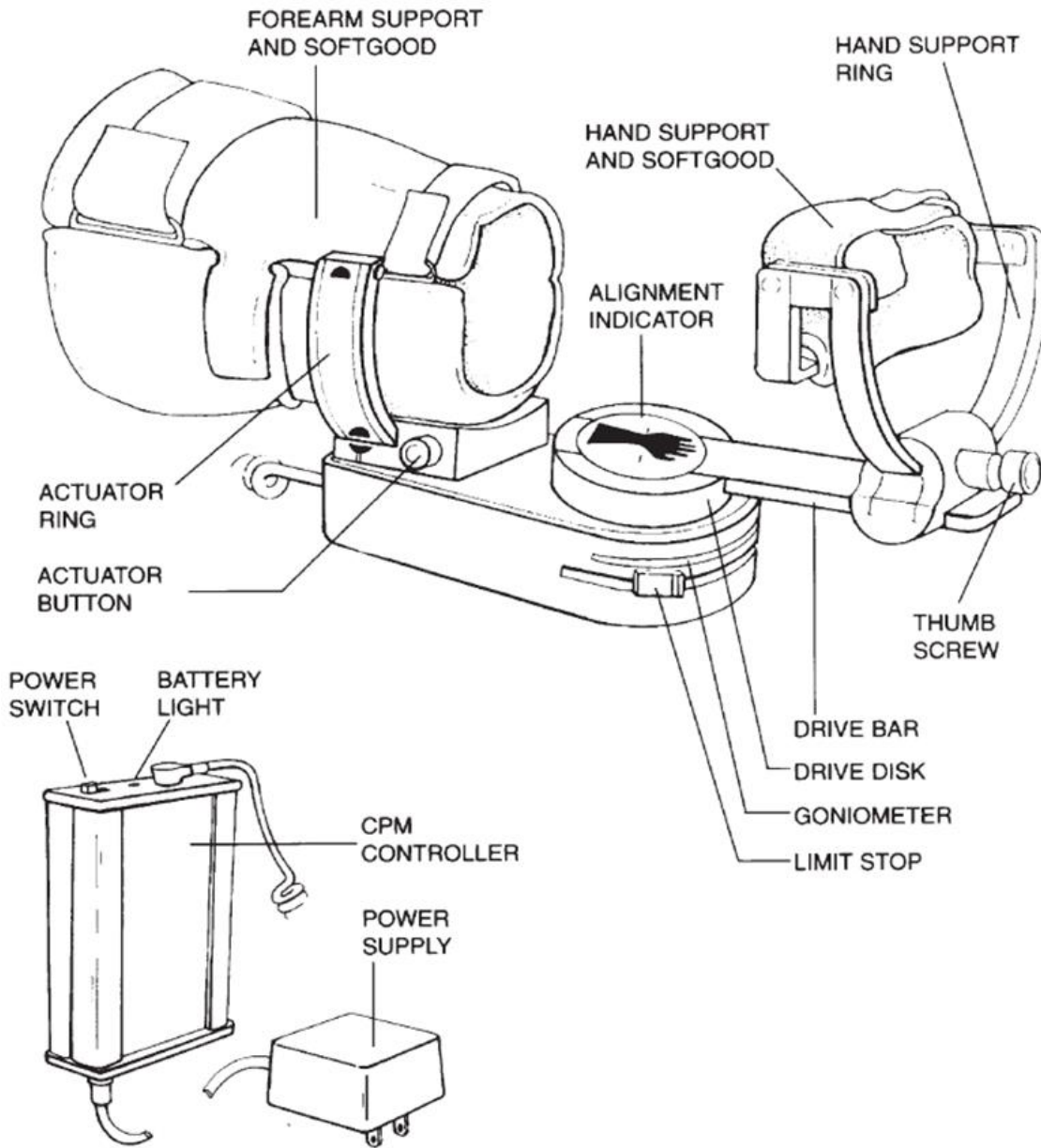
Please make the patient aware of the following considerations:

- Use the device only according to the physician's prescription and instructions for use. Failure to do so may result in damage to the device and/or personal injury.
- Soft goods are for single patient use only. (Not to be reused).
- The device should not be used near flammable materials like anesthetics.
- Use only manufacturer's supplied replacement parts.
- Do not use the device if there are mental or physical conditions that prohibit patient compliance.
- To prevent potential physical injury, such as strangulation and choking hazards, keep the device away from children or individuals with mental or physical conditions that prohibit the safe use of the device.
- Position the device in a comfortable position. Make sure the device is stable through its full range of motion.
- Keep hair and loose clothing, fingers and all parts of the body away from moving parts of the device.
- Do not expose the device to water or extreme temperatures.
- Do not use the device near exposed flames, while smoking or near excessive heat.
- Turn the device off when not in use.
- Do not use the device, power supply or controller if it appears damaged or if there are exposed wires.
- Store the device in its carrying case (if applicable) when not in use.
- Do not pour cleaning solution directly onto the device. This may allow fluids to enter the device and cause electrical problems or wash lubricants away from running components, reducing the life span of the device.
- Do not store device above 40°C (104°F). Only a Qualified Service Technician should service the medical device.
- Use specified power supply only.
- The device will produce minimal electromagnetic fields and has been tested to pass IEC 60601-1:2005 and collateral standard for EMC 60601-1-2:2007.

◆ **Caution:** As with all portable objects, please store the device in a location when not in use to avoid a potential tripping hazard.

◆ **Caution:** Ensure placement of the device allows plug to be disconnected from power source.

2 Components Overview



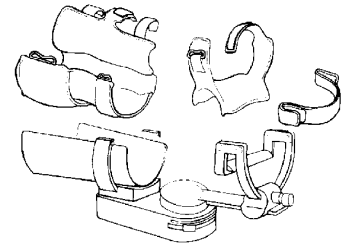
**3 Using the W2**

For assistance in set up, use or maintenance or to report unexpected operations, call QAL Medical®, LLC (contact info included in this document) or your distributor.

**3.1 Setting up the W2**

Install the forearm soft goods by first sliding the large pocket over the forearm support. Fit into place and slide the small pocket over the front end of the forearm support.

With buckle side down, wrap the hand and soft goods around the hand support.



**Optional Soft goods:**

- The MP Block is fixed to the hand support ring across the digits to maintain MP Flexion of the finger joints throughout the range of motion.
- The sling is used to support the device in portable applications.



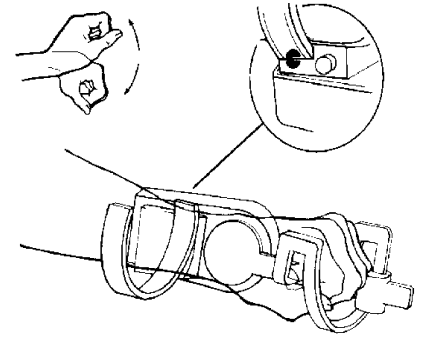
**3.2 Selecting the Plane of Motion  
Three Setup Options**

**3.2.1 Flexion/Extension**

To position the device for Flexion/Extension:

◆**Note: Place the Actuator on the ulnar (or thumb) side of the wrist to avoid possible thumb obstruction.**

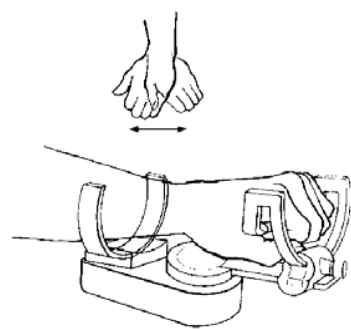
1. Loosen the thumbscrew and rotate the hand support ring to the top end. Tighten the thumbscrew.
2. Turn the Motion Controller on and allow the device to move into a 0° position on the goniometer.



**3.2.2 Ulnar/Radial Deviation**

To position the device for the Ulnar/Radial Deviation:

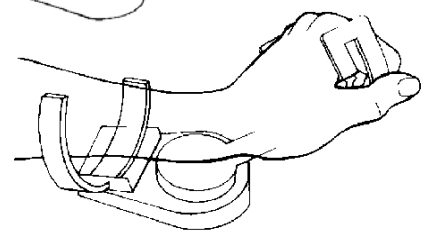
1. Press the Actuator Button to line the Actuator up with the deviation graphics located on the center of the Actuator Ring.
2. Loosen the thumbscrew and rotate the hand support ring to a horizontal position. Tighten the thumbscrew.
3. Turn the Motion Controller on and allow the device to move into a 0° position on the goniometer.



**3.2.3 Combined Axes Motion**

To position the device for combined axes motion:

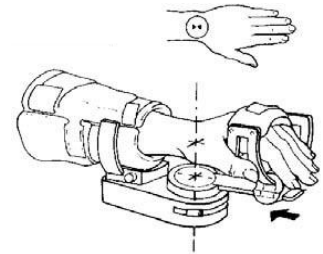
1. Press the Actuator Button to position the Actuator at any of the stop points along the Actuator Ring.
2. Loosen the thumbscrew and rotate the hand support ring to a horizontal position.
3. Tighten the thumbscrew.
4. Turn the Motion Controller on and allow the device to move into a 0° position on the goniometer



### 3.3 Device Application and Alignment

◆ **Note:** The Wrist Alignment indicator is located on the Drive Disk.

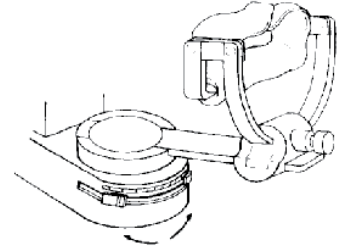
1. Open the hand and forearm soft goods.
2. Slide the Hand Support to the end of the drive bar.
3. Place the patient's forearm in the Forearm Support, and line the center of the wrist with the Alignment Indicator.
4. Slide the Hand support into the palm of the patient's hand.
5. Fasten the soft goods.



### 3.4 Setting Range of Motion

To set the range of motion in any of the three Plan of Motion options:

1. Press and rotate the limit stops to the prescribed range of motion on the goniometer.



### 3.5 Initiate Treatment

The Motion Controller is equipped with two Operating Force Settings as indicated by the large and small graphics next to the Power Switch. The small graphic indicates low force setting; large graphic indicates high force setting.

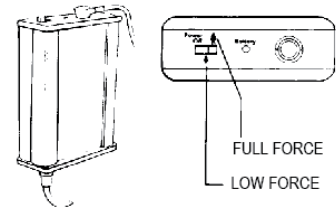
### 3.6 Range of Motion Options

#### Dynamic Traction Mode:

To use the W2 in a dynamic traction mode:

1. Place the Limit Stops just outside the patient's range.
2. Select the LOW force setting on the Motion Controller.

◆ **CAUTION:** This feature should only be used as prescribed by the physician or therapist.



### 3.7 Power Options

#### 3.7.1 To Turn on the Device

1. Slide the power button one click to the right.
2. The force setting is LOW in this position.
3. Sliding the power button one more click to the right, puts the device in the FULL force setting.

#### 3.7.2 To Turn the Device Off

1. Slide the power button all the way to the left.

## W2 Family Instructions for Use

### 4 Technical Data

#### 4.1 Specifications and Operating Limits W2 Family of Wrist CPMs


















































Dimensions of Device	31.0 x 11.0 x 14.0 cm	(12.0" x 4.5" X 5.5")
Dimensions of Digital Motion Controller	9.6 x 18.0 x 3.7 cm	(3.75" x 7.0" x1.5")
Unit Weight, including soft goods	Approx. 1.0 kg	(2.2 lbs.)
Range of Motion (ROM): Flexion Extension Full Ulnar and Radial Deviation	0° to 90° 0° to 90° Up to 90°	
Rate of Motion	180° per minute	
Force Settings Low High	2.8 Nm (25 in-lbs.) 4.0 Nm (35-in lbs.)	
Power Supply:	External, Medical Grade	
Input:	100-240 VAC 50-60 Hz 1.5A	
Output:	12 VDC 5A	
Battery	Part No. EABBF 7.2V, 2.8 AH	
Battery Life	Up to 100 hours	
Device Classification	Class II	
Degree of Shock Protection	Type BF	
Degree of accuracy	+/- 5 degrees	
Environmental, Storage and Transport Conditions	-10 to 35°C (14 to 95°F) temperature, 90% maximum humidity 15% minimum humidity ATM pressure 750 to 1250 hPa	
IP rating*	IP22 for both Device and Controller	

**\*IP Rating is a rating code that identifies the amount of protection a given product has against dust and fluid.**

**◆ Note: The device must remain in the operational environment a minimum of one hour prior to use.**



4.2 Symbols

 <p>Conforms to ANSI/AAMI STD ES60601-1, IEC STD 60601-1-6, IEC STD 62366, IEC STD 60601-1-11 Certified to CAN/CSA STD C22.2 No. 60601-1</p>	<p><b>CE</b> <b>0120</b></p> <p>Indicates compliance to safety and quality standards throughout all member states in the EC</p>																		
<table border="0"> <tr> <td> <b>Power Off</b></td> <td> <b>Deviation</b></td> <td> <b>Type BF Part</b></td> </tr> <tr> <td> <b>Power On</b></td> <td> <b>Attention: Consult Accompanying Documents</b></td> <td> <b>Class II Equipment</b></td> </tr> <tr> <td> <b>High Load Setting</b></td> <td> <b>Contact distributor or the manufacturer listed for disposal of device and components</b></td> <td> <b>Use specified power supply only</b></td> </tr> <tr> <td> <b>Low Load Setting</b></td> <td> <b>Caution: FDA Policy. Federal U.S. Law restricts this device to sale by or on the order of a licensed healthcare practitioner.</b></td> <td> <b>This Way Up</b></td> </tr> <tr> <td> <b>Right Hand Flexion</b></td> <td></td> <td> <b>Fragile</b></td> </tr> <tr> <td> <b>Left Hand Flexion</b></td> <td></td> <td> <b>Keep Dry</b></td> </tr> </table>		 <b>Power Off</b>	 <b>Deviation</b>	 <b>Type BF Part</b>	 <b>Power On</b>	 <b>Attention: Consult Accompanying Documents</b>	 <b>Class II Equipment</b>	 <b>High Load Setting</b>	 <b>Contact distributor or the manufacturer listed for disposal of device and components</b>	 <b>Use specified power supply only</b>	 <b>Low Load Setting</b>	 <b>Caution: FDA Policy. Federal U.S. Law restricts this device to sale by or on the order of a licensed healthcare practitioner.</b>	 <b>This Way Up</b>	 <b>Right Hand Flexion</b>		 <b>Fragile</b>	 <b>Left Hand Flexion</b>		 <b>Keep Dry</b>
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CONSULT INSTRUCTIONS FOR USE MANUAL



CONSULT TECHNICAL MANUAL BEFORE SERVICING

**5 Maintenance**

- Information needed for service personnel can be found in the Technical and Service Manual, Final Inspection and Product Test criteria available through QAL Medical®, LLC Customer Service or your local distributor.
- **Expected Service Life:** The device's expected service life is 2 years, which is limited to the life of the motor. With proper maintenance, the device can last longer.

**Maintenance Between Patients**

***Immediately following each patient use:***

The CPM Patient Kit should be removed and discarded and the unit cleaned. CPM devices are constructed with components made from aluminum (silver), stainless steel (silver), polycarbonate plastic (blue), modified polyphenylene oxide plastic (light blue, trade name Noryl), acetyl plastic (white), polypropylene plastic (translucent white), polyethylene plastic (translucent white), nylon web straps (black). These materials offer excellent resistant to common cleaning materials such as soaps and mild cleaning agents when used as recommended.

- Use a cloth and a mild soap solution to remove dirt and deposits.
- Wipe soap deposits from the equipment using a clean damp cloth
- For stubborn areas, use a household spray cleaner applied to a soft cloth. After cleaning, wipe off residue immediately with a water-dampened cloth.
- Do not pour cleaning solutions directly onto the machine. This may allow fluids to enter the machine and cause electrical problems, or wash lubricants away from the running components reducing the life span of the device.
- Never immerse the device in fluids.
- Soft goods for the device are for single patient use only and cannot be washed for reuse.
- Check the entire device for any visible evidence of damage such as bent components, cracked or broken covers, frayed or damaged wires, etc. If any signs of damage are found, the device must be repaired before use.
- Make sure that all knobs and/or levers are usable and in place.
- Make sure that all moving components move freely as required.
- Check all displays and electronic controls for proper operation.
- Check all mechanical pivot and linkage points for smooth operation and secure mechanical connection. Make sure all screws, nuts, bolts, rivets, pivot pins and other fasteners are secure.
- Gently wipe clean all exposed surfaces with a soft cloth dampened with a mild soap solution or alcohol. Do not use abrasive cleansers. To disinfect, wipe all exposed surfaces with a 10% solution of bleach and water, or other suitable disinfectants.
- Make sure that all labels are present.
- Replace the patient soft goods kit.
- Verify that the device operates to its set limits over several complete cycles.
- For Range of Motion (ROM) settings verify device calibration by observing the ROM of the device while taking a visual reading using a goniometer at the device's anatomic pivot points. Compare the ROM settings of the device with the goniometer readings. ROM readings should be within +/- 5° of the set parameters. If the readings do not fall within the set parameters, the device needs to be checked and recalibrated by a properly trained Service Technician using the Final Inspection and Product Test criteria available through QAL Medical®, LLC Customer Service or your local distributor.

**Maintenance Every Six Months**

Repeat steps under "Maintenance Between Patients."

**Maintenance Every Twelve Months**

Repeat steps under "Maintenance Between Patients."

## W2 Family Instructions for Use

### Maintenance Every Eighteen Months

- A full inspection of the device by a properly trained Service Technician is recommended every 18 months.
- Repeat steps “Maintenance every Twelve Months”.
- Fully inspect all internal and external mechanical drive components, and repair or replace as necessary.
- Perform a complete recalibration and subsequent check of electronic and mechanical safety systems including Reverse-on-Load function and Range of Motion controls.
- Complete a final check of the device in accordance with QAL Medical®, LLC Final Inspection and Product Test criteria. (These are available through QAL Medical®, LLC’s Customer Service or your local distributor.)

### Sterilization

- This device does not require sterilization for use.
- Exposing the device to sterilization conditions will damage the device and may result in a potential hazard.

## 6 Troubleshooting

The following tables provide some common problems that may be encountered with the W2 family of CPM devices, with probable causes and solutions.

Refer to the Service and Technical Manual for troubleshooting/repair. If unable to repair or if a problem continues, contact QAL Medical Customer Service.

### 6.1 CPM Controller

Problem	Probable Cause	Solution
Controller warm when charging.	Overcharging battery	Allow more operating time before recharging.  Reduce charging time.
Very short run time after charging for 8 hours.		Replace battery.  Refer to Technical and Service Manual for troubleshooting/repair. If unable to repair or if problem continues contact QAL Medical Customer Service.

W2 Family Instructions for Use

**6.2 Actuator**

<b>Problem</b>	<b>Probable Cause</b>	<b>Solution</b>
Sticky pushbuttons	Improper shimming at stop ring.	Add or remove shims at stop ring.  Refer to Technical and Service Manual for troubleshooting/repair. If unable to repair or if problem continues contact QAL Medical customer service.
Intermittent operation	Broken wires in cable.	Replace cable.  Refer to Technical and Service Manual for troubleshooting/repair. If unable to repair or if problem continues contact QAL Medical customer service.
Noisy operation – knocking sound	Worn bearings in motor mount assembly.	Replace motor mount assembly.  Refer to Technical and Service Manual for troubleshooting/repair. If unable to repair or if problem continues contact QAL Medical customer service.
Does not reverse at Stop.	Drive belt slipping.	Replace drive belt.  Refer to Technical and Service Manual for troubleshooting/repair. If unable to repair or if problem continues contact QAL Medical customer service.
Pushbutton travel too small to adjust stop position.	Pushbutton installed improperly.	Loosen screws and adjust pushbuttons.  Refer to Technical and Service Manual for troubleshooting/repair. If unable to repair or if problem continues contact QAL Medical customer service.

**7 Ordering and Accessories Information**

W2-3100U or W2-3100G	W2 Wrist CPM device, complete with soft goods, carrying case and rechargeable battery pack.
W2-101	Patient Kit Complete (Disposable)

## **8 Warranty**

### **New Product Warranty**

QAL Medical®, LLC a Division of Quality Assembly & Logistics, LLC warrants the product to be free from defects in materials and workmanship for a period of two (2) years for all critical components (motor, power supply and circuit boards) and for a period of ninety (90) days for all other components, such as housing parts, knobs, hardware and sub-assemblies (excluding disposables). The warranty takes effect from the date of the original purchase from QAL Medical®, LLC or its Authorized Distributor or the original activation date into the QAL Medical®, LLC rental pool, and provided the product is new and unused. No warranty will be recognized or honored unless all applicable service records can be supplied with the service request.

No warranty shall apply if the product has been lost, or damaged by accident, abuse, misuse, or misapplication, or as a result of service or modification by someone other than a person authorized by QAL Medical®, LLC. This warranty shall only apply to the original buyer of the product and is nontransferable. QAL Medical®, LLC liability under this warranty, and the original buyer's exclusive remedy is limited to the cost of the materials and labor to repair the defective products, or to its replacement, and in no event, shall exceed the purchase price.

To obtain warranty service the product must be returned freight prepaid to QAL Medical®, LLC or the selling distributor with a clear indication as to the defect. Upon receipt of a product returned under warranty, QAL Medical®, LLC will inspect the product and will notify the buyer of the extent of repair or replacement that QAL Medical®, LLC will perform under warranty. If the product is received incomplete, missing parts will automatically be replaced at the buyer's expense. QAL Medical®, LLC also reserves the right, at its own cost, to upgrade or replace parts or sub-assemblies to the latest production standards. QAL Medical®, LLC will normally perform the repair and return the product, or provide a replacement, within thirty (30) days from the day of receipt, freight collect.

QAL MEDICAL®, LLC IS NOT RESPONSIBLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE BREACH OF ANY EXPRESSED OR IMPLIED WARRANTY, INCLUDING DAMAGE FOR PERSONAL INJURY. THE WARRANTY CONTAINED HEREIN IS IN LIEU OF ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE. NO STATEMENT OF ANY REPRESENTATIVE SHALL EXTEND QAL MEDICAL®, LLC'S LIABILITY AS HEREIN ESTABLISHED OR LIMITED.

## W2 Family Instructions for Use

### **Returning the Device for Service**

Should the device require warranty repair, buyer must contact either the Customer Service Department or the Authorized Distributor from which the device was purchased for return instructions.

If any warranted product is found by QAL Medical®, LLC to have a defect covered by this warranty, QAL Medical®, LLC shall, at its option, either repair the defective item or install a replacement.

If the device needs to be returned for any repair, pack the components in the original shipping container and contact:

Customer Service  
QAL Medical®, LLC  
Attn: Customer Service  
3000 Woleske Road  
Marinette, Wisconsin 54143 USA  
Tel: 1-888-430-1625  
Fax: 1-715-735-6402  
Email: [cpm-csr@qualityal.com](mailto:cpm-csr@qualityal.com)  
Website: [www.qalmedical.com](http://www.qalmedical.com)

◆ **Note:** Please enclose the following information when returning the Device

- Return Authorization Number
- Ship-to Address
- Purchase order for non-warranty repair
- Name and phone number of a person to contact
- Brief description of the problem

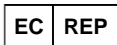
### **Disposal of Device**

For proper disposal of the device, contact your distributor or QAL Medical®, LLC.



**QAL Medical®, LLC**

3000 Woleske Road, Marinette, Wisconsin 54143  
Tel: 1-888-430-1625 Fax 1-715-732-6402



**Emergo Europe**

Prinsessegracht 20,  
2514 AP The Hague  
The Netherlands  
[www.emergogroup.com](http://www.emergogroup.com)



QAL Medical®, LLC is registered to ISO 13485 for Quality Assurance