SAVE THESE INSTRUCTIONS

Federal (USA) law restricts this device to sale by or on the order of a physician.

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ISO 13485 Certified

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RECEIVING / INSPECTION
Remove the Precision Medical, Inc. Vacuum Regulator from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE
The devices are intended to control and show the amount of vacuum from a central vacuum system used in various medical suctioning procedures.

READ ALL INSTRUCTIONS BEFORE USING
This manual instructs a Professional to install and operate the Vacuum Regulator. This is provided for your safety and to prevent damage to the Vacuum Regulator. If you do not understand this manual, DO NOT USE the Vacuum Regulator and contact your Provider.

EXPLANATION OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>l/min</td>
<td>Liters Per Minute</td>
</tr>
<tr>
<td>mmHg</td>
<td>Millimeters of Mercury</td>
</tr>
<tr>
<td>inHg</td>
<td>Inches of Mercury</td>
</tr>
<tr>
<td>kPa</td>
<td>Kilopascal</td>
</tr>
</tbody>
</table>

SAFETY INFORMATION - WARNINGS AND CAUTIONS

**WARNING** Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

**CAUTION** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

**CAUTION** Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards.
(On CE marked Devices ONLY)

There are no components in this product made with natural rubber latex.

**WARNING**

- **DO NOT** use this Vacuum Regulator for anything other than its Intended Use. Personal injury and/or damage to Regulator may result from misuse.
- Only personnel instructed and trained in its use should operate this Vacuum Regulator.
SPECIFICATIONS

GAUGE RANGE:

- PM3300: 0 - 200 mmHg - Full Vacuum
- *PM3300E: 0 - 200 mmHg (0 - 26 kPa)
- *PM3300EHV: 0 - 300 mmHg (0 - 40 kPa)
- PM3300HV: 0 - 300 mmHg - Max Vacuum
- PM3400: 0 - 150 mmHg
- *PM3400E: 0 - 150 mmHg (0 - 20 kPa)

*Counterclockwise direction

GAUGE ACCURACY:

- Analog: ± 5% of MAX
- Digital/Analog, Dual Gauge:
  - Digital Display: ± 1% of Full Scale
  - Analog Gauge: ± 5% of MAX within ref. Indicator

VACUUM PORTS:

1/8 NPT Female

MODES:

- REG. - (Regulated) provides an adjustable, continuous vacuum level
- OFF - No Vacuum
- INT. - (Intermittent) provides an adjustable vacuum level that cycles between ON and OFF

FLOW:

<table>
<thead>
<tr>
<th>Models</th>
<th>Mode</th>
<th>Max Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM3300:</td>
<td>REG</td>
<td>51 l/min</td>
</tr>
<tr>
<td>PM3400:</td>
<td></td>
<td>50 l/min</td>
</tr>
</tbody>
</table>

MAXIMUM FLOW IS OBTAINED WITH A VACUUM SOURCE OF 21" Hg (71.1 kPa)

MAXIMUM VACUUM:

- PM3300: REG. Mode @ Full Vac-396 mmHg (53 kPa)
- PM3300HV: REG. Mode @ Max Vac-396 mmHg (53 kPa)
- PM3400: Restricted to 170 mmHg ± 10 mmHg (1.3 kPa)

INTERMITTENT CYCLE TIME:

Factory set at sixteen (16) seconds ON and eight (8) seconds OFF (Reference only)

Operating Environmental Limits: 0°F to 122°F (-18°C to 50°C)
Recommended Environmental Operating Limits: 55°F to 85°F (13°C to 29°C)
Storage Environmental Limits:
  - Temperature Range: -4°F to 140°F (-20°C to 60°C)
  - Humidity: Max 95% Noncondensing

Battery: 3 Volt Lithium, ½ AA (Digital Vacuum Gauge Models ONLY)

Specifications are subject to change without prior notice.
OPERATING INSTRUCTIONS

CAUTION
Inspect the Vacuum Regulator for visual damage before use, DO NOT USE if damaged.

NOTE: • Overflow protection should be used with the Vacuum Regulator. (i.e. Filter, Vac Trap, Canister equipped with float shutoff).
• Gauges operate independently; if the digital gauge fails, the analog gauge will still function.

1. Turn the Selector Knob to the “OFF” position.
2. Attach the Vacuum Regulator to the vacuum source.
   A. REG MODE (Regulated Mode) ALL MODELS
      1. Turn the Selector Knob to the “REG.” position.
      2. Block the bottom port of the Regulator.
      3. Using the Regulator Knob, set the desired vacuum.
         To INCREASE vacuum - Turn Knob CLOCKWISE
         To DECREASE vacuum - Turn Knob COUNTERCLOCKWISE
   B. INT. MODE (Vacuum cycles ON and OFF.)
      1. Turn the Selector Knob to the “REG.” position, to select desired vacuum level.
      2. Turn the Selector Knob to the “INT.” position.
         NOTE: Intermittent cycles starts in the OFF phase, therefore a delay occurs before the intermittent cycle begins.
      3. Turn the Selector Knob to the “OFF” position to turn the Regulator off.

WARNING
• ALWAYS confirm vacuum setting prior to performing procedure.
• When turning the Vacuum Regulator to “REG.” or “INT.” from any position, the vacuum level will return to its previously regulated setting.
• Full Line Vacuum is present between settings.
• Vacuum levels will remain the same when switching from one mode to the other.

CAUTION
DO NOT operate the Vacuum Regulator when the collection canister is “full”. This may cause loss of vacuum and damage to the Vacuum Regulator. This will void the warranty.
### CAUTION

Missing or illegible labels must be replaced, contact Precision Medical, Inc.

### PARTS LIST

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>PM3300</th>
<th>PM3400</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Housing Assembly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Screw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Analog Gauge Assembly</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Analog Gauge Assembly (Export E)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Analog Gauge Assembly (HV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Digital Assembly</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Digital Assembly (HV)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Digital Assembly (Export E)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Digital Assembly Export E (HV)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>502102</td>
<td>503694</td>
<td>503826</td>
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<td>503923</td>
<td>503923</td>
<td>504225</td>
</tr>
<tr>
<td></td>
<td>504309</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>505244 (0-200 mmHg)</td>
<td>505391 (0-150 mmHg)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>505392 (0-300 mmHg)</td>
<td>505392 (0-300 mmHg)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>506036</td>
<td>506038</td>
<td>506034</td>
</tr>
<tr>
<td></td>
<td>506038</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Snubber</td>
<td></td>
<td>1396</td>
</tr>
<tr>
<td>5</td>
<td>O-ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Selector Assembly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Index Ring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Wave Spring Washer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Case Assembly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Regulator Module Assembly</td>
<td>1567 (*505962)</td>
<td>1567</td>
</tr>
<tr>
<td>11</td>
<td>Set Screw</td>
<td></td>
<td>1391</td>
</tr>
<tr>
<td>12</td>
<td>Control Knob Assembly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Timing Module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Rear Case</td>
<td></td>
<td>1831</td>
</tr>
</tbody>
</table>

*HV MODELS ONLY (PM3300HV)
REPAIR KITS

<table>
<thead>
<tr>
<th>Analog Part#</th>
<th>Digital Part#</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM3300 / PM3300D Vac Reg</td>
<td>RK6300</td>
</tr>
<tr>
<td>PM3300HV / PM3300DHV Vac Reg</td>
<td>RK6300HV</td>
</tr>
<tr>
<td>PM3300E / PM3300DE Vac Reg</td>
<td>RK6300E</td>
</tr>
<tr>
<td>PM3300EHV / PM3300DEHV Vac Reg</td>
<td>RK6300EHV</td>
</tr>
<tr>
<td>PM3400 / PM3400D Vac Reg</td>
<td>RK6400</td>
</tr>
<tr>
<td>PM3400E / PM3400DE Vac Reg</td>
<td>RK6400E</td>
</tr>
</tbody>
</table>

DISASSEMBLY INSTRUCTIONS
(Reference “PARTS DESCRIPTION”)
1. Loosen the Set Screw (Item # 11) in Selector Knob.
2. Pull the Control Knob Assembly (Item # 12) away from case. (The Regulator Module (Item # 10) is threaded onto the Control Knob Assembly.)
3. Remove the screws (Item # 2) from the back of the product.
4. Remove the Rear Case (Item # 14) by pulling away from product.
5. Remove screws (Item# 2) from the top of the Timing Module.
6. Remove the Timing Module (Item# 13) by pulling away from the Housing Assembly (Item# 1).
7. Separate the Case Assembly (Item# 9) by pulling it away from the Housing Assembly (Item# 1).
8. Remove the Selector Assembly (Item# 6) by pulling it away from the Housing Assembly (Item# 1).
9. Remove the Gauge Assembly (Item# 3).

ASSEMBLY INSTRUCTIONS
1. To assemble, perform the “DISASSEMBLY INSTRUCTIONS” in reverse order.
   **NOTE:**
   • Ensure the Selector Assembly is inserted with the groove in the 12 o’clock position.
   • Ensure tabs and slots on various components are properly aligned and engaged when reassembling.
2. Lubricate all O-rings and cavities with Vacuum grease (part# 1775) supplied in the Vacuum Regulator Repair Kit.
3. Repeat steps 1 through 3 of “OPERATING INSTRUCTIONS”.
4. Prior to returning Vacuum Regulator to service verify accuracy of gauge.
CAUTION

• **DO NOT** autoclave or immerse in liquid. This will cause damage to the Vacuum Regulator and will **void the warranty**.

• **DO NOT** set the Vacuum Regulator to the “INT” (Intermittent) mode when cleaning. Pulling cleaning fluids thru the Intermittent mode will damage the timing module and void the warranty.

• If Vacuum Regulator becomes internally contaminated, warranty is voided, **DO NOT** send back to Precision Medical, Inc. for repair. Follow your facilities contaminated equipment protocol.

• This Vacuum Regulator contains magnetic, ferrous material that may affect the results of an MRI.

• Be sure all connections are tight and leak free.
CLEANING / DECONTAMINATION  (As needed)

1. Attach a working Vacuum Regulator with a continuous regulated mode to a minimum vacuum source of 15 inHg.
2. Mix cold disinfection / sterilization solution according to its manufacturer’s directions.
3. Connect tubing as shown in Cleaning Illustration on previous page.
4. Turn the working Vacuum Regulator on to a continuous regulated mode.
5. Adjust the vacuum to a minimum of 120 mmHg.
6. Set the Vacuum Regulator to be cleaned to the “REG .” mode, and set at 100 mmHg.
7. Allow cold disinfection / sterilization solution to pass through and collect in Suction Canister. Procedure should continue for time recommended by the manufacturer of the cold disinfection / sterilization solution for the desired level of disinfection or sterilization.
8. Set working Vacuum Regulator to its maximum vacuum setting.
9. Thoroughly dry the internal components by drawing maximum vacuum through the Regulator to be cleaned for at least 30 seconds in “REG.” mode.

NOTE: If it is not possible to pass cold disinfection / sterilization solution through the Regulator, then the passageways are totally blocked and disassembly of the Regulator is required. Be sure to follow your facilities’ Biohazard protocol.

MAINTENANCE
Before each use; visually inspect Vacuum Regulator for any sign of damage, DO NOT USE if damaged.

RETURNS
Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

Manuals available on our Website; www.precisionmedical.com
DISPOSAL INSTRUCTIONS
Dispose of the Vacuum Regulator in accordance with the local regulations.

Please Recycle

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product should be cleaned before being disposed of. Potential for Biohazard.</td>
</tr>
</tbody>
</table>

TROUBLESHOOTING
If the Vacuum Regulator fails to function, consult the Troubleshooting Table below. If problem cannot be solved, consult your Provider.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Probable Cause</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| No vacuum at bottom port (gauge at zero) | 1. Regulator turned “OFF”  
2. Loose connection  
3. No vacuum to Regulator  
4. Clogged vacuum Port | 1. a. Turn selector knob  
1. b. Adjust Regulator knob  
2. Tighten connection  
3. Connect to a known working vacuum source  
4. Disassemble & clean |
| No vacuum at bottom port (gauge showing vacuum) | Clogged Regulator | Disassemble & clean |
| Vacuum at bottom port (No reading on gauge when port is blocked) | Defective Gauge | Replace Gauge |
| Gauge will not return to zero | 1. Clogged Snubber  
2. Damaged Regulator Module  
3. Defective Gauge | 1. Replace Snubber  
2. Replace Regulator Module  
3. Replace Gauge |
| Vacuum Regulator erratic | 1. Dirty Regulator Module  
2. Defective Regulator Module | 1. Disassemble & clean, Lubricate O-ring  
2. Replace Module |
| Stiff movement of Selector Knob | 1. Dirty Regulator Module and/or Selector Module | 1. Disassemble & clean, Lubricate O-rings |
| No Intermittent (INT.) cycle | 1. Improper mode selected  
2. Defective Timing Module | 1. Turn Selector Knob to “INT.” mode  
2. Replace Timing Module |
| No digital display | Dead Battery | Replace Battery |
LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Medical Vacuum Regulator (the Product) will be free of defects in workmanship and/or material for the following period:

Ten (10) years from date of shipment.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representative of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.
DECLARATION OF CONFORMITY

Precision Medical, Inc
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Northampton PA 18067
Emergo Europe (European Office)
Motenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31 (0) 70.345.8570
Fax: +31 (0) 70.346.7299

Vacuum Regulators:
PM3300E, PM3300E-P, PM3300EHV, PM3300DE,
PM3300DE-G, PM3300DE-MG, PM3300DE-Y,
PM3300DEHV, PM3300DEHV-MG, PM3400E, PM3400DE

Classification: IIa
Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards: BS EN 1041, EN ISO 10079-3, EN ISO 14971, ISO 15223-1

Notified Body: AMTAC Certification Services Limited CE 0473
Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK

Certification Registration No's: 1126 CE
Date of Expiry: 03 August 2017

Devices already manufactured: S/N traceability Device History Records
Validity of DOC: 04 August 2012 to Date of Expiry

Manufacture Representative: Quality Manager
Position: Quality Systems/ISO Representative
Date of Issue: 04 August 2012

Tell us how we are doing!
Visit us at www.precisionmedical.com