ANAPOD™ Instructions For Use

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**Warranty:**
All Westmed products are warranted to be free of defects in material and workmanship for a period of ninety (90) days from date of purchase.

**Disposal:**
- The controller is considered waste electrical and electronic equipment per WEEE directive 2002/96/EC and should be recycled as such. For recycling purposes, the controller is RoHS compliant.
- All disposable products should be treated as bio-hazardous waste.
- Controller should be treated per the WEEE directive, 2002/96/EC

**Servicing:**
Beyond the replacement of the back panel fuse or the controller cable, there are no user serviceable parts associated with the ANAPOD™ Humidification System. Disconnect AC plug from the AC power connection before replacing the fuse or performing any service related functions.

Replacing the main fuse (Refer to Figure A): To replace the main fuse (250VAC, 1A, time delay), locate the AC inlet and remove the power cord. The center section of the AC inlet houses the fuse holder and is opened by using a small standard screwdriver to gently pry the center section loose. Once the fuse holder has been dislodged, the fuse holder easily slides out and the fuse may be replaced. There is a section at the top of the fuse holder that stores a back-up fuse. After replacing the failed fuse with the same rated fuse, insert the fuse holder back into the AC inlet housing and plug in the AC power cord. Your ANAPOD Humidification System is now ready to use.

**NOTE:** Only trained Westmed service representatives can diagnose and/or repair your ANAPOD Humidification System. If your system needs either, contact your Westmed customer service representative to obtain a return material authorization.

**Cleaning:**
Periodically the ANAPOD Humidification System controller may be wiped off using a damp cloth with mild detergent.

**Preventive Maintenance:**
The ANAPOD Humidification System should be inspected by an authorized Westmed Inc. repair specialist five years from the date of manufacturing. Prior to this, the device is intended to provide safe and reliable operation provided it is operated and maintained in accordance with the instructions provided by Westmed Inc. As with all electrical devices, if any irregularity becomes apparent, take caution and have the device inspected by a Westmed Inc. repair specialist.

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**Description:**
The ANAPOD Humidification System and associated breathing circuit is a wick-type anesthesia gas heated humidifier system intended for use in an operating room setting. The system is designed to heat and humidify dry medical gas of up to 100% oxygen.

**Overview:**
The ANAPOD Humidification System consists of the ANAPOD Controller, Heated Wick Circuit, Power Cable, Controller Cable.

1. **Controller:** (Figure A) The ANAPOD Controller is the electronic unit that controls the heated wick circuit and monitors the temperature of the system.

**Indications:**
- The ANAPOD Humidification System is used to heat and humidify dry gas as recommended by a physician.
- The ANAPOD Humidification System is intended for use with patients whose upper airways have been bypassed, as well as patients whose upper airways have not been bypassed.

**Contraindications:**
- Do not use at a flow rate greater than 20 LPM.
- Use only with ANAPOD breathing circuits supplied by Westmed, Inc.

**Cautions!**
1. Read all instructions prior to use.
2. Do not operate the Controller if damaged.
3. Do not use in the presence of flammable anesthetic agents or flammable supplemental gases.

**General Warnings!**
A warning alerts you to possible injury. Specific Warnings and cautions appear next to the relevant instructions in the manual.
- Unplug the AC power cable from the ANAPOD Humidification System prior to cleaning. Do not immerse Controller in water or other liquid as this may cause damage.
- Use the ANAPOD Humidification System for its intended use ONLY as described in this manual.
- The ANAPOD Humidification System controller and Heated Wick Circuit should only be used with delivery tubes or accessories recommended by Westmed Inc. Utilization of other delivery tubes or accessories could result in patient injury or damage to the device.
- Do not attempt to dismantle the ANAPOD Humidification System controller. Repairs and internal servicing should only be performed by an authorized Westmed service representative.
- Do not operate the ANAPOD Humidification System if it is not working properly or if any part of the device has been damaged.
- Keep the cable assembly away from hot surfaces.
- Do not pull or allow the ANAPOD Humidification System to hang freely from the cable assembly.
- Explosion hazard – Do not use in the vicinity of flammable anesthetics or flammable supplemental gases.
- Follow all precautions when using supplemental oxygen.
Starting and Stopping Treatment:

1. Ensure the ANAPOD Humidification System is set up correctly per the individual circuit product instructions for use. Specific instructions for use of the breathing circuits are provided in their individual packaging.

2. To add water, (Refer to Figure B) remove screw cap from water bottle included with the ANAPOD circuit; hold the end of the tube at a 45° angle. Slowly pour approximately 75% of the volume into the opening of the inspiratory limb that connects to the anesthesia machine. Lower the patient end of the tube to saturate the wick of the patient end first. Then lower the machine end of the tube to complete the absorption of the water into the wick material. Gently shake the circuit to distribute the water evenly onto the entire length of the wick. There should be no pooling of water within the circuit. The water that was initially introduced into the circuit should be sufficient to provide up to 6 hours of operation in a 48” circuit, and up to 4 hours in a 72” circuit. If the case runs longer, or condensation is no longer visible within the inspiratory tubing, add more water. Add approximately 12 cc of water for each additional hour of humidity. Do not overfill. If you accidentally overfill the circuit, simply drain excess water out at the end of the tube. The ANAPOD cable assembly connects to the front of the controller. The other end of the cable assembly has a white 6-pin plastic connector that connects to the 6-pin plastic connector on the heated wick circuit. These two connectors lock together with a “snap” when properly connected and are “keyed” to prevent improper connection.

3. The heated wick circuit will remain at a constant temperature regardless of flow. As the water in the wick circuit is depleted, the condensation will slowly dissipate, beginning at the machine end of the circuit. When only the last 8 – 10 inches of the breathing circuit shows condensation, additional water should be added. This condensation is a gauge/indication of the need to add water to maintain humidification.

4. Turn the On/Off control of the ANAPOD Humidification System to “ON”.

5. Set the Temperature Control to the desired temperature 34° – 45°C.

6. Set gas flow to desired settings.

7. Ensure the desired temperature setting in the heated wick circuit is reached before connecting the circuit to the patient airway. Confirm visually on the front panel display.

8. To stop treatment turn the On/Off Control to Off. Disconnect the circuit from the cable assembly by depressing the latch on the white connector and separating the connectors.

9. Dispose of the used circuit (all disposable products should be treated as bio-hazard waste.)

NOTE: The cable assembly is designed to be reused, do not dispose with the breathing circuit.

Controls and Displays: (see figure A)

Rear panel
A - Main power switch
B – Fuse (1A, 250VAC, time delay)
C - AC power connection

Front panel
D - Temperature control (34 to 45° C)
E - Audible alarm silence button
F – Sensor cable connector

L.E.D. Indicators:
G - Breathing circuit temperature display (degrees C)
H - High Temp Alarm – Illuminated when temperature probe senses an overtemp condition (>47.5°C)
I – Probe Failure Alarm - Illuminated when probe malfunction or circuit disconnect occurs.
J – Heater Power Indication - Illuminated when wick circuit is being heated.

Display: (Refer to Figure A.)

Green LED is illuminated when power is applied to the heater in the wick circuit.

Red LED is illuminated when an overtemp condition is sensed at the patient end of the breathing circuit.

Red LED is illuminated when a probe failure or circuit disconnect occurs

Temperature Display illustrates breathing circuit temperature.

Audible Alarm:
An alarm will activate when:
- Patient breathing circuit temperature exceeds 47.5°C.
- A defective or damaged sensor is detected in the wick circuit.
- The cable assembly is damaged or disconnected from the controller.
Specifications:

- **Input Voltage:** 120VAC +/- 10%, single phase, 50 – 60Hz
- **Input Current:** 1.0A AC rms (maximum at 20 Liters / Minute and 45°C.)
- **Rated Power –** 100W max
- **Current leakage:** Double insulated. Designed to meet UL 544.
- **Output Temperature Range:** 34°C to 45°C @100% RH
- **Maximum output temperature:** 47.5°C.
- **Minimum Humidification output:** 33mg H₂O / Liters/Minute (at 34°C)
- **Maximum Humidification output:** 44mg H₂O / Liters/Minute (at 45°C)
- **Input Flow rate:** To 20 Liters per minute
- **Warm up time:** 15 min maximum
- **Maximum system operating pressure:** 70cm H₂O
- **Operating Temperature Range:** 16°C to 45°C
- **Gas Inlet Temperature Range:** 16°C to 45°C
- **While packed for Transport or storage, equipment is capable of being exposed to a temperature range of -20°C to +60°C**

Classification according to IEC 60601-1

- **Classification of protection:** class II
- **Type of applied part:** BF
- **Protection from ingress of water:** none IPXØ
- **Mode of operation:** capable of continuous operation
- **No known potential for adverse affects from electromagnetic or other interference between this device and other known devices**
- **No known adverse effects on the performance of the humidification system when exposed to electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference.**

Gross Dimensions of Controller:

- **Weight –** 1700 g (3.75lbs)
- **Height –** 102 mm (4.0”)
- **Length –** 123 mm (4.85”)
- **Width –** 110.5 mm (4.35”)

Controls:

- **O f** On / off switch: Turns the power on and off for both the ANAPOD Humidification System and heated wick circuit
- **Temperature Control Knob:** Sets the desired temperature
- **Alarm Silence button:** Silences the audible alarm for 2 minutes.

Alarms:

- All alarms generate both a visual indication and an audible alarm. The audible alarm can be silenced for 2 minutes by pressing the Alarm Silence button; however, the alarm LED will remain illuminated as long as the alarm condition exists. All alarms will disable the heater in the wick circuit.
- **Probe Sensor Alarm:** Indicates a probe failure or circuit disconnect.
- **Over temperature Alarm:** Indicates the wick circuit internal temperature probe has detected temperatures at or above 47.5°C.

Temperature Measurement:

The ANAPOD uses one temperature sensor which is located inside each heated wick circuit. There are no external probes to attach. This probe is calibrated to measure the temperature of the flowing gas at the patient end of the wick circuit. As with all heated systems, there is a certain drop in temperature in unheated wyes, elbows, and ET tubes. You can expect a temperature drop of approximately 4 – 5°C from the wick circuit outlet to the inlet of the ET tube under normal operating room conditions. It may be necessary to overcome heat loss in the last few non heated inches of the tubing, cuff, patient wye, elbow and/or ET tube. You may also need to compensate for ambient temperatures and/or low airflows. Using the ANAPOD Humidification System outside of the operating temperature range of 16°C to 45°C has the potential to affect the performance. It is recommended that it be kept within this temperature range during use. Testing shows the following typical temperature drops between wick circuit output and ET tube:

<table>
<thead>
<tr>
<th>Displayed</th>
<th>Delivered at ET tube</th>
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<tbody>
<tr>
<td>37°C</td>
<td>34°C</td>
</tr>
<tr>
<td>41°C</td>
<td>37°C</td>
</tr>
<tr>
<td>45°C</td>
<td>40°C</td>
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