Coventor Adult Manual Resuscitator Compressor
Instructions for Use

* Due to COVID-19 Pandemic, FDA has authorized the emergency use of this device. *

### Intended Use

This device is intended for compression of an adult manual resuscitator device intended for pulmonary resuscitation of adult patients under continuous clinical supervision for whom no other appropriate means of mechanical ventilation exists due to resource limitations from pandemic conditions in the region of use.

### Device Description

Coventor consists of a frame and mechanical actuator that will stabilize and compress a commercially available resuscitation bag connected to the patient’s endotracheal tube and external compressed oxygen, or if oxygen is not available, ambient air. It is intended to be used by healthcare providers to mechanically ventilate a patient until a traditional ventilator becomes available.

- The expected tidal volume (Vt) may be up to 621 mL depending on the resuscitator bag used and the patient’s lung compliance.
- The respiratory rate (RR) is adjustable up to 30 breaths/minute.
- Respiratory rate must be calculated by the clinician.

### Figure 1: Coventor

1 – Control Panel (see Figure 2)
2 – Motor housing
3 – Plunger

### Figure 2: Control Panel

4 – Power switch
5 – Power inlet
6 – Respiratory rate dial
**Warnings**

- The device has no safety features relating to power interruption or cessation of ventilation. In case of power interruption or cessation of ventilation, patients that cannot spontaneously breathe will suffocate, unless rapid action is taken.
- This device requires continuous close monitoring by personnel appropriately trained in the techniques of pulmonary resuscitation to ensure appropriate function. Continuous clinical vigilance is required for safe use of device.
- A pressure relief valve with a recommended relief pressure of 40cm of water is required for safe use of the device.
  - If an adult manual resuscitation bag is not available with an integrated pressure limiting valve, a separate pressure limiting valve must be placed into the inspiratory limb of the breathing circuit for safe use.
  - Failure to do so may increase the airway pressure of the patient.
- Clinician must continuously monitor the patient condition for ongoing synchrony between chest rise and bag compression during patient ventilation.
- During Coventor use, it is important to observe if the self-inflating adult resuscitation bag is reinflating sufficiently during exhalation, before the next inhalation is initiated by the piston.
- Resuscitation bags equipped with oxygen reservoir bags may require supplemental gas flow to fully reinflate the bag and achieve adequate ventilation
- Coventor may generate heat; use extreme caution in the presence of flammable anesthetics, oxidizing gases, or volatile solvents.

**Cautions**

- This device must be used by individuals with appropriate training in pulmonary resuscitation.
- Only use self-inflating resuscitation bags.
- Not intended for use with bag valve masks.
- Sedation levels of the patient must be monitored by appropriate clinician
- Proper function of the adult manual resuscitative bag should be verified prior to placement of bag into the automated adult manual resuscitator bag compressor. If the bags are not properly functioning the patient may not receive proper ventilation.
- Clearance must be maintained to prevent foreign material or other blockage into the breathing circuit. Ensure the device is not in direct contact with the patient.
- Valves should be verified to be free of obstruction. If the pressure relief valve is occluded or is not functioning correctly, it may not allow for proper relief of pressure causing it to exceed the safety limits.
This device has no means of measuring inspiratory or expiratory pressures, volumes, or flows.

Respiratory rate must be counted, and ventilation should be verified by observing the patient for chest rise and fall with compression and release of the adult manual resuscitator bag, respectively.

Continuous capnography, and frequent monitoring of venous or arterial blood gases are recommended to ensure appropriate ventilation with continued use.

Continuous pulse oximetry should also be performed when the device is being used.

There is no internal backup power source.

In the case of any serious concern, the bag should be manually removed from the machine and squeezed by hand until the concern is addressed.

Avoid device exposure to liquids; do not allow liquids to drip or seep inside the device.

To prevent injury, do not insert or remove the resuscitation bag when the plunger is moving.

The following table provides information about the Coventor capabilities in comparison to ARDSnet Conformance parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ARDSnet Conformance</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC/VC</td>
<td>VC</td>
<td>Can only be operated in VC mode. Pressure limited to 40cm H₂O</td>
</tr>
<tr>
<td>4-8cc/kg TV</td>
<td>Yes</td>
<td>TV 4-8 cc/kg PBW. Limited to Males w/ PBW ≥ 61.5kg and Females w/ PBW ≥ 61.6kg</td>
</tr>
<tr>
<td>FiO₂ (.21-1.0)</td>
<td>Yes</td>
<td>To achieve an FiO₂ of 1.0 requires the use of an oxygen flow rate generally greater than 10 Lpm and the use of a manual resuscitator with either a corrugated oxygen reservoir or an oxygen reservoir bag. Consult the IFU for the specific resuscitator bag.</td>
</tr>
<tr>
<td>I:E ratio (1:1-1:3)</td>
<td>1:1</td>
<td>I:E ratio is fixed at 1:1. The I:E ratio cannot be adjusted on the Coventor.</td>
</tr>
<tr>
<td>RR (up to 35)</td>
<td>No</td>
<td>RR max 30</td>
</tr>
<tr>
<td>PEEP (Positive End-Expiratory Pressure) [up to 24cm H₂O]</td>
<td>No</td>
<td>PEEP valves provide adjustable PEEP up to 20cm H₂O.</td>
</tr>
<tr>
<td>P&lt;sub&gt;plateau&lt;/sub&gt;</td>
<td>No</td>
<td>P&lt;sub&gt;plateau&lt;/sub&gt; is not measurable with a manual resuscitator bag. P limited to 40cm H₂O by the required pressure relief valve, therefore limiting P&lt;sub&gt;plateau&lt;/sub&gt; to &lt; 40cm H₂O.</td>
</tr>
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</table>
## Validation and Performance Conformance

<table>
<thead>
<tr>
<th>Validation and Performance Conformance</th>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Validated reservoir bags</td>
<td>Yes</td>
<td>Tested self-inflating, adult Vyaire, Ambu, and Mercury Medical resuscitation bags.</td>
</tr>
<tr>
<td>Accuracy of Monitored parameters (as applicable)</td>
<td>No</td>
<td>No parameters are measured.</td>
</tr>
<tr>
<td>Accuracy Delivered (as applicable)</td>
<td>Yes</td>
<td>Tidal volume will be dependent on the chosen resuscitation bag, dead space, and patient’s lung compliance. Internal testing demonstrated a maximum tidal volume of 504.8 ± .06 mL (AMBU), 620.9 ± 0.2 mL (Vyaire), and 516.8 ± 0.5 mL (Mercury Medical) for the 5-inch resuscitator bags tested.</td>
</tr>
<tr>
<td>Spontaneous Breathing detection</td>
<td>No</td>
<td>Device cannot detect spontaneous breathing.</td>
</tr>
<tr>
<td>Internal power source ventilation duration capacity</td>
<td>No</td>
<td>There is no backup power source.</td>
</tr>
<tr>
<td>Contamination risk to environment</td>
<td>No</td>
<td>*Need HMEF (99.7% efficiency at ETT-Wye adaptor interface)</td>
</tr>
<tr>
<td>Durability</td>
<td>Yes</td>
<td>Tested to 14 days with a single resuscitation bag. Replace bag as needed to achieve ventilation and between patients.</td>
</tr>
</tbody>
</table>

### Alarms

<table>
<thead>
<tr>
<th>Alarms</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Device power off alarm</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>Disconnect Alarm (Low PIP alarm)</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>External power supply failure Alarm</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>Back-up Battery</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>Low FiO2 alarm</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>Maximum PIP alarm</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>Occlusion alarm/Continuing Pressure</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
<tr>
<td>TV not met/exceeded alarm</td>
<td>No</td>
<td>No alarms are present.</td>
</tr>
</tbody>
</table>
Implications for additional clinical monitoring

| Continuous pulse oximetry should also be performed when the device is being used. Respiratory rate should be counted, and ventilation should be verified by observing the patient for chest rise and fall with compression and release of the adult manual resuscitator bag, respectively. Continuous capnography, and frequent monitoring of venous or arterial blood gases are recommended to ensure appropriate ventilation with continued use. |

Training

| Training required | This device requires continuous, close monitoring by personnel appropriately trained in the techniques of pulmonary resuscitation to ensure appropriate function. |

Accessories

Refer to supplied Instructions for Use for breathing circuit. Review all warnings, precautions, and instructional steps provided in the Instructions for Use prior to using the accessory products with this device.

The Coventor is supplied with one (1) power supply and three (3) power cords for compatibility with different international requirements.

Instructions for Use

To safely operate the Adult Manual Resuscitator Compressor, the following accessories are required:

- Self-inflating adult manual resuscitator bag
  - No testing has been performed using a flow-inflating bag.
- Endotracheal tube
- Pressure relief valve of 40cm H₂O (if not included as part of the bag)
- HEPA (High Efficiency Particulate Air) filter

The following accessories are recommended:

- External compressed oxygen (if applicable)
- Oxygen corrugated reservoir tube or oxygen reservoir bag
- PEEP valve
- Manometer
- Extension tubing (if applicable) and any corresponding adapters to ensure all fittings are secure

Orientation of the bag within the Coventor is illustrated in Figure 3 and Figure 4.

Three recommended airway setups are illustrated in Figure 5, Figure 6, and Figure 7.
Figure 3: Coventor with Bag (view from above)

Figure 4: Coventor resting on long edge (side view)

Figure 5: Airway Setup Option A
Figure 6: Airway Setup Option B

Figure 7: Airway Setup Option C
Prior to Use

CAUTION: The Coventor is intended to be used with the patient already intubated.

1. Obtain an adult manual resuscitative bag (bag).

2. Prior to connecting the breathing circuit to the patient, perform safety checks on the bag according to the Manufacturer’s instructions. This must include at a minimum:
   - Verify function of the bag by occluding the patient connection and squeezing the bag. Confirm that an audible hiss of air can be heard through the pressure limiting valve.

3. Connect required accessories to the bag to complete the breathing circuit according to Manufacturer's Instructions for Use. The length of the connection from the non-rebreathing valve to the patient endotracheal tube or artificial airway should be no more than 12 inches to prevent rebreathing of CO₂ and decreases of delivered tidal volume.

WARNING: A pressure limiting valve of 40cm H₂0 is required for safe use. Failure to include either an integrated or a separate pressure limiting valve may harmfully increase the airway pressure of the patient.

4. If the bag assembly does not have an integrated pressure limiting valve, connect one into the breathing circuit between the bag and the patient.

5. Assemble the breathing circuit using the guidance provided in Figures 5, 6, and 7.

6. Connect the oxygen supply to the bag and ensure the oxygen supply is working properly.

7. Check the function of the circuit and manual resuscitator bag by manually squeezing it and verifying patient chest rise and fall.
**Connect Breathing Circuit to Coventor**

1. Orient the Coventor so that it rests horizontally on its long edge.
2. Place the resuscitator bag into the Coventor, as shown in Figure 8, so that the bag is centered under the plunger head.

**CAUTION:** The motor housing should face away from the patient for safety.

*Note:* The plunger is intended to stay in contact with adult sized bags to inhibit bag movement. The bag may need to be squeezed to place it in the Coventor.

**WARNING:** Improper placement of the bag underneath the plunger may inhibit function.

**Operation**

1. Ensure power switch is in “off” position before connecting power supply to unit.
2. Connect the appropriate power cord to the Coventor device and the wall outlet.
3. Turn power switch to “on” position to initiate bag compressions.
4. Adjust the Respiratory Rate Dial to the desired respiratory rate. Adjusting the dial changes the rate of compression applied to the bag. A noise may be heard as the plunger moves up and down.
   - To determine the respiratory rate, count either bag compressions or the rise and fall of the patient’s chest.

**WARNING:** Respiratory rate must be calculated by the clinician.

**WARNING:** Always ensure that the Coventor is free from other materials. Do not cover with sheets, drapes, or other materials. Ensure that the device is not in direct contact with the patient.

5. Confirm that the patient's chest rises and falls during ongoing use.
WARNING: If the patient’s chest is not moving during ventilation, check the following:
  - Patient’s airway
  - Breathing circuit connections
  - Bag position within the Coventor
  - Compression to the bag via the plunger
  - Adequate refilling of the bag between breaths
  - Power supply connection
  - Inline filter for saturation

Discontinue use if not able to resolve immediately and revert to alternate means of ventilation.

6. Closely monitor the patient using standard techniques for ventilated patients using pulse oximetry, arterial and venous blood gasses and/or capnography.

WARNING: Continue to inspect the bag for wear over time. Replace the bag if there is visible damage.

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**Disconnect from Patient**

1. Adjust the Respiratory Rate Dial so that bag compression stops.
2. Turn power off via the power switch.
3. Disconnect the bag from the breathing circuit and remove from Coventor.
4. Dispose of the breathing circuit components in accordance with hospital, administrative, and local government policy.

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**Cleaning and Disinfection**

CAUTION: Make sure unit is unplugged from electrical supply before cleaning.
  - The Coventor must be cleaned in accordance with CDC policies and procedures for COVID decontamination.
  - The external surfaces and contact points of the Coventor must be cleaned in between patients; follow cleaning procedures per hospital and safety regulations.
  - Clean the exterior of the Coventor with a damp wipe and desired cleaning solution such as 70% IPA, 5-5.5% sodium hypochlorite, or Super Sani-Cloth Germicidal Wipe.
  - Do not allow water or other liquids to drip or seep inside the Coventor.
### Troubleshooting

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Potential Cause(s)</th>
<th>Troubleshooting Steps to Resolve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device does not turn ON</td>
<td>Power cable to the device is disconnected from the power outlet or from the device</td>
<td>Ensure that the cable is plugged in and the power switch is ON.</td>
</tr>
<tr>
<td></td>
<td>Respiratory rate dial is down</td>
<td>Adjust the respiratory rate dial to increase the compression rate</td>
</tr>
<tr>
<td></td>
<td>Coventor is damaged</td>
<td>Turn the power switch OFF then back ON.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If unsuccessful, stop using Coventor and use alternate means of ventilation.</td>
</tr>
<tr>
<td>Plunger head stops moving</td>
<td>Power cable to the device is disconnected from the power outlet or from the device</td>
<td>Ensure that the cable is plugged in and the power switch is ON.</td>
</tr>
<tr>
<td></td>
<td>Motor may have reached torque limit</td>
<td>Turn the power switch OFF then back ON. Follow Operation instructions to establish appropriate ventilation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evaluate if there is an obstruction with plunger motion. Remove obstruction and follow Operation instructions.</td>
</tr>
<tr>
<td></td>
<td>Motor may have overheated</td>
<td>Turn the power switch OFF. Ensure that the Coventor is free from other materials. Do not cover with sheets, drapes, or other materials. Turn the device back ON.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If unsuccessful, stop using Coventor and use alternate means of ventilation.</td>
</tr>
</tbody>
</table>

### System Specifications

**Operating Conditions**
- Temperature: 0 to 40°C
- Humidity: 0 to 90%, non-condensing

**Storage Conditions**
- Temperature: -20 to 80°C
- Humidity: 0 to 90%, non-condensing
Mechanical Specifications
  Weight:  16.8 pounds (18.9 pounds with power supply)
  Height:  5.90 inch
  Footprint:  10.1 x 17.5 inch

Electrical Specifications
  Input Voltage: 100 to 240 VAC, single phase
  Input Frequency: 50 – 60 Hz
  VA Rating: 72 VA
  IP Rating:  IP00
  Fuse Rating: T 7A
  Electrical Protection: Class II, Type B protection against shock

Power Supply
  The system is designed to be used with the provided power supply.
  Power supplies that may be provided with Coventor include either the
  G lobtek GTM961600P18024-T3 (Output specifications: 24 VDC,
  7.5 ADC) or a modified Meanwell (Output specifications: 24 VDC,
  9.2 ADC)

Electromagnetic Compatibility and Immunity (EMC and EMI)

The Coventor has been tested for compliance to a limited set of EMC and EMI requirements
in accordance with IEC 60601-1-2. This testing was performed to minimize the risk that the
device will produce electromagnetic disturbances that will affect the performance of other
equipment and that it will fail in the presence of electromagnetic disturbances from other
equipment.

WARNINGS
  ☐ The Coventor may still produce electromagnetic disturbances that will affect the
    performance of other equipment and it may fail to perform as expected in the
    presence of electromagnetic disturbances from other equipment. When starting the
    equipment observe the performance of nearby equipment and the operation of the
    Coventor. Relocate equipment or cables if any disturbances are observed.
  ☐ The Coventor relies on the integrity of the protective earth ground to reduce the risk
    of electrical shock. Check the integrity and verify the function of the protective earth
    ground of the supply mains receptacle prior to use.
  ☐ Use of a power supply other than the one provided may result in increased emissions,
    decreased immunity of the device, or device malfunction.
  ☐ The Coventor should not be used adjacent to or stacked with other equipment.
  ☐ Portable RF communications equipment may affect the Coventor causing it to
    operate improperly.
Service and Maintenance

None of the device components are user serviceable. Contact Boston Scientific Corporation for all service requirements.

**WARNING: No modification of the Coventor device is allowed.**

Coventor Disposal

The Coventor must be disposed of in accordance with hospital, administrative, and local government policy.

Complaints

Report complaints to: BSCcomplaints@bsci.com.

Please report the following information if available:

- Initial Reporter information (i.e. Name, Contact Information)
- Facility Name and Address
- Physician/Health Care Provider (HCP) Name and Contact Details (if different than initial reporter information)
- Date of Event
- Product UPN
- Product Lot/Batch #
- Event Description
  - Please provide as much detail as possible/available:
    - What happened?
    - How was event resolved?
    - What was the patient outcome?
    - Was there patient injury or death? If so, was it related to the product or the progression of underlying condition/COVID-19?
    - Was the product discarded or is it remaining in use?
    - What was the size and brand of the resuscitation bag used with the Coventor?
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>📃</td>
<td>Contents</td>
<td></td>
</tr>
<tr>
<td>REF</td>
<td>Catalog Number</td>
<td>Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.</td>
</tr>
<tr>
<td>GTIN</td>
<td>Global Trade Item Number</td>
<td>Non-Sterile</td>
</tr>
<tr>
<td>📆</td>
<td>Date of Manufacture</td>
<td>Separate Collection</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
<td>CAUTION Attention: Consult ACCOMPANYING DOCUMENTS.</td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
<td>Type B Applied Part</td>
</tr>
<tr>
<td>🏭</td>
<td>Manufacturer</td>
<td>MR Unsafe</td>
</tr>
<tr>
<td>🕐</td>
<td>Follow Instructions for Use</td>
<td>Speed Adjust</td>
</tr>
<tr>
<td>☑️</td>
<td>Do not use if package is damaged.</td>
<td>Power On</td>
</tr>
<tr>
<td>☂️</td>
<td>Keep Dry</td>
<td>Power Off</td>
</tr>
<tr>
<td>☀️</td>
<td></td>
<td>Direct Current</td>
</tr>
</tbody>
</table>