MRI Safety Information

The **butterflyBVM** is MR Conditional. A patient with the **butterflyBVM** may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	*Condition of Use/Information*
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	19-T/m (1,900-gauss/cm)
Important Note:	The butterflyBVM is intended for use on a patient while inside an MR system. However, the butterflyBVM is not intended for use during the operation of the MR system for a diagnostic imaging procedure. Therefore, the butterflyBVM was assessed for force and torque at 3-Tesla MR system, according to its intended use.

Symbols

Symbol Indication	Description	Symbol Indication (cont.)	Description (cont.)
	Do not reuse Single-use only	LATEX	Latex Free
	Manufacturer	MR 3T or less	MR Conditional 3 Tesla or Less
US	Country of manufacturer		Caution
	Important Information		Do Not Use if Package is Damaged
LOT	Lot Number	QTY	Quantity Number
#	Model Number	Rx only	Only to be Used Under Supervision of a Licensed Healthcare Professional

Table 4: Explanation of symbols used

Instructions for Use

ButterflyBVM™ Resuscitator

compactmedical INCORPORATED

Compact Medical Inc.

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Contents

Storage

⚠ **CAUTION:** NEVER store the resuscitator in a compressed state.

Store device if not used immediately. Storage environmental limits are -40°C - +60°C, and between 40% - 70% relative humidity.

Long-term Storage: For long-term storage, the resuscitator should be kept in closed packaging in a cool place away from sunlight.

Inspect Dropped Device

If the device is dropped,

1. **Inspect** the device fully for broken or damaged parts.
2. **Ensure** that PIP dial has not adjusted from its desired setting. If needed, correct PIP by rotating it back to the desired setting.
3. **Ensure** that Vt dial is still firmly in place. If needed, push Vt dial toward the bellows while compressing the side arms until an audible ‘click’ is heard, and then set the Vt dial to the desired setting.
4. **Resume** patient care.

NOTE: Discard the resuscitator and select a new resuscitator if any part of the device is broken or missing.

Technical Specifications

The ButterflyBVM™ Resuscitator connections comply with industry ventilation standards ISO 5356-1, EN 13544-2, and EN ISO 10651-4. The device has no components made of natural rubber latex.

Operating Environmental Limits: -18°C to +50°C. Up to 98% relative humidity.
Resuscitator Deadspace: <6.5ml
Expiratory Resistance: 0 - 2.2cmH_2O
Inspiratory Resistance: -3.2 - 0cmH_2O
Device Dimensions: ≈ 11 x 15 x 29cm
Device Mass: ≈ 450 g
Shelf Life: 3 years from date of manufacture

Using the BVM to Ventilate Patient

Always use your clinical judgment and expertise during pulmonary ventilation and monitor the patient's response by observing the rise and fall of their chest.

⚠ **WARNING:** ALWAYS monitor airway for obstruction during use with a face mask to prevent insufficient oxygen delivery. Use an alternative patient interface if needed.

⚠ **WARNING:** ALWAYS monitor chest movement to assess for adequate ventilation.

⚠ **WARNING**: ALWAYS leave PIP set to 40cmH2O if unsure of the appropriate setting for a given patient. Only increase PIP if needed. Setting the PIP too high can cause barotrauma.

⚠ **WARNING**: AVOID using the resuscitator in toxic or hazardous environments to avoid tissue injury.

1. **Position** patient to open the airway.
2. **Attach** the resuscitator to the patient interface (an appropriate-sized mask, endotracheal tube, or similar attachment), in addition to other accessories and supplemental oxygen if desired, before applying the resuscitator on the patient. If using a face mask, ensure you hold the mask firmly against the patient's face to reduce leak.
3. **Hold** the side arms.
4. **Squeeze and release** the side arms at the appropriate ventilation rate for the patient according to published resuscitation standards. The volume of air delivered in a full stroke includes a margin to accommodate potential mask leaks.

⚠ **WARNING**: **Squeeze** the bellows only enough for chest rise; a full squeeze may not be needed. This device opens slower than standard bag-valve-mask systems to prevent hyperventilation. Always squeeze the bellows at the rate most appropriate for the patient to ensure safety and not necessarily at the rate that the device opens. Excess air can cause injury.

5. **Observe** for chest rise and fall.
6. **Release the bellows** and listen for exhaled air from the patient valve and observe for chest fall.
7. **Monitor and assess** the airway for obstruction throughout ventilation.
8. **Reposition** airway if there is resistance to insufflation.
9. **Adjust** tidal volume and PIP as needed to ensure adequate chest rise and fall

Disposal

⚠ **WARNING:** DO NOT clean or sterilize the device. The ButterflyBVM™ is for single-use only. **Dispose** of device and accessories after use according to your facility's procedures.

Important – Read Before Use:

⚠ **WARNING:** Read all instructions before using the ButterflyBVM™ to ensure proper use and avoid patient harm. This IFU describes operation of the ButterflyBVM™ and all safety related information; it does not provide general clinical resuscitation procedures. Users must be qualified and trained in resuscitation techniques to use this device. **Federal law restricts this device to sale by or on the order of a physician.** There is no warranty on the ButterflyBVM™ resuscitator. The ButterflyBVM™ resuscitator IFU is on the Compact Medical Inc. website at www.butterflyBVM.com.

Indications for Use

The ButterflyBVM™ when used in transport and non-clinical emergency settings (e.g., EMS, non-hospital) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, infants, and neonates.

The ButterflyBVM™ when used in professional healthcare facilities (e.g., hospitals) is a single-use resuscitator that may be manipulated to provide pulmonary resuscitation of patients including adults, adolescents, children, and infants.

Contraindications

The ButterflyBVM™ is contraindicated for use in neonates in hospital-based clinical settings.

Warnings and Cautions

⚠ **WARNINGS** alert you to situations that, if not avoided, could result in injury or potential adverse reactions.

⚠ **CAUTIONS** alert you to situations that could lead to damage to the device or accessories. Throughout this User Manual, warnings and cautions are marked with a safety ⚠ symbol.

ButterflyBVM™ Overview

The ButterflyBVM™ [Figure 1] is a three-in-one bag-valve-mask capable of resuscitating adults, adolescents, children, infants, and neonates. The maximum tidal volumes (Vt) delivered by the ButterflyBVM™ can be set, as needed, to ranges that are generally appropriate for the size of patient receiving care. The ButterflyBVM™ also has an adjustable peak inspiratory pressure (PIP) valve which replaces a manometer to help prevent barotrauma. Patient-facing accessories such as masks, laryngeal mask airways, endotracheal tubes, end-tidal CO_2 samplers, and the like can be connected to the patient connection port. Exhalation accessories such as bio filters and PEEP valves can be connected to the exhalation port. Supplemental oxygen can be added via the oxygen (O_2) port.

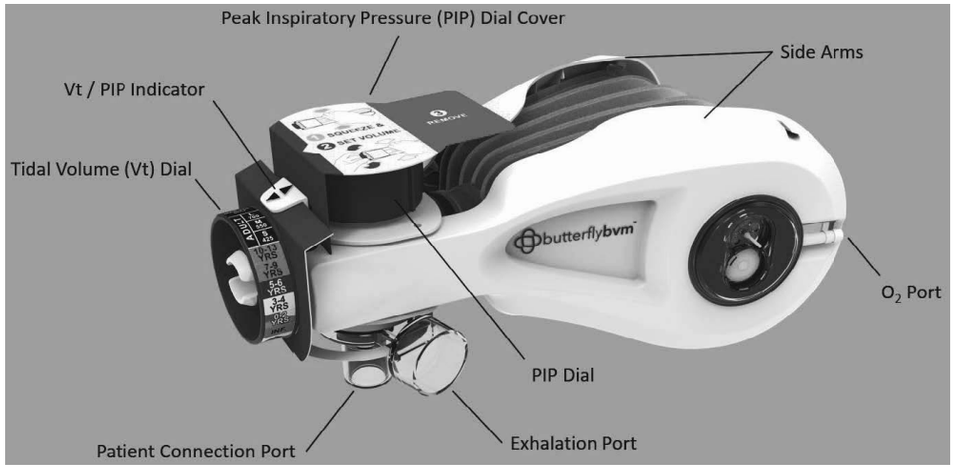

FIGURE 1: The ButterflyBVM™

Setting	Inspiratory Rate (BPM)	Stroke Volume* (ml)	Nominal Oxygen Concentration (%) at a Given O_2 Flow Rate		
			5 LPM	10 LPM	15 LPM
Adult Large	10	565	61	78	90
Adult Med	10	510	62	79	91
Adult Small	10	415	66	83	93
10-13 YRS	20	380	62	79	90
7-9 YRS	20	275	72	87	95
5-6 YRS	20	225	76	90	97
3-4 YRS	20	185	81	93	99
1-24 MOS	20	150	83	95	99
NEO	30	30	93	100	100

Table 2: Expected oxygen concentration at a given O_2 flow rate, inspiratory rate, and stroke volume. *Tested according to EN ISO 10651-4.

Attaching Accessories

⚠ **WARNING:** Use a different BVM product with a manometer if patient care requires real-time monitoring of PEEP values, as this product cannot report real-time PEEP values.

⚠ **CAUTION:** Only use with accessories that are correctly sized to connect with the device. The patient connection port should only be used with accessories that fit a 15mm inner diameter or a 22mm outer-diameter. The exhalation port should only be used with accessories that fit a 30mm outer diameter. ⚠ **CAUTION:** Refer to the accessory packaging for instructions and specific handling information to ensure proper use.

1. **Attach** third party masks, endotracheal tubes, laryngeal mask airways, end-tidal CO_2 samplers, etc. to the 15mm inner diameter or 22mm outer diameter of the patient connection port as clinically indicated.
2. **Attach** third-party biofilters, PEEP valves, and other accessories to the 30mm outer diameter of the exhalation port as clinically indicated.
3. **Access** the Mercury Medical PEEP Valve with Filter instructions for use here, if applicable:

Excessively high pressures can lead to barotrauma. **WARNING**:

⚠ ALWAYS leave PIP set to 40cmH2O if unsure of the appropriate setting for a given patient. Only increase PIP if needed. Setting the PIP too high can cause barotrauma.

To adjust the PIP setting:

1. **Remove** cover from PIP dial, if needed.
2. **Rotate** the PIP dial in either direction until the indicator arrow points to the '40cmH_2O' setting, or desired starting PIP based on patient needs. See Figure 5.

NOTE: If pressure limiting is not necessary, rotate the PIP dial clockwise to 'OVERRIDE'.

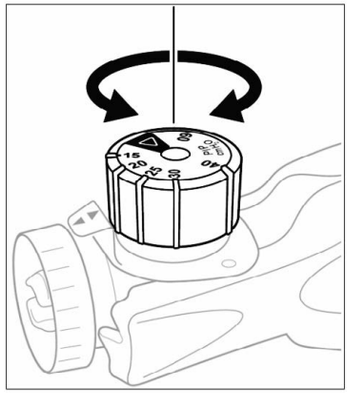

Figure 5: Setting Peak Inspiratory Pressure

Oxygen Administration

⚠ **WARNING:** DO NOT use supplemental oxygen near open fire, oil, grease, or other flammable objects, or items that cause sparks to avoid the risk of fire and explosion.

⚠ **WARNING:** DO NOT use this device for administering free-flow oxygen ('blow-by oxygen') or use on a patient's face without squeezing to prevent inadequate oxygen administration and hypoxia.

To administer oxygen:

1. **Attach** the free end of oxygen tubing to the oxygen source.
2. **Set** O_2 flow rate on oxygen source. Do not exceed 15 LPM oxygen flow. Refer to Table 2 for the expected oxygen concentration corresponding to different patient sizes, inspiratory rates, stroke volumes, and oxygen flow rates.

Pre-Use Test / Equipment Check

Ensure there are no air leaks, and the device is functioning properly before use.

1. **Lift** cover from PIP dial, if needed (see Figure 2).
2. **Rotate** the PIP dial to the 'OVERRIDE' setting.
3. **Ensure** tidal volume is at 'Adult Large' setting.
4. **Forcefully squeeze** the side arms of the resuscitator once and ensure air exits the patient connection port.
5. **Plug** the patient connection port and squeeze the side arms again; the resuscitator should resist the squeeze, and you should not detect a leak. If a leak is detected, discard the resuscitator, and select a new one. Proceed to step 6 below if no leak is detected.
6. **Unplug** the patient connector.
7. **Rotate** the PIP dial until the indicator arrow points to the '40cmH_2O' setting.
8. **Return** PIP cover and return unit to storage bag

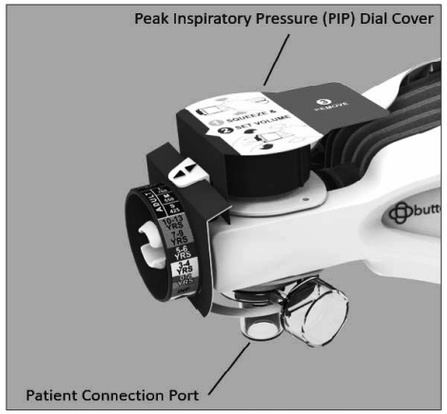

Figure 2: Isolation view of PIP Dial Cover and Patient Connection Port

NOTE: Discard if leak is detected when performing the pre-use functional test.

Operating Instructions

Setting Tidal Volume

⚠ **CAUTION**: ALWAYS wear gloves when handling the ButterflyBVM™.

⚠ **WARNING:** ALWAYS determine and set appropriate tidal volume setting based on patient size to ensure appropriate ventilation and to avoid patient injury.

1. **Hold** device so the indicator arrows are on top. See circle in Figure 3.
2. **Squeeze and hold** the side arms compressed. See Figure 4.
3. **Turn** the tidal volume (Vt) dial while holding the side arms compressed to set the appropriate Vt limit based on the age, or

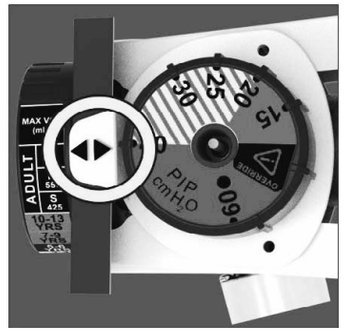

Figure 3: Top-down view of device with PIP and Vt dial indicator arrows found inside circle.

size of the patient, then release the side arms. The tidal volume setting determines the maximum available stroke volume with each ventilation by determining how much the bellows can open. See **Table 1.**

4. **Remove** PIP dial cover.

NOTE: The air volume delivered includes a margin for potential mask leaks, so a full squeeze may not be necessary even if the Vt dial is set correctly. Squeeze the device only until you see chest rise, which may require less than a full squeeze.

5. **Release** the side arms and the bellows will expand to the set tidal volume limit.

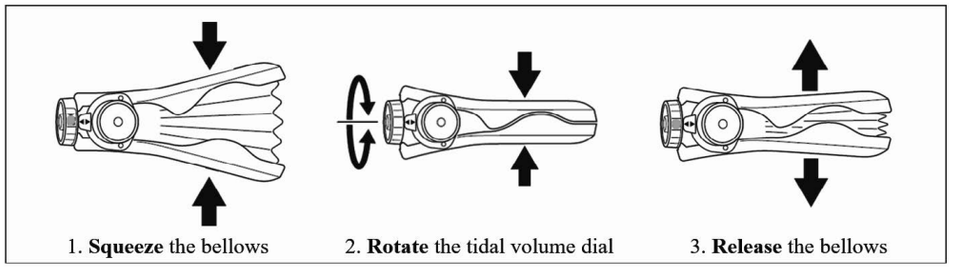

Figure 4: Setting the tidal volume dial.

Device Setting - Body Size or Broselow Color	Patient Length		Ideal Body Weight	One-Handed Ventilation* Max. Stroke Volume	Two-Handed Ventilation** Max. Stroke Volume
Adult Large	≥183 cm	≥72 in	≥72 kg	565 ml	715 ml
Adult Medium	160-182 cm	63-71 in	55-71 kg	510 ml	610 ml
Adult Small	140-159 cm	55-62 in	46-54 kg	415 ml	485 ml
10-13 YRS = Green	132-139 cm	52-54 in	30-45 kg	380 ml	430 ml
7-9 YRS = Orange	122-131 cm	48-51 in	22-29 kg	275 ml	290 ml
5-6 YRS = Blue	107-121 cm	42-47 in	19-23 kg	225 ml	240 ml
3-4 YRS = White	97-106 cm	38-41 in	14-18 kg	185 ml	190 ml
1-24 MOS = Pink/Red/ Purple/Yellow	58-96 cm	23-38 in	6-13 kg	150 ml	150 ml
NEO = Gray	≤57 cm	≤22 in	up to 5.5 kg	30 ml	70 ml
	* Nominal value, single handed squeeze with PIP set to "40cmH_2O". ** Nominal value, two handed squeeze with PIP set to "OVERRIDE". Tested according to ISO 10651-4:2002.				

Table 1 Expected Maximum Stroke Volumes

Setting PIP Limit

The PIP dial feature regulates peak inspiratory pressures (PIP) without the use of a manometer to better control pressures and prevent barotrauma. The default setting is 40 cm H_2O (4.0 kPa), which is generally appropriate for most patients. For each setting, the expected PIP delivered is ±7.0cmH2O. Adjust the PIP setting based on patient needs.

⚠ **WARNING:** Use an alternative device for resuscitation in clinical scenarios where the use of a manometer is preferred, as this product cannot be used with a manometer.

⚠ **WARNING:** Use the lowest peak inspiratory pressures (PIP) necessary for patient ventilation.