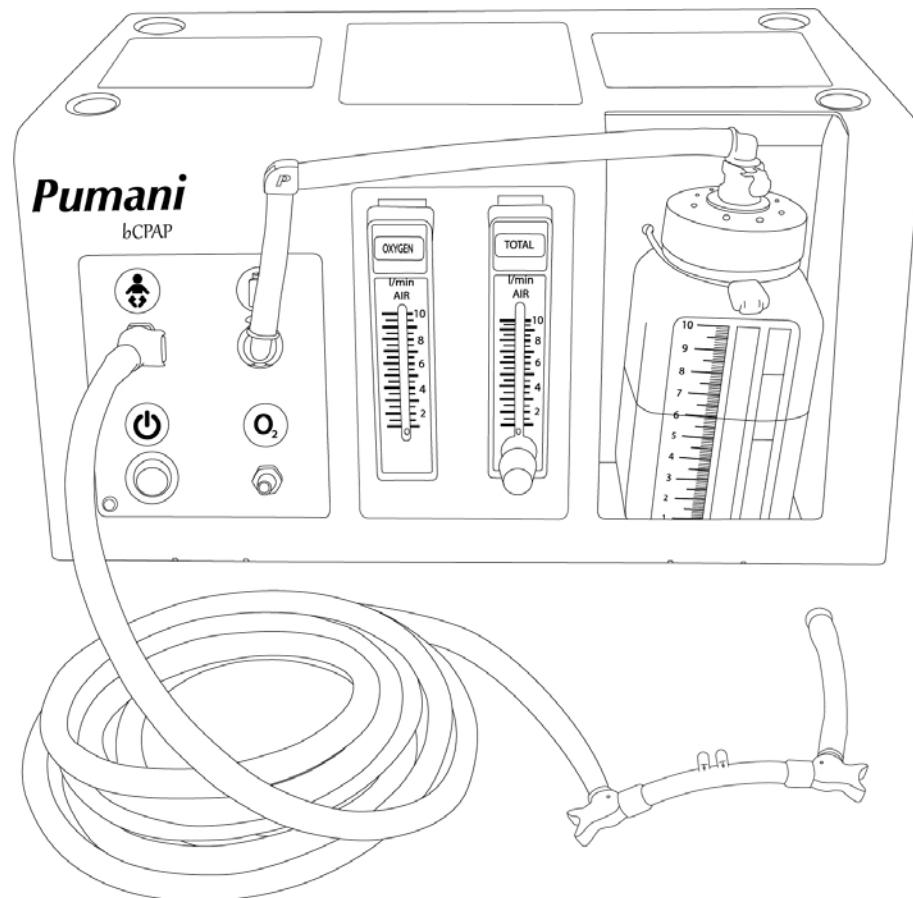


# *Pumani* User Manual & Repair Manual

bCPAP



CE 0120

 HADLEIGH HEALTH  
TECHNOLOGIES

# Introduction

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Complications due to premature birth, including respiratory distress, are the leading cause of child mortality worldwide. Bubble continuous positive airway pressure (bCPAP) is a safe, effective intervention for infants with respiratory distress and is widely used in developed countries.

The Pumani bCPAP is a low-cost, easy-to-use, easy-to-repair device to treat infants in respiratory distress, and it has been designed specifically to operate in low-resource settings. Clinical results show that use of the Pumani bCPAP can significantly reduce neonatal mortality in low-resource settings.

The Pumani bCPAP has been designed, developed, and manufactured by Hadleigh Health Technologies in San Rafael, CA. See pg. 52 for contact information.

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# General Information

**Important:** Read these instructions carefully before using the Pumani bCPAP. If you have any questions or problems with the product, please contact your local healthcare provider or Hadleigh Health Technologies at +00 1 415 454 3005.

**Intended Use:** The Pumani bCPAP is intended for use in treating respiratory distress and other forms of respiratory illness in infants up to one year of age/below 10 kg.

**Indications for Use:** Use on the advice and prescription of a clinician to help relieve the symptoms of respiratory distress and other forms of respiratory illness in infants.

**Contraindications:** Do not use the Pumani bCPAP on non-spontaneously breathing patients, patients with cleft palate, trachea-esophageal fistula, diaphragmatic hernia, severe cardiac instability, and severe birth asphyxia.

## Pumani bCPAP Specifications

Size.....	36.2cm x 25.4cm x 19.4cm
Weight.....	7.5 kg
Electrical Requirements AC.....	220-240V/50 Hz
Maximum Power Consumption.....	15 VA
Pressure Range.....	5-10 cmH <sub>2</sub> O ( $\pm 0.05$ cmH <sub>2</sub> O)
Flow Range.....	0-10 L/min ( $\pm 0.4$ L/min)
Operating/Storage/Transportation Temperature Range.....	-18°-60°C
Operating/Storage/Transportation Humidity Range.....	0-90% RH
Sound Pressure Level.....	75 dB
Maximum Oxygen Input Pressure.....	34.5 kPa
Fuse Rating.....	M1AI, 250V

## Other Specifications

Warranty.....	2 years
Equipment classification: protection from electric shock.....	Class I
Degree of protection from electric shock.....	Type BF Applied Part
Mode of operation.....	Continuous

## Symbol Definitions

	Connection to the patient
	Connection to the bottle
	Power on/off
	Connection to an external oxygen source
	Attention
	This device contains electrical and/or electronic equipment that must be recycled per EC Directive 2002/96/EC – Waste Electrical & Electronic Equipment
	Indoor Use Only
	Temperature Limitation
	Manufactured by
	European Representative
	Type BF Symbol
	Do Not Reuse



# Warnings

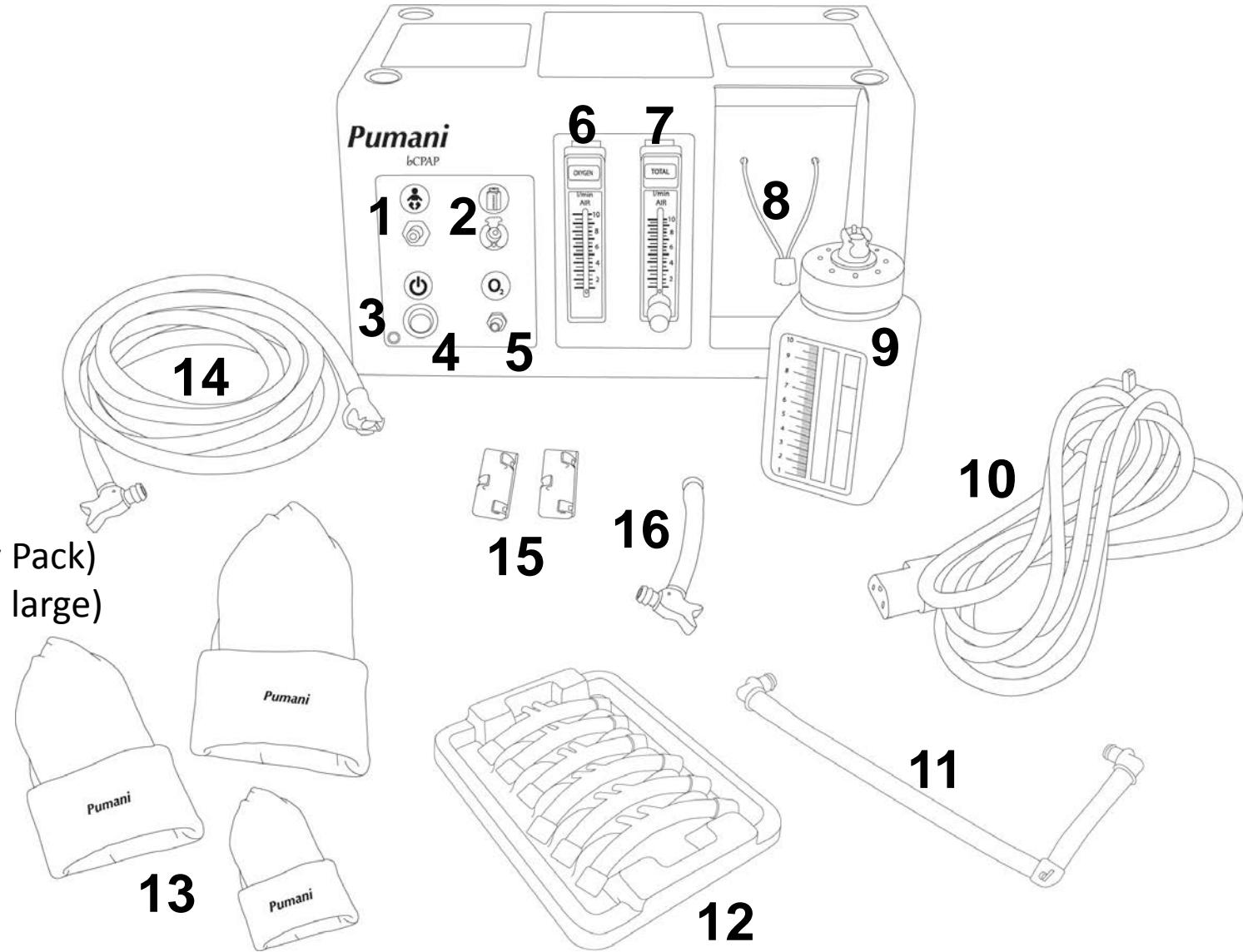
1. Use the device for its intended purpose as described in this instruction manual as a bubble CPAP system for respiratory therapy. Any other use constitutes improper use and may be dangerous. The manufacturer cannot be held liable for any damage caused by improper, incorrect, or unreasonable use of if the unit is connected to electrical installations not complying with safety regulations.
2. If the device has been outside of the operating conditions, allow it to come back to normal operating specifications before use.
3. Keep this manual for future reference.
4. Use the product in a clean environment.
5. Device should not be used around flammable substances.
6. No modification of this equipment is allowed.
7. It is normal for the device to be warm to the touch when in use.
8. Electromagnetic information: Portable and RF communication devices such as cellular phones, pagers, etc. can interrupt operation of electrical medical equipment. For this reason, your Pumani bCPAP must be placed far enough away from these devices to prevent interference. This device meets IEC 60601-1-2 standard for electromagnetic compatibility (EMC). EMC datasheets are available from Hadleigh Health Technologies customer service at 415-454-3005.
9. In case of failure and/or malfunction, read the "Troubleshooting" section.
10. The proper function of the device can be compromised if original replacement parts (e.g., filters) are not used.
11. There is a risk of electric shock when the unit is open.
12. Follow the manufacturer's instructions for installing the device. The manufacturer cannot be held responsible for any damage caused by incorrect installation.
- 5       13. Some parts are small enough to be swallowed by children. Do not let unattended children have access to the unit.
14. When using any electrical appliance, certain important safety measures must always be followed, including the following:
  - Use only manufacturer-supplied original accessories and components;
  - Never submerge the unit in water as the device is not protected against water penetration;
  - Never touch the unit when your hands are wet or moist;
  - Do not leave the unit outdoors;
  - Place on a stable and horizontal surface when operating;
  - Make sure the air vent openings are not obstructed;
  - Do not turn off the unit by simply pulling out the plug from the electrical socket;
  - Do not use if the device has cracks or is damaged.
  - Make sure that the electrical rating shown on the rating label on the bottom of the unit corresponds to your main voltage and frequency before plugging in the device.
  - Do not use any adapter, simple or multiple, and/or extension cord.
  - Do not leave the unit plugged in when not in use. Turn off and unplug the device from the electrical outlet when not in operation.
  - To isolate the device from mains power, unplug the device.
  - Keep pathway to the device plug clear.
15. The power cord cannot be replaced by the user. In case the power cord becomes damaged, contact Hadleigh Health Technologies for replacement.
16. Before performing any cleaning operation or filter replacement, disconnect the device from the main supply by unplugging it.
17. If you no longer use the device, dispose of according to local regulations in force.

# Part I: How to Assemble the Pumani CPAP

# Pumani CPAP Components

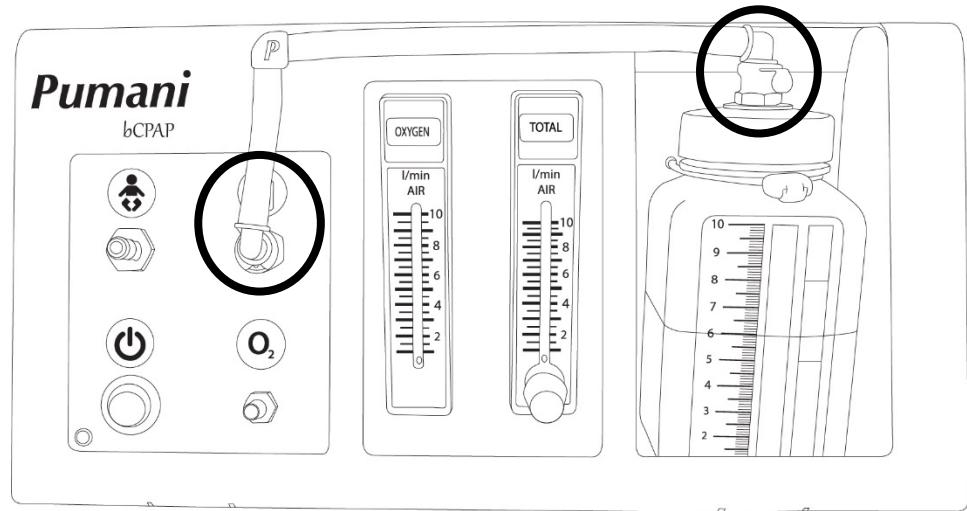
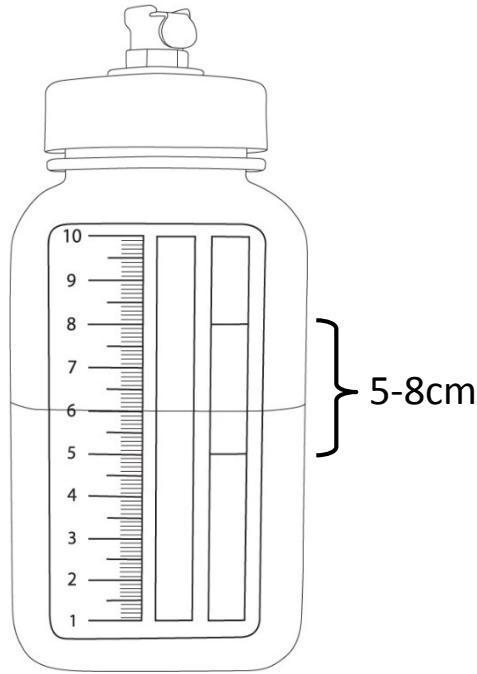
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1. Patient Tubing Port
2. Bottle Tubing Port
3. Power Light
4. Power Switch
5. Oxygen Port
6. Oxygen Flow Meter
7. Total Flow Meter
8. Bottle Strap
9. Bottle and Lid
10. Power Cord
11. Bottle Tubing
12. Nasal Prongs (Variety Pack)
13. Hats (small, medium, large)
14. Patient Tubing
15. Hat Clips
16. End Cap



# Step 1: Filling and Connecting the Bottle

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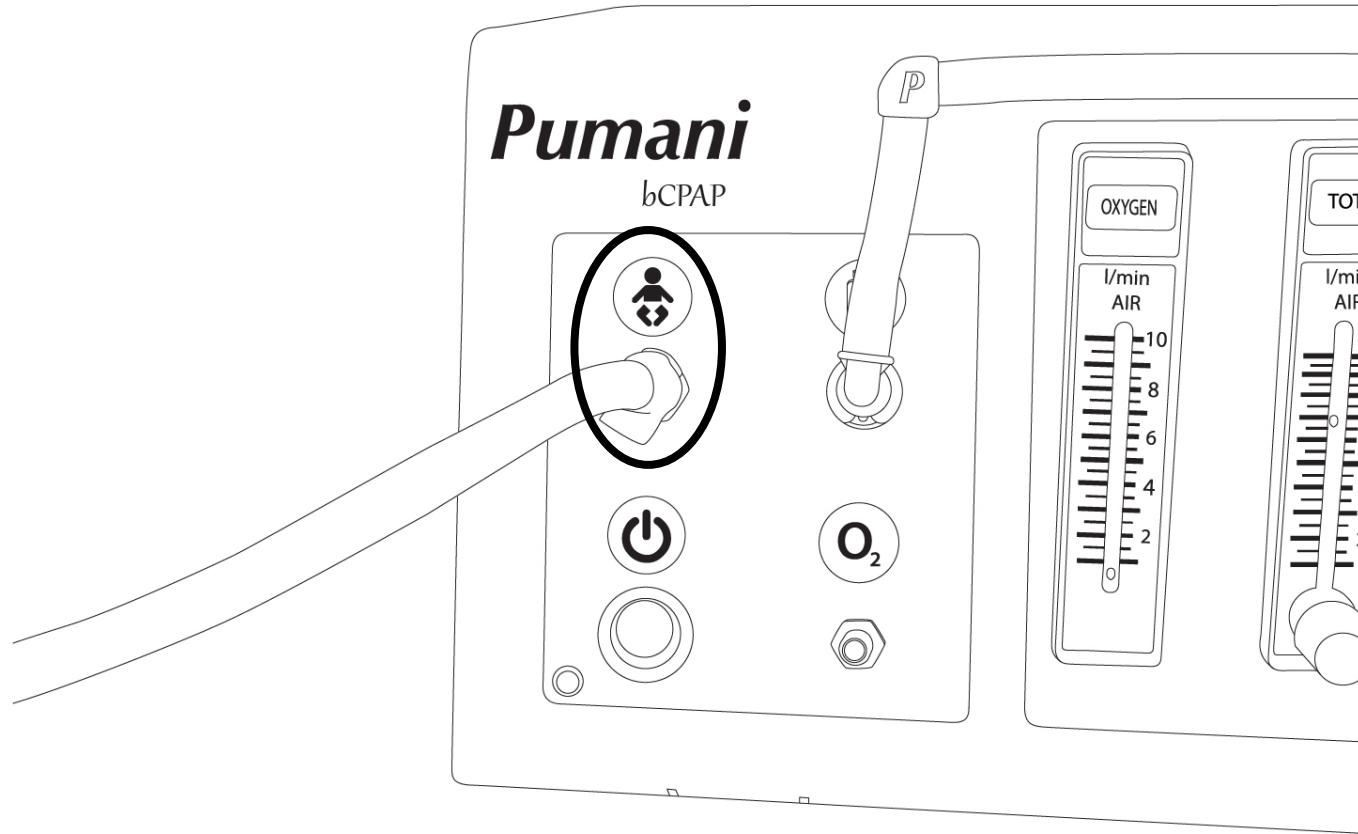


- A. Fill bottle with 5-8cm of water and attach the lid to the bottle.
- Most patients start at **6 cm** of water pressure.
  - Be careful to not fill the bottle above or below the specified level.

- B. Place bottle into bottle strap and connect the bottle tubing to the bottle and to the Pumani CPAP machine.

# Step 2: Connecting the Patient Tubing

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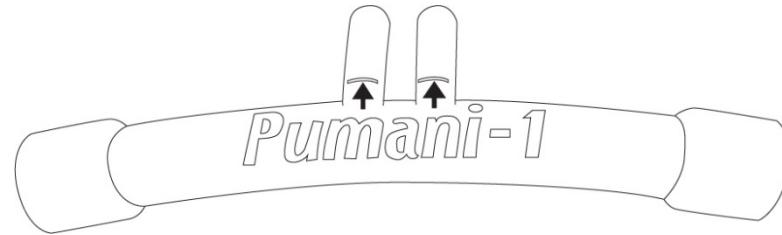


Connect the patient tubing to the Pumani CPAP at the patient tubing port.

# Step 3: Choosing the Prong Size

---

Patient Weight Range	Prong Size
Less than 1,000 grams	0
1,000 grams to 1,250 grams	1
1,250 grams to 2,000 grams	2
2,000 grams to 3,000 grams	3
3,000 grams to 4,000 grams	4
Over 4,000 grams	5

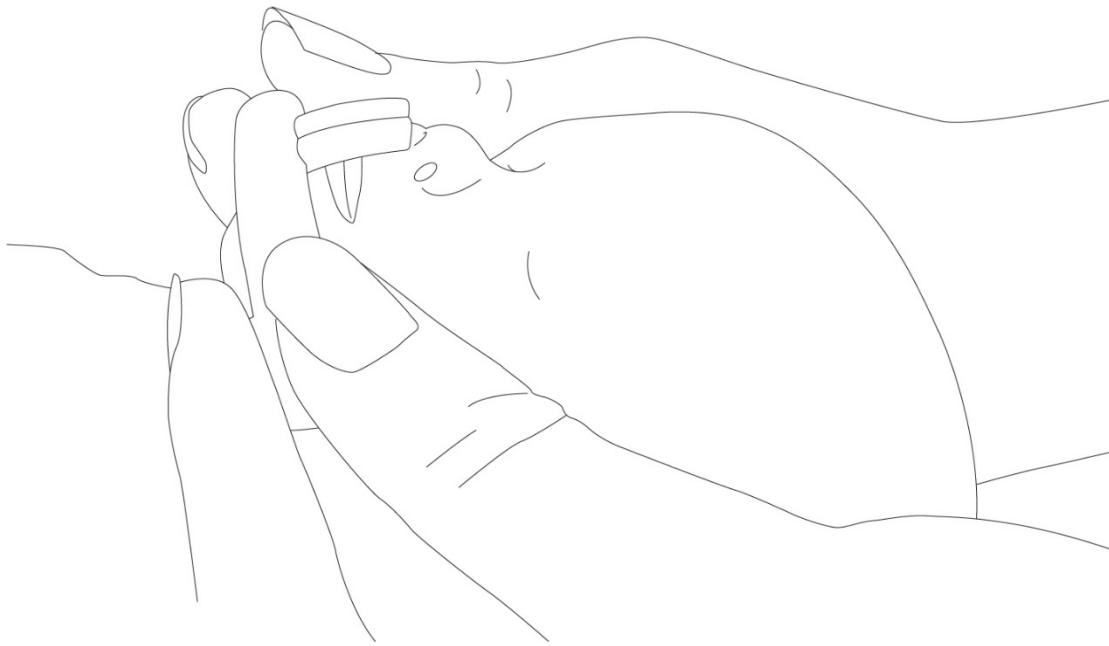


1. Use the patient's weight as a guide to choose the prong size\*.
2. The prong size is located on the nasal prongs.

\*Note that some patients may require a prong size that does not correspond to his or her weight.

# Step 4: Checking Prong Size

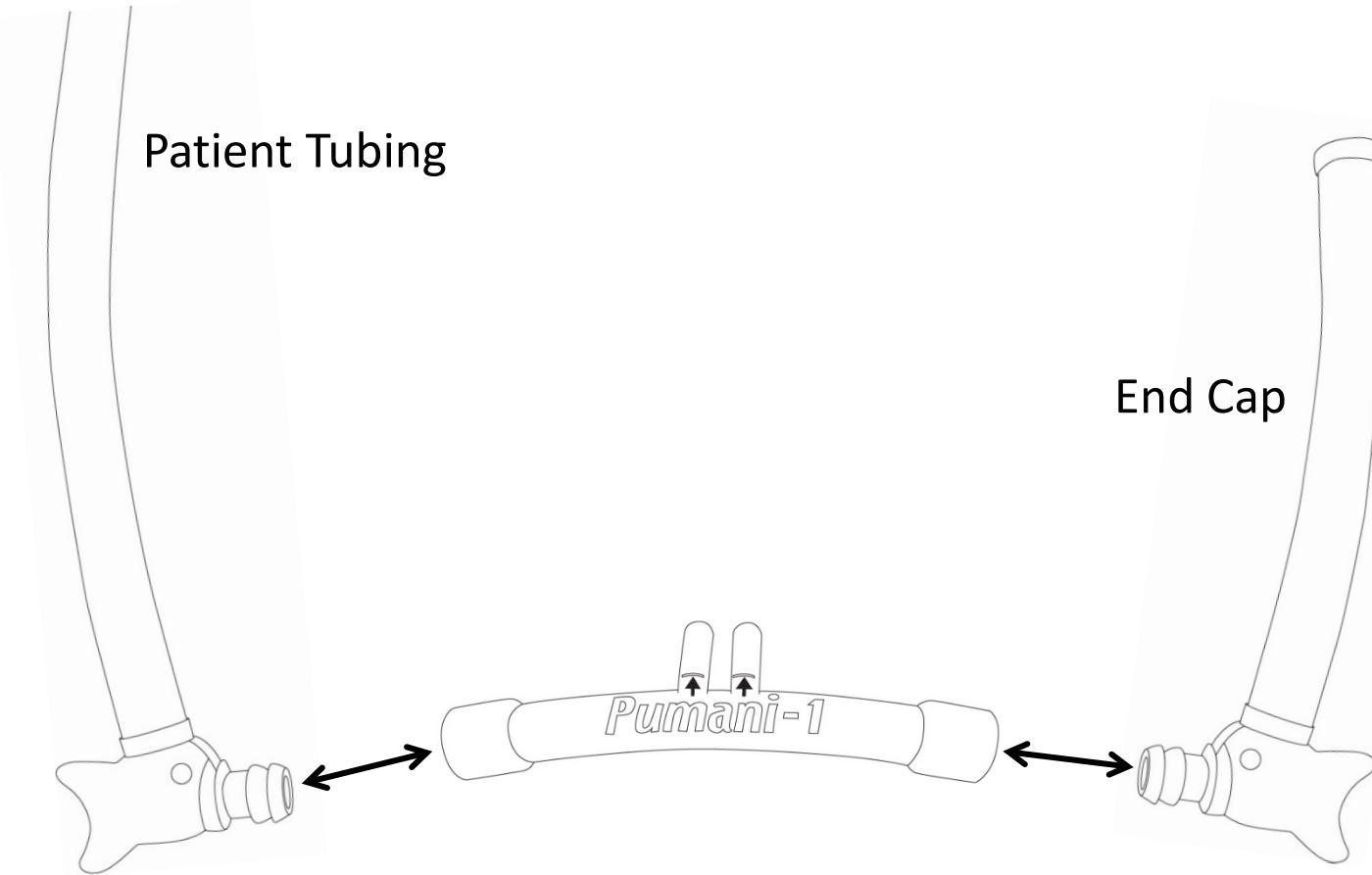
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1. Check the prong size by placing the prongs in the patient's nose.
  - The prongs should be placed curved-side down, as shown.
  - The prongs should **completely fill** each nostril.
  - **Immediately** remove the prongs.
2. If the nostrils are not completely filled, air will leak and the patient will not get the necessary pressure. You will need to replace the prongs with the next largest prong size.

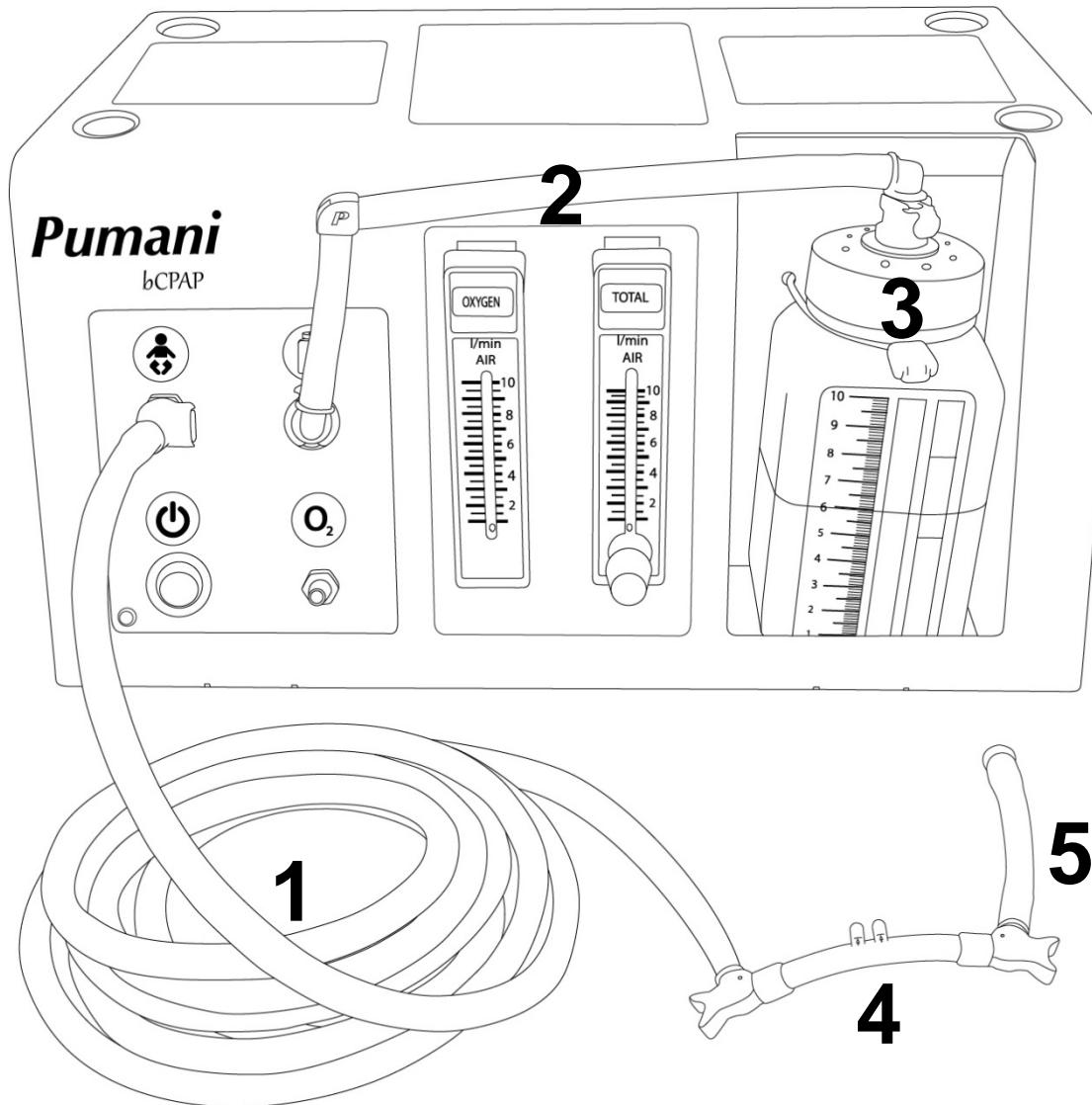
# Step 5: Connecting the Prongs

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Connect the prongs to the patient tubing and to the end cap, as shown above.

# Step 6: Checking the Pumani CPAP Assembly

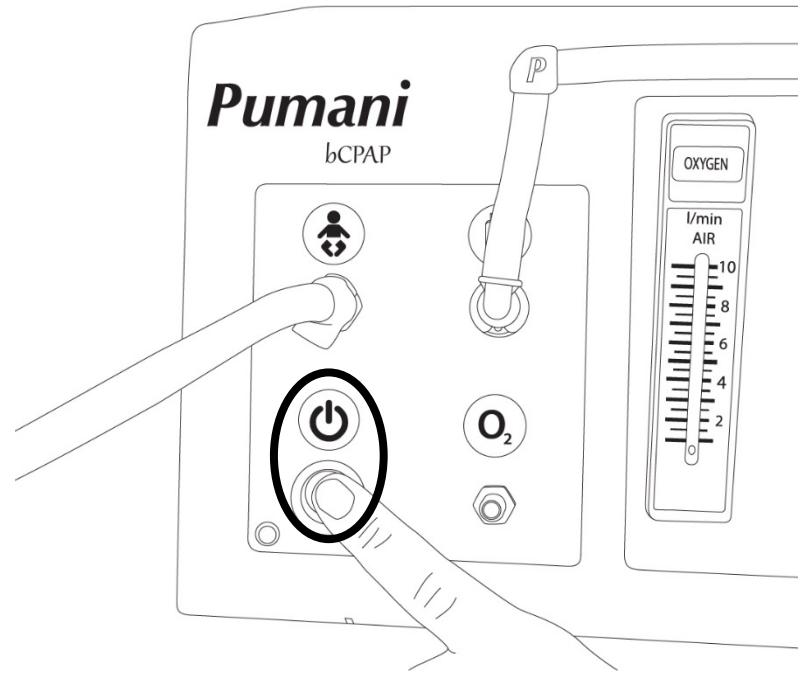
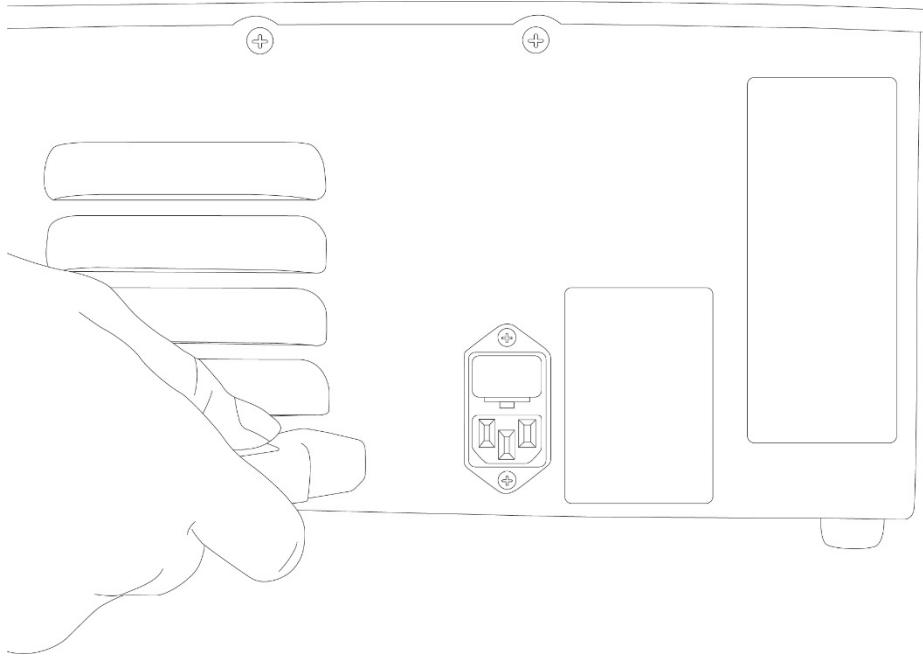


Make sure all of the CPAP components are properly assembled:

1. Patient Tubing
2. Bottle Tubing
3. Bottle and Lid
4. Nasal Prongs
5. End Cap

# Step 7: Turning the Pumani CPAP On

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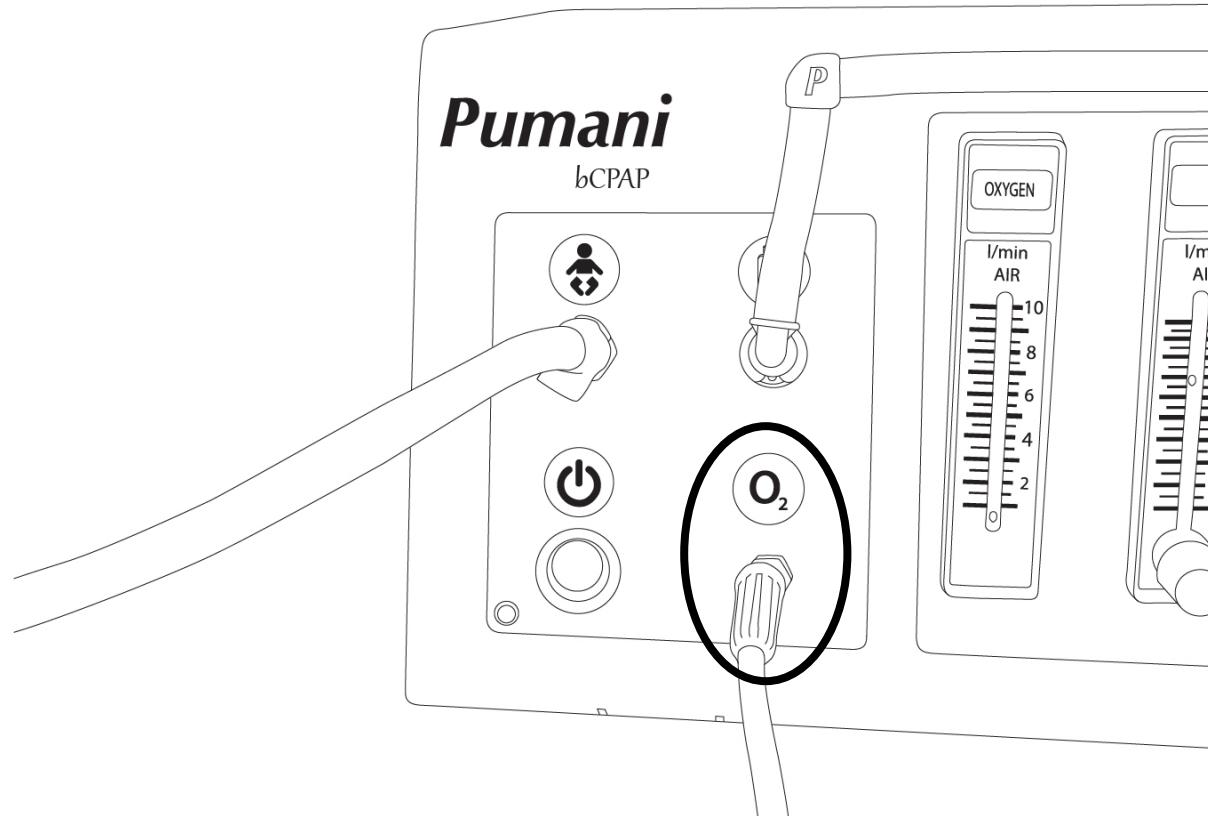


- A. Connect the power cord to the back of the Pumani CPAP and to an electrical outlet.
- B. Turn on the Pumani CPAP power switch. A green light next to the switch should be lit when the Pumani CPAP is on.

# Step 8: Attaching the Oxygen Concentrator

If the patient needs oxygen:

1. Turn on the oxygen concentrator\*.
2. Attach tubing from the oxygen concentrator to the O<sub>2</sub> port\*\*.



\*It is possible to add a bubble-through humidifier after the oxygen concentrator to increase the humidity of the oxygen delivered to the patient.

\*\*The oxygen input pressure should not exceed 34.5 kPa.

# Step 9: Setting Oxygen Flow and Total Flow

Most patients will start at the same settings\*:

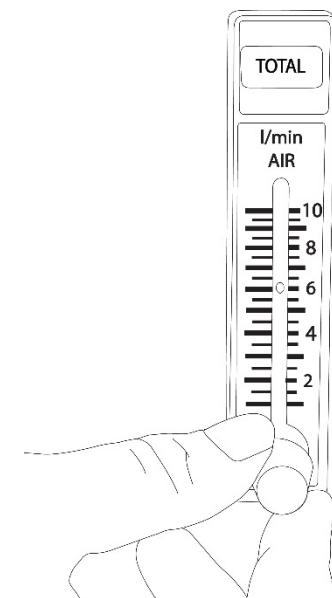
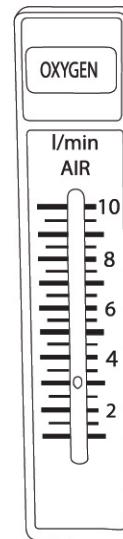
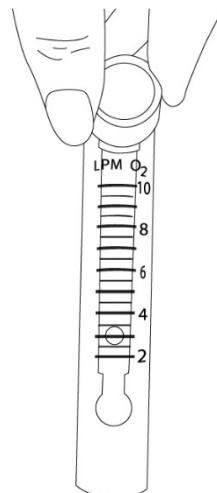
	<b>Concentrator Flow</b>	<b>Oxygen Flow</b>	<b>Total Flow</b>
Neonate	3 L/min	3 L/min	6 L/min
Child	4 L/min	4 L/min	6 L/min

**1**

**2**

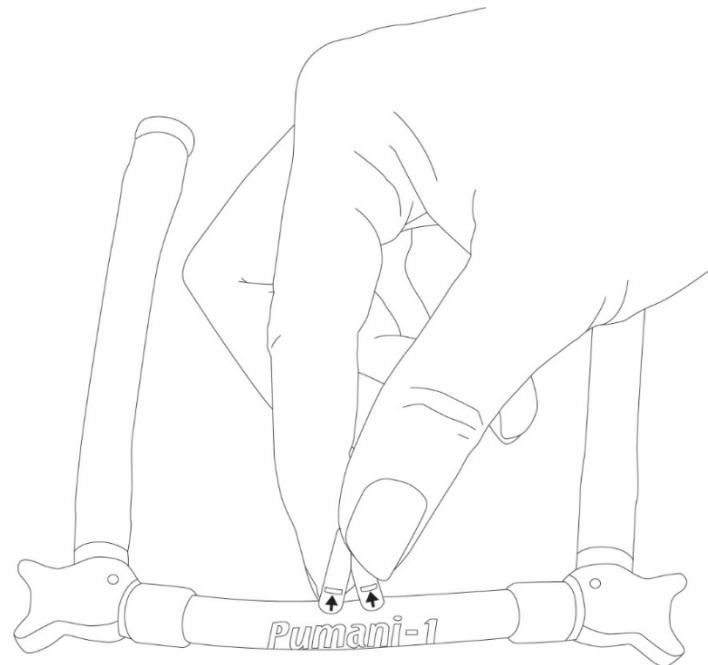
**3**

Set the Concentrator Flow → check the Oxygen Flow → set the Total Flow



# Step 10: Checking the Bubbling Function

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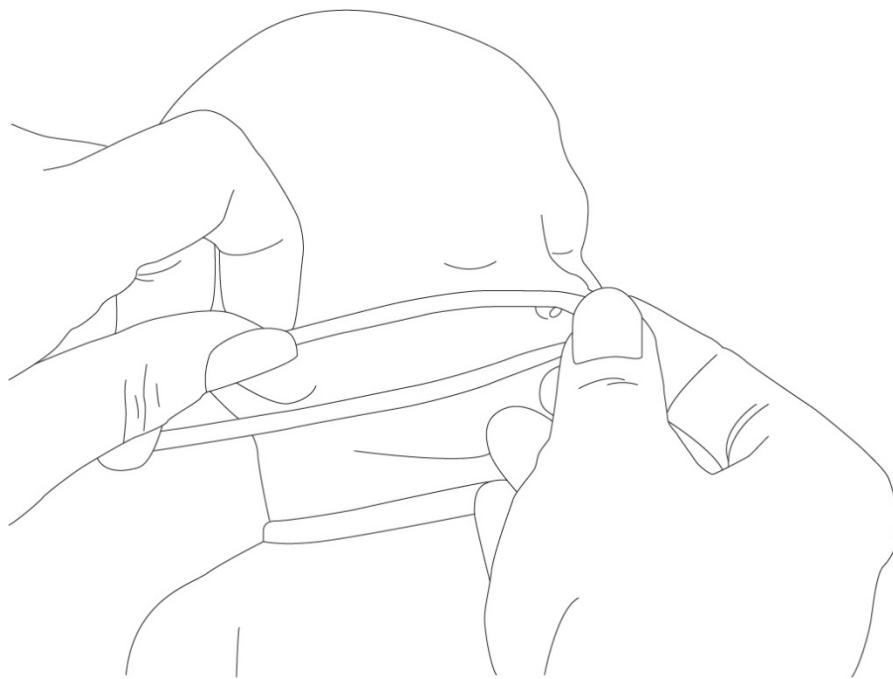


1. Cover the prongs. Water in the bottle should bubble, and you should hear air flowing through the end cap.
2. Remove fingers from prongs. Bubbling should stop.
3. If the bubbling does not start or stop, refer to the Pumani CPAP troubleshooting (page 36).
4. Turn the Pumani CPAP off and continue to Part II: How to Prepare the Baby for CPAP.

## Part II: How to Prepare the Baby for CPAP

# Step 1: Suctioning the Nose & Mouth

---



1. Measure from the nose to the ear and halfway back to determine suction depth of the nose.
  - For example: if the distance is 6 cm, the depth should be 9 cm ( $6+3 = 9$ ).
2. Briefly remove the  $O_2$  tube from the nose. Put a drop of saline in one nostril, insert the tube to the determined depth, then cover the suction port as you pull out the suction tube.
3. Repeat in the other nostril.
4. Place the  $O_2$  tube back into the nose.
5. Suction the mouth.

# Step 2: Inserting the Orogastric (OG) Tube

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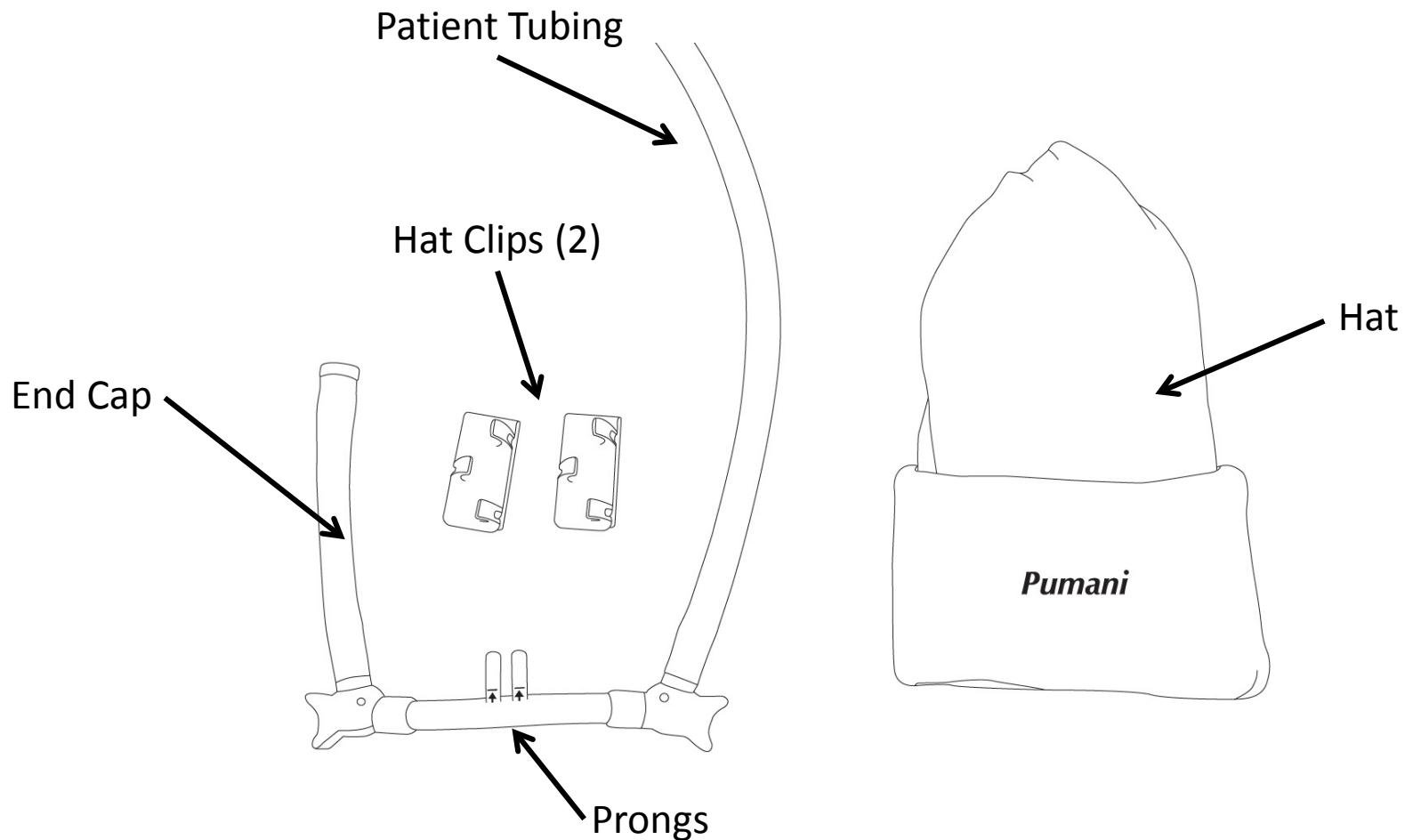
1. Measure from the mouth to the ear, and then to the bottom of the sternum.
2. Make note of the measurement.
3. Insert the OG tube in the mouth to this depth.
4. Check that the OG tube is in the stomach by placing the end of the tubing in water. If it does not bubble, it is in the correct place. (You can also aspirate the OG tube with a syringe to check for stomach contents\*)
5. Tape the OG tube to the chin.

# Part III: How to Attach the Baby to the Pumani CPAP

# Prongs & Hat Components

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These are the items you need to attach the prongs to the baby:

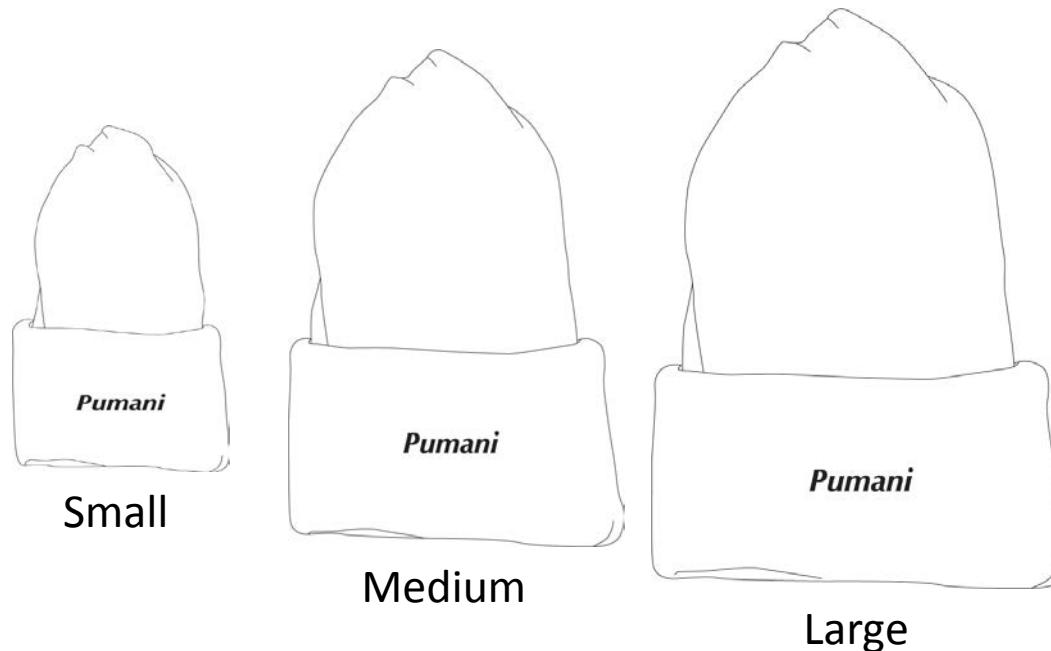


# Step 1: Selecting the Hat Size

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Select hat size based on size of the patient's head or the weight of the patient.

Patient Weight Range	Hat Size
Less than 1,500 grams	Small
1,500 grams to 3,000 grams	Medium
Over 3,000 grams	Large



# Step 2: Placing the Hat on the Patient

---



## 1. Place hat on the patient.

- Make sure that the hat fits tightly to prevent the prongs from moving.
- The back of the hat should be low, near the baby's neck.
- Hat may need to be replaced at least every **24 hours** to keep a tight fit on the baby's head.

# Step 3: Inserting the Prongs

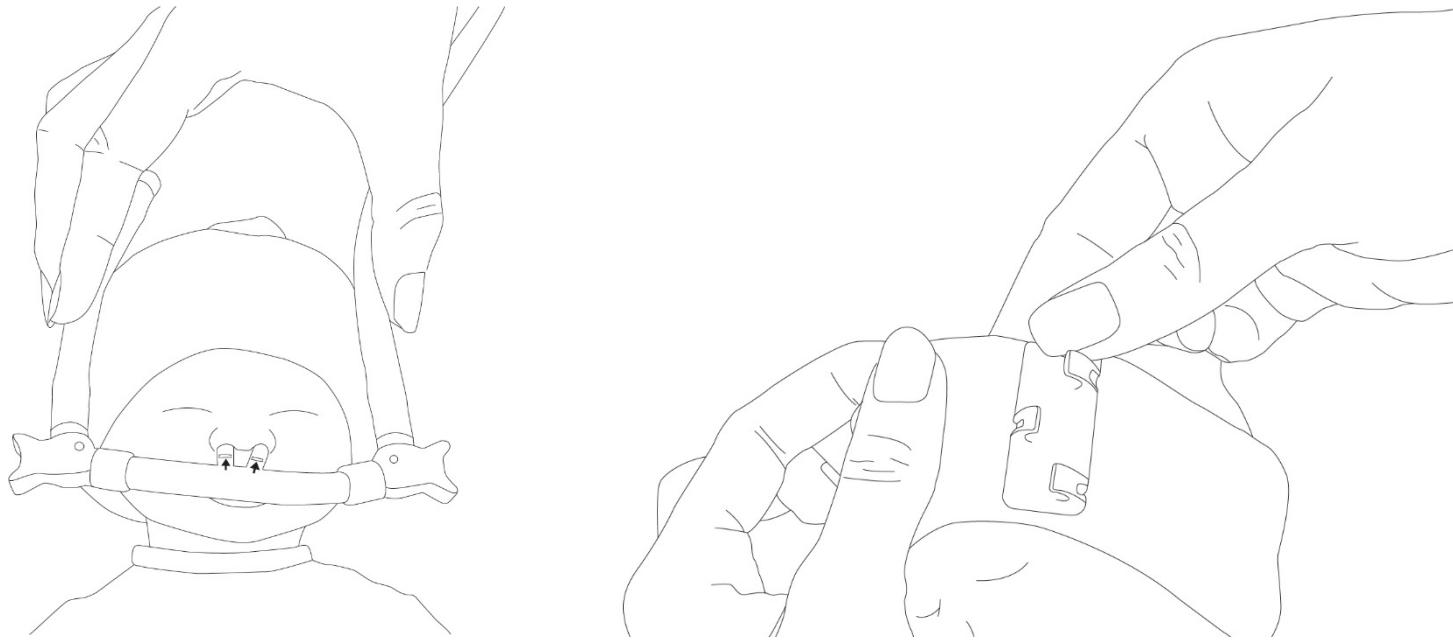
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- 1. Turn on the Pumani CPAP.**
2. Make sure the flow and pressure are still set correctly.
3. Add saline drops in the nose.
  - Do not use creams or ointments, as these can cause breakdown of the skin and block the prongs.
4. Place the prongs into the nose.
  - There should be a  $\frac{1}{4}$  cm space between the prongs and the nose.
  - If you cannot see the lines on the prongs, the prongs are inserted too far into the nose. Pull the prongs slightly out of the nose until you see the lines.

# Step 4: Attaching the Hat Clips

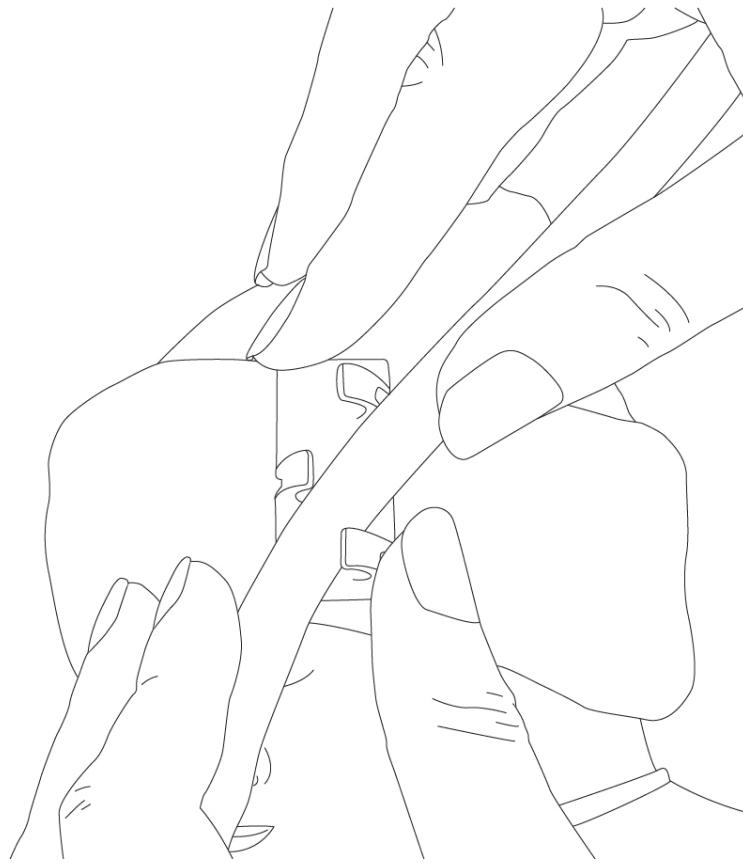
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1. Hold the prongs on the hat to determine where to place the hat clips on the hat. Make sure the prongs stay in the nose.
2. Place fingers under the brim of the hat to maintain space between the hat and the head when placing the hat clips.
3. Slide the two hat clips onto the brim of the hat.
  - The hat clips should **never** be in contact with the patient.

# Step 5: Inserting the Tubing into the Clip

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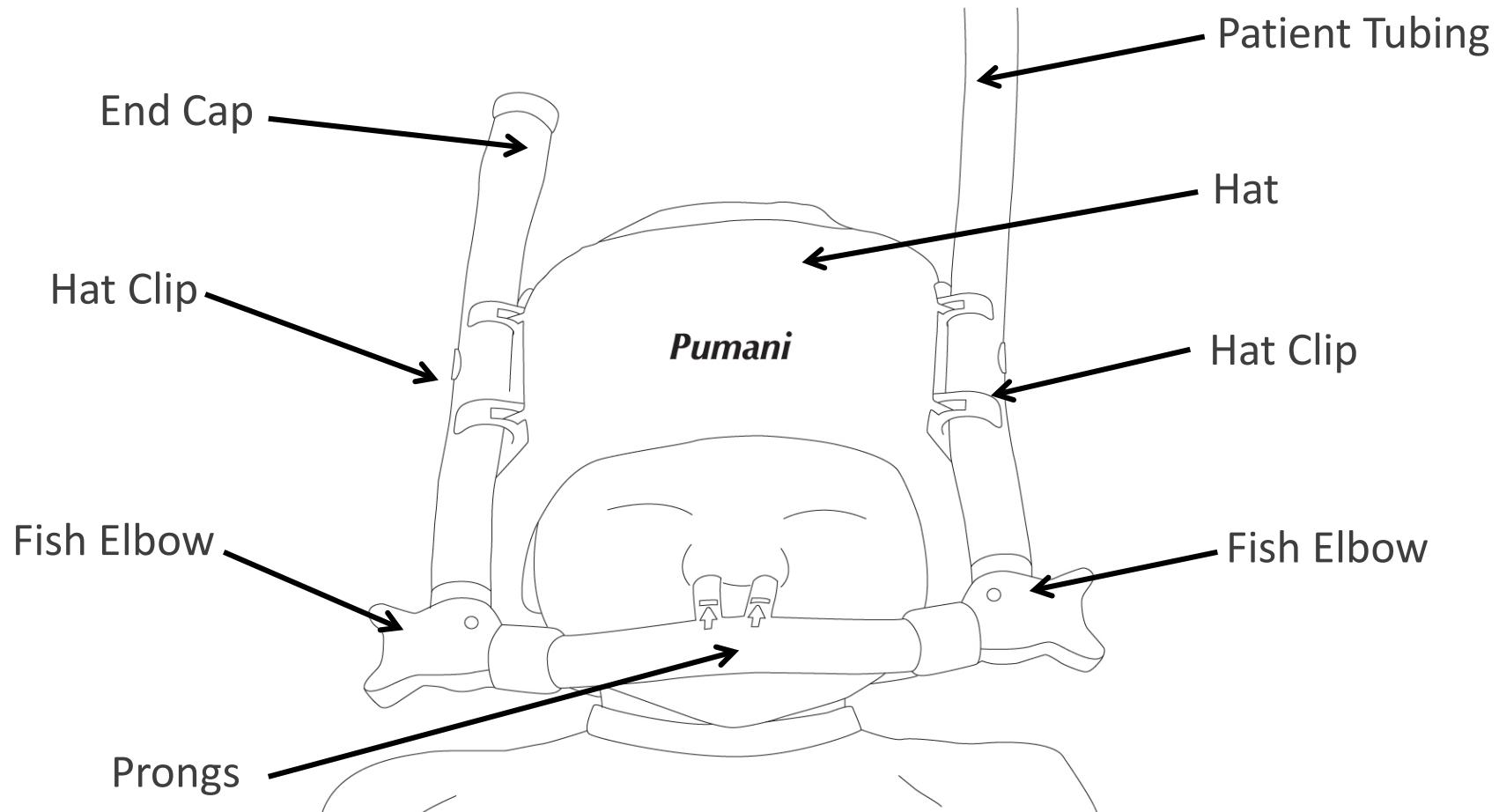


1. Insert the tubing into the hat clip, between the 3 tube holders.
2. Rotate the tubing until it fits tightly into the hat clip.
3. Repeat for the other hat clip.

# Step 6: Check the Prongs

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This is how the prongs should appear once they are attached to the patient:

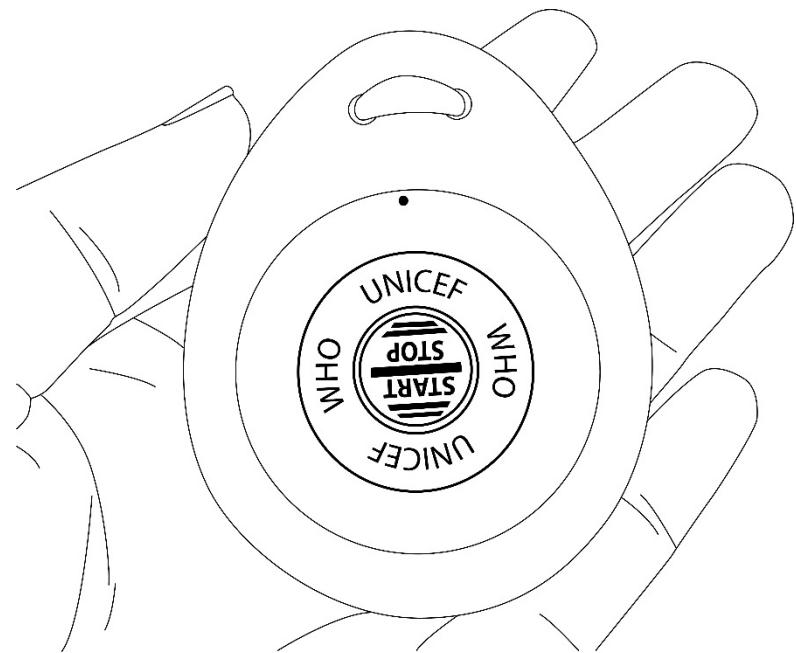


# Part IV: How to Monitor the Baby

# Checking the Respiratory Rate

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1. Once the patient is settled on the Pumani CPAP, the respiratory rate should be measured.
2. To measure the respiratory rate:
  - Uncover the patient's abdomen so you can view the chest.
  - Press the respiratory rate timer to start the **60-second** count.
  - As soon as you press the timer, begin counting the patient's breaths.
  - The timer will beep once after 30 seconds – do not stop counting. When the timer beeps **twice**, stop counting.
  - Record the respiratory rate.

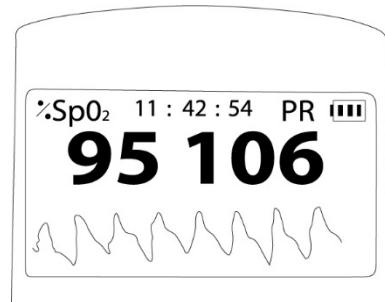


# Checking the Oxygen Saturation

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1. Once the patient is settled on the Pumani CPAP, the oxygen saturation should be checked with a pulse oximeter.
2. Place the pulse oximeter probe on the patient.
  - For smaller babies, wrap the probe around the palm of the baby's hand
  - For larger babies, place the finger probe on the patient's finger
3. Turn the pulse oximeter on.
4. Watch the waveform for 1-2 minutes until it is constant.

Good Waveform:



Bad Waveform:



5. Record the oxygen saturation and heart rate.
6. If the oxygen saturation is <90%, increase the oxygen flow rate by 1 L/min.

# Patient Monitoring Checklist

What to Check For	Response
Is the power on?	If the power is <b>NOT</b> on: <ul style="list-style-type: none"><li>– Remove the prongs <b>immediately</b></li><li>– Place the patient on oxygen</li><li>– Turn off the Pumani CPAP (this will stop the alarm)</li><li>– If possible, take the Pumani CPAP to a ward with power</li><li>– Document how long the patient was off CPAP and how long the patient was on oxygen</li></ul>
Are the nostrils moist?	If the patient's nostrils are not moist: <ul style="list-style-type: none"><li>– Place saline drops in the patient's nostrils</li></ul>
Are the prongs in the patient's nose?	If the prongs are not in the patient's nose: <ul style="list-style-type: none"><li>– Re-insert the prongs into the patient's nose</li><li>– You may need to reposition the hat or hat clips to keep the prongs in place</li></ul>
Is the hat tight on the patient's head?	If the hat is not tight on the patient's head: <ul style="list-style-type: none"><li>– Remove the hat and replace the hat with a new hat</li></ul>
Is the water bubbling?	If the water is <b>NOT</b> bubbling: <ul style="list-style-type: none"><li>– Check the water level (the water may evaporate)</li><li>– Check that the prongs are in the patient's nose</li><li>– Add water, if necessary</li><li>– Make sure the oxygen and total flow settings are correct</li></ul>

## Part V: Alarm Instructions

# Alarm Instructions

---

The alarm inside of the Pumani bCPAP will sound when power to the unit is lost.

***The alarm can be turned off by switching the power switch off.***

To verify the functionality of the alarm system, unplug the Pumani bCPAP while the unit is running and confirm that the alarm sounds. This functionality should be confirmed at least once per year.

These are the alarm conditions:

Starting State		Event 1	Behavior	Event 2	Behavior
Power	Switch				
Disconnected	On	Power Connected	Alarm does not sound		
Disconnected	Off	Power Connected	Alarm does not sound		
Connected	On	Switch Turned off	Alarm does not sound		
Connected	Off	Switch Turned on	Alarm does not sound		
Connected	On	Power Loss	Alarm sounds for 3 min*		
Connected	On	Power Loss	Alarm Sounds	Switch turned off	Alarm does not sound

# Part VI: Troubleshooting

# Pumani CPAP Troubleshooting

Problem	Possible Cause	Solution
The Pumani CPAP does not turn on.	The Pumani CPAP does not have power.	Check to see that the Pumani CPAP is plugged in and that the outlet is switched on.
	The switch is not in the “on” position.	Turn switch to “on” position. A green light should be lit when the Pumani CPAP is on.
The alarm is sounding.	The power to the Pumani CPAP has been lost.	Turn switch off. Turn switch on when power returns.
Water does not bubble when I cover the prongs with my fingers.	The bottle tubing and patient tubing are not correctly connected.	Correctly connect tubing. Connectors should snap into place.
	The total flow is not high enough.	Slightly increase the total flow until the water starts to bubble.
Water bubbles when the prongs are uncovered.	The bottle tubing or patient tubing is pinched or blocked.	Check for and resolve any pinches or blocks.
	The total flow is too high.	Slightly decrease the total flow until the water stops bubbling.
There is no O <sub>2</sub> flow.	The oxygen tubing is improperly connected.	Fix concentrator tubing connections.
	The concentrator is improperly connected.	Make sure the concentrator is plugged in, turned on, and the nozzle is completely attached.
The flow knob has detached from the meter.	The knob was fully loosened.	Insert the knob into the meter and turn the knob to the right until it reattaches.

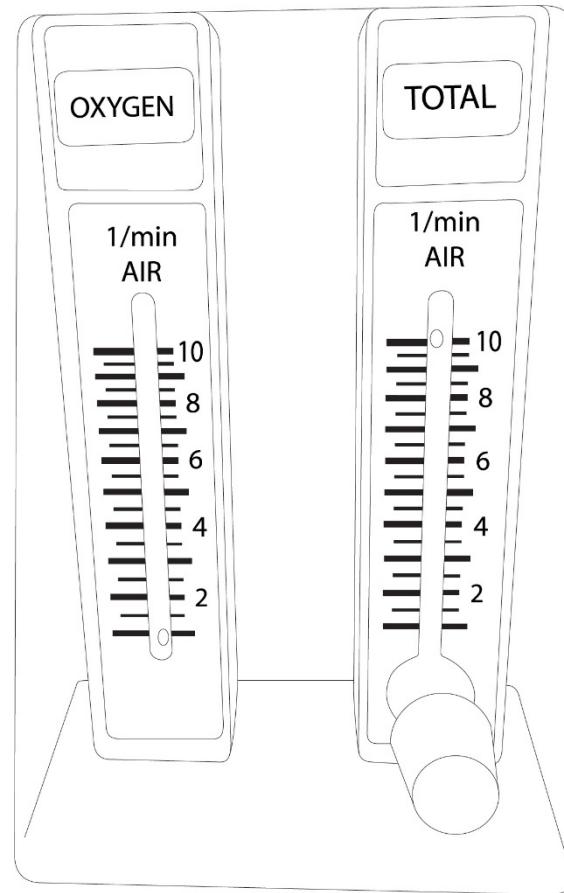
# Prong Troubleshooting

Problem	Possible Cause	Solution
Water does not bubble when the prongs are placed in the airway.	The prongs are too small.	Replace the prongs with a larger size.
	The prongs are positioned incorrectly.	Reposition the prongs.
	Air is leaking out of the mouth.	Gently close the baby's mouth for a few moments to encourage nose breathing.
The prongs do not stay in the nose.	The prongs are too small.	Replace the prongs with a larger size.
	The hat is stretched out or too large.	Replace the hat with a new or smaller hat.
	The hat clips are improperly aligned.	Realign the hat clips.
	The tubing on the hat is improperly positioned.	Reposition the tubing on the hat.
The patient does not tolerate the prongs.	The prongs are too small or are pinching on the patient's septum.	Replace the prongs with a larger size.
	The prongs are pushing up against the septum.	Increase space between the prongs and the septum. Consider replacing the prongs with a larger size.
	The patient has not settled.	After the prongs are placed, wait for the patient to settle. This may take a few minutes.

## Part VII: Pumani CPAP Repair Instructions

# Checking the Total Flow

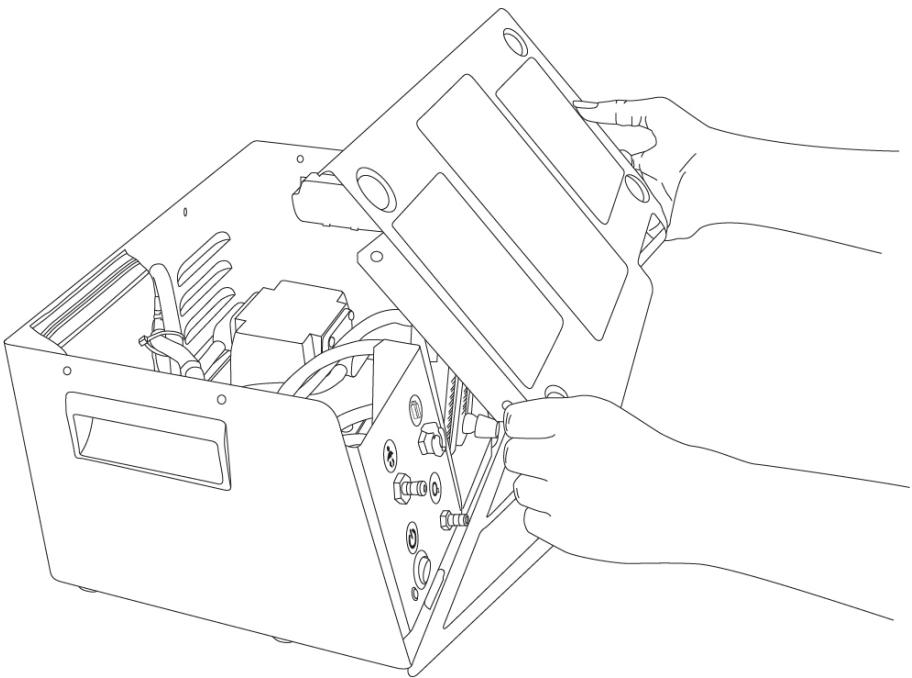
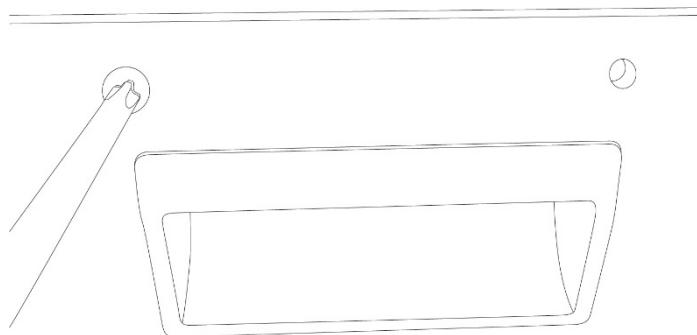
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1. First, check the total flow of the Pumani CPAP. It should go up to 10 L/min (without oxygen flow).
2. If it is below 10 L/min, you should open the Pumani CPAP to determine why the total flow is low.

# Opening the Pumani CPAP

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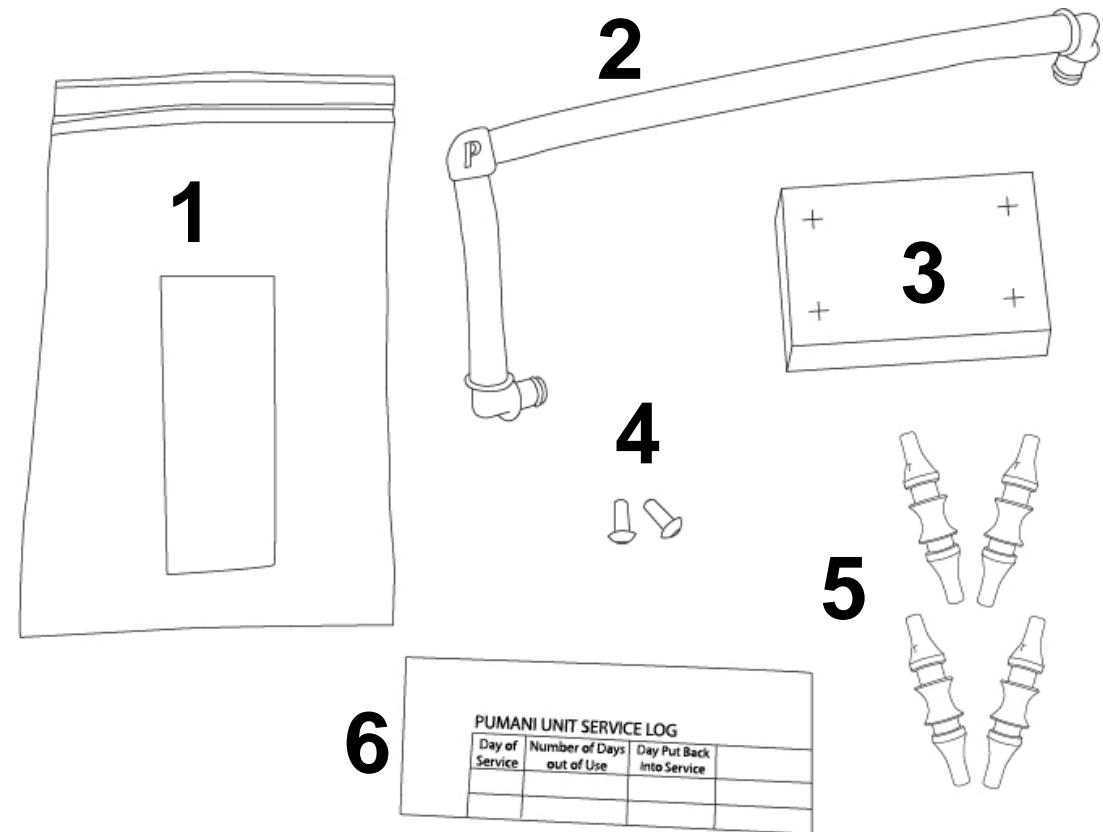
1. Turn off and unplug the Pumani CPAP.
2. Detach the bottle tube from the machine.
3. Unscrew and remove the 6 screws around the top of the CPAP using a Philips head screwdriver.
4. Pull the lid of the CPAP away from the machine.

# Spare Kit Bag Contents

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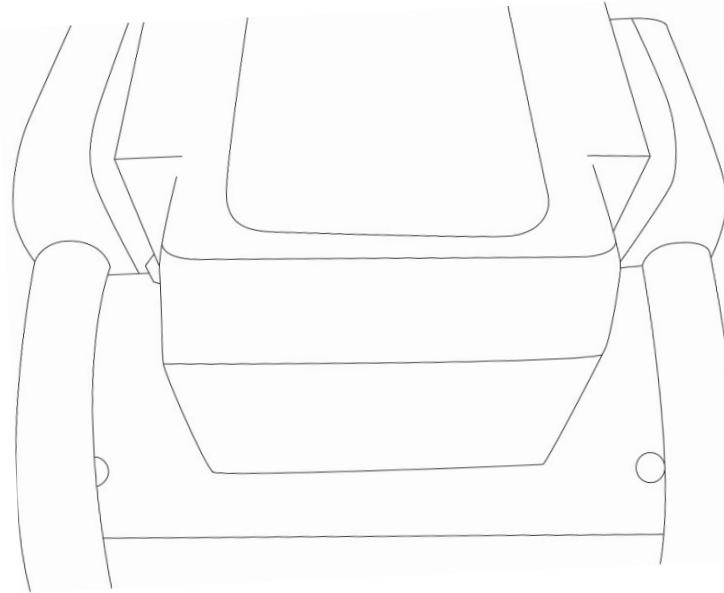
The Spare Kit Bag, found on the right wall of the Pumani CPAP, contains:

1. Spare kit bag
2. Bottle tubing
3. Pump filter
4. Two Phillips screws
5. Four rubber feet
6. Pumani Unit Service Log



# Pump Troubleshooting - Tubing

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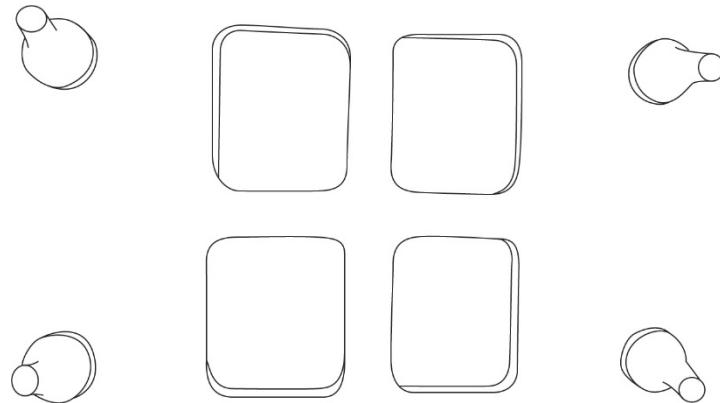
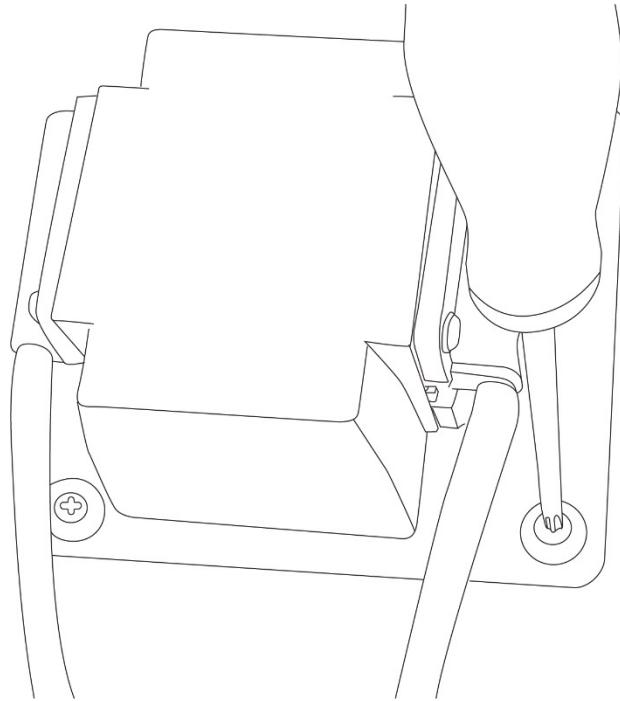
Tubing correctly attached to the pump outlet.

Inside of the Pumani CPAP, check that the tubing is attached to both pump outlets and that the outlets are intact (not broken).

- If the tubing is not attached, reattach it.
- If the tubing has come off the pump, reattach the tubing to the pump outlet.
- If the pump outlet has broken off, contact the manufacturer to replace the pump.

# Pump Troubleshooting - Filter

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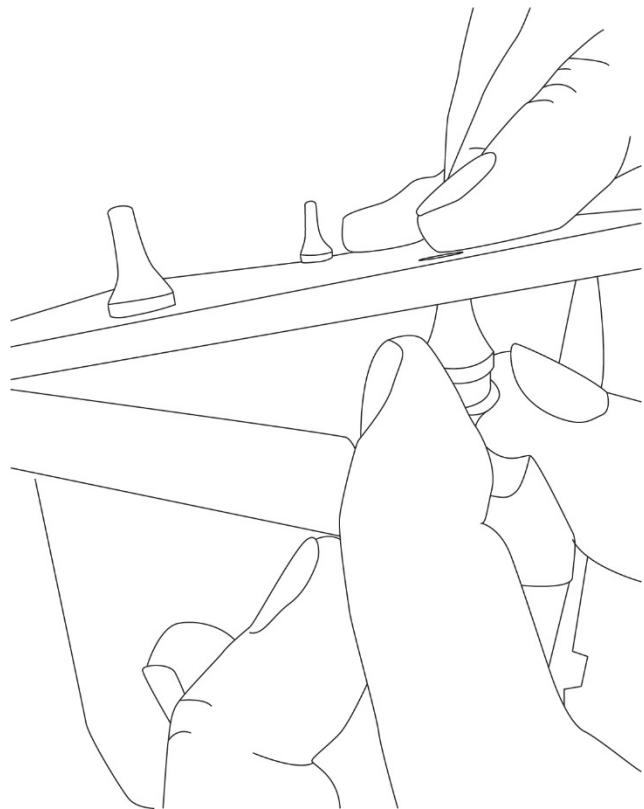
No visible dust on the filter. Do not replace the filter.

## Check the pump filter:

- Unscrew and remove the 4 screws holding the pump mounting plate with a Phillips head screw driver.
- Turn the pump over.
- Inspect the filter for any visible dust.
- If dust is visible, you may need to replace the filter. The dust in the filter can limit the air flow out of the Pumani CPAP.
- To replace the pump filter, go to Repair Step 1.

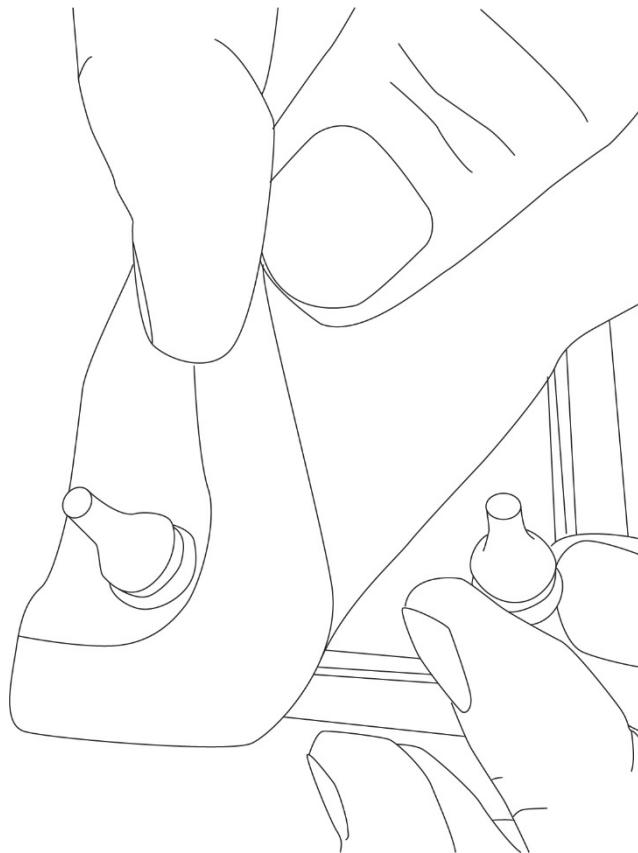
# Pump Repair Step 1

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Pull the pump mounting plate through the rubber feet.

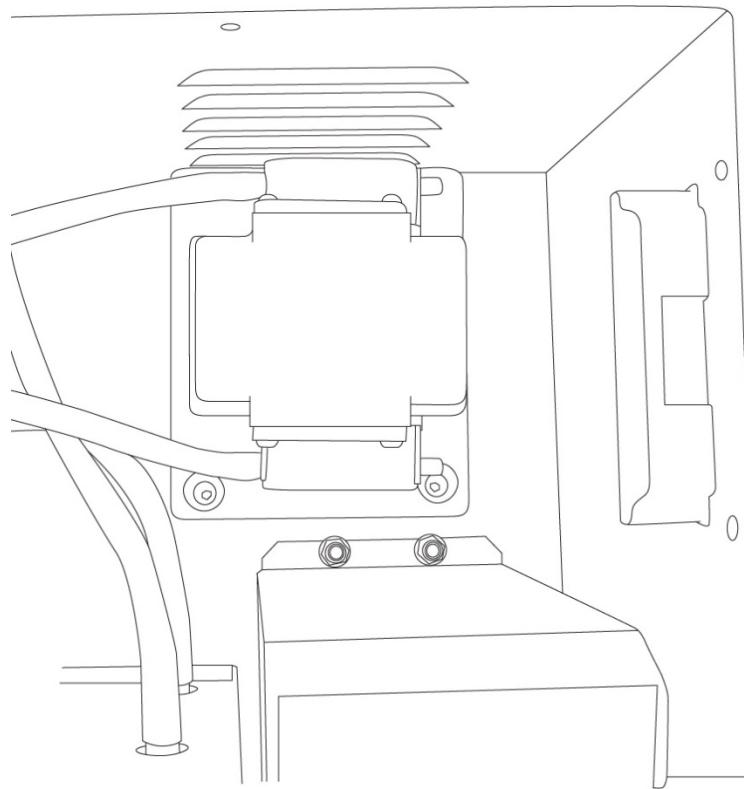
\*If the rubber feet break, go to  
Pump Repair Step 6.



Pull the filter through the rubber feet. Set the filter aside.

# Pump Repair Step 2

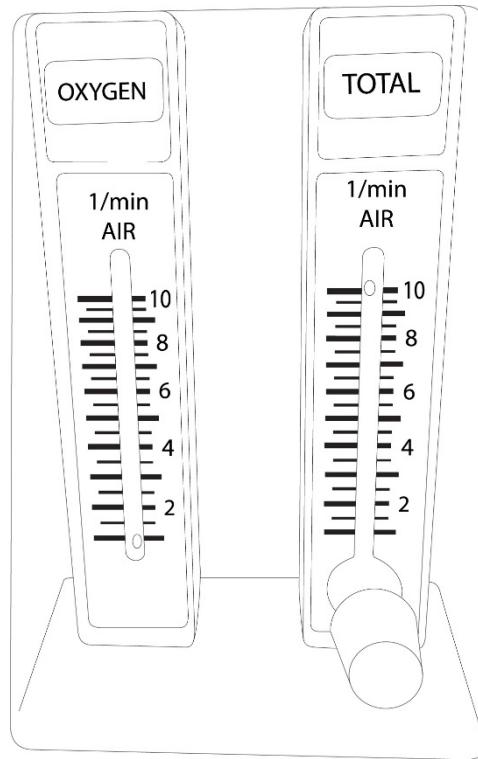
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Reattach the tubing to the pump outlets. Lay the pump back into the enclosure but do not secure the mounting plate with the screws.

# Pump Repair Step 3

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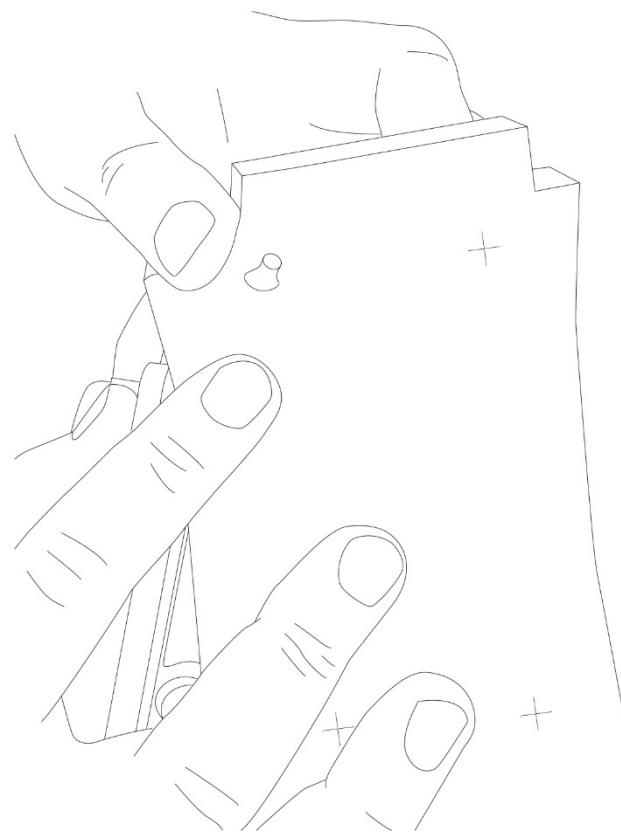


Plug in and turn on the Pumani CPAP. Check to see if the Total Flow is now 10 L/min. If the Total Flow is now 10 L/min, you will need to replace the filter. Go to Pump Repair Step 4.

If the Total Flow is less than 8 L/min, you will need to replace the pump. Contact the manufacturer to replace the pump.

# Pump Repair Step 4

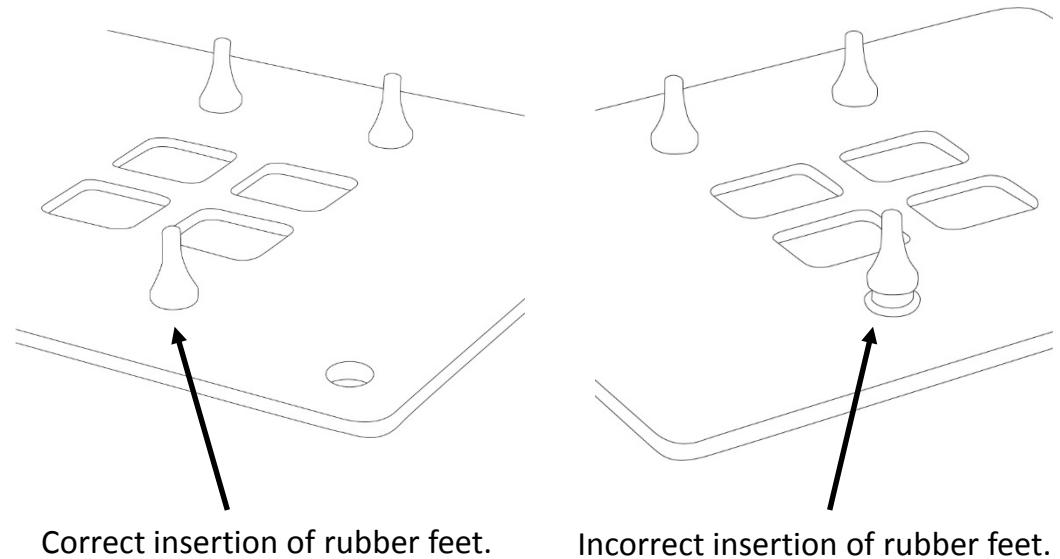
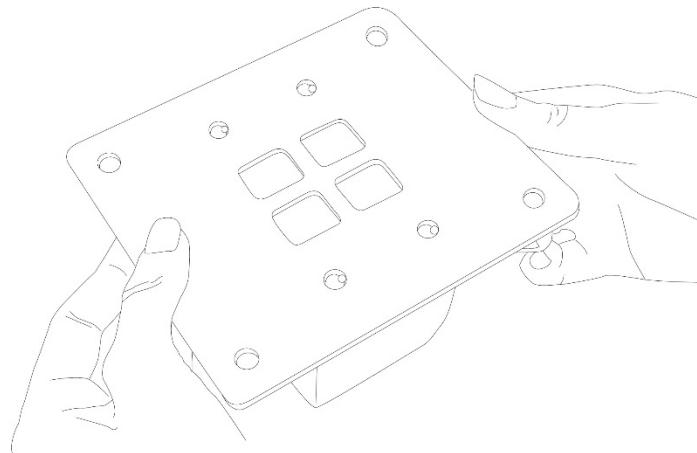
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Dispose of the old filter. Take the replacement filter out of the spare parts kit. Pull the rubber feet through the 4 holes in the filter.

# Pump Repair Step 5

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Align the 4 mounting plate holes over the rubber feet. Gently pull the rubber feet through the mounting plate (but not completely through the plate).

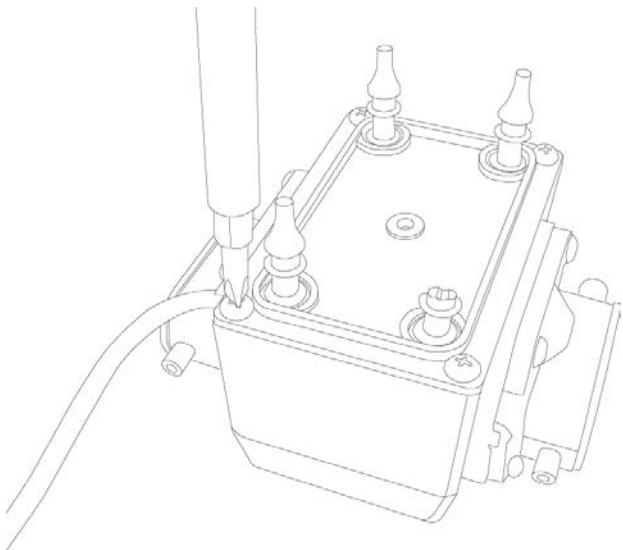
\*If the rubber feet break, go to Pump Repair Step 6.

# Pump Repair Step 6

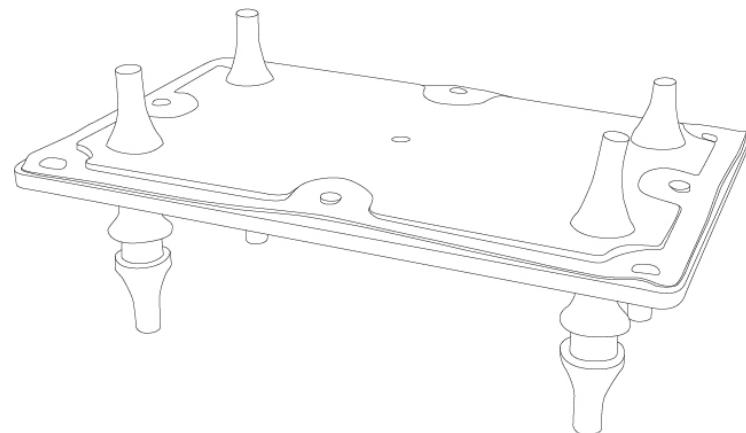
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If the rubber feet are not broken, proceed to Step 7.

If the rubber feet are broken, you will need to replace the broken rubber feet with replacement feet found in the spare parts kit.



Remove the four screws holding the pump base. Remove the pump base from the pump.

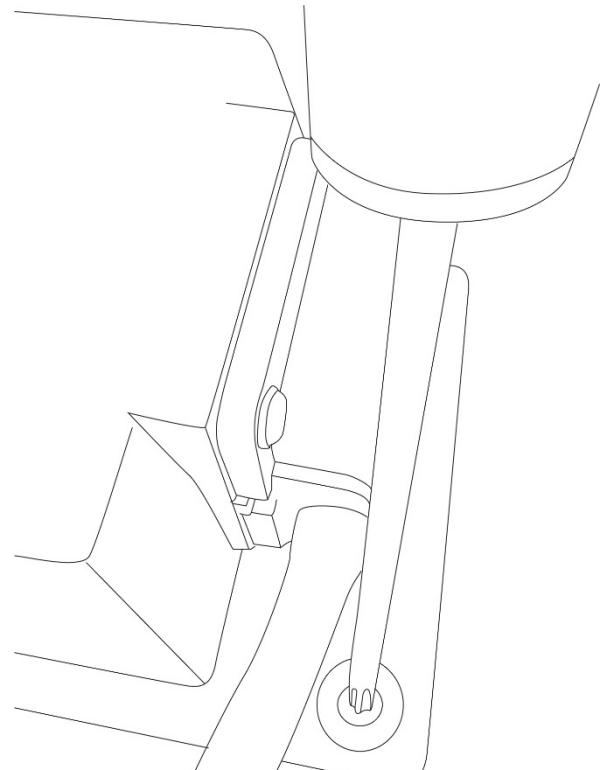


Remove and discard any broken rubber feet. Insert the spare rubber feet into the pump base as shown above.

Reattach the pump base.

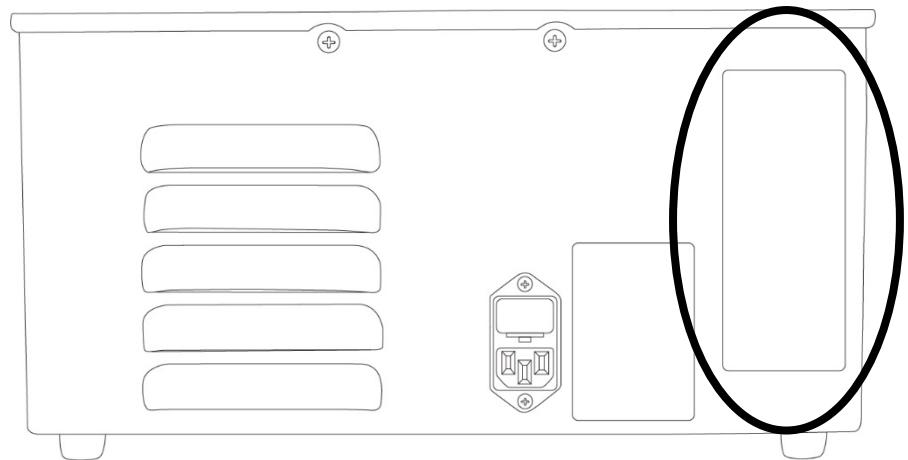
# Pump Repair Step 7

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Record work done:

PUMANI UNIT SERVICE LOG		
Day of Service	Number of Days out of Use	Day Put Back into Service



Screw the mounting plate back onto the base of the Pumani CPAP.

Record all work done in the Pumani Unit Service Log (in the spare parts kit) and on the maintenance label on the back of the machine.

- 50 Close the Pumani CPAP with the six Phillips head screws.

# Appendix A: Oxygen Blending Table

1. Choose the Total Flow Rate (L/min) to deliver to the patient.
2. Choose the Fraction of Inspired Oxygen ( $\text{FiO}_2$ ) Level to deliver to the patient.
3. The table value where the Total Flow Rate and  $\text{FiO}_2$  Level meet is the Suggested  $\text{O}_2$  Flow Rate\*.

An **Example Setting** is shown in the table to the right:

A patient requires a Total Flow Rate of 8 L/min and an  $\text{FiO}_2$  Level of 60%. Therefore, the Suggested  $\text{O}_2$  Flow Rate is 5 L/min.

$\text{FiO}_2$ Level	Total Flow Rate (L/min)					
	5	6	7	8	9	10
	Suggested $\text{O}_2$ Flow Rate (L/min)					
20% $\text{O}_2$	0	0	0	0	0	0
30% $\text{O}_2$	1	1.5	2	2	2.5	2.5
40% $\text{O}_2$	2	2.5	3	3.5	4	4.5
50% $\text{O}_2$	3	3.5	4	4.5	5	5.5
60% $\text{O}_2$	3.5	4	4.5	5	5.5	6.5
70% $\text{O}_2$	3.5	4.5	5	6	6.5	7.5
80% $\text{O}_2$	4	5	5.5	6.5	7	8.5
90% $\text{O}_2$	4.5	5.5	6	7	8	9



For questions or comments concerning the Pumani bCPAP Design and Manufacture by Hadleigh Health Technologies:



Hadleigh Health Technologies, LLC

30 Castro Ave

San Rafael, CA 94901, USA

+1 (415) 454-3005

[info@hadleighhealthtechnologies.com](mailto:info@hadleighhealthtechnologies.com)

[www.hadleighhealthtechnologies.com](http://www.hadleighhealthtechnologies.com)



Emergo Europe

Molenstraat 15

The Hague, 2513 BH

The Netherlands