ENG

Baby CPAP 10 & 20

Instructions for use

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Read this page first

INTENDED USE

This device is suitable for use in hospital settings with limited resources or in any field or outreach locations (where a suitable power source is available) and is suitable for neonates and paediatric patients. CPAP 10 for neonates (< 5kg only) and CPAP 20 for neonates and paediatric patients (<20kg)

Note: These weights and parameters should be considered by the clinical team as a guideline only. Clinical decisions should be decided by the clinical team on a case by case basis depending on the patient's condition.

The Diamedica Baby CPAP provides effective and efficient non-invasive airway pressure support to neonate and paediatric patients in difficult environments.

FOREWORD

This manual is intended to provide guidance on the function, performance and user maintenance of the Diamedica Baby CPAP. The information given in this manual is correct at the date of publication.

A separate user manual for the oxygen concentrator is also included and must be reviewed for specific safety and maintenance requirements before use.

The policy of Diamedica (UK) Ltd is to continuously improve its products. Changes may be made to this manual without notice being given.

Users of the Diamedica Baby CPAP must read, understand and follow the guidance given in this manual before using the system.

THE NEED FOR PATIENT MONITORING

The Diamedica Baby CPAP delivers adjustable mixtures of oxygen-enriched air to the patient and the device should be monitored at all times.

It is essential that the patient's oxygen saturation and other vital functions are also monitored.

The ultimate responsibility for patient safety remains with the operator.

Observations of the patient must take precedence over machine settings in judging the condition of the patient.

The system is only intended for use by competent medical personnel.

CONTRAINDICATIONS, CAUTIONS & WARNINGS

CPAP should not be initiated in patients for whom improvement on nasal CPAP is unlikely, or whose condition requires alternative intervention. These conditions could be, but are not restricted to the following.

Known pneumothorax
Upper airway obstruction including croup, epiglottitis, suspected tracheitis.
Following traumatic injury
Facial and nasal abnormalities

The use of nasal cannula is contraindicated for patients with nasal atresia or patients with facial structure deformities that prohibit adequate respiratory support.

Improper selection of size, improper positioning or improper use of nasal cannula may result in inconsistent CPAP pressures, septal trauma or necrosis.

Always begin gas flow prior to inserting prongs into patient's nares.

Frequent observation of prongs position in patient's nares may be necessary.

Cannula tubing can pose a potential strangulation hazard.

Discontinue immediately if skin irritation occurs.

Do not leave unit running while not in use.

Do not use in the presence of a naked flame.

Do not smoke in vicinity of unit whilst in use.

Please refer to all warnings listed in accompanying Oxygen Concentrator manual before use.

Only persons who have read and understood this entire manual and therefore deemed competent, are authorized to operate this equipment

DIAMEDICA BABY CPAP 10 / 20 MANUAL

1. INTRODUCTION

CPAP is the application of continuous positive airway pressure throughout the respiratory cycle. The use of CPAP can assist children with severe respiratory distress.

Worldwide new-born deaths account for more than 40% of the mortality in children under the age of five years. Respiratory dysfunction is a common cause of death in new-borns and is often associated with prematurity/low birth weight, infections as well as peri-partum complications.

The most common causes of respiratory dysfunction in neonates are:

- Respiratory infections
- Surfactant deficiency (respiratory distress syndrome/RDS)
- Meconium aspiration
- Respiratory problems associated with critical illness/severe sepsis.
- Congenital heart diseases and congenital pulmonary/thoracic abnormalities are less common.
- Severe respiratory problems can be associated with persistent pulmonary hypertension of the new-born.

The introduction of bubble CPAP on a neonatal unit should be an important element of an improved “neonatal care package” adapted to resource limited contexts.

The Diamedica Baby CPAPs are self-contained mobile units that are powered by mains electricity. Based on an oxygen concentrator, these units supply their own oxygen and medically filtered air to deliver and maintain a positive airway support at an adjustable set oxygen concentration level.

The unit has a bubble container to adjust the delivery pressure and adjustable flow rates for achieving the required oxygen concentration. This unit also warms and humidifies the delivered gas mix. The gas mix is delivered to the patient via a nasal cannula.

Supplied as two variants (CPAP 10 and CPAP 20) both deliver adjustable pressure up to 10cm H_2O

The CPAP 10 version is suitable for neonates, with the CPAP 20 version having a higher flow capacity being suited to the support of both neonates and larger infants.

Both units are supplied with integrated voltage protection to protect them from irregular power fluctuations that could otherwise cause damage.

Both units can be supplied with an optional UPS (Uninterruptible Power Supply) unit which provides not only voltage stabilisation but also battery backup for power outages. For more information, please contact Diamedica.

2. CLEANING, GENERAL MAINTENANCE AND DISPOSAL

The following guidelines should be reviewed in line with the facility's own cleaning procedures and PPE requirements.

What You Need:

1. Soap for initial clean.
2. Disinfectant solution: (sodium hypochlorite 0.05% or household bleach, diluted to 0.05% hypochlorite. The household bleach bottle will indicate its strength, dilution is essential) Note 5 ml (1 teaspoon) household bleach (5.25% sodium hypochlorite) + 500 ml water= **0.05%.**
3. Brush to clean both inside and outside of circuit. All brushes and cleaning implements must be properly cleaned after use.
4. Drying rack.

Cleaning of the Circuit Tubing and Bottles:

This should be done after each patient has used the CPAP, and weekly if the same child is on CPAP for over a week.

The CPAP circuit which comprises of an inspiratory and expiratory limb, bubble bottle, lid and connections, humidification bottle and water trap must all be thoroughly cleaned as follows:

1. Remove any gross contamination by first washing all components thoroughly in a detergent solution (soap and water). Use a clean container and brush the equipment thoroughly under water to prevent splash and ensure all visible soiling is removed.
2. Rinse with water that has been boiled and allowed to cool to tepid. Let it dry.
3. Wash next in diluted bleach or disinfectant and leave soaking for one hour. Soak all items together, do not keep use solution for subsequent components. Once used, bleach should not be re-used or kept in storage, discard after use.
4. Rinse with water that has been boiled and cooled to tepid (rinse also inside, for example, using a sterile syringe), let it drip dry over the sink, do not leave it coiled on the sink.
5. Check that there is no pooled water in the circuit. Store the circuit and bottle in a clean plastic bag (labelled and dated). Store in the dry and clean area (separate from a soiled equipment area).

Infection prevention and CPAP circuit

a. CPAP circuit & tubing

- Change after 1 week.
- Change earlier if any significant soiling.
- Ensure that there is no accumulation of condensed water in any part of the circuit.
- External cleaning of the tubes in case of soiling (with water & soap).

Humidification

Change water for humidification every shift (every 12 hours).

Change humidification bottle weekly.

Always keep a stock of single patient use- humidification bottles on your bubble CPAP trolley.

Autoclavable bottles can be used. Before use, ensure that they are working correctly (e.g. no leaks)

- Use sterile water or normal saline.
- During the change of water/humidification bottle – ensure patient- safety. The circuit should be interrupted only for a short period of time.

Water trap

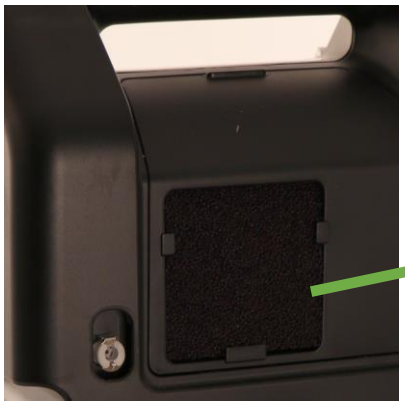
- Change every 1 week.
- Empty at least every shift or when significant amount of water accumulated.
- Wash and clean water trap container (with soap and water)
- During change of water, ensure that circuit is not interrupted. The water- trap is designed in a way, that during the emptying of the bottle, the circuit will not be interrupted.
- Make sure that there is no accumulation of water or condensation in the circuit (see above).

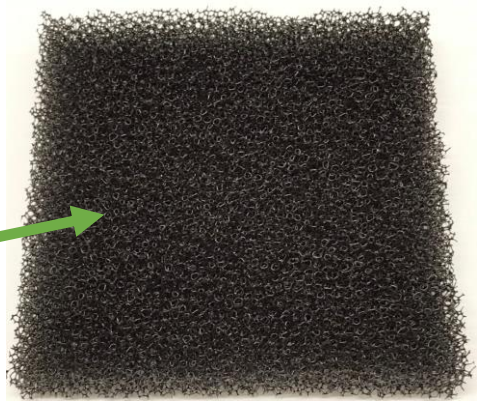
Water- trap – bottle can be detached from the “green section”, without interrupting the CPAP circuit.

Cleaning the CPAP unit

This should be carried out once per week as a minimum.

The CPAP units have a large particulate filter over the air inlet opening. This filter stops dust and other airborne particles from entering the unit and is easily removed from the inset panel on the back of the machine shown below.





The filter should be removed and cleaned in warm soapy water, completely dried with an absorbent towel and replaced. Have a spare dry filter to replace with so there are minimal interruptions to the concentrator function.

Warning. Do not attempt to operate the unit without the air filter or while the filter is still damp.

The exterior of the Bubble CPAP should be cleaned with a mild disinfecting cleaning agent or a diluted solution of bleach (usually 5.25% sodium hypochlorite) in line with the facility's own equipment cleanliness procedures.

Please also refer to the accompanying concentrator manual and the CPAP maintenance manual to understand and plan preventative maintenance requirements.

Accessories and spares

All accessories used with the Baby CPAP must:

- Be oxygen compatible,
- Be biocompatible,
- Comply with the general requirements of the 93/42/EEC European Directive

A full list of available spares is available by contacting Diamedica – support@diamedica.co.uk

3. THE COMPONENT PARTS OF THE BABY CPAP

Image shown is 10l version 20l may differ in appearance

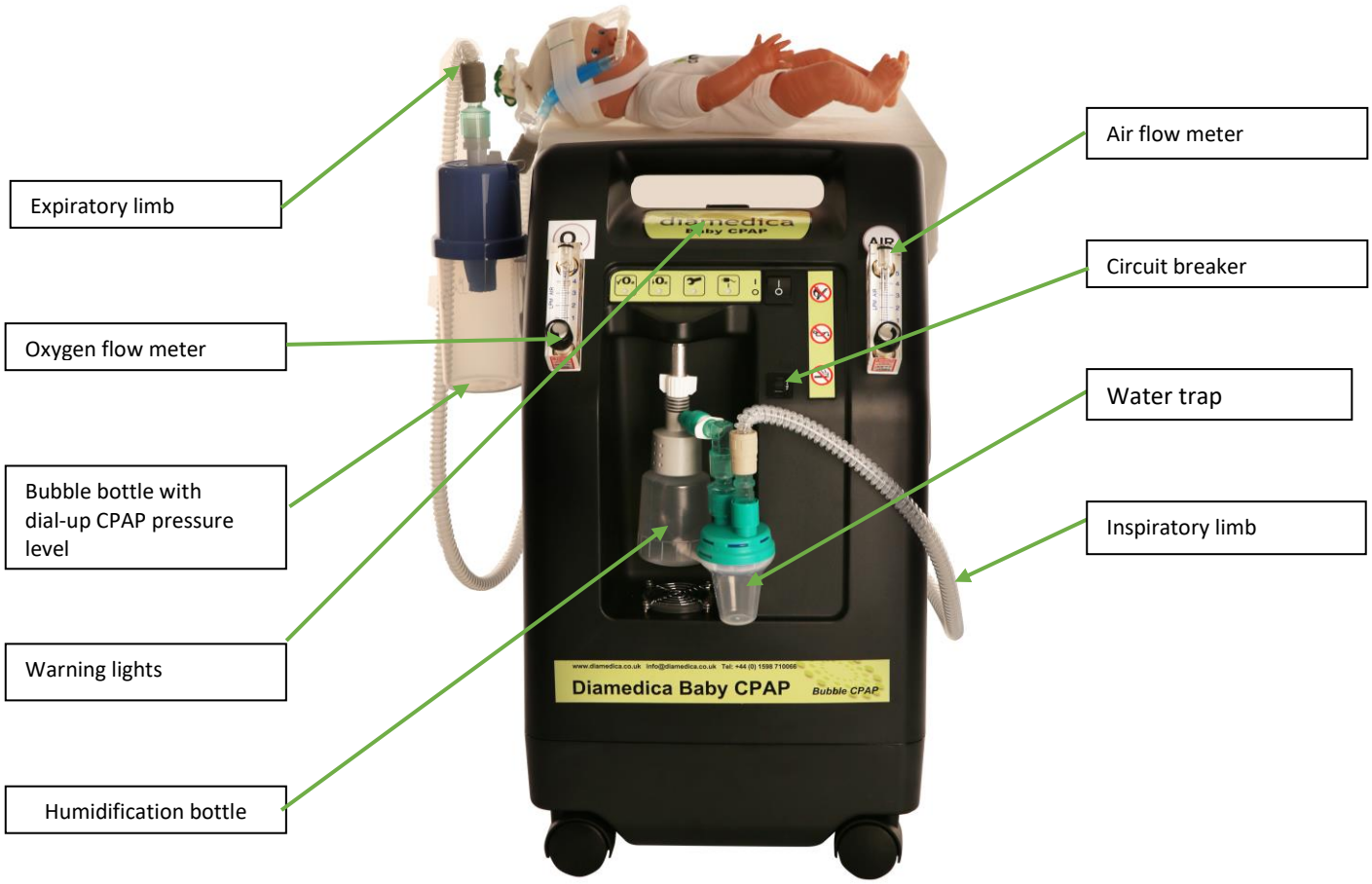


Image shown above is 10l version, 20l may differ in appearance.

4. SETTING UP THE BABY CPAP

Follow the steps below to use the Baby CPAP:

1 Position the unit so that it is at least 30 cm away from walls or curtains, so that the inlet opening at the back is not obstructed.

2 Plug the power cord into the mains electricity supply and turn on the supply.

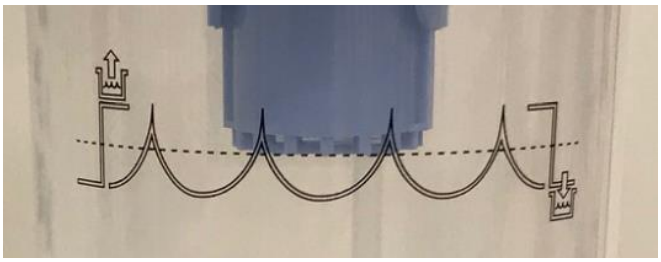
3 Switch on the unit.

4 On start up all lights on the unit should illuminate with the alarm sounding for one second.

5 Following start up if the oxygen purity is below the acceptable level, the yellow low oxygen light will remain illuminated until 87% O_2 delivery concentration has been reached.

6 After a few seconds but up to a few minutes the low oxygen light (yellow) will then go out and the correct oxygen level light (green) will come on.

7. Fill the bubble bottle to the level indicated with boiled (or sterile) water that has been allowed to cool and screw the lid back on. Once filled to the correct level attach bubble bottle to the bracket on the side of the CPAP unit.



8.Fill the humidifier bottle with sterile water or N-Saline (do not over fill). Connect the humidifier bottle to the gas port outlet and ensure the grill below is not obstructed.

9. Connect the inspiratory limb of the circuit to the main gas outlet. A water trap can be attached to the inspiratory circuit if required.

10. Connect the expiratory limb of the circuit to the bottle, ensuring that connections are firmly engaged.

11. Dial up the level of CPAP required: start at 7 cm H_2O (see figure below).

12. Dial the flows of air and oxygen required (check the mixing chart to ensure that these settings give the required O_2 concentration) to see a constant stream of bubbles in the water. Occlude nasal prongs to ensure bubbles in the bubble bottle. Starting values as follows:

Children > 5kg: start with 5 L/min of oxygen and 5 L/min of air.

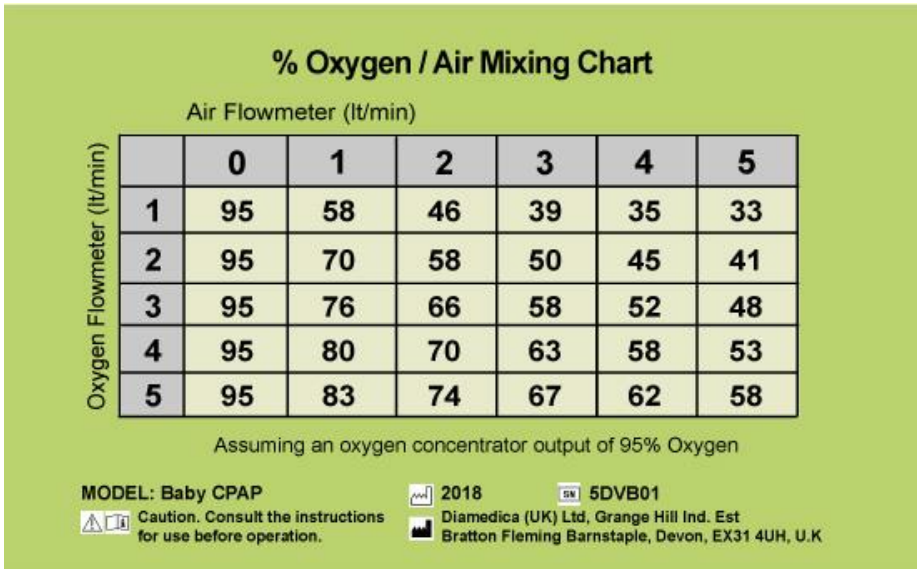
Infants and neonates 2.5 – 5kg: use an initial total flow of 6-10lpm.

Neonates <2.5kg: use an initial total flow of 4-6lpm.

Start pressure of 7 cm H_2O

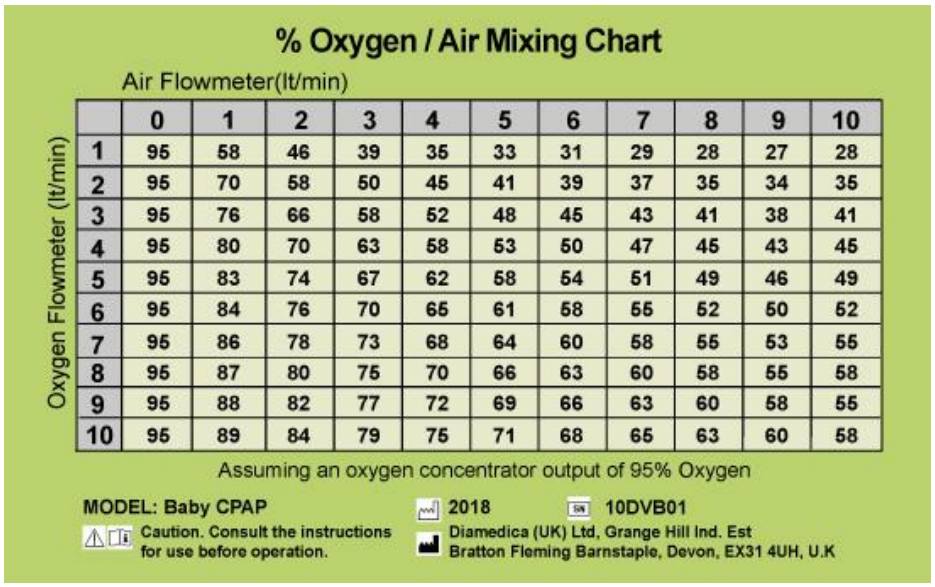
Check and record the flows dialled and the oxygen concentration this provides. The equal starting flow rates will deliver 58% O_2 concentration as can be seen on the mixing charts shown below. In most cases these values will be enough to deliver CPAP, which you can see by continuous bubbling in the bottle.

Baby CPAP 10 oxygen /air mixing chart



	0	1	2	3	4	5
1	95	58	46	39	35	33
2	95	70	58	50	45	41
3	95	76	66	58	52	48
4	95	80	70	63	58	53
5	95	83	74	67	62	58

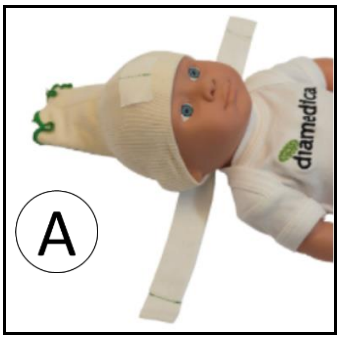
Baby CPAP 20 oxygen /air mixing chart



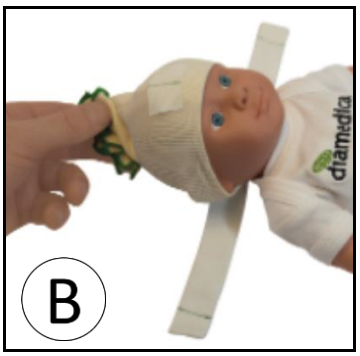
	0	1	2	3	4	5	6	7	8	9	10
1	95	58	46	39	35	33	31	29	28	27	28
2	95	70	58	50	45	41	39	37	35	34	35
3	95	76	66	58	52	48	45	43	41	38	41
4	95	80	70	63	58	53	50	47	45	43	45
5	95	83	74	67	62	58	54	51	49	46	49
6	95	84	76	70	65	61	58	55	52	50	52
7	95	86	78	73	68	64	60	58	55	53	55
8	95	87	80	75	70	66	63	60	58	55	58
9	95	88	82	77	72	69	66	63	60	58	55
10	95	89	84	79	75	71	68	65	63	60	58

13. Connect the nasal prongs to the child as below:

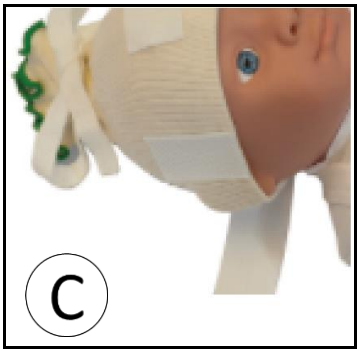
- Make sure no pressure is put on facial skin. Special care needs to be taken to not exert too much pressure on the nasal septum.
- The prongs should not completely obstruct the nares. A leak on this level is acceptable and can be compensated by increasing the air/oxygen flow.
- Non- nutritive sucking with sucrose or some expressed maternal milk can help to improve the comfort of the child.



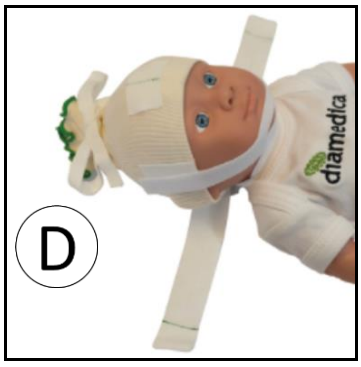
Place the bonnet on patient's head, centring the securement line indicator.
With the bonnet centred at nape of neck, place remaining bonnet on infant.



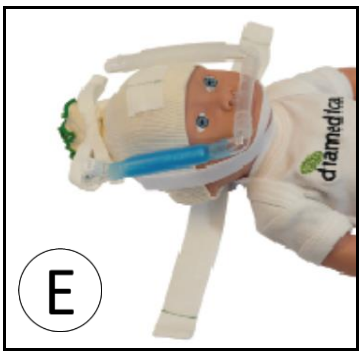
Close the top of bonnet by twisting bonnet until tightly secure to head crown. Secure with ribbon provided.



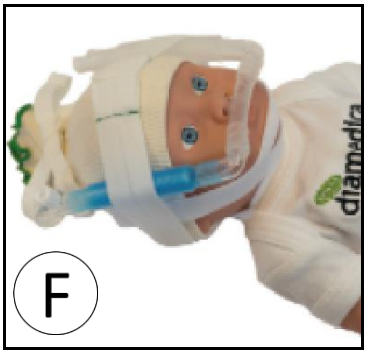
Cut self-adhesive Velcro in half and secure to the bonnet.



Attach chin strap to the infant and secure to Velcro.



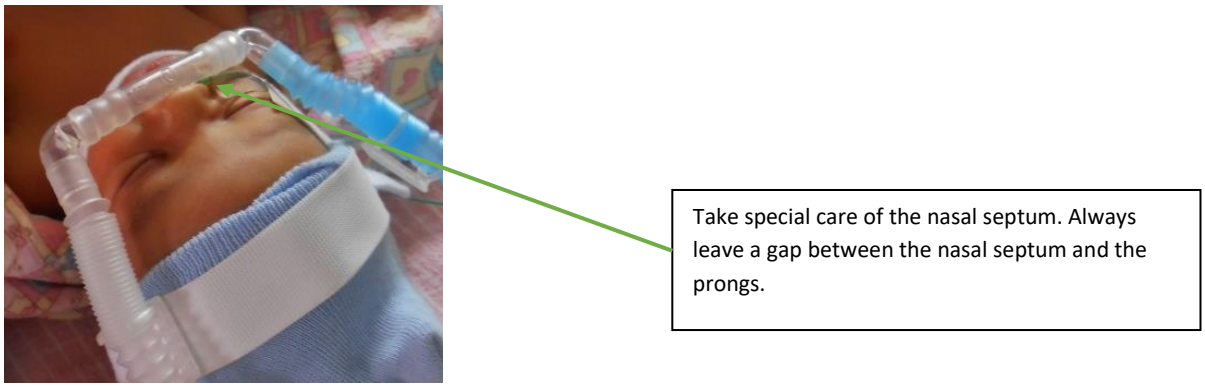
Place the nasal prong into the infant's nostril.
Ensure gas flow is on prior to inserting the prongs into patient's nostril.



Secure tubing by placing elastic strap over tubing and secure to Velcro. Elastic strap is correctly positioned when strap is in line within the securement line indicator.

Positioning of prongs

- Prongs should be inserted into patient's nostrils with a small gap between patient's septum and base of prongs.
- Correct fitting prongs will fill approximately 80% of the nostril. Ensure that prongs do not fill nostrils completely.
- Ensure, that no part of the nostril/skin is exposed to pressure.
- A leak can be compensated by increasing the flow.



Skin care

- All tapes used (e.g. for naso or oro-gastric tubes, IV lines) need to be "skin- friendly".

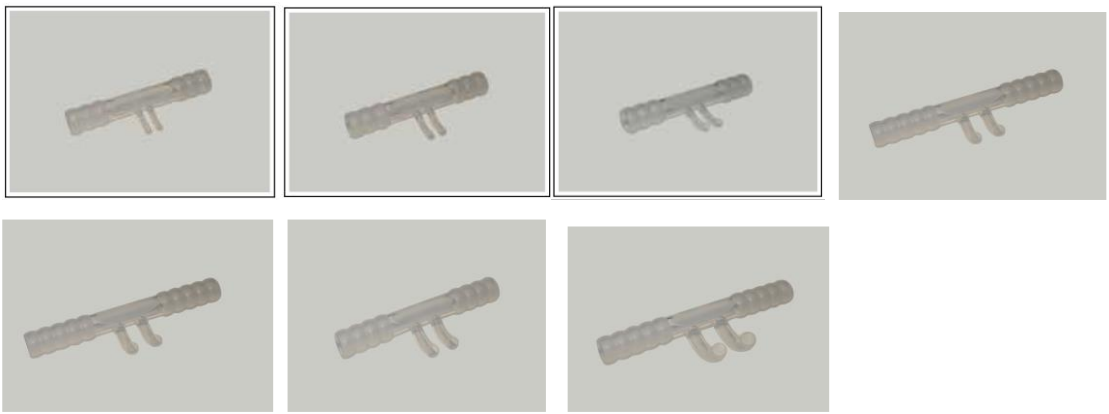
Prongs

- Change every 3 days or earlier if any significant soiling or obstruction.

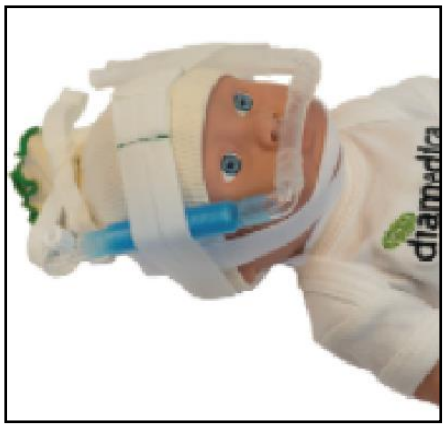
Different sizes and types are available:

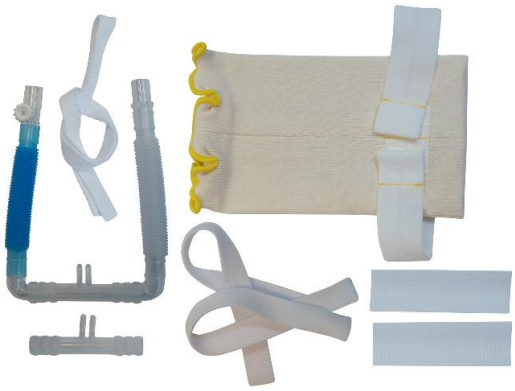
Options:

1) **Hudson prongs (different sizes)**



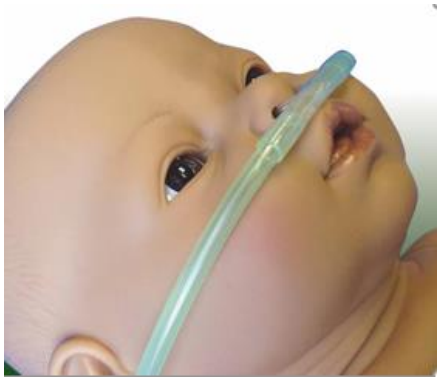
Nasal Prong kits

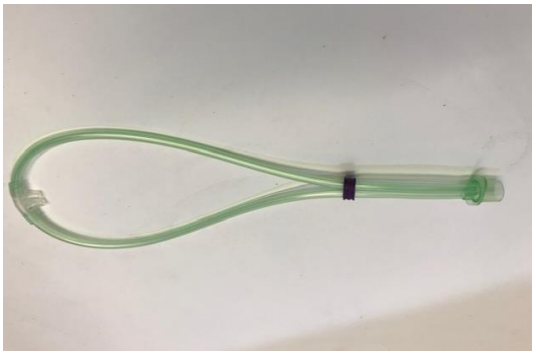




Product code	*Description*	*Bonnet Size*
CPAP/SP2/S	CPAP Nasal Kit (prong # 0 - 1)	Size 1, S (22-25cm)
CPAP/SP2/M	CPAP Nasal Kit (prong # 2 - 3)	Size 2, M (25-28cm)
CPAP/SP2/L	CPAP Nasal Kit (prong # 4 - 5)	Size 3, L (28-31cm)
CPAP/SP2/XL	CPAP Nasal Kit (prong # 6 - 7)	Size 4, XL (31-34.5cm)

Ram cannula option





Product code	*Item size*	*Nasal prongs septal space*	*Nasal prongs outer diameter*
N4900	Micro Preemie	2.5 mm	3 mm
N4901	Preemie	4.2 mm	3 mm
N4902	New-born	4.8 mm	3.5 mm
N4903	Infant	5 mm	4 mm
N4904	Small	5.75 mm	5.25 mm
N4905	Medium	6.75 mm	5.75 mm
N4906	Large	7.75 mm	6.5 mm

CO_2 gas sampling port

There is a CO_2 gas sampling port fitted to the nasal prong inspiratory connector (Blue).

Patient monitoring

14. Check the child for signs of respiratory distress, check the SpO_2, and check if there are bubbles in the bottle.
15. If the SpO_2 is below 90% or the child has severe respiratory distress, set **CPAP pressure level to 7 cm H_2O** and then, if no response, increase the **oxygen flow meter** and reduce the air flow meter by equal amounts as required.
16. If there are not continuous bubbles, check the nasal prongs are attached properly, and reposition them so they fit snugly inside the nostrils. Refer to fitting note on previous page.
17. If there are still not continuous bubbles, check for leaks along the circuit, and adjust the oxygen or air flows according to the chart below.

Check for bubbles in the pressure regulation bottle.

- Bubbles should be present during the whole respiratory cycle.
- Exclude any obstruction in the circuit and the patient's airway.

	SpO_2 > 90% and mild or no respiratory distress	**SpO_2 > 90% but moderate to severe respiratory distress**	SpO_2 < 90%
Bubbles	No immediate change needed, may be able to reduce CPAP level gradually	Increase CPAP level	Increase CPAP level. Increase oxygen flow
No bubbles	Check nasal interface and complete air/oxygen circuit (including humidifier and water- trap). Consider weaning CPAP pressures & FIO_2.	Check nasal interface and complete air/ oxygen circuits. Increase air flow, check for bubbles. Increase CPAP level	Check nasal interface and complete air/oxygen circuit. Increase oxygen flow, check for bubbles. Increase CPAP level

5. ALARMS AND INDICATORS

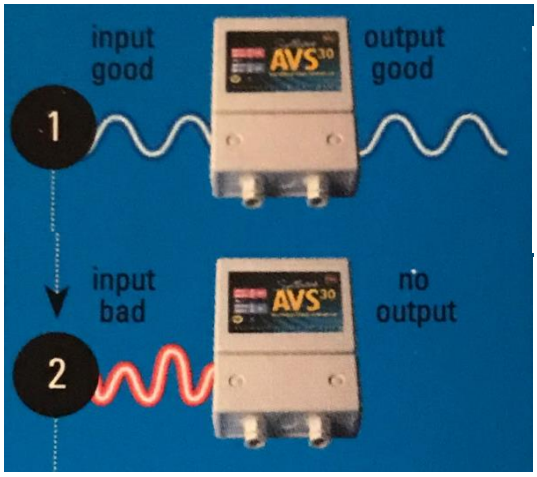
Warning and information indicators:

	CPAP 10 & 20	Indicates that the unit is producing an acceptable level of O_2	If light is not illuminated refer to other warning lights
	CPAP 10 & 20	Indicates that the unit is not producing an acceptable level of O_2 (<87%)	If unit has just been switched on allow up to 15 minutes to complete start up period If light remains on or comes on during continuous operation check that air filter is clean and that no machine vents are obstructed.
	CPAP 10 & 20	Indicates service requirement or fault. May be illuminated with low O_2 light also.	Check that air filter is clean and that no machine vents are obstructed. Check tubing and connections from gas outlet for blockage. If no obvious fault, refer to concentrator manual or contact Diamedica support.

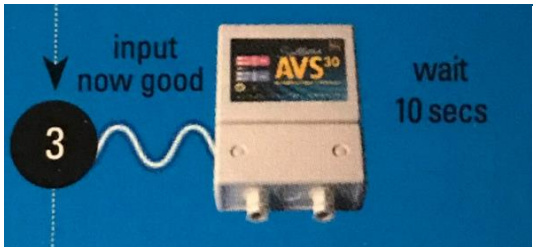
6. POWER CIRCUIT PROTECTION

This Baby CPAP unit has been fitted with an AVS30 Voltage Protection unit to automatically protect the on-board circuitry from damage due to unstable voltage.

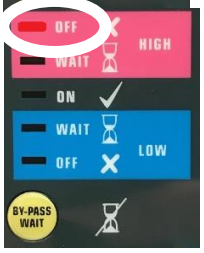
The AVS30 is an Automatic Voltage Switcher rated at 30 Amps. The AVS30 will switch off the equipment connected to it if the mains power goes outside pre-set acceptable limits and will reconnect automatically when the mains power returns to normal. Reconnection takes place after a delay, to ensure stability of the mains.



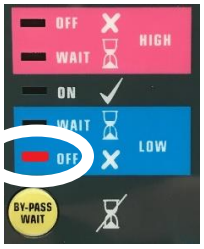
Input good
GREEN LIGHT
Power OK



Input unstable
RED LIGHT
No Power output

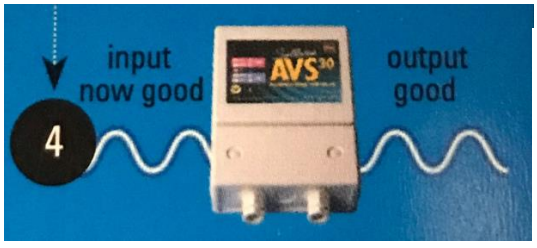


OR



Input now good
AMBER LIGHT
No Power output
for 10 seconds

OR



Input good for 10
seconds
GREEN LIGHT
Power OK

Note If AVS30 unit displays green light but CPAP unit is still without power the secondary trip reset on the front of the unit may need to be pressed to reset the unit.

Circuit breaker reset on front of unit.
3A on CPAP 10 version.
5A on CPAP 20 version.

7. SPECIFICATIONS

	Baby CPAP 10	Baby CPAP 20
Power	220 - 240 VAC 50Hz	220 - 240 VAC 50Hz
Operating power range	190V – 250V	205V – 260V
Power Consumption	312 Watts	670 Watts
Flow rates	Up to 5 l/min Oxygen Up to 5 l/min Air 10 l/min combined flow	Up to 10 l/min Oxygen Up to 10 l/min Air 20 l/min combined flow
Delivered Oxygen concentration range (@95% Oxygen)	21% - 95%	21% - 95%
Generated Oxygen concentration	92% ±5% @ 5l/min	93% +3%/-6% @ 10l/min
System pressure relief	310 kPa ±34.5 kPa	310 kPa ±34.5 kPa
Operating environment	41˚F (5˚C) to 95˚F (35˚C) Up to 95% humidity	41˚F (5˚C) to 95˚F (35˚C) Up to 95% humidity
Storage environment	-4º F to 140º F (-20°C to 60°C), up to 95% relative humidity	-4º F to 140º F (-20°C to 60°C), up to 95% relative humidity
Visual alarms / Audible alarms	High/Low pressure, Low flow, Low oxygen, Power fail	High/Low pressure, Low flow, Low oxygen, Power fail
Weight	16.3kg	19kg
Dimensions	Height 63 cm x Width 35 cm x Depth 31 cm	Height 63 cm x Width 35 cm x Depth 31 cm
Bubble bottle Adjustable Range: Accuracy:	 0 to 10 cm H_2O ± 1.5 cm H_2O to lid set point	 0 to 10 cm H_2O ± 1.5 cm H_2O to lid set point

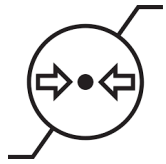
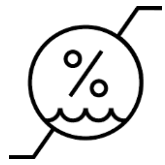
For EMC and electrical safety compliance data please refer to the accompanying Concentrator manual.

8. SYMBOLS GLOSSARY

Some or all the following symbols may be used within this manual or found on the product or packaging labels. Please familiarize yourself with them:

Symbol	Description	Comment
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC.
	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent tothe symbol.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Fragile, handlewith care	Indicates a medical device that canbe broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.

	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Refer to the Instruction Manual	Indicates the user must read the instructions for use before using the equipment.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Class II equipment	
	Type BF applied part	
	Recycling symbol	Products with this symbol should not be disposed of in the bin
	The battery recycling symbol	Chemical symbol for battery type included beneath
	Does not contain or presence of natural rubber latex	
	Indicates that an object is capable of being recycled	

	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Medical device	Indicates the item is a medical device
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information

