ENG

Portable CPAP

Instructions for use

Diamedica (UK) Ltd
Grange Hill Industrial Estate
Bratton Fleming, Barnstaple, Devon, EX31 4UH,
United Kingdom

Tel: +44 (0)1598 710066
WhatsApp: +44 (0) 7716 503156
Email: support@diamedica.co.uk
Web: www.diamedica.co.uk

EC REP

Alphamed Consulting Ltd, Knock, Barnaderg, Tuam,
Co. Galway, H54 W220

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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 may be limited or unavailable) and issuitable for pre-term babies, neonates, and paediatric patients.

Note: Clinical decisions and appropriate patients should be decided by the clinical team on a case-by-case basis depending on the patient's condition.

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

FOREWORD

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

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 Portable CPAP must read, understand, and follow the guidance given in this manual before using the system.

THE NEED FOR PATIENT MONITORING

The Diamedica Portable CPAP delivers air (with or without supplementary oxygen) 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 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.

This device should only be used while the patient is under the continuous, direct supervision of healthcare professional and frequent observation of prongs position in patient's nares is necessary

Cannula tubing can pose a potential strangulation hazard.

Discontinue immediately if skin irritation occurs.

Do not leave unit running while not in use.

If supplementary oxygen is being used:

Ensure suitable flow metering device is used to control input to < 10 L/min.

Do not use in the presence of a naked flame.

Do not smoke in vicinity of unit whilst in use.

The battery supply indicator is for information purposes only, the operator should ensure that the unit is fully charged prior to initiating support.

The onboard Lithium Polymer Battery has a lifespan of 300+ cycles. In the event that it fails to hold charge it should only be replaced with the same battery model by a suitably competent technician as detailed in section 2

The patient circuit should be kept as free form as possible during use and not be coiled as this can reduce or increase delivered flow and pressure.

Ensure unit is kept free from standing and dripping liquid.

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

DIAMEDICA PORTABLE CPAP 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 CPAP in a delivery room or a neonatal unit should be an important element of an improved “neonatal care package” adapted to resource limited contexts.

The Diamedica Portable CPAP is a self-contained portable unit that is powered by internal battery. This unit generates filtered air to deliver and maintain positive airway support at a set pressure and flowrate.

Supplementary oxygen can be added either from cylinder oxygen via an appropriate regulator/ flowmeter, or from an oxygen concentrator.
WARNING. Only add supplemental oxygen whilst unit is running and switch off supplemental supply prior to turning off the unit

The unit uses ambient air as a main gas source which generally contains higher humidity than concentrator or cylinder gases and there is some additional humidification retained by the cannula. The gas is delivered to the patient via nasal cannula.

The high flow gas blower in the device generates > 60 litres per minute of gas flow restricted to appropriate levels by the patient circuit and cannula interface. The delivered flow rate to the patient being between 5 - 8cmH_2O.

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:

This should be done after each patient has used the CPAP.

The CPAP circuit which comprises of silicone smoothbore inspiratory and expiratory limbs, and connections:

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).

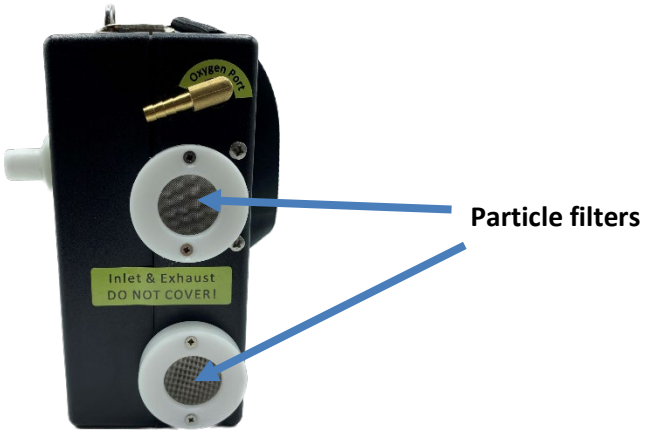
The above information is supplied as guidance only and is subordinate to each facility's own protocol, under which the patient conditions and clinical environment are considered.

Cleaning the CPAP unit

The 300-micron stainless steel mesh dust filter should be cleared of particles before use. This can be done by directing the inspiratory tube gas flow at the filter.

Warning. Do not operate the unit with the filter blocked with dust.

Warning. Do not operate the unit with the filter removed.



Accessories and spares

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

Replacement of Lithium Battery.

In the event that a new battery is required (Typical lifespan 300+ cycles), this must be done by a suitably competent service technician.

The battery is a 'Tracer' 12V 8ah Lithium Polymer Battery. This is available by contacting Diamedica – support@diamedica.co.uk

3. THE COMPONENT PARTS OF THE PORTABLE CPAP

1. Master power switch
2. On / Off switch
3. Oxygen port
4. Inspiratory circuit connection
5. Expiratory circuit connection
6. Over-charge trip
7. Battery charge port
8. Battery charge level
9. Expiratory filter
10. Inspiratory filter

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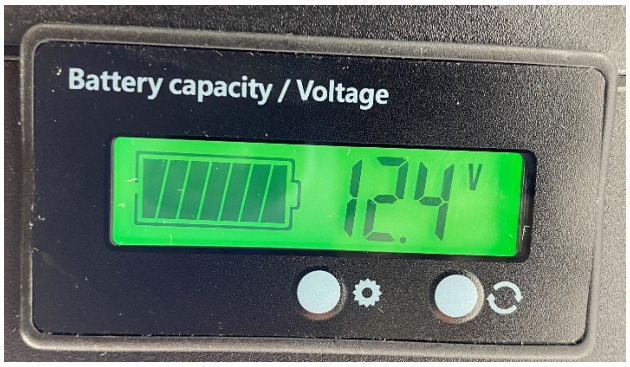
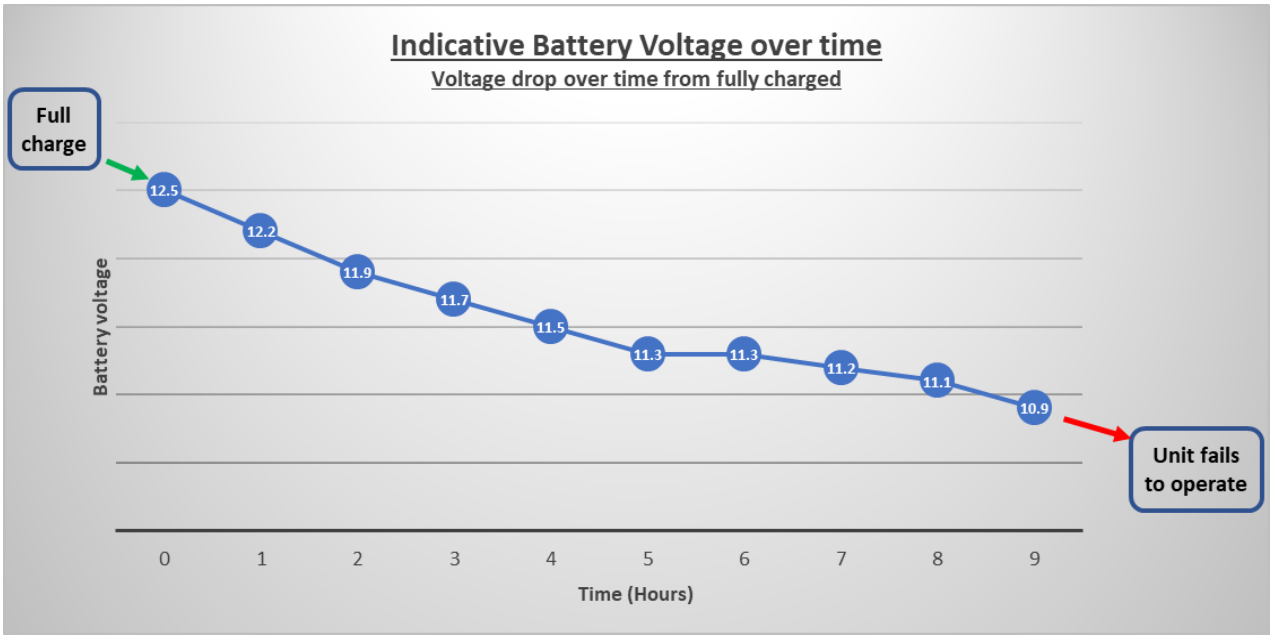
Note: The Master Power switch is turned off for delivery and will need to be turned on before use and for charging. Turn it off if the unit is not being used for long periods or for air transport.

4. SETTING UP THE PORTABLE CPAP

Follow the steps below to use the portable CPAP:

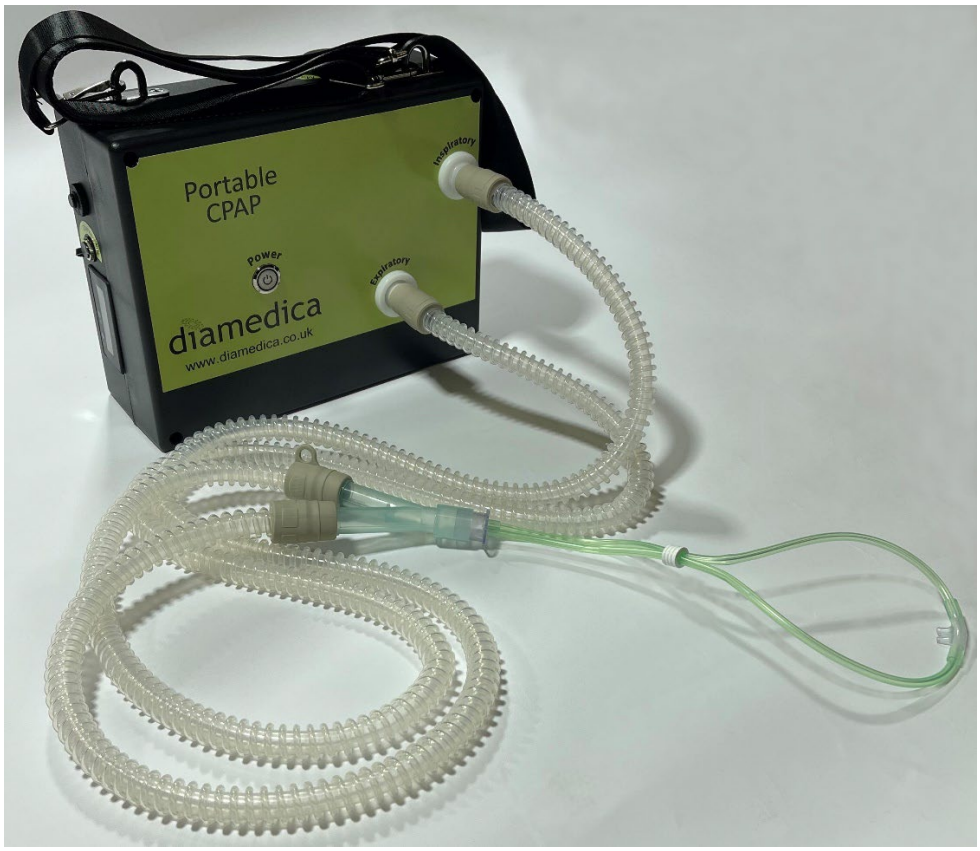
1. Switch on the Master Power Switch, then check the battery charge always ensure sufficient remaining battery life for intended patient support (Refer to indicative chart below). Always Maintain battery level to ensure immediate use is possible



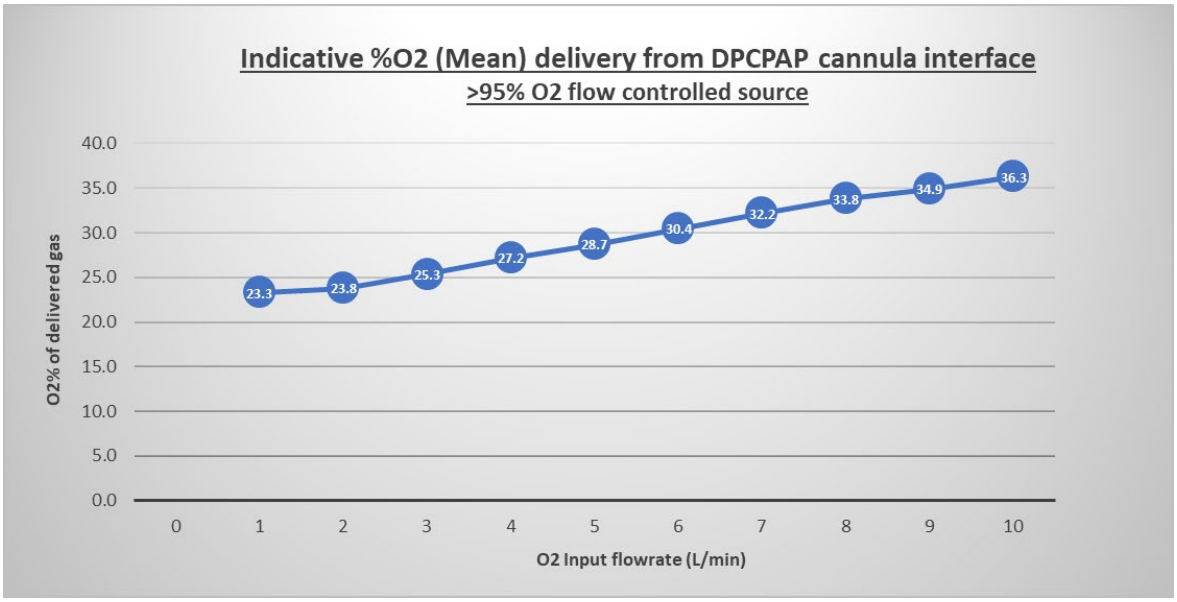


2. Plug the battery charger into either the mains electricity supply or the vehicle 12volt supply if not fully charged.
3. Switch on the power switch on the front of the device. A blue light should turn on at the switch and gas will be generated through the inspiratory outlet.
4. Connect one limb of the circuit to the inspiratory connection and the other limb to the expiratory connection.
5. Connect the other ends of the limbs to the 'Y' connector.
6. Fit the RAM cannula to the 'Y' piece.

7. Connect the RAM nasal prongs as below:



8. The flowrate and pressure levels of the Diamedica Portable CPAP are design set.
9. Supplemental flow-controlled oxygen may be added via the oxygen port on the side of the unit. Refer to the indicative graph below for expected supplemented output values.

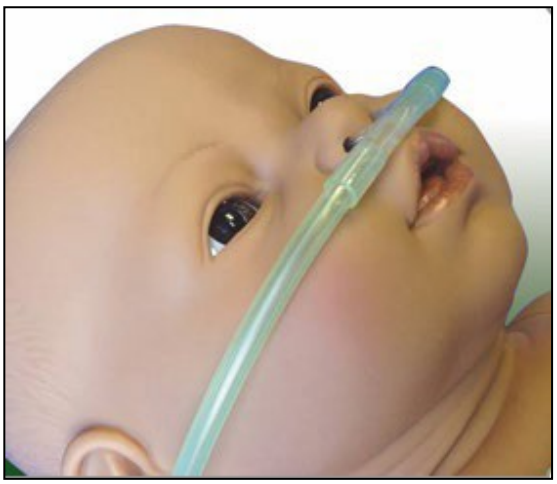


10. Following use, ensure that unit is switched off at Master power switch (See section a)

Ram cannula

The product is supplied with RAM cannula

Connect the nasal prongs to the child as below:



- Select suitable size cannula. Ideal prongs size will fill approximately 80% of nares. Ensure that prongs do not fill nares completely.
- Attach cannula to single end of Y-Piece connector. Ensure all joint connections are properly secured.
- Ensure unit is running and that there is flow from the cannula before fitting to the patient.
- Insert prongs into patient's nares allowing a small gap between patient's septum and base of prongs always taking care not to exert pressure on the nasal septum.
- Secure cannula in place using suitable method.
- Continually monitor position of cannula during connection to patient.

NOTE: Ensure that patient circuit is as free form as possible and not crushed at any point causing restriction.

Connect Cannula connection to 15mm female connection on Y-Piece connector

Connect Inspiratory & Expiratory tubes to 15mm male connections on Y-Piece connector
Orientation is not important

The product can also be used with suitable Hudson cannula if required.

5. Specifications

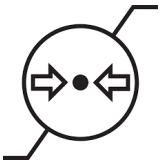
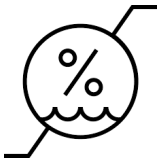
	Portable CPAP
Car Charger	11.5V-13.5V
Mains Charger	95V – 250V
Battery type	Lithium Polymer (8000mAh)
Battery run time	> 8 hours (Full charge / Healthy battery)
Cannula flow rates	Micro preemie, Preemie, New-born, and Infant, up to 8 L/min Child Small, Medium, and Large, up to20 L/min
Oxygen supplementation range (@95% up to 10l min supplemental flow rate)	21% - 36% mean (40% peak)
Maximum pressure	8cmH_2O (100% nares occlusion)
Operating environment	Temperature 5 - 40° C Humidity 35% - 90% H Altitude 79 – 106 kpa
Storage environment	Temperature -10 - +45° C Humidity 15% - 93% H Altitude 79 – 106 kpa
Battery charge indicator	Percentage 1% - 100% Voltage reading
Weight	2.8kg
Dimensions	Height 187 mm x Width 243 mm x Depth 103 mm

6. SYMBOLS GLOSSARY

Some or all the following symbols may be used within this manual or found onthe 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 EuropeanCommunity	Indicates the Authorized representative in the European Community.
	Date of manufacture	Indicates the date when the medicaldevice 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 thatneeds 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

