3CPAP® overview

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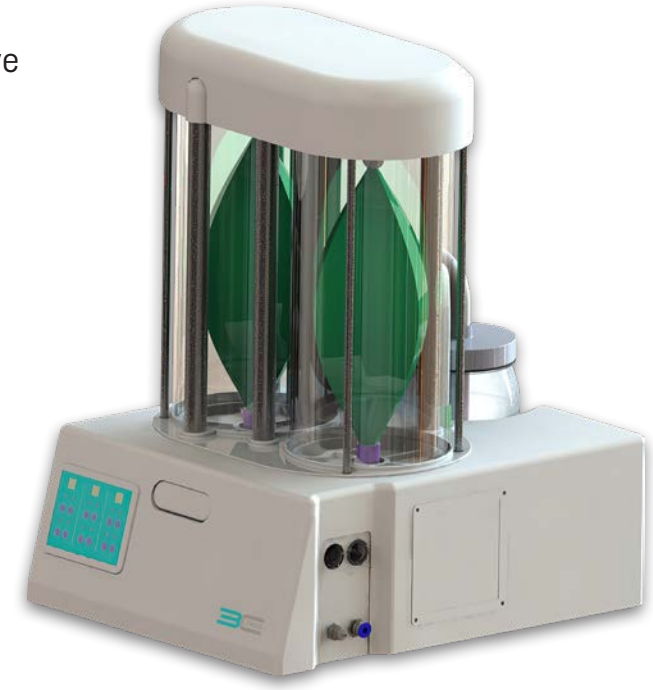

What is 3CPAP®? A Closed Circuit Continuous Positive Airway Pressure device. 3CPAP® is used for treating patients with respiratory failure, consuming as little as one litre per minute of oxygen. As well as CPAP, 3CPAP® can provide near ambient pressure face mask oxygen at a fractional inspired concentration of up to 1.0. Originally conceived during the first wave of COVID-19 in the UK, 3CPAP® delivers CPAP with adjustable fractional inspired oxygen concentrations, using very low fresh gas (oxygen) flow.

CPAP devices in use today are "open circuit" and rely on high gas flow to deliver the continuous pressure to the patient. This means, these devices can use anything up to 150 L/min of oxygen, and commonly 40-120litres per minute for the requirements of patients with COVID19. While it is a common assumption that oxygen is an unlimited resource, this is often not the case, as highlighted in NHS hospitals, and hospitals worldwide during this pandemic. High gas flows to cohorted groups of patients can risk reduced flows to other patients as a result of the constraints of oxygen pipework, especially in older buildings, and particularly in areas outside operating theatres or critical care. This presents a serious patient safety issue.

Further, high oxygen consumption poses a significant limitation on patient transfer: a patient on CPAP with high oxygen flows could not generally be transported by ambulance to a different hospital as a result of the oxygen constraints. Moving patients between hospitals is a key feature of how the NHS plans to safely manage future COVID-19 surges, including this winter, and therefore, the market for this device to the NHS is considerable. 3CPAP® presents a viable alternative to face mask oxygen or endotracheal intubation for patients who are critically unwell with hypoxia when ambulance services arrive at home, thereby potentially reducing morbidity and mortality.

There are two further disadvantages or challenges with high flow rate devices: first, the average patient consumes (metabolises) less than 1 L/min of the oxygen administered, so at a 60 L/min most of the oxygen is vented back into the room via the CPAP system exhaust, presenting a fire risk if ventilation of the ward is not adequate.

Second, because so much gas is being pumped around the ward, there is an increased risk of cross-infection due to aerosols in the gas. In a recent incident in a UK NHS hospital, 20 patients were infected with Sars Cov 2 during a single incident where a suitable filter was not fitted to a conventional CPASP circuit.

The key feature that makes 3CPAP® different is that 3CPAP® closed-circuit system. This is the same type of circle system used in anaesthesia machines where the exhaled breath from the patient is recycled, the CO2 removed (or scrubbed) from the gas and then oxygen is added to top it back up to the desired level. Crucially, this means that the system has to replace only the oxygen that is metabolised - typically around 1 L/min. This not only substantially reduces oxygen consumption but also mitigates the risks of fire and cross infection.

Using an example from another closed-circuit system, a a Size E medical oxygen cylinder of the type used for intra-hospital patient transfers, would have enough capacity to supply a patient for up to 12 hours running at 1 litre/minute, as opposed to 12 minutes in a high flow system at 60 L/min. An important and unique application of 3CPAP® is that as it does not rely on a high-volume oxygen supply, it is well suited for use outside hospitals. Examples of this type of indication would be ambulance transfers as detailed above, or in care homes or temporary pandemic response hospital facilities as the devices could be run off small portable oxygen concentrators without concern over oxygen supply.

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How does it work in theory?

Closed Circuit systems (often known as circle systems or rebreathers) have been around for many years, with basic oxygen rebreathers being used as far back as the First World War. The principle is very simple: the average human metabolises only a fraction of the oxygen in the air we breathe (around 250ml/min at rest) and the majority of the oxygen intake is simply expelled as we breathe out. Because our atmosphere consists of roughly 21% oxygen, we exhale around 17% oxygen. Using this physiological framework, it's clear that if we provide a patient with a gas mixture at an elevated oxygen level such as 80%, the exhaled breath is a highly valuable oxygen-rich resource that, when fed back to the patient in a closed circuit, can maintain the given oxygen fraction prescribed and requires topping up only at the rate it is metabolised by the patient.

Our bodies produce CO2 at around the same rate as the oxygen we consume (ie. 1 L/min oxygen in, 1 L/min of CO2 out). All circle systems use a CO2 scrubbing canister (soda lime) to absorb the CO. Soda lime is a low cost, single use material that an average patient would consume at around 3kg in a 24 hour period.

3CPAP® features

Sensors – 3CPAP® has 3 sensors built in: Oxygen, CO2 and Pressure. These give the clinicians a real-time view of the state of the system and maintain safe levels. In the unlikely event if a dangerous situation developing, the machine automatically bypasses itself so that the patient is breathing atmospheric air, while sounding audio visual alarms. There is a built-in calibration system for both the O2 and CO2 sensors. It should be noted that the CO2 sensor is placed in the inhale line, so it is measuring the effectiveness of the soda lime filter rather than the patient.

Telemetry – 3CPAP® has Wi-Fi built in, so all the available telemetry is not only displayed but can be automatically forwarded to a monitoring station in real time, allowing a single clinician to remotely monitor several patients at the same time, allowing best possible use to be made of medical resources.

Dimensions	Front to rear depth	468mm
	Width	381mm
	Height	573.5mm

How does 3CPAP® work in practice?

The 3CPAP® device has been designed by a team that brings together extensive experience as medical practitioners, rebreather diving technology design and medical device manufacturing under the UK accreditation standard of ISO 13485.

3CPAP® is primarily a mechanical device using a fan and a series of electronically controlled valves for monitoring and fine tuning oxygen content, pressure, and ensuring patient safety. In recent testing 3CPAP® achieved x pressure swing over the breathing cycle, industry eating performance.

Any closed-circuit system must maintain a sufficient breathable volume, with enough compliant space in the system to allow both breathing in and out. 3CPAP® encapsulates 2 standard breathing bags in clear plastic tubes, each with a valve: one is an under-volume valve (adding gas if there is not enough to supply the patient) and the other is an over-volume valve (getting rid of gas if there is too much gas in the system).

The clear tubes have air pumped into them by a medical grade blower, controlled by our revolutionary master valve. This air exerts force on the breathing bags which, in turn, exert pressure onto the breathing gas, which remains a clean and separate supply at all times. The master valve controls the flow of gas to match it to the constant desired pressure as the patient breaths in and out, with a higher flow of air into the chambers resulting in a higher CPAP pressure and vice versa.

What are 3CPAP®'s technical specifications?

3CPAP® can achieve the following parameters:

- **Continuous airway pressures – from 5 cm/H2O to 20cm/H2O, stable to +/- 0.5H2O across the range, selectable in 1cmH2O increments;**
- **Fraction of inspired Oxygen – 0.35 to 0.95, selectable in 0.05 increments**
- **Oxygen use - Whilst dependent on patient physiology and mask leakage, on average, 3CPAP used less than 2 L/min of oxygen.**
- **Power – the whole system draws around 1.5A at 24V. There is also an on-board battery back-up system that will run the whole system for at least 45 mins.**