

Buyers' guide

Continuous positive airway pressure for the treatment of obstructive sleep apnoea / hypopnoea syndrome

CEP10054

March 2010



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CEP buyers' guides are intended to provide prospective purchasers of healthcare products on the UK market with general guidance on the technical, operational, and economic considerations to be taken into account in selecting the most appropriate product where a range of similar products exists. They do not include product-specific information, which is published separately via market reviews (which contain product specifications only) or evaluation reports (which contain additional technical and/or user evaluation data).

Scope

This buyers' guide provides a review of the application and use of continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP) and auto-titrating positive airway pressure (APAP) devices and their interfaces (*ie* face masks) as a treatment for obstructive sleep apnoea/hypopnoea syndrome (OSAHS). The umbrella term of CPAP will be used throughout this report to refer to all types of positive airway pressure devices including CPAP, BiPAP and APAP machines, unless otherwise stated. The focus of this guide will be on the use of CPAP devices within the home rather than the hospital setting. This guide also outlines the ergonomics aspects of CPAP devices and interfaces.

No independent testing of the CPAP devices and their interfaces was conducted. CPAP has not been considered with regards to any other medical condition other than OSAHS. This buyers' guide will only be relevant to the adult population as supported by the NICE guidelines [1].

Obstructive sleep apnoea/hypopnoea syndrome

Apnoea can be described as temporary absence or cessation of breathing [1]. Obstructive sleep apnoea (OSA) or obstructive sleep apnoea/hypopnoea syndrome (OSAHS) is a medical condition defined as the cessation of air flow through the upper airway (pharynx), due to an obstruction during sleep which prevents air from entering the lungs. The obstruction is caused by a relative reduction in upper airway muscle activity leading to partial or complete airway collapse resulting in a hypopnoea or apnoea respectively lasting between 10 and 45 seconds. This leads to periods of reduced ventilation. Most individuals with sleep apnoea have a combination of apnoeas and hypopnoeas and this will be referred to as OSAHS throughout the report [1-3].

All individuals suffer from a loss of stability of the pharynx when asleep; when awake, there is sufficient muscle tone to keep the airway open allowing for normal breathing. The loss of stability leads to snoring, which is the vibration of the unstable airway. IMPRESS states that in approximately 20 – 30 % of loud snorers the pharynx is so unstable that it narrows and may occlude periodically during sleep, resulting in recurrent apnoeas and/or hypopnoeas [3]. These episodes are accompanied by a

reduction in blood oxygenation (desaturation) and only stop when the brain automatically intervenes to partially awaken the patient. Individuals will experience these waking episodes many times during the night and consequently complain of excessive daytime sleepiness; often with irritability or restlessness [3].

It is estimated that about 4% of middle aged men and 2% of middle aged women, suffer from OSAHS, with 1% of men in the UK having severe OSAHS [1]. Recent estimates suggest that only 20-30% of affected individuals have currently been diagnosed in the UK [3].

Any normal variation or pathological abnormality which tends to reduce the size of the upper airway when a person is awake, will predispose them to the development of apnoeas during sleep [3]. Other risk factors for developing OSAHS are increasing age, obesity (particularly of the upper body and neck), being male, smoking and the use of alcohol or sedatives. Certain craniofacial characteristics such as enlarged tonsils and enlarged tongue may also be a problem [1, 3].

The breathing problems of OSAHS are confined to sleep but the main symptoms are experienced when awake [3]. General symptoms of OSAHS can include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction [1].

Diagnosis

The patient requires an accurate diagnosis that eliminates other sleep disorders, eg narcolepsy. Moderate to severe OSAHS can be diagnosed using patient history and a sleep study using oximetry or other monitoring devices [1]. Some types of sleep study can be performed in the person's home. The severity of OSAHS is often defined by the number of events occurring per hour. This could either be identified by the number of oxygen desaturation events (measured using the oxygen desaturation index) or the number of apnoeas or hypopnoeas that occur. These can be assessed using the sleep study results which will show the frequency of apnoeas and hypopnoeas per hour of sleep by using the apnoea/hypopnoea index (AHI) or the oxygen desaturation index [1].

OSAHS can be subdivided into three categories of breathing abnormality, depending on the AHI:

- 5 -14/hr AHI - mild
- 15 - 30/hr AHI - moderate
- > 30/hr AHI - severe[3, 4].

Other symptoms, such as daytime sleepiness, can be measured using the Epworth Sleepiness Scale (ESS) [5]. The ESS measures daytime sleepiness using a short

questionnaire which asks the person to rate their probability of falling asleep on a scale of increasing probability from 0 to 3 in eight different common daily situations. The scores for the eight questions are added to obtain a single number. A number in the range 0 -10 is considered to be normal, 11 -14 is mild, 15 -18 is moderate and 19 - 24 is severe [5]. A score within the mild to severe range indicates that specialist medical advice should be sought. The questionnaire is completed by the patient prior to using CPAP as a treatment and then after use to measure any improvement.

After diagnosis of OSAHS patients should inform the Driver and Vehicle Licensing Agency (DVLA) of the diagnosis. It is possible that OSAHS, if left untreated, can contribute to impaired cognition, hypertension, cardiovascular disease, strokes and an increased risk of accidents [3, 6]. If patients comply with an effective treatment regimen they should be able to maintain their driving licence [4].

The DVLA recommends [7]:

Group 1 licences (normal car licence) - driving must cease until satisfactory control of symptoms has been attained, confirmed by medical opinion.

Group 2 licences (HGV, PSV) - driving must cease until satisfactory control of symptoms has been attained, with ongoing compliance with treatment, confirmed by consultant / specialist opinion. Regular, normally annual, licensing review required.

Treatment options for OSAHS

All OSAHS treatments aim to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experience during sleep [1, 8]. CPAP is recommended as a treatment option by NICE [1]. Once the diagnosis of OSAHS is established, it is important that the patient receives follow-up annually to ensure compliance and clinical effectiveness of the CPAP device. Alternative treatments to CPAP include lifestyle management, dental devices and surgery [1].

Dental devices/oral appliances

Dental devices and oral appliances are designed to keep the upper airway open during sleep and can be used for patients with symptomatic mild or moderate sleep apnoea [1]. They can be used if they are preferred to CPAP or if CPAP has failed or cannot be tolerated [8]. The devices fit over the upper and lower teeth and are moulded, with the aim of producing some protrusion of the lower jaw during sleep [3]. There are two main types of dental devices; tongue repositioning or mandibular repositioning [9].

Lifestyle management

Recommended lifestyle management treatment includes [1, 8]:

- weight loss - an increase in the body mass index is associated with increased risk of sleep apnoea. It is possible that weight loss can cure OSAHS or prevent it from occurring [2]
- smoking cessation - smoking produces upper airway mucosal oedema and increases upper airway resistance
- alcohol avoidance - if possible, or at least, stop drinking four hours before bedtime
- sleep deprivation avoidance - lack of sleep can blunt hypoxic and hypercapnic ventilatory chemoreceptiveness during waking hours which may prolong apnoeas during sleep by depressing the arousal response
- body position modification during sleep - to help stabilise the upper airway.

Surgery

Surgery may be considered for someone who is unwilling or unable to tolerate CPAP. Multilevel surgery of the upper airway addresses obstruction of the nose, palate and tongue [8]. Surgical procedures include nasal reconstruction, palate reduction, tongue advancement or reduction and maxillary and mandibular advancement. Success rates of clinical outcome from surgical treatment for OSAHS vary.[10, 11]. People with mild to moderate symptoms may not benefit from this treatment option [12].

Continuous positive airway pressure

There are several levels of sleep apnoea, ranging from mild to severe cases. NICE recommend CPAP as a treatment option for adults who have moderate to severe OSAHS and is considered highly effective [1]. However, it can also be an option for patients with a mild form, especially if they have excessive daytime sleepiness or co-existing problems such as hypertension [1, 2].

CPAP devices have a unit that generates airflow; the airflow is directed to a person's airway via a mask. The positive pressure that is generated by the airflow supports the upper airway, preventing the soft tissues from collapsing [1, 2]. For CPAP treatment to be effective, the person must always wear their device whenever they sleep.

There are currently three types of positive air pressure devices; CPAP, APAP and BiPAP (see *Technical considerations*), with a large number of these devices available to the UK market. Many full face, total face, nasal, oral, nasal pillow and oral nasal interfaces have also been developed; each may be supplied by several manufacturers and are provided in various sizes (see *Operational considerations*).

It is essential that the patient has the correct device and interface as problems in the early stages may result in the patient withdrawing from the treatment.

Clinical effectiveness of CPAP

CPAP clinical effectiveness studies published between January 2007 and November 2009 have been summarised in this guide (tables 1-4). The period was determined by the publication of two National Institute for Health and Clinical Excellence (NICE) reviews and a Health Technology Assessment (HTA) report on CPAP and its uses where evidence for these was evaluated up to January 2007 [1, 9, 13].

Table 1. Cochrane review: pressure modification

Study	Comparison	Conclusions
Smith & Lasserson 2009 [14] Pressure modification for improving usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea (review).	Determined the efficacy of pressure level modifications and additional humidification in increasing CPAP machine usage. These comparisons were used: 1. APAP vs. CPAP (30 studies) 2. BiPAP vs. CPAP (6 studies) 3. C-Flex vs. CPAP (6 studies) 4. Humidification plus CPAP vs CPAP (3 studies).	There was a statistically significant difference in machine usage of 0.21 hours/night in favour of APAP rather than CPAP. There was no significant difference found in usage between BiPAP and CPAP. There was no significant difference found in usage between C-Flex and CPAP. Conflicting findings in machine usage with regards to humidification found that two parallel group trials found no significant difference but a cross-over study did find a significant difference.

Table 2. Cochrane review: interventions

Study	Comparison	Conclusions
Smith <i>et al</i> 2009 [15] Educational, supportive and behavioural interventions to improving usage of continuous positive airway pressure machines for adults with obstructive sleep apnoea (review).	Critically assessed strategies that are educational or supportive or behavioural in encouraging people who have been prescribed or offered CPAP to use their machines.	Ongoing support led to increased average machine use of 0.59 hours per night. There was significant variation between the results of the studies. Short course educational intervention was no more successful in improving average machine usage than usual care. Cognitive behaviour therapy led to an improvement in average machine use in 2 studies by 2.92 hours/night.

Tables 3 and 4 specifically relate to comparisons between the different types of CPAP devices.

Table 3. CPAP and APAP comparisons

Study	Comparison	Conclusions
Galetke <i>et al</i> 2008 [16] Comparison of automatic and continuous positive airway pressure in a night-by-night analysis: a randomized, crossover study.	Compared the efficacy and adherence between APAP and CPAP based on a night-by-night analysis in 20 patients. One machine was used that was switched between both modes.	There was no difference in treatment efficacy between the two modes. The mean pressure was not significantly different.
Meurice <i>et al</i> 2007 [17] Evaluation of auto CPAP devices in home treatment of sleep apnoea/hypopnoea syndrome.	Clinical effectiveness was compared between 1 fixed CPAP machine and 4 APAP machines by assessing compliance and a quality of life survey (SF 36) in 83 patients.	There was no difference in clinical symptoms or survey results between the two methods leading to the conclusion that APAP is equally as effective as fixed CPAP for long term home treatment.
Nolan <i>et al</i> 2007 [18] Auto-adjusting versus fixed positive pressure therapy in mild to moderate obstructive sleep apnoea.	Determined whether APAP would be better tolerated because it delivers a lower mean pressure. Overnight polysomnography and an ESS were recorded in 29 patients.	No differences were found between the two treatment modes but the mean APAP pressure levels were significantly lower than CPAP. Patients requiring higher fixed pressure preferred APAP but those requiring lower fixed pressure preferred CPAP.
Parish <i>et al</i> 2008 [19] Autotitration positive airway pressure therapy in patients with obstructive sleep apnoea who are intolerant of fixed continuous positive airway pressure.	Patients, who could not tolerate fixed CPAP, tested APAP machines to check their tolerance to these devices. Twenty-five patients who had previously rejected CPAP were included in the study.	Eleven patients were able to tolerate APAP therapy with a mean number of 6.2 hours of use per night and a mean percentage of 89% nights of use. This indicates that APAP is an effective alternative for patients unable to tolerate fixed CPAP therapy.

Table 4. CPAP and C-Flex comparisons

Study	Comparison	Conclusions
Dolan <i>et al</i> 2009 [20] Longitudinal comparison study of pressure relief (C-Flex) vs. CPAP in OSA patients.	A study was completed that compared CPAP users with C-Flex users.	<p>The two groups were comparable on the number of nights on which treatment was available, with the CPAP users having an average of 174 days and C-Flex users averaging 176 days.</p> <p>C-Flex users achieved a slightly higher (but not significantly) average hours of use per night at 6.23 compared to 6.05 for CPAP users.</p> <p>C-Flex users had a greater total number of hours of treatment use, 557 hrs, compared to CPAP at 518 hours. The users of C-Flex had a comparable decrease in daytime sleepiness (measured by change in the Epworth Sleepiness scale (ESS) scores).</p> <p>Using the multivariate analysis of variance (MANOVA) the C-Flex users reported a higher degree of interface comfort than CPAP users.</p> <p>However the study did state that the overall satisfaction with interface comfort was only 53% so they concluded that the ideal treatment is still to be developed.</p>

Study	Comparison	Conclusions
Leidag <i>et al</i> 2008 [21] Mask leakage in continuous positive airway pressure and C-Flex.	Many patients with OSAHS using CPAP complain of leaky masks or too high pressure during expiration. A study was completed that compared C-Flex to CPAP with regards to these two issues.	It was found that there was no difference in leakage and compliance between CPAP and C-Flex but 9 patients chose C-Flex as opposed to 4 choosing CPAP at the end of the study due to unknown factors.
Marshall <i>et al</i> 2008 [22] Randomised trial of compliance with flexible (C-Flex) and standard continuous positive airway pressure for severe obstructive sleep apnoea.	A randomised trial comparing the compliance between C-Flex and standard CPAP was completed.	The results showed that people treated with C-Flex exhibited a trend toward higher compliance with their devices compared to standard CPAP devices (4.7 ± 2.9 vs. 3.0 ± 2.1 hours per night). However improvements in subjective sleepiness (Epworth Sleepiness Scale) were greater in those who received CPAP rather than C-Flex ($8.1 + 4.9$ vs. $2.1 + 4.0$ points). There were no significant differences in objective wakefulness and simple reaction times. Overall the trial provided some evidence that initial compliance is higher using C-Flex rather than CPAP but this greater compliance was not associated with better short-term treatment outcomes for patients.
Canisius <i>et al</i> 2009 [23] C-Flex technology: effects on breathing parameters and inspiratory flow limitation.	Investigates the effect of pressure relief CPAP on respiratory parameters and possible inspiratory flow limitation with increased difference between inspiratory and expiratory pressure compared with conventional CPAP.	The increase in the inspiratory duty cycle with C-Flex might indicate either an increase in the work of breathing or a decrease in the work of breathing due to a lower peak end-expiratory pressure and consecutive alleviation of passive expiration. Both treatments appeared equivalent regarding the occurrence of inspiratory flow limitation.

CPAP and adherence

Although CPAP is considered a successful treatment for OSAHS, the effectiveness of the symptomatic therapy mainly depends on regular use [24]. The value of CPAP and its related products can therefore be undermined by poor adherence [25].

In the UK, CPAP machines are provided free of charge by the NHS, so the main barriers to maintaining usage are due to perceived side effects and alleged poor efficacy [26]. Reasons for stopping CPAP treatment include poor mask fit, pressure intolerance and upper airway symptoms such as nasal dryness, nasal bleeding and throat irritation [1, 9], difficulty in adapting to the pressure, dislodgement of the mask during sleep and the social consequences of using the unit [9]. It should be noted that some people may discontinue because they show an improvement in their symptoms due to surgery or losing weight [9].

It is difficult to obtain a precise estimate, from available published study results, on the rates of adherence to CPAP treatment. Two important aspects to consider with regards adherence are the initial acceptance of treatment and the long-term adherence. These can be measured by examining the frequency of use and the number of hours of use per night [9]. Rates of adherence can also be observed from data obtained from performance management software on the CPAP device, if this feature is available. If a person uses CPAP for a minimum of 4 hours per night then this is considered acceptable adherence to the product [25]. Regular use of the device for 3 months is considered the best predictor of long-term adherence to CPAP therapy [2].

A low AHI was identified as a risk factor for non-compliance with CPAP treatment [27]. A low AHI indicates a more mild form of OSAHS; if a person has less severe symptoms they may not experience a significant benefit from using CPAP.

Interventions to improve the use of CPAP can be categorised as 'high technology' (advances in equipment) and 'low technology' which refers to educational and behavioural interventions [26]. The levels of intervention should always be considered together as a treatment package. The addition of humidification to CPAP and the use of alternative pressure delivery systems (APAP and BiPAP) would be considered high technology interventions. Intensified education and follow up programs would be considered low technology interventions. Both types of interventions have been highlighted as possible interventions that could improve the acceptance and compliance of CPAP [6]. Adequate information and education can reduce the fear, anxiety and non-adherence [28].

National guidance

NICE have published two reports; one recommending CPAP as a treatment option for OSAHS and one providing advice on the implications of cost when CPAP is introduced to clinical organisations [1, 13]. The Department of Health have published an 18 week commissioning pathway for adult sleep disorders [29]. The Association for Respiratory Technology & Physiology (ARTP) and IMPRESS (improving and integrating respiratory services) have also published reports that provide guidance regarding the use of CPAP [3, 30, 31]. Table 5 summarises these national guidance documents.

Table 5. National guidance on CPAP machines and their interfaces

Origin	Title	Key recommendations
National Institute for Health and Clinical Excellence (NICE)	Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome, March 2008 [1].	<p>CPAP is recommended as a possible treatment for adults with moderate or severe OSAHS.</p> <p>It may also be a possible treatment for people with mild OSAHS but only if:</p> <ul style="list-style-type: none"> • their symptoms affect their quality of life and ability to go about their daily activities and • lifestyle advice (eg losing weight, stopping smoking and reducing alcohol intake) and all other possible treatments have not worked or are not appropriate for that person. <p>The diagnosis and treatment of OSAHS and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.</p>
NICE	Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. Costing template and report, March 2008 [13].	<p>This report aims to help organisations to plan for the financial implications of implementing the recommendations made by the NICE guideline [1].</p> <p>Estimates of national cost and local cost impact have been provided based on assumptions of current practice and prediction of how this may change following implementation.</p>
Department of Health (DH)	18 Week Commissioning Pathway – Adult sleep disorder pathway 2008 [29].	Information developed to support the implementation of the 18 week commissioning pathway for the sleep apnoea and sleep disorders pathway.
Association for Respiratory Technology & Physiology (ARTP)	ARTP Standards of care for sleep apnoea services (CPAP), October 2008 [30].	This document outlines basic standards and a code of conduct to protect patients and maintain high standards of quality care for CPAP services. See <i>Operational considerations</i> for further details on this guideline.
IMPRESS: Improving and integrating respiratory services	Service specification for investigation and treatment of obstructive sleep apnoea syndrome, March 2009 [3].	<p>The nature of the OSAHS is explained, its epidemiology, effective types of investigations and treatment and the optimal requirements for the commissioned services:</p> <ul style="list-style-type: none"> ▪ the most common symptom is excessive daytime sleepiness which impairs quality of life and can affect cognitive function ▪ adverse effects on work performance are common and people with uncontrolled OSAHS have a high rate of road traffic accidents ▪ assessment of suspected OSAHS requires both clinical expertise and appropriate sleep investigation ▪ the most effective treatment for OSAHS is CPAP. Few other medical treatments produce such improvements in quality of life, social functioning and relationships ▪ a comprehensive service for suspected OSAHS requires a specialist multidisciplinary team and includes initial clinical assessment, investigation, diagnosis, provision of treatment, education and support of patients, clinical and technical follow-up, long term supervision of treatment and prompt revision of replacement equipment and parts.

Types of CPAP device

The lifespan of a CPAP device is approximately 7 years and that of a mask is approximately 6-12 months [1]. CPAP machines deliver positive pressure to keep the upper airways open. A number of factors affect the level of positive pressure required for this to function effectively. Higher levels of pressure are needed if the user is in a supine position (laying on the back) as opposed to non-supine and during rapid eye movement (REM) compared to non-REM sleep [32].

Different types of machine are available which can deliver varying levels and patterns of airway pressure. The CPAP machine delivers a constant air pressure throughout the night. The APAP device adjusts the delivered pressure throughout the night, increasing the pressure when signs of airway obstruction are detected and slowly decreasing it when respiration is normal. The BiPAP device increases the delivered pressure when the onset of inspiration is detected and reduces it at the onset of expiration. The aim of APAP and BiPAP is to improve patient comfort, minimise side effects and increase compliance. BiPAP augments each breath and is of value when the patient has a degree of hypoventilation as well as OSAHS.

CPAP

CPAP devices are portable, electrically powered pumps that generate and deliver air by way of a tube, through an appropriate interface to the patient. The air is delivered at a continuous fixed pressure during inspiration and expiration for the period of use [1-3, 33]. The pressurised air enables the airway to be held open and prevents it from collapsing cylindrically during sleep [33]. The ideal pressure for each individual can be determined during a sleep study or initial consultation but this may require modification over time due to changes in the condition of the patient, such as weight fluctuations [34].

APAP

APAP devices are commonly known as auto-titrating, auto-adjusting or automatic positive airway pressure devices.

APAP devices deliver treatment by supplying air at a variable pressure which automatically adjusts throughout the night in response to changes in airflow, respiratory events and snoring [1, 2].

High and low pressure limits are set on the device and the device adjusts the pressure within these limits to maintain the patency of the airway [14]. Pressure is increased when an airflow obstruction is identified and decreased when the airway is open again [24]. Continuous adjustment of pressure in APAP devices yields a lower mean pressure [24]; this can possibly reduce the associated side effects [9, 14]. Manufacturers' devices vary, using different sensors, methods and algorithms to achieve pressure changes [2].

BiPAP

The BiPAP (bilevel) machines provide alternating fixed pressures for inspiration (IPAP) and expiration (EPAP) [23]. The two levels of pressure are co-ordinated with patient breathing to deliver a higher pressure when the patient inhales and a lower pressure when they exhale [14, 34]. The devices have individually determined IPAP and EPAP pressures where the pressure can be alternated between fixed inspiratory and lower expiratory levels during the respiratory cycle [2, 3]. They may be used in obese patients with nocturnal hypoventilation, those with associated restrictive lung or chest wall diseases and patients with congestive heart failure who cannot tolerate high pressures during exhalation [8].

There is also a BiPAP spontaneous timed (ST) device available for patients who may develop either central apnoea or severe hypoventilation. The BiPAP ST will initiate a breath if a breath is not taken within a preset time. For example, if the BiPAP ST is set with an inspiration pressure of 10 and an expiration pressure of 5 with breaths per minute (BPM) set at 12. The BiPAP ST will initiate a breath if the user does not inhale 12 times a minute [34].

Interfaces

The interface (mask) connects the CPAP machine to the user's airway [3]. This is fitted over the nose or mouth, or nose and mouth, and allows the intake of the air pressure that opens up the upper airway enabling the patient to breathe freely [28]. The mask is held in place over the required area using elastic head gear or straps [35].

It is very important that the mask is comfortable and provides an effective seal for the airflow; the proper air pressure level cannot be established unless the fit is correct. A comfortable mask that fits well will make using CPAP easier. The mask should fit and seal over the nose and/or mouth ensuring that the straps are not too tight. Both the size and style of a mask should be considered (see table 4) [36].

Mask related complications include skin abrasion, bruising, chafing and ulceration [8]. Air-leaks can cause conjunctivitis. Airflow related complications include abdominal cramping and nasal congestion or dryness [8]. The efficacy of CPAP may be limited by poor compliance, which may be due to mask discomfort, nasal drying or irritation and intolerance of the pressure [6].

Humidification devices

Humidifiers can also be used in conjunction with some CPAP devices to help reduce potential side effects such as nasal dryness, nasal bleeding and throat irritation. Humidifiers can be integrated into a CPAP device or can be a totally separate device. These devices warm and humidify the air from a CPAP machine prior to delivery to

the patient. The humidifier usually has a reservoir of water which can be refilled every night [3].

Technical product requirements

Table 6 lists general requirements for CPAP devices, and applicable standards.

Table 6. Technical product requirements applicable to CPAP devices

Technical requirements	
Medical devices regulations	<ul style="list-style-type: none"> ▪ All products must comply with the Medical Devices Regulations 2002 [37] as amended 2008 [38].
Labelling & instructions for use	<ul style="list-style-type: none"> ▪ A copy of the user guide must be supplied with instructions for use and maintenance. ▪ All parts of the system should have the following permanently and prominently affixed: <ul style="list-style-type: none"> ▪ CE mark according to the appropriate class from MDD 93/42 EEC [39]. ▪ name of the manufacturer (and/or supplier if different) ▪ model and serial or batch number ▪ year of manufacture ▪ safe working load.
Cleaning / decontamination	<ul style="list-style-type: none"> ▪ Cleaning instructions should be provided, including any information on specific cleaning products that must or must not be used. ▪ Products must comply with the national infection control guidelines [40] and must be easy to clean and disinfect.
Applicable standards	<ul style="list-style-type: none"> ▪ BS EN 60601-1-1:2006 (electrical safety) [41]. ▪ BS EN ISO 17510-1:2009 (sleep apnoea devices) [42]. ▪ BS EN ISO 17510-2:2009 (sleep apnoea masks and accessories) [43]. ▪ BS EN 60601-1-8:2007 (guidance related to alarm systems) [44]. ▪ BS EN 5356-1:2004 (guidance related to conical connectors) [45]. ▪ BS EN ISO 8185:2009 (guidance related to humidifiers for medical use) [46]. ▪ BS EN ISO 10993-10:2009 (guidance related to tests for hypersensitivity) [47]. ▪ BS EN ISO 17664:2004 (guidance related to sterilisation of devices) [48].

Device selection

The CPAP machine and interface chosen should be matched to the users' needs. Table 7 presents operational characteristics and table 8 interfaces for CPAP devices.

Table 7. Operational characteristics of CPAP devices

Operational characteristics of devices	
Types	The different types of devices are CPAP, APAP and BiPAP (see <i>Technical considerations</i> chapter). For this table, the term 'CPAP' encompasses CPAP, APAP and BiPAP unless APAP and BiPAP are specifically mentioned.
Operational mode	There are two operational modes on a CPAP machine: prescriber/clinical and user. The prescriber mode enables settings to be made and adjusted by the prescriber and these must be locked before supply so the user cannot change parameters. The user mode enables a limited range of comfort settings to be accessed by the person using the machine at home. This allows different pressure limits to be used to maintain comfort and clinical efficacy.
Dimensions	The size and weight of the device should be considered if the device is to be used regularly outside of the home environment eg for travel, work. Devices that do not have an integral humidifier will be larger in size.
Power options	CPAP machines can be operated by using standard mains electricity, battery or both. Battery power is useful for travel purposes. Power cord length can provide greater positioning flexibility.
Fixture options	Connectors must be 22mm, conical and comply with BS EN ISO 5356-1 [45]. Tubing: the tube should be flexible and of a suitable length to accommodate the users requirements eg between the bed and CPAP device. The hose should also have an appropriate connector for the CPAP device used. If the tube is longer than 3.7 metres then increased pressure may be required [36]. 360° swivel connection: is available on some devices. This function allows a level of flexibility at the point of connection between the tube and the device, thereby reducing the possibility of the hose detaching from the device when used in bed.
Performance management	Digital display/buttons: many devices have a large LCD back-lit display. User instructions are provided by the manufacturer. The ease of use and size of the buttons and the display may need to be considered for some individuals. Software/Memory card (USB): some devices use either software incorporated into the device or a memory card (USB) system to record motor usage and/or compliance hours. This function allows the clinician to download patient compliance data at the patients annual review. Compliance meter: will measure motor usage and the numbers of hours the device has run at pressure. Data is stored using either software incorporated into the device or on a memory card (USB). This allows the clinician to determine whether the user is complying with treatment. Alarm: an adjustable low saturation alarm may be advisable in certain patients but it should be possible to turn off in order to record the patients usual saturations [31].
Settings	Pressure measurement: from the 01.01.09 the unit of pressure measurement for CPAP devices is the hectopascal (hPa), however cmH ₂ O was previously used. 1hPa = 1cm H ₂ O and 1hPa = 100 Pa. Pressures >20hPa present a known risk of swallowing air and subsequent regurgitation [42]. The maximum steady limiting pressure [42]: <ul style="list-style-type: none"> • CPAP and self-adjusting (APAP)

Operational characteristics of devices

- 20hPa (20 cm H₂O) + pressure stability under normal use
- 30hPa (30 cm H₂O) under single fault condition
- Bi-level devices
 - 30hPa (30 cm H₂O) + pressure stability under normal use
 - 40hPa (40 cm H₂O) under single fault condition

Annual pressure checks are performed by the service provider to ensure pressure settings remain clinically effective and comfortable for the patient.

Operating temperature °C: this is the temperature range in which the device should typically operate in and usually ranges between 5°C to 40°C [42].

Altitude adjustment: this function is available on some devices and should be considered for those who travel either for holidays or for business. The adjustment can either be manual or automatic depending on the device.

Leak compensation: some devices have a function to detect large unintentional air leaks from the exhalation port allowing adjustments to be made. These are usually undertaken by Any leaks are shown on the display screen

Sound/noise level: the World Health Organisation (WHO) recommends that the sound pressure level should not exceed 30dB(A) for undisturbed sleep [42].

Ramp start/Softstart function: this user feature reduces the air pressure when the patient is trying to fall asleep and then gradually increases (ramps) the pressure until reaching the set prescription. This can assist with falling asleep more comfortably. Although the ramp start is a user feature it is enabled and set by the service provider.

Auto adjust facility: this feature is found on APAP devices. The function automatically adjusts air pressure by measuring the patients snoring and breathing patterns on a breath-by-breath basis, and compensating to meet the pressure needs. Changes in pressure are made gradually enough to prevent disturbing sleep, but quickly enough to respond to pressure needs. Pressure is reduced to maximise comfort in the absence of respiratory events.

C-Flex™ or Expiratory Pressure Relief (EPR): is an optional feature on some devices that makes breathing back against CPAP pressure easier to do and only works at the start of exhalation unlike BiPAP [34]. A basic pressure is set for the period of use but the machine tracks the users effort and drops from the basic pressure by a preset amount at the start of expiration, increasing back to the basic pressure at the end of expiration [14]. The function allows the reduction of the expiratory mask pressure below the end-expiratory level that has been set by the clinician in proportion to the patients expiratory airflow [23]. Table 4 provides published high level clinical effectiveness study results comparing standard CPAP with C-Flex use.

A-Flex: an optional feature matching pressure delivery to the whole breathing cycle making breathing more comfortable at inhalation and exhalation. Flow-based pressure relief is provided at the start of exhalation, softening pressure transition from inhalation to exhalation.

Humidifier	Humidifiers warm the air from the CPAP device prior to delivery to the patient. This function can improve comfort and reduce irritation such as nasal dryness. The system can be integrated into a CPAP device or can be a totally separate device. Some humidifiers require distilled water for use. It may harm the device if the wrong type of water is used. Individual manufacturers can advise on the type of water required.
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Filters	These can be either reusable or disposable. The reusable filters should be periodically removed, cleaned and allowed to dry before replacing back in the machine. The disposable ones need replacing regularly depending on each manufacturer. They are used to clean the air which moves through the device by removing bacteria, pollen and allergens, ensuring that people inhale clean air while using the machine [49].
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Operational characteristics of devices

Infection control Information regarding cleaning and disinfection prior to first use and for maintenance thereafter should be provided in the user instructions from the manufacturer. Devices should be constructed so that all parts used in the gas pathway can be dismantled for cleaning and disinfection or cleaning and sterilization [42]. Processing or (re)processing instructions for the equipment and their parts shall comply with ISO 1766 [48]. If the gas pathways cannot be dismantled for cleaning, a filter should be provided at the point of the gas output port to minimise the potential for contamination. Filters can either be reusable or disposable [42].

Portability For portability, some devices are supplied with a carry bag which can hold the device and associated accessories. The size of the device and the carry bag should be considered in relation to international aviation specifications for hand luggage.

Manual/ Instructions The operating instructions should be in a language the patient can understand and have appropriate diagrams, figures and pictures for setup and use of the device and associated accessories.

Training Training is usually provided by the manufacturer to the clinicians and then the clinicians train the patient on how to use the device before it is supplied. The hospital encourages CPAP users to contact them if they have any issues once they start to use the device.

Purchasing A product can be bought, rented or provided as part of a contracted service. See *Purchasing* for details. Suppliers will usually provide demonstrations of their products for training purposes. This should include the accessories that have been bought as part of the system.

Maintenance The device, mask and hose will require external cleaning and changing/cleaning of particular filters. Details regarding maintenance will be provided by the service provider and manufacturer. The devices last between 5 and 7 years [1]. The machines should be regularly checked for safety and clinical efficacy at the patients' annual review.

Guarantee / warranty Contact manufacturers for details regarding warranty and guarantee periods.

Table 8. Operational characteristics of CPAP interfaces including head straps

Operational characteristics of interfaces	
Type of mask	<p>Full: these are usually triangular shaped masks designed to fit over both the nose and mouth and are held in place with straps or headgear. These are used if a patient cannot breathe through their nose or are mouth breathers (mouth drops open unintentionally whilst asleep). This type of mask combats the problem of a person opening the mouth during sleep which can impact on the therapeutic effect of CPAP [30]. These masks need to comply with safety standards that avoid risk of asphyxiation if the device fails or there is a power cut [43].</p> <p>Total: these masks seal over the entire face at the forehead, down the sides and under the chin. It can only be used when sleeping on the back and is therefore only used when other options have been unsuccessful [34].</p> <p>Nasal: this mask is designed to fit over the nose; it seals around the entire nose and is held in place with straps or headgear. It is sometimes called a nasal cushion. These are the most popular and are the first line of treatment when using CPAP. The patient has to be able to breath through their nose for this to be suitable. It is available in many different sizes and models as well as differing cushion types [34, 36].</p>
	<p>Oral: this mask is designed to fit over the mouth only. They are usually only used if the nose is completely blocked. The CPAP air is not conditioned by the mucous membranes in the nose so an oral mask tends to dry out the mouth and therefore should be used only with a heated humidifier. People who grind their teeth cannot use this mask [36].</p> <p>Nasal pillows: this interface is more lightweight than a standard nasal mask. It is designed to fit over both nostrils and provide a seal around the circumference of each nostril instead of around the entire nose. The pillows open into the nostrils but are not inserted inside to seal. The CPAP therapy is applied directly through the nasal passages via the nasal pillows. This is preferred by side sleepers, stomach sleepers, can be used for those with claustrophobia and those with facial hair as skin contact is reduced to a minimum. It may also solve allergy problems as the pillows do not rest on the nose, upper lip or cheeks [36].</p> <p>Oral nasal: this combines a nasal pillow and oral mask. This allows a person who breathes through both the nose and mouth the option of using nasal pillow in conjunction with a mouth cushion. This is useful for a person who is claustrophobic as it touches the face less than a full face mask. They are not used often; only if a person cannot fit a full face mask [34, 36].</p>
	<p>Single use All masks for CPAP home use are single use.</p>
	<p>Sizes Most masks are available in the following sizes: petite, XS, S, M, L, XL to ensure the whole population can be covered. The masks can be standard size or shallow.</p>
	<p>Material For mask materials, including headgear, intended to contact the patient's head, the materials should be evaluated as skin contacting and categorized in ISO 10993 [43, 47]. The interface material must be reasonably break-proof and transparent (to allow impurities to be recognised) [30]. Consideration should be given to patient comfort and hypoallergenic materials should be used where appropriate.</p>
	<p>Interface cushioning It has been stated by clinicians that although the mask lasts approximately 12 months, the cushions only last about 4 months; so when masks are provided, 1-2 extra cushions are provided. The cushions can be made from gel, foam, silicon and memory foam. The cushions should be removable to allow them to be replaced.</p>

Operational characteristics of interfaces

Settings	Adjustable tension: masks and headgear can be adjustable for comfort and to ensure the best fit for the individual.
	Quick release clips: most masks offer a quick release mechanism to allow for quick removal of the mask and also means that they do not have to be adjusted every time the mask is used [36].
	360° swivel connection: there is the availability for two swivel connections; one forms an attachment between the machine and the tubing and the other between the mask and the tubing. It allows the user more manoeuvrability in bed with fewer disturbances.
Cleaning	Recommendations for cleaning masks and filters should be included in the instructions for use provided by the manufacturer [42].
Interface options	The compatibility of which interface fits each CPAP device should be confirmed with the manufacturer before purchase/use. Ideally, each interface should be compatible with any device but this is not the case particularly with APAP machines. However, all manufacturers do provide both interfaces and machines for purchase.

Ergonomics and CPAP

Main principles

Ergonomics is a systems-based approach to the development of products and services, which places the user at the centre of the design process. This approach has significant benefits, particularly in the healthcare sector, where abandonment of equipment or treatment can be costly to the individual, the service provider and the state.

Abandonment of CPAP systems is a recognised issue, and the interface is often cited as the main reason [1, 9]. This suggests that better matching of the user to this element of the design may be able to reduce these rates, improving outcomes as well as saving resources. This may be achieved by the use of better design, more appropriate materials or, if the design is already optimised, through expectation management in the user.

When applying an ergonomics approach it is essential to identify who the primary (and normally secondary and tertiary) users are such that their needs can be properly identified. Consideration is then given to the task to be undertaken and the environment in which those tasks take place which contextualises the use and highlights possible conflicts between the product and the user.

For CPAP devices, the primary users will be UK adults, although within this population, middle-aged males are dominant. Additionally, there is a high probability that the user will be obese. This information suggests that whilst the user will be typically larger than average, their mobility, dexterity and general health are all likely

to be compromised. Accordingly, the design of acceptable CPAP devices must accommodate these limitations if abandonment is to be minimised.

The task for the user is to self-administer this therapy in an error free and consistent manner. Clearly within this there are a range of sub tasks, but each will be part of this greater activity.

The environment in which the device must be employed will cover the user's home, hospitals and other healthcare establishments, hotels, caravans and camping, lorry cabs, domestic residences and periods (and modes) of travel in between. Each of these will provide different requirements but the user's home, other domestic residences and travel are likely to be those situations where the user requires the most suitable equipment.

In order to provide additional value to the Buyer's guide, the significant elements of usability are presented as subsections below. Each subsection offers guidance as to possible features and/or requirements of the equipment which will serve to make it more acceptable to users. These features and requirements may be used to generate questions for potential suppliers to evaluate the likely performance of their products in use and hence the satisfaction of the user, thereby securing continued use and better value.

The user interface

The user interface is the component which connects the user to the CPAP device and which therefore offers the greatest possibility of fit and satisfaction issues. Whilst there is logical sense in a user accepting limitations in equipment since its function is vital healthcare, the abandonment rates suggest that many users overlook the immediate and important benefits because the interface is so problematic. This will inevitably result in a costly outcome in terms of rejected products and use of clinician's time.

In order to ensure best value and best performance (since an abandoned device will always be inferior to even the most poorly performing device which is actually used) investment in ensuring that the most satisfactory interface is chosen at the outset will be well rewarded.

It is clear that most interfaces have been developed to provide as much comfort as possible, but they differ widely in style and structure. Users should be allowed to try, in their own homes, a wide range of these interfaces, subject to individual circumstances, in order to select the one they find most comfortable. This might require some additional assistance and education such that the user can be aware of optimising the fit and performance, but this should focus around the user's preference rather than clinical convenience.

Ideally, the user should be able to select the interface of their preference and this should be mated to the device which offers optimum clinical performance. Stakeholders have demanded that all interfaces should be fully interchangeable with all CPAP devices through universal fittings, but this does not yet seem to have been adopted. This feature should be explored with potential suppliers.

Interface design

The interface should offer the following ergonomic features:

- it should be shatter proof (all components)
- it should perform to a consistent standard for its service life and the service life should be stated by the manufacturer
- the interface seal should be as soft and pliable as possible to ensure a good fit to the user's face – inflatable seals are a way of allowing users to self-tailor the fit to their own preferences
- the interface should not decay (in fit or performance) with age and cleaning
- if decay is inevitable because of the nature of the design or materials, then an indicator should be provided such that the user knows when the interface needs to be changed
- the interface design should address user needs. Accordingly, the supplier should be able to define the range of users for whom it is designed. This should be expressed as percentiles of the population, which will indicate how many people will potentially be excluded from effective use. This information should support the categorisation into sizes such as "small", "medium" or "large", etc. but should also recognize that facial features may not reflect overall morphology (i.e. small people may have large heads) and that a significant proportion of users will be obese, which will skew any fitting guidance. Correct fitting will be more likely if this information is secured from suppliers, as well as highlighting suppliers who have a less thorough understanding of their product's role
- other user characteristics should also be taken into consideration, such as the presence of dentures, the effect on preferred hairstyles, mobility during sleep etc. Suppliers should be able to provide information on the suitability of their equipment with regard to these issues since they will be important to the user
- the interface should be able to be assembled and disassembled by the consumer without tools
- the interface should be capable of being cleaned effectively with household products, whilst withstanding more rigorous hospital cleaning agents and sterilisation
- the interface should be clearly marked as to whether it is reusable or for single use – colour coding would be appropriate
- the interface should fail-safe, such that no negative outcomes occur if the equipment fails or if power is lost

- the interface should feature a quick or easy release such that the user may easily remove it in case of panic
- the interface should be fully assembled at the point of first contact with the consumer
- the interface should allow correction to its fit if the user loses weight, since CPAP likely to be used as part of a lifestyle management programme
- the sleeping arrangements of the user should be considered in assessing the appropriate interface (including allowing users to trial equipment). Users who sleep on their own may have different requirements which can be identified through consultation. Users may also have individual preferences for other sleep equipment (cushion or pillow arrangement, for example to address back discomfort) which will need to be considered when choosing the appropriate interface
- the interface should work effectively in the position in which the user wishes to wear it rather than in a particular specified manner controlled by the manufacturer
- any interface straps should be breathable, hypoallergenic and made in such a way as not to entrap hair
- the interface design should be sensitive to religious or cultural issues which may interfere with satisfactory use. These could include modes of dress, or contact with sensitive areas of the body
- the fit of the interface may change over the duration of a day. If fitting is undertaken during daylight hours then fit may be different at night time. Users need to be exposed to normal use conditions before selecting a preferred interface design.

Interface fit and anthropometry

Anthropometry is the study of human measurement and the data generated from this discipline can be used to help predict the likely fit of equipment to users. There are two elements to anthropometry; static anthropometry which deals with physical dimensions and dynamic anthropometry which relates to the body in movement. Anthropometric data is published and offers the ability to match users and devices. Most data is expressed in percentiles and in safety critical applications it would be normal for a design to accommodate from the 1st to the 99th percentile; excluding the largest 1% and the smallest 1%, 2% in total. However, greater inclusion can be further secured by extending the percentile range although no product can claim to cover 100% of the population.

For a product such as a CPAP device, it would be appropriate to expect a very low exclusion rate, particularly since the interface has to fit quite extreme individuals due to the prevalence of obesity. However, since the interface locates on the head, variation in the actual dimensions is quite small. Accordingly, it is recommended that interfaces are selected from a range which accommodates between 0.01st percentile

and 99.99th percentile individuals (or greater, if possible) so as to only exclude 0.02% of the population. In this way the physical fit of the device should not be a limiting factor to user acceptance.

Table 9 presents several typical dimensions for the face and head and their respective 0.01st, 1st, 99th and 99.99th percentile values to indicate the range of fit that is required.

Table 9. Typical head dimensions for UK adults (mm)

Variable	0.01 st %ile	1 st %ile	99 th %ile	99.99 th %ile
Head girth	486	512	617	645
Chin to top of head	185	198	250	265
Lip length (relaxed)	35	41	62	70
Nose breadth (widest)	19	25	43	49
Nose breadth at top (bridge)	10	12	18	20
Face breadth at cheekbones	114	122	156	167
Face breadth at ears	111	120	156	165
Distance between brow ridges	91	98	123	131
Maximum head breadth (above & behind ears)	123	133	167	178
Chin to back of head	151	164	214	232
Nose depth	10	14	25	29
Nose length	36	41	58	65

CPAP interfaces are likely to be offered in more conventional fit categories, such as medium or large, but the range of interfaces should be sufficient to ensure that all potential users can be adequately accommodated. Suppliers should be able to provide the dimensional data which can be compared against percentiles to indicate likely levels of poor fit or exclusion.

It should be noted that anthropometric data only predicts the fit for an individual but the actual fit can only be established by use. Accordingly, whilst an appropriate interface size might be selected on the basis of the user's size, the user should be allowed to experiment with other sizes to accommodate preference and individual characteristics.

Usability of the CPAP controls

The CPAP is controlled by some interactive mechanism, which would normally be called an interface. However, given that this term is already defined for this product group, this mechanism will be referred to as the user control system.

Examination of prospective systems can be undertaken using established principles of usability, as highlighted in table 10 below. Evaluation of particular systems in light of these considerations will illustrate those that have better considered user usability and hence are more likely to be accepted. Alternatively systems can be appraised against these principles by human factors experts or evidence of such appraisal can be required of potential suppliers.

Table 10. The control system principles

Principle	Description	Application
Visibility of the system status	The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.	An LCD light to show the system is working correctly or a command has been entered.
Match between the system and the real world	The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.	Use of pictograms or icons to show control functions, avoid jargon or technical terms.
Consistency, standards and stereotypes	Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.	Up arrow to increase values, down to lower. Use of de facto standard e.g. lock symbol, red for off or stop, green for on.
Aesthetic and minimalist design	Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.	Some control systems have complex layouts and labelling which will impair the efficiency of the user. The device should have a dedicated layout for patients with restricted options and accessible language.
Help and documentation	Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation.	Provide a simple booklet prompt, card or label located on the device to give explanatory information about its use.
Perceivable information	The design must communicate necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.	Written text should be no smaller than a 14 point, and readable in both low and bright ambient lighting conditions. Contrast between text and background should be high.
Low physical effort	The design must be usable efficiently and comfortably and with minimum fatigue.	Provide a design such that the user can press and operate all buttons comfortably with one hand, even if suffering from restricted dexterity.

Principle	Description	Application
Tolerance for error	The design must minimise hazards and the adverse consequences of accidental or unintended actions.	Ensure that the control system requires confirmation of commands to avoid unwanted errors.
Permit easy reversal of actions	This feature relieves anxiety, since the user knows that errors can be undone; it thus encourages exploration of unfamiliar options. The units of reversibility may be a single action, a data entry, or a complete group of actions.	Link related controls such as increase and decrease with adjoining buttons so that operators can easily reverse an adjustment action.
Conformity with user expectations	The control should be intuitive to use for new users and for more experienced users accessing new controls or commands.	The system control should be tested with inexperienced users to see if they operate the equipment quickly and easily without practice as might be required in a real context.

In addition to the design principles, there are also a range of broad considerations regarding the specific design elements of the control system. Whilst these are normally assessed by expert appraisal, it is possible to review the design of specific products with regard to their likely usability. Alternatively, suppliers can be asked to provide evidence as to their consideration of these matters in order to provide a separate means of assessment. The main issues are outlined in table 11.

Table 11. Main issues regarding design elements of the control system

Design element	Application
Design the control system to be intuitive	<ul style="list-style-type: none"> • Important functions should be mapped to dedicated buttons. Users often struggle with controls that require a switch between 'modes' to access features. • Buttons should be clearly distinguished from each other. Group related buttons using size, texture, shape and colour to make buttons stand out. • Avoid using logos and ambiguous icons on buttons. These are often too subtle and require a text label or some explanation to communicate their purpose.
Ensure the control system is accessible for the target users	<ul style="list-style-type: none"> • Ensure buttons are a good size and well spaced to allow easy access. • Users with large fingers, long finger nails or dexterity impairment often hit the wrong button. • Co-locate buttons that are often used in combinations. For example, putting directional arrows together. • Make sure the control system works well for both right-handed and left handed users.
Ensure the control system is responsive in operation	<ul style="list-style-type: none"> • Consider providing a light or audible response to indicate when a button has been pressed – users often repeatedly

Design element	Application
	press buttons in the absence of good visual and tactile feedback. <ul style="list-style-type: none">• Design buttons so that they provide firm feedback when pressed.
Ensure the functions of the control system are recognisable	<ul style="list-style-type: none">• Use recognisable symbols and shapes – to an international standard where possible or by user testing where not.• Identify the most important and frequently used buttons on the control system, and make these easy to find even when the user is not looking directly at the system.

The control system design features

The control system is an important element of the CPAP product which faces some design conflicts – the need to be accessed by both the user and the clinician for example. The temptation in such scenarios is to design for the technical user since the consumer can be ‘taught’ the correct use. This is a dubious approach since it assumes that any such teaching is effective and that the user will be in a fully cognitive and physically able state when needing to use the equipment. In practice it is likely that the user of a CPAP device will be compromised; either by being in a darkened environment or by being partly asleep or a number of other factors. Accordingly, the control system needs to be simple, error proof and easy to use. With these requirements in mind, the following design requirements will enable closer scrutiny of a supplier’s products and a better illustration as to the consideration to usability in the design.

- The control system should possess a means of clearly conveying the system status, which should include the following elements:
 - on/off condition
 - error or system malfunction indicator
 - system service requirement indicator
 - filter change requirement indicator
 - low battery warning indicator (where applicable).
- The control system should be self illuminated for use in dark ambient conditions. The level of lighting should be adjustable to allow for the user to customise it such that it doesn’t disturb their sleep. A low level of background illumination with an associated brighter illumination of fixed duration following operation, would allow for location of the controls and effective changes to the settings without providing a disturbing light in the room
- The control system should provide an audible warning if the system has suffered a critical failure or problem.

- The control system should be operated by means of buttons (or other devices) of suitable size to allow those with both cognitive and dexterity impairments to be confident of correct and easy operation. Current practice suggests buttons of at least 22mm in diameter, for example, to permit ease of use. Smaller buttons can lead to errors or difficulty in operation.
- Considerations should be given to the storage of the CPAP system, not just during transit but also for the interface during periods when it is unused. Such storage facility will prevent degradation through chemical or UV sources as well as protecting from damage. It may also facilitate a user who does not wish for such apparatus to be openly on display.
- The assessment of noise levels generated should be undertaken in consideration of the fact that noise is context based. Given that the system is intended to be used at night whilst the user, and others, are sleeping, then the environment will be particularly quiet. Accordingly, even very low levels of noise may be highly intrusive. Users may need to experiment with different systems to ensure that the noise does not interfere with sleep, either through volume or frequency.
- The controller must be physically stable – intrinsically and able to resist reasonable external forces applied in use through deliberate, accidental or human movement induced forces.
- The assembly of the device and, in particular, the attachment of the ventilating tube should be capable of being undertaken using no more force than can be generated by a 5th percentile female user. Force requirements can be compared against anthropometric data depending on the actions required to complete assembly.
- The mains power lead for the CPAP controller should be of sufficient length to accommodate reasonable use in the home and in more unfamiliar environments. Hotels and other places of temporary residence may not be optimised for bedside location so the lead should be a minimum of 1.5 metres. It may be appropriate for longer leads to be available as optional extras.
- The CPAP control system should be fitted with an effective child lock which can be operated by the user. This should prevent the settings being tampered with without the system being unlocked and should require a suitable code or process to disable.
- Routine equipment servicing relating to consumables such as batteries and filters should be easy to undertake without tools and the need to change these items should be indicated by a specific service indicator light for the component in question.

- It is important that any data files generated by the CPAP system can be read by proprietary software rather than specialist software provided by the supplier. The user should be able to download and read their own data files. Failing this, the software should be supplied without restriction and updates provided free of charge to the user and clinician.
- Any memory card facility should use standard contemporary format memory cards. This will reduce on-costs associated with the product and enable downloading of information on conventional PC computers.
- The system should be programmed such that it is reset failsafe. In this way it should reset to the last saved settings (as opposed to factory default) following an operating error.

Instructions, labelling and warnings

Instructions, warnings and labelling associated with any CPAP system should be assessed for effectiveness, or evidence of such assessment sought from the supplier. This should include the appropriateness of the language, content and structure of the instructions, the comprehension and impact of the warnings and the durability of information such as warnings and labels. Guidance on such issues is beyond the scope of this guide. However, certain elements should be essentially contained within the instructional material. These should include the following:

- a helpline contact number for users to access assistance. This should be provided as a human contact, not as an automated assistance system
- advice should be contained within the instructions on likely causes of early abandonment and how to minimise the likelihood of these occurring
- a specific advice should be given to users as to what steps to take if they are considering abandonment. These steps should be practical, timely and achievable. It is likely that they will be consulted at a critical time in the product's use, so ill considered advice such as 'write to' or 'contact your consultant' would not be effective. Alternative coping strategies for managing their current difficulty with the product, contacts for immediate help and other such meaningful advice may convert a costly abandonment into a high value adoption by a user
- an instructional road map containing only critical information (such as the correct way to connect the appliance) but then guiding the user as to where they can find additional information should be available
- contact information for spares, maintenance and non-urgent advice should be provided as a matter of course. Ideally this should not be via the same contact as the users helpline mentioned above

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- in addition, because of the complex relationship with other elements of the user's life, more localised advice should be available via the instructions. This should include reminders and additional information regarding integrating the CPAP into an improved lifestyle, reminders of the benefits of such a lifestyle and where to find information regarding trying new equipment or swapping current equipment for an alternative version
 - any instructions should be printed in an appropriate typeface (minimum 14 point, sans serif etc.) and in a format that will enable them to be kept with the CPAP device. This may require a specific pocket in the travel or storage case, or even an on-product storage facility.

Cost of CPAP

When considering a CPAP machine, the costs should include the initial price of the machine, technician time and the interface/mask. Costs should also include the yearly cost of replacement for the mask and cushion and the yearly maintenance engineer visit. NICE also reported that CPAP machines have a lifespan of approximately 7 years [1, 13]; so it is important that the full replacement cost of a device be taken into account when calculating whole-life costs.

According to NICE, the price of CPAP devices ranges from £250 to £550, but these prices may vary due to negotiated procurement discounts [1]. During stakeholder consultation, clinicians stated that the minimum price for a device was approximately £150 +VAT with interfaces varying from £100 +VAT for a full face mask and £40 +VAT for a nasal mask. The NICE report concluded that the different CPAP models available are broadly similar, with no robust evidence on patient preferences. Therefore, the make and type of CPAP device to be issued should be made through an assessment of individual requirements [1].

The IMPRESS report estimated that an average Primary Care Trust responsible for a population of about 0.5 million, might expect approximately 500 new referrals to be made per annum; with two hundred new patients provided with CPAP annually and a cumulative follow up population of 1500 under supervision and receiving long term CPAP treatment [3].

Cost effectiveness of CPAP

A systematic review, including economic analysis, was commissioned by the Health Technology Assessment (HTA) programme on behalf of NICE [9]. A separate paper discussing the results of the economic analysis from the HTA systematic review was also published [50]. The results of the review informed the NICE technology appraisal guidance TA139 and costing template [1, 13]. The results for the HTA report are outlined in table 12.

Table. 12. Summary of the Health Technology Assessment systematic review

Study	Comparison	Conclusions
McDaid <i>et al</i> 2009 [9] Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnoea/hypopnoea syndrome: a systematic review and economic analysis, HTA.	Determined the clinical effectiveness, safety and cost-effectiveness of CPAP devices for the treatment of OSAHS compared with the best supportive care, placebo and dental devices.	<p>There was clear evidence that CPAP is an effective treatment for OSAHS compared to usual care and placebo in populations with moderate to severe daytime sleepiness. There may also be benefits where the disease is mild.</p> <p>Using a Markov model, on average, CPAP was associated with higher costs and benefits than were dental devices or conservative management. The incremental cost per quality-adjusted life year (QALY) gained of CPAP was below £20,000 in the base-case analysis and most alternative scenarios.</p> <p>In the base case analysis the incremental cost-effectiveness ratio (ICER) for CPAP compared with dental devices was £3,899 for men and £4,335 for women.</p> <p>The probability of CPAP being more cost-effective than dental devices or conservative management at the threshold of £20,000 per QALY was 0.78 and 0.80 for men and women respectively.</p> <p>There was a high probability of CPAP being more cost-effective than dental devices and conservative management for a cost-effectiveness threshold of £20,000 per QALY gained.</p> <p>Dental devices may be a treatment option in moderate daytime sleepiness but the evidence to support this is unclear.</p>

A second cost-effectiveness study used a Markov model to analyse management of a 55 year old patient with severe OSAHS as defined by the AHI >30 and daytime sleepiness (ESS score ≥12) [51]. The model covered 14 years. The relevant results are shown in table 13.

Table. 13. Markov model results

	Untreated patients	Patients treated with CPAP
Life expectancy	57%	72%
Cost to NHS	£10,645 (95% CL £7,988-£14,098)	£9,672 (95% CL £8,057-£12,860)

Treatment with CPAP was found not to be a cost-effective option for a period of one year because the cost per QALY gained was expected to be >£20,000. After two years the cost per QALY gained was expected to be £10,000 or less. After 13 years of treatment CPAP becomes a dominant treatment (more effective than no treatment for less cost). Overall conclusions were that, as well as CPAP being found to be more clinically effective than no treatment, it also became a cost-effective strategy after a minimum of 2 years treatment.

Within the NICE report, an appraisal committee considered four economic evaluations where CPAP was compared with a 'do nothing' alternative [1]. The resulting incremental cost effectiveness ratios (ICERs) were converted from US or Canadian dollars in August 2007:

1. approximately £1,688 per QALY gained from a third-party payer perspective and £158 per QALY gained from a societal perspective
2. £5,348 per QALY gained over a 5-year time horizon and £3,359 per QALY gained for a lifetime time horizon
3. £8,300 per QALY gained at 1 year and £5,200 per QALY gained at 2 years
4. £4,654 per QALY gained for the high-cost estimate and £1672 per QALY gained for the low-cost estimate.

ResMed (UK) produced an economic model for the NICE report that compared fixed and auto-titrating CPAP devices with a 'do nothing' alternative. The results showed that both fixed and auto-titrating CPAP devices are associated with more QALYs and lower costs than 'non-treatment' after a minimum of 2 years of treatment [1].

Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [52].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1st 2008) [53] (appendix 1). The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (www.supplychain.nhs.uk), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Sustainable procurement

The UK Government launched its current strategy for sustainable development, *Securing the Future* [54] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
- climate change and energy – confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

End-of-life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [55]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is

again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

Purchasing decision

The method for CPAP procurement varies across NHS trusts. Local practice has been developed and applied to include mini-tendering procedures, either independently or with the support of the relevant regional collaborative procurement hub. Short term contracts are common, usually lasting up to two years, either with one manufacturer supplying a range of devices and interfaces or with multiple manufacturers. Contracts usually include the provision of maintenance and training, as well as mask and cushion replacements. There is usually a limit on how many masks can be supplied per machine. Other factors which may be considered when negotiating contracts include:

- ability to order in bulk
- extended warranty period
- 'package' pricing including device, mask, tubing, bag *etc.*

Within the various NHS trusts, CPAP contract specifications are usually designed by the purchasing team in consultation with key clinicians, for example clinical physiologists. However, the person responsible for the ultimate purchasing decision can vary between trusts. Whilst clinicians who will be using the devices are consulted regarding their preference, the final decision is often made by senior management with budgetary responsibility.

We should like to thank the following for their contribution to this buyers' guide.

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Andrew Hall, Consultant in Anaesthesia, Intensive Care & Sleep Disorders Medicine, University Hospitals of Leicester NHS Trust

Chris Hanning, Honorary Consultant in Sleep Medicine, University Hospitals of Leicester NHS Trust

Dena Muirhead, Principle Clinical Physiologist, Derby Hospitals NHS Foundation Trust

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Prof. John Stradling, Sleep Unit Director, Churchill Hospital

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Glossary term	Recognised abbreviation	Meaning
Apnoea		Temporary absence or cessation of breathing as a result of an obstruction.
Apnoea-hypopnoea index	AHI	The average frequency of apnoeas plus the number of hypopnoeas per hour of sleep.
Auto-titration positive airway pressure	APAP	APAP devices have different names; the most common are auto-titrating machines, auto-adjusting machines or just automatic positive airway pressure machines. APAP provides continually adjustable pressure during inspiration and expiration throughout the night in response to changes in airflow, respiratory events and snoring.
Bilevel positive airway pressure	BiPAP	These provide alternating fixed pressures for inspiration and expiration. It delivers two separate and distinct pressures; that being a higher pressure when the patient inhales and a lower pressure when they exhale [34]. There are two types of BiPAP devices; inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The devices have individually determined IPAP and EPAP pressures where the pressure can be alternated between fixed inspiratory and lower expiratory levels during the respiratory cycle.
Chemoreceptors/chemoreceptiveness		A sensory nerve cell or sense organ that responds to chemical stimuli.
Continuous positive airway pressure	CPAP	These are portable, electrically powered pumps that generate and deliver air at a continuous fixed air pressure during inspiration and expiration via an interface for the period of use. CPAP is the umbrella term for all positive airway pressure devices so can also refer to APAP and BiPAP devices.
Epworth Sleepiness Scale	ESS	The ESS measures daytime sleepiness using a very short questionnaire. The person rates their probability of falling asleep on a scale of increasing probability from 0 to 3 in eight different situations. The scores for the eight questions are added to obtain a single number.
Hectopascal	(hPa)	The unit of pressure measurement for CPAP devices is the Hectopascal. Previously the pressure unit used was cmH ₂ O with reference to an atmospheric pressure of 0 cmH ₂ O. One Pascal is equal to 0.010 cmH ₂ O. 1 hPa ≡ 100 Pa.
Humidifier		An in-line system which warms and humidifies the air from a CPAP device prior to delivery to the patient; usually a simple reservoir which is refilled with water every night.
Hypercapnic / hypercapnia		Abnormally high level of carbon dioxide in the blood.
Hypoxic/hypoxia		A subnormal concentration of oxygen.
Incremental cost-effectiveness ratio	ICER	Method used in health economics and is the ratio of the change in costs of a therapeutic intervention (compared to the alternative, such as doing nothing or using the best available alternative treatment) to the change in effects of the intervention. Often, the change in effects is measured in terms of the number

		of quality-adjusted life years gained by the intervention.
Interface		A device connecting the CPAP machine to the patient's airway. This is usually a close fitting mask over the nose or nose and mouth.
Markov model		An economic model used to evaluate disease states.
Nocturia		The need to get up during the night to urinate, thus interrupting sleep.
Obstructive sleep apnoea/hypopnoea syndrome	OSAHS	A medical condition in which the absence of breathing occurs due to the narrowing or closure of the upper airway (pharynx) during sleep. This cessation of breathing is caused by an obstruction and can result in either complete (apnoea) or partial (hypopnoea) closure. Most individuals with the OSAHS have a combination of apnoeas and hypopnoeas.
Quality-adjusted life year	QALY	The measure of both the quality and the quantity of life lived whilst having a medical condition. It is used in assessing the value for money of a medical intervention. It is based on the number of years of life that would be added by the intervention.

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Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [56].

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1st 2008) [53] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers' bids.

Preparing a business case

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [57] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual*, Procedure 1-01 [52].

The EU tendering exercise

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [58].

The procurement panel

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers

Criteria for supplier selection must be established. A pre-qualification questionnaire, seeking background information (eg on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

Evaluation criteria

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers' technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract

Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier's request.

Buyers must be aware of the 'Alcatel' procedure (see the *Trust Operational Purchasing Procedures Manual* [52], Procedure No.T-08, section 6 - *Mandatory Standstill Period*).

For more information on procurement please refer to the Department of Health Website [59].

Buyers' guide: Continuous positive airway pressure for the treatment of obstructive sleep apnoea / hypopnoea syndrome

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About CEP

The Centre for Evidence-based Purchasing (CEP) is part of the NHS Purchasing and Supply Agency. We underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe and

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