

**COMMONWEALTH OF AUSTRALIA**  
**Patents Act 1990**

**IN THE MATTER OF** Australian patent application 2009221630  
in the name of RESMED LIMITED

**AND**

**IN THE MATTER OF** Opposition thereto by FISHER & PAYKEL  
HEALTHCARE LIMITED

**STATUTORY DECLARATION**

I, Alistair Edwin McAuley, consultant, of Rotorua, New Zealand do solemnly and sincerely declare that:

**1. Background**

- 1.1 I am a medical device consultant, including in relation to devices for the treatment of obstructive sleep apnea (OSA). I am the sole director of the company Medlands Consulting Limited (Medlands).
- 1.2 I currently work as a consultant to the CEO of Airway Management, a company that produces and sells products for the treatment of sleep apnea. In my current role I do design work, marketing and intellectual property (IP) analysis. The main focus of my role currently is product design and upgrades, and finding buyers for the company's products and ultimately the company's assets.
- 1.3 I am a part owner and director of a distribution business Airway Management Asia Pacific, distributing Airway Management products, and other companies' products, in New Zealand and Australia. These products are all in the OSA field and include an oral appliance, a CPAP interface, CPAP machines and other accessories. I travel in the market making sales and training calls and attended the Australasian Sleep Association tradeshow in 2014, where we exhibited our products.
- 1.4 I also do some consulting with Auckland University of Technology, around the commercialisation of its IP, in the OSA field.
- 1.5 I also consult to Human Design Medical (HDM), a United States based medical device company. That work involves giving them advice on product design, testing, manufacturing and regulatory requirements.

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- 1.6 I graduated with a Bachelor of Technology degree, with honours, in engineering and automation from Massey University in 1998 (my final year of study at Massey was 1997).
- 1.7 I started my career with Fisher & Paykel Healthcare Limited (FPH) in 1997 and started working in the company's sleep apnea treatment business in 1998.
- 1.8 I worked for FPH for 14 years. From 1998 I was in the new mask development team. FPH was producing CPAP (continuous positive air pressure) devices, but needed an interface to be sold with them (an interface is the part of the device for treating sleep apnea which connects the CPAP to the patient, for example, a mask).
- 1.9 In 2000, I was made the head of that team, where I stayed until 2010. I then spent two years as the Business Development Manager for sleep apnea. During my time at FPH and with Airway Management I have been involved extensively in the intellectual property management area. This includes conducting freedom to operate searches or reviewing them, filing new inventions and helping to respond to examiners' responses. I have filed over 75 United States patent applications as an inventor, of which 45 have been granted. All the applications have been related to the OSA field, mostly interfaces with some related to CPAP and CPAP humidification. These patents have been cited by 478 other patent applications due to their relevance in the OSA device field.
- 1.10 In 2011, I left FPH to set up a company that operated as a joint venture with a United States company, Airway Management (Airway Technologies). My involvement with Airway Management began when Airway Management had initial discussions about a joint venture with Medlands. The idea behind the joint venture was that we would design and tool a nasal pillow mask, and design an oral appliance. As part of this, it was agreed that I would go over to the United States for six months to help Airway Management get their new products into the market. The company's main product line was oral appliances to treat OSA (devices that fit inside the patient's mouth, to adjust how the jaw sits). I was also assisting with Airway Management getting FDA and ISO 13485 approval for its devices. For one year I worked on research and development working very closely with Airway Management. We developed a CPAP interface there.
- 1.11 After about a year of the joint venture, Airway Management wanted help integrating its products into the market and into Europe, so I became president of the company for a year and a half. The CEO decided to appoint me as president to allow me to manage the company, integrating the new products and upgrading the quality systems to achieve ISO 13485 compliance. The owner and CEO of Airway Management was part time so did not have daily involvement in the running of the company. I was the most experienced person in the company, from a medical device design and manufacturing point of view. My president role was the equivalent of being a general manager, with all functions reporting to me. I reported to the CEO.



- 1.12 A copy of my curriculum vitae as at February 2015 is attached as exhibit AM-1.
- 1.13 I have read the Federal Court of Australia Practice Notes CM7 titled 'Expert witnesses and proceedings in the Federal Court of Australia'. I understand what is expected of me as an expert witness and I confirm I give the following evidence in accordance with Federal Court guidelines.
- 1.14 In particular the issues I address and the evidence I give in this declaration are within my areas of expertise. I realise that my overriding duty is to assist the Commissioner impartially on relevant matters within my areas of expertise and I am not an advocate for FPH who has engaged me as a witness.
- 1.15 I am being paid within my standard range of remuneration for consulting work, for my time spent in preparing this evidence and attending at the hearing if necessary.
- 1.16 The evidence I give is my own assessment and opinion. My opinions are wholly or substantially based on my specialised knowledge.
- 1.17 AJ Park asked me to explain how interfaces are generally developed within the industry, and the considerations and features that go into the development of an interface. Unless stated otherwise, the points I make in this declaration reflect the position as at February 2008. I also discuss some examples of headgear. My discussion of headgear is to reflect the position as at January 2003, unless I state otherwise.
- 1.18 Where I refer to examples of masks or patents, I confirm that these are masks I was aware of (which the patents record details of), prior to February 2008, when I was working in this area. I have done some limited patent searching in order to refresh my recollection of the masks and patents I was aware of prior to that date. I restricted this searching to patents before 2008.
- 1.19 To assist, I have prepared a document that details common terms and definitions in this area. I attach this as exhibit AM-2.

## 2. **The interface market**

- 2.1 The market for CPAP treatment (CPAP machines and interfaces) is a global market. There is no real variation in the products available throughout the market, just the size of the distribution in different areas.
- 2.2 The major players in the market are ResMed (who has around 50% of the market), Philips (who acquired Respironics, a significant manufacturer of CPAP machines and interfaces, around seven years ago), and FPH, who are large, but distinctly smaller than the other two big players. There is then a second tier, of companies who have around a 1-2% market share each, these include Breas and DeVilbiss Healthcare. And a third tier which would encompass less than 5% of the total market between them. Airway Management sits in this third tier.

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- 2.3 In the 2014 calendar year, ResMed had revenue of US\$1.616 billion. I estimate this represents around 50% of the total OSA market, from a manufacturer's point of view. I estimate Philips had revenue from CPAP machines and interfaces (Sleep Therapy business, excluding hospital and other non CPAP related respiratory business) of around US\$1.2 billion and this represents around 38% of the market. I estimate (based on reported results and extrapolations) that FPH had revenue of around US\$210 million from CPAP machines and interfaces and this represents around 6.5% of the market. The remainder of the market has a revenue of around US\$160 million, which is around 5% of the market, once again this is an estimate as not all of these companies report revenue.
- 2.4 My assessment of the Philips market share is an estimate. When Philips bought Resironics it stopped publically reporting its OSA market results separately. At the time Philips bought Resironics it was around 50% of the market. I estimate it is now more like 38%, being stronger in CPAP and weaker in interfaces.
- 2.5 ResMed primarily operates in the OSA business. It publically reports its results, and reports on the CPAP machine side of its business and the interface side of its business separately. FPH also reports its OSA financial information.
- 2.6 Philips is relatively strong in CPAP machine market, however its masks are regarded as not as good as ResMed or FPH masks. I estimate that they have a lesser share of the mask market than they have in the CPAP market. Philips, or Resironics as it was then, was very strong in the 1990s because they were an early player in the market. But ResMed and FPH have since taken a lot of market share from Philips, particularly in the interface market. There is a feeling that Philips masks were overly complex and consumers did not rate them as highly in areas of comfort and leak performance. ResMed and FPH are stronger in their interface business than CPAP machine business. They would both have a greater market share in the interface business than the CPAP side, although ResMed's CPAP revenue is higher than its interface revenue as the CPAP market is larger. It is common for consumers to have a CPAP machine supplied by one company and an interface supplied by another. For example, it would be quite common for a consumer to have a Philips CPAP machine used with a ResMed interface.
3. **Knowledge of the market**
- 3.1 From my experience, people involved in the development of interfaces need to have a knowledge of the market. At FPH, the design team would spend time in the market, at trade shows, and with sales reps visiting sleep labs, doctors' offices and CPAP dealers. This enabled FPH to get feedback on the products and develop products that best meet the users' needs.
- 3.2 The New Zealand market, and to some extent the Australian market is very small and as there is no need to develop interfaces specifically for New Zealand or Australian



needs it is important to visit the larger markets of North America and Europe regularly to gain feedback from the key markets. Furthermore, as the New Zealand market is so small even if there were some specific needs identified it would most likely be uneconomical for companies to develop specific products for it. Products are developed for the market globally, but developers do focus to some degree on the North American market, because it is around 50% of the market, and insurers' have particular requirements there. For example, insurance may provide for a replacement seal every three months. Therefore, United States dealers are likely to prefer masks that have a seal that is able to be replaced. Because of this, developers would try to develop masks with a replaceable seal.

3.3 While with FPH, I travelled several times a year to major trade shows, conferences, and sales meetings. FPH would also visit overseas component manufacturers, such as tooling suppliers or headgear fabricators such as Acumed Technologies in the United States, a global leader in the design and manufacture of headgear for CPAP masks. When I was managing the FPH interface R&D team I would usually take a two week trip to the United States once or twice a year and a three week trip to Europe every couple of years. The marketing team would also travel regularly in the same manner. I was also in email and phone communication, almost every week, with the marketing manager for FPH in the United States, he would give us feedback on the market, specifically about any performance issues with our products and the key competitors.

3.4 Of these United States trips one week would be spent at a trade show. The following are examples of these trade shows:

3.4.1 APSS (Associated Professional Sleep Societies—a joint meeting between the American Academy of Sleep Medicine and the Sleep Research Society) conference. This is a show where clinicians, sleep technicians and physicians attend. At the APSS conference there would be presentation of clinical papers and research in the sleep field, as well as a trade show area where manufacturers would display their products and highlight new products. At the APSS I have seen sleep lab staff from New Zealand, as well as sleep physicians from New Zealand and Australia. They would attend the clinical sessions and visit the manufacturers' booths to see the latest products on offer. This is relevant to them as manufacturers release the same products in the United States as they do in Australia and New Zealand. I have also visited these people in New Zealand and Australia, at their sleep labs or offices. I have also seen independent medical distributors from Australia attending this show, as they source many of their products from United States manufacturers exhibiting at these types of shows.

- 3.4.2 MedTrade, which was a show primarily for CPAP dealers (home care medical equipment providers), with all major manufacturers displaying and marketing their products. I first went to a MedTrade show in 2000 and I recall going every year up to and including 2013, apart from 2012. There would typically be representatives from the large national home care medical equipment (HME) providers attending, as well as regional and local HMEs that may be located close to the show.
- 3.5 There are also trade shows in Europe (eg Medica), which I also visited while with FPH.
- 3.6 The North American market is approximately 50% of the global market for CPAP interfaces, so it was the market FPH visited the most. It was common for CPAP dealers and clinicians from other countries to attend the United States based shows as they were generally the largest. For example people from Europe, Asia, Central and South America would also attend.
- 3.7 ASA is the Australasian sleep association, which also has an annual conference. I did not attend that show until 2014, where I exhibited with my distribution company Airway Management Asia Pacific. However, FPH does exhibit at ASA (or its equivalent) every year, and has done since around the early 2000's. The other big two manufacturers would also exhibit at this. I attended a Thoracic Society of Australia and New Zealand meeting in the early 2000's with the OSA sales representative for New Zealand, where FPH exhibited its OSA products. I also spent some time travelling with sales reps in Australia, conducting 'road show' tours where FPH presented its new products at evening functions. I also spent many weeks on several occasions in the Brisbane area conducting patient trials of new interfaces, involving 30-80 patients per trial. I recall these trials were conducted around 2000 and 2002.
- 3.8 The trade shows would be held in a building like an exhibition centre. The companies producing interfaces would be present, with their products displayed. The companies also sent product specialists, not just the marketers, so that they could answer technical questions and often at the same time provide training to local staff.
- 3.9 I also attended some of the FPH national (annual) sales meetings in the United States. This would consist of all the FPH sales reps in North America, getting together for about three days to conduct new product training, sales training, award sales performance from the past year and participate in team building activities. FPH has approximately 50 sales reps, sales managers and marketing personnel for OSA in North America. It was common for someone from the R&D team to go to these meetings to deliver information and training on products.
- 3.10 Sales reps get feedback every day, from doctors, sleep clinics, and CPAP dealers. The people trying to sell the products are getting that direct feedback from customers about what they do and don't like about the products. The sales reps would feed this

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feedback back to the development team, either informally in discussions between sales reps and members of the development team, or formally from the marketing team. For example, the FPH United States marketing manager would visit FPH at Auckland around once per year.

- 3.11 At the trade shows we would get feedback from the customers. This would not be the end users, but people like the CPAP dealers. These dealers receive a lot of feedback directly from the users of the masks, who would then feed this back to FPH.
- 3.12 At the trade shows FPH would also sometimes run surveys by having a laptop present that people could answer the survey on. For around the last four years of my time at FPH, FPH would run these surveys at a trade show once or twice a year. Examples of the types of questions asked are:
  - 3.12.1 What percentage of the time do you set up patients on full face, nasal or pillow masks respectively?
  - 3.12.2 What are the top three full face masks you prefer to use?
  - 3.12.3 What are the top five features important to you when considering a mask?
  - 3.12.4 Rank the following mask attributes in order from highest to lowest—reliability, ease of use, price, comfort, noise level, having all sizes in one box, appearance, sealing performance, size, etc.
- 3.13 There is relatively little clinical research on specific masks (compared with CPAP itself). Masks are updated every two to three years, so as this technology is moving quite quickly, studies may take too long to do. It's also hard to see that clinical studies would produce data that would help the market. However, Sleep Review Magazine (<http://www.sleepreviewmag.com>), an industry magazine, runs surveys and reports on product trends. CPAP.com is also another good source of user feedback and general product sales trends.
- 3.14 The website CPAP.com is a retailer of masks, which has been operating since around the beginning of 2003. On that site it is possible to see all new products, customer feedback from user reviews, and consumer trends by seeing which masks are forming what percentage of total sales. While this is a reasonable indication of sales trends it doesn't accurately represent the total market, as its sales are cash sales, whereas most product in the United States is sold through insurance coverage and large HME providers.
- 3.15 To lower costs, the home care companies will try to limit the range of products they offer to increase their purchasing power, and to work with the companies that have the broadest range of product. This results in the top three companies (ResMed, Philips and

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FPH) having most of the HME market, and the smaller companies having more share of the retail (CPAP.com) market than they have of the HME market.

- 3.16 FPH would also analyse competitors' products. FPH would trial products internally, and get feedback on them from users. If a competitor launched a new product in the market, FPH's sales reps would tell the OSA interface team. FPH also did patent searching, to make sure it was not going to run into problems. I, and the FPH development team more generally, regularly reviewed patents covering technology in this area. All major companies were going to the same conferences, where everyone would see each other's products. The companies would also swap new products, to save each other having to buy them, as they were freely available anyway. FPH would buy competitors' new products if necessary.
- 3.17 Magazines from within the industry were circulated in the FPH office. In particular, Sleep Journal carries the latest scientific papers, and Home Care Medical Equipment News (HME News) and Sleep Review carried a lot of dealer advertising. There are full page adverts of new products from major manufacturers and sometimes third tier manufacturers.
- 3.18 The OSA interface team would also look at patents for scuba diving masks, and masks from other industries (eg aviation), when considering different options. At FPH the design team also looked at 3M industrial protection masks (for example, dust and painting masks) and similar brands. I recall we purchased some of these around 2002, the time we were developing our first full face mask. These masks had similar contours as they covered the nose and mouth, had a flexible seal to accommodate facial variation and had straps to hold them in place. They were made out of silicone or rubber, were of a full face style that sealed around the nose and mouth, and had filters and valves.
- 3.19 The team would also sometimes look to other areas entirely, for example, at one point it looked at how speaker covers were constructed and how they connected to the main speaker housing, for clipping mechanisms. The FPH team also looked at the type of straps, buckles and clips used to adjust bags or back packs that could be applied to headgear straps, adjustment and connection to the mask. We also looked at scuba mask headgear to see how they adjusted, connected to the mask and the materials that were used. I recall in the early 2000's (in around 2002), designing and prototyping a silicone headgear strap similar to a scuba mask strap for the Oracle mask.
- 3.20 There were also several large folders containing interface prior art that were in the interface R&D team's office area. They contained a large number of disclosed or expired IP for interfaces. Some of the patents were for CPAP interfaces, but many were also for aviation masks or industrial protection masks. They contained most of the key features that were required, such as a face seal, connection to an air supply, headgear and connection mechanisms for the headgear to the body or frame of the interface. Many of



the fighter pilot or aviation masks dated back to the early to mid 1900's and contained hand drawn images as they were filed before electronic means were available. I recall they stood out for this reason, they seemed very dated. As they covered the nose and the mouth they seemed to be most relevant to full face masks and in particular headgear for full face masks.

- 3.21 FPH would identify the problems with existing products from feedback from these various sources, and take this back into development of new products.
- 3.22 The feedback FPH constantly received was that the most important considerations for a mask were comfort, seal and ease of use. Comfort means how the mask feels to the patient when in use. Seal means the mask would seal well without leaks. Ease of use refers to that it can't be overly complex, have too many components, be overly engineered and you need to easily be able to get it to work well and take it apart for cleaning and put it back together, or simply easy for the patient and provider to setup and use. The commonness of this response meant that comfort, seal, and ease of use became an FPH tagline. After we started using this as an internal focus the marketing manager for interfaces picked up on this and started using it for external marketing material related to FPH interfaces, in brochures and magazine advertising. The term 'C-S-E' was used to represent 'comfort, seal and ease of use'.
- 3.23 It was apparent that for masks price was less important than those three features. The masks have a large influence in helping the patient to become compliant with their CPAP treatment. Dealers are required to get patients compliant with their treatment, to receive ongoing payment from medical insurance companies for the CPAP machines. Therefore, from a dealer's point of view, using a cheap mask is not going to result in the best outcome for the patient or for the dealer from a financial point of view.
- 3.24 Also, as CPAP compliance is very poor, in large part due to mask comfort issues, the latest masks that work the best will not be subject to strong price erosion. If there is a strong-performing mask on the market, a less-comfortable mask will not be able to compete effectively with this, even if it is cheaper. This means that the price of masks is only a strong competitive factor if there are two to three strong performers on the market between the top manufacturers. This is not the case with CPAP. CPAP is regarded as being closer to a commodity, where price is more important. This may explain why Philips is able to compete better in the CPAP market, and why CPAP profit margins are very low and interface profit margins are very high.
- 3.25 The approach that FPH took is for staff to be cross functional or multifunctional. FPH staff were therefore required to have a good knowledge of the market. As far as I know, at least ResMed was taking a similar approach. I recall reps that had worked for ResMed in the past or customers that we visited stating that they had met an interface engineer from ResMed (Philip Kwok), who had been travelling and asking similar

questions to me in the market. I note that he is also a significant inventor for ResMed. I also saw some ResMed engineers at the United States tradeshow—they came to the FPH booth to see the latest products. At one United States tradeshow a Philips marketing or sales manager was talking to me, stating that they were not happy with some of their interfaces but had recently hired new engineers into the R&D team to create some new products. Having a high rate of staff turnover and not getting good customer feedback may be some of the reasons for Philips' loss of interface market share.

- 3.26 In recent years FPH would have several interface R&D managers that travel in the market and would have around 10 years' experience in that field.
- 3.27 I believe that it is relatively rare for engineers to remain focused on one product type for over a decade, so my level of involvement in the market over the length of time may be relatively rare. At FPH I estimate that the average term for an engineer would have been around 4–6 years before they moved overseas or to a different product group or company. Secondly, I believe only the three major companies would have maintained a permanent interface R&D team. For example DeVilbiss, which is a second tier company in the market, do not have any internal interface R&D engineers. It outsources the R&D to a design contractor or design house when it wants a new interface, resulting in people with little or no interface-specific experience designing a mask. Philips seems to have a higher turnover and their engineers seem to spend less time in the market, although they may do this outside of tradeshow without my knowledge. It seems ResMed have staff that have a similar level of experience to me, or at least Philip Kwok seems to, having filed around 167 United States patent applications as an inventor.
- 3.28 Sales staff seem to be longer serving in the industry, many working for decades in the same industry, in the United States. They are focussed more on selling what they have today, and overcoming objections, as opposed to conducting research and digging deep into the underlying customer needs, as that is not their role. So while the sales reps are a good source of customer feedback, they do not necessarily explore the fundamental reasons for that feedback.

#### 4. **Development of interfaces**

- 4.1 An interface is designed by a team. The ideal team to develop patient interfaces would be made up mostly of mechanical engineers, and someone with clinical knowledge (possibly with a degree in physiology, or through consultation with doctors or other clinicians).
- 4.2 The engineers would spend time in sleep labs, talking to patients and sleep technicians, testing products in sleep labs, travelling with sales reps, visiting customers and attending tradeshow to get feedback and learn about market needs.



- 4.3 In New Zealand there is no formal tertiary training for medical device engineering, or at least there wasn't 10-15 years ago. This means that most develop their interface design skills on the job, after initially gaining an engineering degree, typically some form of mechanical engineering or general product industrial design. Useful skills include materials science skills, particularly in plastics, tooling and manufacturing skills, as it is important the designs are able to be manufactured in high volumes, general product development skills, industrial design, and practical skills so that they can make products and prototypes themselves. Other useful skills may include knowledge of fluid dynamics, CAD-CAM (computer assisted design and manufacture), and general problem solving.
- 4.4 FPH would also provide training to its engineers, for example engineers would go on courses in physiology, plastics processing, and CAD-CAM etc.
- 4.5 While I was at FPH there was also someone in the team with knowledge of fluid dynamics. That employee did his Masters in that area for a specific OSA project FPH was working on. At FPH we spent some time looking at fluid dynamics, particularly for the issue of condensation in masks. We wanted to understand the variability for why condensation would accumulate in some areas of masks and not others. Someone also looked at fluid dynamics in relation to the bias flow, in relation to the design of the holes and what influenced the sound of the airflow.
- 4.6 At FPH there were three or four teams working on patient interfaces. One on nasal masks (masks that just seal around the nose), one on nasal pillows (interfaces that sit under the nose and seal the nostrils), and one on full face masks (masks that seal around the nose and mouth). Later FPH also had a greenfields team, which would look at development in a less structured way, I believe one of these teams was established around 2008, this resulted in the development of the Pilairo mask. Also, when FPH started developing new mask types, at the beginning when it did not have that type of mask it may also be considered to be a greenfields approach, as there was no existing base to start from. That was the case around the years 1999, 2002 and 2004 when FPH started to develop their first nasal, full face and pillow masks, respectively. The teams would also see what each other were working on, and would talk to each other about problems and developments.
- 4.7 These teams would work on developing one new mask at a time.
- 4.8 New developments depended on feedback. If an existing product was getting good feedback and had a good market share, the teams at FPH could spend time on developing something more radical, as there was the comfort of knowing that the company had a good performer in the market. In this case the team would spend many months looking into any and all options. If a product was not going well, but was obviously upgradeable in a short time period that would resolve the issue, it would be

worth the resources to upgrade that product. An example of an update was taking the 407 nasal mask and upgrading the seal connection to include a rigid clip, to improve the ease of use. The 407 was released in 2003, and smaller size was released (the 406) in 2005 and the Zest upgrade was released in 2008. The foam cushion was also upgraded to improve durability.

- 4.9 At FPH, development of an upgraded mask could occur within 12-18 months. This was the case if we had existing knowledge or had done previous work on the particular issue we were addressing. This would lead us to having a clear understanding of what we wanted to achieve and wouldn't require drastic changes from the existing model, many components of the mask may remain unchanged with work focusing on the components that were being upgraded, for example the clip upgrade from the 407 to the Zest.
- 4.10 However, at FPH if we were aiming to deliver something and we weren't sure how it was going to look or how we would be able to achieve the aim, we were more likely to be producing a new iteration every one to two months, which would then be evaluated in house. This was a process of iterative improvements, where through a process of trial and error you found an improved version.
- 4.11 Sometimes, identifying the best way to create an improvement was a short process. Other times, like if we were introducing a concept different to those we had used in the past, these improvements would take more trial and error.
- 4.12 There is a lack of clinical research on various features of masks. This is because when you are comparing masks it is very hard to identify various features that are making a difference in the overall feel for a patient.
- 4.13 At FPH when developing a new mask we had to prove it was as good as, and ideally better than the previous versions. FPH would do this through user evaluations. FPH would use a dealer, who would get 30-50 or so patients to try the new mask and then answer a one to two page questionnaire. While new masks were being developed FPH would usually work in a sleep lab and trial these masks in development on individual patients. We would scan faces, use databases with face shape information, and use a lot of trial and error. We would also test them on ourselves. It is possible for anyone wearing a mask to tell how the seal is working and this can be measured using flow meters to determine leak rates and various CPAP pressures. There was a bed in a small room next to the interface design team where we could lay down, test mask and measure leak rates. It is very hard to get a good prototype to replicate the quality of a final product. Therefore, sometimes you need to develop the mask all the way through to the production stage before really knowing how it would perform, at least on large numbers of people.

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## 5. **Designing a new mask**

- 5.1 When designing a new mask, it is important to start with the goals for the mask, determined based on feedback of user needs. You need to consider the existing IP, for what you can't use, look at prior art to determine what you can use, as sticking to expired or disclosed prior art is a safer approach from an IP point of view. You may then choose to add specific new feature(s) that you can do detailed freedom to operate searching on. You are also aware that including too many features that the user needs to adjust, or manually interact with, would increase the complexity of the mask, so you need to balance this with the ease of use for patients. And you also consider the time to market—generally major companies want to have a new mask to introduce to the market every two to three years, in each of the three main categories—nasal, full face and pillow masks.
- 5.2 In a well-qualified design team, you would want to have people with the following types of skills:
- Someone with experience in the industry, like a sleep technologist, with experience in dealing with patients.
  - Mechanical engineers, industrial designers, or people who can:
    - bring design experience
    - have good analytical, problem solving skills
    - do methodical bench testing
    - understand fluid dynamics, particularly for pressure drop and bias flow issues
    - make prototypes and understand how they are mass manufactured.
  - Someone with physiological or clinical experience, to understand things like the risk from CO<sub>2</sub>. The basics of this can be well understood and tested by most design engineers, and are now well documented in the mask development standard—ISO 17510-2. This standard was not released when FPH started developing masks, but it was released and available from 2007.

## 6. **Problems with interfaces**

- 6.1 The biggest problems with interfaces relate to:
- comfort of the interface
  - quality of the seal
  - ease of use.
- 6.2 These problems affect CPAP compliance. Around 40% of users stop using CPAP within 12 months, and this is commonly because of issues with the interface.

- 6.3 Comfort is mainly to do with pressure sores where the mask contacts the face, in particular on the bridge of the nose and the forehead. This can be redness, tenderness, and sometimes cutting of the skin. Some patients will even alternate between two different masks in an attempt to alter the pressure points.
- 6.4 The seal refers to the ability of the mask to form an airtight seal on the patient's face. Leakage through the seal can lead to problems with noise, irritation (through feeling the draught), and patients worrying about the leak meaning that treatment is not effective.
- 6.5 It is possible to strap the mask on very tightly to improve the seal, but this is more likely to lead to pressure sores after a couple of hours' use. Also, some seals perform worse if they are over tightened, making leaks and pressure sores worse.
- 6.6 Movement of the mask can lead to leaks, so mask stability is a big issue to consider in the design of interfaces. FPH would try to engineer the mask to give a better seal by adding stability features. For example, through the headgear design, ensuring the headgear was stable, designed to fit and adjust to different head shapes and sizes.
- 6.7 It is also important to ensure materials used did not stretch out of shape overnight, or over several months.
- 6.8 It is desirable to minimise the width of the mask, to minimise contact with the pillow for people who sleep on their side. Contact with the pillow can cause sideways movement of the mask and cause leaks.

## 7. **Features of nasal pillows interface**

### 7.1 Nasal pillow interfaces have standard features:

- Headgear, sometimes with more rigid elements to provide extra support for the mask. Headgear of a nasal pillow mask is typically 'Y' shaped, with a single strap coming off the mask frame which then splits into two arms, one going over the head and the other behind the head, encircling the crown of the user. This concept is documented in US patent 6,119,694 (published in 2000). It has adjustments that can be made over the top and behind the head. This patent also demonstrates the angular adjustment that can sometimes be made between the headgear and the mask.
- Prongs, or pillows, which contact and seal with each nostril.
- The pillow interface being provided in different sizes.
- The pillows may be formed integrally with part of the frame, such as is in the Nasal Aire (released in early 2000's). Or be formed separately and assembled, such as in the Breeze nasal pillow mask, that was also on the market in the early 2000's.



- A frame or mechanism for connecting the pillows to the air supply. The frame typically forms a sealed chamber that allows the delivery of the pressurised air to be transferred from the inlet hose, elbow or CPAP tube to the pillow seals. The headgear usually attaches to the frame, to hold the mask in place.
- Often a length of thinner, more flexible tube, to deliver the CPAP air supply to the frame while minimising contact of the bulky CPAP tube to the face. The flexibility also reduces torque or other force being applied from the CPAP tube to the frame, which can cause mask movement and leakage. The tube will typically have a swivel and/or clip connection to the main CPAP tube, to allow for easy connection and disconnection.
- There may also be an elbow that connects the smaller tube, or main CPAP tube, to the frame. This elbow changes the direction of the air flow and can swivel to allow the tube to rest in different positions relative to the frame, further reducing forces that are applied to the mask by the CPAP tube.
- Venting through a series of small holes. This venting will optionally have a diffuser, like a small piece of material, which will break up the flow (and therefore the draught), and make it quieter. This flow is often called 'bias' flow, exhaust flow or intentional leak. It is designed to flush expired CO<sub>2</sub> from the mask, preventing rebreathing of CO<sub>2</sub>. The holes can be located anywhere on the mask, but preferably as close to the patient end as possible. They are typically located in the elbow or the frame.

## 8. **Features of a nasal mask**

### 8.1 Nasal masks have standard features:

- A cushion, to form an airtight seal against the face. I generally refer to this cushion as the 'seal'.
- A frame to support the cushion and allow for connection to the headgear.
- Headgear, to hold the mask in place on the head, and a connection mechanism for the headgear to connect to the frame.
- The nasal mask being provided in different sizes. In some cases the seal is simply changed out, in other cases components may vary, such as the mask frame, seal and even headgear.
- A bias flow/exhaust flow mechanism. This is holes in the mask to allow CO<sub>2</sub> to vent. These holes are designed in a way to make the venting quiet, and to control the level of leak (compared with an uncontrolled leak out of a poor seal).
- An elbow connected to the inlet tube, which most masks have. This is a 90° bend that swivels 360° to allow the tube to point in any direction. A small

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number of nasal masks do not have elbows, they have a direct connection for the tube, or a smaller tube, into the mask frame.

## 9. **Full face mask essentials**

### 9.1 Full face masks have standard features:

- A non-rebreathing valve (NRV, also known as an anti-asphyxia valve (AAV)). This valve is biased to be open, so that it stays open (and provides air to the mask cavity) unless the CPAP pressure is pushing it closed. This means that if the CPAP machine stops working, and air is not being forced into the mask, the valve will open so that the patient can continue breathing, without rebreathing their own CO<sub>2</sub>.
- The other features common to a nasal mask:
  - A cushion.
  - A frame.
  - An elbow (which 90–95% of masks have).
  - Headgear. This can typically be a bit more elaborate with a full face mask, as it can go over the top of the head to counter the effect of the mask sitting on or under the chin, which affects the seal if the jaw is opened. Also, as full face masks have a greater contact area with the face, and are typically used at higher pressures the force of the CPAP pressure that is acting to lift the mask away from the face is greater. For these reasons, full face mask headgear may have larger straps, or more straps, such as the crown strap to attempt to stabilise the mask.

9.2 Apart from the NRV, and the fact that they cover the mouth, a full face mask is not really different to a nasal mask. Often they will have the same family name across the two types, and be a similar product, using the same seal technology, brand, look and feel.

9.3 A full face mask is often used as a last resort, and is used for patients with high 'mouth leak'. Mouth leak is where the patient's palate does not fully close or seal the patient's airway in the mouth during sleep, which means that some mouth breathing or leaking will occur while the patient is sleeping. Accordingly, if the patient only has a nasal mask, some of the air being delivered through the mask will leak out through the mouth, rather than heading to the patient's lungs.

9.4 Another mask type that has been used is a kind of hybrid, with a mouth mask and nasal prongs or pillows. The ResMed Mirage Liberty mask is an example of this.

## 10. **Headgear**

10.1 Straps originally just provided a tension element, to pull the mask onto the face. However, designs moved to straps that are designed to provide different forces. An

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example of this is the straps shown in US patent 6,119,694 (published in 2000). US 6,119,694 discloses support arms that are designed to rest on the cheek bones, transferring loads to the sturdy cheek bone structure. It also shows the use of headgear formed in semi-rigid plastic to retain shape and transfer support forces along the entire periphery of the headgear assembly. Also by using rigid elements tensional forces may be transferred in a non-linear or curved manner, for instance above the ears to avoid discomfort as indicated in 6,119,694, or below the eyes.

- 10.2 Straps are designed so that the same straps could work on a range of different head sizes. The whole key to using headgear is to create stability for the mask.
- 10.3 Movement of the headgear was minimised by adding features such as a 'crown strap' or a part of the headgear that goes over the top of the head, this feature was on the 431 full face mask released in April 2004. The crown strap also included an adjustment so the length of the strap over the top of the head could be adjusted to suit different head sizes, ensuring the headgear did not slide down the back of the head.
- 10.4 The Simplicity nasal mask by Philips is an example of a crown strap on a nasal mask, it goes from the front of the head to the back, rather than from side to side, but ultimately performs the same function, it has been on the market since the early 2000's.
- 10.5 The Acclaim nasal mask, launched in 2001, also had a type of crown strap. It was a fifth strap that passed over head from front to back performing the same function, that is to provide vertical support, over the top of the head preventing the headgear or mask from moving down. This is connected to the upper strap and acts in addition to the upper strap not as a replacement for it.
- 10.6 A crown strap is more common on a full face mask because the mask is larger, has more pressure lifting it from the face, and is therefore more prone to movement.
- 10.7 FPH worked on introducing rigid elements into the headgear, to give the mask more stability on the face, and to prevent the straps covering the eyes when they are pulled tight. For example, the Opus nasal pillow mask had relatively rigid supports that formed part of the mask. These were made of nylon, contoured to the cheeks and helped to stabilise the mask on the nose. These rigid elements were also used in the Mirage Swift nasal pillow mask, which was on the market before 2005.
- 10.8 The Puritan Bennet Breeze also included rigid plastic and metal components, as well a softer fabric strap in its headgear. Patents for this mask technology date back into the 1990's. US 5,724,965 (published in March 1998) is another example of the use of rigid materials in combination with fabric in headgear for patient interfaces.

- 10.9 Another example of this kind of headgear is disclosed in US patent 6,119,694, by Respirionics (Phillips). It shows a mask with rigid headgear elements on the cheeks with softer fabric straps having adjustments over the top and behind the head.
- 10.10 The 'glider' feature was also added to the first nasal mask FPH released in 2001, the Acclaim. The glider was designed to allow the headgear to move from side to side as a user moved their head, while keeping the mask centrally located on the face. The glider would move across the mask, equalising the force of the lower left and right strap, without causing the mask to move.
- 10.11 It is common (in 80-90% of the masks) to make the headgear of the triple laminate material. The outer layer is a laminate of loop material, ie Velcro. It is common to use a middle layer of something breathable like polyurethane foam. This gives some form to the straps so they are easier to put on and off without tangling. This middle layer could be excluded from the straps but it would make the straps more floppy. The third layer is something like Lycra, which goes next to the skin. The combination of all three materials contributes to stretch and recovery properties, and it is common for the foam layer to be manufactured with a specific density of foam, to achieve the designer's target stretch and feel. This is soft, breathable and flexible and it has a bit of stretch. A common brand of material for straps is Breath-o-prene, which is a trademark developed by Acumed Technologies in the early 2000's.
- 10.12 Straps can also be made from liquid silicone rubber (LSR), such as the FPH Infinity, released in 2005.
- 10.13 The elasticity of the headgear is considered, to get the right balance of flexibility and support. This flexibility is an issue well known in the industry. As mentioned above, one of the leading manufacturers, Accumed, produced headgear material with an internal layer of foam to specific densities, as this density affected the stretch. For example, typical foam densities were in the range 6lbs to 10lbs, with a higher density the straps are more rigid and less stretchy.
- 10.14 Headgear is also designed with areas of greater stretch where needed, to allow the headgear to stretch around the lower part of the head, while remaining firm around the upper head where stretch was not required. FPH called this feature 'Stretchgear' and this was launched around 2003 in the 407 nasal mask. The headgear included a section that had a higher amount of stretch behind the head in the lower part of the headgear where it rested in the neck. It is also disclosed in US 2003/0051732 A1, published on 20 March 2003—fig 4 feature #407.
- 10.15 Straps generally have four contact points, usually two upper points around the forehead support, which 80-90% of masks would have, and two lower straps from the side of the mask. These join around the back of the head. There are many examples of this type of headgear such as used in the FPH 405 launched in 2003, and the prior art disclosed

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in fig 1 of US 6,412,487 (published in 2002), this shows the ResMed Mirage nasal mask, and is another example of a standard four point headgear that has two connections in the upper part of the mask, on or near the forehead support and two in the mid to lower part of the mask frame. These straps are then connected to each other around the back of the head.

- 10.16 Another variant is the Comfort Classic Nasal mask from Respironics (now Philips) and launched approximately in the early 2000's, or possibly late 1990's.
- 10.17 If there is no forehead support on the mask, the upper straps might go from below the eyes and then above the ears around the back of the head. The lower straps would go from below the ears from around the bottom one third of the mask and connect at the upper part at the back of the neck. The connection at the back of the head is achieved by either cutting all the straps out of one piece of fabric, thereby forming them integrally, or by stitching the upper and lower straps together, either directly to each other or by another piece of fabric. It is important that the straps are connected at the back of the head otherwise the straps would slide about or fall off. This connection provides a tension element holding the upper and lower straps in place.
- 10.18 It is usual that the upper strap goes above the ears. The lower straps go below the ears and they meet at the back of the head. All mask headgear is designed to avoid contact with the ears as it can cause discomfort when lying on the straps.
- 10.19 Nasal mask and full face mask headgear have similar configurations. However, for a full face mask it is also common to have a crown strap on top of the head (as discussed above). A full face mask generally has more seal (more area of cushion contacting the face), and will therefore have to adapt to more facial variations because of the greater area of the face the seal contacts. A full face mask also has more area that is subject to mask pressure lifting it from the face, and is often used with air supply at higher pressures. Therefore, full face mask straps may be wider and there may be more tension in the straps because of the larger area and the greater force applied to the mask.
- 10.20 Some nasal pillow masks only have one strap extending from the mask. The strap then branches out from the back of the head into two straps to provide more stability at the back of the head. Examples of this are the FPH Opus, launched in February 2005, the Philips Optilife available in early 2007, and the design disclosed in US 6,119,694 (published in 2000). The latter shows generally 'Y' shaped headgear extending from side support arms that extend from the mask.
- 10.21 These configurations of straps that I have described have been very common since CPAP masks started being used. However, the use of rigid elements became more widely used in the early to mid 2000's, with the release of the Opus (2006), Mirage Liberty (2007), Swift LT (2008), Quatro FX 2011, GoLife (2011) and the Wisp (2013).

- 10.22 There are various ways to connect the headgear to the mask. These include using a hole in the mask to thread the straps through, and buckles and clips. The most basic and historically common option is for the straps of the mask to have a Velcro outer layer. The strap simply loops through a slot on the mask and fastens back on itself. Another common option is to use a friction buckle. Other options include clips, made from rigid materials with a button to press to release the clip.
- 10.23 The headgear will also be adjustable in length, and include Velcro hook and loop material to secure the end of the headgear back to itself, or may be passed through a friction buckle to secure the desired setting. These elements are common on all types of interfaces.
- 10.24 With a full face mask, you can include an emergency release, for quick removal of the mask in the case of panic or when a patient is sick. This feature is now less common.
- 10.25 You want to avoid the patient having to adjust the straps to take off the mask. Having to adjust the straps means the patient loses their settings and the mask might not be of the appropriate tightness when it is put back on. For this reason, straps typically have some form of release built into the mask connection, to allow the patient to remove the mask without undoing the straps.
- 10.26 Masks can also use clips to remove the straps from the mask to take it off. For a full face or nasal mask you typically need these straps because the straps go around the lower part of the head. Because this has a smaller circumference than around the middle of the head, there will not be sufficient flex in the straps to enable the mask to be pulled up over the head. The patient can generally just pull off a nasal pillow mask as the lower strap sits higher on the back of the head, nearer the apex or point of greatest circumference.
- 10.27 Another option to using clips is the kind of mechanism used by Philips, which is a ball that is slotted into a receptacle. For example the Comfort Full mask (which has been in the market since at least Q2 2005) uses this kind of friction fit ball.
- 10.28 The Mirage mask (which has been in the market since most likely the very late 1990's or around 2001 at the latest), uses a tension hold attachment. This feature was also disclosed in US 6,412,487 (published in 2002).

## 11. **Seal**

- 11.1 When I refer to the seal in this context, I mean the 'cushion' part of the mask, the part that contacts the patient's face, and provides the seal between the mask and the patient.
- 11.2 Seals are predominately manufactured from LSR.
- 11.3 The nasal bridge is the hardest part of the face to create a seal with, this includes the area either side of the apex of bridge near the eye. Leaks around the eye area are a big

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issue, as this can be very irritating for the patient. The nasal bridge is also the biggest area of pressure sore issues.

- 11.4 There is also a lot of variation between people in the nasal bridge area. For example, some patients have a very high bridge and some have a very deep bridge, or flat bridges. The skin in that area is very thin, with the bone behind the skin. If you don't make this area flexible enough for someone with a large bridge they will get pressure sores.
- 11.5 For these reasons, a lot of effort is put into designing an effective and comfortable seal in the nasal bridge region.
- 11.6 There is also a large amount of variation around the chin. So, while there is not as much focus on this area as the bridge, this can be another area where the seal is thinner or has greater flexibility. An example of a full face with cushion variation in the chin area is the Forma, by FPH, released in 2008.
- 11.7 To counter these issues, it is standard to try to design masks that can move to adapt to the individual patient's face, but that distribute a uniform force. This means that bigger or bridges can be accommodated. A lot of this work is about engineering the collapse of the cushion in the bridge area.
- 11.8 The most common way to account for variation in the nasal bridge area is to make the seal thinner in that area. This is because you are trying to provide stability in some areas and account for the variations in facial geometry in others. This means you can use thinner areas or areas of greater flexibility for areas in the face where there is more variation between patients. There is a lot of design detail in the thickness of the cushion, and the different parts of the cushion that conform to the face.
- 11.9 A thinner seal conforms better to the face, but if it is too thin everywhere it could collapse and deform (and not hold the mask in the correct position on the patient's face). Because of this, you put the thicker part where there is less variation between face shapes (eg, the cheeks or the area beside side of the nose), and the thinner parts where there is more variation (eg, the bridge of the nose).
- 11.10 Further stability was improved by the addition of an internal cushion, such as the foam cushion, to help stabilise the mask. This foam cushion was included in the FPH's first nasal mask, the Acclaim, which was released in 2001. The foam cushion was used in a series of nasal and full face masks, including the 405, 407, Zest, 432 and Forma.
- 11.11 The foam cushion geometry can be varied to allow more support to be placed either side of the nose, while allowing flex in the bridge region, and to allow deformation in certain areas. FPH uses a polyurethane foam cushion inside the silicone walls of the seal. By cutting out part of that polyurethane foam in certain regions it collapses more in those regions. FPH call this feature 'flexifit' and it involved the foam cushion in the bridge

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region being designed to flex as it was placed on the nose, attempting to provide as close to a uniform force on the bridge as possible, to maintain a seal and reduce pressure on the bridge.

- 11.12 The FPH nasal mask, the Acclaim, used the design—detailed in US 2003/0062048 (published in April 2003). The Acclaim was upgraded to include the flexifit technology in the bridge region in around 2002–2003. This was detailed in US 2000/50257792 A1, (published in November 2005). That patent also disclosed relieving pressure in regions other than the bridge, such as the lip region. The 405, 407 and Zest masks also included this technology. Later, the 432 full face mask (August 2006) and Forma full face mask (November 2008) used variations of this foam technology. This gives the same functionality as using dual walls (discussed below).
- 11.13 FPH also constructed a mask so the inner wall still extended the whole way around the mask, but removed some of the back area of the cushion in the nasal bridge area.
- 11.14 Other manufacturers used a second, thicker, inner silicone (or polyurethane foam or gel) wall to provide stability. Examples of this include the Mirage nasal mask that was launched to the market in approximately 1998-2000. These were known as 'dual wall silicone seals'. These inner walls were not necessarily uniform all the way around the nose, for example, they contacted the area beside the sides of the nose more than over the bridge. This was because the area either side of the nose is less sensitive and varies less in shape than the bridge of the nose.
- 11.15 ResMed uses dual wall silicone cushions. The theory behind the dual walls is that the outer wall of the seal is thinner, which is the face contacting part and sits outside of the central cushion and provides the sealing function. The inner wall is more significant in the cheek region of the mask but at the bridge the inner wall is lessened or cut away completely. The inner wall might also be reduced or removed at the chin area. The idea behind configuring the mask this way is that it stops the mask rocking side to side and to a certain extent up and down. But the outer wall retains the sealing ability.
- 11.16 In a nasal mask, the inner wall is more likely to extend to the upper lip zone (compared to a full face mask, where it may be cut away in the chin region). The inner wall or the thicker part of the cushion provides the stability. Without this the mask will move too much and is likely to leak, or it would put too much pressure on areas such as the bridge of the nose.
- 11.17 The outer wall provides the sealing against the face. This concept was somewhat disclosed by ResMed's 'Bubble masks', some of which contained a thicker inner wall and were released in the early to mid 1990's and disclosed in US 5,243,971. The patent shows a thin sealing outer membrane with a thicker internal wall designed to provide support. The later Mirage nasal mask also used this feature and may have varied the inner wall to a greater degree, it was release sometime in the range of 1998–2001. The

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details of the Mirage mask seal are disclosed in US 6,357,441 (published in 2002). The patent describes the thin outer layer as a 'membrane of resilience material' and the inner wall as a 'generally triangular shaped frame of resilient material... including a notch in the region of the rim adapted to receive the bridge of the wearers' nose...'.

- 11.18 In some cases there was no inner wall in the bridge region, or it was so small it was effectively not putting pressure on the face in the bridge region. By doing this the mask achieved stability while minimising contact with more sensitive areas of the nose.
- 11.19 Other masks, such as the 431 that was released in 2004 had a single wall silicone seal, which varied in the wall section. There were thicker areas either side of the nose and thinner flexible sections such as over the bridge of the nose. The thin section allowed the seal to flex or deform to different bridge depths while minimising pressure in the area and still maintaining a seal.
- 11.20 Other manufacturers use a gel cushion to provide support. Philips has a range of these. Their gel masks have the thin outer sealing silicone cushion, with a thicker inner cushion made primarily with gel. This gel is most likely a low durometer polyurethane, or may be a LSR. An example of this is the Comfort Gel Original, released some time before 2005. The outer LSR sealing layer used in these mask was effectively a design upgrade from the earlier Respironics masks that simply contained a gel cushion, such as the Profile Lite gel nasal mask, which was launched in the early 2000's. The gel in this mask could be heated and moulded to the face.
- 11.21 Others, such as the IQ nasal mask by Sleepnet (which has been in the market since at least Q1 2008) use the gel cushion without an additional seal. This gel cushion is connected to a more rigid shell, which in turn is connected to a frame that the headgear is connected to. Another example is the Phantom (which has been on the market since the early 2000's), which has a flexible frame made with malleable wire so that the frame can be bent to flex away from the patient's bridge.
- 11.22 Other designs looked at using gussets or pleats in the nasal bridge area. These compress like an accordion.

## 12. **Attaching the cushion to the frame**

- 12.1 Traditionally the cushion would be permanently attached to the frame, which was the case with some masks in the 1990's. This could be done by over moulding. That is, moulding the cushion onto the frame or by permanently hard clipping them together.
- 12.2 However, increasingly patients wanted to be able to clean and replace parts. This meant that masks were manufactured so the frame and cushion could be taken apart. For that reason manufacturers moved to a push fit connection between the frame and cushion. This was done by a portion of the cushion connecting, or push fitting into a channel in the frame or vice versa.

- 12.3 This was quite fiddly for users. The cushions are traditionally silicone, with very little structure, which made them hard to insert into the frame. Therefore, more rigid elements were introduced. A rigid element can be added to the silicone seal so that this rigid element of the seal can be clipped into the frame. Alternatively this can be a separate piece for example a polycarbonate (PC) or similar material ring that is over moulded into the silicone, so that they are integrally formed (the LSR is moulded over the frame). It may be that the seal will only clip into the frame in several places on the frame, or it might clip in all around. An example of a clip moulded integrally with a seal is the FPH Zest nasal mask, released in August 2008.
- 12.4 If separate pieces are used, it is common to use a triangular shaped ring. To assemble, the ring is placed on the inside or outside of the seal and pokes through to seal to contact the frame. For example, in the Mirage Quattro full face mask (which has been in the market since at least Q2 2007) the seal clips into the frame in three places and the clip goes through the seal and engages with holes in the frame by using a snap fit mechanism. The clip is then acting in tension and the seal with compression to engage all around the frame. The Mirage Activa also had the same style clip, which was on the market since mid 2006 and possibly earlier.
- 12.5 Other manufacturers such as Philips continued through the mid 2000's to make some of their masks, such as the Comfort Full 2 full face mask, with a seal that was permanently attached to the frame. However, this was not popular with the HME (CPAP dealers) as this did not allow them to replace the seal on a regular basis. Instead the whole frame would need to be replaced, and the frequency for this replacement was lower than the seal alone.
- 12.6 For a nasal pillow mask, one option is to use a silicone sheet around the frame which is connected by a plastic clip on the opposite side of the device from the nose. This was used in the Mirage Swift nasal pillow mask, which was launched on the market before 2005. Generally speaking, most pillow seals have been basic silicone parts, that are not integrally formed with other materials, which are then inserted into a frame or channel made from a more rigid plastic.
- 12.7 The Hans Rudolph 7600 V2 mask (on the market since at least Q1 2008) uses a seal around and into the nasal region. The frame pushes on the cushion but the frame and cushion are only sealed around the elbow.
- 12.8 It was common for one sized frame to be provided with various sized cushions or for various sized masks and cushions to be produced in the same range. FPH often had a mask with one size frame that fitted multiple sized cushions. An example of this was the first Acclaim mask which was FPH's first nasal mask, produced in 2001. By the mid 2000's FPH was producing small, medium and large sized versions of their nasal masks range, which ResMed and Respironics had done earlier. Typically, the FPH full face

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masks had one frame with different sizes available, where most of the nasal masks had a different frame size for each size variation, at least this was the case with the FPH nasal masks released after the Acclaim and 405.

- 12.9 ResMed and Philips (Respironics) also had variations in the cushions to be used with the same frame in relation to nasal masks. This would account for patients with deeper nasal bridges, and provide options that were wider and narrower at the bottom, to account for different nose shapes. As an example, the Ultra Mirage II has standard, wide, shallow, shallow-wide and large seals available.
- 12.10 Consumers generally desire as small a mask as possible for function. This is one reason for providing different seals for multiple frame sizes, where one could be used with different size seals.
- 12.11 The focus has since shifted to having less variation in the masks which, due to the construction and design, can cater for more people. For example the more recent Mirage FX has only standard or wide sizing.

### 13. **Frame**

- 13.1 The frame ties everything together. It is the anchor point for all the components of the mask. The frame typically connects to the seal and connects to the headgear.
- 13.2 Mask frames are generally made of polycarbonate because it is rigid, clear (for aesthetic reasons), and is autoclavable, so it can be sterilised. This material has commonly been used at least since the 1990's as a key material for mask frames. However, other materials such as nylon or polypropylene can be used. The need to autoclave CPAP masks is now less important.

### 14. **The tube and elbow connection**

- 14.1 The tube coming from the CPAP machine connects to an ISO standard, 22mm medical taper. The ISO 17510-2 standard dictates that manufacturers have to use particular connectors so that any hose that comes from a CPAP machine will be able to be connected to a mask from any manufacturer. The taper and tube connect by way of a push fit.
- 14.2 The taper usually has a swivelling mechanism which prevents the hose from tangling. This swivel component usually has a push or clip fit to the mask so the main CPAP hose can be easily removed by the patient. The clip is a push clip with hard or semi rigid plastic, such as PC, nylon or a similar material.
- 14.3 Masks usually have a 90° elbow. The swivel usually clips into the elbow by a push fit, or there may be a short length of small more flexible tubing between the elbow and the swivel.

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- 14.4 The elbow and the frame connect together. Or, more broadly speaking, the elbow will connect to the main gas chamber of the mask, for example in some cases this may be considered the seal. Typically in older masks this was done by an O ring, where the elbow was pushed into the frame and the O ring clipped around the frame to secure it. It then became common to have a push fit connection, where a ridge on the elbow clips into a recess on the frame. The elbow typically swivels by the ridge connector being able to turn inside the recess in the frame.
- 14.5 Another option is to use a ball and socket connector where the pressure of the air travelling through the tube pushes the ball out to the external walls to seal the connection. An example of this is the Opus released in 2006 or the Infinity released in 2005.
- 14.6 An optional feature is to have a section of smaller diameter hose which is generally the case in nasal pillow masks. For example, the Opus, released in 2006 or the Acclaim, released in 2001. The main CPAP hose connecting directly to the pillows can put a lot of force on the masks, causing them to move. Having a smaller, more flexible tube reduces this force. Another effect of the smaller hose is to reduce the impact of the hose on the patient if the hose is going between the patient's eyes.
15. **Bias flow**
- 15.1 The bias flow can be in the elbow or the mask air chamber (which may mean the frame, or the seal in some cases). It is considered the chamber is preferable because this avoids dead air sitting in the chamber. This is a subtle theoretical difference and in reality both variations will pass a FDA test. At a measurable level the effects on CO<sub>2</sub> retention in the mask are comparable.
- 15.2 If the bias flow is in the frame it can typically sit just around the elbow connection or in the upper front of the mask above the nose.
- 15.3 As a general rule most nasal masks will have the bias flow holes on the elbow and full face masks are more likely to have them on the mask frame. I believe this is because there is more area on the full face mask frames to place the holes. There are, however, examples of nasal masks with the bias flow on the frame, and full face masks with holes located on the elbow. Examples are the Acclaim nasal mask and the Comfort Full II full face mask.
- 15.4 It is considered common engineering knowledge, for any engineer that has studied fluid dynamics or process engineering, that in order to reduce noise or sound in a fluid system you need to reduce turbulence, and in order to reduce turbulence you need to remove sharp edges and maintain a smooth transition long the path of flow, ideally maintaining a laminar flow, and minimising turbulent flow. There are also other ways to reduce sound output such as reducing the velocity of the air or fluid, as reducing the velocity reduces the turbulence.

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- 15.5 There has been a great variation in the number of holes used in a bias flow. Initially three to five holes were used. At one point a silicone insert with holes was placed into the frame in the belief this would be quieter. However this did not prove to make a significant difference and it was reverted back to having the bias flow directly into the frame.
- 15.6 FPH trialled a lot of variations in the bias flow to test different approaches in the number of holes, thickness of holes and the shape of the holes.
- 15.7 The optimal is to have a greater number of holes that are smaller. This means there is less velocity in the airflow, causing less turbulent flow, which means it is quieter.
- 15.8 However, there are manufacturing limitations on how small the holes can be reliably injection moulded in typical materials such as PC. So this determines how many holes are needed to achieve sufficient airflow. Below 0.7mm diameter holes are unreliable to manufacture. In this way the size of the hole drives the number of holes needed, based on keeping CO<sub>2</sub> within the mask below a certain level.
- 15.9 Typically, masks will have a bias flow rate of around 30 litres per minute at 10 CM H<sub>2</sub>O air pressure, although the critical flow is actually at the lowest rated CPAP pressure for the mask. This pressure is typically 4cm or in some cases 3cm.
- 15.10 The smoother you can make the channel for the holes, the better. Making the holes lead in smoothly and lead out of the masks smoothly, avoiding sharp edges, generates less turbulent flow and therefore less noise.
- 15.11 The direction of the holes is critical. You don't want the holes to blow straight out as this increases the likelihood the exhaust flow will blow onto the partner. Typically, you want the holes to be angled up. In the elbow this can be done by making the holes tend in a 45° upward angle. Or if the holes are at the top of the mask, it is easier to send the airflow up.
- 15.12 In some instances there has also been a diffuser placed on the outside of the vent to further defuse the airflow and reduce the velocity and therefore noise. This diffuser would typically be replaceable. Sometimes the diffuser is used to direct the air in a particular direction, such as in the same direction as the main CPAP tube. An example of this is the Ultra Mirage II.
- 15.13 Other designs have used sintered material to form the bias flow.
- 15.14 Still other designs such as the Wisper Swivel by Phillips, on the market in the early 2000's, created a controlled leak or bias flow between two components of a swivel that connected to the elbow of the mask. The clearance between the parts was designed to create a controlled leak. Once again, air was directed generally back down the CPAP tube.

A-H  
A-H

15.15 Other factors to consider are the depth of the hole or the thickness of the material the holes pass through. Testing showed that having the holes in thinner material made them quieter.

16. **Non-rebreathing valve**

16.1 A non-rebreathing valve (NRV) became part of the standard, ISO 17510-2, released in 2007. It is common to have this in, or around, the elbow. Usually, the NRV is on the elbow, or immediately before or after the elbow.

16.2 This is a hole, which opens to atmosphere. The valve is configured so that CPAP pressure pushes a (typically LSR) flap over the hole. In the absence of sufficient pressure, the flap reverts to its biased state which opens the hole and stops rebreathing of CO<sub>2</sub>, as it allows air to be exhaled and inhaled out to atmosphere.

16.3 In some cases the NRV will block the exhaled air from going back down the CPAP hose, ensuring predominantly atmospheric air is breathed. An example of this mask is the Comfort Full face masks by Respirationics, on the market before 2005.

16.4 FPH put the valve into the swivel, which achieved the same purpose. An example of this is the 431 full face mask, released in 2004.

16.5 ResMed also had a circular valve on the frame which went around the area where the frame connected to the elbow. I believe this was on the Mirage full face mask, on the market around 2000 or possibly earlier.

17. **Forehead support**

17.1 Some masks will have a forehead support. Forehead supports were added to improve side to side stability and reduce pressure on the bridge of the nose.

17.2 Some forehead supports can be adjusted to effectively change the angle the mask sits on the face, reducing pressure on the bridge of the nose, such as the Mirage nasal mask.

17.3 Most forehead supports are adjustable pieces, which allow for bridge depth variation by changing the angle the mask sits on the face. For example if the patient has a deep bridge that protrudes a great deal from the face, the patient can move the forehead support further towards the forehead, to move the mask away from the bridge region. This maintains the seal, while stopping or reducing pressure or discomfort in that area.

17.4 Some forehead not adjustable, and are there mainly to stabilise the mask. Others are fixed but have different pads that can be changed, to adjust the spacing in a similar manner to adjusting the angle.

17.5 The forehead support clips into the frame, or in some cases is integrally formed with the frame.



## 18. **Optional ports**

- 18.1 Oxygen ports are optional in a mask. Some mask will have an oxygen port to allow additional oxygen to be provided to the patient if they have another issue requiring oxygen as well as OSA.
- 18.2 Another optional port is for a pressure reading, which is especially the case when masks are used in a sleep lab. A pressure reading and oxygen can also be taken or added by a connector in the tube.

## 19. **Differences for nasal pillow masks**

- 19.1 For nasal pillow masks the connection to the tube might be via the side of the mask or via the front. Both would be fairly similar forms of connection.
- 19.2 With a nasal pillow mask an elbow is still common.
- 19.3 You also still need a bias flow vent, which operates in the same way.
- 19.4 Before nasal pillow technology improved, nasal prongs were popular. CPAP.com for example lists nasal prong masks as a different category to nasal pillow masks. The prong masks typically have a tubular shaped prong that is inserted into the nares (nostrils) and creates an internal seal.
- 19.5 Nasal pillow masks also have a small section of the pillow seal that is inserted into the nares, with the main sealing occurring against the outer surface of the nares. By inserting the pillow partially into the nares it allows some movement of the mask without the airflow being disrupted by keeping the nasal pillow in the nose to a small degree.
- 19.6 Philips has released at least one nasal pillow style mask without any prong or pillow in the nares, which had the effect of just sealing the mask across the lower part of the nose. This was called the Optlife with CradleCushion. This is also a similar concept to the mask disclosed in US 6,119,694.

## 20. **The process for how a patient chooses a mask**

- 20.1 In the United States, a patient complaining of sleepiness would go to their primary care physician, who would then refer them to a specialist sleep doctor. The patient would then have a sleep study done in a lab, and that lab would report back to the specialist.
- 20.2 Patients will most likely see a mask first in a sleep lab. The sleep lab staff are not necessarily concerned with offering the patient the best mask for long term use, their focus is getting a good seal for the night with a mask they are familiar with and have access to in the lab. The lab staff will typically have a favourite mask that they will start with, and this is normally a nasal mask, or more recently nasal pillow masks have also been used in labs.

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- 20.3 The large companies will supply the sleep labs with a stock of masks that they can use, to obtain that attraction with patients.
- 20.4 It is not desirable to start patients on full face masks unless they have good reason to do so. If the mask doesn't seal during the night in the sleep lab it may be changed for another nasal mask or a full face mask may be used if the patient has significant mouth leak.
- 20.5 Home sleep studies (HST) are also conducted at peoples' homes, the overall process is similar as far as the mask choice is concerned.
- 20.6 Once the patient's OSA is diagnosed, they will be given a prescription for CPAP from a sleep physician and sent to a HME or CPAP dealer.
- 20.7 Approximately 50% of the time the physician will write a mask-specific prescription that the HME should use to start with. This is typically the mask used in the sleep lab. The rest of the time the HME may offer the patient a relatively small range of options that they prefer to use as first choice mask, chosen due to a combination of performance and price. If this mask, or the mask the physician requested, doesn't work out for the patient, the patient will be offered more choice.
- 20.8 If the patient does not like the initial mask they are given, a respiratory therapist (employed by the HME) will work with the patient to change their mask. It is in the HME's interests that the patient is compliant with their mask within 90 days, because the HME's ongoing payments from the insurance company, for the CPAP and on going mask consumables, are dependent on compliance. It is for this reason that dealers won't necessarily use the cheapest mask in the market—they still want to get the patient compliant.
- 20.9 Most large mask manufacturers offer a 30 day mask guarantee program, which allows the patients to return masks and dealers to get new replacements at no charge. This means there is no cost to the dealer or patient for trying different masks in the initial 30 day period.
- 20.10 In the United States, the patient will have about 80% of the cost of the CPAP equipment covered by their medical insurance, so long as they have met their annual deductible or excess. Patients would usually get a new mask every six months, depending on their insurance cover. Accordingly, patients could choose a new mask at that six month period.
- 20.11 Once patients become more experienced with CPAP therapy they often look on the internet for focus groups or online retailers who offer more information. There are forums like CPAP Talk, where consumers can talk about the masks they are using. In this way other consumers can receive information about the masks available and the kind of features they have.



- 20.12 Patients may see another mask they would like to try and request this through their HME provider. The provider may supply that mask, or they may not depending on the request and the level of insurance the patients have. So in some cases patients purchase masks (independently from their insurance schemes) from online retailers to get what they want.
- 20.13 Patients can use sites like cpap.com to buy their own masks. This can be cheaper for the consumer than paying the excess on their insurance, or they may simply wish to have a greater choice in mask (outside of those approved by their insurance company).
- 20.14 The process is similar in New Zealand and Australia. There are both public and private (self paying) patients.
- 20.15 In New Zealand most of the volume tends to be public cases, and the local DHB will put out a tender which the large manufacturers will fill with a full range of products. The DHB will then mainly use the tendered product.
- 20.16 In New Zealand, only relatively moderate to severe patients are publicly funded into equipment, due to the amount of funding available.
- 20.17 In New Zealand and Australia patients typically have to pay for their replacement masks, which means they tend to use them for longer. As the market is smaller, retail prices tend to be two to three times higher. However, the masks are the same as used in the United States and other parts of the world, and patients see the equivalent specialists and sleep labs in Australia and New Zealand, as the United States.
- 20.18 One point of difference in New Zealand is that the DHB that conducts the sleep study, also supplies the CPAP and mask. Having said that, there are also a small number of private CPAP equipment retailers, similar to the HMEs in the United States.
- 20.19 In Australia patients will typically go on to a CPAP rental, where they try CPAP, after the same sleep lab process. They will rent a CPAP and a trial mask for 1-3 months, after which they will either decide to purchase the CPAP machine and mask or not continue with therapy as they cannot tolerate it. Once again there is no difference between the masks on offer in the Australian market, United States market or other major markets around the world. Australia is also closer to the United States model for CPAP and mask supply—the patient goes to a CPAP dealer similar to the United States' HMEs to purchase their equipment.

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21. I have made all the inquiries that I believe are desirable and appropriate and that no matters of significance that I regard as relevant have, to my knowledge, been withheld from the office.

**AND I MAKE** this declaration conscientiously believing the statements contained in this declaration to be true in every particular.

DECLARED at Auckland, New Zealand )  
this 9<sup>th</sup> day of April 2015 )



Alistair Edwin McAuley

BEFORE ME



Amy Katherine Cunniffe  
Solicitor  
Auckland

A Solicitor of the High Court of New Zealand



**COMMONWEALTH OF AUSTRALIA**  
**Patents Act 1990**

**IN THE MATTER OF** Australian patent application 2009221630  
in the name of RESMED LIMITED

**AND**

**IN THE MATTER OF** Opposition thereto by FISHER & PAYKEL  
HEALTHCARE LIMITED

**EXHIBIT NOTE AM-1**

This is exhibit **AM-1** referred to in the annexed statutory declaration of  
**ALISTAIR EDWIN McAULEY** declared at  
Auckland, New Zealand this 9<sup>th</sup> day of April 2015 before me:



Amy Katherine Cunniffe  
Solicitor  
Auckland

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Solicitor of the High Court of New Zealand

## **Alastair McAuley – Curriculum Vitae**

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Email: [alastair1.nz@gmail.com](mailto:alastair1.nz@gmail.com)

### **Summary**

Over 16 years in the Obstructive Sleep Apnea (OSA) medical device market, with experience in product development, manufacturing, intellectual property management, business development and general management. Held roles such as President of a USA based medical device manufacturer, Product Development Manager and Business Development Manager for a large multinational.

Overseen the development of around 15 major products that have been, or continue to be, among the top selling medical devices and an inventor in over 70 US patent applications in the OSA product field. Founded a company with other business partners that conducted a successful joint venture project to develop, tool and assist in bringing to the market an award winning CPAP mask.

### **EMPLOYMENT HISTORY**

#### **Medical Device Consultant**

April 2014 – Present

Medlands Consulting Ltd (NZ)

**Consultant to the CEO - Airway Management (Dallas TX)** – Provide advice on business strategy and work directly on business development globally. Oversee the engineering, product development and the Intellectual Property of the company. Provide support to achieve on going FDA and ISO 13485 compliance.

**Medical device consultant** - Provide medical device design, manufacturing, business development and commercialisation advice and services.

**Shareholder/Director** – Airway Management Asia Pacific Ltd – AMAP is a medical device distribution business marketing and selling medical devices for the treatment of OSA into the Australian and New Zealand markets.

#### **President**

Jan 2013 – April 2014

Airway Management (Airway Technologies LLC – TX, USA)

Airway Management is one of the market leaders in the Oral Appliance market. The role included planning, coordinating, and controlling the daily operation of the organization through the organisation's managers. During this time two major products were launched into the market, the company quality system was upgraded to achieve ISO13485 compliance, which enabled the sale of products into new overseas markets, and the company also successfully passed a FDA inspection. Sales were expanded to other major overseas markets through new distributors.

#### **Managing Director**

Dec 2011 – Jan 2013

Medlands Technologies Ltd (NZ)



Designed and launched the TAP PAP nasal pillow mask into the US and other key markets, under a joint venture arrangement with a US based company. It was awarded the “Providers Choice” award at the Medtrade show in Las Vegas in 2013 and was an award winner in the New Zealand “Best Design Awards” in the same year.

**Business Development Manager - OSA**

March 2010 – Dec 2011

Fisher & Paykel Healthcare Ltd

Conducted research to identify market trends and customer needs for R&D and strategic planning. Create monthly reports for the Board of Directors, presenting sales data along with market commentary. Review business case, market opportunity and intellectual property issues for internal and external product opportunities.

**Product Development Manager – OSA Interface**

2002 - 2010

Fisher & Paykel Healthcare Ltd

Managed 5 teams totalling 30 engineers designing Interfaces for the OSA market and developing or procuring the production equipment to manufacture the products. Conduct market research in various countries. Manage the Interface IP portfolio, reviewing competitor IP, drafting patent applications and responding to patent examiners objection in conjunction with external Patent Attorneys.

**Project Leader – OSA Interface**

2000 - 2002

Fisher & Paykel Healthcare Ltd

**Product Development Engineer – OSA Interface**

1998 - 2000

Fisher & Paykel Healthcare Ltd

**Product Development Engineer – Respiratory Humidification**

1997 – 1998

Fisher & Paykel Healthcare Ltd

**EDUCATION**

Bachelor of Technology with Honours majoring in Engineering and Automation. Massey University, New Zealand. 1994-1997

**INTERESTS**

Sailing – race small yachts and larger keelboats. I also have had many sailing holidays with friends, renting yachts for a week at a time in New Zealand, Turkey, Cuba and Tonga. Flying – I have a private pilot license, have been flying around many parts of New Zealand.

**REFEREES**

**Peter Herbert**

Tooling and Plastics Consultant. Board Member of the NZ Manufactures and Exporters Association (NZMEA). Ex Chairman of COMPETENZ  
Ph. +64 21 881 022

**David Wixey**

OSA Product Group Manger (General Manager) – Fisher & Paykel Healthcare  
Retired December 2010 – Direct Manager for 10 years.  
Ph. +64 21 447 807

**COMMONWEALTH OF AUSTRALIA**  
**Patents Act 1990**

**IN THE MATTER OF** Australian patent application 2009221630  
in the name of RESMED LIMITED

**AND**

**IN THE MATTER OF** Opposition thereto by FISHER & PAYKEL  
HEALTHCARE LIMITED

**EXHIBIT NOTE AM-2**

This is exhibit **AM-2** referred to in the annexed statutory declaration of  
**ALISTAIR EDWIN McAULEY** declared at  
Auckland, New Zealand this 9<sup>th</sup> day of April 2015 before me:



Amy Katherine Cunniffe  
Solicitor  
Auckland

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Solicitor of the High Court of New Zealand



Term or Name of Item	Description
Mask/Interface/Patient Interface/CPAP mask	A device used to deliver pressurised air to the patient, starting from the connection point to the patient end of the main CPAP tube and everything down stream that connects to the patients face or head, including the headgear.
Seal/Cushion/pillow	Part of a mask that is in contact with the patients face and creates an almost airtight connection between the mask and the face and includes a hole or holes for the air to pass into and out of the patients nose and or mouth.
Cushion clip, cushion ring, seal clip	A component that holds the cushion or seal to the mask frame. This may be a separate part or formed integrally with the seal, for example by over molding during the manufacturing process.
Headgear/Harness	A component of a mask that secures the mask to the patients head, typically by passing around the patients head and providing a compressive force to the mask against the face.
Headgear clip/headgear hook/headgear loops	A component designed to attach the headgear to the mask frame
Strap	Part of the headgear, normally an elongated and section that can be adjusted in length
Headgear buckle	A component of the headgear that allows for the adjustment of the size of headgear or the length of a headgear strap
Crown strap	Part of the headgear that passed over the top of the head or crown.
Tubing/hose	A flexible pipe that delivers air from the CPAP to the mask. Typically around 1.8m in lengths with 22mm diameter connectors at each end. Smaller sections of tubing can also form part of a mask.
Bias flow/exhaust flow/intentional leak/controlled leak	This is the flow of air from the mask that is designed to flush the users exhaled CO <sub>2</sub> from the mask during normal operation.

Bias diffuser/vent cover/diffuser	A component designed to slow the bias flow and/or change the direction of the flow
Bias flow holes, bias vent, vent holes	This is the physical feature in a mask, such as a series of holes, that allow for the controlled leak of air or in other words creates the "bias flow".
Elbow	This is a mask component that typically connects to the mask base or frame, has a 90 degree bend and rotates to allow for different tube positions relative to the mask
Mask base/Mask frame	This is a component of the mask that connects the headgear and seal together.
Swivel/connector	This is a component that connects the mask to the main CPAP tube, it can rotate or swivel and is commonly removable from the mask and used as a connector to the CPAP tube
Forehead rest, Forehead support, "T" piece	This is part of the mask that sits in the forehead region. It commonly rests against the forehead to stabilize the mask and may be adjustable to change the angle of the mask on the face
Forehead Pads	A component that sits between the forehead support and the forehead and is designed to reduce the pressure being applied to the forehead of the user.
Non Rebreathing Valve (NRV), Anti-asphyxia valve (AAV), entrainment valve	This is a valve that includes a flap and hole that opens to atmosphere. The valve is closed to atmosphere when normal CPAP pressure is applied, and opens to atmosphere when CPAP pressure at the mask falls below minimum operating levels. It is designed to prevent rebreathing dangerous levels of CO <sub>2</sub> .
Nasal Pillow Mask	A mask that has two generally round or oval cushions, per size that seal primarily on the outer surface of each of the patients nares
Nasal Mask	A mask that has one cushion, per size, that is generally triangular in shape and seals on the face in the area around the nose and over the bridge of the nose. It delivers pressurised air only to the nose.



Full Face Mask	A mask that has one cushion, per size, that is generally triangular in shape and seals on the face in the area around the nose, below the mouth and over the bridge of the nose. It delivers pressurised air to the nose and mouth.
Hybrid Mask	This is a combination of a Nasal mask and a full-face mask. It has one cushion covering the mouth and two nasal pillow style cushions sealing each naris.
Nasal Prong Mask	This is a mask that has two tubes that are inserted into each naris, and generally seal inside the users nares.