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D E C I S I O N
of 21 January 2004

Case Number: T 0802/02 - 3.2.2

Application Number: 95307394.7

Publication Number: 0709107

IPC: A61M 16/00

Language of the proceedings: EN

Title of invention:
Standby control for CPAP apparatus

Patentee:
Sunrise Medical HHG Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 84

Keyword:
"Clarity (yes), novelty (yes), inventive step (yes)"

Decisions cited:
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Catchword:
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Case Number: T 0802/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 21 January 2004

Appellant: Sunrise Medical HHG Inc.
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Representative: Wardley, Diana Mary
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 5 March 2002 refusing European application No. 95307394.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 5 March 2002 to refuse European patent application No. 95 307 394.7.

The ground of refusal was that claim 1 was not clear and therefore did not meet the requirement of Article 84 EPC. However, if the claim were to be interpreted by reference to the description, then the subject-matter of claim 1 was not novel, having regard to any one of the following documents:

D1: EP-A-0 505 232

D2: WO-A-88/10108

D3: US-A-5 245 995

II. On 3 May 2002 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same date. On 3 July 2002 a statement of grounds of appeal was filed by letter dated 2 January 2004.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 6 filed

IV. Claim 1 reads as follows:

"A standby control (17) for apparatus (10) for applying a continuous positive airway pressure to a patient's respiratory system, the apparatus including a blower (12) for establishing a positive air pressure, a mask

(11) adapted for sealed communication with a patient's nose, and a hose supplying pressurized air from said blower to said mask characterised in that said control (17) includes means for operating said blower in a standby mode in the absence of breathing of the patient into the mask wherein no or a low airway pressure is provided and in a normal mode wherein a positive pressure is maintained by the blower during breathing, means (16) for detecting when the patient begins breathing into said mask, and means for changing the operation of said blower from said standby mode to said normal mode in response to the detection of the patient breathing into said mask.".

Claims 2 to 6 are dependent on claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. *The application*

The decision is based largely on a misconstruction of the terms "standby mode" and "normal mode", so that it will be useful to first set out the Board's understanding of the application and the meaning of these terms as derived therefrom.

The application concerns continuous positive airway pressure (CPAP) respiratory therapy apparatus having a blower for applying airway pressure to a patient's respiratory system. A sufficiently high continuous positive pressure is applied to the patient's airway to

prevent its collapse or blockage, and this is termed a pneumatic splint. The opening parts of the description review the relevant prior art which describes apparatus which operates in a bi-level manner wherein the air pressure is adjusted according to the patient's breathing pattern and applied to a mask through which the patient breathes. In particular there is described apparatus employing a "soft-start" in which, for patient comfort, a low pressure is applied while the patient falls asleep and the applied pressure is increased subsequently.

The technical problem with the prior art apparatus is set out in column 2, lines 28 to 44 of the A1 document, and may be summarised as follows: In the event that the apparatus is switched on before the mask has been applied to the patient's face in a sealing manner, or the mask is accidentally knocked so as to break the seal, or the patient removes the mask before turning the apparatus off, then the prior art apparatus would tend to increase the pressure at the mask, which is futile and could lead to discomfort should the patient then refit the mask.

The solution proposed in the application and defined in claim 1 is to provide a control which operates the blower in a standby mode in the absence of breathing of the patient into the mask, and means are provided for detecting when a patient begins breathing into the mask and changing the operation of the apparatus from the standby mode to the normal mode in response to the detection of the patient breathing into the mask.

In the standby operating mode, according to the application, (column 5, lines 52 to 56) the apparatus is switched on but the blower is off or operated at a low speed. However, this low speed must be even lower than that necessary for a soft start since the application states that when the controller senses breathing in the mask, the controller begins a soft start cycle (column 5, lines 57 and 58). A person skilled in the art would know the difference between the pressure during a soft start and the low pressure in the standby mode, given their respective functions.

Therefore, according to the application, the "standby mode" is the state in which the apparatus is switched on but in a dormant condition, ie not active as a pneumatic splint, and this mode is operative when the patient is not breathing into the mask. Nevertheless, the apparatus is in a state of readiness poised to apply pressure sufficient to act as a pneumatic splint upon detection of the patient breathing into the mask. Two types of standby mode are provided if no breathing into the mask is detected. The apparatus initially may enter a low pressure standby mode and, if no breathing is sensed during a predetermined time interval, it may be switched to a blower off standby mode to save energy.

This definition of "standby mode" is consistent with everyday usage as applied, for example, to commonplace apparatus such as domestic electronic apparatus including television sets, VCRs, etc which are provided with a "Standby" button. The apparatus, when not in use, is in the standby mode in which the apparatus is switched on but not active, and rapidly switches into

active use upon operation of the "Standby" button. The purpose of such a state is to save power yet enable a rapid transition into the fully operational state without a tiresome waiting period.

By "normal mode" is meant the standard operating mode of such apparatus in which positive pressure is applied to the mask as per the patient's requirements so as to deliver a therapy, for example to apply a pneumatic splint. The normal mode is described in column 5, lines 29 to 51.

3. *Amendments*

Claim 1 corresponds to claim 16 as originally filed, but amplified to explicitly define the terms "standby mode" and "normal mode", which definitions, as explained above, are consistent with the application and hence properly supported by the original disclosure.

Dependent claims 2 to 4 correspond to original claims 17 to 19, respectively. Claim 5 is supported by the description in column 10, lines 19 to 25, for example, and claim 6 claims a combination of the control together with the apparatus for applying a continuous positive airway pressure to a patient's respiratory system, and is also supported by the original disclosure.

4. *Article 84*

4.1 From point 2 above it should be evident that the expressions "standby mode" and "normal mode" are clear in the context in claim 1 and their definition is also consistent with the description. The reservations expressed in the decision under appeal in this respect are misplaced, accordingly.

Although claim 1 relates to a standby control and defines features of the control, it additionally defines features of the respiratory apparatus which the control is meant to supervise. It is clear, however, that the scope of the claim is restricted to the control itself and not to the combination of the control and the respiratory apparatus.

This does not, as argued by the examining division, lead to lack of clarity since the control is an independent vendible product and entitled to patent protection per se. A recitation of the features of the respiratory apparatus, such as the mask, in the claim facilitates the understanding of the control itself. The control is a dedicated device since it clearly has no application other than to respiratory apparatus of the kind defined in claim 1 and no confusion arises in claiming a control **for** the respiratory apparatus. The combination of the respiratory apparatus and the control is now claimed in claim 6.

The claim is consistent with the objects of the invention. As stated above in point 2 above problems arise in prior art apparatus consequent upon the mask being accidentally knocked or removed before turning

the apparatus off, in which case the prior art apparatus would tend to increase the pressure at the mask which could lead to discomfort should the patient then refit the mask. The problem is solved by the claimed control which, in the absence of breathing of the patient into the mask, operates the blower in the standby mode and no excessive pressure is applied to the mask which could lead to patient discomfort. The features of the control, as defined in claim 1, solve this problem.

4.2 Since the decision is based on a misunderstanding of the claimed invention, it is not surprising that the examining division found that its own interpretation of the claim was not supported by the description. With the understanding of the application and the claims as set out above there is no inconsistency between the description and the claims, the latter being fully supported by the description.

5. *Novelty*

None of the prior art documents D1 to D3 describes a standby control for apparatus for applying a continuous positive airway pressure to a patient's respiratory system, which is capable of operating in the standby mode. While the prior art apparatus is capable of operating in two different modes, neither of these can reasonably be considered to be a standby mode.

D1 describes a CPAP apparatus which can operate at two different predetermined pressure values during each breath, a low pressure during the exhalation phase and a higher pressure during the inhalation phase. However,

both of these are a normal operation of such apparatus whilst the patient is breathing. No other mode of operating the apparatus is described including what may reasonably be termed a standby mode. In particular the low pressure mode of operation described in D1 cannot be equated with a standby mode since the apparatus is not in a dormant state but in an active state during an active phase of a patient therapy. Also, there are no means for operating the blower in a standby mode in the absence of breathing of the patient into the mask.

The apparatus of D2 and D3 are similar to D1 and they primarily use snoring sounds for controlling air pressure in a CPAP apparatus. They commence operation at a low pressure level when switched on, and increase the pressure depending on different factors such as detecting snoring sounds. The initial low level is for the duration that the patient is falling asleep, and corresponds to the "soft-start" described in the application, and the pressure is increased thereafter to a therapeutic level. Again, no described state of the apparatus can reasonably be said to be a standby state, and there are no means for operating the blower in a standby mode in the absence of breathing of the patient into the mask. As explained in point 2 above the low pressure soft start mode is not the same as a low pressure standby mode. Another distinction is that according to claim 1 the apparatus is in the standby mode in the absence of breathing of the patient into the mask, whereas in D2 and D3 the low pressure soft start mode is active while the patient is breathing into the mask.

6. *Inventive step*

The technical problem arising in prior art apparatus consequent upon the mask being accidentally knocked or removed before turning the apparatus off, which could lead to discomfort should the patient then refit the mask, is solved by the claimed control since it operates the blower in the standby mode in the absence of breathing of the patient into the mask and has means for detecting when a patient begins breathing into the mask so as to change the mode to the normal mode of operation. The apparatus of D1 to D3 do not have a standby mode and do not have means for detecting when a patient begins breathing into the mask, nor do they address the above problem.

In D1 a control unit modifies the air pressure applied to a patient mask as a function of the breathing cycle of the patient. A slight overpressure is applied in the inhalation phase, and when the start of the exhalation phase is detected the overpressure is lowered to facilitate exhalation by the patient (D1, column 2, lines 43 to 57). There is no disclosure of a standby mode of operation when the patient is not breathing into the mask, or of any other mode of operation, nor is this apparatus equipped to cope with the problem of the application.

In D2 and D3 the control apparatus is responsive to snoring sounds, and characteristic patterns of other respiratory parameters such a breathing rate, or inhaled/exhaled air volume or flow rate may be used for detecting apneas (see, for example, D3, column 4, lines 28 to 41 and column 7, lines 1 to 12). Upon the

occurrence of an extended period of snore-free breathing the pressure is decreased (D3, column 10, lines 31 to 35), but this low pressure phase is again not equivalent to the standby mode since the patient is still breathing and a therapeutic dose of air is being administered, ie the system is active and not in a standby mode.

The D2 and D3 apparatus are not concerned with the detection of cessation or starting of breathing, only that case is illustrated in which the snoring ceases, which of course occurs when the patient is still breathing. There is also no disclosure of a standby mode of operation when the patient is not breathing into the mask. Were the mask to be knocked creating a large air leak, the microphone in the mask may continue to detect snoring sounds and carry on working as intended, and since it has no means for detecting either when a patient **begins breathing** or that it begins breathing **into the mask**, it is not capable of solving the problem of the application.

Therefore, the standby control of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of claims 1 to 6 filed on 5 January 2004 by letter dated 2 January 2004, description pages 1, 2, 5 to 15 as originally filed, page 4b filed on 21 December 1999, and pages 3, 4, 4a filed on 20 February 2001, and Figures as originally filed.

The Registrar: The Chairman:

V. Commare W. D. Weiß