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RESPONSE TO EXAMINATION REPORT
FISHER & PAYKEL HEALTHCARE LIMITED
Australian patent application 2020201324
CONTROL FOR RESPIRATORY DEVICE
AJP ref 873062 HRB/JKB/rlp

Thank you for the examination report dated 29 October 2021.

1. Attachments

With this letter we include:

- A Statement of Proposed Amendments
- A marked-up copy of the specification with the proposed amendments
- Replacement specification pages 1 to 50

2. Amendments

We propose amendment of claim 1 to address the examiner's clarity objection, and to further clarify the applicant's invention in view of the inventive-step objection.

We also propose amendment of the statements of invention in the Summary of the Invention for alignment with the pending claims.

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3. Objections raised

3.1 Clarity – section 40

Claim 1 has been amended to refer to a "first communications module" and a "second communications module" to address the examiner's clarity objection.

3.2 Inventive-step

The examiner asserts that at least independent claim 1 lacks inventive-step in view of the combination of D1 (US7,610,094) and D2 (WO2012/080941). We respectfully disagree, for the reasons set out below.

The applicant's invention

The applicant's invention is directed at solving the problem of improving the control system associated with a respiratory device configured to deliver a heated and humidified flow of gases for respiratory therapy. In particular, the invention enables upgrading of the functionality and control of existing devices, and/or reducing the hardware cost and complexity associated with new respiratory devices, in regard to the control system being responsive to controlling or adjusting operational parameters of the device based on local environment data indicative of climate or weather conditions.

The prior art approach required respiratory device hardware to be upgraded with new sensors for determining ambient conditions for example, which required changes to existing hardware architecture. Likewise, for new respiratory devices, the hardware design required dedicated additional sensors for determining ambient conditions of the environment, which added to cost and complexity of the design, and increased processor resource burden.

The applicant's invention represents a technical solution to the above problem which reduces the burden, costs and/or complexity of incorporating additional control functionality responsive to local environment conditions. The applicant's invention utilises a mobile computing device (such as a smartphone or other portable electronic device) to sense and/or source local environment data and which is in communication with the respiratory device, and which is able to control operational parameters of the respiratory device based on the local environment data. This configuration enables the overhead and intelligence of determining local environment data to be delegated from the respiratory device to the external mobile computing device and to leverage off the inbuilt sensor and data capabilities of such mobile computing devices, including the processor resource associated with modifying operational parameters based on determined local environmental conditions.

The applicant's invention therefore alleviates the hardware and processor burden associated with upgrading an existing product to respond to local environment

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data, and also reduces the hardware and processor burden of new respiratory device product designs, as the local environment data sensing and/or related control aspects can be delegated to an external mobile computing device.

Additionally, mobile computing devices are widely used and constantly upgraded in terms of technology and sensing ability. As such, the system configuration enables the respiratory device to benefit and utilize these improvements in sensing technology of the mobile computing devices without the respiratory devices requiring hardware changes.

Additionally, the system configuration with the mobile computing device allows for more accurate control and improved control, as the respiratory device can respond to changes in the environmental conditions with appropriate adjustments to the operational parameters of the device. This results in more effective control as the respiratory device can respond to changes in the local environment.

D1 – US 7,610,094

The examiner asserts that the embodiment described in column 8, lines 5-55, relating to the system 200 of Figure 2 is relevant to the applicant's invention.

The examiner asserts that the 'respiratory therapy device 254' in D1 corresponds to the 'respiratory device' of the applicant's claim 1, and that the 'remote system 240' corresponds to the 'mobile computing device' of the applicant's claim 1, when providing basis for the inventive-step objection.

Firstly, the applicant's claim 1 comprises a system for providing respiratory therapy to a patient in which the mobile computing device communicates with the respiratory device via their respective communication modules. In contrast, the system 200 in D1 is not configured in this manner. In D1, the remote system 240 communicates with an intermediate medical device 201. A therapy control unit 230 of the medical device 201 then in turn controls the respiratory therapy device 254 (see column 12, lines 5-20). Therefore, the remote system 240 does not communicate and directly control the respiratory therapy device, as required by the applicant's claim 1. The system 200 in D1 is based on central medical device 201, which independently communicates with the remote system 240 and the respiratory therapy device 254. The remote system 240 in the system 200 of D1 is a passive device providing data to the central medical device 201 and its therapy control unit 230. The remote system 240 in system 200 does not directly control any operational parameter of the respiratory therapy device 254.

Secondly, the system of D1 discloses non-physiological conditions, including ambient temperature, humidity, an air pollution index, may be sensed by the remote system 204 and then data collected being transmitted to the medical device 201 (see column 8, lines 20-45 of D1). D1 discloses in column 8, lines 46-

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50, that the set of patient conditions in Table 1 (which includes contextual and environmental conditions such as ambient temperature, humidity, and pollution) can be used "in connection with a coordinated approach to patient monitoring, diagnostics, and/or therapy". As noted above, the remote system 240 does not directly control the respiratory therapy device 254. It is controlled by the therapy control unit 230 of the medical device 201. And still, even in regard to the therapy control unit 230 of the medical device 201, D1 does not teach or disclose that the therapy control unit 230 controls at least one operational parameter of the respiratory therapy device 254 based on the contextual/environment data from the remote system 240 – see column 12, lines 5-20 of D1 – which is silent on such a feature.

A skilled person, faced with the technical problem addressed by the applicant's invention, would not turn to the teachings of D1. Firstly, D1 does not teach that the respiratory therapy device 254 provides a heated and humidified flow of gases to a patient in accordance with a respiratory therapy using a device having a blower and humidifier unit. Secondly, D1 does not teach or acknowledge the problems associated with upgrading or producing new respiratory devices which are capable of determining or accessing local environment data and controlling (e.g. adjusting) operational parameters of the respiratory device based on such local environment data to enhance the operational performance or efficacy of the respiratory therapy delivered to the end user in the environment. In fact, D1 teaches away from the applicant's solution and configuration. D1 teaches a system 200 embodiment configuration which requires providing an additional medical device 201 which controls the respiratory therapy device 254, and the medical device in turn receives the contextual/environmental condition data from a further separate remote system 204. This three-device configuration further adds to the hardware requirement and increases complexity of the system. In contrast, the applicant's solution leverages off a mobile computing device (e.g. a smartphone or similar) to access or determine the local environment data, and which then directly controls the respiratory device based on the local environment data, e.g. by adjusting operational parameters to enhance operational and/or therapeutic efficacy of the respiratory therapy delivered to the patient.

D2 - WO2012/080941

The examiner cites D2 as an example of a respiratory system providing a flow of heated and humidified gases with a ventilator 101 connected to a humidifier unit 107. In paragraphs 07-09, D2 merely discloses the humidifier unit may include an ambient temperature sensor, which can be used in a closed loop feedback process to achieve received humidifier set points.

D2 does not teach or disclose a mobile computing device configured to directly control operational parameters of the respiratory device such as controlling the power/temperature of heater plate and/or heated breathing tube, controlling

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pressure and/or flow rate settings, controlling humidity settings, controlling display brightness, based on local environment data indicative of climate and/or weather conditions determined by the mobile computing device, as defined in amended claim 1.

Furthermore, D2 does not teach or disclose the problems associated with upgrading or producing new respiratory devices which are capable of determining or accessing local environment data and controlling (e.g. adjusting) operational parameters of the respiratory device based on such local environment data to enhance the operational performance or efficacy of the respiratory therapy delivered to the end user in the environment.

Summary
We submit the applicant's invention as now defined by amended claim 1 is inventive over the combination of D1 and D2. Neither D1 or D2, taken alone or combined, teach the combination of features and specific configuration of amended claim 1 as explained above. Furthermore, neither D1 nor D2 are directed at solving the problem addressed by the applicant's invention. The remaining dependent claims are inventive by virtue of their dependency on claim 1.

We request the objection to lack of inventive-step be reconsidered and withdrawn.

4. Postponement of acceptance

We would like to withdraw the postponement of acceptance of this application.

We look forward to receiving the examiner's reply.

Yours sincerely



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