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PMD SOLUTIONS

MAKING EVERY BREATH COUNT
Our Vision

To improve patient outcomes by making every breath count and to become the industry leader by 2020

Supported by the European Union’s Horizon 2020 research and innovation programme under grant agreement No 711269
Novel Technology at the core
A brand new approach to Respiratory Effort Monitoring - a significant engineering challenge

Measuring the most sensitive indicator to well-being
Breathing: Respiratory Effort is a total system indicator of wellness offering up to 48 hours early indication of sickness

Ongoing research & development into preventative monitoring & diagnostic technologies
Making every breath count by developing real time breath by breath monitoring - a true industry leader in this field

PMD Solutions

Ongoing excellence in clinical and applied research

Constant clinical investigation to prove the effectiveness of our technology

Global focus with an international presence

Genuine concern over patient’s outcome in acute care together with international partners
Impact to European Society

Acute Care - Chronic Disease - Sleep Disorders

• People are living longer
• COPD (respiratory diseases) 3rd biggest killer by 2030
• Emergency and Urgent Care under severe pressure
• Sleep disorders going undiagnosed for up to 2 years post symptoms being recognised

Preventative monitoring is key, early detection is vital

• Healthier living: More years and Better Life
• Better acute care management (Lower Event Rate)
• Reducing preventable comorbidities thus improve healthcare economics + Quality of Life
Platform - 2 applications: 1 product
Presently both clinical applications use the same device

**RespiraSense**
In-patient RR monitor

- OTS tablet device
- Android
- Disposable single use sensor
- Respiratory rate trend monitoring
- Continuous monitoring
  4 days battery

**RS Sleep Screener**
Home Sleep Test

- Mobile Device
- Android or iOS
- Zero patient engagement needed
- Cloud processing + report generation

All comm’s are BT
RespiraSense

Why is RR important?

Continuous rate Monitoring allows;  
» The first sign of abnormal breathing  
» To trigger the earliest intervention  
» Leading to better patient outcomes  
» And improved healthcare economics
RespiraSense can give >80% ROI by impacting 1 in 20 patients.

Incidence of Respiratory Compromise to Increase by 31% by 2020:

- 7% General Ward & 11% Post-op
- Costing €18,000 per event
- Up to 7 additional bed days
- RespiraSense can give >80% ROI by impacting 1 in 20 patients.
Goldhill and colleagues reported that 21% of ward patients with a respiratory rate of 25-29 breaths/minute assessed by a critical care outreach service died in hospital. These patients could have been identified as high risk up to 24 hours before the event with a specificity of over 95%.

Recent evidence suggests that an adult with a respiratory rate of over 20 breaths/minute is probably unwell, and an adult with a respiratory rate of over 24 breaths/minute is likely to be critically ill.

In another study, just over half of all patients suffering a serious adverse event on the general wards (such as a cardiac arrest or ICU admission) had a respiratory rate greater than 24 breaths/minute.

In 1993, Fieselmann and colleagues reported that a respiratory rate higher than 27 breaths/minute was the most important predictor of cardiac arrest in hospital wards.

Subbe and colleagues found that, in unstable patients, relative changes in respiratory rate were much greater than changes in heart rate or systolic blood pressure, and thus that the respiratory rate was likely to be a better means of discriminating between stable patients and patients at risk.
RespiraSense - Continuous Respiratory Rate Monitor

First Principles
a) The core technology is piezoelectric film technology.
b) Measures movement or in this application the mechanics of breathing
c) Ribcage dynamics are common to enable spontaneous respiration and are a direct measure of rate & effort

Can it work
a) First study in 2014 compared the technology with ECG derived RR and Manual Counting by trained nurses
   - Respiratory rate was +/-3BPM when compared against ECG & +/-7 when compared with Manual Counting
   - Product demonstrated non-inferiority to ECG given 3 breath per minute was deemed clinical significant.
b) In 2015 a study comparing Capnography and the CE marked device was undertaken with bland Altman showing +/-3 breaths per minute with in-patient volunteers.
c) Since 2015 over 300 patients have used the product with their healthcare fellows accepting the results

Planned Activities
a) Advance clinical investigation into the use of the device in specific clinical pathways:
   - Respiratory
   - Triage for A&E admissions
   - ICU outreach
   - Discharge screener
b) To evaluate how a single parameter track and trigger event can give timely escalation of care for a given clinical pathway e.g.
   - Respiratory Compromise in Respiratory Departments or
   - Sepsis for post A&E admissions
c) Bariatric Study, 45 patients, evaluation of BMI as parameter of accuracy when compared to capnography
d) HTA - See next Slide
RespiraSense Health Technology Assessment

2017
Evaluation of Economic Impact to Healthcare

Observational Study to evaluate the potential impact of continuous RR monitoring has as a single track and trigger metric for rapid response activations in terms of reducing preventable events:

- Denmark
- Cork, Ireland
- ~ 12 months, 500+ patients, 2 publications, foundation for 2018 Randomised Controlled multi-site Study
Sleep Disorders affect 3% of the global patient population

» Although all are treatable

» Up to 24 months waiting for diagnosis

» 94% remain presently undiagnosed

» Costing 0.8% GDP to treat comorbidities resulting from delayed diagnosis
Why Screen?

A simple and accurate event screener;

Can enable sleep service providers
With minimum increases in resources

To increase their patient coverage
To identify and serve more apnoea sufferers

Consumer application potential for home screening

Status Quo
Bands slip, leading to re-tests
Bands are uncomfortable

PMD is changing the Status Quo
- Bands replaced with simple adhesive RS sensor
- Cloud Based Analytics allowing instant review of data
- Chest & gut measurements + Position + Activity
Example Data

Examination of good detection epoch

Piezo 1 reading
Piezo 2 reading

SpO₂ Event
SpO₂ reading

Apnoeic Event
PMD - Predicted

Normal

Time (minutes)
First Principles

a) The core technology is piezo-electric film technology.
b) Measures the mechanics of breathing
c) Ribcage dynamics are common to enable spontaneous respiration and are a direct measure of rate & effort.
d) First indications for detecting apnoea discovered during the initial product evaluation (Lee 2014)

Can it work

a) The proof of concept was evaluated with 12 randomised PSG Lab Sleep patients.
b) Measurements were undertaken both with the technology by itself and when coupled with a pulse oximeter
c) Technology Performance:
   • +/-2 AHI across 10-30 when compared to PSG results when on its own; and
   • +/-7 AHI across 0-10 when
   • +/-3 AHI across 0-30 when compared to PSG and coupled with Pulse Oximetry.
d) The R3S on its own demonstrated superiority to SpO2 on its own for the 10+ AHI range; and
e) Superiority when joined across entire AHI range

Planned Activities

a) Presently undertaking 100 patient study comparing with Embletta Gold Limited Home Sleep Device (Kiely 2016 -completed December 2016)
b) Upcoming evaluations with other Home Limited Devices include e.g
   • ApneaLink - Resmed
   • Alice One Night - Philips
   • Nox - ResMed
Thank you for the opportunity to present our offering.

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