

Sensium Respiration Rate Algorithm

Robust and accurate software algorithm for clinical ambulatory applications

Overview

This document presents a description of the Sensium Respiration Rate (RR) software algorithm. Independent testing has shown that this embedded algorithm provides reliable and accurate RR monitoring at low computational cost and power consumption.

Respiration rate is an important vital sign in clinical practice, and an abnormal respiratory rate can be a strong indicator of serious underlying illness, including shock and sepsis. There is substantial evidence that alterations in respiratory rate can be used to predict potentially serious clinical events such as cardiac arrest or admission to the intensive care unit [1-4], and these studies have shown respiratory rate to be better than other vital measurements such as blood pressure and pulse rate in discriminating between stable patients and patients at risk [2].

Sensium measures respiration rate using the technique of impedance pneumography (IP), which involves the direct measurement of thoracic impedance changes associated with respiration [5]. Impedance pneumography transmits a very small alternating current (~10 μ A at 32kHz) between standard ECG electrodes connected to the Sensium Patch, as shown in Figure 1. This current passes mostly through the skin surface and measures the small

impedance change across the chest as the lungs expand and contract during breathing.

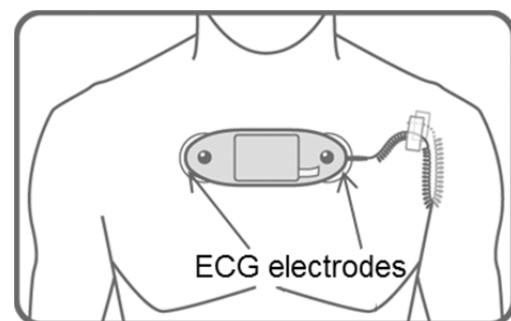


Figure 1: The Sensium Patch

Calculation of RR via impedance pneumography is relatively straightforward if the patient is at rest and breathing smoothly. However patient motion (such as a change in position) can also cause a change in thoracic impedance, resulting in corruption of the measured respiration signal by this motion artifact as shown in Figure 2. Additionally the respiration signal may itself become very irregular – for example when the patient is talking, eating or drinking, coughing, or sneezing, illustrated in Figure 3. During such periods of irregular/erratic breathing, the respiration rate measured will not have real clinical value.

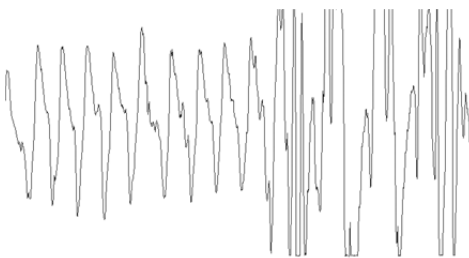


Figure 2: Respiration signal corrupted by motion artifact

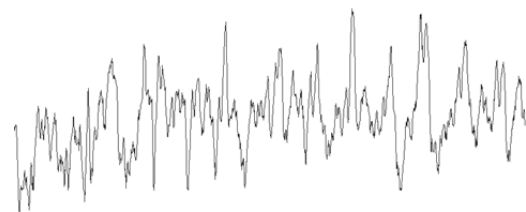


Figure 3: Irregular respiration signal while talking on a mobile phone

The RR algorithm developed by SENSIMUM is able to detect when segments of the respiration waveform are corrupted by motion artifact, and these segments are excluded from the RR calculation. The algorithm also excludes respiration waveforms which are very irregular or erratic; this ensures that false RR values (resulting from motion, talking etc.) are not reported. The rejection of false RR values is an important feature of the Sensium system, since it minimizes the instance of false alerts that can lead to 'alarm fatigue' in a busy ward environment [6].

The operation of the Sensium Patch is shown in Figure 4. Following measurement of Temperature (T) and Heart Rate (HR), the Respiration measurement circuitry is switched on and allowed to stabilize, and then a 60 second period of respiration is recorded and processed to calculate the average respiration rate, and the respiration circuitry is then switched off. The complete measurement cycle (for T, HR and RR) takes two minutes, after which the whole process repeats. Therefore every two minutes, new values of T, HR and RR are measured and transmitted by the Patch.

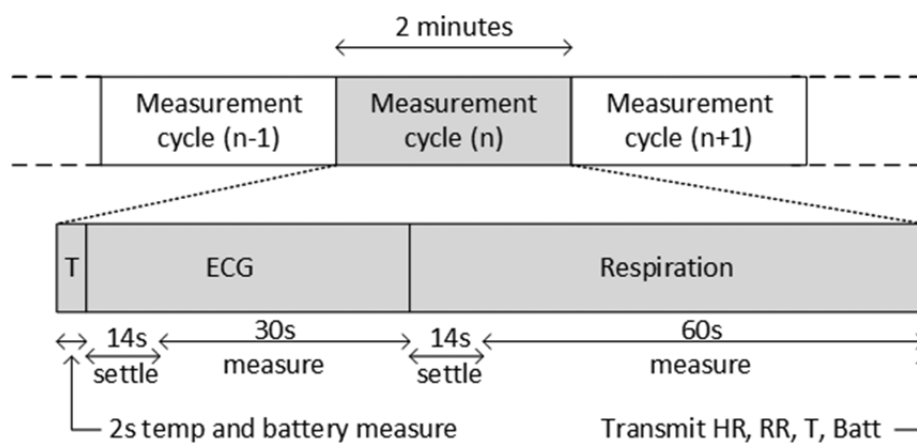


Figure 4: Sensium Patch vital signs measurement cycle

RR Algorithm

The RR software algorithm deployed in the Patch comprises two main stages as illustrated in Figure 5.

- A pre-processing (conditioning) stage that filters the raw respiration waveform to minimize noise due to heart activity and motion artifacts. The pre-processing stage also suppresses irregular signals while enhancing regular breathing signals using a mathematical technique known as autocorrelation.

A processing (detection) stage that applies a number of thresholds and a set of heuristic and physiological rules to detect and discriminate regular breathing signals from spurious/corrupted ones. Respiration rate calculations are performed only on valid breaths contained in periods of regular breathing.

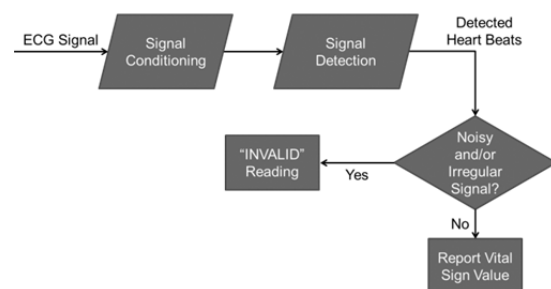


Figure 5: RR algorithm

For every new 60 second respiration cycle, the algorithm initializes its variables and registers, and then processes the incoming sample firstly to condition the signal and then to detect the breaths as described above.

Once the respiration cycle is completed, the algorithm either calculates the average RR, or it rejects the signal as invalid due to excessive contamination by noise.

The RR algorithm has been carefully optimized to maximize accuracy while minimizing power

Reliability

The performance of the RR algorithm was first assessed using artificial data recorded from a Rigel 333 patient simulator (Rigel Medical, Durham, UK) connected to the patch. The reason behind this choice was to verify the accuracy of the patch at two extreme values, 5 and 60 breaths per minute (brpm), often difficult to reproduce with healthy volunteers. The data comprised 28 signals, acquired at different combinations of body and breathing impedances (250 - 1000 Ω with dynamic breathing values of 0.5 and 1.0 Ω). Data analysis showed mean absolute bias \pm SD was equal to zero. This demonstrated that the device was accurate when calculating extreme RRs values (5 and 60 brpm) from clean simulator signals.

Results collected from healthy volunteers (21 subjects; age 32.1 ± 6.9 years old) during paced breathing exercises revealed that there were no statistical significant differences ($p > 0.05$) between Sensium and a clinical reference monitor (Philips IntelliVue MP30, using capnography). In this experiment, the mean bias was 0.15 ± 1.17 brpm, with a 95% CI of [-0.08, 0.38] brpm. Figure 6 shows the Bland-Altman plot for this case, with LoAs between -2.20 and 2.50 brpm. Sensium also successfully rejected 18 respiratory traces that were severely corrupted by motion artefacts.

Clinical data was also collected during a study performed at St Mary's Hospital, London (part of the Imperial College Healthcare NHS Trust) in 2010 (NRES reference: 09-H0712-63) [7]. Research ethical approval was obtained and the Medicines and Healthcare Products Regulatory Agency (MHRA) issued a certificate of non-objection. All patients gave written informed consent. The clinical study involved two groups of post-operative and acutely ill patients respectively. The respiratory data were recorded simultaneously using our Patches and a reference monitor (Philips IntelliVue, via Capnography). The two methods for measurement of RR are fundamentally different

consumption, through the use of very efficient calculation techniques. Without such efficient optimization, the Patch would not be able to maintain a 6-day battery lifetime.

experimental errors. For example, capnography may give a more accurate reading than IP during periods of gross patient movement, but the IP technique may provide a truer reading than capnography during periods when the patient breathes through the mouth. Thus, the major aim of the study was not to assess the accuracy of IP, which is typically validated using patient simulators or patients lying still, but to evaluate how well the two different methods compare, and to assess the ability of the processing algorithms to reject invalid data and minimise false alarms under realistic hospital conditions.

The first group comprised patients undergoing elective surgery (20 patient, age range 33-65 years). The mean difference in RR between the Patch and the bedside monitor was 0.4 Brpm, with limits of agreement of ± 6.7 bpm; correlation coefficient was 0.67 ($p < 0.0001$).

Patients from the second group (41 patients, age range 18-85 years old) were acutely ill and presented various comorbidities (i.e. arrhythmias, morbid obesity, diabetes mellitus, pulmonary conditions, and abnormally QRS morphologies), which posed interesting challenges to the system. The data from this group was found not to be normally distributed; therefore the Wilcoxon's test was applied showing statistically significance differences ($p < 0.05$). However, the mean bias was very small (0.18 Brpm) with 95% CI of [-0.05, 0.42] Brpm. The Limits of Agreement (LoA = ± 1.96 sd) were -8.1 and 8.5 Brpm with 6.25% of data outside these limits as illustrated in Figure 6.

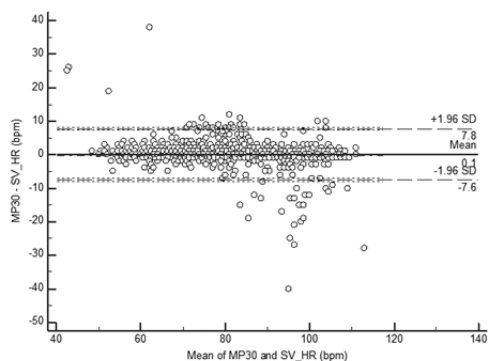


Figure 6: BA plot of RRs for patients with different comorbidities. LoAs (red dashed lines), 95% CIs (blue dashed lines).

Table 1 shows the amount of data rejected by the Sensium system as invalid. RR data were rejected around 50% of the time, partly due to the nature of the IP technique which is very sensitive to motion artifacts, but also due to the fact that the respiratory signal is irregular during periods of talking, coughing, eating and drinking and a clinically valid RR cannot be reported at

these times. Nonetheless, valid data were typically reported for 50% of the time, providing a useful information update rate for the caregiver.

Group	Respiration rate availability (%)
1 Operative	64
Low voltage QRS	56
2 High body mass index	54
Diabetes mellitus	45

Table 1: Proportions of data available from the Sensium patch; these data largely reflect the patch algorithm rejecting data that did not pass the internal quality assurance step

Conclusions

This document presents a description of the Sensium RR software. Preliminary assessments revealed that this embedded algorithm provides highly reliable and accurate respiration monitoring at low computational cost and power consumption.

References

1. Fieselmann JF, Hendryx MS, Helms CM, et al. Respiratory rate predicts cardiopulmonary arrest for internal medicine patients. *J Gen Intern Med*, 1993;8:354-360
2. Subbe CP, Davies RG, Williams E, et al. Effect of introducing the Modified Early Warning score on clinical outcomes, cardiopulmonary arrests and intensive care utilisation in acute medical admissions. *Anaesthesia* 2003;58:797-802
3. Goldhill DR, McNarry AF, Manersloot G, et al. A physiologically-based early warning score for ward patients: the association between score and outcome. *Anaesthesia* 2005;60:547-553
4. Cretikos M, Chen J, Hillman K, et al. The Objective Medical Emergency Team Activation Criteria: a case-control study. *Resuscitation* 2007;73:62-72
5. Freundlich JJ, Erickson JC. Electrical impedance pneumography for simple non-restrictive continuous monitoring of respiratory rate, rhythm and tidal volume for surgical patients. *Chest*, 1974; **65**: 181-4.
6. Cvach M. and Graham K.C. *Monitor Alarm Fatigue: Standardizing Use of Physiological Monitors and Decreasing Nuisance Alarms*, American Journal of Critical Care, 19(1): 28-34, 2010.
7. Brett S.J. et al, Assessment of the feasibility of an ultra-low power, wireless, digital patch for the continuous ambulatory monitoring of vital signs, *BMJ-Open* (details TBC)

For further information please contact:

Building 3, 115 Milton Park, Abingdon, OX14 4SA, UK
Tel: +44 1235 438 950 **Email:** info@sensium.co.uk

SH-FCS-MKT-069 Iss. 01 Mar 2018