

Sensium Heart Rate Algorithm

Robust and accurate software algorithm for clinical ambulatory applications

Overview

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

Heart rate is one of the most important vital signs in clinical practice, and an unexpected high or low heart rate in a resting patient may be an early indication of physical deterioration. Sensium measures heart rate by analyzing a single-lead electrocardiogram (ECG) which is detected through standard ECG electrodes connected to the Sensium Patch, as shown in Figure 1. As can be seen in Figure 1, the Sensium electrodes are closer together than in a conventional Lead-I position, where the electrodes are normally placed on the shoulders or wrists. We refer to this as position as 'modified Lead-I', and it can sometimes give the ECG waveform a slightly different shape to that of a conventional Lead-I as shown in Figure 2.

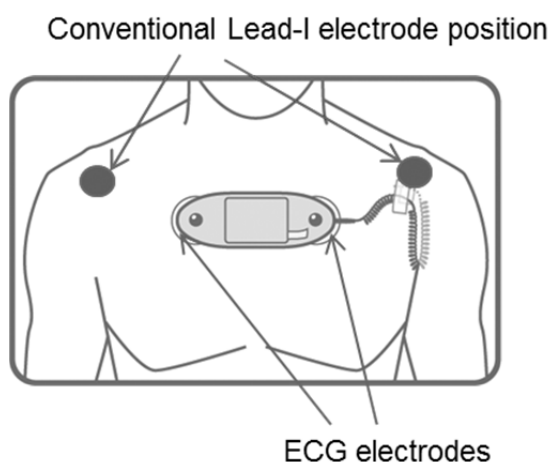


Figure 1: The Sensium Patch

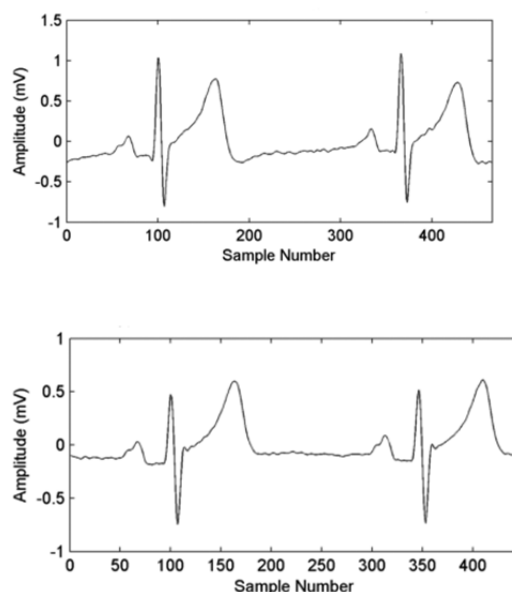


Figure 2: Lead I (top) and Modified Lead I ECG (bottom) signals.
Note the modified Lead I R-wave is smaller, so the ST segment appears elevated

Calculation of HR from a single-lead ECG is simple and straightforward as long as the ECG signal used for this purpose is of good quality. In practice the ECG signal may become occasionally corrupted, particularly for ambulatory patients whose movements may generate motion artifacts as illustrated in Figure 3 [1].

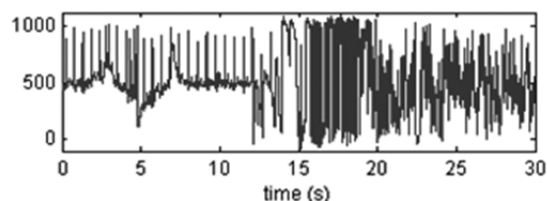


Fig 3: ECG signal corrupted by motion artifact

Motion artifacts arise mainly from a change in the electrical properties at the skin-electrode interface (for example due to relative movement between the skin and the electrode); careful attention to skin preparation prior to electrode application, and the use of good quality electrodes, can go a long way to minimizing the effects of motion artifact.

The HR algorithm developed by SENSIMUM is able to detect when segments of the ECG waveform are corrupted, and these segments are excluded from the HR calculation. This ensures that false HR values due to noise (such as motion artifact) are not reported. The rejection of false HR values is a very 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 [2].

The operation of the Sensium Patch is shown in Figure 4. The ECG measurement circuitry is switched on and allowed to stabilize, and then a 30 second period of ECG is recorded and processed to calculate the average heart rate. The ECG circuitry is then switched off and the Patch proceeds to measure respiration rate (RR) and then temperature (T). The complete measurement cycle (for HR, RR and T) takes two minutes, after which the whole process repeats. Therefore every two minutes, new values of HR, RR and T are measured and transmitted by the Patch.

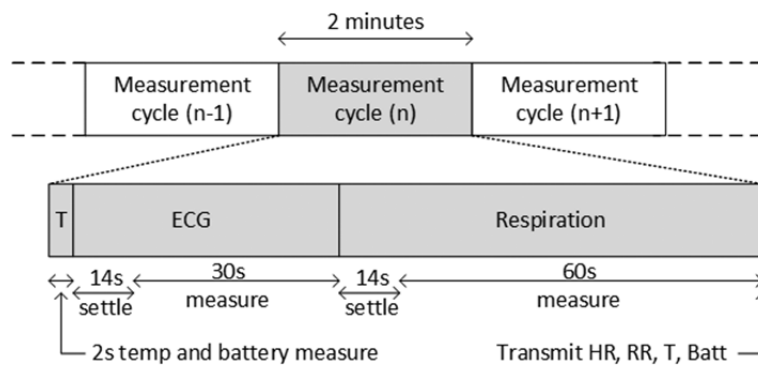


Figure 4: Patch vital signs measurement cycle

HR Algorithm

The HR software algorithm deployed in the Patch is based on the approach proposed by Hamilton and Tompkins [3]. The reason behind this choice is the very high accuracy and reliability of this method as reported by different studies [4, 5]. The algorithm has been adapted to take into account the 'non-conventional' ECG waveform shape resulting from the modified Lead-I position, and comprises two main stages as illustrated in Figure 5.

A pre-processing (conditioning) stage that filters the raw ECG to minimize noise due to muscle activity, mains, baseline wandering and motion artifacts; and then enhances the energy of the heartbeats.

A processing (detection) stage that applies a number of thresholds and a set of heuristic and physiological rules to detect and discriminate actual heartbeats and ECG signals from spurious/corrupted ones. Heart rate calculations

are performed only on valid heartbeats contained in valid ECG signals.

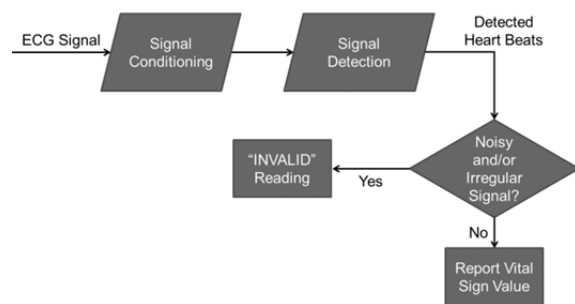


Figure 5: HR algorithm

For every new 30 second ECG cycle, the algorithm initializes its variables and registers, and then processes the incoming sample to determine whether it corresponds to a heartbeat or to a spurious peak resulting from noise. If the sample corresponds to a heartbeat, then the

instantaneous HR is computed and stored. If the peak does not comply with the time and amplitude requirements to be valid it is counted as spurious. This operation continues until the full ECG signal is processed. Once the ECG cycle is completed, the algorithm either calculates the average HR using the instantaneous values stored in memory, or it rejects the signal as invalid due to excessive contamination by noise.

The HR algorithm has been carefully optimized to maximize accuracy while minimizing power consumption, through the use of very efficient calculation techniques. Without such efficient optimization, the Patch would not be able to maintain a 5-day battery lifetime.

Reliability

This algorithm was first evaluated using artificial signals from calibrated patient simulators. Firstly a Rigel 333 patient simulator (Rigel Medical, Durham, UK) was used to generate synthetic ECGs comprising a reasonable representation of different sinus rhythms (bradycardia, tachycardia, and normal rhythms) with HR values within the range of 30 to 210 bpm. Secondly a more advanced simulator (Simman[®], Laerdal Medical Ltd, UK) was used to challenge the system with irregular rhythms and conditions affecting the morphology of the signal (i.e. atrial flutter (AFL), ventricular tachycardia (VT), abnormal

(elevated/depressed) ST segments (AST), and atrial fibrillation (AF), with rates between 75 and 240 bpm. Analysis of artificial sinus rhythms showed that the SensiumVitals[®] system was accurate with absolute mean difference equal to zero for rates between 30 and 200 bpm. The results obtained from the evaluation of 65 observations involving aperiodic rhythm and abnormal morphologies are listed in Table 1. We found the differences for all the rhythms to be within ± 1 bpm, except for atrial fibrillation, where larger differences were observed due to the very irregular rate presented by this arrhythmia.

Simulated heart condition	HR range under test (bpm)	N	Abs_diff \pm SD (bpm)	Max_diff (bpm)
AFL	75-150	12	0.58 \pm 0.51	1
AF	90-160	14	4.36 \pm 1.74	6
AST	60-145	25	0.80 \pm 0.41	1
VT	180-240	14	0.43 \pm 0.51	1

Table 1: Assessment using a simulated irregular rhythm and abnormal morphologies

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) [6]. 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. All the ECG data were recorded simultaneously using our Patches and a reference monitor (Philips IntelliVue).

The first group comprised patients undergoing elective surgery (20 patient, age range 33-65 years). The mean difference in HR between the Patch and the bedside monitor was -0.5 bpm, with limits of agreement of ± 3.47 bpm; correlation coefficient was 0.99 ($p < 0.0001$) over 834 data points.

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 (0.13 bpm) with 95% CI of [-0.11, 0.37] bpm. The Limits of Agreement (LoA = ± 1.96 sd) were -7.6 and 7.8 bpm, with only 4.3% lying outside these limits as illustrated in Figure 6.

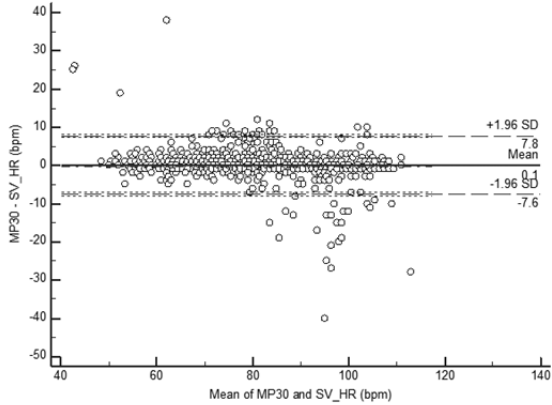


Figure 6: BA plot of HRs for patients with different comorbidities

Table 2 shows the amount of data rejected by the Sensium system due to signal corruption by motion and other artifacts. In all cases the amount of available data are high apart

Conclusions

This document presents a description of the Sensium HR V1 software. Preliminary assessments revealed that this embedded algorithm provides reliable and accurate HR monitoring at low computational cost and power consumption.

References

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2. 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.
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6. 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)

from the case of atrial fibrillation, where a large percentage of the data were rejected. Since this arrhythmia is characterized by aperiodic R-R intervals and irregular ECG morphology (e.g. the absence of P waves), such irregular waveforms are rejected by the algorithms to avoid false alarms due to motion artefact or the transmission of data with low certainty of accuracy.

Group		Heart rate availability (%)
1	Operative	98.6
	Low voltage QRS	92
	Atrial fibrillation	45
2	High body mass index	80
	Diabetes mellitus	77

Table 2: 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