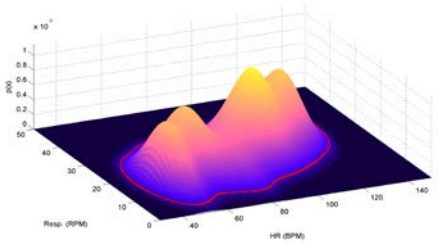
Visensia – The Safety Index

Proof of concept

John Radcliffe Hospital, Oxford, UK (2001-2003)

3,500 hours of continuous vital sign monitoring data collected from "high-risk" patient groups to create the "Training data set":

- Patients monitored for at least 24hrs after a myocardial infarct and again 5 days later
- Patients with severe heart failure
- Patients with acute respiratory problems
- Elderly patients with hip fractures (monitored before and after operation)



From these data a computer model of normality for the vital signs for these high risk patients was developed called Visensia.

- Using the Visensia model of normality, we can determine the probability that any new set of vital signs were "normal" for a high risk patient
- A Visensia Alert is generated when the probability of a patients vital signs are outside of "normal" and the Visensia Safety Index VSI ≤ 3

Publication:

British Journal of Anaesthesia. 97 (1): 64-68 (2006). L. Tarassenko et al

Integrated monitoring and analysis for early warning of patient deterioration.

John Radcliffe Hospital, Oxford, UK (2003-2005)

Visensia used to detemine periods of "abnormal" physiological vital sign and compliance to mandated monitoring

- 5,645 hours of continuos vital sign monitoring data collected
- 402 randomised controlled trial of mandated five channel physiological monitoring vs standard care
- High risk patients admitted as medical or surgical emergencies or undergoing major elective surgery

Publication:

Anaesthesia. 61: 1031-1039 (2006). P.J Watkinson et al

A randomised controlled trial of the effect of continuous electronic physiological monitoring on the adverse event rate in high risk medical and surgical patients

Results:

- 95% of the episodes of severe physiological abnormalities identified by Visensia in 168 monitored patients were deemed, after review by two senior clinicians, to have been valid alerts
- Compared to Single-channel monitoring which is subject to high false alarm rates (86%) in some studies[1]
- Data fusion is capable of detecting critical events in advance of single channel alerts

Validation:

Phase 1: University of Pittsburgh Medical Center, Pittsburgh, USA (Nov 2006 – Jan 2007)

The largest continuous collection of cardiorespiratory variables in a non-ICU patient population to date, provided the clinical evidence for the FDA clearance of Visensia.

- 323 Patient blinded trial in 24-bed Step-Down Unit (SDU)
- 18,248 hours of continuous vital sign monitoring data
- Data were analysed for cardiorespiratory instability using Visensia Alerts and local MET activation criteria

Publication:

Arch Intern Med. Vol 168 (no.12) 1300-1308 (2008). M. Hravnak et al

Defining the incidence of cardiorespiratory instability in patients in step-down units using an electronic integrated monitoring system.

Results:

- All Medical Emergency Team (MET) events of respiratory and/or cardiac were detected in advance
- The mean advanced detection time prior to MET activation was 6.3 hours
- Only 1.6 false alerts per 100 hours of monitoring

FDA certification for patient monitoring using the Visensia Index approved

Phase 3: University of Pittsburgh Medical Center, Pittsburgh, USA (Apr 2007 to Aug 2007)

- 308 Patient trial in 24-bed Step-Down Unit (SDU)
- 18,314 hours of continuous vital sign monitoring data
- Visensia Index displayed and audible alert activated
- Clinical action to respond to VSI trend and alert implemented

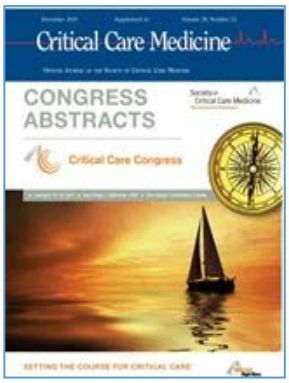
Publication:

Critical Care Med. Vol 39 (no.1) 65-72 (2011). M. Hravnak et al

Cardiorespiratory instability before and after implementing an integrated monitoring system

Results:

- 58% reduction in the number of times critical care unit patients became unstable
- 60% reduction in the duration critical care unit patients were critically unstable
- No unexpected deaths in the 8 weeks using Visensia Index, compared to 6 unexpected deaths for the same unit in the 8 weeks prior to use of Visensia Index



After phase 3, no patient on the Visensia monitor had an unexpected fatal cardiac event[2]

References:

1. *Tsien CL, Fackler JC. Poor prognosis for existing monitors in the intensive care unit. Crit Care Med. 1997; 25(4): 614-619*
2. *Pinsky 2006, Regenerative Medicine. "No patient on the Visensia monitor has had an unexpected fatal cardiac event". http://www.regenerativemedicine.net/testdisplay.asp?qEmpID=715*