Visensia® – The Safety Index

First-ever FDA-cleared algorithm for use on the WAVE patient surveillance and predictive algorithm platform

VISENSIA
The Safety Index

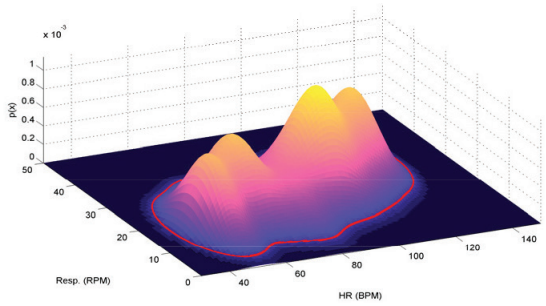
OBS Medical
Data for Life

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 24-hours 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.

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Proof of Concept

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

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

- 5,645-hours of continuous vital sign monitoring data collected
- 402 randomized 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. From these data a computer model of normality for the vital signs for these high risk patients was developed called Visensia.

Publication:

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

A randomized 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

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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 analyzed 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

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Validation:

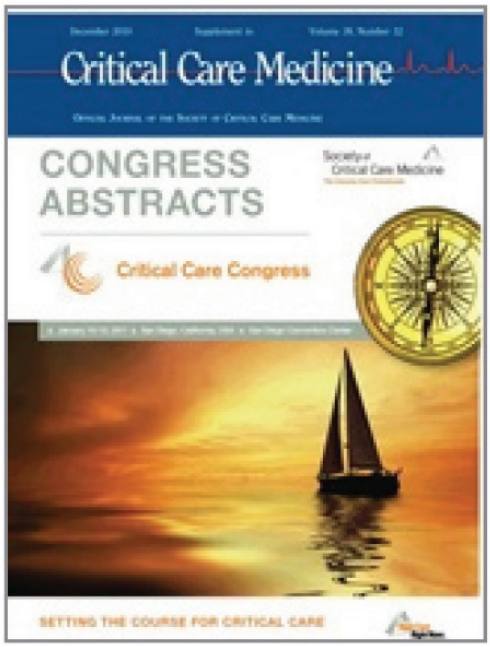
Phase 2-3: University of Pittsburgh Medical Center, Pittsburgh, USA (Apr 2007 to Aug 2007)

- 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 all

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): 614Ð619*
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