CHT Centre for Healthcare Technologies

HeartLight:
An Engineering and Clinical partnership for improving newborn resuscitation

Professor John Crowe – Faculty of Engineering

Dr Don Sharkey – School of Medicine

Dr James Carpenter – HeartLight Systems Ltd

The University of Nottingham

UNITED KINGDOM · CHINA · MALAYSIA

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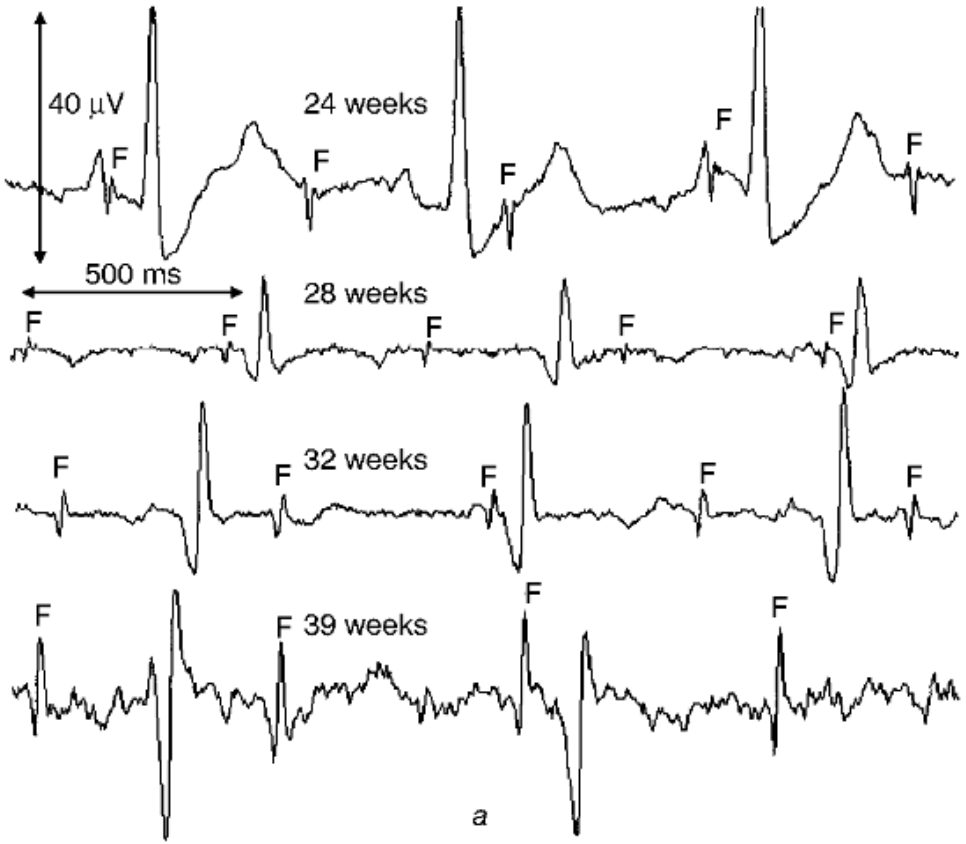
Nottingham University Hospitals NHS

NHS Trust

Antenatal fetal heart rate monitoring



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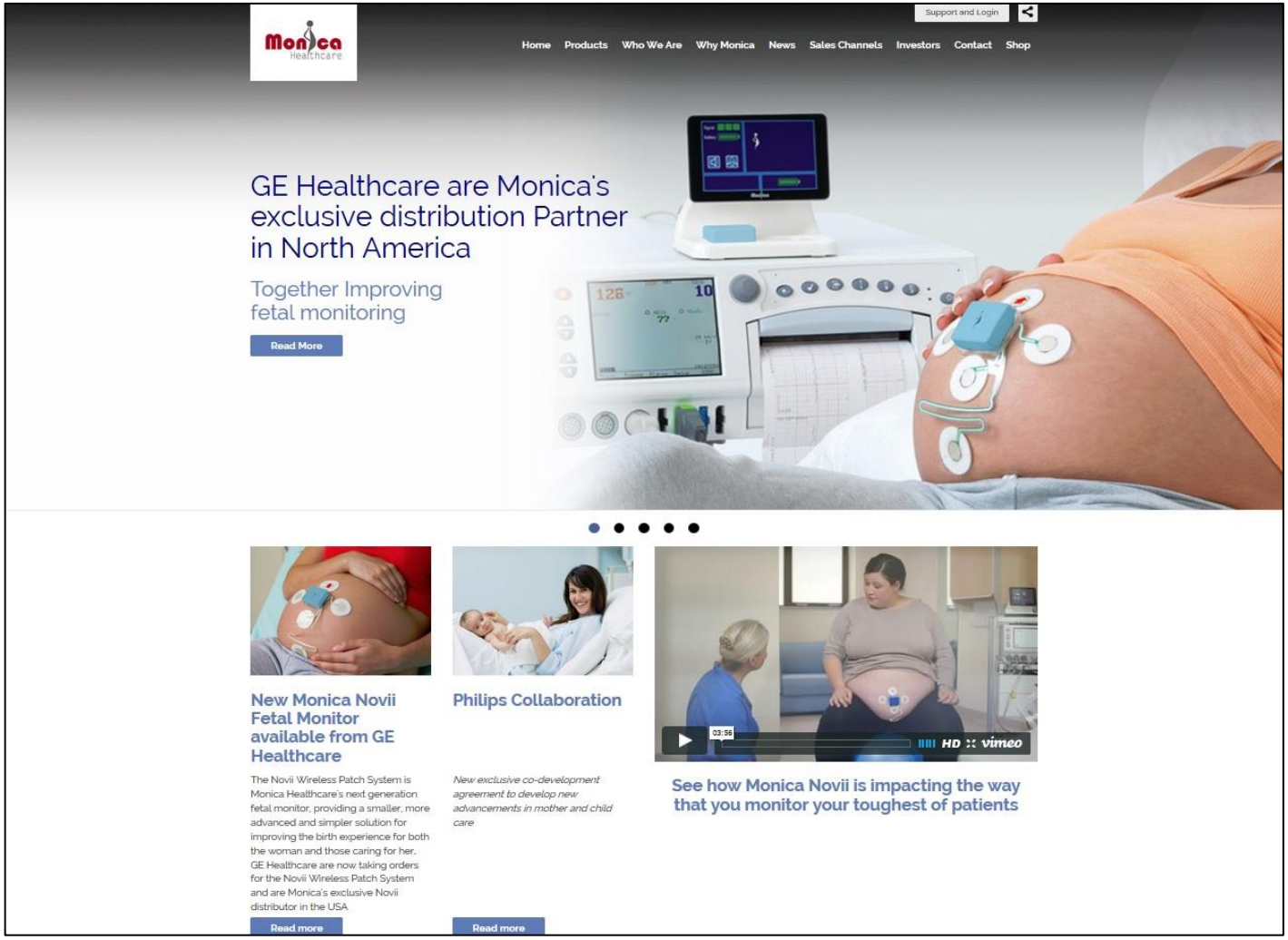


"Detection of previously unrecognized daytime desaturation in children with chronic lung disease"

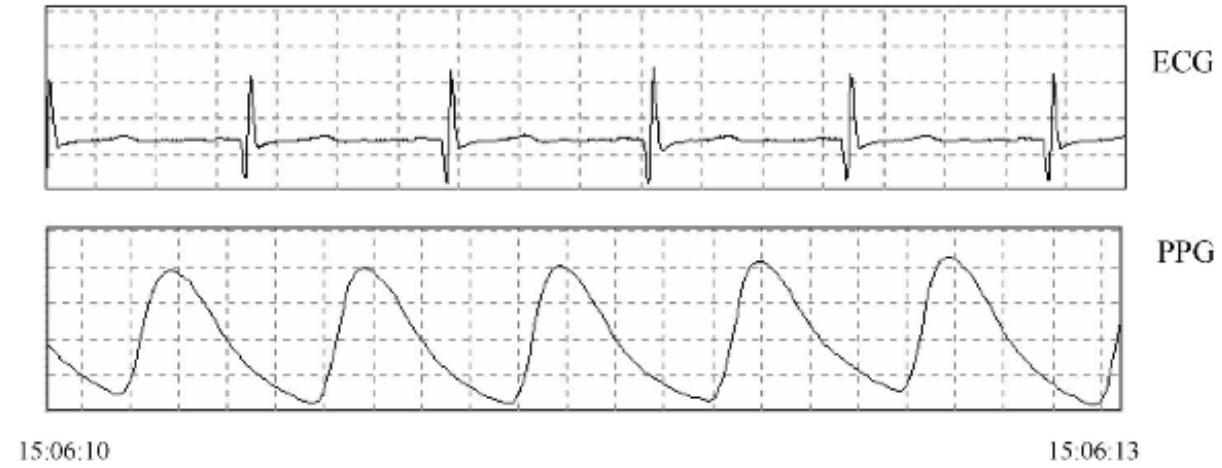
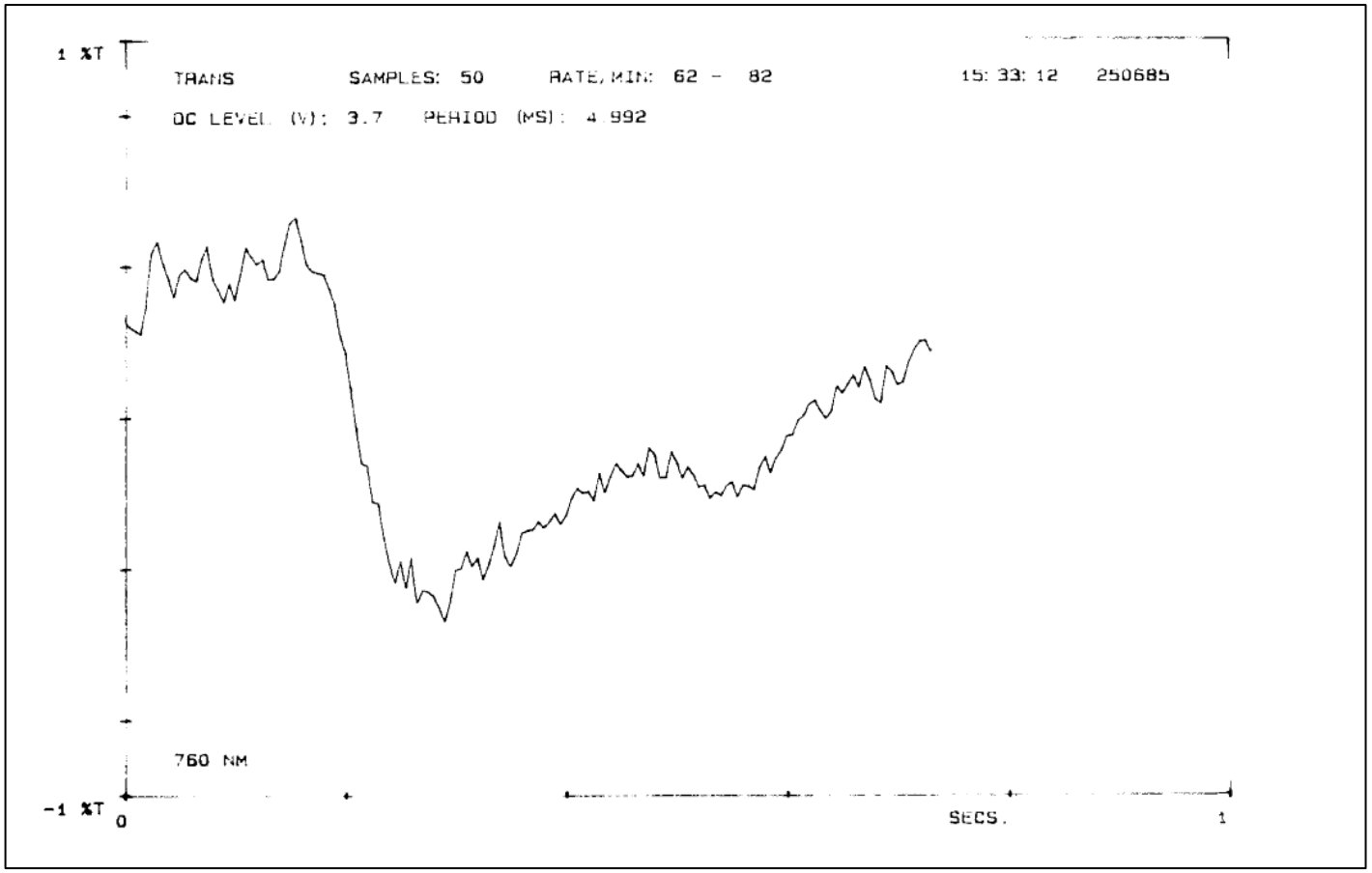


Figure 5. A three-second sample of the photoplethysmographic waveform and concurrent electrocardiogram during a period of desaturation with no evidence of motion artefact. SpO_2 = 91%; Pulse = 108 bpm; Ecg HR = 111 bpm; Temp = 24.1; Perfusion = High; TX error = valid.


1 %T
TRANS
SAMPLES: 50
RATE/MIN: 62 - 82
15: 33: 12
250685
DC LEVEL (V): 3.7
PERIOD (MS): 4.992
760 NM
-1 %T
0
SECS.
1

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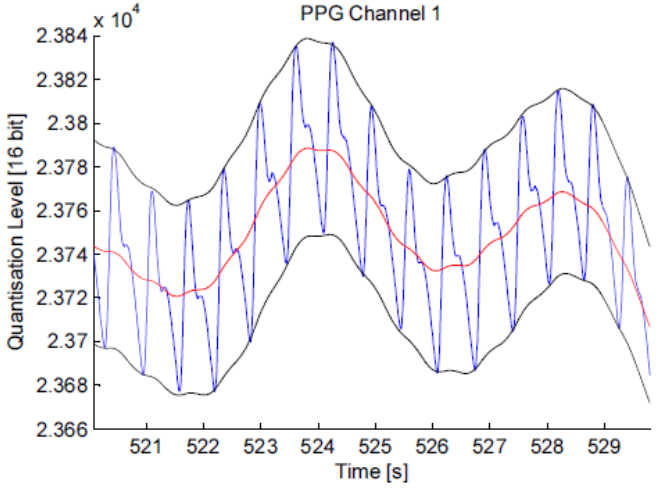

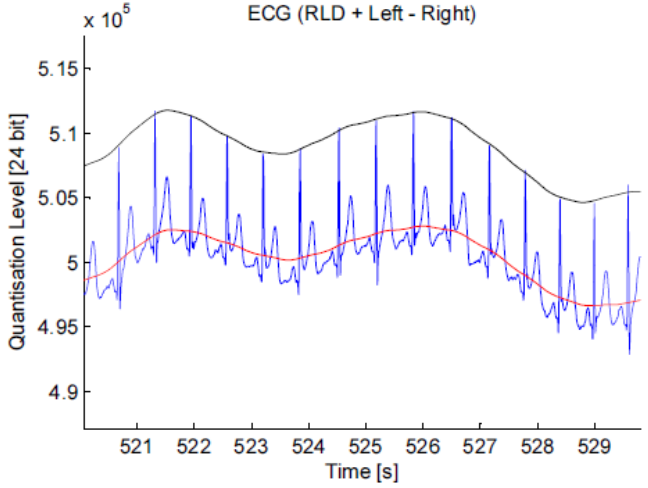

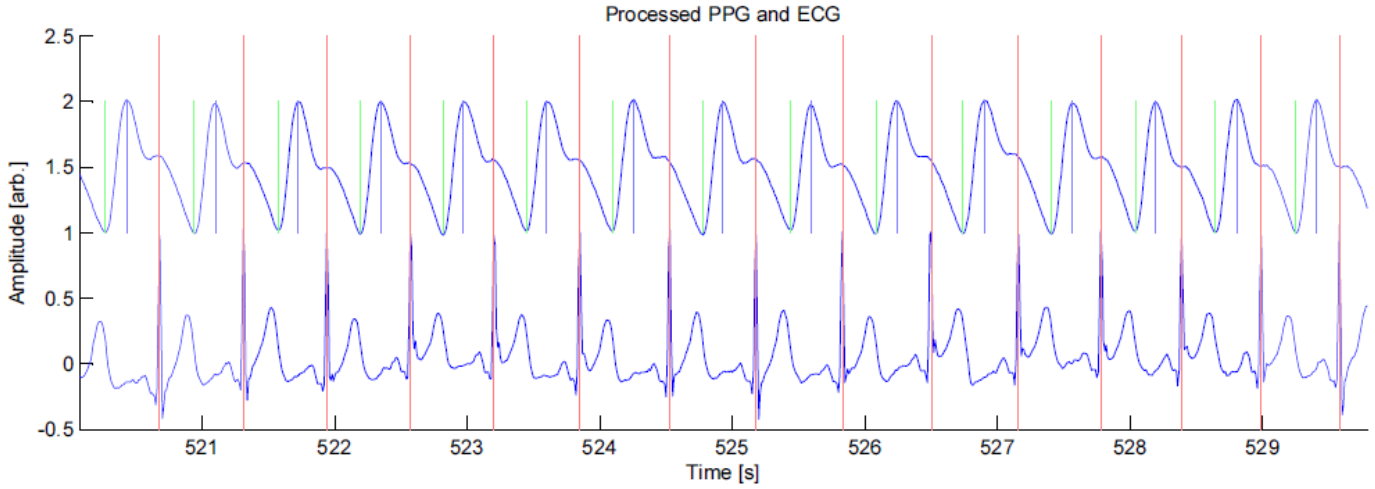

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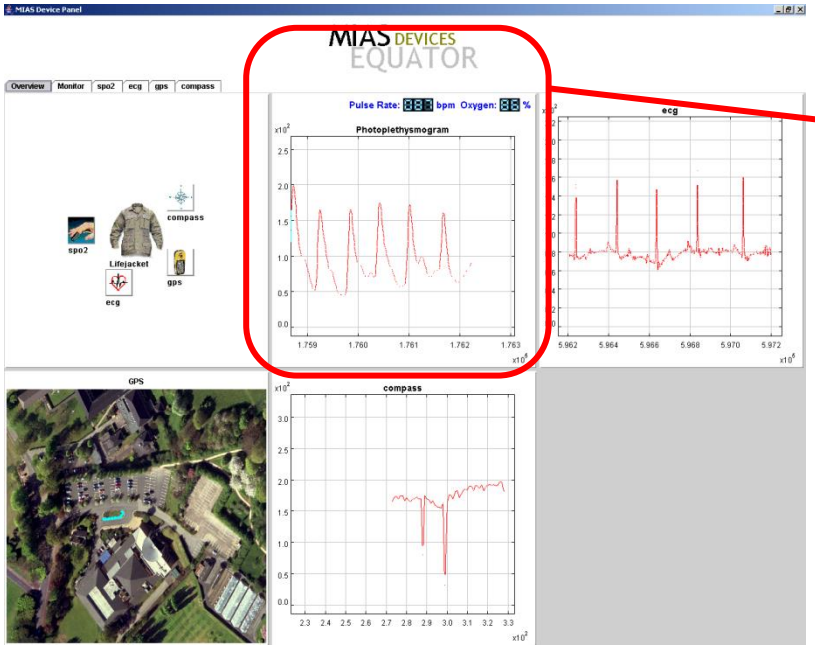
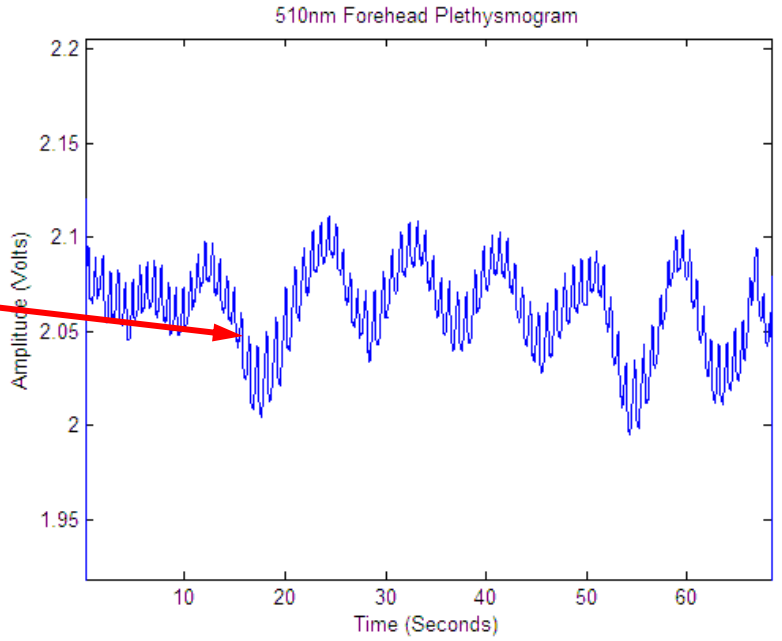
"Modular sensor architecture for unobtrusive routine clinical diagnosis"

PPG ECG





compass

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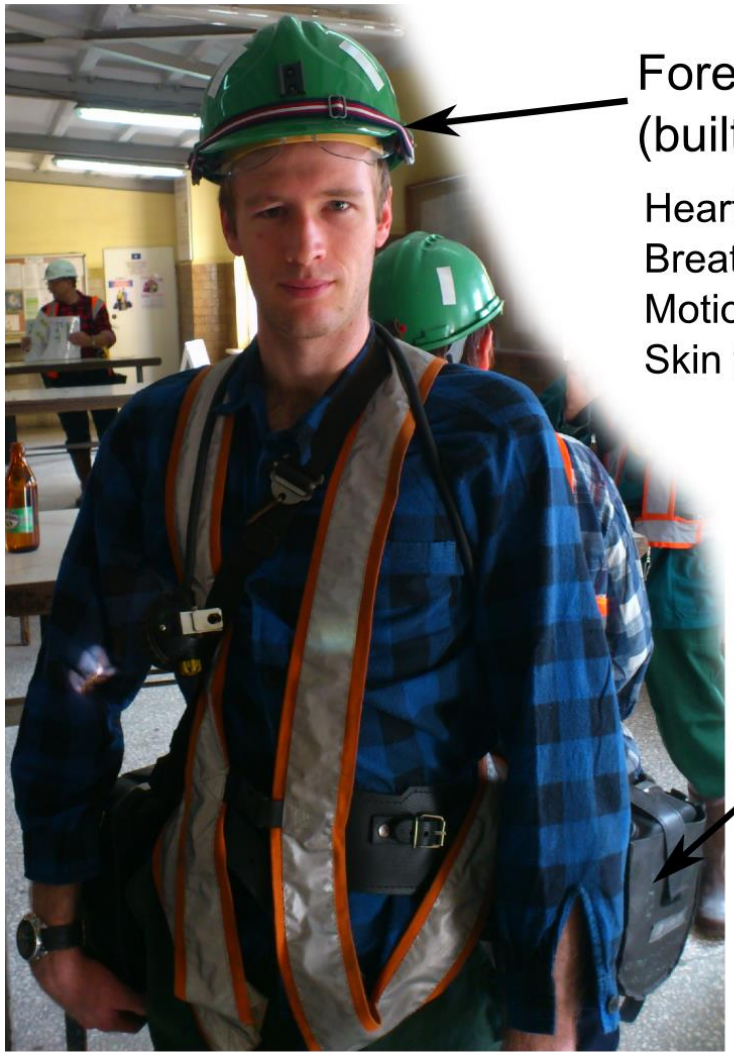

Forehead sensor
(built into hard hat)

Heart rate
Breathing rate
Motion and fall alert
Skin temperature

Main board
(within battery pack)

Location
Ambient temperature and humidity
Emergency button and warning light
Data storage
Wireless communication

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The Clinical Need

- 10% Newborns require resuscitation
  - Annual birth rate
  - UK 800,000 = 80,000
  - Global 135 million = 13.5 million
  - 140,000/year VLBW <1500g preterm births (USA & Europe)

- Heart rate best indicator of success
  - Stethoscope currently used
  - Count for 10-15 seconds
  - Delays resuscitation
  - Calculation subject to errors (20-30%)
  - Non-continuous
- Other methods of assessment
  - Pulse oximetry – unreliable
  - ECG – technical and application issues

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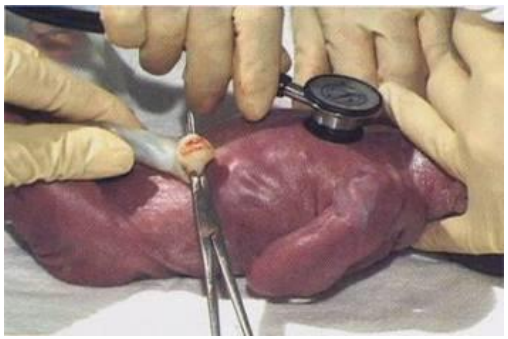
The "Golden Minutes"

- Babies resuscitated increased risk:
  - Death
  - Disability - deafness/blindness/cerebral palsy
  - Low IQ even if well after resuscitation (Lancet 2009)
- The longer the resuscitation the greater the risk



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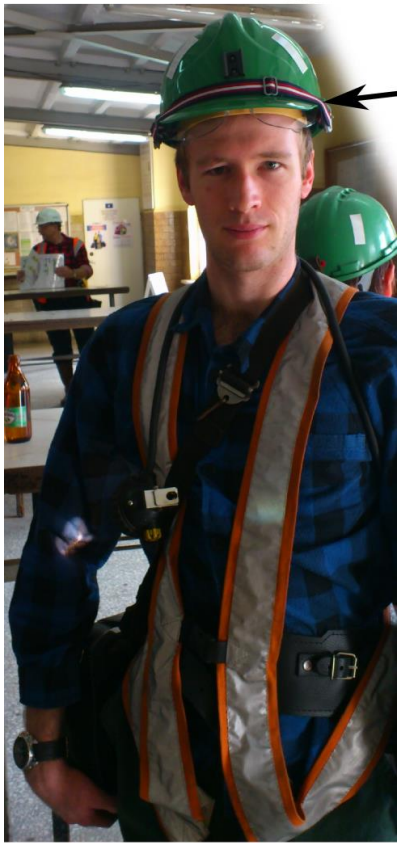
- Internal seminar - Engineering and Child Health



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1st
- Action Medical Research
- ~120 babies recruited

2nd
- Clinical Research Network
- Extension ~20 babies

3rd
- MRC DPFS portfolio
- Further development and ~70 babies

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HeartLight

When reliability matters

Dr James Carpenter, CEO

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HeartLight = The University of Nottingham UNITED KINGDOM · CHINA · MALAYSIA + tioga electronic assembly

- Joint Venture
  - University of Nottingham
  - Tioga Limited
- Intellectual property + commercial expertise

Commercialising HeartLight technology:

"better heart rate monitoring when it's needed most"

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The Opportunity for HeartLight

- 70-80,000 babies/yr (UK) need resuscitation, >13.5M/yr world wide
- Delivery rooms currently low tech compared to other resuscitative or intensive care environments
- Clinicians want better heart rate technology after birth
- HeartLight fits naturally into the existing care pathway
- Improving outcomes in the golden minutes after birth will save healthcare costs associated with ongoing short and long term care

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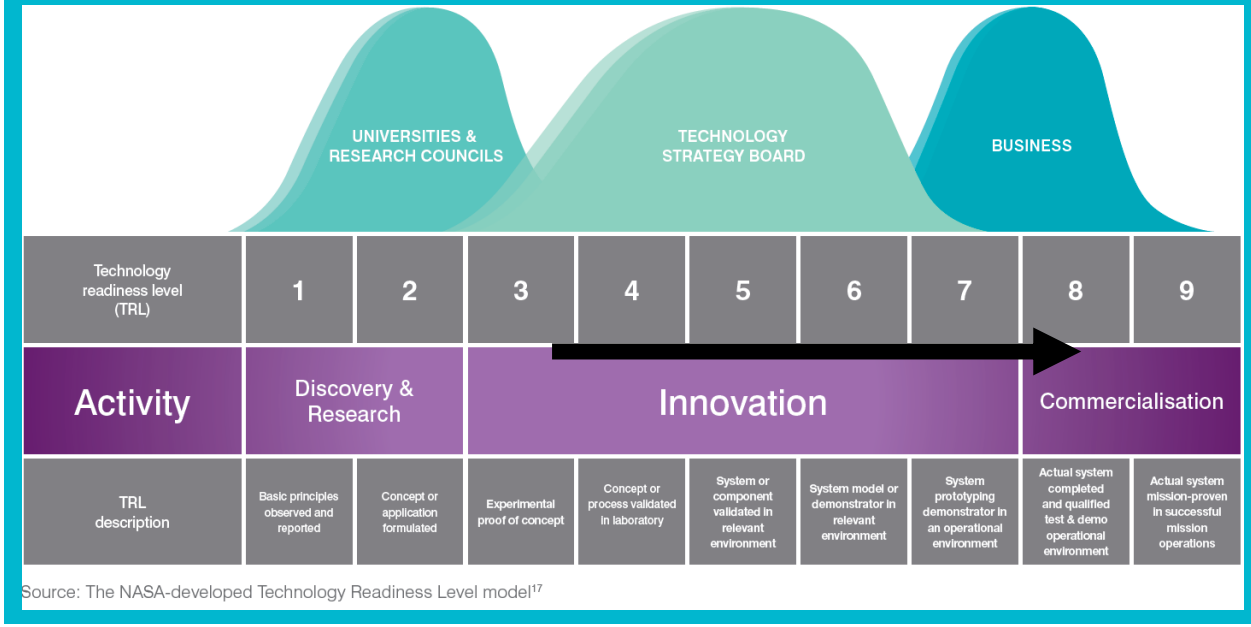
Commercialisation

- £250k investment
  - JV partners & Angel investors
- £243k grant
  - part of £1.7M Innovate UK Biomedical Catalyst



Source: The NASA-developed Technology Readiness Level model[17]

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£1.7M Biomedical Catalyst

- Heart Rate Monitor for Newborn Resuscitation
- Patient Trials on >100 babies
- Regulatory submissions (CE/FDA)

The University of Nottingham
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maddison Product Design

Innovate UK
Technology Strategy Board

tioga electronic assembly

CHEATA

NHS

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Clinical

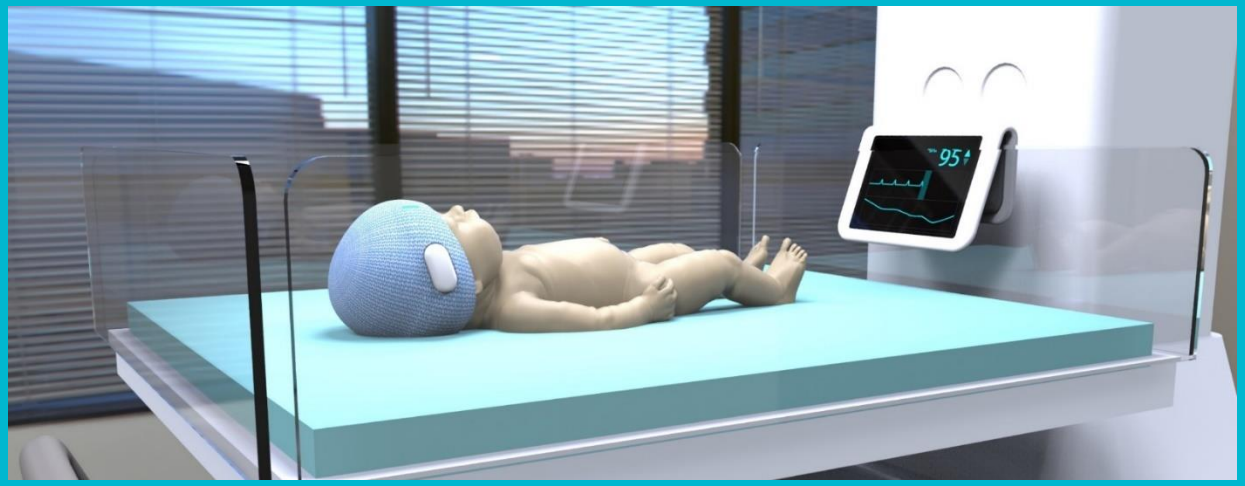
- Does it work?
- Does it improve outcomes?

Regulatory

- Electrical safety
- Usability
- Software
- Biocompatibility
- Risk based approach

Commercial

- Cost
- Manufacturability
- Market Viability



Intellectual Property

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Status

- Prototype design produced
- NICU trials imminent
- Working towards
  - Delivery Room trials
  - Further fund raising
  - European & USA regulatory approvals
  - Convince someone to buy it!

HeartLight
When reliability matters

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HeartLight Systems is a joint venture between the University of Nottingham and Tioga Ltd, an electronics manufacturer based in Derby

HeartLight technology has received over £2.5M of research funding since 2004

HeartLight Systems was set up in 2014 to commercialise the technology, initially for newborn babies requiring resuscitation at birth

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Novel, automated, non-invasive perfusion device to identify sick children

EPSRC Engineering and Physical Sciences Research Council

Nottingham Hospitals Charity At the heart of your care

MRC Medical Research Council

Developing next generation neonatal transport system to improve outcomes

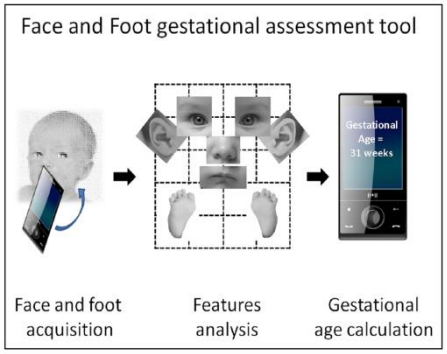
Nottingham Hospitals Charity At the heart of your care

MRC Medical Research Council

NHS National Institute for Health Research

ParAid Medical

Software algorithm to estimate newborn gestational age using an App



BILL & MELINDA GATES foundation

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Thank you

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