Analysis of the Alar PPG: Does the data improve patient care?

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January 17,2014

Disclosure

I have a proprietary interest (conflict of interest) related to the information I am presenting. I am an inventor of the technology and I am an employee of the company, Xhale, Inc., which licensed it from the University of Florida Research Foundation.

Agenda

- Background
- What is unique about "central/alar" oximetry/PPG?
- Can it reliably detect additional parameters of importance for general care floor patients (earlier and more reliable detection of instability/trends)?
- Other unique clinical applications

Background

- Serendipitous discovery when asked to design a sensor for burn patients due to inability to determine oxygen saturation with conventional digit sensors
- Initially designed sensors for lip, cheek, tongue and nasal septum
- Also evaluated superficial temporal and posterior auricular arteries
- Ultimately chose nasal ala based on clinical evaluation

Why the ala?

- Photoplethysmography (PPG) measures beat to beat blood volume changes using the signal from at least one LED and a photodiode (PD) such as used in pulse oximeter sensors.
- *"Central" PPG (cPPG) measures from sites above the thoracic inlet where intrathoracic pressure variations (e.g. respiration) are reflected in the signals.*
- Surrogate for cerebral blood flow?

Why the ala?

- Surrogate for venous capacitance?
- Ability to measure nasal air flow/pressure/capnometry = respiratory rate and respiratory “effort”
- Ability to administer oxygen (incorporated into nasal cannula)

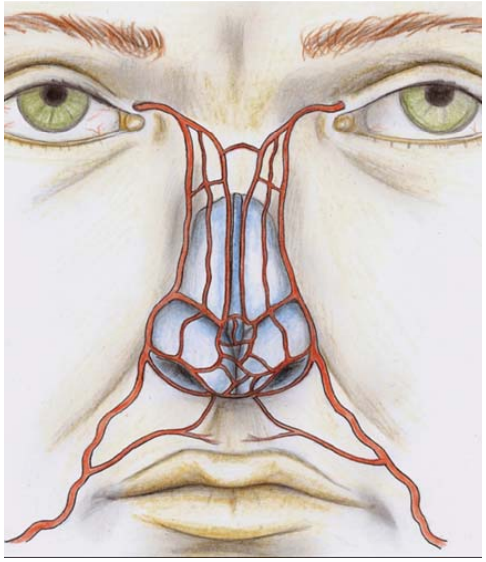
Critical Location on Nasal Ala (central vs. distal)

Nasal ala site is optimal signal source:

Last branch of external carotid artery

First branch of internal carotid artery

Signal quality & source superior to fingertip



From: Saban, et al. **Nasal Arterial Vasculature: Medical and Surgical Applications**

Arch Facial Plast Surg. 2012;14:429-436.

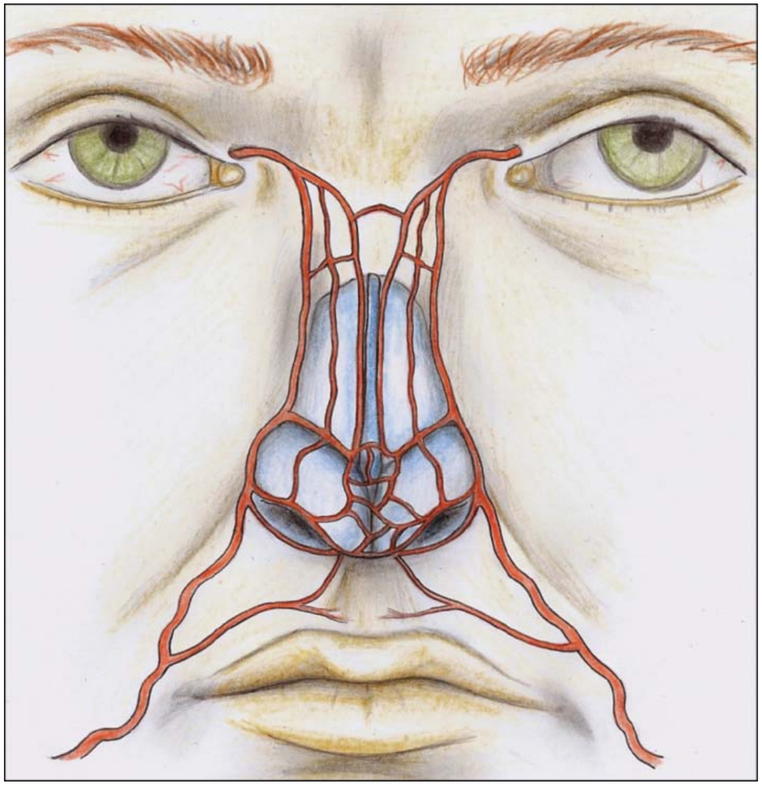
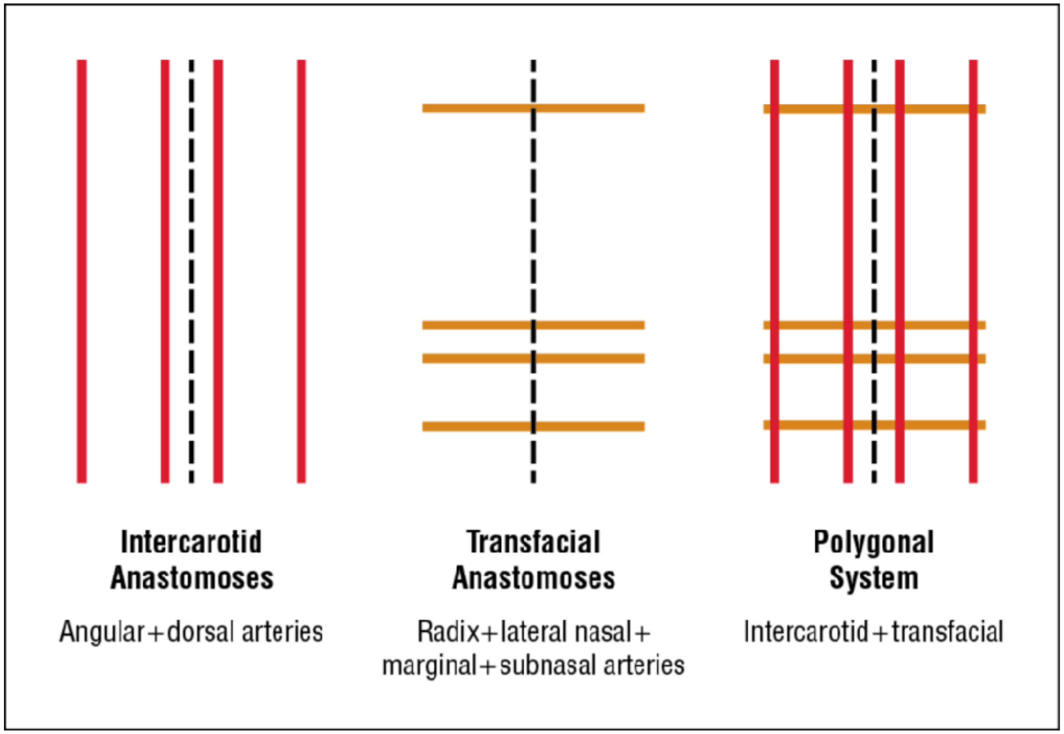


Figure Legend:

Figure 10. Concept of the nasal arterial vasculature, showing a complete anastomotic polygonal system. This is not present in all patients but demonstrates the basic data, from which anatomic and physiological variations can occur.

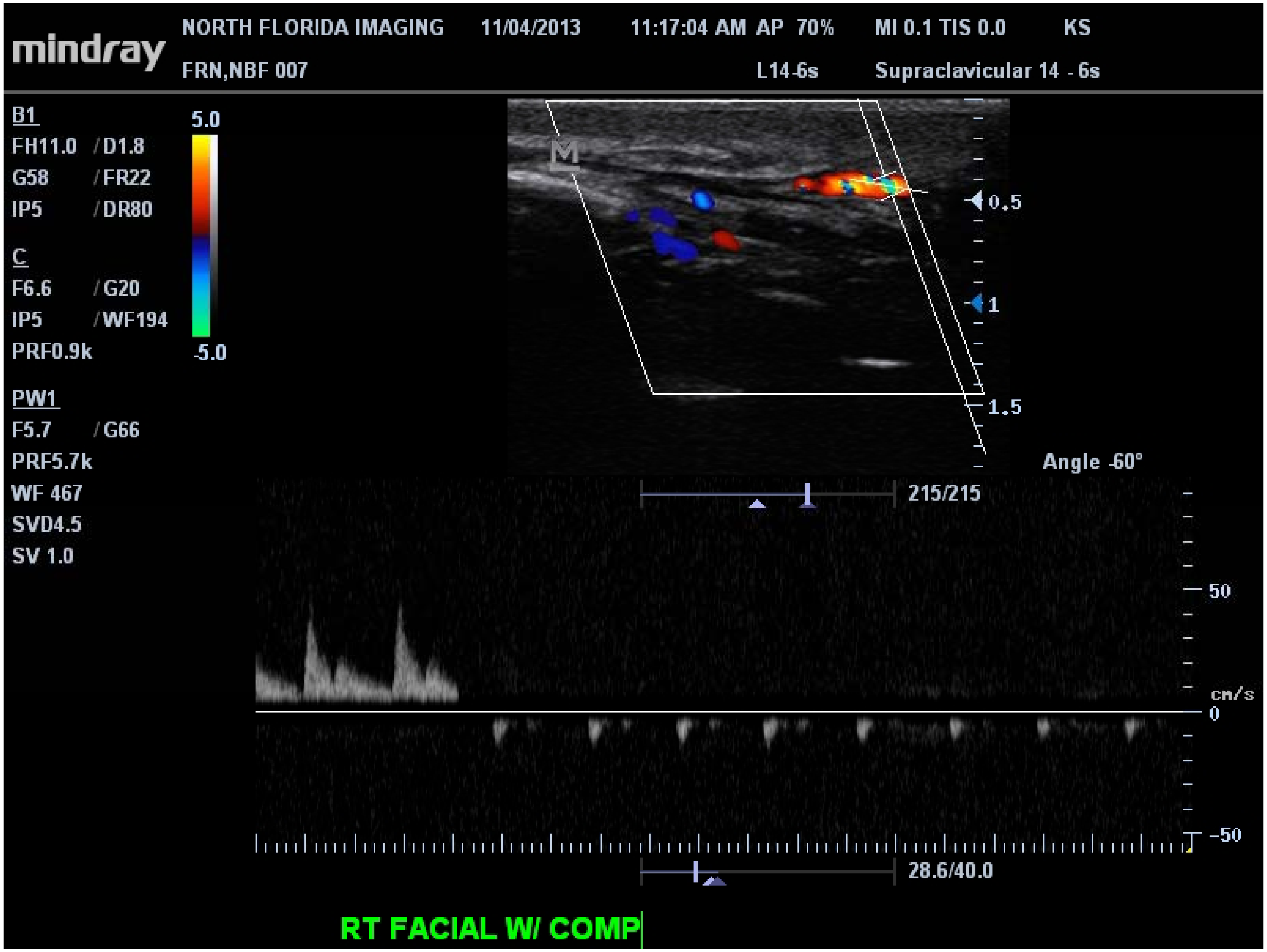
From: **Nasal Arterial Vasculature: Medical and Surgical Applications**
Arch Facial Plast Surg. 2012 Nov;14(6):429-36.



Complete nasal arterial vasculature, demonstrating the polygonal system. **A multidirectional system** of interconnected arteries forming a vascular network. In this system, **3 arcades** (marginal alar, **alar valve**, and radix) that connect both hemifaces and are considered transfacial arcades; whose blood flow can be provided by **the facial artery or by the ophthalmic artery depending on physiological or pathologic situations.**

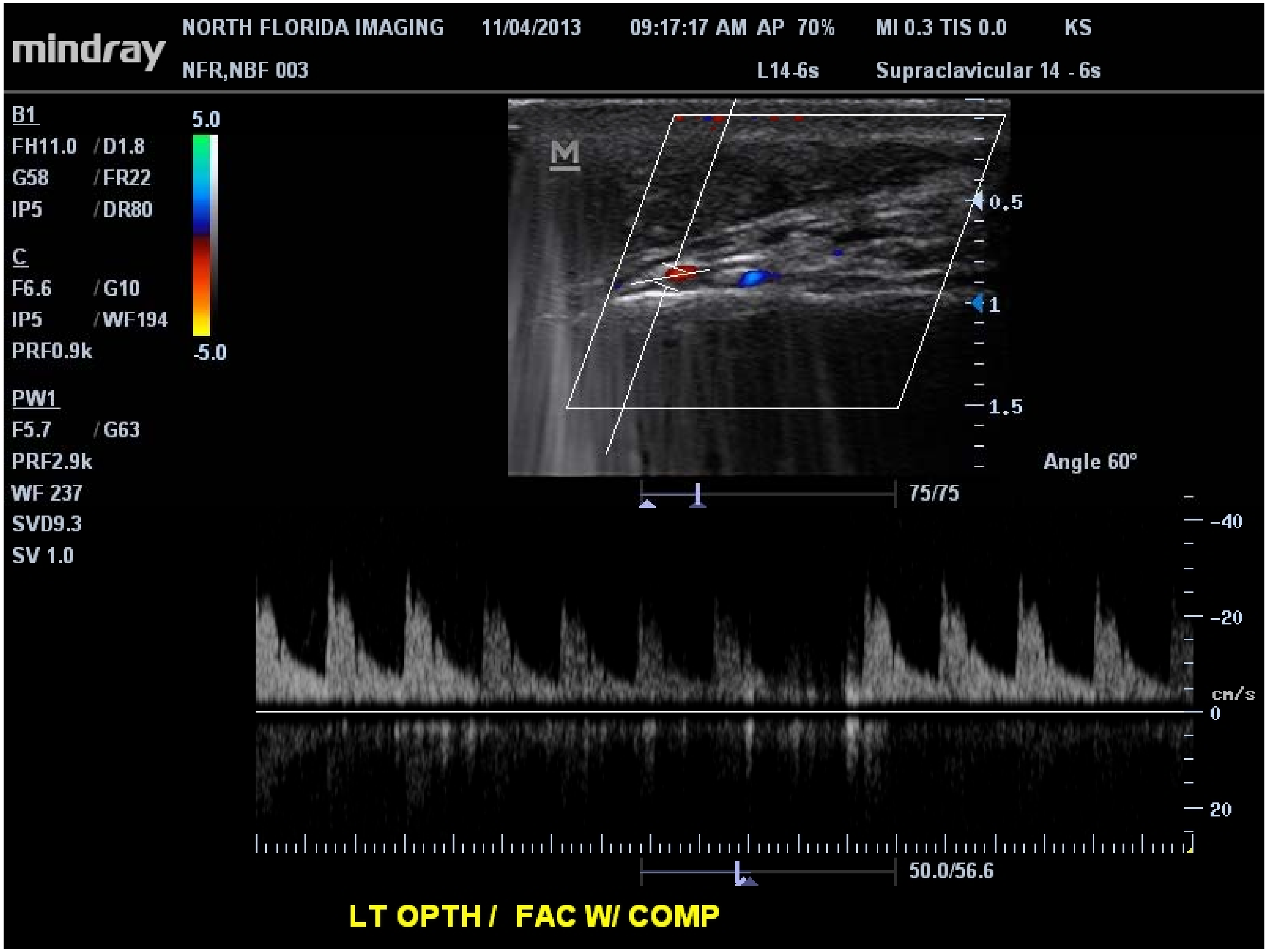
Nasal blood flow studies

Compression of facial artery with reversal of flow from the ophthalmic artery

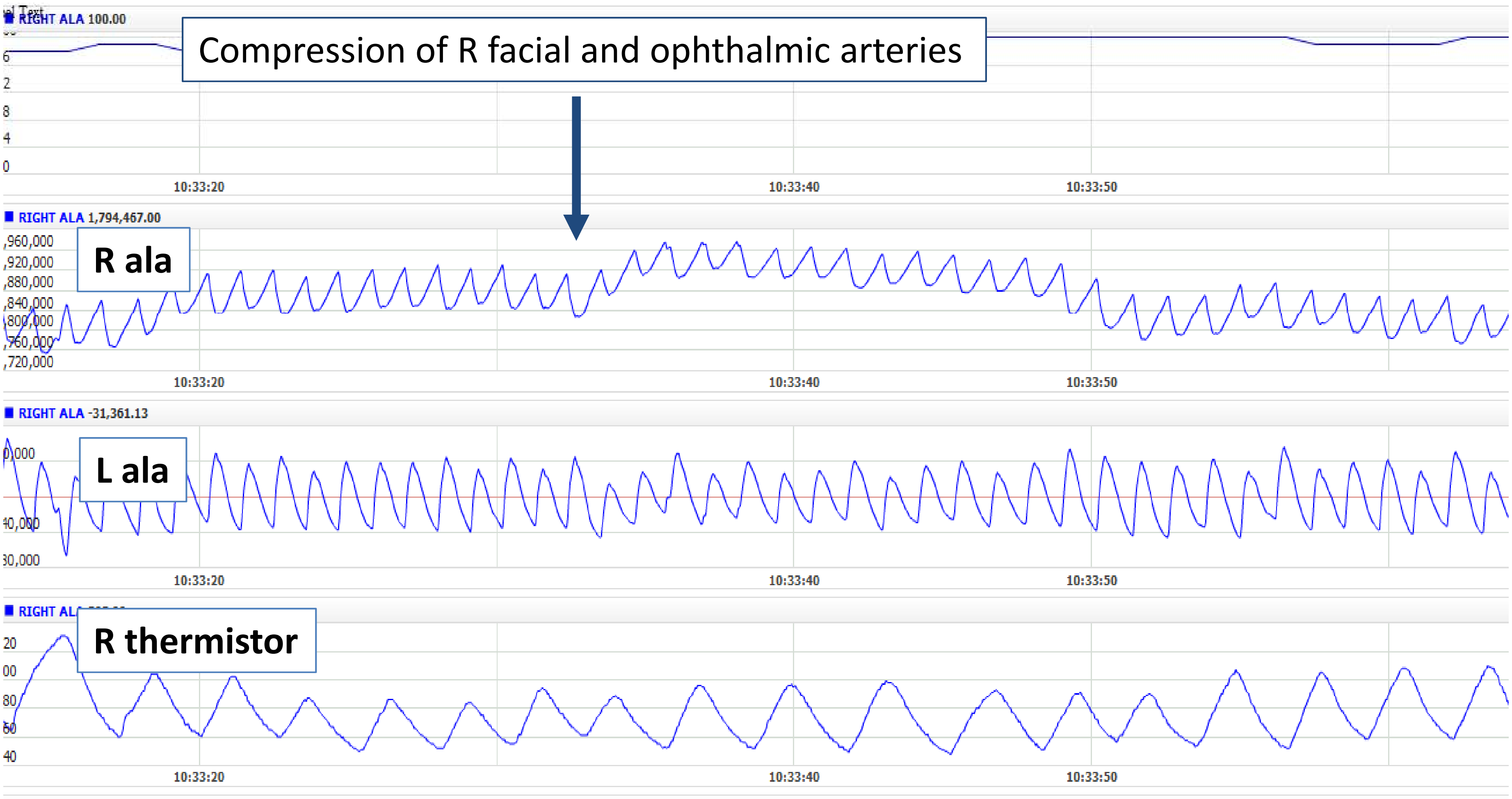


Nasal blood flow studies

Compression of facial and ophthalmic arteries – diminished flow



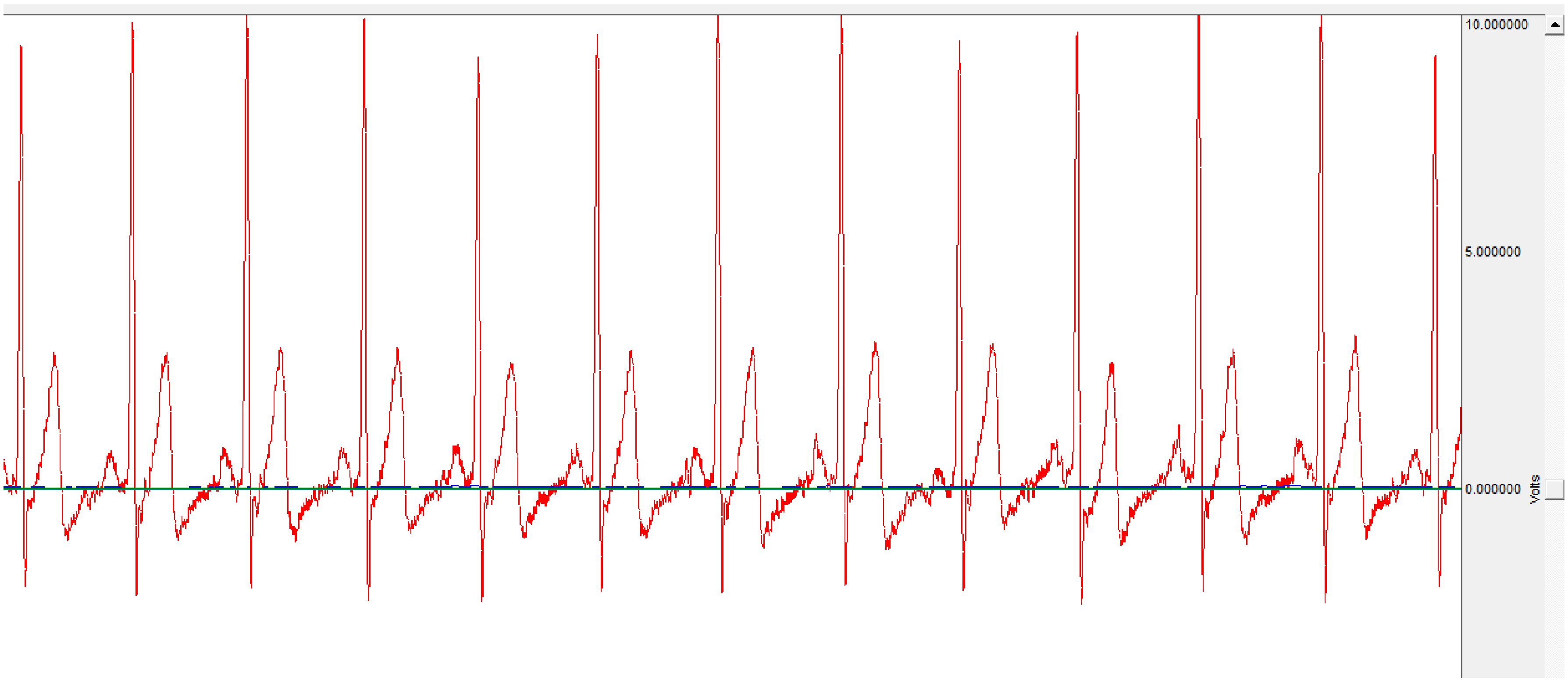
Nasal blood flow studies



Single Point of Contact (SPOC) Monitoring

- Pulse Oximetry
  - Heart rate
  - Oxygen saturation
- Photoplethysmography (PPG)
- Thermistor - airflow
- Transducer - NAP
- Accelerometer/Actigraphy (Gen. 2)
- ECG (Gen. 2)

“Alar ECG”



Processed PPG

- Derived cardiorespiratory parameters:
  - **Respiratory rate (RR) and breathing patterns**
  - **Respiratory effort**/intrathoracic pressure variation (airway obstruction/CVP)
  - Arterial blood flow (cerebral BF surrogate)
  - Venous capacitance
  - Heart rate and patterns (arrhythmias)
  - Volume status
  - Optimize PEEP during mechanical ventilation (oxygenation)
  - PTT, PWTT, HRV, etc.
  - Time dependent changes in parameters (trending analysis)

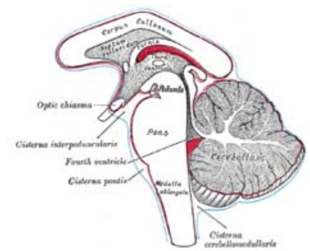
Monitoring Drug Effects on Cardiorespiratory Function in Real-time Using PPG

Xhale Assurance

Example: IV Fentanyl Infusion for Pain Relief

Drug Dose

Drug Blood Concentration



Biological Effect

Opioid Infusion to Treat Pain
- **Example: Fentanyl**

Benzodiazepines

Ethanol

CNS Drugs:
- **Antidepressants**
- **Antipyschotics**

PK (ADME)

$C_{Fentanyl}$

$C_{Non\text{-}Opioids}$

Medulla

PD

PD **Gain** to Opioids

Integrated Cardiorespiratory Effects

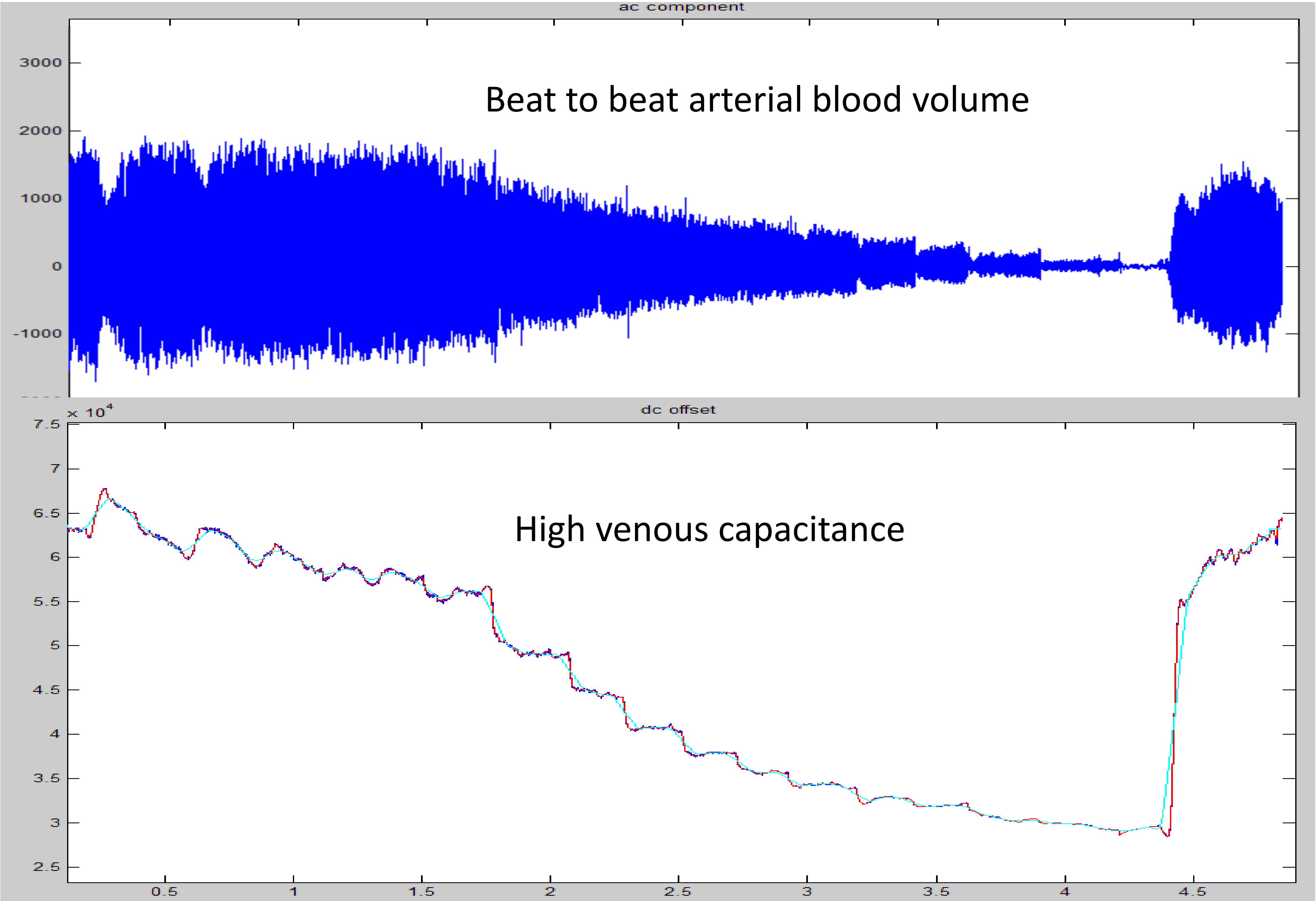
Diseases (non-drug)
- CNS
- non-CNS
- OSA

Multiparameter Alar Sensor
(Analysis of PPG)

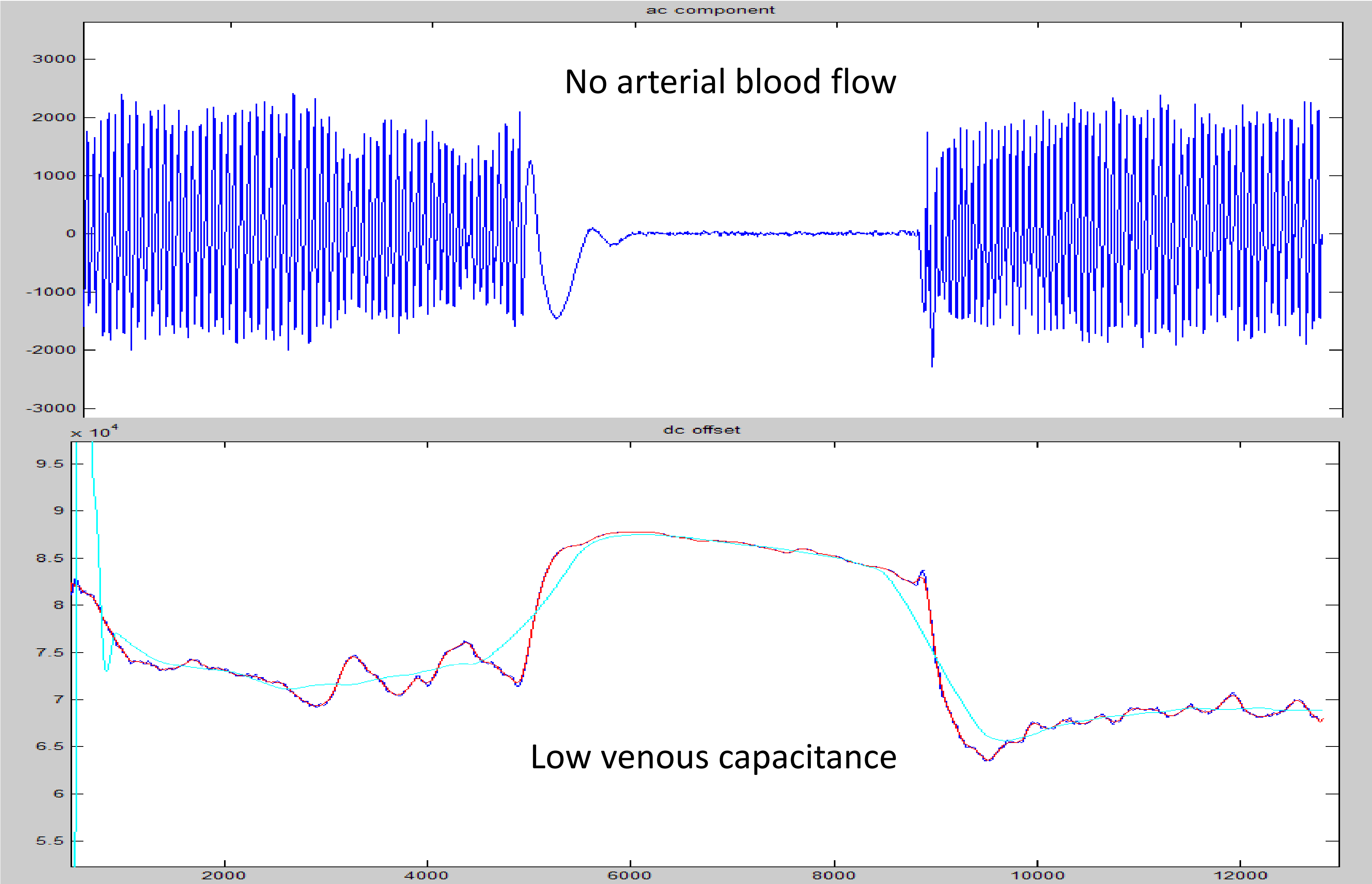
Feedback Control of Opioid Dosing

Physiology

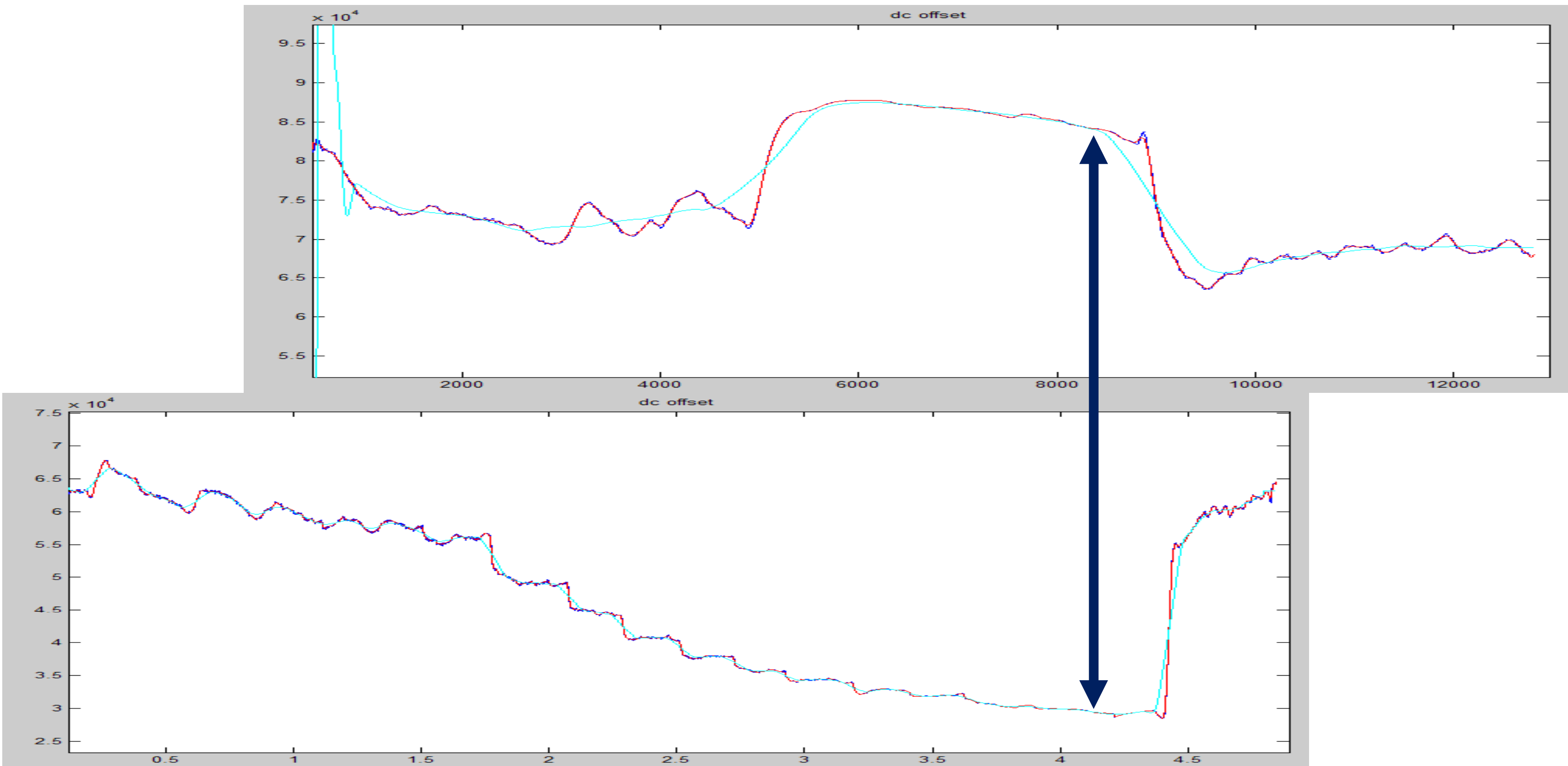
BP cuff application - PPG



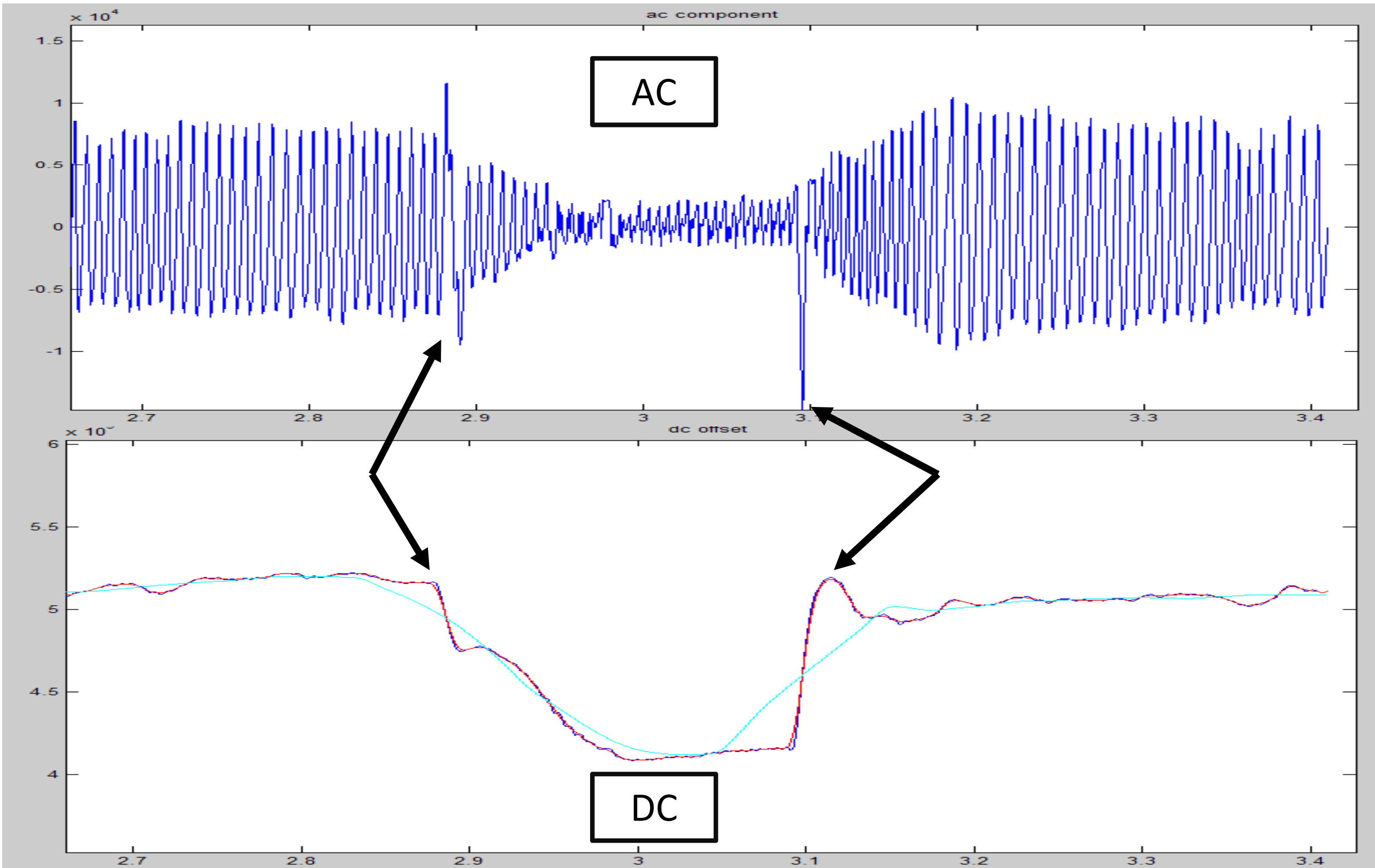
Press on brachial artery



Arrow – venous capacitance in finger!

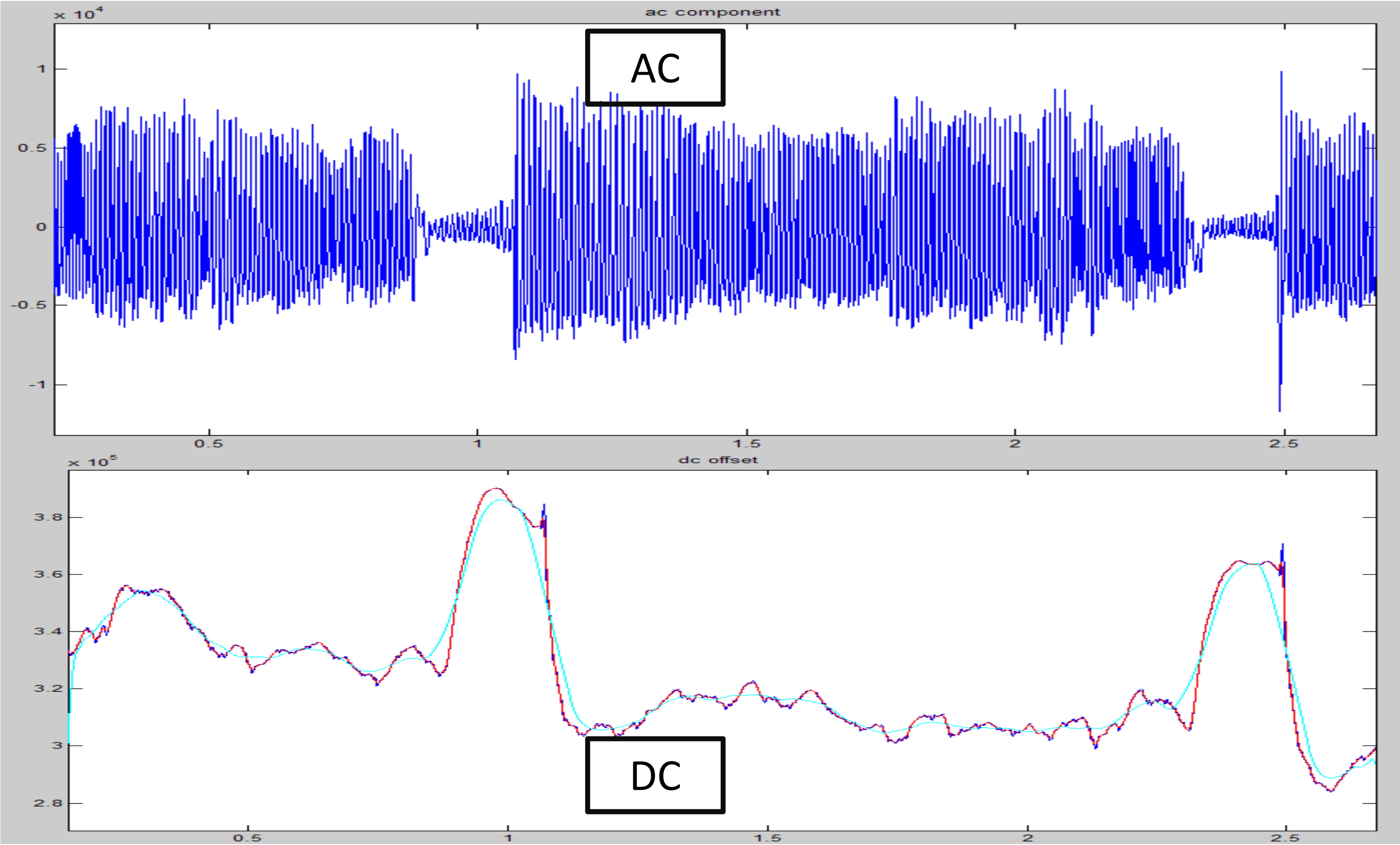


Valsalva maneuver – nasal septum

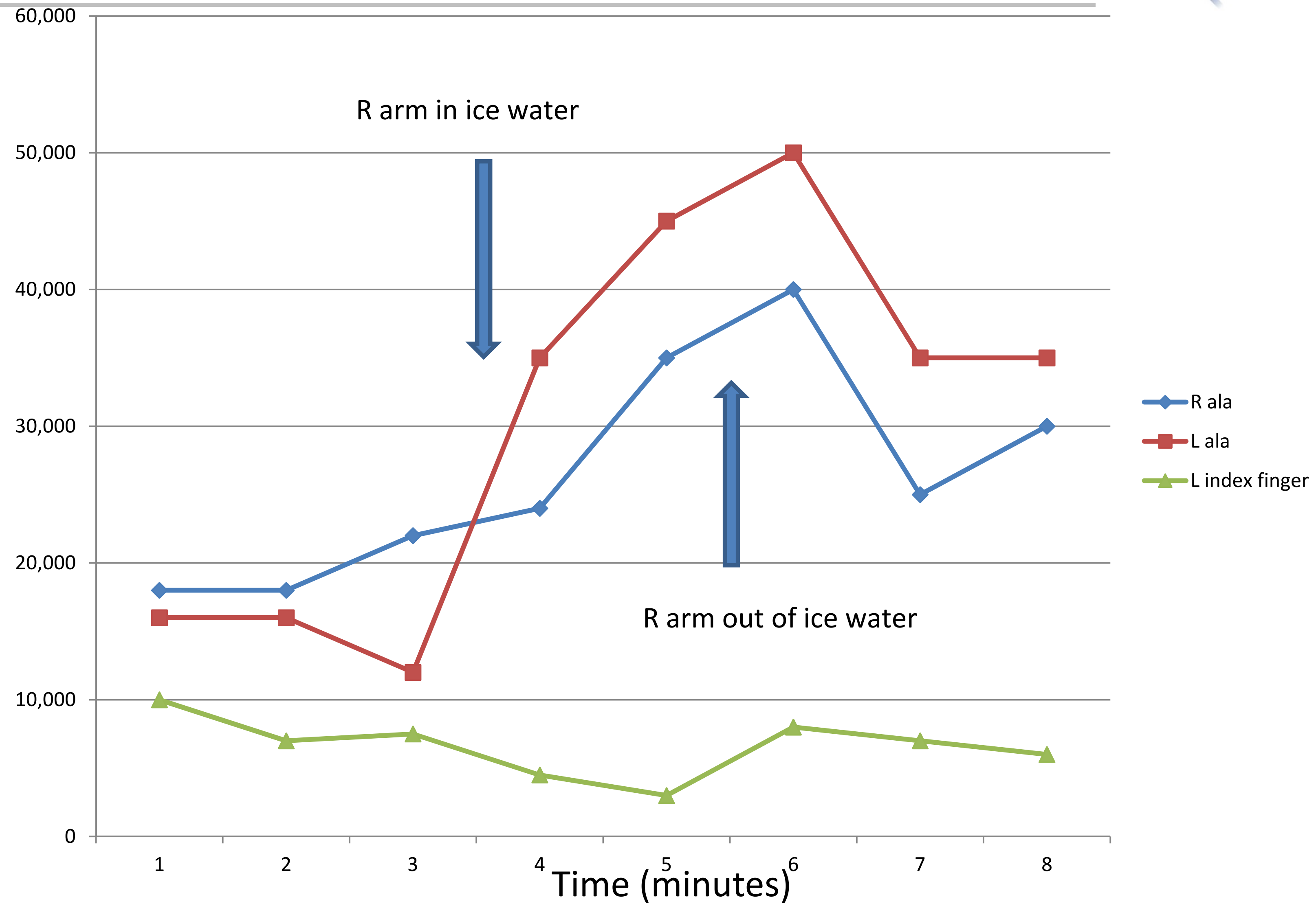


- Increase in intrathoracic pressure impedes venous return and decrease arterial flow

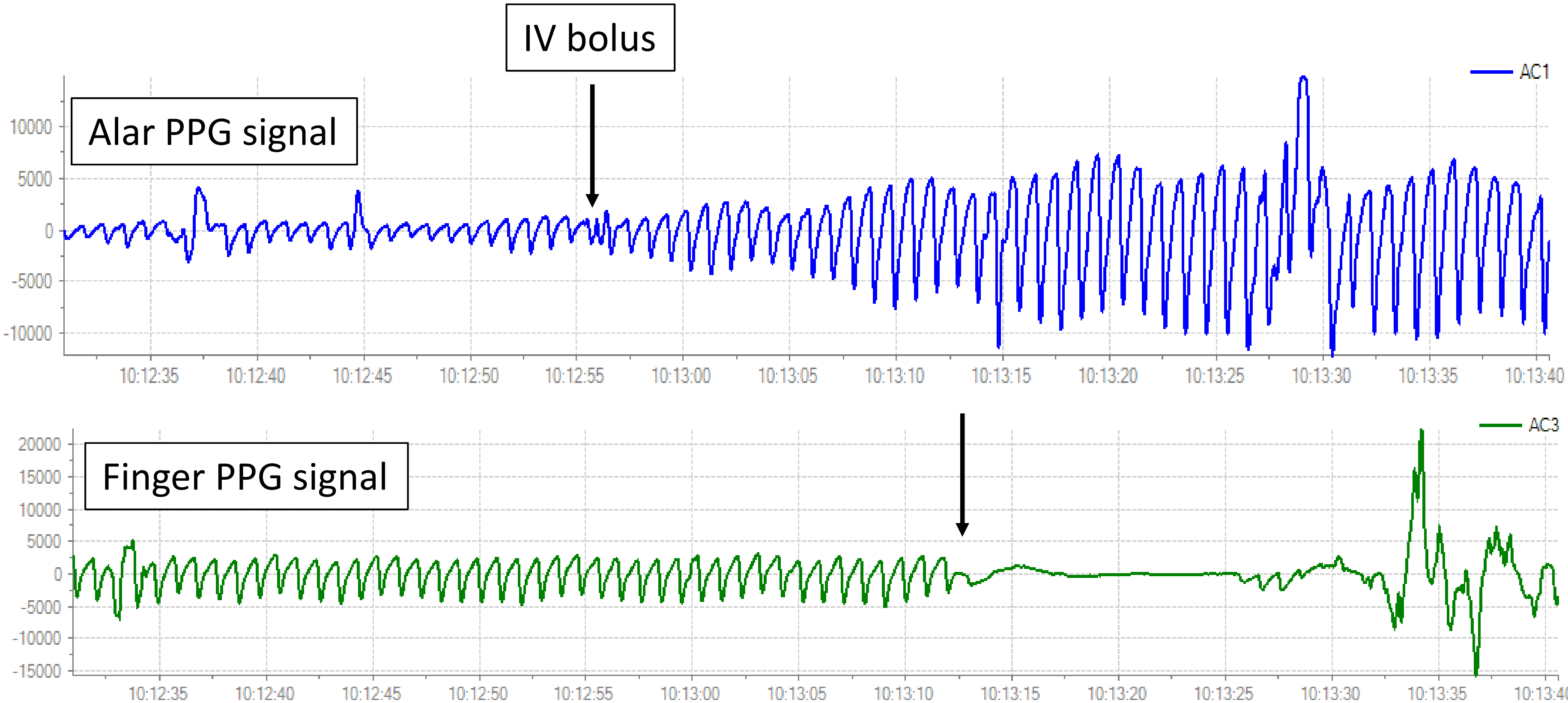
Press on R common carotid – monitor R cheek



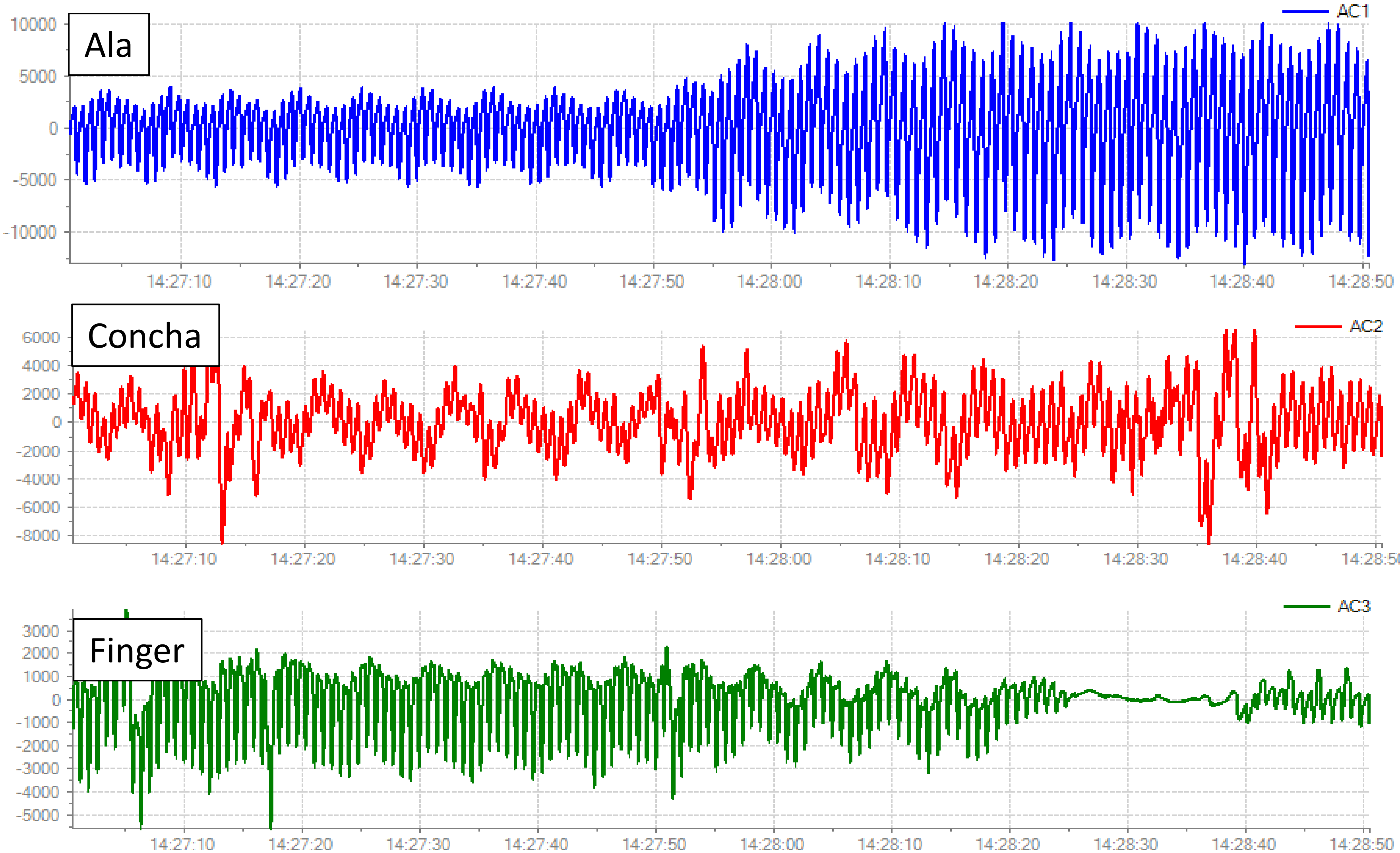
Evidence for lack of (intrinsic) sympathetic innervation and response to vasopressors


60,000
50,000
40,000
30,000
20,000
10,000
0
R arm in ice water
R arm out of ice water
1
2
3
4
5
6
7
8
Time (minutes)
R ala
L ala
L index finger

Response to neosynephrine



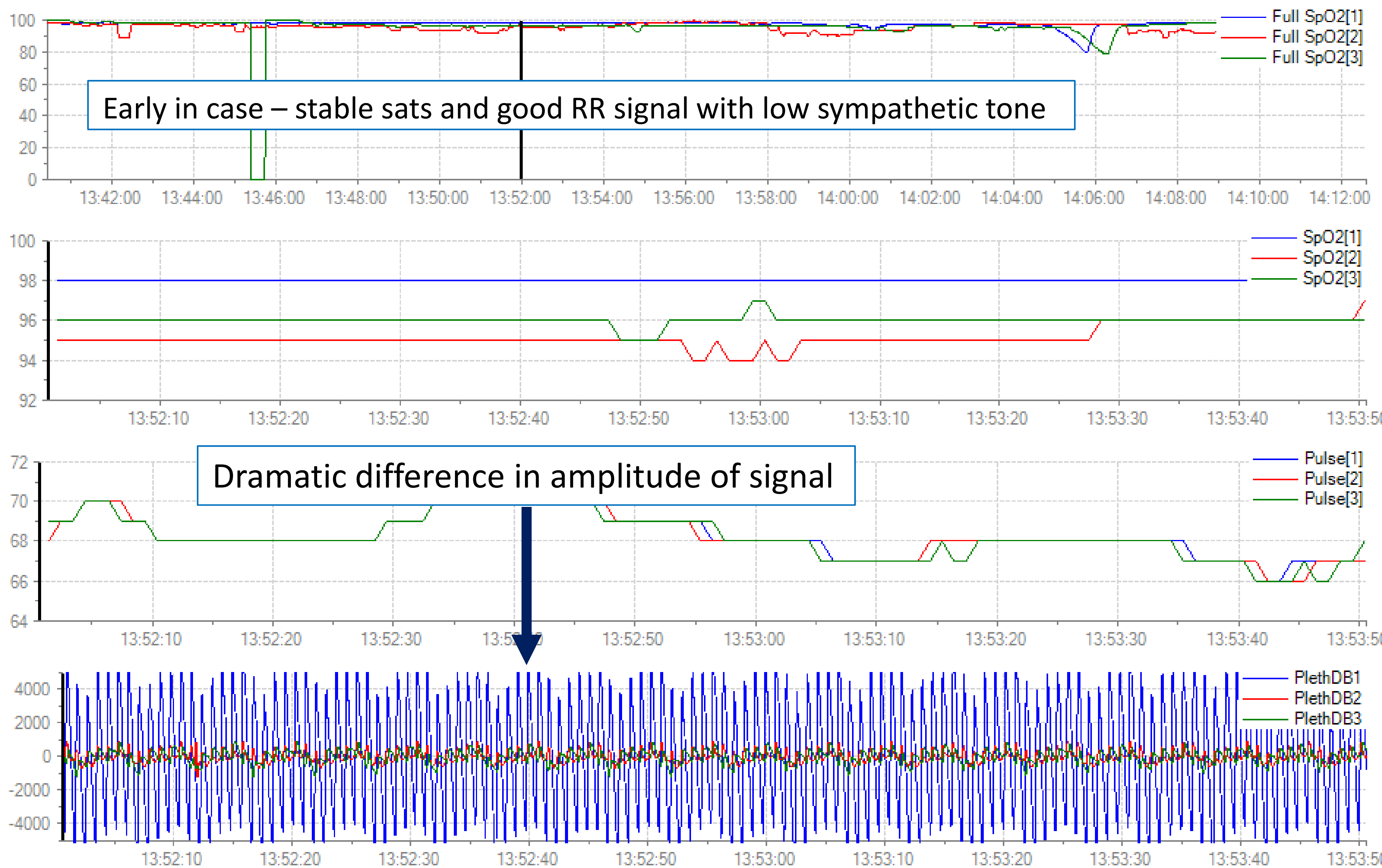
Response to phenylephrine



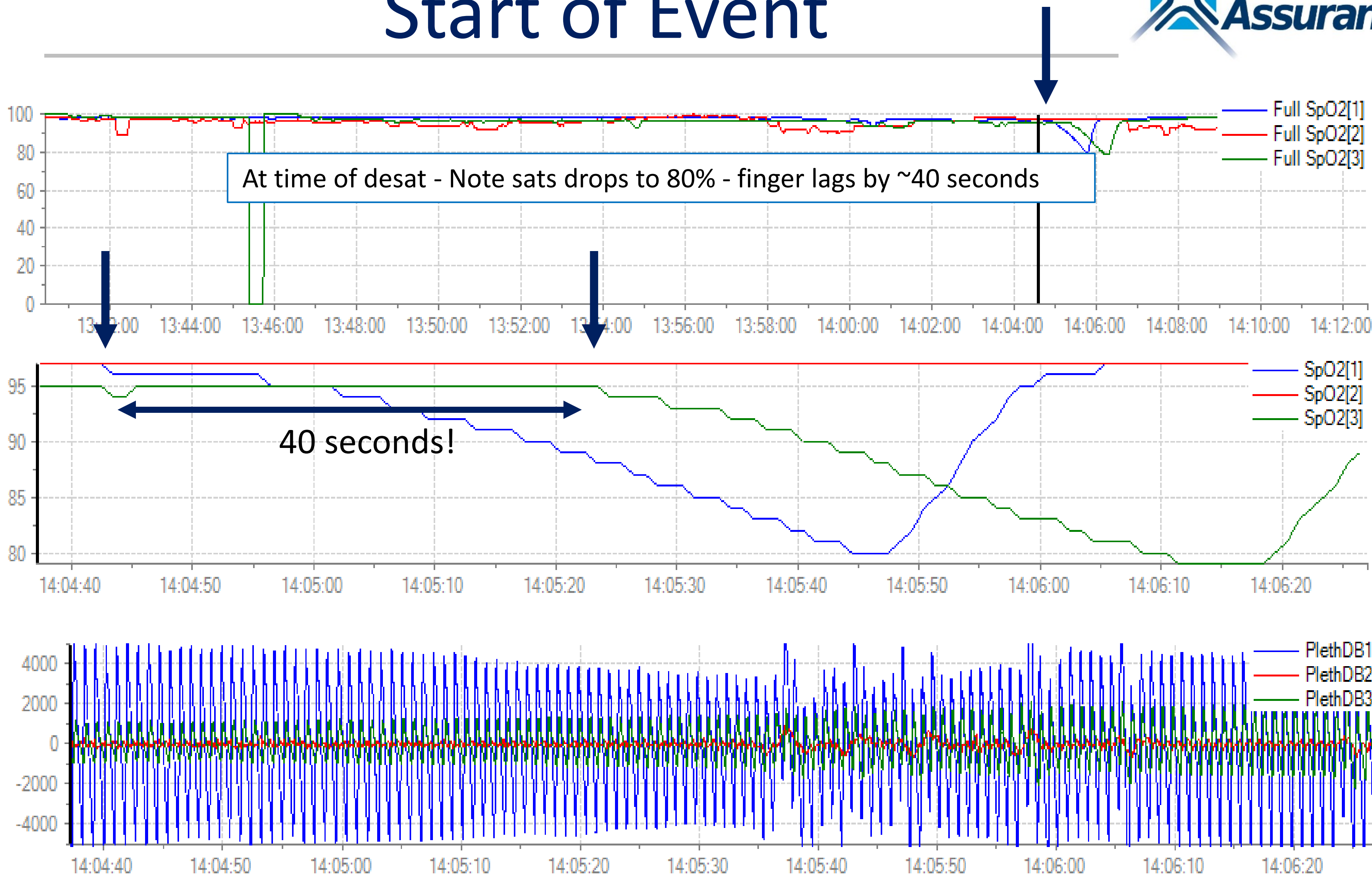
OR data

(over 200 subjects - >180 breathing spontaneously)

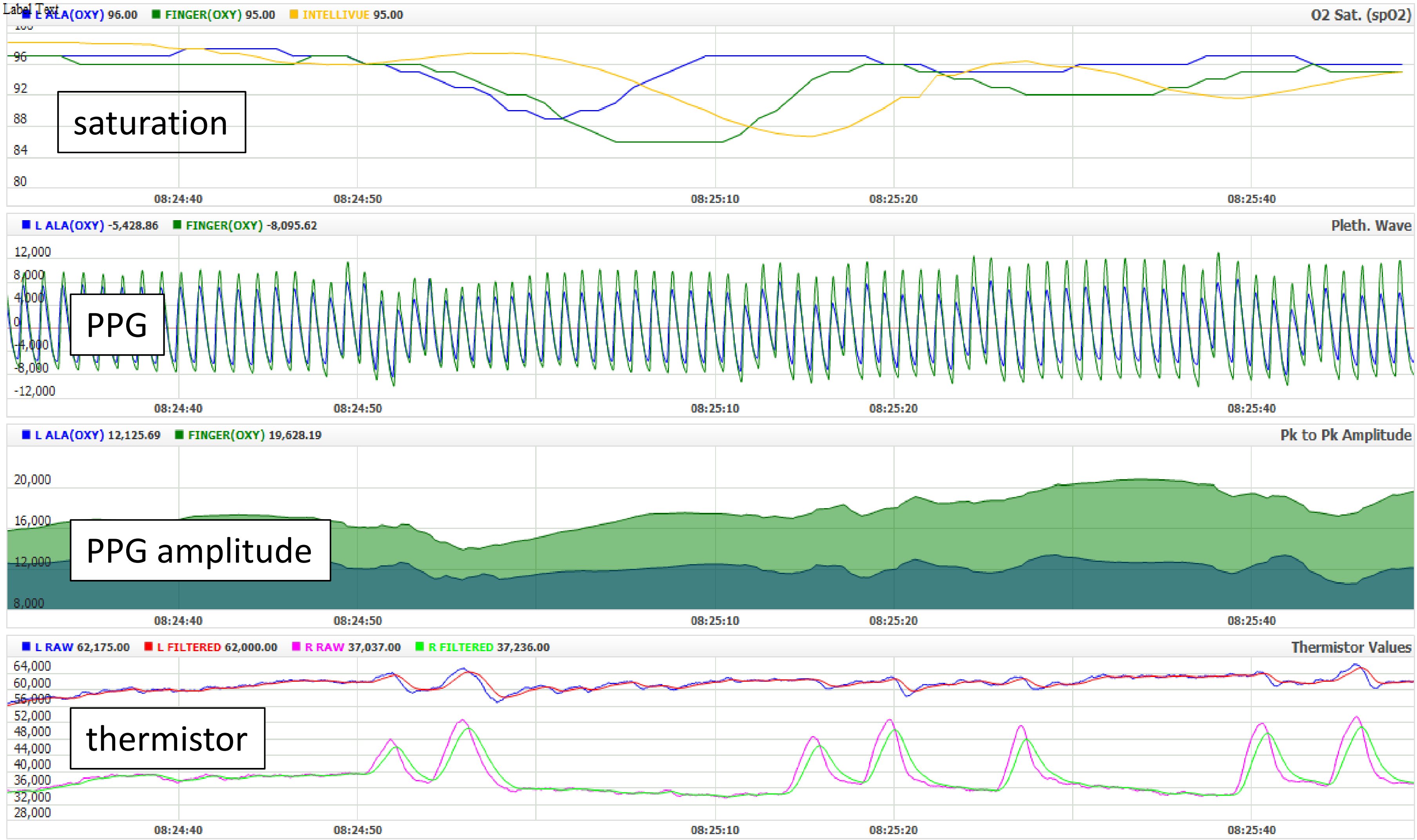
Alar Benefit – Faster Response



Start of Event



Desats detected earlier at ala

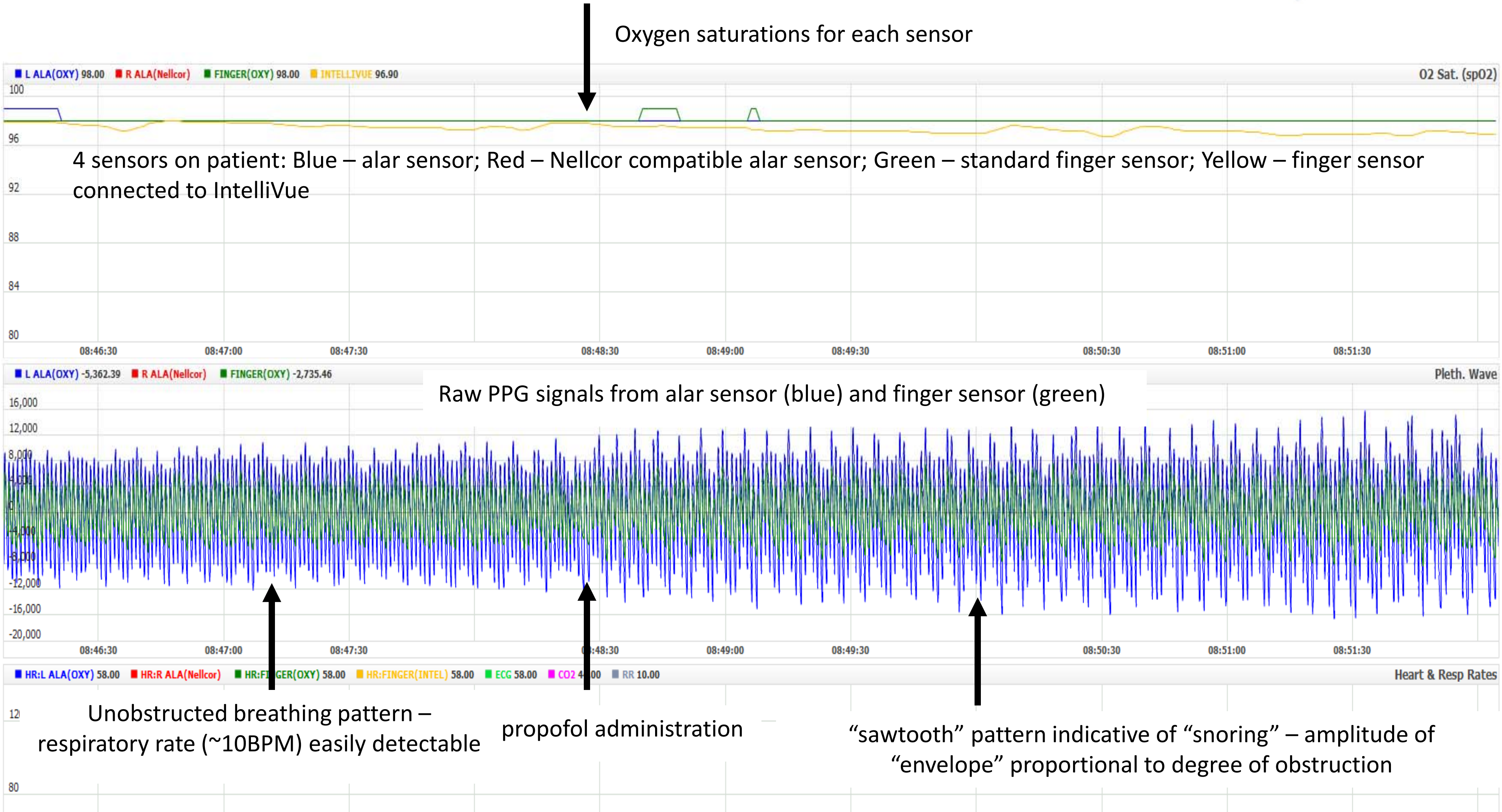


UF OR study (80 subjects*)

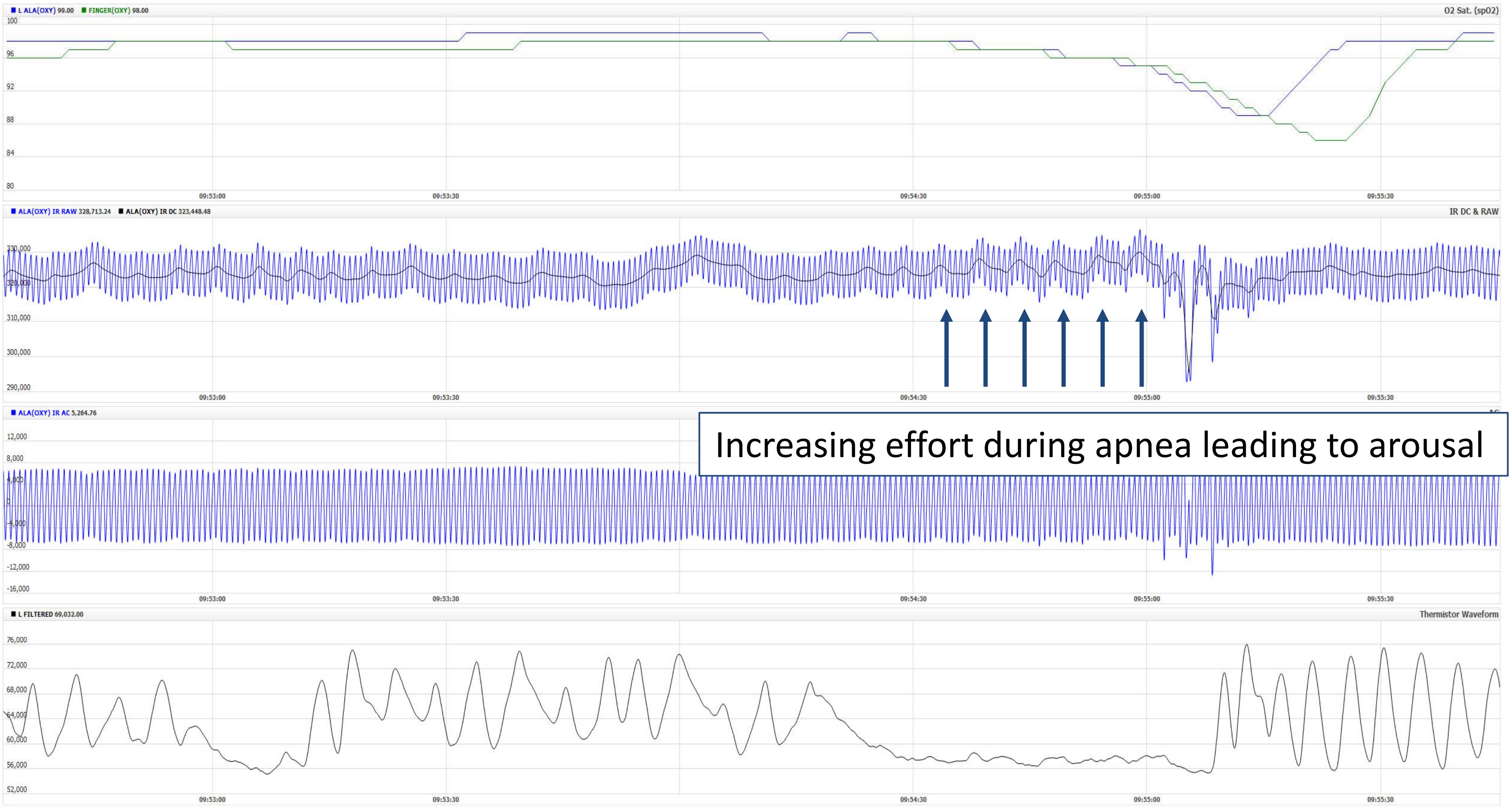
	PO1 ala v. PO1 finger (sec)	PO1 ala v. PO2 ala (sec)	PO1 ala v. PO3 finger (sec)
Mean	10.05	6.25	15.58
Std. Dev.	8.25	4.52	14.00
95% Confidence Interval (CI)	3.76	2.87	4.24
99% Confidence Interval (CI)	5.12	4.05	5.81

*Outpatients, spontaneous respiration, ASA Physical Status 1 and Status 2, MAC usually including propofol.

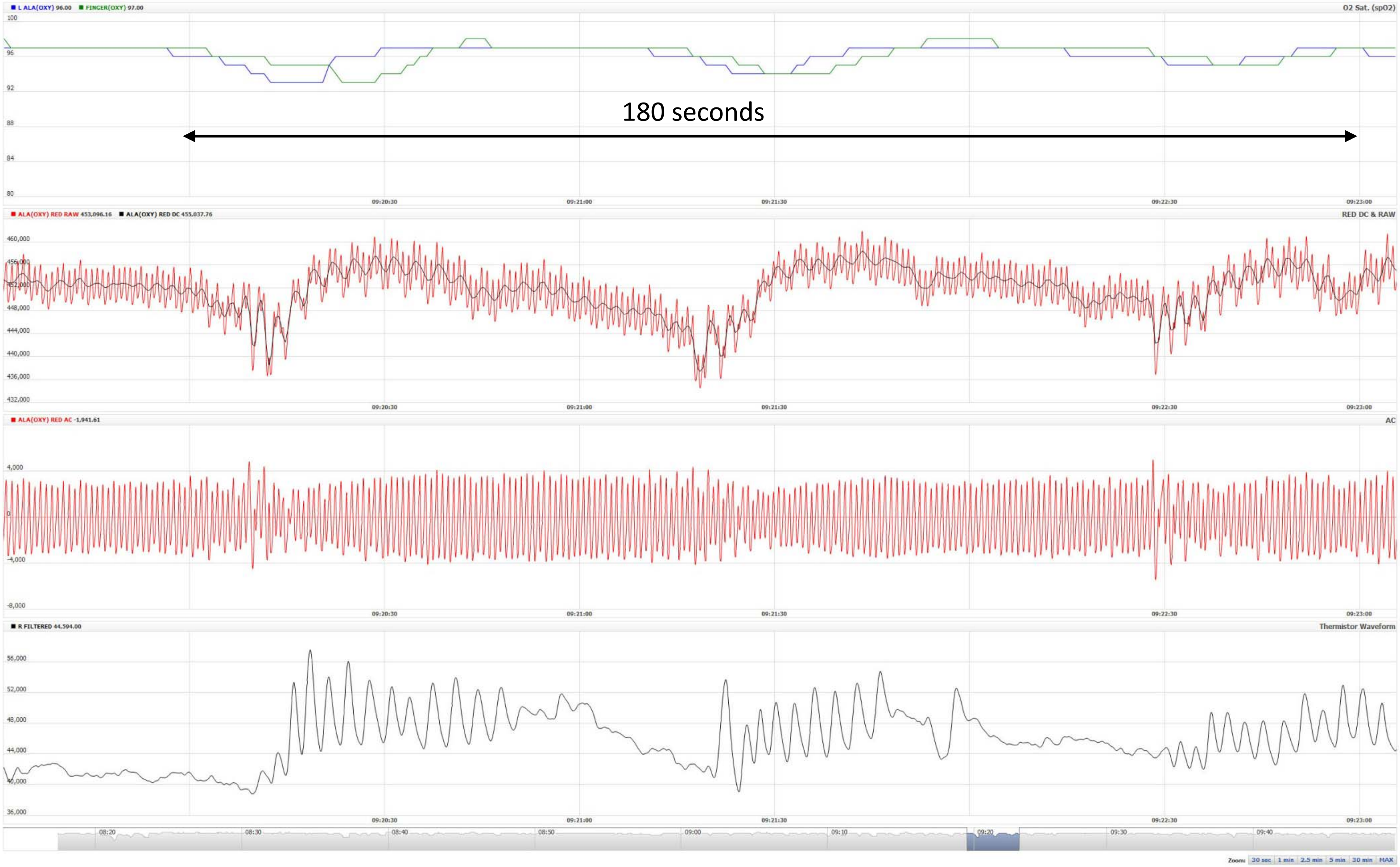
Transition from patent airway to obstruction



Self Rescue (arousal)



Multiple apneas, arousals and desats



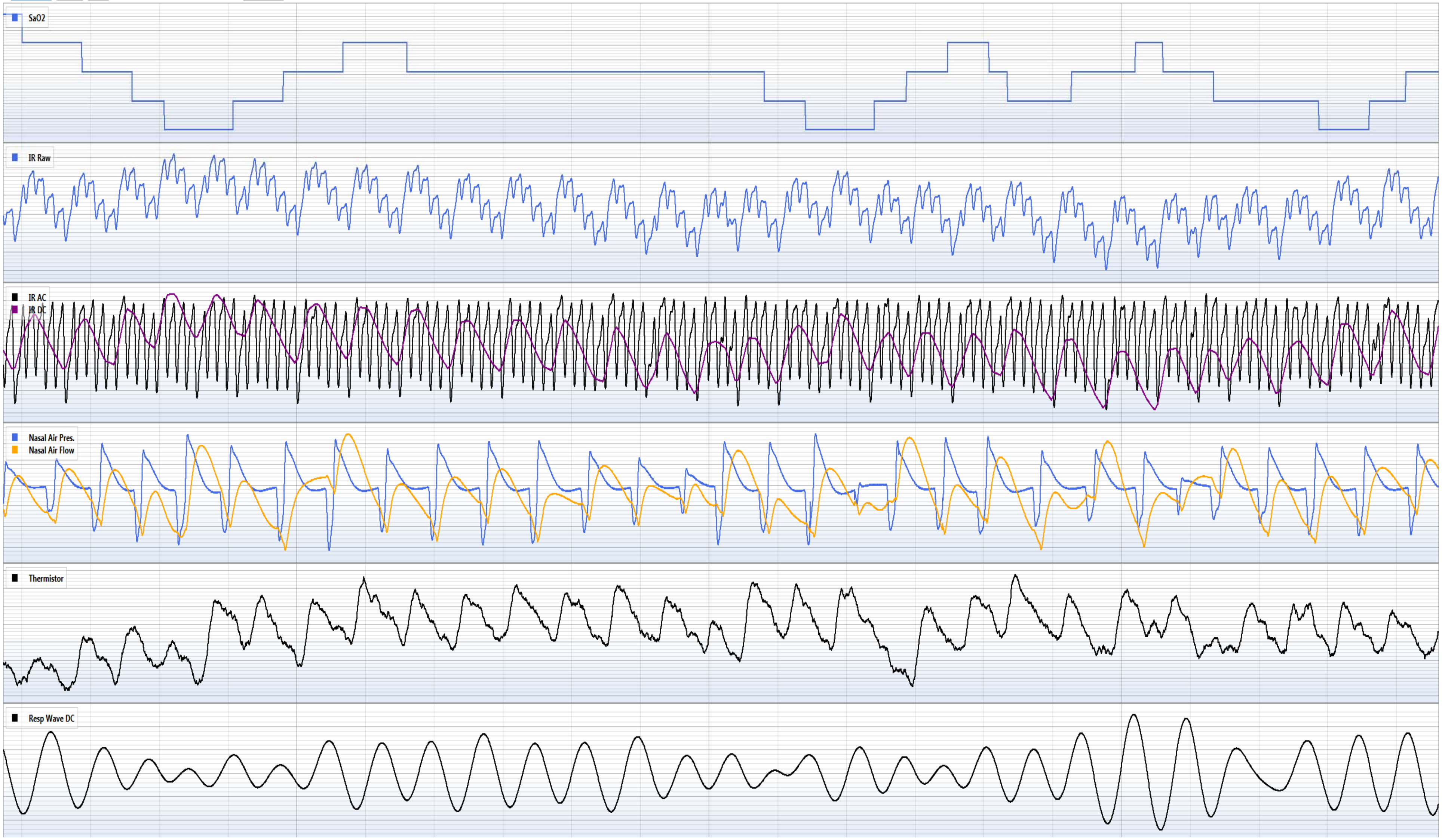
Sleep data

(60+ subjects – on-going study)

no subject has ever removed sensor
nor objected to wearing it

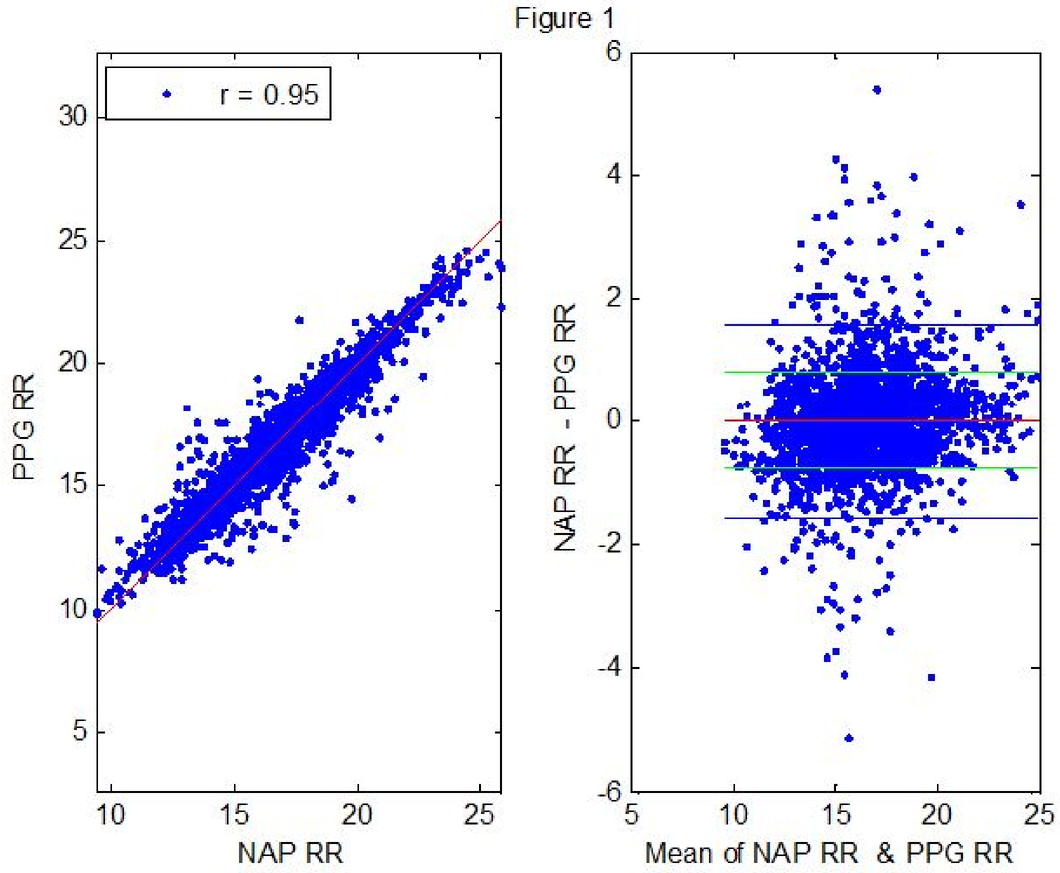
Sheep data before and during forced obstruction with tongue

OSA with desats – snoring pattern



Results

- Pearson coefficient between the RRs was $r=0.95$, $r^2=0.9$



Other data

Flow (volume) v. PPG+therm

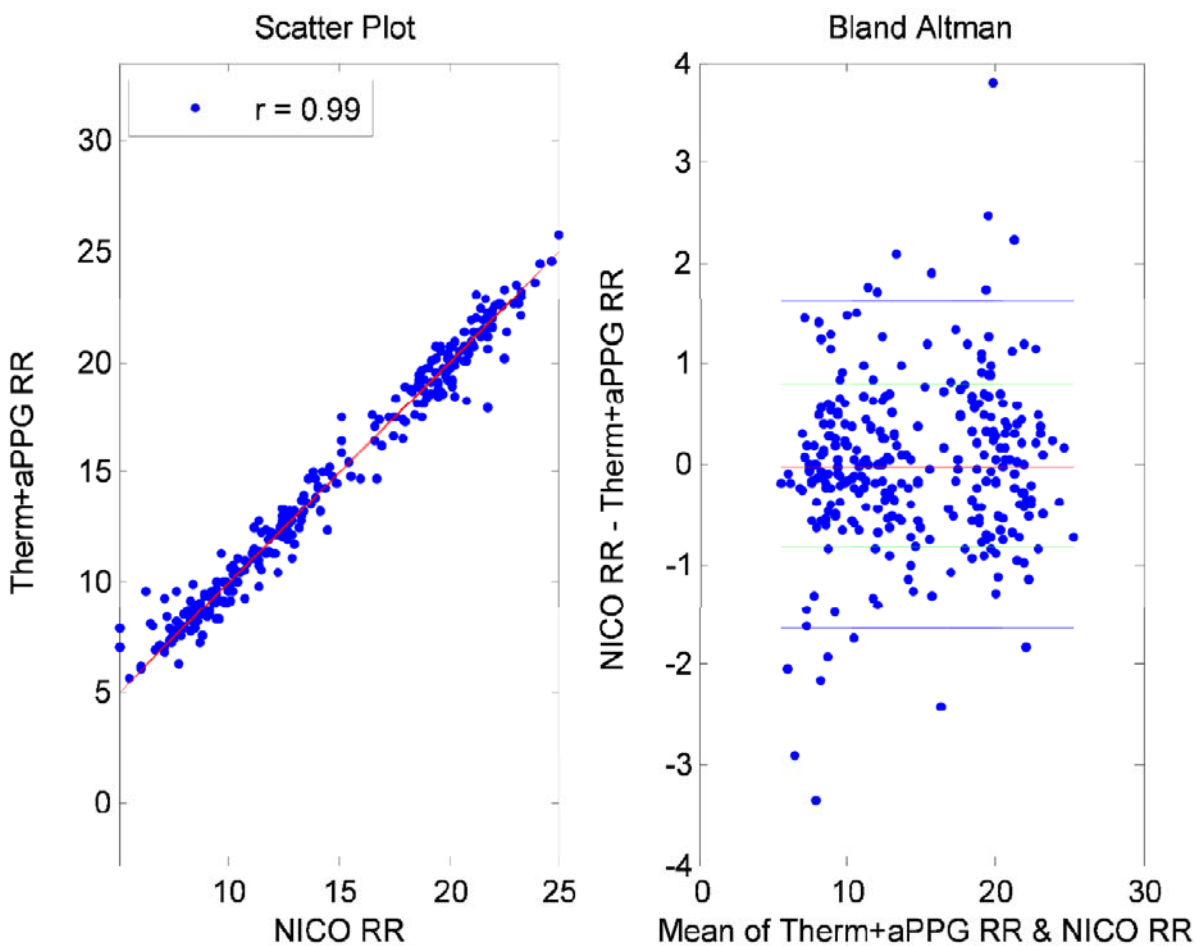
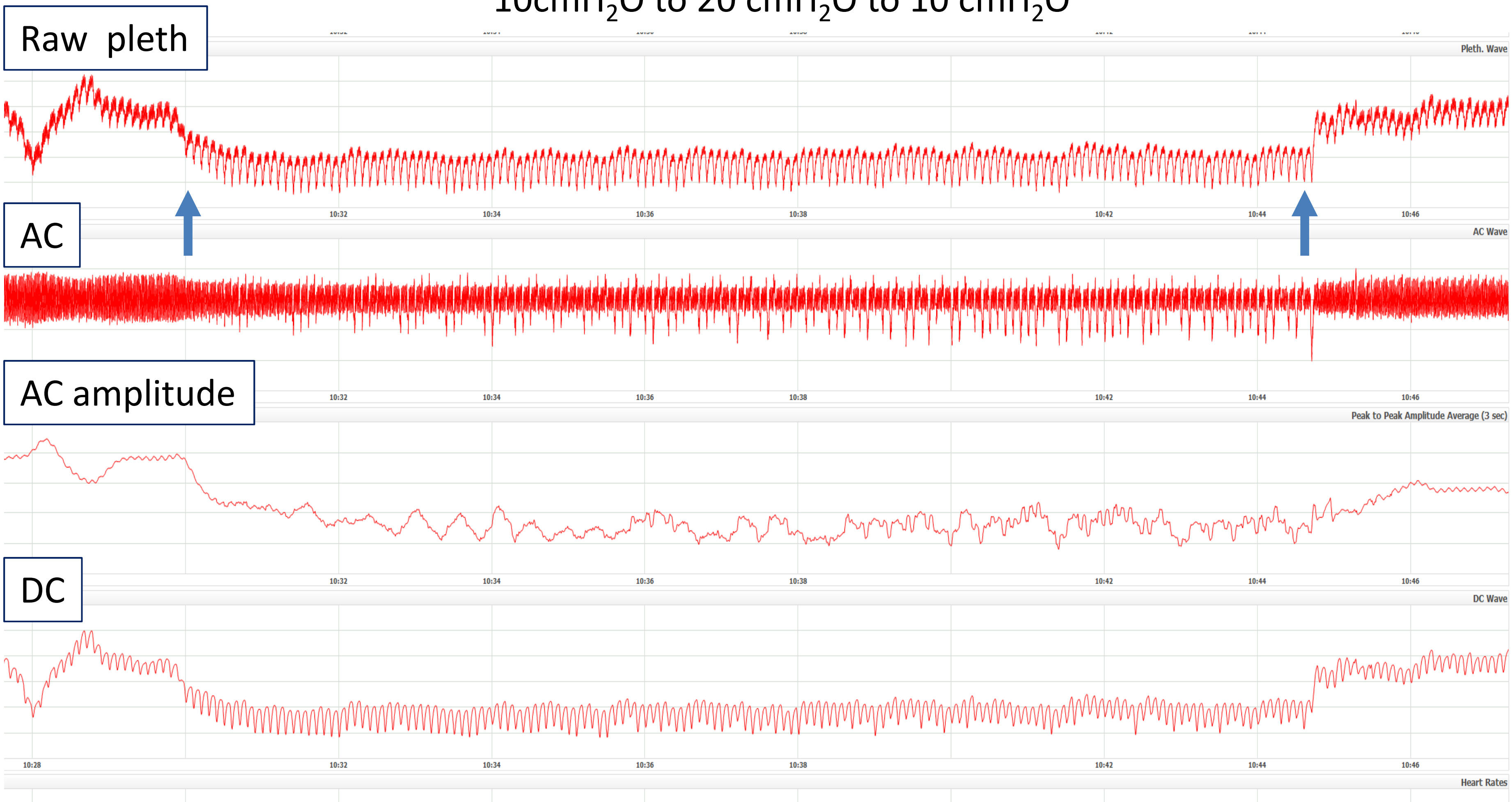


Fig. 1

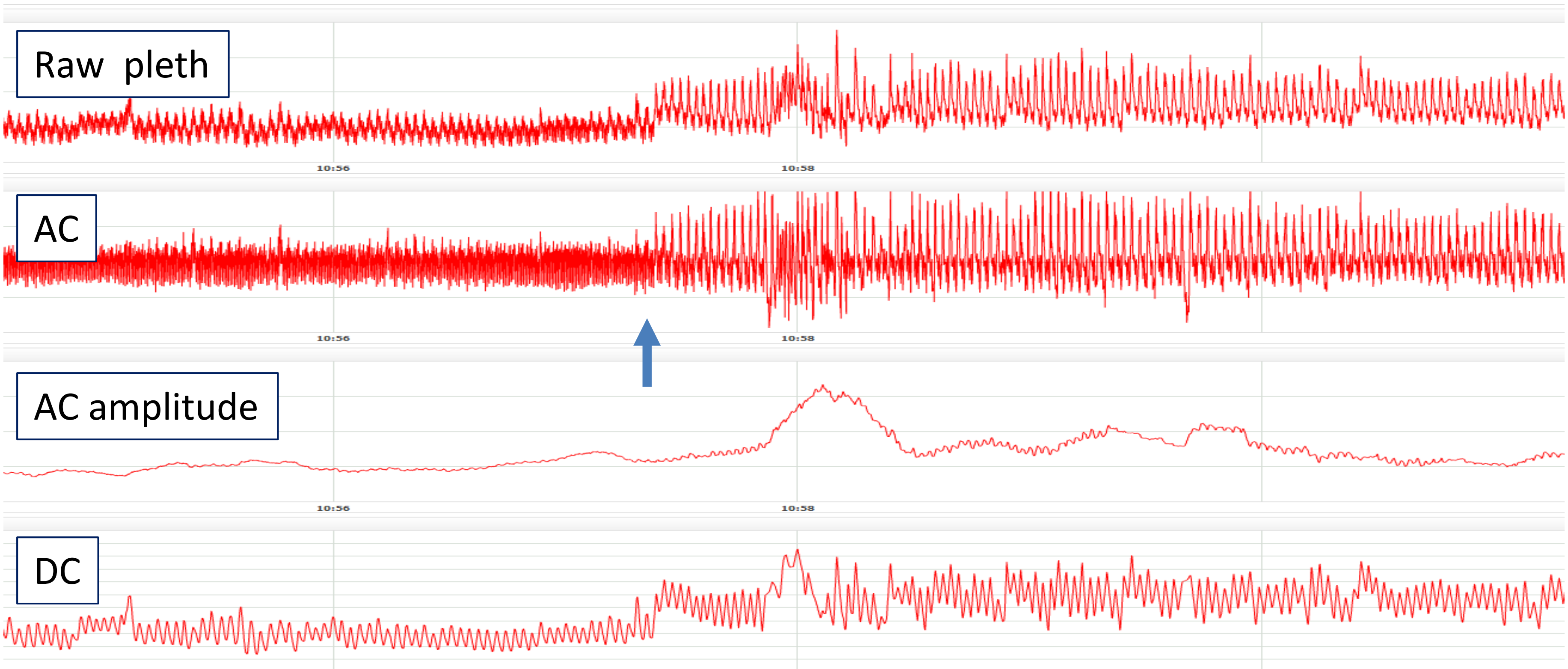
PEEP optimization

10cmH$_2$O to 20 cmH$_2$O to 10 cmH$_2$O



PEEP optimization

10cmH$_2$O to 15 cmH$_2$O



SPOC (alar) sensor = improved patient safety

	$P_{ET}CO_2$[1]	RR	S_pO_2[2]	HR	Resp. Effort	Resp. pattern	Arrhythmias	Actigraphy
Cap	+/−	+	−	−	−	−	−	−
PPG	−	+	+	+	+	+	+	+

1. *"The accuracy of the $ETCO_2$ reading, however, cannot be relied upon because it has been shown to correlate with alveolar $ETCO_2$ only upon a full vital capacity breath, which rarely occurs in our setting. Thus, its value may lie in trend analysis." Overdyk FJ, et. al. Anesth Analg 2007;105:412-418*

2. *"Hypoventilation can be detected reliably by pulse oximetry only when patients breathe room air. In patients with spontaneous ventilation, supplemental oxygen often masked the ability to detect abnormalities in respiratory function in the PACU." Fu ES, et. al. Chest 2004;126:1552-1558*

Alar monitoring - The Paradigm Shift

Finger-Based Pulse Oximetry

- Oxygen Saturation
- Heart Rate (pulse)

VS

Alar Multi-Parameter Monitoring

- Oxygen Saturation
- Heart Rate
- Respiratory Rate
- Respiratory Effort
- Arterial Blood Flow (cerebral surrogate)
- Venous Capacitance
- Arrhythmias
- ECG
- Pulse Transit Time, other derived parameters
- PEEP optimization

Central Monitoring (nasal ala)
= Real-time Comprehensive Patient Monitoring of Sleep, General Care Floors, OR (spontaneous breathing)

Conclusions

- Alar sensors offer:
  - Superior reliability in broad range of clinical conditions
  - Faster response to desaturation, even in healthy subjects
  - PPG signal which is relatively immune to issues that hamper reliable monitoring at other sites (poor perfusion, motion artifact, vasopressors, hypothermia)

Conclusions

- Alar sensors offer:
  - Reliable detection of RR and RE
  - Addition of thermistor to increase reliability of RR detection
  - Ability to track changes in cerebral blood flow
  - Ability to track changes in venous capacitance
- Much more work to be done!