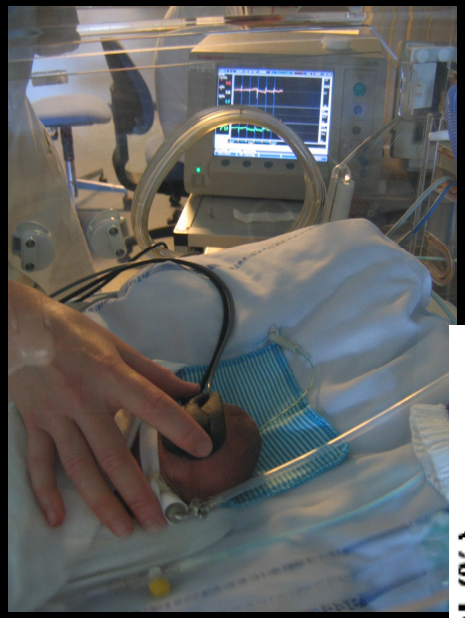
BabyLux: Critical evaluation of clinical results

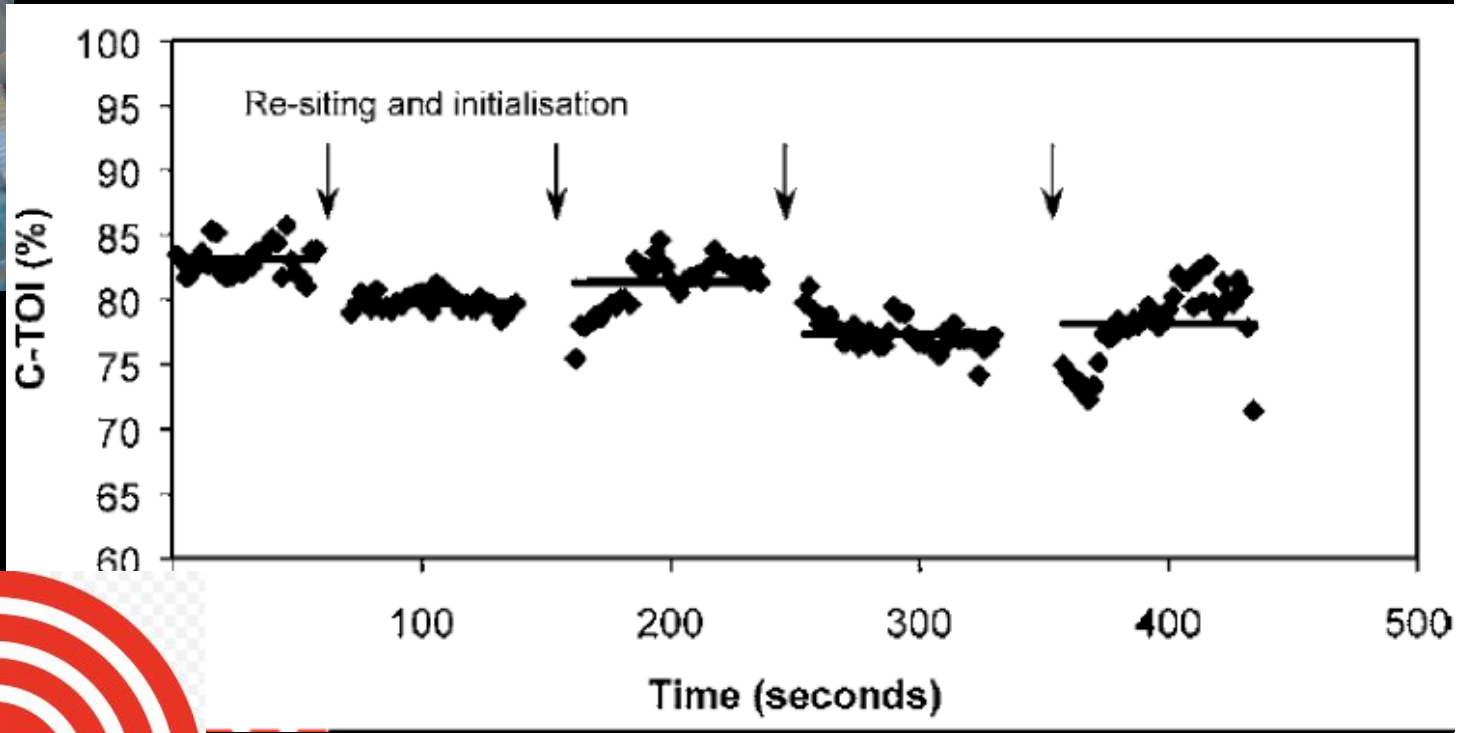
Milan, April 2017

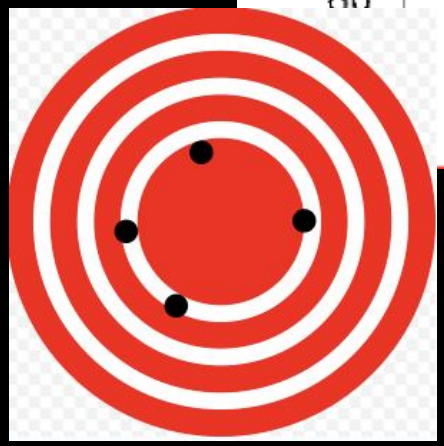
Gorm Greisen
Department of Neonatology
Rigshospitalet, Copenhagen University
Denmark

Repeatability



Precision (≈ repeatability)

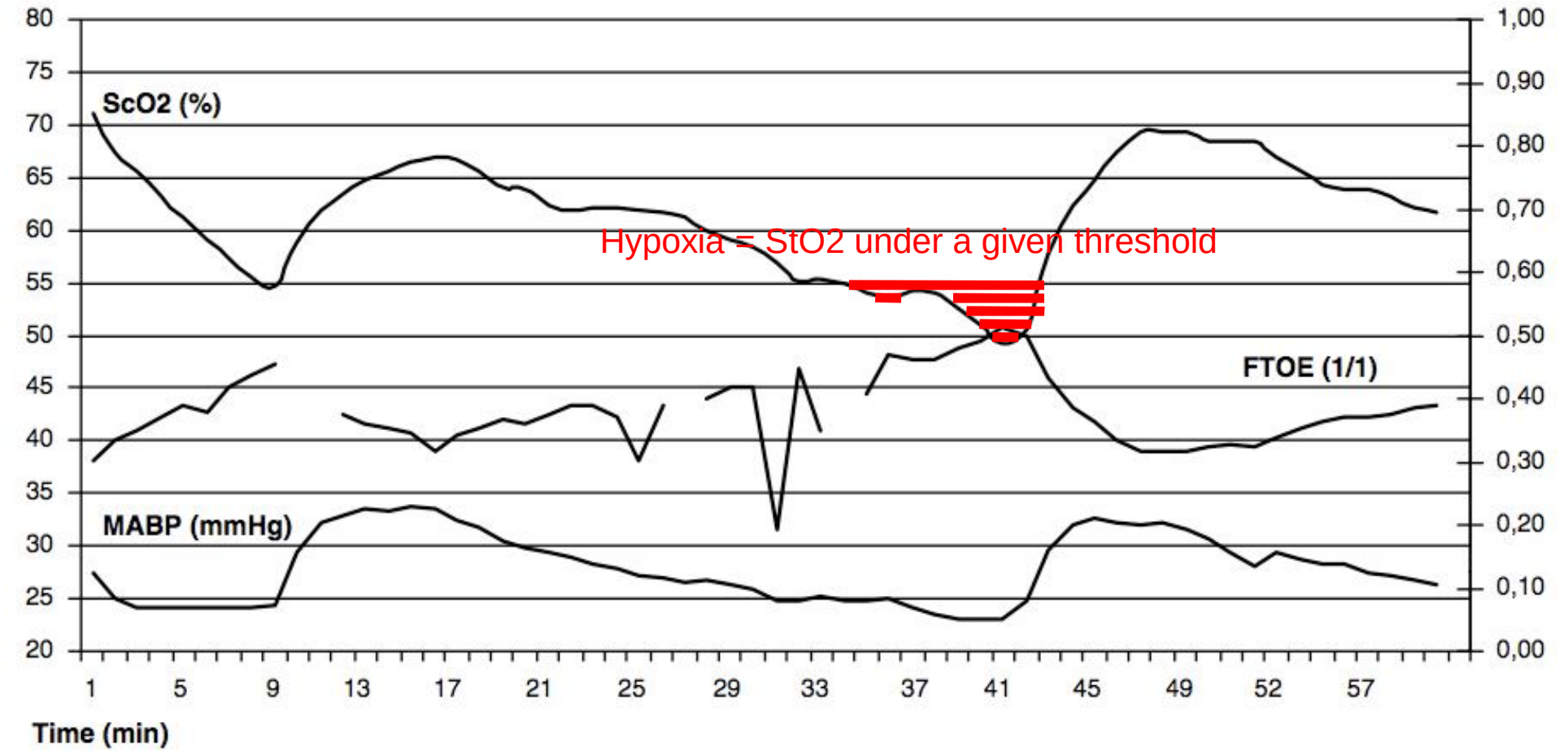




Repeatability (precision) = 5.2%

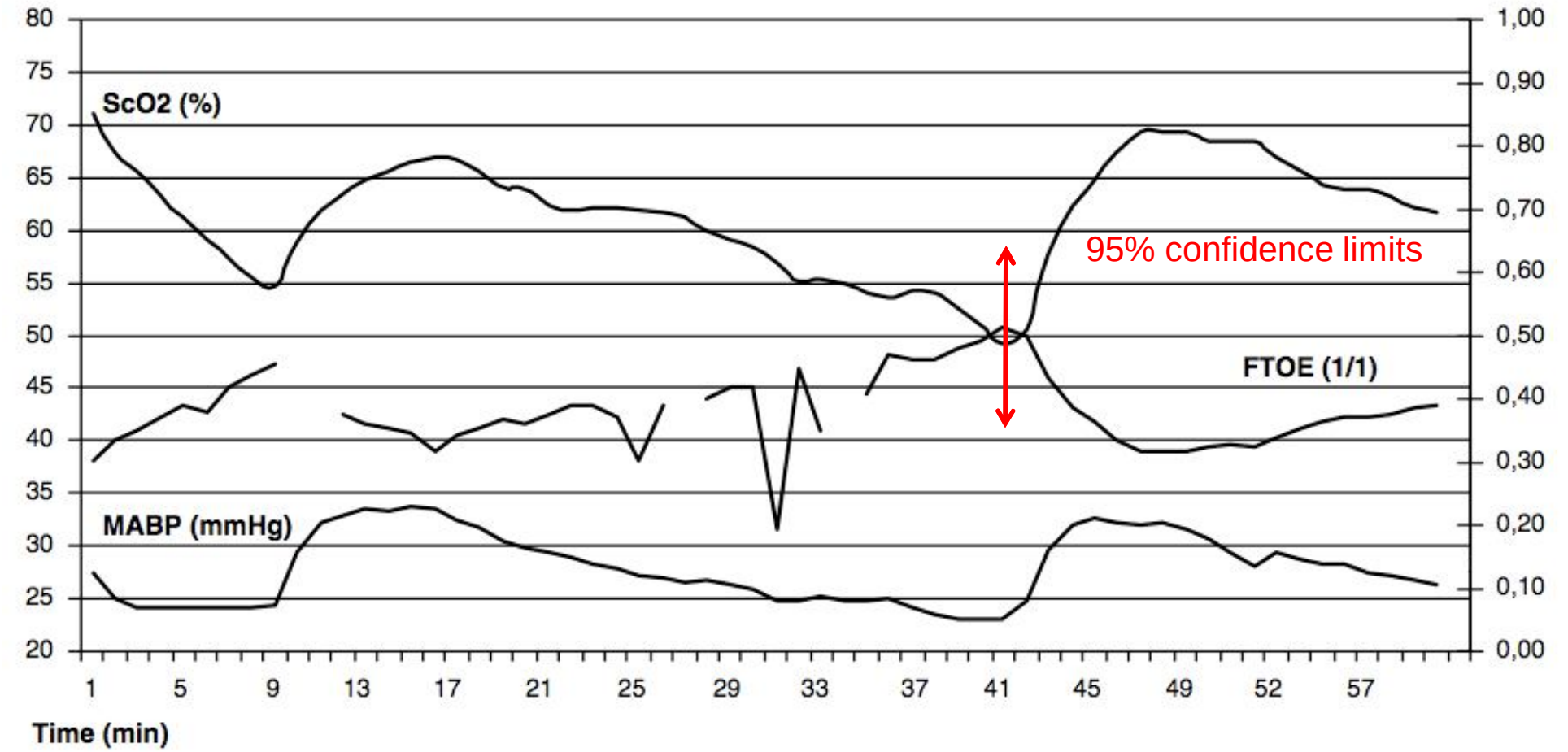
(Sorensen J Biomed Opt 2006)

One hour of monitoring of StO2 in an extremely preterm infant



Modified from Lemmers 2010 (thesis)

Precision is essential



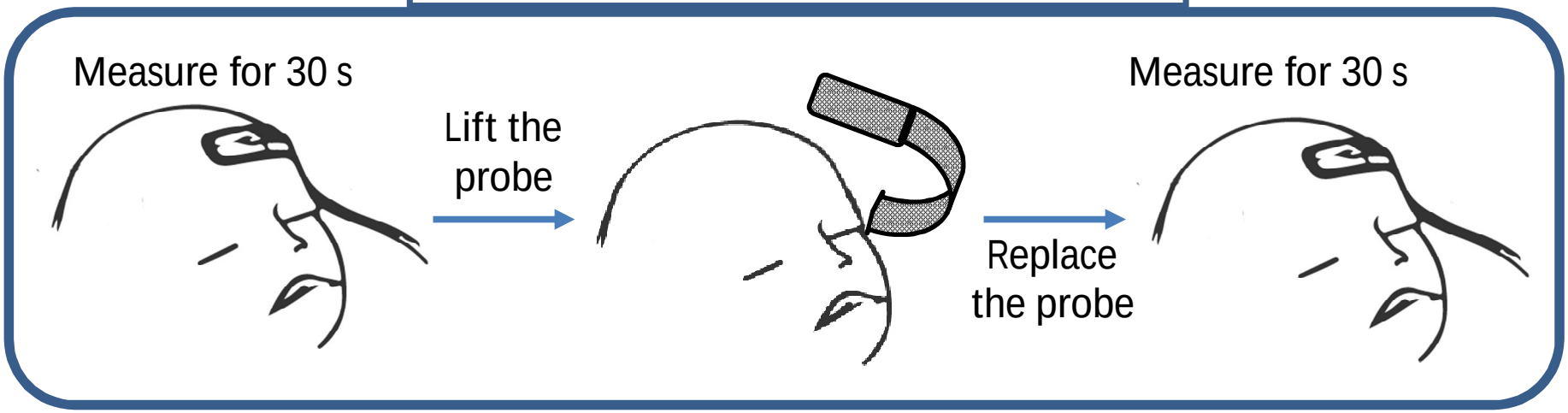
Modified from Lemmers 2010 (thesis)

Protocol

Inclusion criteria

- term newborns (with a gestational age > 37 weeks)
- planned to be delivered by an uncomplicated elective caesarean section

Repeat until 6 measurements are acquired



Main goal: less than 5% variability in StO2

to remarkably improve what obtained with CW-NIRS [Hyttel-Sorensen, BOE, 2011]

Measurement performed in two clinical sites:

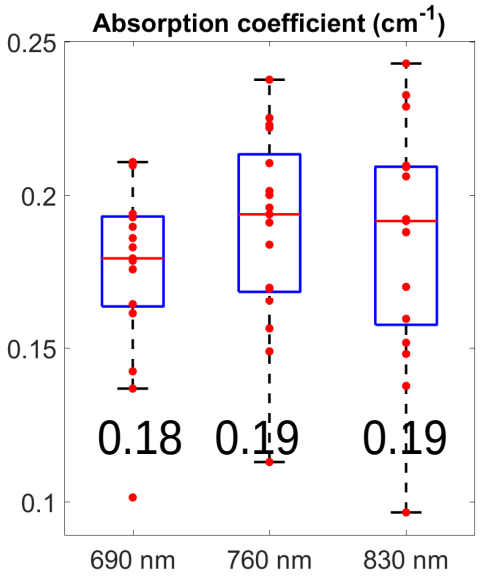
Region Hovedstaden

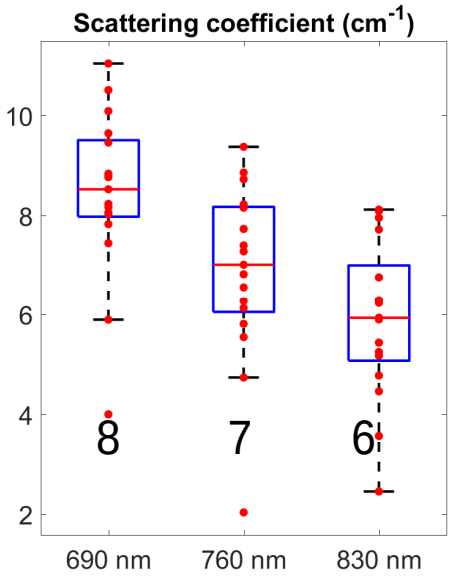
FONDAZIONE IRCCS CA' GRANDA
OSPEDALE MAGGIORE POLICLINICO

The BabyLux probe in place

Optical properties and derived measures

Optical properties

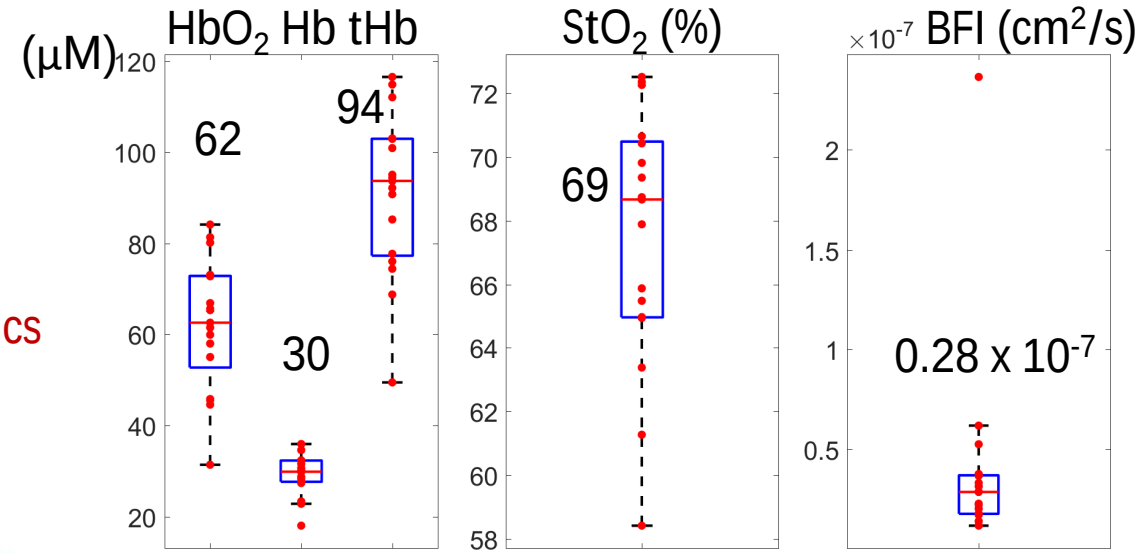




n=17

In accordance to previous work [Ijichi (2005), Pediatr. Res.]

Haemodynamics properties

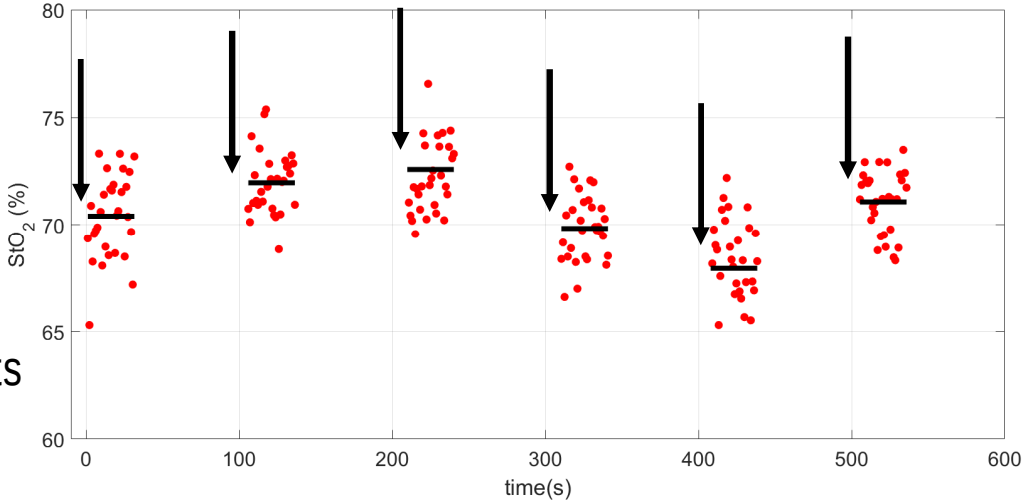


Median indicated for each of the variables

Precision

$CV = std/mean$ presented;
averaged over all the subjects

It indicates each of the six replacements



over 30 s of continuous measurement

wavelength	Absorption coefficient	Scattering coefficient
690 nm	4.3 %	4.6 %
760 nm	3.4 %	4.0 %
830 nm	3.9 %	4.8 %

Hb	HbO_2	tHb	StO_2	BFI
5.6 %	6.0 %	3.3 %	3.4 %	11.1 %

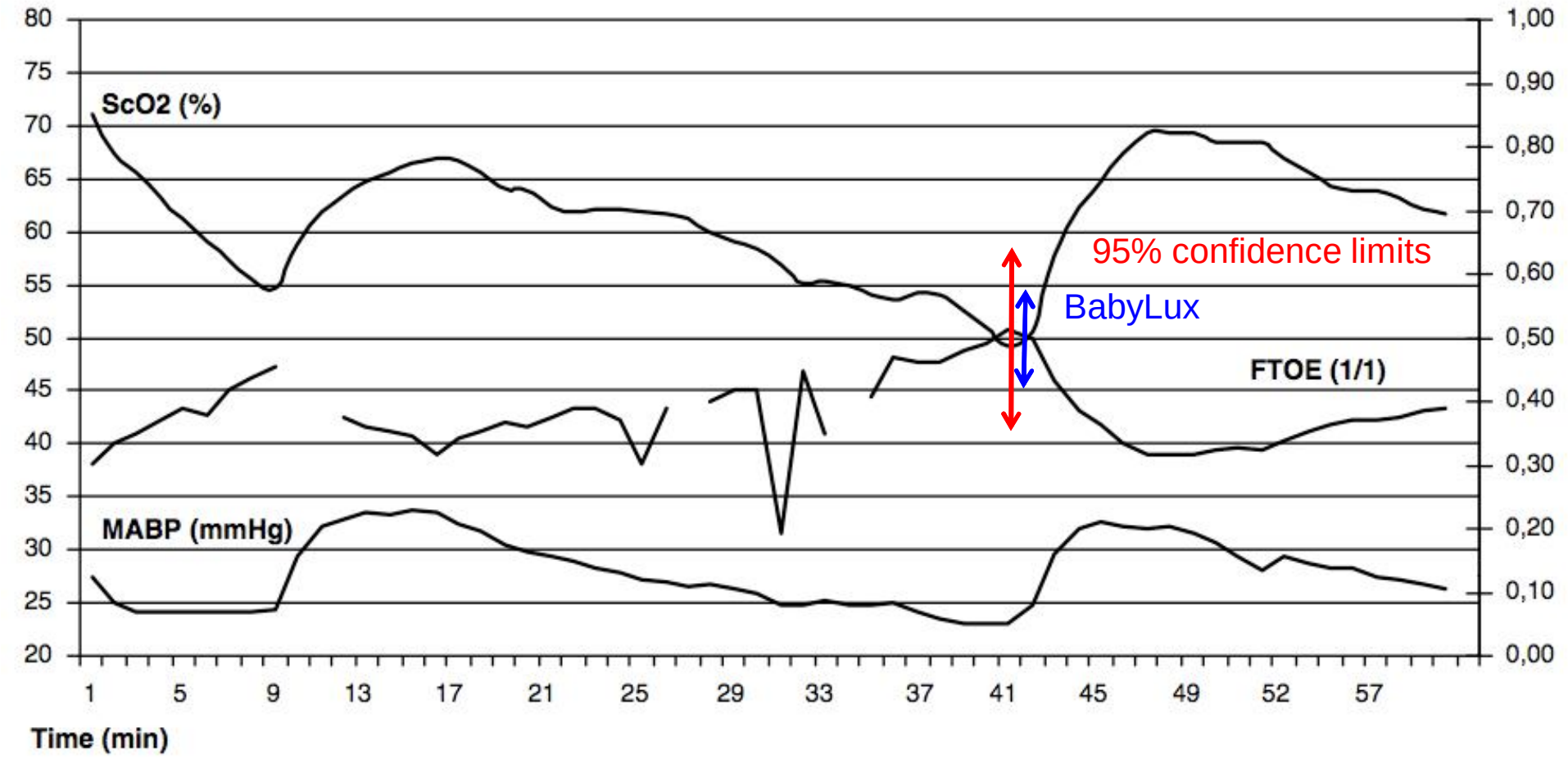
over six replacements

wavelength	Absorption coefficient	Scattering coefficient
690 nm	6.4 %	7.6 %
760 nm	7.0 %	9.9 %
830 nm	7.7 %	9.5 %

Hb	HbO_2	tHb	StO_2	BFI
6.7 %	9.2 %	7.5 %	**2.7 %**	21.7 %

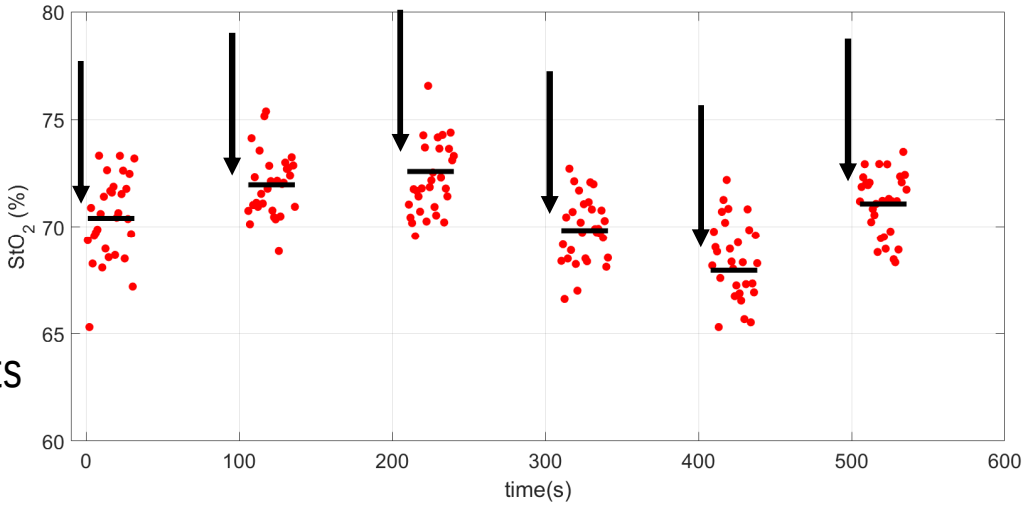
less than 5 % for all the subjects

BabyLux


ScO2 (%)
MABP (mmHg)
FTOE (1/1)
95% confidence limits
BabyLux
Time (min)
80
75
70
65
60
55
50
45
40
35
30
25
20
1,00
0,90
0,80
0,70
0,60
0,50
0,40
0,30
0,20
0,10
0,00
1
5
9
13
17
21
25
29
33
37
41
45
49
52
57

Precision

$CV = std/mean$ presented;
averaged over all the subjects



It indicates each of the six replacements

over 30 s of continuous measurement

wavelength	Absorption coefficient	Scattering coefficient
690 nm	4.3 %	4.6 %
760 nm	3.4 %	4.0 %
830 nm	3.9 %	4.8 %

Hb	HbO_2	tHb	StO_2	BFI
5.6 %	6.0 %	3.3 %	3.4 %	11.1 %

over six replacements

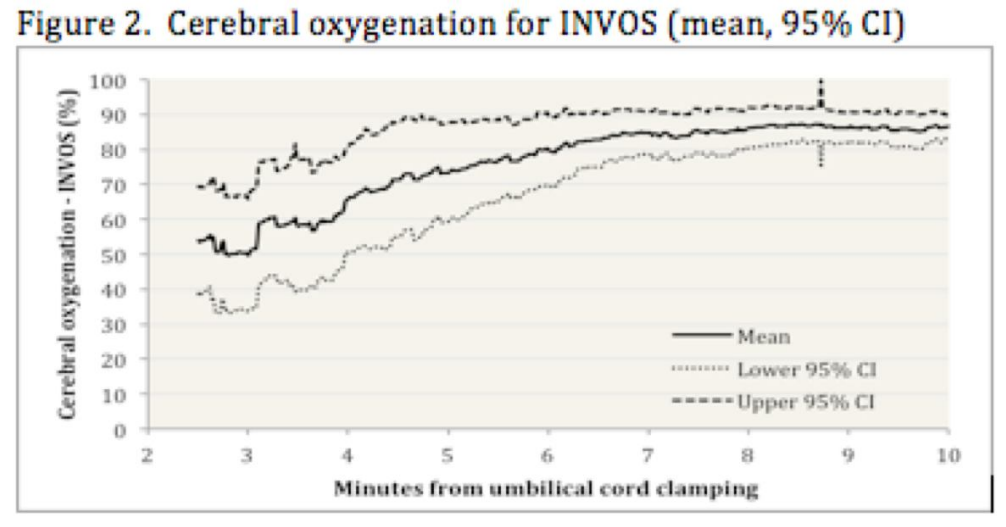
wavelength	Absorption coefficient	Scattering coefficient
690 nm	6.4 %	7.6 %
760 nm	7.0 %	9.9 %
830 nm	7.7 %	9.5 %

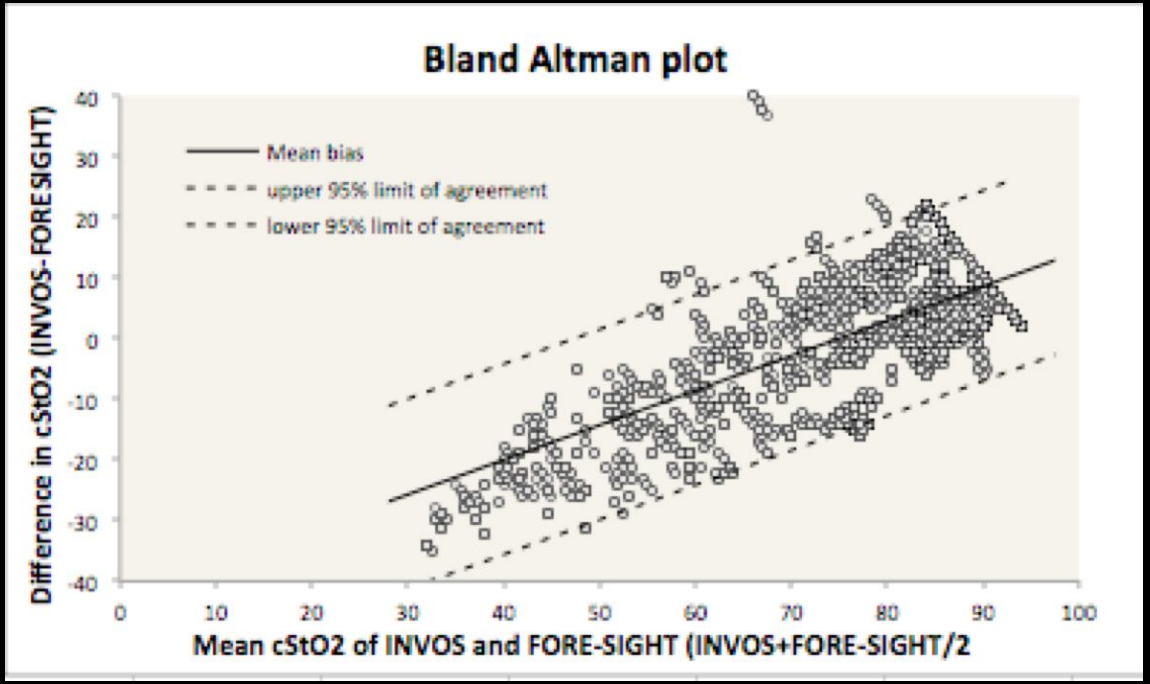
Hb	HbO_2	tHb	StO_2	BFI
6.7 %	9.2 %	7.5 %	**2.7 %**	21.7 %

May be OK since clinical range is wider

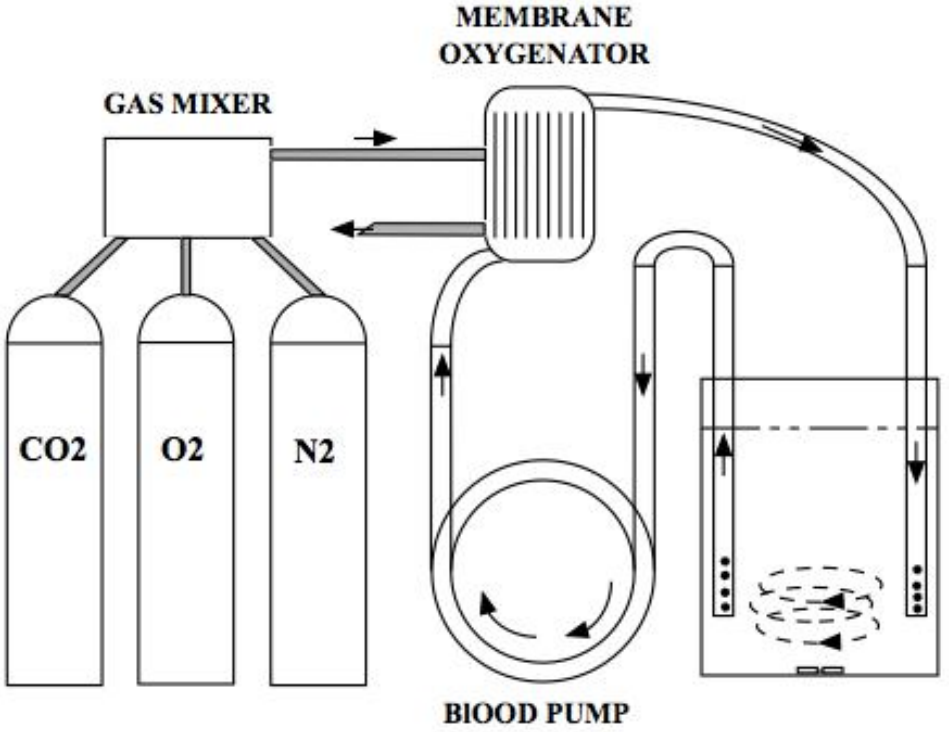
Accuracy

Cerebral oxygenation in term infants after CS from min 3 to 10 min

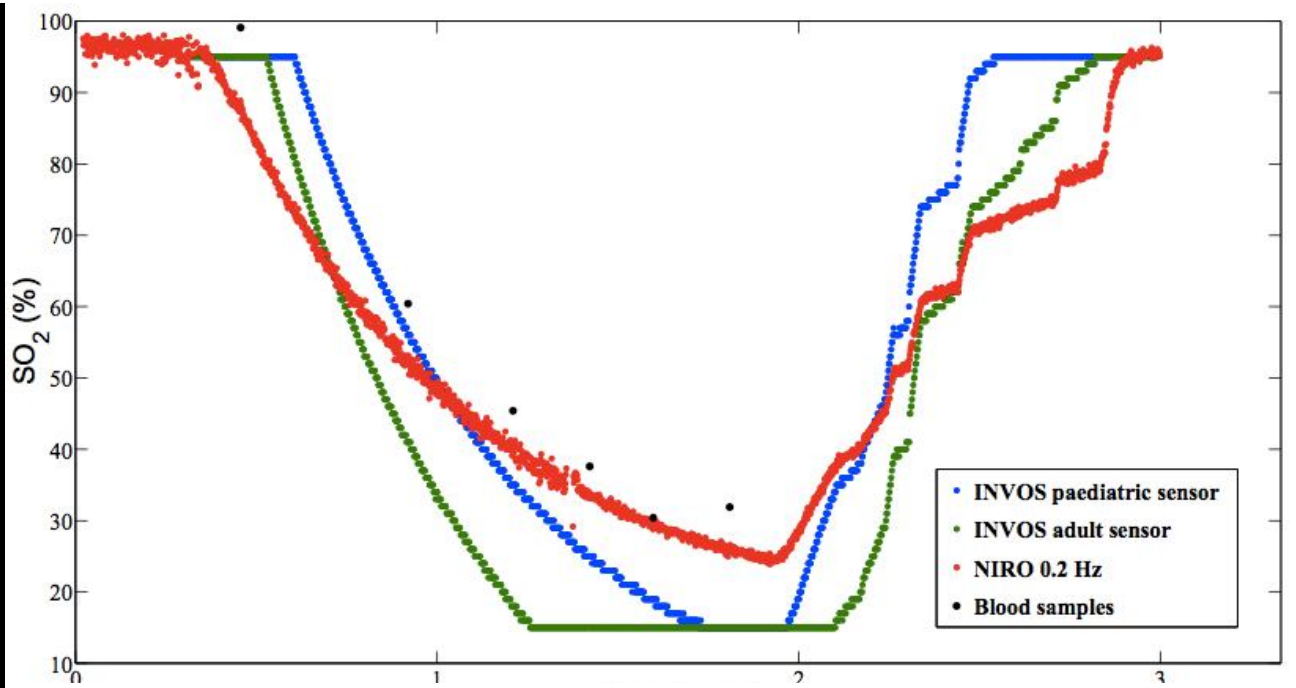


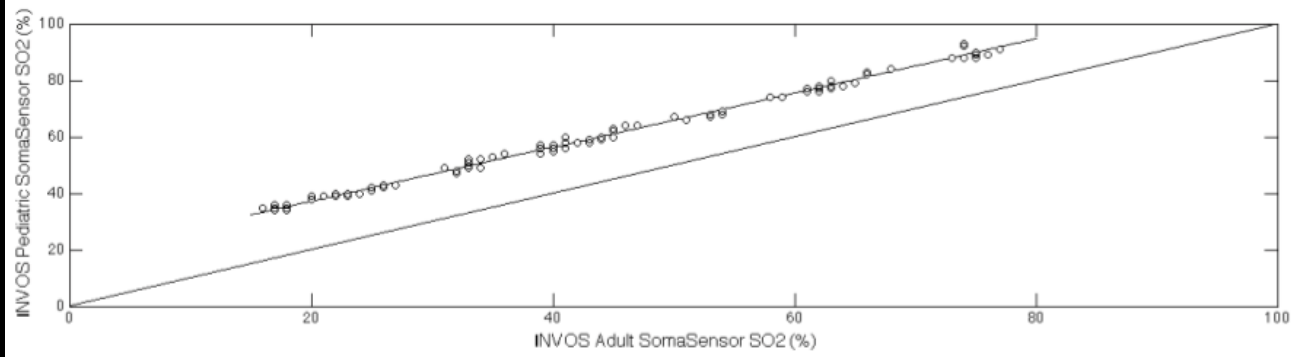


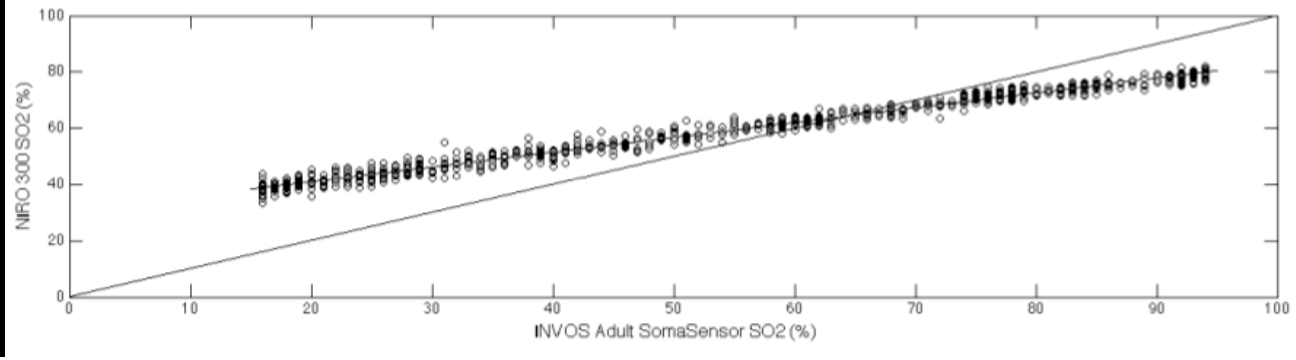
(Hessel et al Acta Paediatr 2014)



(Hyttel-Sørensen et al. Biomed Opt Exp 2013)

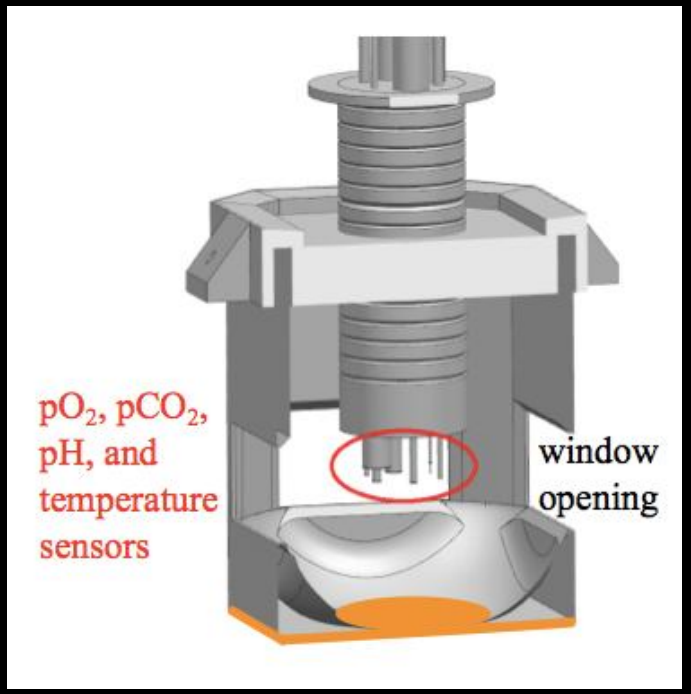


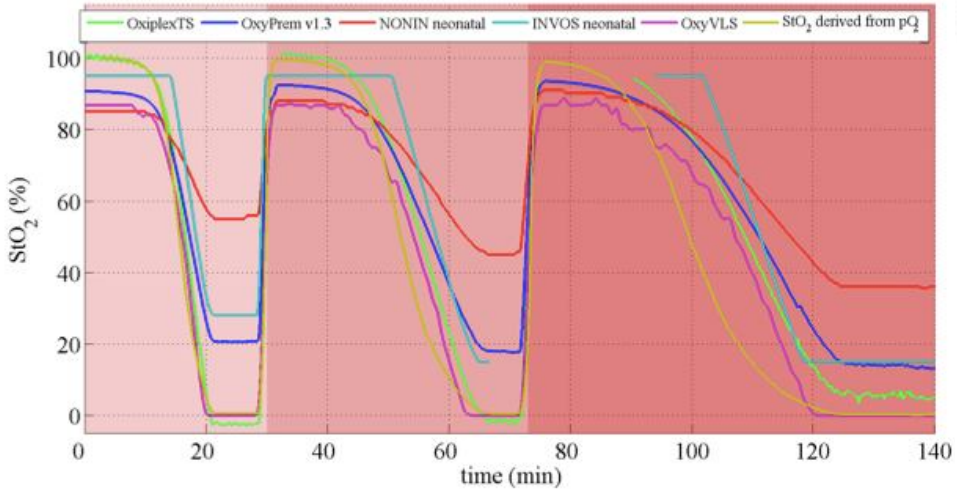


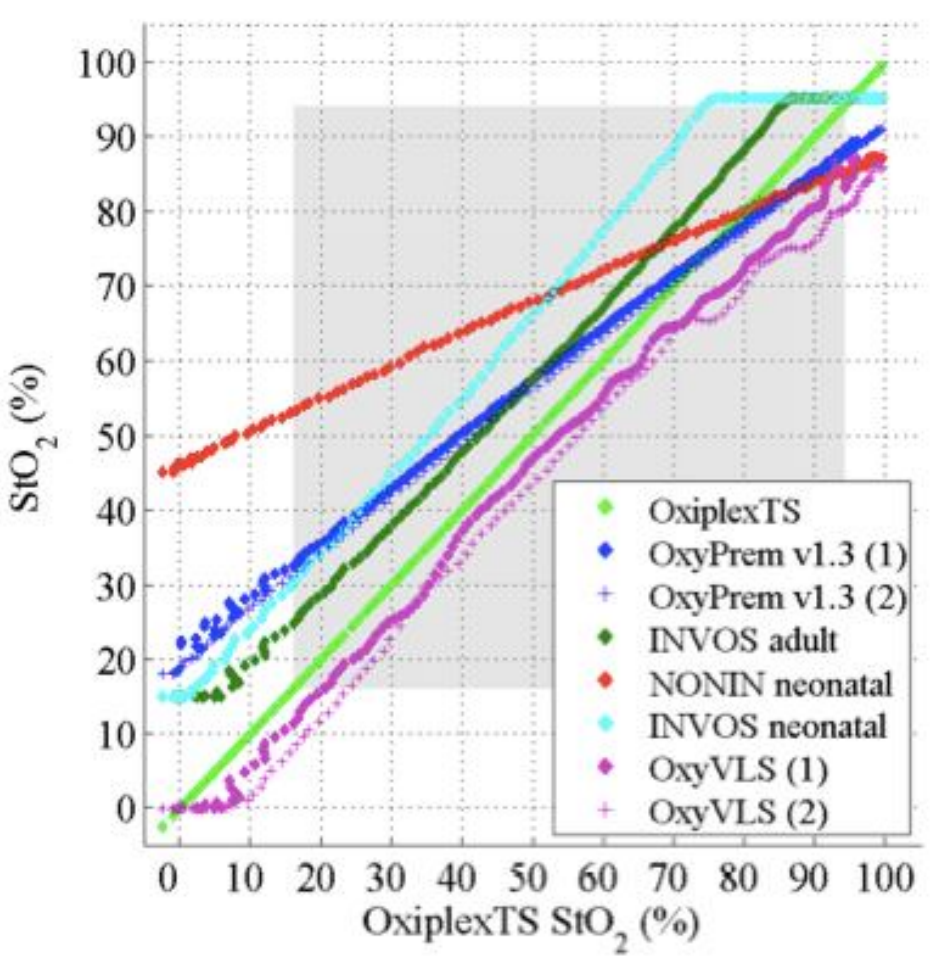


(Hyttel-Sørensen et al. Biomed Opt Exp 2013)

A better blood-lipid phantom

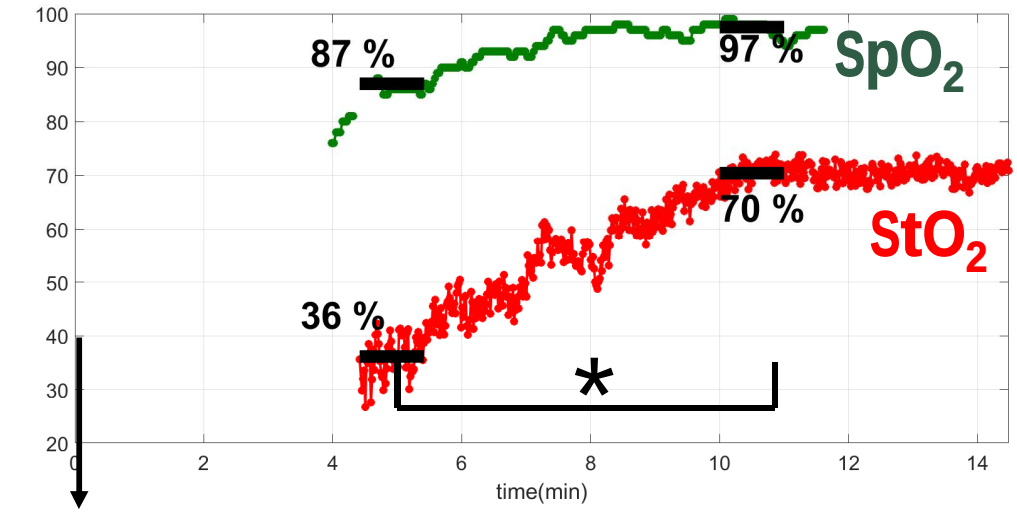






(Kleiser. Biomed Opt Expr 2016)

Oxygenation after birth



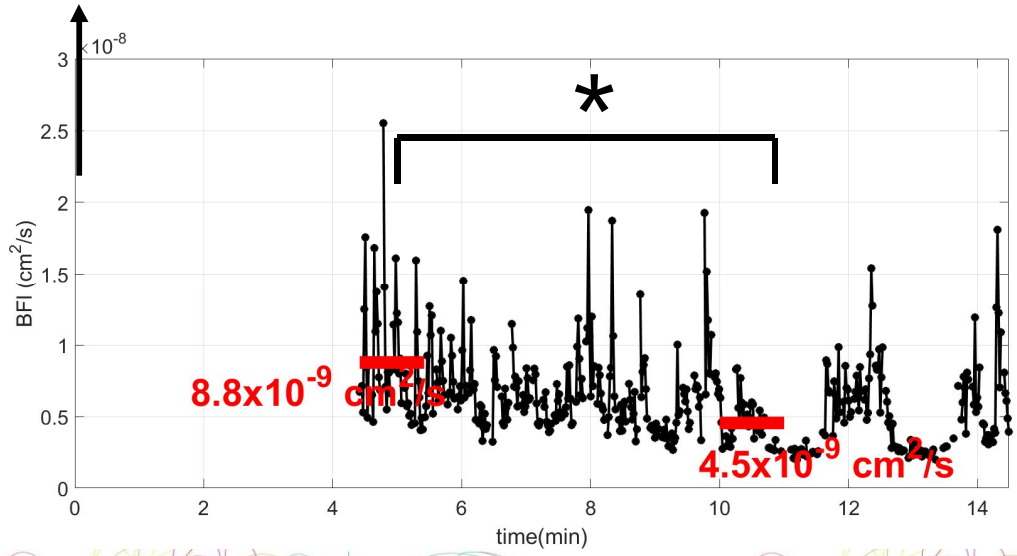
Time of birth

- **StO_2 increases**

Comparable to what was previously measured in literature [Pichler et al., (2013), *Journal of Pediatrics*.]

- **Cerebral blood flow CBF** (expressed as blood flow index BFI) **decreases**

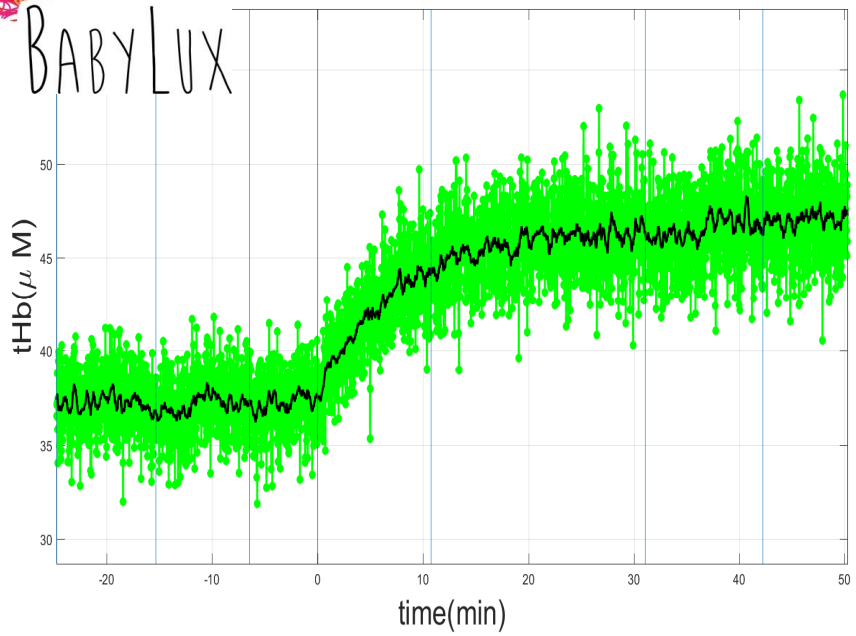
A decrease in CBF velocity reported in literature [Noori et al., (2012), *Journal of Pediatrics*]

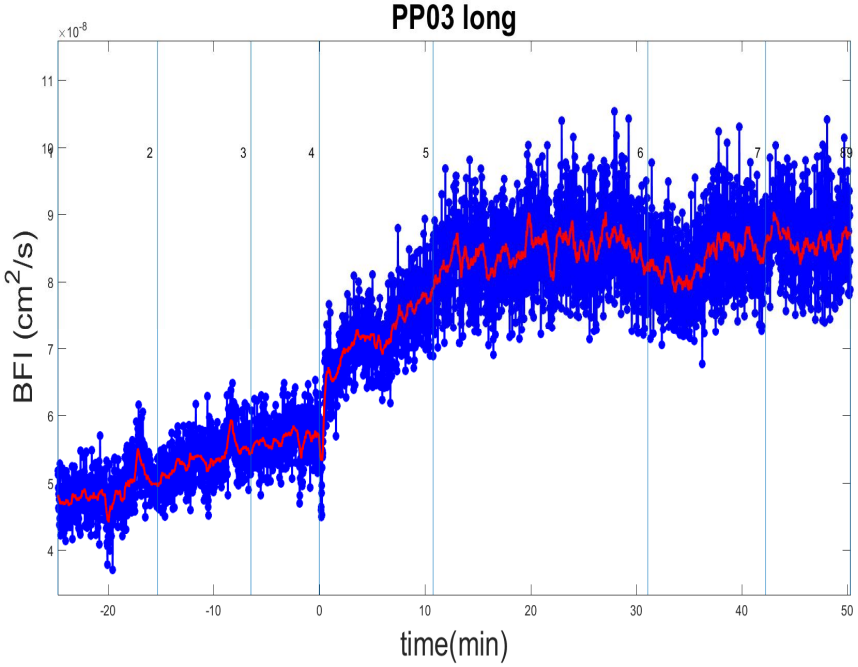


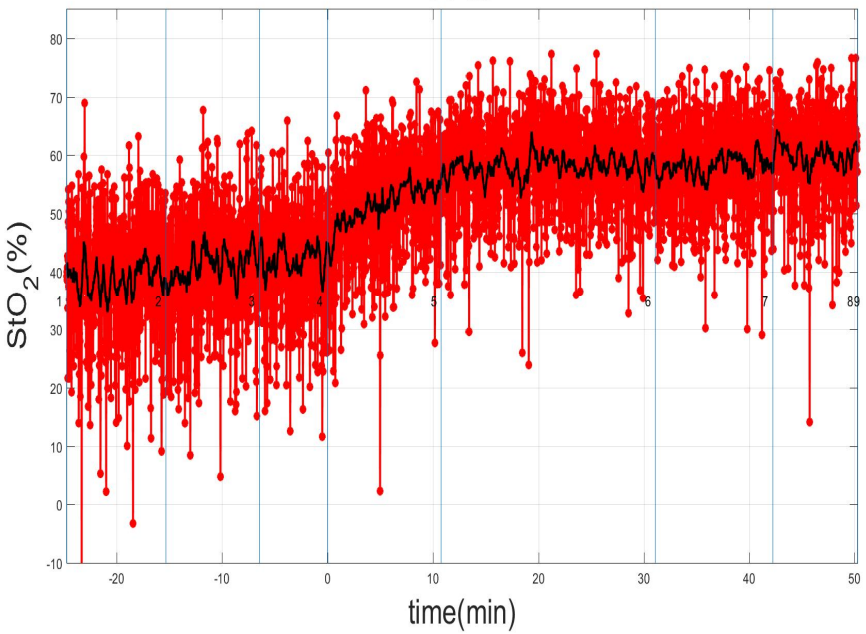
* Statistical significance

Acetazetamide injection in newborn pigs

BabyLux



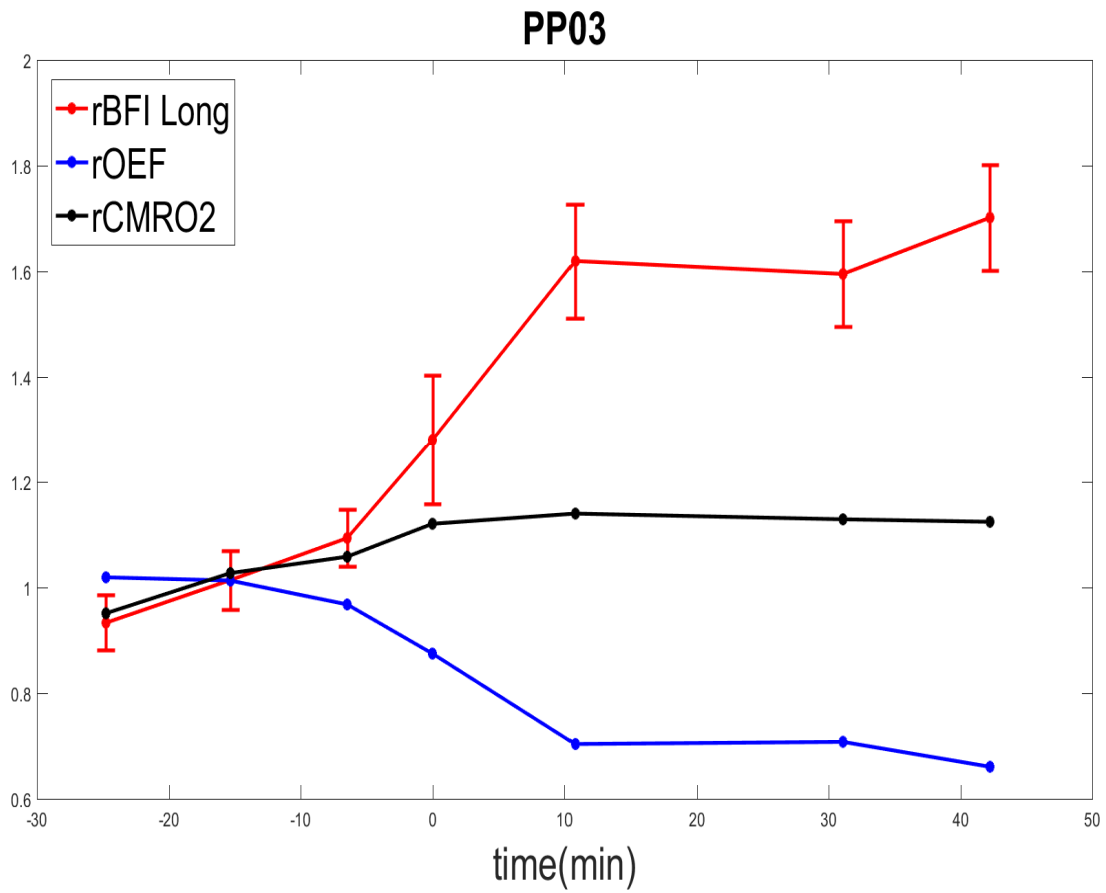




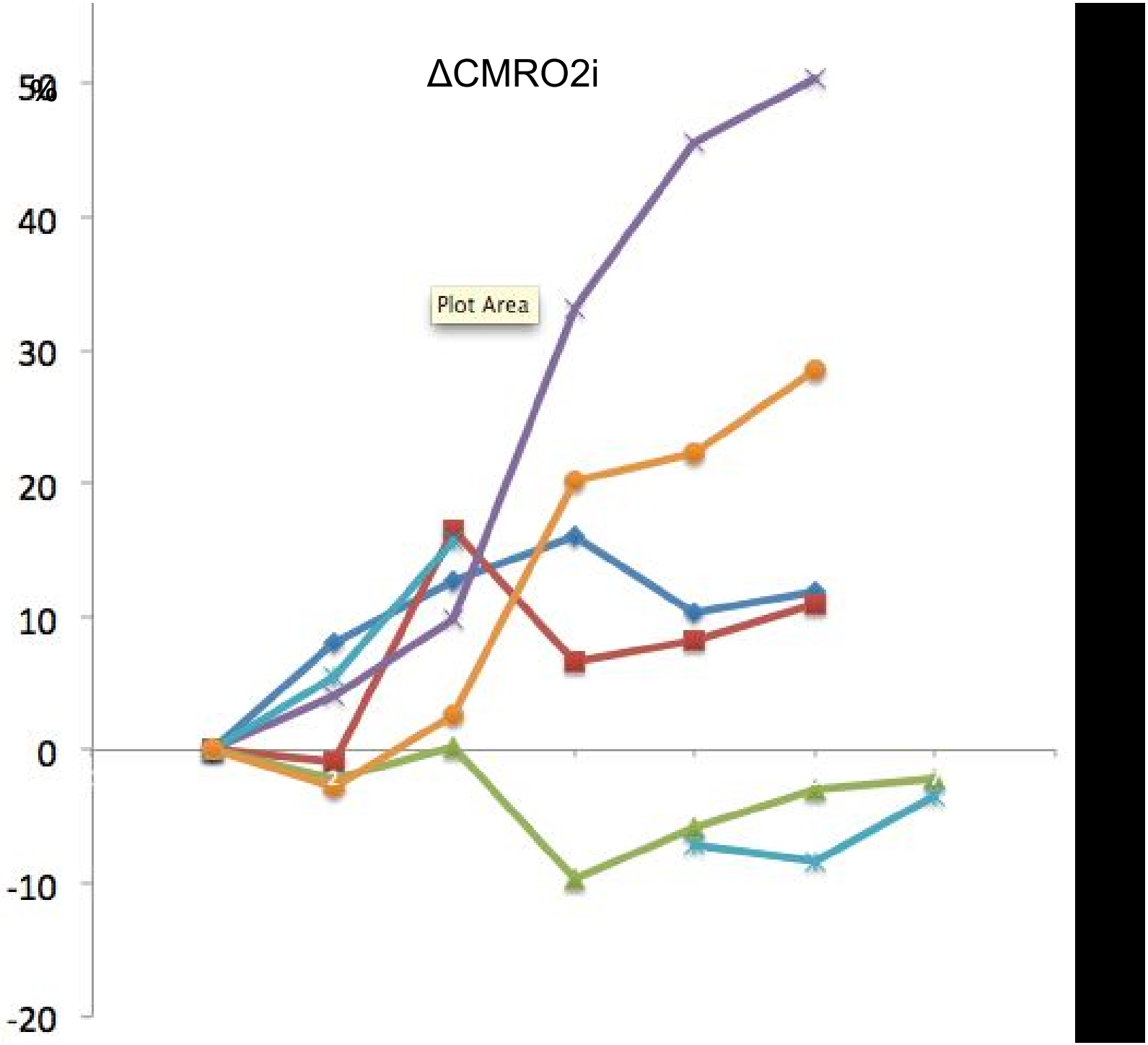
BabyLux

Cerebral metabolic rate of oxygen

Parameters calculated in the 3 minutes after each PET scan



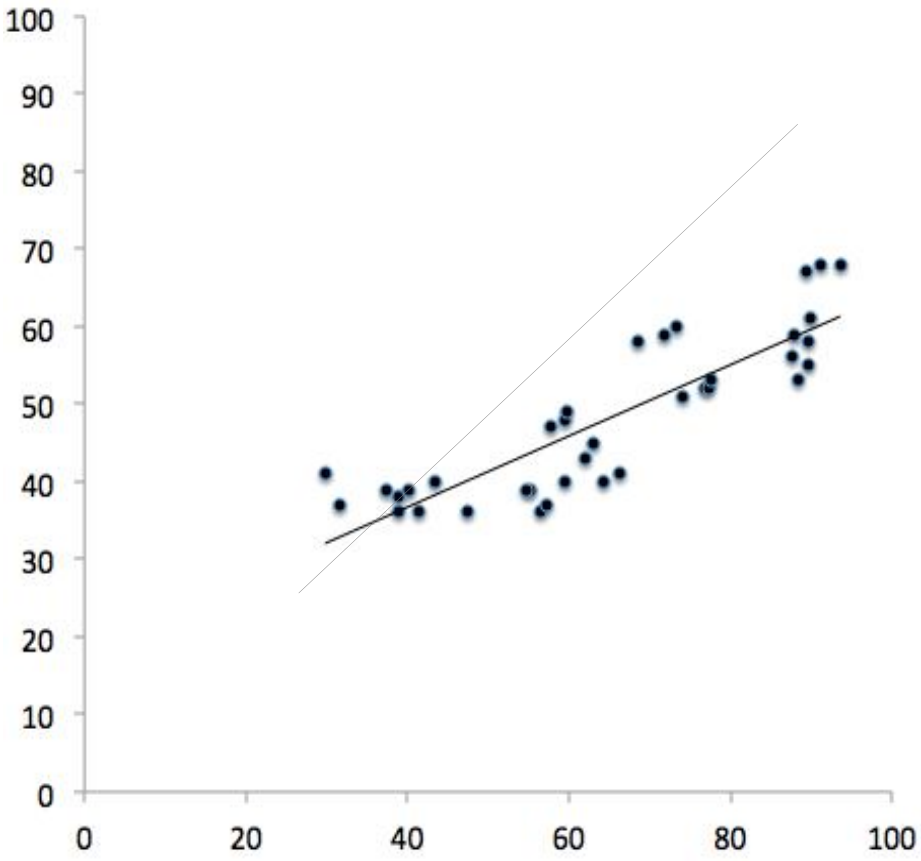
BabyLux



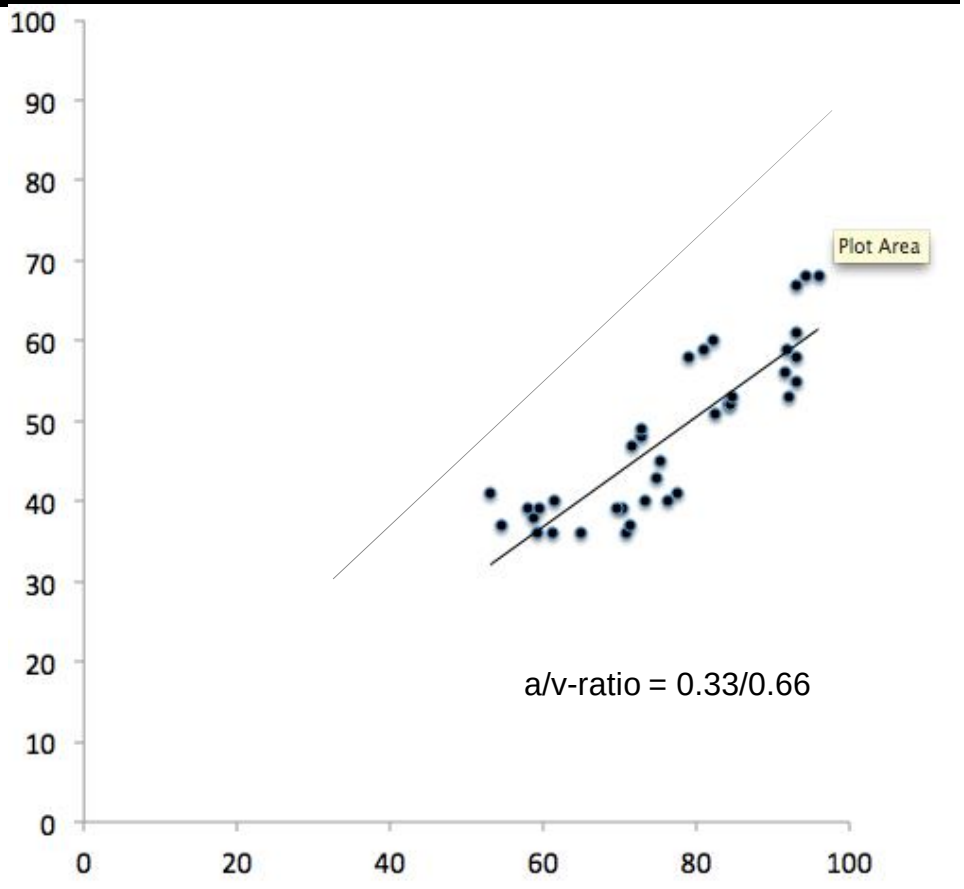
BabyLux

StO2 compared to co-oximetry on blood draw from veins and arteries

StO2 vs SvO2



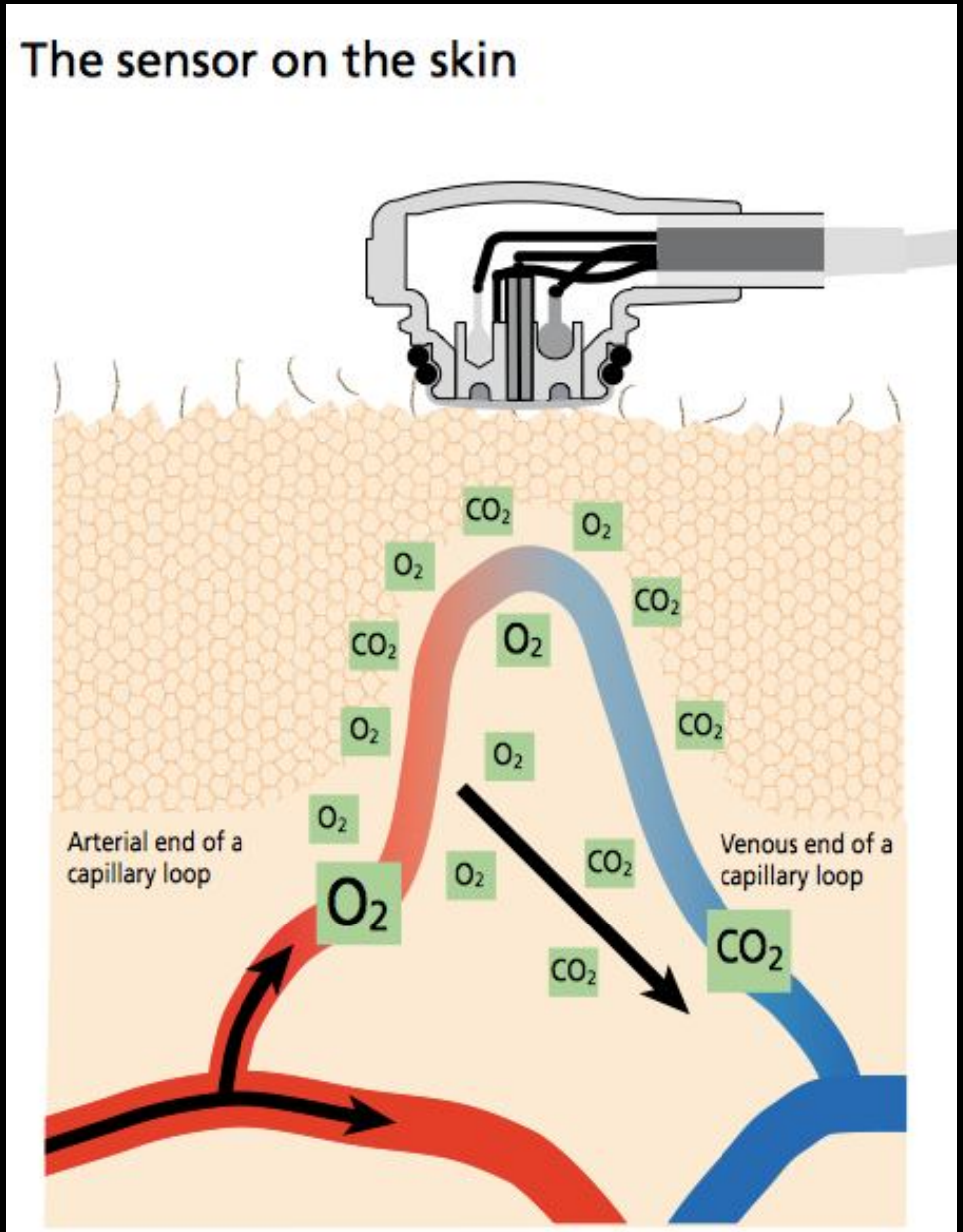
StO2 vs Sco-oxO2



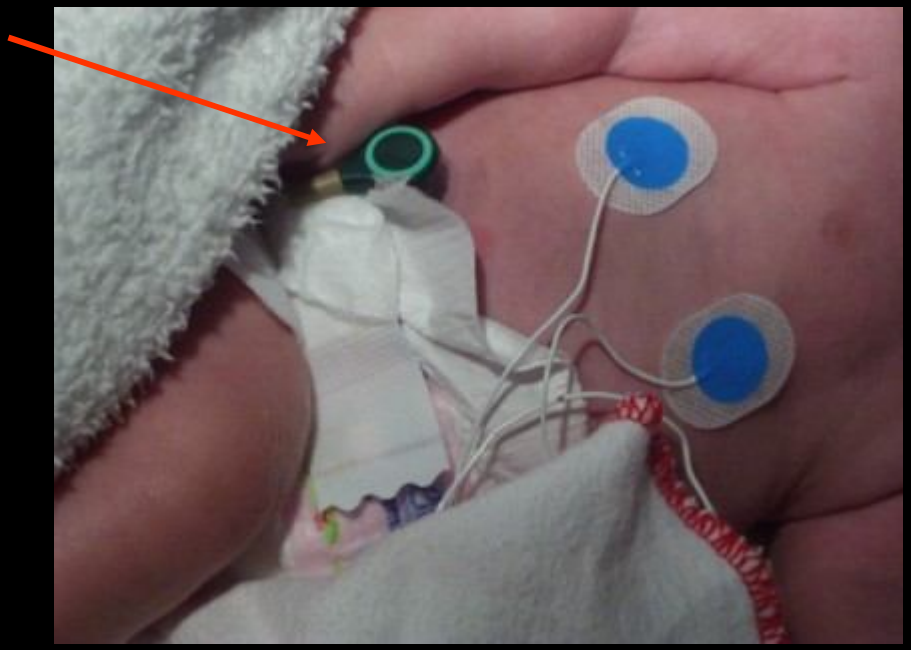
a/v-ratio = 0.33/0.66

User friendliness = clinically useful

Transcutaneous monitoring of pO2 og pCO2 – marginally clinically useful



30 years of refinement – and still not standard of practice



Challenges for BabyLux

- Eye safety
- Calibration
- Automated, real-time output
- Probe for monitoring
- Probe for ‘spot’ assessment

… the end