

# Addressing skin pigmentation bias in NIRS tissue oximetry

M. Lacerenza<sup>1,\*</sup>, V. Rossi<sup>2</sup>, S. Zanelli<sup>2</sup>, C. Amendola<sup>3</sup>, G. Sgarzi<sup>1,3</sup>, D. Contini<sup>3</sup>, M. Buttafava<sup>1</sup>, A. Torricelli<sup>3,4</sup>, L. Spinelli<sup>4</sup>, G. Zuccotti<sup>2,5</sup> and V. Calcaterra<sup>2,6</sup>

<sup>1</sup>PIONIRS s.r.l., Milano, Italy;

<sup>2</sup>Pediatric Department, Buzzi Children's Hospital, Milano, Italy;

<sup>3</sup>Dipartimento di Fisica, Politecnico di Milano, Milano, Italy;

<sup>4</sup>Istituto di Fotonica e Nanotecnologie, Consiglio Nazionale delle Ricerche, Milano, Italy;

<sup>5</sup>Department of Biomedical and Clinical Science, University of Milan, Milano, Italy;

<sup>6</sup>Pediatric and Adolescent Unit, Department of Internal Medicine, University of Pavia, Pavia, Italy.

\*mail: lacerenza@pionirs.com



## 1. INTRODUCTION:

The presence of melanin in human epidermis influences the optical properties in the first layer of probed tissues, affecting light absorption and possibly hindering the accuracy of NIRS measurements. Intrinsic features of the time-domain (TD) NIRS technique can potentially avoid these issues, enhancing the accuracy of oximetry readings across diverse skin pigmentation ranges.



INTERACT!

## 2. METHODS:

A three-fold approach was adopted to test the effect of skin pigmentation on TD-NIRS measurements:

1. Phantom measurements; 2. Static in-vivo measurements; 3. Dynamic in-vivo measurements. Acquisitions were performed using two research-grade commercial TD-NIRS oxymeters (NIRSBOX, PIONIRS s.r.l) with a compact optical probe having 2.5 cm S/D separation. Data analysis was based on the semi-infinite homogeneous modelling.

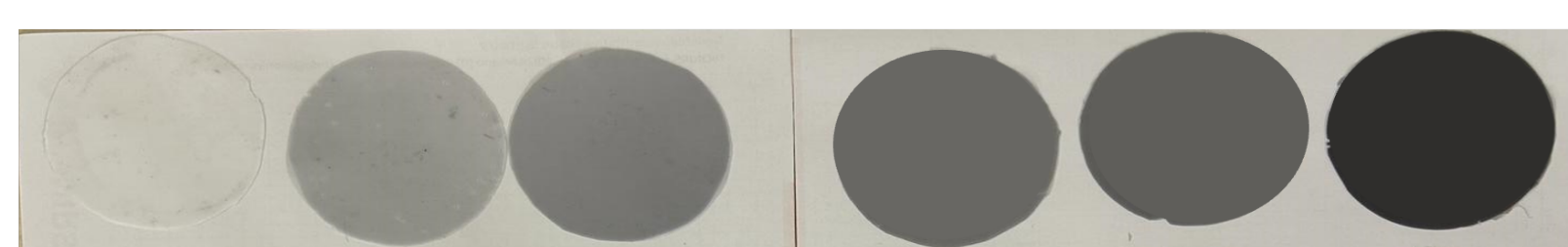
### 1.

A full set of silicone-based high optical fidelity skin mimicking phantoms was manufactured, encompassing the full range of melanosome (volume) fraction (Mf) in human skin. The effect on accuracy of different skin phantoms placed on a bulk homogeneous tissue mimicking phantom was assessed.

#### 6 Skin phantoms

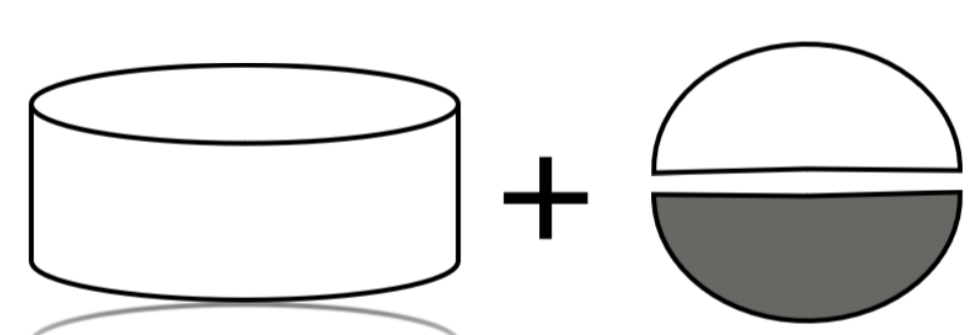
Thickness =  $0.27 \pm 0.01$  mm

$\mu_s' = 20$  cm<sup>-1</sup>



Mf	0%	2%	6%	14%	30%	43%
$\mu_a$ [cm <sup>-1</sup> ]	0	3.4	10.2	23.9	51.2	73.5

Experimental set up

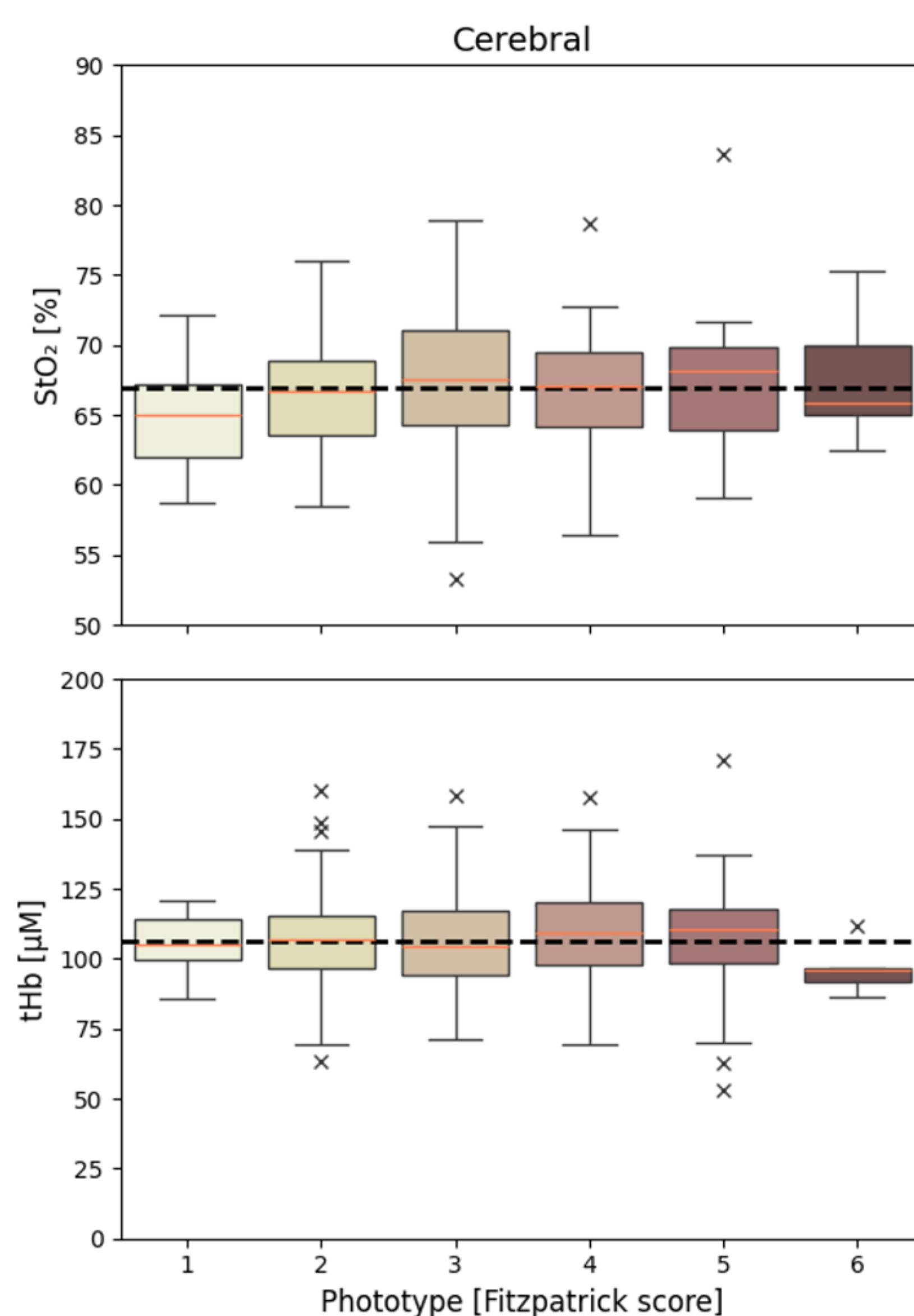


Human tissue mimicking substrate

Skin phantom pair

### 2.

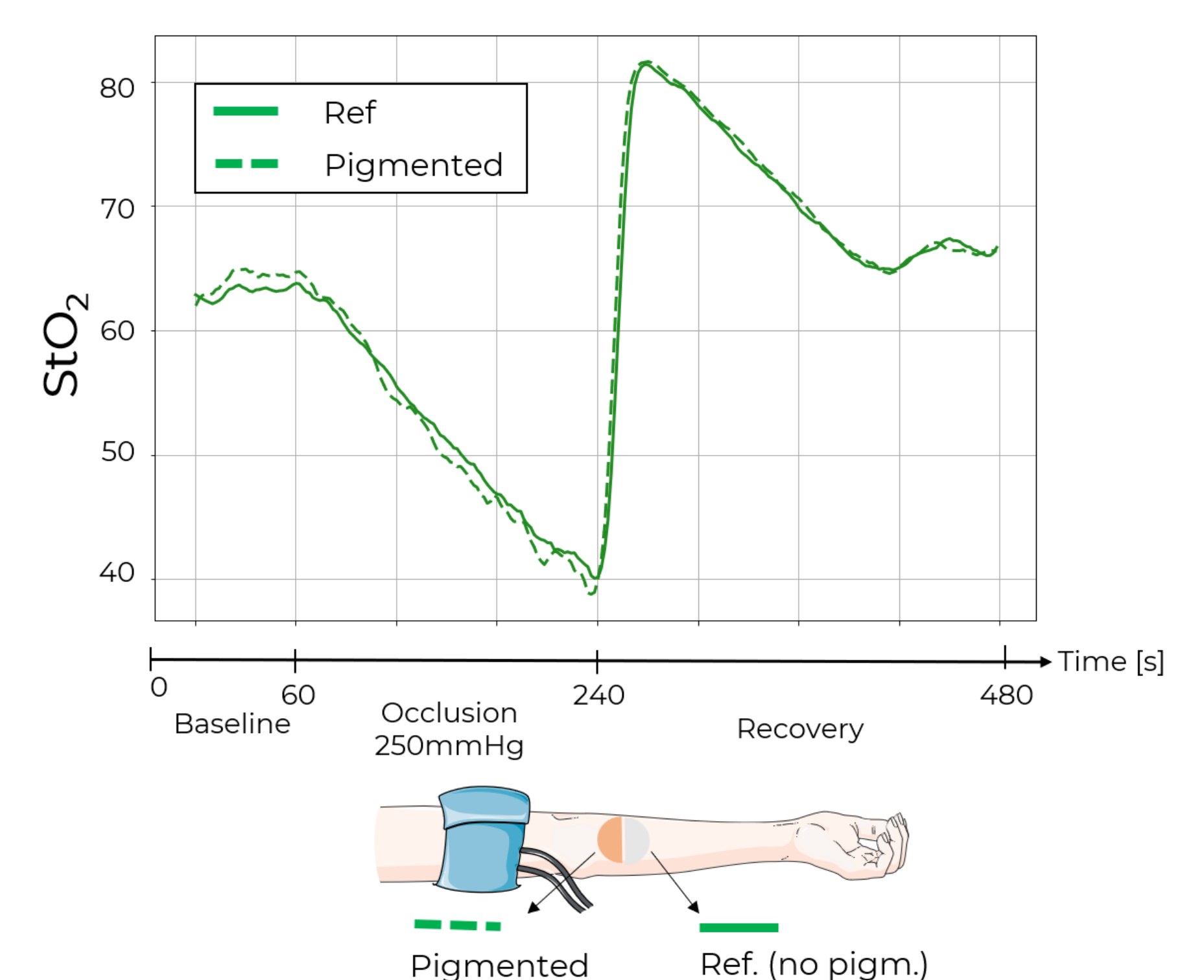
Cerebral tissue StO<sub>2</sub> and tHb were measured on the forehead of a large cohort (350+) of pediatric healthy subjects. Then, differences between skin pigmentation clusters (Fitzpatrick skin tone from 1 to 6) were evaluated.



### 3.

Forearm hemodynamic variations have been induced on six healthy subjects, through a vascular occlusion test (VOT). Artificial skin phantoms (0% Mf vs pigmented) have been placed in nearby locations between the optical probe and the forearm muscle. Realtime differences between parallel measurements were assessed, to investigate pigmentation induced biases.

Skin phantom pair over the arm	$\Delta$ Desaturation Slope [%/min]	$\Delta$ Reoxygenation Slope [%/min]	$\Delta$ AUC [% x min]
M <sub>f</sub> = 0% - M <sub>f</sub> = 2%	-0.5 (0.2)	-3.6 (11.2)	1.9 (1.3)
M <sub>f</sub> = 0% - M <sub>f</sub> = 14%	-0.5 (0.9)	3.2 (10.2)	1.1 (1.0)
M <sub>f</sub> = 0% - M <sub>f</sub> = 43%	-0.6 (0.9)	4.5 (12.8)	1.4 (0.6)
ANOVA p-value	0.97	0.49	0.42
ANOVA f-value	0.03	0.72	0.93



## 3. RESULTS:

Phantom measurements showed maximum deviations from bulk phantom nominal values lower than 1% for StO<sub>2</sub> and tHb values, across all combinations of pigmentation-mimicking phantoms. From the in-vivo campaign, the statistical analysis (one-way ANOVA) did not reveal significant differences within different clusters for both tHb and StO<sub>2</sub> values. Also, StO<sub>2</sub> dynamic variations (difference from the reference, i.e. the non-pigmented phantom), have been found to be lower than 1% on average, regardless the pigmentation level and the StO<sub>2</sub> reference value itself.