Continuous Monitoring of Physiology and Vital Signs with Photoplethysmography

Mathieu LEMAY

Signal Processing and AI Group Leader

CSEM S.A.

Agenda

1. CSEM at a glance
2. The long journey of photoplethysmography
3. Cardiac monitoring
4. Sleep monitoring
5. Blood pressure monitoring
6. Open question(s)

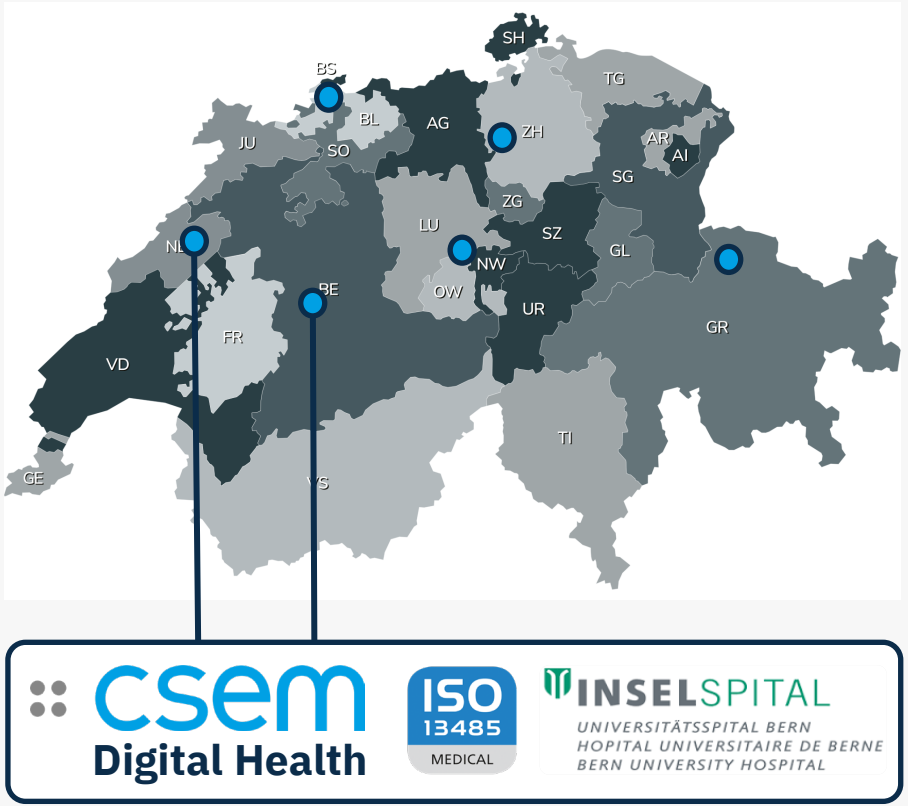
csem at a glance

CSEM is a public-private, non-profit, **Swiss technology innovation center**.

We enable competitiveness through innovation by developing and transferring world-class technologies to industry

1984
FOUNDED

> 560
SPECIALISTS

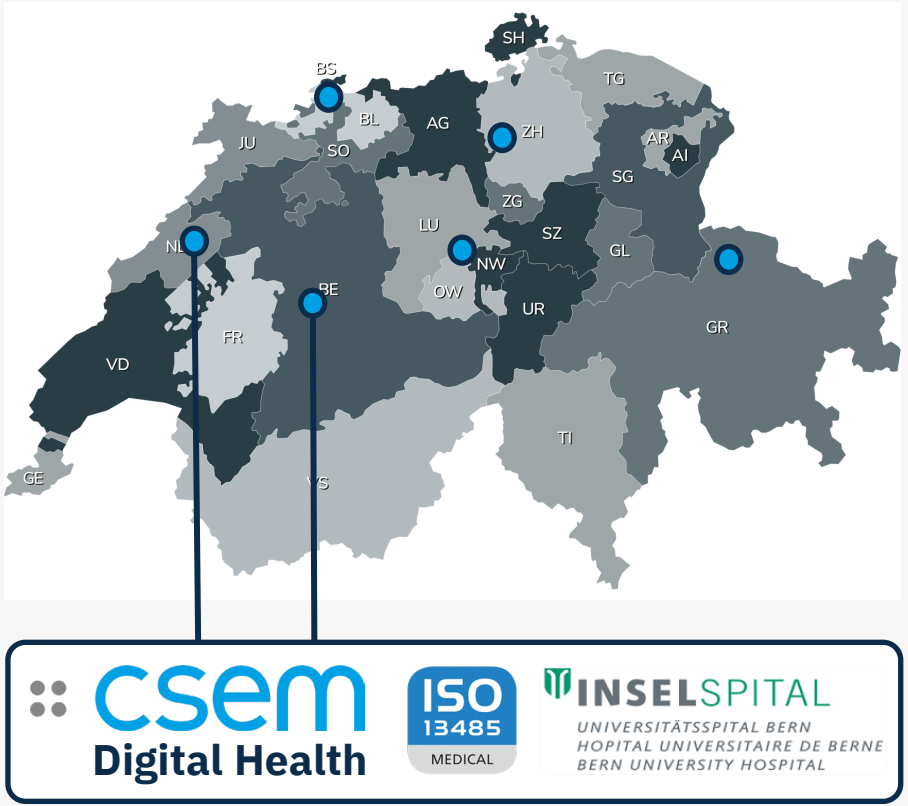


csem at a glance

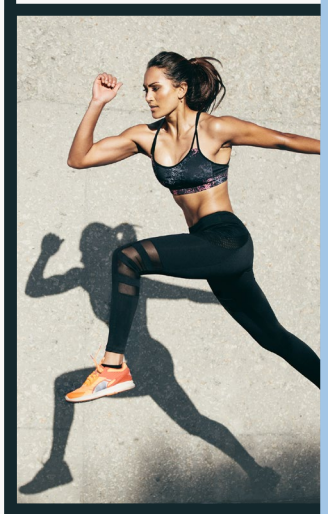
Digital health

Track record of +20 years in **consumer health** and **medical devices** to strengthen competitivity through:

- Patented sensor technologies and algorithm portfolio
- ISO-13485 certification (since 2014)
- Multi-disciplinary integrated teams
- Located on the University Hospital Campus in Bern

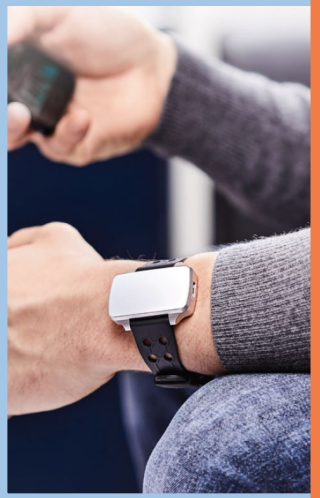


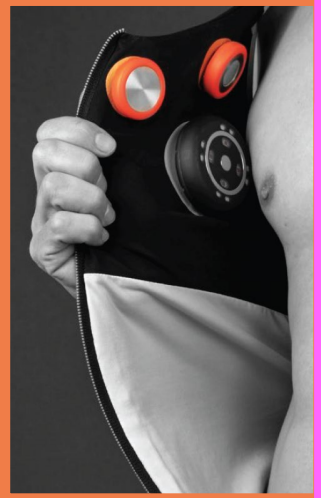
Technology pillars and knowhow



Movement analysis

Optics (PPG)





ExG

Data science

Medical development & validation

The long journey of photoplethysmography

ADDS 2024

Photoplethysmography (PPG) @ csem

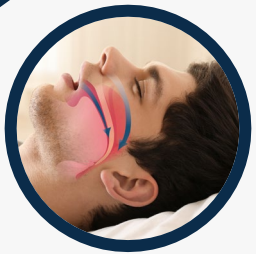
Heart rate

First CSEM patent on PPG in 2001

AFE control, **IBI**, quality index, min. requirements, ...

Respiratory disorders

SpO2, respiration



oAFD®

Cardiac arrhythmia detection & classification

oBPM®

Continuous, cuff-less blood pressure

Photoplethysmography (PPG) @ csem

AFE control, **IBI**,
quality index,
min. requirements, ...

inside Actigraph's LEAP™

Heart rate

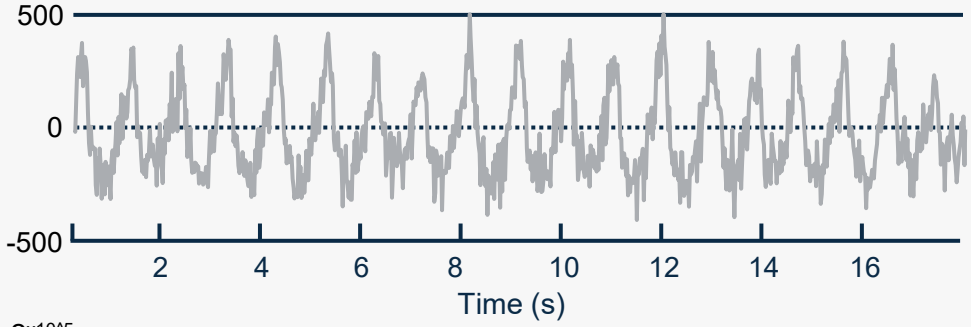
First CSEM patent on PPG in 2001

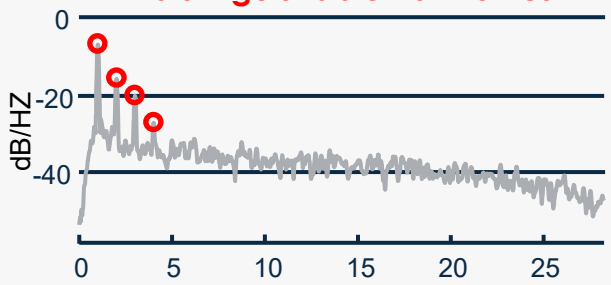
Cardiac monitoring

ADDS 2024

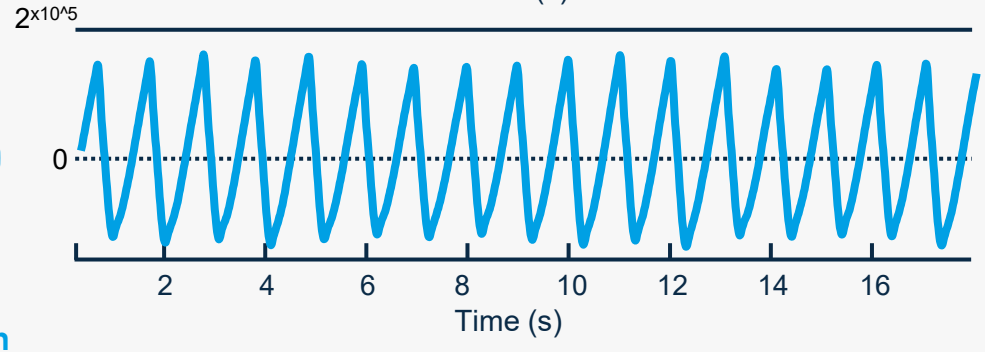
PPG high-quality signals

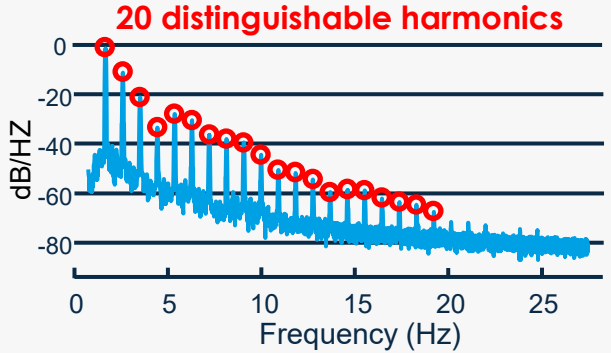
Commercial PPG solutions





CSEM PPG reference design





Optical heart rate monitoring - performance on the wrist

Overall dataset acquired with CSEM proprietary devices:
629.7 hours of wrist PPG (HIGH QUALITY) & accelerometer data with ECG reference from 391 subjects

	Lab[1]	Outdoor[1]	Sleep	Daily activities
Number of subjects	87	146	117[2]	41[3]
Total duration (hours)	56.9	74.1	455.2	43.5
Mean error (bpm; μ ± σ)	0.6 ± 1.7	0.5 ± 4.7	0.5 ± 0.7	0.6 ± 1.9
MAE (bpm; μ ± σ)	3.0 ± 1.6	3.8 ± 4.4	1.7 ± 0.9	3.3 ± 2.2
MAPE (%; μ ± σ)	2.9 ± 1.5	3.1 ± 3.6	3.0 ± 2.4	5.8 ± 7.3
RMSE (bpm; μ ± σ)	5.0 ± 2.9	5.5 ± 5.8	4.1 ± 4.5	4.9 ± 3.5
Reliability (%<10 bpm; μ ± σ)	94.9 ± 5.4	92.1 ± 16.1	97.9 ± 2.1	92.9 ± 9.2

[1] Mainly includes walking, running, biking, VO2max tests
[2] Includes 63 patients with sleep disorders
[3] Includes 12 patients with atrial fibrillation

μ ± σ stands for **average ± standard deviation**

Heart rate tracking with LEAP™

Reference:

Protocol:

- 3 min of rest
- 3 min of typing
- 3 min of walking
- 3 min of running on treadmill

Population:

- Fitzpatrick I to VI

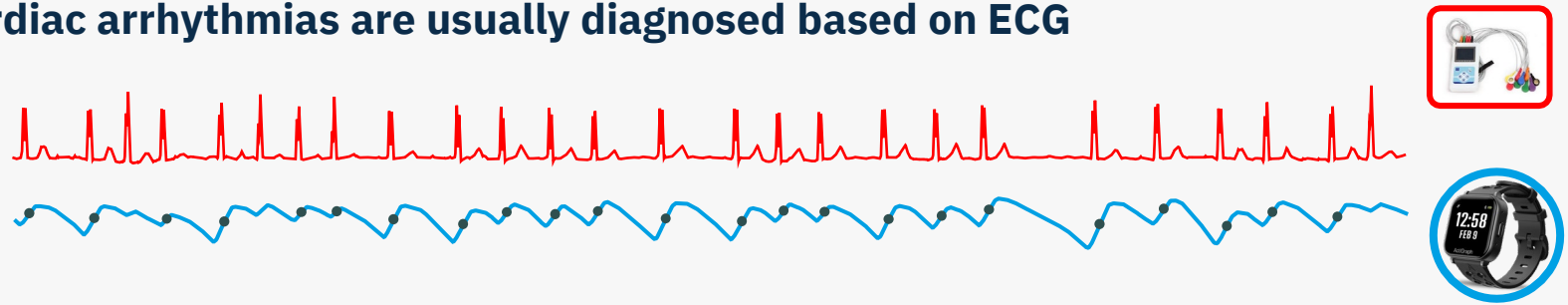
Performance:

body location	MAE (bpm)	P5 (%)	P10 (%)
@upper arm	2.1	91	98
@wrist	2.9	85	95

LEAP adjusts light intensity based on skin color

Cardiac arrhythmia detection with PPG

Cardiac arrhythmias are usually diagnosed based on ECG



Watch-based atrial fibrillation detection (n=772)

Metric	CSEM watch	FibriCheck	AliveCor
Accuracy	**99.6%**		
Sensitivity	**100%**	95.6%	94.1%
Specificity	**97.8%**	96.6%	97.5%

… other cardiac arrhythmia detection

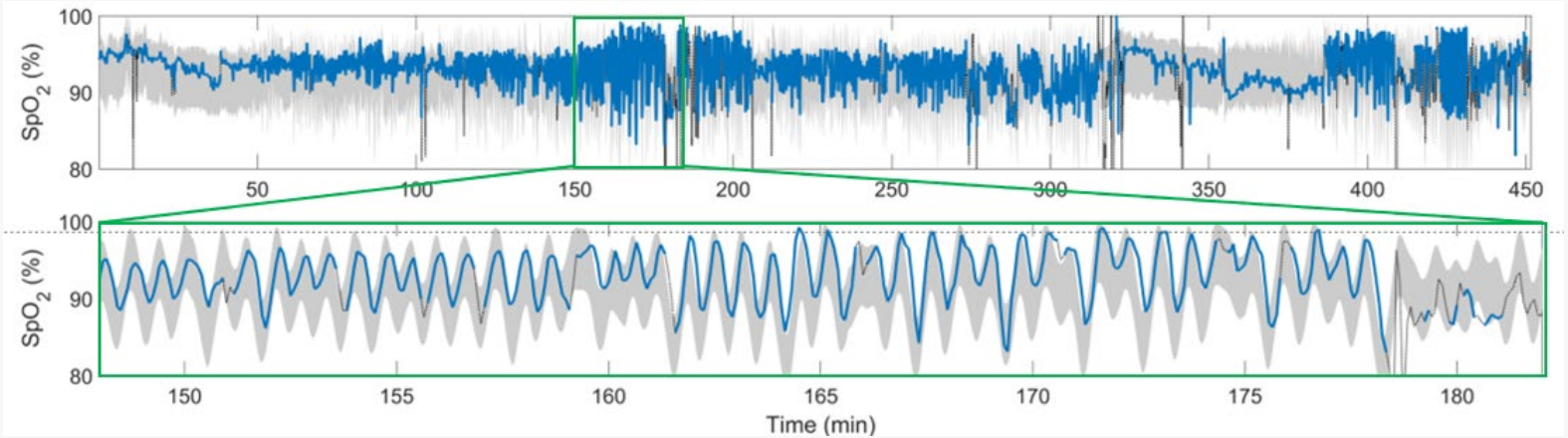
Atrial tachycardia (n=136)	Accuracy of **100.0%**
AV reentrant tachycardia (n=36)	**96.4%**
AV block (n=41)	**93.1%**
Ventricular tachycardia (n=292)	**80.2%**

Sleep monitoring

ADDS 2024

Towards the Unobtrusive Detection of Sleep Apnea

- **RR-intervals:** 6.5 ± 5.4 milliseconds
- **Respiratory rate:** 1.6 ± 1.0 breaths/min
- **Oxygen saturation (SpO2):** 2.5%*†



*Compliant ISO 80601-2-61:2017 (A_{RMS}≤4.0%)
†Compliant with FDA guidance for reflectance SpO2 (A_{RMS}≤3.5%)

Clinical validation of SpO2: Measurement locations

Measurement Location	Subjects	A_{RMS} Error	Data Acceptance	Clinical Trial	Publication
Upper-arm	9 sleep apnea patients	1.8% *†	81%	BASEC Nr- 2019-00450	EMBC2021
Wrist		2.5% *†	75%		
Wrist	27 healthy 39 patients	3.2% *†	84%	NCT03823105	DGSM2020 EMBC2020
Forehead	25 newborns ICU	3.9% *	88%	BASEC Nr. 2016-00720	EMBC2018
Forehead	8 healthy	1.9% *†	99%	-	
Shoulder		3.1% *†	70%	-	
Ear	16 healthy	2.9% *†	23%	NCT02723032	Sensors2020
Ear	20 patients	2.5% *†	53%		
Chest	10 heatlhy	2.7% *†	63%	CER-VD 268/13	EMBC2015

*Compliant ISO 80601-2-61:2017 (A_{RMS}≤4.0%)
†Compliant with FDA guidance for reflectance SpO2 (A_{RMS}≤3.5%)

Sleep staging with different models

time resolution: sample

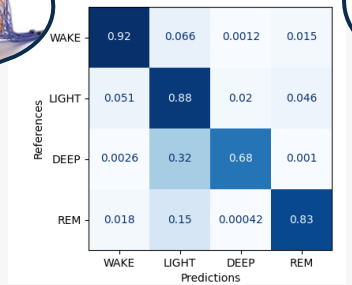
Sleep-wake classification (n=18 healthy + 15 sleep disorders)

Accuracy: 90.0%, Specificity 97.5%, Sensitivity: 43.3%

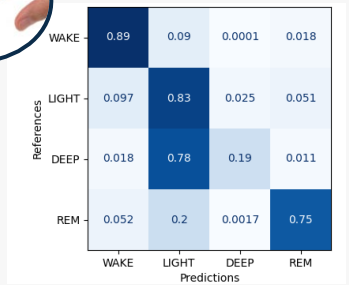
in comparison with Philips[1] (n=49)

Accuracy: 91.8%, Specificity 97.1%, Sensitivity: 45.5%

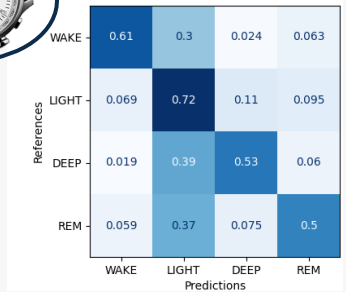
[2]



Accuracy: 88.0%
(Sleep-EDF, n=153)



Accuracy: 80.8%
(MESA, n=1698)



Accuracy: 63.4%
(n=66)

time resolution: 8.5 minutes

[1] P. Fonseca *et al.*, *Sleep*, vol. 40, no. 7, Jul. 2017.
[2] E. Türetken *et al.*, *IEEE SDS*, 2019, pp. 95-96.

Sleep staging with different models

time resolution: sample

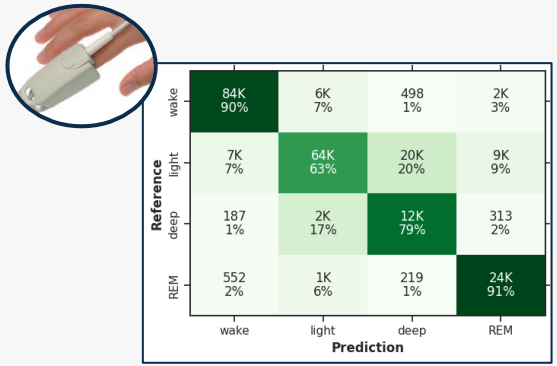
Sleep-wake classification (n=18 healthy + 15 sleep disorders)

Accuracy: 90.0%, Specificity 97.5%, Sensitivity: 43.3%

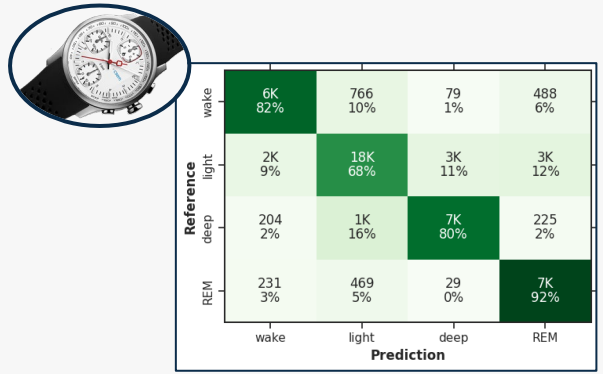
in comparison with Philips[1] (n=49)

Accuracy: 91.8%, Specificity 97.1%, Sensitivity: 45.5%

[2]
[3]



Accuracy: 78.6%
(MESA, n=1698)



Accuracy: 78.1%
(n=66)

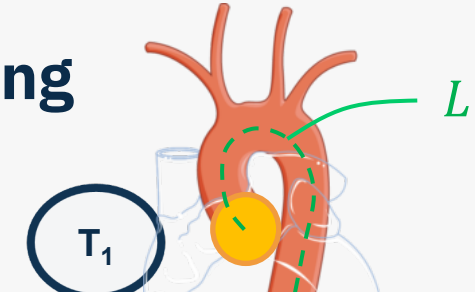
time resolution: >10 hours

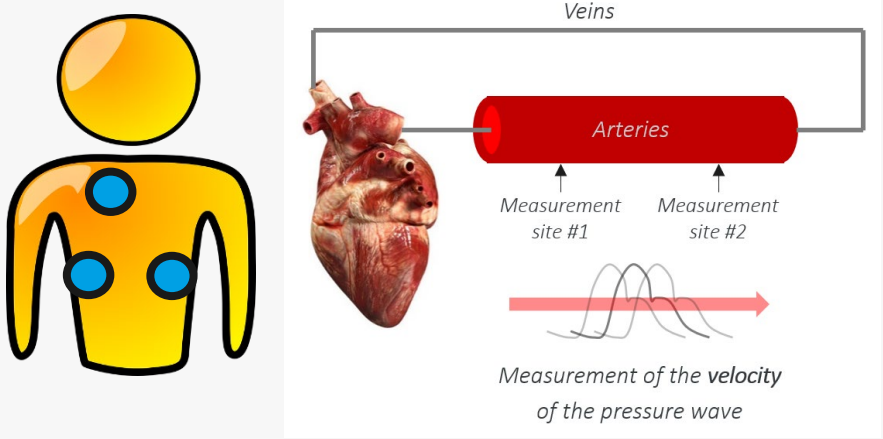
[1] P. Fonseca *et al.*, *Sleep*, vol. 40, no. 7, Jul. 2017.
[2] E. Türetken *et al.*, *IEEE SDS*, 2019, pp. 95-96.
[3] K. Kotzen *et al.*, SleepPPG-Net, *IEEE JBHI*, 2022, pp. 1-8.

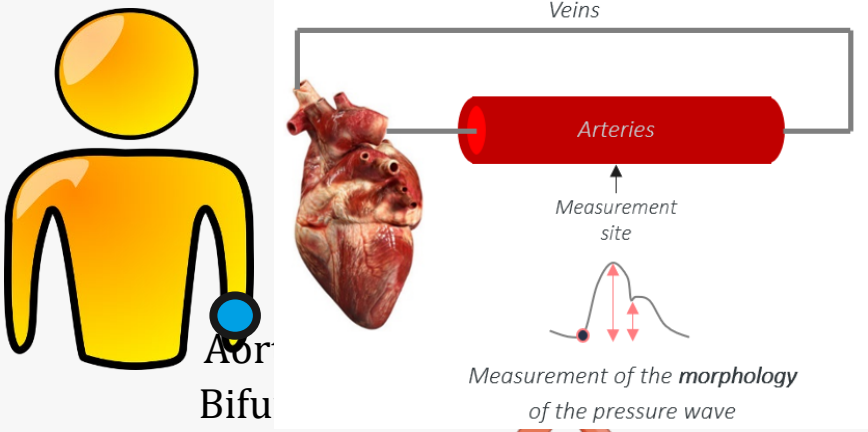
Blood pressure

ADDS 2024

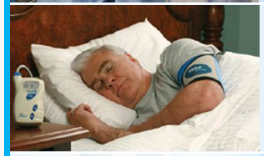
PPG-based technologies for BP monitoring







Clinical validation of optical BP technology

Use Cases		Datasets	Performance	Publication / Clinical Trial / Industry
	**Clinical Settings**	**1912** patients Radial catheter reference	CR ~ 94-100% SD: ~10-13 mmHg (SBP); ~ 6-8 mmHg (MBP); ~ 5-6 mmHg (DBP)	Ghamri2020, Aguet2021, Hofmann2022, **NCT02651558**, **NCT03875248**, **NCT02914444**, **NCT03710473**
	**24-hour Ambulatory Monitoring**	**120** patients Oscillometric cuff reference	CR = 98.5% SD: ~ 6-9 mmHg (SBP); ~ 5-7 mmHg (MBP); ~ 4-5 mmHg (DBP)	Proença2023, Vischer2022, **NCT04119518, NCT04461834**
	**Hypertension Management**	**104** patients Auscultatory meas. & Oscillometric cuff references	ISO 81060-2 compliance in clinics; 3-month stability in healthy subjects	Proença2019, Degott2021, **NCT03875248**
	**In-lab Research**	**>200** subjects Oscillometric cuff reference	CR > 95% SD variable, protocol-dependent	(internal/confidential)

ONWARD EMPOWERING MOVEMENT

AKTiiA

biospectal

ADDS 2024

Open questions?

Thank You for Your Time.

mathieu.lemay@csem.ch

@linkedin.com/in/mathieu-lemay-221855a