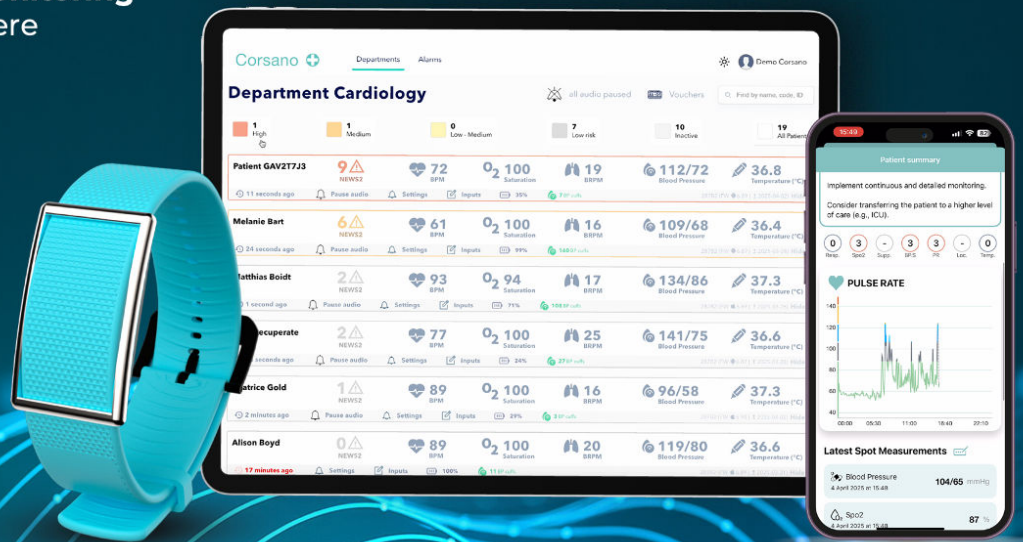




Continuous Patient Monitoring
Anytime, Anywhere



White Paper

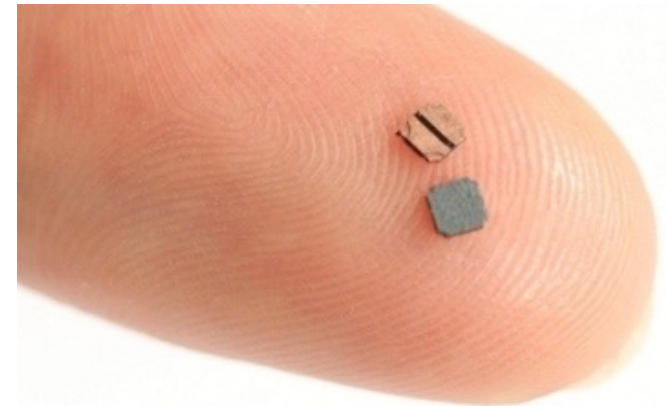
Core Body Temperature

Explanation

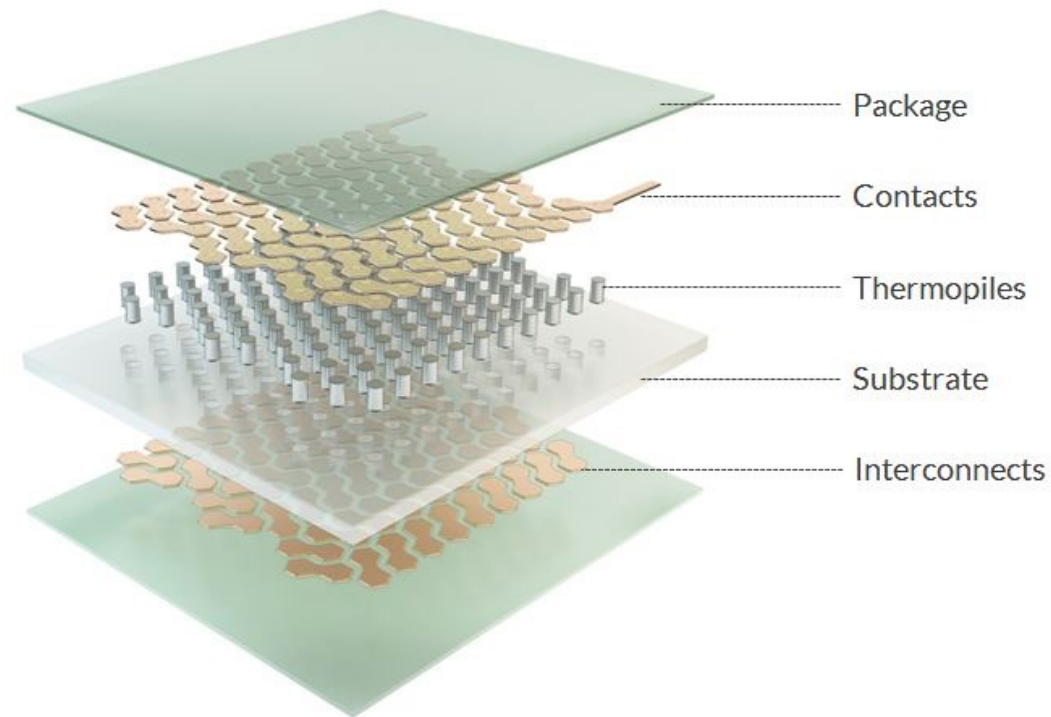




CardioWatch 287-2



Heat Flux Sensor



- Heat Flux is the rate of heat energy that passes through a surface
- Its unit is expressed as W/m^2 , originating from from temperature differences in a system

CBT Algorithm Type	Wrist (fever)
Description	Medical grade wrist core body temperature algorithm.
Data streams	T, HF, HR
Data stream update rate	T, HF, Acc: 1 Hz HR: 1 per minute
Accuracy: MAE/Bias/95% LoA*/Corr	0.29/0.14/0.68/0.76
Environmental temperature	< 35 °C, > 5 °C
Comments	Not suitable for heat stroke, clinical hypothermia, cold fever, persons with thermoregulatory problems, direct sun exposure

Study description:

This study investigates the feasibility of continuous fever tracking of participants having fever symptoms in a home setting, using wearable body temperature sensors. Body temperature as measured by the wearable sensors will be compared with body temperature as measured by ingestible electronic pills (reference).

Goal:

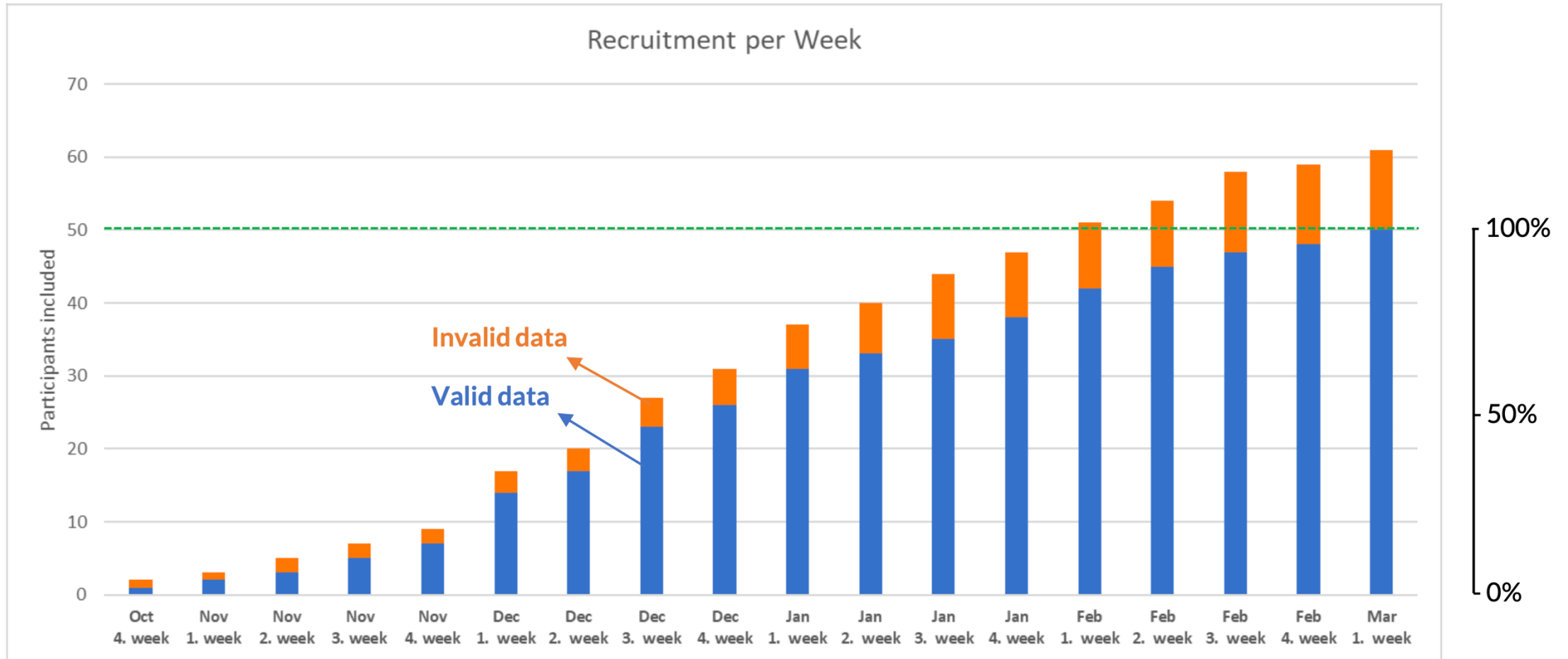
To build a machine learning algorithm which predicts body temperature from skin-based signals, and to compare the predicted temperature with the reference temperature. Endpoints are the mean absolute error, bias and standard deviation of this comparison.

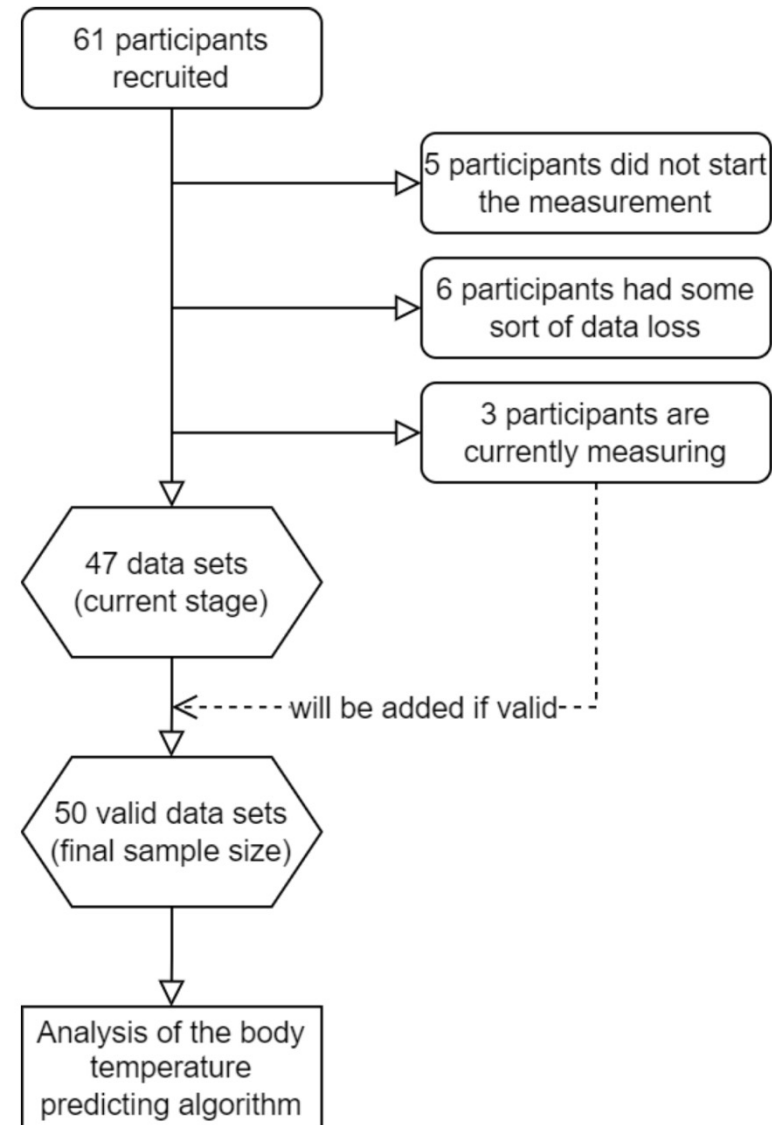
BodyCap e-Celsius ingestible CE
Certified connected pill that monitors
the body's core temperature.



Final number of participants:
N = 50 (~24h continuous on-body data)

Wrist Fever Tracking Study

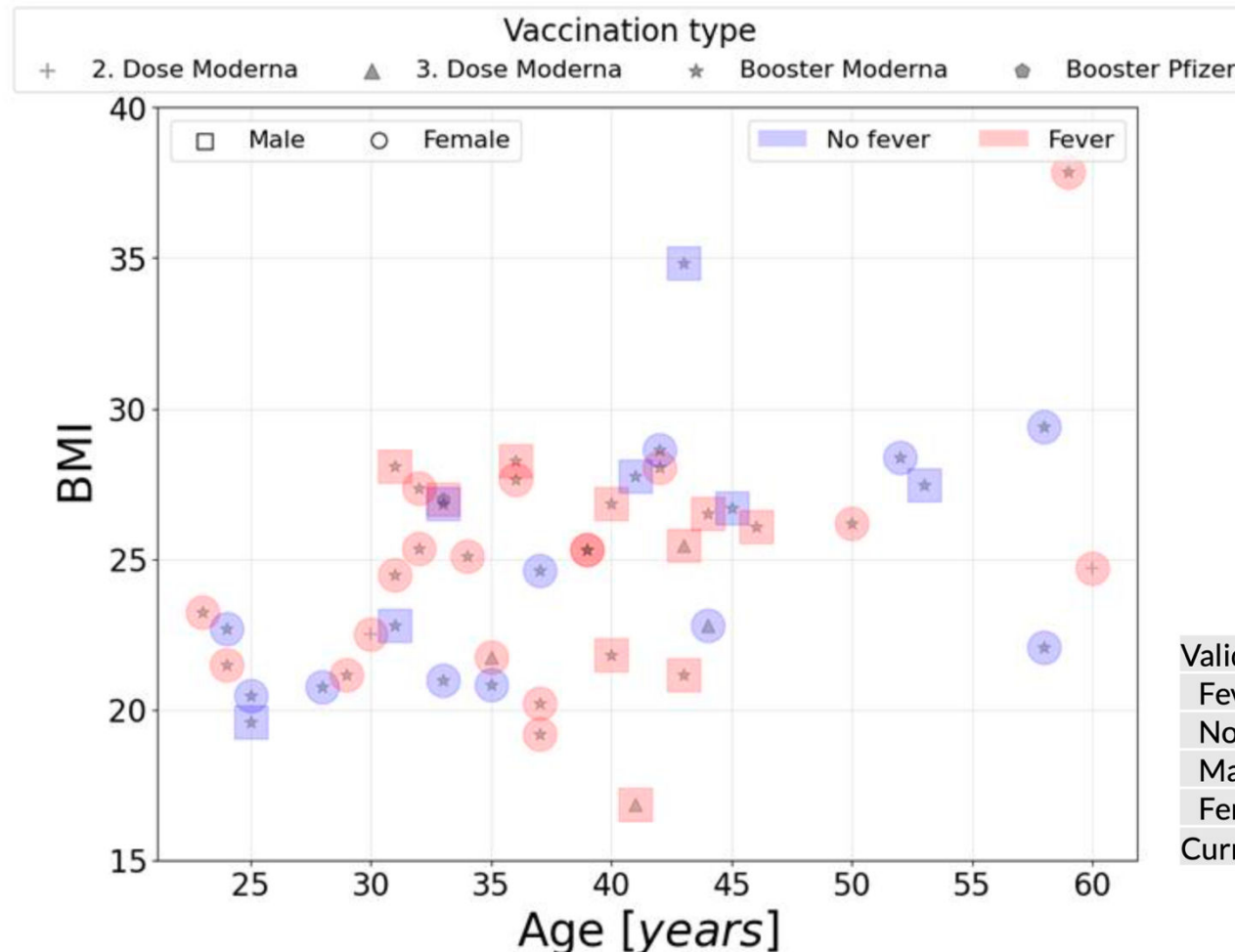




Etienne S, Oliveras R, Schiboni G, et al. *Free-living core body temperature monitoring using a wrist-worn sensor after COVID-19 booster vaccination: a pilot study*. BioMedical Engineering OnLine, 2023;22:25. DOI 10.1186/s12938-023-01081-3 (PubMed 36915134, PMC10010220).

Participants Demography

Participant summary and demographic data of current 47 valid data sets



Valid Datasets	47
Fever	26
No Fever	21
Male	18
Female	29
Currently measuring	3

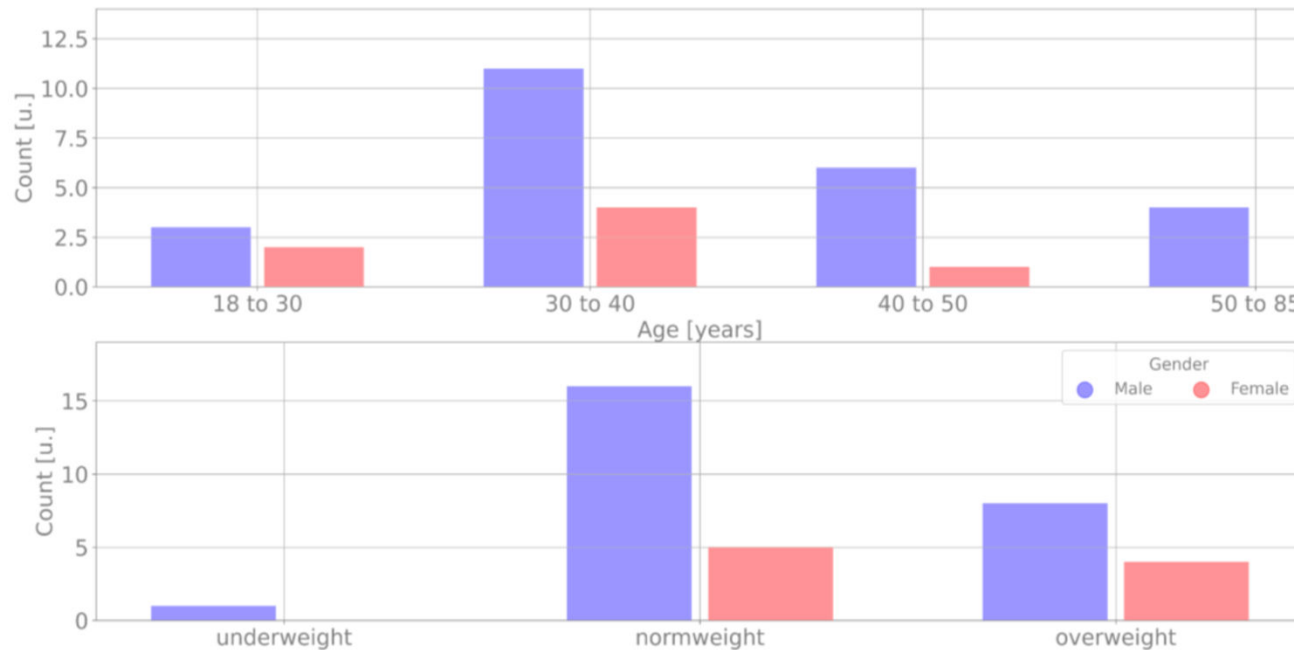
Inclusion criteria:

- Signed informed consent
- 18-60 years of age

Exclusion criteria:

- Cannot follow study instructions
- Gastrointestinal disease
- Previous surgery in the gastrointestinal system
- Problems to swallow (pills)
- Allergies on plastic and latex
- Bodyweight < 40 kg
- An MRI examination up to 7 days after inclusion
- Impairments
 - Wounds where the sensors are applied
 - Amputations
 - Intravenous access
 - Dialysis-Shunt
 - Edema
 - Axillary lymph node resection
 - 24-h RR-measurement
 - Tattoos

Training a holistic model, using “healthy” and “vaccination” free-living measurements, previously optimized using hyperparameter search and leave-one-participant-out cross-validation, i.e. a data batch never used in any study.

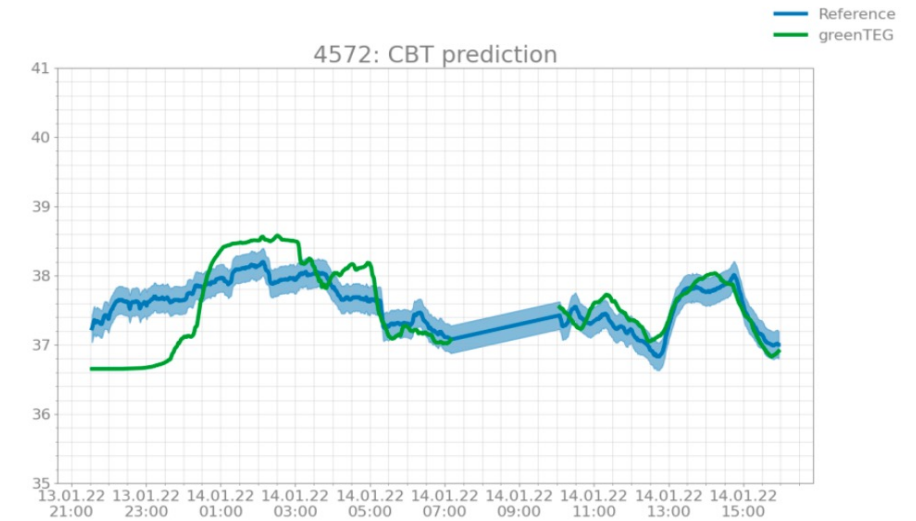
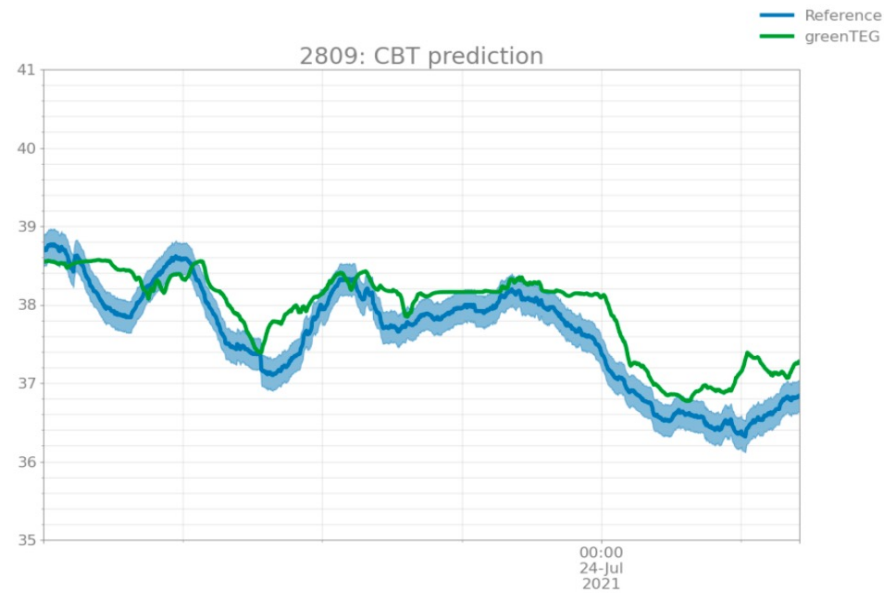
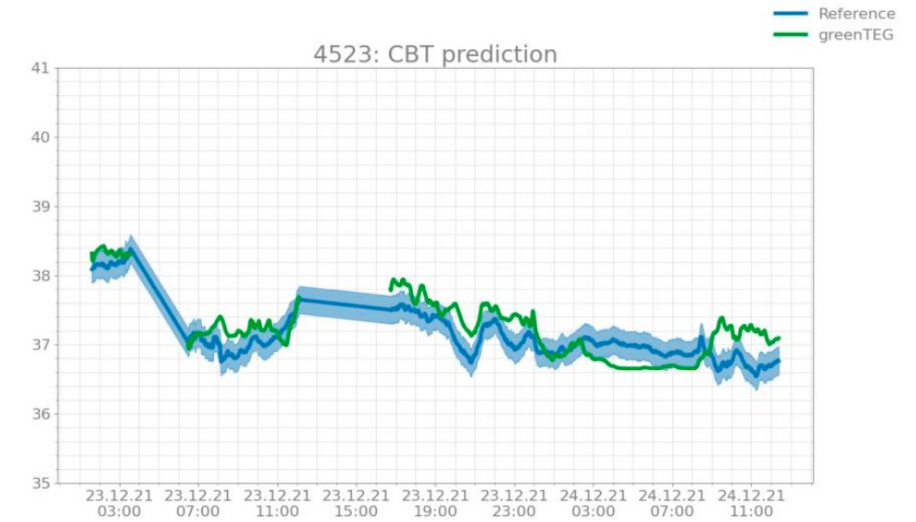
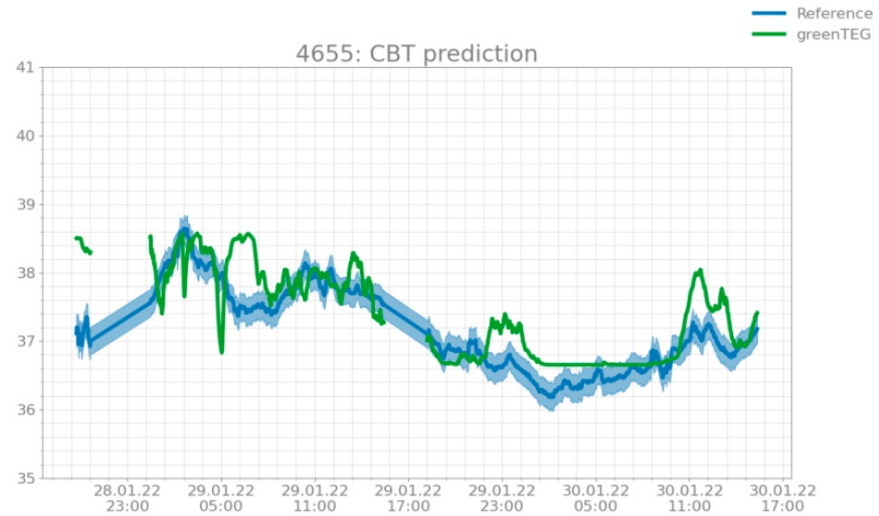


Validity criteria for data sets:

- Sensor streams:
 - Wrist heat flux
 - Wrist skin temperature
 - Heart rate
 - Valid reference data
- > 10 h of on-body data

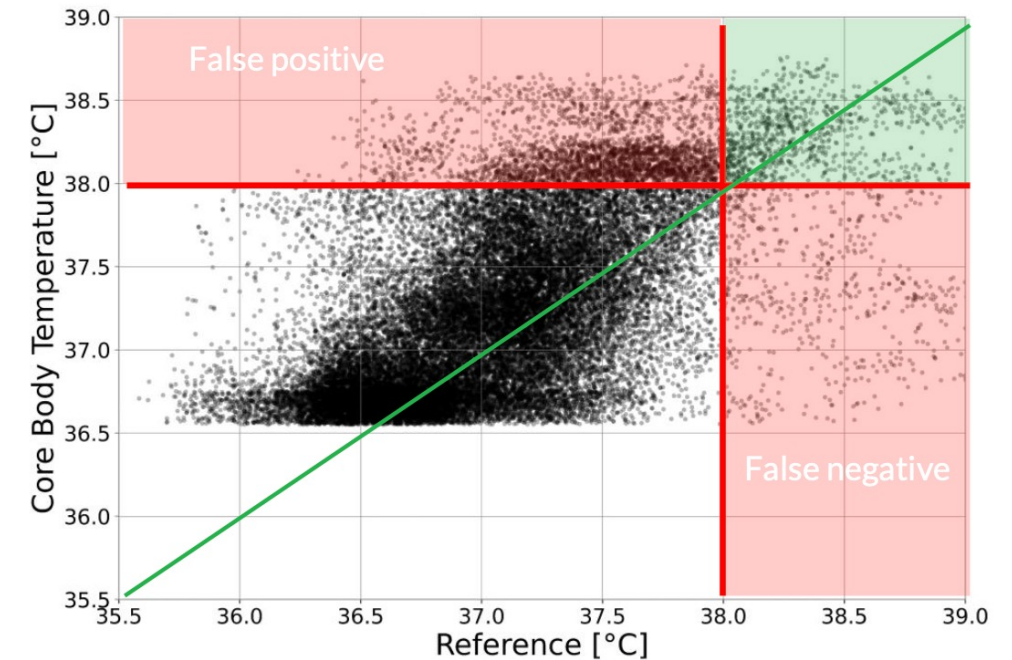
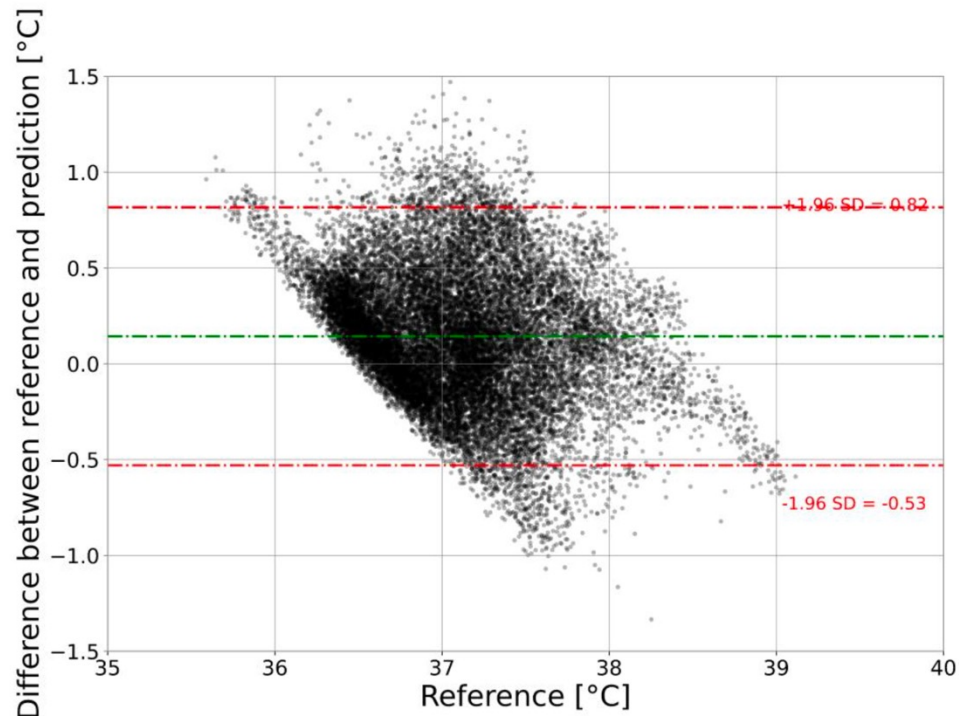
Etienne S, Oliveras R, Schiboni G, et al. *Free-living core body temperature monitoring using a wrist-worn sensor after COVID-19 booster vaccination: a pilot study*. BioMedical Engineering OnLine, 2023;22:25. DOI 10.1186/s12938-023-01081-3 (PubMed 36915134, PMC10010220).

Sample Patients



Results of Wrist Fever Algorithm

	Deviation (°C)
Bias	0.14
Stan dev.	0.34
Correlation	0.76
Lower (LoA)	-0.53
Upper (LoA)	0.82
95% LoA	0.68



Etienne S, Oliveras R, Schiboni G, et al. *Free-living core body temperature monitoring using a wrist-worn sensor after COVID-19 booster vaccination: a pilot study*. BioMedical Engineering OnLine, 2023;22:25. DOI 10.1186/s12938-023-01081-3 (PubMed 36915134, PMC10010220).

- Core Body Temperature measurements have been evaluated on patients with fever and showed an accuracy of 0.68°C (Limit of Agreement)
- This is within the range of an ear fever thermometer
- Correlation of 0.76 is very good for the wrist

Compare with Masimo Device Radius T LoA of 0.96°C

<https://techdocs.masimo.com/globalassets/techdocs/pdf/lab-10714a-eifu.pdf>