

Product Name: c-med° alpha Version No.: 03 Basic UDI-DI.: 426046302CMED4F

Experience 4000 meters altitude in just 30 minutes!!

Compensation: 250€

Study participants wanted!

Desaturation study with altitude generator

For our desaturation study we are looking for healthy adult volunteers. With the use of an altitude generator, various elevations are simulated to assess oxygen saturation and heart rate. This measurement is conducted concurrently with an arterial blood oxygen measurement, as well as a finger clip, chest strap, and an innovative in-ear sensor.

The trial will take place in the summer of 2024, and includes a short pre-fitting to determine your optimal sensor size. If you meet the requirements on the next page and are interested in participating in the study, or if you have any questions, please contact us via e-mail and include your phone number so we can get in touch with you!

E-Mail to: study-subjects@cosinuss.com As we are measuring with optical sensors, we aim to represent the population diversity accurately, so we ask you to voluntarily state your skin tone according to the Fitzpatrick scale:





Intention and objectives of the study	This desaturation study is a validation of the measurement accuracy of the c-med ^o alpha pulse oximetry unit. (required according to FDA-2007-D-0205 - ISO 80601-2-61).		
Duration	Maximum of 2 x 30 minute resting measurements in a sitting position (total duration: approx. 2 - 3.5 hours)		
Procedure	 Under medical supervision at the Klinikum Rechts der Isar (TUM) 1. Reading of the informed consent form and signing if no further questions (≈ 5 minutes). 2. Completion of the questionnaire to collect personal and anthropometric data, taking the medical history (≈ 10 minutes) 3. Placing arteral access (≈ 10 minutes) 4. Venous access is placed as a physician-recommended preventive measure. 5. performance of a maximum of 2 controlled desaturations with continuous measurement of oxygen saturation, respiratory rate, and an EEG for control (≈ 30 minutes). 6. follow-up (≈ 30-90 minutes). 		
Participants compensation	250€		
Definition of "Controlled Desaturation"	Hypoxemia (oxygen deficiency or decreased oxygen content in arterial blood) induced in human subjects. An altitude generator is used for desaturation.		
Altitude simulation	The generator selectively directs reduced levels of oxygen into a breathing mask to be worn.		
Possible risks	Desaturation:	ation: Arterial access:	
	A lack of oxygen in the blood may be manifested by an increased feeling of malaise combined with a feeling of weakness and dizziness. As a result, shortness of breath, breathing problems, tightness, chest pain, tremors, sweating, sensations of hot and cold, and altered cognition or even unconsciousness may occur.	General Risks: Infections, bleeding, haematoma	Unlikely: Permanent/long-lasting damage to the nerve, which usually runs directly next to the artery, i.e. a tingling sensation in the thumb and index finger Artery can be irreversibly damaged, i.e. it can lead to circulatory disorders in the hand with numbness and coldness in the fingers
Desaturation limit	70%		
Exclusion criteria	 Subjects with known respiratory diseases (self-report and screening by physician)): History of: Asthma / COPD / Pulmonary disease Current state: Shortness of breath / Common cold / Pneumonia / bronchitis / Covid -19 Subjects with known cardiovascular (pre-)existing disease (self-report and screening by physician): History of High blood pressure Heart attack or coronary heart disease Stroke Circulatory disorders Arterial hypertension Peripheral arterial occlusive disease Coronary artery disease Myocardial infarction Apoplexy 		 Other: Age > 50 years or < 18 years BMI ≥40kg/m2 Pregnancy or breastfeeding Impaired circulation, injury, or physical malformation of the fingers, wrist, hands, ears, or other body parts that would limit the ability to test the sites needed for the study (note: Certain malformations may still allow subjects to participate if the condition is noted and does not affect the sites used). Subjects with known coagulation disorders. Subjects with known blood disorders (anemia, sickle cell anemia) Subjects with susceptibility to fainting Subjects with pathological changes or edema of the ear canal or middle ear Smokers: except no consumption in the last 48h

