

Product Name: c-med^o alpha

Basic UDI-DI.: 426046302CMED4F

Version No.: 01

In 30 min at 4000 meters altitude!!!

Participants salary: 100 Euro

Study participants wanted!

Desaturation study with height generator

For our desaturation study we are looking for volunteers, healthy adults. By means of an **altitude generator**, different elevations are simulated in order to **measure oxygen saturation and heart rate** in parallel with a finger clip, chest strap and an **innovative in-ear sensor**.

If you meet these requirements (please see the table) and are interested in participating in the study, please contact us via e-mail and include your phone number so we can get in touch with you!

As we are measuring with optical sensors, we aim to represent the diversity of our society accurately, so we ask you to voluntarily state your skin tone according to the Fitzpatrick scale:



e-mail to: sophie.wagner@cosinuss.com

Intention and objectives of the study	This desaturation study is a validation of the measurement accuracy of the c-med° alpha pulse oximetry unit and the respiratory rate. (required according to EN 80601-2-61:2019).
Duration	Maximum of 2 x 30 minute resting measurements in a sitting position (total duration: approx. 2-2.5 hours)
Procedure	<p>Under medical supervision at the Klinikum Rechts der Isar (TUM)</p> <ol style="list-style-type: none"> 1. rapid Covid-19 antigen test (≈ 15 minutes) 2. reading of the informed consent form and signing if no further questions (≈ 5 minutes). 3. completion of the questionnaire to collect personal and anthropometric data, taking the medical history (≈ 10 minutes) 4. performance of a maximum of 2 controlled desaturations with continuous measurement of oxygen saturation, respiratory rate, and an EEG for control (≈ 30 minutes). 5. follow-up (≈ 30-60 minutes). <p>Please note that the study can only be performed on individuals with full Covid-19 vaccination protection.</p>
Participants salary	100 Euro
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. The generator selectively directs reduced levels of oxygen into a breathing mask to be worn.
Altitude simulation	An altitude generator is used for desaturation. The generator selectively directs reduced levels of oxygen into a breathing mask to be worn.
Possible risks	<p>A lack of oxygen in the blood may be manifested by an increased feeling of malaise combined with a feeling of weakness and dizziness.</p> <p>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.</p> <p>Venous access is placed as a physician-recommended preventive measure (optional).</p>
Desaturation limit	70%
Exclusion criteria	<ul style="list-style-type: none"> • Age > 50 years • Pathological obesity • Impaired circulation, injury, or physical deformity of the fingers, wrist, hands, ears, or other body parts that would limit the ability to test the sites needed for the study. • Pregnant women • Subjects with known respiratory conditions (self-report): <ul style="list-style-type: none"> ◦ Asthma ◦ Common cold ◦ Pneumonia / bronchitis ◦ Shortness of breath ◦ COPD ◦ Pulmonary disease • Subjects with known cardiovascular disease (self-report) • Subjects with known coagulation disorders • Subjects with hypertension • Subjects with known blood disorders (anemia, sickle cell anemia) • Smokers: except no consumption in the last 48h • Subjects with fainting disorder