

Objective/Requirement

Transcutaneous blood gas monitoring device for testing in elevated CO2 environment. This includes supporting equipment for the transcutaneous blood gas monitoring device:

- Monitor
- Power supply
- Country specific power supply,
- Sensor Adapter Cable
- Cable Hook
- 2x Tilting feet
- Manual

Characteristics, Scope, and Spec

Ingress Protection: IPx2 (protection against dripping water when tilted at 15°)

Carrying: Foldable handle to carry the monitor Mounting: Mountable on 75x75 VESA compatible roll/ infusion stands, wall mounts/ railings, transport incubators, etc.

Tilting: Optional feet to add on the VESA mounting points to adjust angle for improved table-top viewing (screen perpendicular to the standing surface)

Cable storage: Optional cable holder can be attached on the right or left rear side of the monitor to stow cable during transport or storage. Electrical Monitor: 12 VDC Power, max. 3 A, by external power supply Power supply for hospital use: Class II FE (with functional earth), Electrical Safety (IEC 60601-1)

Power supply for home use: Class II (without functional earth), Electrical Safety (IEC 60601-1) Type BF, Applied Part, Defibrillation Proof. Internal battery type: rechargeable, sealed Li Ion Battery / Capacity (new fully charged battery): up to 4 hours (if Sleep Mode=OFF) Charging Time: approx. 4 hours Environmental Transport/ storage temperature: 0 to +50 °C (32 to 122 °F) Transport/ storage humidity: 10 to 90% non-condensing Operating temperature: +5 to +40 °C (41 to 104 °F)

Milestone 1:	
<ul style="list-style-type: none"> - Summary report with a description of how the prototype images will be synced with OCT2 Spectralis images and enable follow-up analysis. - Envelope pictorial (high-level drawing of how prototype will fit in drawer) - External interfaces list (e.g., power interface) 	
Milestone 2:	
<ul style="list-style-type: none"> - Prototype of Macula OCT device including delivery to JSC - Conduct Training to JSC Cardiovascular Lab (CVL) personnel - Software needed to obtain and view images - Simple user manual (e.g., voltages, use of device), electrical safety- and laser safety assessment <ul style="list-style-type: none"> o <i>Note: the device will have no FDA clearance</i> 	

Period of Performance: 3/20/23 – 9/22/23
