SBIR 25.4 Release 5 Q&A Telecon Transcript
18 February 2025

- SOCOM254-D002 Operator Portable Oxygen Generation Device
- SOCOM254-003 Aviation Goggle Mount

SBIR Process Timeline

05 February 2025: Topics issued for pre-release
26 February 2025: USSOCOM begins accepting proposals via DSIP
12 March 2025: DSIP Topics Q&A closes to new questions at 12:00 PM ET
26 March 2025: Deadline for receipt of proposals no later than 12:00 PM ET

SOCOM254-D002 Operator Portable Oxygen Generation Device

1. **Will all reference documents provided in the announcement be made available?** They're posted on the SOFWERX website and available on the Defense SBIR/STTR Portal, which is called DSIP, and all instructions, including the SOCOM specific BAA instructions, and the topic descriptions will be on that portal, just make sure you're looking at the correct effort. Any questions outside of technical questions can be submitted to sbir@socom.mil.
2. **How many prototypes are expected / requested?** At a minimum, we're looking for just one prototype. We want to place most of the cost burden on developing something that works, so we are trying to limit the number of prototypes that have to be built. If you choose to do a prototype, we're requesting that it be something that demonstrates that you're able to perform as per the specs that are in the announcement.
3. **What is the anticipated long-term production volume?** The requirement is for entire SOCOM enterprise. We cannot speak on the production volume requirement.
4. **Can you please provide a minimum for each requirement?** What is listed in the topic description for key equipment attributes is what we would consider the threshold requirement for the product.
5. **Can you please prioritize the requirements (i.e., which requirements are non-negotiable)?** Getting a device that meets the D-size oxygen cylinder mount and weight requirement of five pounds or under would be a significant requirement or priority, then the next being the 15 liters per minute at 93% O2 purity, +/- 3%. I would prioritize solving the hardest technical problems in the scope of this initial Direct Phase II, as long as in the future you could solve other ones.
6. **Are there high likelihood use cases / missions / configurations that should be focused on?** The most focused case is the prolonged field care setting, such as a situation where a dismounted medic or team is on foot and far from a hospital setting. Submitters should concentrate on being able to deliver the 15 liters per minute and being able to set or reconfigured in a manner that doesn't have to go to a higher level maintenance. For example, one of the drawbacks of the Zoros is that the sieve bed, the Zeolite, must be replaced and it can't be done at that individual level.
7. **What are the key clinical expectations of the device in addition to flow and purity? What is the min and max output pressures?** The purity levels are 93%, +/- 3% and being able to deliver 15 liters per minute at that pressure.

8. I**s the expectation that the single device be used for only one patient?** The threshold would be one patient, but if it is able to do more, that may make it more competitive. I would try to prioritize looking at what is the most technologically difficult thing to do and try to be successful with that.
9. **Is a single device expected to produce 15 LPM and for what period of time?** What is the minimum LPM output expectation and for what period of time? Our threshold is providing 15 liters and then having a runtime of six hours battery powered and indefinitely at shore power. We understand that sea level is a pretty good discriminator to the performance of the device.
10. **Is Pulse Flow Mode an option in addition to Continuous Flow? Can the 15 LPM be met with an equivalent pulse dose setting?** Yes or with a nonrebreather.
11. **Please explain "Shore" power in more detail and any limitations to be aware of.** Shore power is the ability to plug it into a wall, whether that's at a hospital or inside the aircraft, and it continues to work without a disconnect between turning on or plugging the power in. We are not expecting it to be able to be plugged into a cigarette lighter, although that would be desirable. The threshold is 110 or 240 Volt AC and the battery itself could run charged off any USB-C compatible charger, understanding there are different rates on that.
12. **Is the expectation that a single battery operate up to 6 hours continuously, or can additional batteries be hot-swappable to meet the requirement?** We are looking for both. A battery that has a runtime for six hours but is also hot swappable with a recharge time to that battery less than 35 minutes.
13. **Clarify conflicting requirements on battery operation which is listed as 6 hours in the Description section and 4 hours in the Phase II section**. We are looking for six hours. We will have that corrected.
14. **Is the USB-C a mandatory requirement and is it required for power supply, communications, or both?** USB-C is a power supply requirement. We are trying to have universal cables, as dismounted medics or operators are limited on what they can carry, or we don't want them to have to carry a separate battery power unit for a separate widget. This is also important so that if they do have an issue with the power supply or cables, we can find a similar capability in the local economy.
15. **Is the D-cylinder form factor an absolute requirement?** The D-cylinder is a requirement to fit into the aircraft stanchions.
16. **What additional components or accessories should be included in the kit along with the unit itself?** It needs the ability to have replaceable sieve bends, replaceable or cleanable filters, and standard connectors for the device to actually be connected.
17. **What other medical devices will this device need to interact with?** It only needs to interact with the standard delivery devices for oxygen, so your nasal cannula, your nonrebreather, your venturi mask. I think the first Save02 ventilator was able to sync on demand, that could be desirable, but the new Save02 device doesn't necessarily have that, and I'm not sure if the Sparrows connects. If there's a way to get it to interact then, that is desirable, but it doesn't need to like connect a network or anything of that nature, unless there's some sort of a thing that necessitates a network, like a software upgrade or calibration, which is not desirable, but that is not a requirement on our end.

18. **Should units be designed to accommodate drone transport?** The primary focus is that the device be transportable by a single person. We can discuss development for working on a drone based on where we are with the technology.
19. **Are there any electronic / EMI interference specifications?** In the topic description, it is written that the device needs to meet the MIL standard 810 and the environmental joint enroute care equipment test standards so then it meets the safe to fly or airworthiness standards across the services for both rotor wing and fixed wing aircraft.
20. **Is there a more detailed sound specification in addition to <45db?** Not at this time, but we are looking for something that's quiet for folks that are far forward on a battlefield.
21. **Will SOCOM be providing a Letter to Expedite / Fast Track request to the FDA for 510(k) clearance?** There are no guarantees, but the more successful we are, the better the chance of that.
22. **Our technology requires some technical capability that is only available in Israel. Could we still apply for this opportunity if Israel is a site of work?** All work needs to be done in the US, so that is not a possibility.
23. **We have an advanced oxygen mask that has 3 military studies, it would be key to deliver higher oxygen concentration, how can we be involved?** If you want to try to submit something that you think will give the equivalent to 15 liters a minute using a different mask, that would be something that you would need to explain in depth in your submission and that we would consider, otherwise connect with us offline and we can show you how to submit to our Broad Agency Announcement or how to do business with SOF on the eSOF website, that way the information can make it to us and we can action it appropriately.
24. **How many Direct to Phase IIs are you planning to fund?** This will come down to evaluations. Generally, anywhere from one to three are funded.
25. **The current system only delivers 3LPM for less than 1 hr and is heavier than the current requirement. What trade-offs are acceptable?** You should prioritize being able to deliver 15 liters and minute and fitting into the staunches on an aircraft. It says it must weigh less than five pounds and should be transported by a single person. If you're able to deliver the 15 liters per minute, the five pounds might be something that we could work out at a later date. Regarding being transported by a single person, it doesn't necessarily mean it has to be lifted - it could be put into a dolly or something, that would also be acceptable.
26. **I think I heard a SOO will be released on this. Is that in addition to what is published on DSIP?** Go on DSIP and go to Topics and Topics Q&A and then go to 25.4, you'll see where they're supporting documents, and you should be able to locate it there.
27. **Could JP8 be used as a fuel instead of a battery?** That seems dangerous, but pretty much anything is on the table. Look at the use case scenario and ask yourself if a medic is trying to carry this on a rucksack, which is probably not feasible, or on a vehicle or aircraft, is this going to be logistically feasible or not?
28. **What is the operating temperature range?** Device must meet MIL-STD-810H. Threshold requirement is 40°F to 120°F (4°C-49°C). Objective requirement is 25°F – 120°F (-33°C – 49°C).
29. **Would you prefer a lower TRL approach that might not meet all the requirements or a lower TRL fairly untested approach that might meet the requirements?** If you propose work that doesn't meet all the attributes that we've outlined, you're going to need to justify that. If you can only meet two or three of these requirements, you need to justify that, and your work

should be appropriate for the amount of funding you're looking for as well. Our evaluators will look at it and you'll be graded and awarded or not awarded accordingly.

30. **How long after proposals are submitted will a contract be awarded?** There are a few factors that weigh into that, but once the evaluations are completed and notifications go out, there's about 60 to 75 days to get on contract.
31. **Are there any requirements with regard to "intrinsic safety" or "permissibility", that is, using device in atmospheres that have ignitable vapors?** We are looking for a device that works in environments that are considered unsterile. It needs to be optimally as safe as an oxygen cylinder. Obviously, oxygen is an oxidizer, and it needs to be safe based on that, so anything you propose should be as safe or safer than a standard oxygen cylinder.
32. A**re there any requirements regarding maintenance?** We want this device to be as low maintenance as possible. The SAROs required what we call level 10 and level 20 maintenance or end user and a biomedical maintenance specialist servicing. The ability to replace a Zeolite cartridge by end user is desirable and the absence is the holdup battery is sort of the limits of what we're talking about for maintenance. The most desirable is end user level maintenance or at the very least something that would give an end user an indication of the fact it needs to be maintained, calibrated, reconfigured, or maintained in some manner so that the individual would be aware of that and wouldn't have to turn it on and then not work and then have to turn it in for maintenance to figure that out. We want to have a requirement for services where biomedical technician conducts a calibration and verifies the liters per minute and the oxygen purity are at that satisfaction level and we're hoping it would be no more than one year. Any further than that will increase the cost of the unit, so if we can reduce that cost, it will make it a bit easier to get more units to organizations.
33. **We may be missing direct to phase 2 specs but the solicitation topic has a Phase I section. Are we required to address the scopes of both Phase I and Phase II?** This is a direct to Phase II SBIR, we are looking for solicitations that meet the scope of Phase II.
34. **The topic states O2 separation from atmosphere. We can do this, but we would need an energy hungry compressor to store O2 in a tank. Do we need to fill tanks?** We are looking for a system that is standalone and can capture ambient air and converts it into 93% (+/- 3%) O2 purity that can directly be used for patient use. The system itself does not need to charge other tanks.

Please submit any additional questions to the DSIP tool here. Questions are typically answered within seven days.