JUSTIFICATION AND APPROVAL
OTHER THAN FULL AND OPEN COMPETITION

1. Identification of the agency and the contracting activity.

This justification is executed by the Naval Medical Research Command (NMRC), Silver Spring, MD, on behalf of the Navy to meet Navy Expeditionary Medical Research requirements.

2. Nature and/or description of the action.

The procurement action supports previous contracting of the Thera Tactics Enhanced Pulse Oximeter, an intended for tactical aviation, forehead mounted pulse oximeter system with correction factors for accuracy at altitude. The Thera Tactics system is designed to monitor pilot heart rate, blood oxygenation, and environmental conditions in real time, enabling early detection of physiological episodes or other adverse events experienced by aircrew. This system has been flight-tested and validated on Navy platforms including the T-45, F-18, and F-35

3. Description of Supplies or Services.

The proposed procurement is for a sole source due to the proprietary nature of the Thera Tactics measurement methodology, which collects samples at the capillary bed that is supplied by the supra-orbital artery. The planned advancements for the device include integration into currently used and in development tactical aviation helmets. The required technical specifications demonstrate the Thera Tactics' uniqe capability in clinical-grade pulse oximetry development, design, and field deployment, particularly under tactical aviation conditions, that are met by a limited number of qualified vendors based on prior validation against arterial blood gas (ABG) analysis and military airworthiness standards. See Salient Characteristics for explicit requirements.

4. Identification of the statutory exceptions permitting other than full and open competition.

The statutory exception permitting other than full and open competition for this acquisition is

10 U.S.C. 2304(c)(1) and FAR 6.302-1 sole source (including brand name) acquisitions or FAR 13.106-1(b)(1) soliciting from a single source.

Identification of the statutory exceptions permitting other than full and open competition.

The statutory exception permitting other than full and open competition for this acquisition is 10 U.S.C.2304(c)(1) or 10 U.S.C.2304(c)(3) and FAR 6.302-1(c) for brand name justification.

5. Demonstration that the proposed contractor's unique qualifications or the nature of the acquisition requires use of the authority cited.

Thera Tactics is the only vendor capable of providing the specified pulse oximetry system. The technology is not commercially availably and was developed specifically for military aviation. The technology is protected by patents US11517227B2, US2021007647A1, US10772562B2, and US2018344247A1.

6. Description of efforts made to ensure that offers are solicited from as many potential sources as practicable.

Market research was performed, the results of which are in paragraph 8. This requirement will be posted to the government point of entry in accordance with FAR 5.202.

7. Determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

The Contracting Officer shall determine the anticipated cost to the Government of the supplies/services covered by this Justification and Approval will be fair and reasonable by conducting a price analysis before an award is made. In addition, the Government anticipates that the negotiated contract price will reflect a discount from the vendor's commercial price list and will be determined fair and reasonable.

8. Description of the market survey conducted and the results, or a statement of the reasons a market survey was not conducted.

Market research was conducted, but only 1 vendor (Thera Tactics) was contacted due to the company being the only provider for the system, maintenance, and service for the device. The technology is not commercially available and was developed specifically for military aviation.

9. Other facts supporting the use of other than full and open competition.

Not applicable

10. Listing of Sources, if any, which expressed, in writing, an interest in the acquisition.

Not applicable

11. Statement of actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the supplies or services required.

For the reasons set forth in Paragraph 5, (contracting activity) has no plans at this time to compete future contacts for the types of supplies/services covered by this document. If another potential source emerges, (NMRC) will assess whether competition for future requirements are feasible.

12. Point of Contact:

The point of contact at the Naval Medical Research Command, Silver Spring, MD, regarding the contents of the sole source justification are the Contracting Officers in the Material Management Department (MMD) and can be reached by emailing usn.detrick.nmrc.mbx.mmd-contracts@health.mil.

TECHNICAL AND REQUIREMENTS CERTIFICATION REQUIRED BY NAVSUP 4200.83 series

I certify that the facts and representations under my cognizance which are included in this justification and approval and which form a basis for this justification are complete and accurate.

Technical POC

Digitally signed by WARNER.STEPHANIE.ANN.1409469210 Date: 2026.06.12 10:07:44 -04'00'		937-938-3917	12 JUN 2026
Name Title Department/Command	Stephanie Warner Biomedical Engineer EP/NAMRU-D	Phone	Date

Department Head

VENTO.KAILA.ANN.1513071120 Digitally signed by VENTO.KAILA.ANN.1513071120 Date: 2026.06.12 10:26:43 -04'00'		385-636-1146	12 JUN 2026
Name Title Department/Command	LT Kaila Vento Department Head CHC/NAMRU-D	Phone	Date

CONTRACTING OFFICER CERTIFICATION

I certify that this justification is accurate and complete to the best of my knowledge.

JOHNSON.NATAKI.SHIDONA.1515567492 Digitally signed by JOHNSON.NATAKI.SHIDONA.1515567492 Date: 2026.07.01 15:39:29 -04'00'			
Contracting Officer		Phone	Date