FEDERAL BUREAU OF INVESTIGATION

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION

JUSTIFICATION FOR OTHER THAN FULL AND OPEN COMPETITION IN ACCORDANCE WITH
(STATE AUTHORITY E.G., 10 U.S.C. 2304 (C)(1) OR 41 USC 253)
Requisition Number: DJF-23-0700-PR-0002386

Date: 02/21/2023
Estimated Contract Dollar Value: $

1. Identification of the agency and contracting activity.

The U.S. Department of Justice, Federal Bureau of Investigation (FBI), Laboratory Division (LD) Technical Hazards Response Unit (THRU), has prepared this justification for other than full and open competition for medical equipment on behalf of the THRU Medical Program which supports FBI technical and hazardous forensic response.

2. The nature and/or description of the action being approved, i.e., sole source, limited competition, establishment of a new source, etc.

Four (4) **Tempus Pro ALS Patient Monitors** and (4) **Tempus LS Manual Defibrillators** with the following features:

Tempus Pro ALS Patient Monitor with the following features:

- B73 EMS US Package 7
- 12 Lead ECG monitoring and interpretation
- Non-invasive blood pressure monitoring (NIBP)
- Non-invasive Blood Saturation Monitor that will include SpO2, SpOC, SpHb, SpMet and SpCO
- End Tidal C02 monitoring and wave form interpretation
- Internal/External temperature monitoring probes
- Integrated wired and wireless communication options for device-to-device communications as well as device-to-medical control communication
- Integrated patient data recording with PCR export capability
- Integrated ECG and data printer

Tempus LS Manual Defibrillator cardiac monitor/defibrillators with the following features:

- 5.7” color screen
- 3 Lead Electrocardiogram (ECG)
- Manual, hands free Cardiac Defibrillation (DFib)

- External Cardiac Pacing
- Synchronized Cardioversion

Each of these systems will be shipped with appropriate supplies and equipment needed to place the units in service, including:

- Rechargeable batteries and appropriate battery charging cables
- NIBP tubing and assorted sized cuffs (child to XL adult)
- ETC02
- Non-invasive temperature cable and disposable probes
- Non-invasive, re-usable SP02 cable
- 4 Lead/12 Lead modular ECG cable
- Printer paper
- Rail system and pouches for both sides of the monitor

Additionally, upgrades to previously purchased Tempus Pro ALS Monitors.

- Non-invasive Blood Saturation Monitor that will include SPO2, SpOC, SpHb, SpMet and SpCO

The Vendor will conform to FBI requests and requirements to provide portable medical cardiac monitor/defibrillators in quantities outlined above, in ruggedized DoD configuration to be utilized in support of FBI forensic operations. The portable cardiac monitor/defibrillator must be in a rugged package with additional leads which is FDA cleared for use in aircraft. Air Worthy is required for this purchase as many of the missions that THRU performs are in US Government aircraft, both fixed and rotary wing.

3. A description of the supplies or services required to meet the agency's needs.

Vendor will provide four (4) each of the following as outlined below:

- 867422 Tempus Pro with Printer
- B73 EMS US Pkg7
- 05-2055 12 Lead ECG License (AAMI) w/ 12 lead cable
- 01-2080 ECG electrodes pack of 10
- 05-2026 ST and QT Real Time License
- 05-2071 Intellispace Corsium Reachback
- 01-2153 YSI 400 Series Reusable 401C Contact Temp Probe
- 01-2051 Tempus Li Battery
- 01-1012 Tempus Battery Charger
- 01-2161 Tempus Battery Charger Earthed Cable
- 01-2187 Tempus Pro Printer Paper
- 01-2041 Tempus Pro Tactical Headset Adapter Cable
- 01-1019 Tempus Wired Headset
- 05-2039 Tempus Pro Pouch Rail System-Right
- 05-2238 Saddlebag for Tempus Pro-Right

- 00-3020 Tempus LS Manual Defibrillator
- 01-3020 Adult Defibrillation Pads
- SPO2
- SpOC and SpHb Factory License
- SpMet Factory License
- SpCO Factory License

4. The statutory authority permitting other than full and open competition.

The statutory authority permitting other than full and open competition is 41 U.S.C.253(c)(1)(or 10 USC 2304(c) (1)) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. Demonstrate the unique qualifications of the proposed contractor or the nature of the action requiring the use of the authority.

Philips is uniquely qualified to provide these services to the FBI LD THRU based upon the following:

- This is year two of a two year purchase plan for these medical devices. These purchases were spread over two years for budgetary reasons. Year one of this purchase was awarded to the Vendor.
- Philips is the manufacturer of the Tempus Pro cardiac monitor/defibrillator, providing the most competitive cost for the devices:. These units are controlled medical devices that have been recently FDA approved. This being the case, there are limited options to purchase or do market research. The only other seller that the author could find advised to contact the manufacturer directly.
- As the manufacturer, the FBI will be dealing directly with Philips for any repairs, updates, preventative maintenance or warranty issues.
- All accompanying and replacement products provided by Philips will be compatible with the units and consistent with the warranty and function of the units.
- No other manufacturers of cardiac monitoring/defibrillation devices provide the scalability options that Phillips/Tempus provides. Frequently, deployment planning requires that the size and weight of all equipment be taken into consideration due to current FBI aircraft. While emergency medical gear is critical to a mission, the Tempus manual defibrillator is much smaller and lighter (4.1 Lbs.) than the current cardiac defibrillator carried by THRU Paramedics, the Physio Control LP-15 (19lbs).
- Purchase of the Tempus products allows the THRU Medical Program the ability to "right size" the amount of equipment issued to THRU Paramedics. In 2010 Paramedics were each issued a Physio Control LP-15 cardiac monitor/defibrillator at a cost of approximately per unit. By purchasing the Phillips Tempus system, each Paramedic will be issued a manual defibrillator for less than per unit which represents a significant savings to the FBI.

Additional patient monitoring capabilities within the Tempus ALS base units will be available for check out as needed to meet mission parameters.

6. A description of efforts made to ensure that offers are solicited from as many potential sources as is practicable, including whether a notice was or will be publicized as required by Subpart 5.2 and, if not, which exception under 5.202 applies.

There are limited vendors nationally who provide these medical devices. These units are controlled medical devices that have been recently FDA approved. This being the case, there are limited options to purchase or do market research. The only other seller that the author could find advised to contact the manufacturer directly. An on-line search of the vendors and the costs of their products was conducted.

7. The anticipated dollar value of the proposed acquisition, including options if applicable, and a determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

This purchase, as outlined above will cost approximately. The manufacturer, Phillips Tempus, does allow for other vendors to sell these Tempus units but does not sell to these vendors at a discount. One vendor that was contacted simply advised that Phillips Tempus would offer the best price and did not provide a quote. A second vendor did not respond to a request for quote.

8. A description of the market research conducted and the results.

On-line searches and requested quotes of items on the company websites of each of the vendors listed above. A Market Research report was completed.

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

In conducting research for this requirement, it was determined that only a single source could meet the overall needs to include the scope of options available, the services to follow purchase, and options for loaner units during PM or repairs.

10. A listing of any sources that expressed a written interest in the acquisition.

Since the procurement was not advertised, no other companies have expressed an interest either orally or in writing.

11. A statement of any actions the agency may take to remove or overcome any barriers to competition, if subsequent acquisitions are anticipated.

The cardiac monitoring capabilities requirements are established by FBIHQ, HRD, Office of Medical Services and are founded on national standards of emergency medical care, the

American Heart Association, the National Registry of EMTs and specialty training certification standards for dive medicine, wilderness medicine and austere medicine. The FBI can reduce the standard of care internally, but cannot implement changes to overcome any obstacles imposed by national certification bodies for which we are bound to comply. Even if changes in the capabilities of the devices was enacted, the FBI does not control the pricing imposed by the vendors. The efforts provided in this document reflect the most reasonable and cost-effective manner to execute the requirement.

Reviews and Approvals (Not exceeding $700,000)

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

_____ _____
David L. Janey
Signature Date

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

_____ _____
Signature Date