

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: 36C248-19-AP-4131

1. **Contracting Activity:** Department of Veterans Affairs, VISN 8, James A. Haley VA Hospital, Medical Service, 13000 Bruce B. Downs Blvd, Tampa, FL 33612, referenced 673-19-3-084-0155
2. **Nature and/or Description of the Action Being Processed:** This is a one-time procurement for the brand name product Vyntus ONE Pulmonary Function Test (PFT) system and the Vyntus BODY System. Manufacturer: CareFusion 211, Inc. (DUNS: 128297095), 22745 Savi Ranch Parkway, Yorba Linda, CA 92287; (800) 231-2466. Two Service-Disabled Veteran-Owned Small Business (SDVOSB) brand name distributors have been identified through market research that are capable of providing quotes for brand name requirement. Solicitation will be posted at Federal Business Opportunities (FedBizOpps) website (FBO.gov) for brand name using Tiered Evaluations (Cascading) including large business concerns.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for new and updated Pulmonary Function Testing (PFT) equipment. The upgrades are needed to ensure the security of the patient database as the current operating system (Windows XP) will soon be obsolete and not supported, as instructed by Biomed and OI&T. Current testing equipment is over two years its replacement date and current database is not compatible with new therapeutic modalities required to support the Mission Act. Due to increased workload/demand for PFTs, new equipment will ensure accuracy in results and will improve patient care in a timely manner.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Vyntus ONE Pulmonary Function Test (PFT) System from CareFusion 211. Quantities: 2 Vyntus ONE Systems and 2 Vyntus BODY Systems.
 - a. VYNTUS BODY DIFFUSION SYSTEM; MODEL/PRODUCT NUMBER: 31802-001
 - b. STANDARD CART WITH SHELVES, TOP HALF-CART IS ADJUSTABLE UP/DOWN HEIGHT; MODEL NUMBER: V-859140-13
 - c. GAS .3% CO .3% CH4 21% O2 BAL N2 (ED); MODEL NUMBER: 768093
 - d. ADDITIONAL BREATHING CIRCUIT FOR VYNTUS ONE; MODEL NUMBER: 32925-001
 - e. VYNTUS ONE PFT SYSTEM; MODEL NUMBER: 31788-001
 - f. ADDITIONAL BREATHING CIRCUIT FOR VYNTUS ONE; MODEL NUMBER: 32924-001
 - g. GAS .3% CO .3% CH4 21% O2 BAL N2 (ED); MODEL NUMBER: 768093
 - h. GAS 99.00% OXYGEN (USP); MODEL NUMBER: 761819
 - i. GAS 16% O2 5% CO2 0.3% CO/CH4/BAL N2 E CYL; MODEL NUMBER: V-892590-13
 - j. MS PNEUMO SES HEATED WITH PC 1PR4P; MODEL NUMBER: 27265-001
 - k. ADD APS PRO SES ADD-ON PNEUMO/IOS SP APS; MODEL NUMBER: 27267-001
 - l. MS IOS SES WITH PC 1PR4P; MODEL NUMBER: 27270-001
 - m. PULMONARY OR EXERCISE ONSITE TRAINING 4 DAYS; 97075-PM4-OS

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- n. WEB BASED MOBILE REVIEW APPLICATION FOR PHYSICIAN INTERPRETATION AND REPORTING WORKFLOW MANAGEMENT. INCLUDES MAIN LICENSE AND 5 CONCURRENT USERS; MODEL NUMBER: V-577090
- o. ADDITIONAL 25 CONCURRENT USERS (30 TOTAL) FOR THE MOBILE REVIEW APPLICATION; MODEL NUMBER: V-577092
- p. IMPLEMENTATION SVCS - PFT W/WORKFLOW; MODEL NUMBER: 97060-101
- q. SENTRYSUITE SERVER SOFTWARE WIN 10; MODEL NUMBER: V-577400-13
- r. SENTRYCONNECT SEAT LICENSE FOR SES; MODEL NUMBER: V-577201-100
- s. SENTRYCONNECT SEAT LICENSE FOR VMAX; MODEL NUMBER: V-577201-102
- t. SENTRYCONNECT SEAT LICENSE FOR SOMNOSTAR; MODEL NUMBER: V-577201-103
- u. SENTRYCONNECT SEAT LICENSE FOR NOXTURNAL; MODEL NUMBER: 27217-001
- v. SENTRYSUITE TEST LICENSE; MODEL NUMBER: 28404-001
- w. VMAX PREMIUM TEST LICENSE; MODEL NUMBER: 28405-001
- x. SOMNOSTAR TEST LICENSE ; MODEL NUMBER: 28408-001
- y. NOX TEST LICENSE; MODEL NUMBER: 28409-001

Equipment description:

Vyntus ONE PFT System. Includes analyzer module (O₂, CO₂, Multigas), breathing circuit (including Ultrasonic sensor, Flow Path Valve, and Demand Valve), SentrySuite software, standard cart and arm with adjustable height and left/right mousepad, validated WIN 10 PC with sanitizable medical keyboard/mouse, 27 flat panel infinity-edge monitor, Office Jet printer, 3-L manual syringe, O₂, DLCO and calibration gas regulators, 6 cylinder gas stand, 1 box of MicroGard IIB and IIC (80 each) filters.

Tests performed: Spirometry (FVC, SVC, MVV), Lung subdivisions (VTG, FRC-N₂, RV, TLC), Real-time DLCO (both Single Breath and (No Suggestions)), MIP/MEP, pre/post bronchodilator. Standard software includes: Guidance and Stabilitrac instructional applications, pre-formatted reports and reference sets with design tools for modification, automated interpretation algorithms, QA checks and physician interpretation templates. 1 year warranty plus 4 additional years premium contract included.

Vyntus BODY Diffusion System. Includes 1110L body plethysmograph with 551 pound patient bench and 25 inch telescoping arm, breathing circuit (including Ultrasonic sensor, Flow Path Valve, and Demand Valve), SentrySuite software, validated WIN 10 PC with sanitizable medical keyboard/mouse, 27 inch flat panel monitor, Office Jet printer, 3-L manual syringe, DLCO 7bar pressure regulator, 6 cylinder gas stand, box of 80 MicroGard IIB filters.

Tests performed: Spirometry (FVC, SVC, MVV), Lung subdivisions (VTG, FRCpl, RV, TLC, Raw, Conductance and specific resistance and Resistance Volume Loops), Realtime DLCO (both Single Breath and Intra-breath), MIP/MEP, and pre/post bronchodilator. Standard software includes: Guidance and Stabilitrac instructional applications, preformatted reports and reference sets with design tools for modification, automated interpretation algorithms, QA checks and physician interpretation templates. 1 year warranty plus 4 additional years of premium contract included.

MS PNEUMO SES HEATED WITH PC 1PR4P. MasterScreen Pneumo with Desktop PC and Printer. Heated pneumotach spirometry system. Validated Windows 10 Desktop PC with 22 inch monitor, sound bar, and color deskjet printer included. MasterScreen Pneuomo performs all the essential spirometry tests; FVC with Flow Volume Loop, Slow Vital Capacity (SVC), Maximum Voluntary Ventilation (MVV). Pre and Post Bronchodilator testing levels and Bronchial Challenge Testing

software also included. SentrySuite software provides user guidance and feedback regarding test quality according to ATS/ERS or other author's standards. Other software features included; powerful report designer, 10 parameter-linked animated incentives, interactive guided calibration, customizable reference modules, and offline data entry. Device can be used as standalone or can take advantage of our growing family of SentrySuite solutions for workflow and connectivity such as Sentry.Net and SentryConnect. 3-liter calibration syringe included. Box of 80 Microgard filters included. 1st year complete warranty, 2nd - 5th year parts only warranty included.

4. Statutory Authority Permitting Other than Full and Open Competition:

- ☒ (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- ☐ (2) Unusual and Compelling Urgency per FAR 6.302-2;
- ☐ (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ☐ (4) International Agreement per FAR 6.302-4
- ☐ (5) Authorized or Required by Statute FAR 6.302-5;
- ☐ (6) National Security per FAR 6.302-6;
- ☐ (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: *The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*

- 5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The James A. Haley is currently using the VMAX Encore Pulmonary Function Testing (PFT) Equipment from manufacturer CareFusion. The VMAX operating system is Windows XP and the current database is not compatible with new therapeutic modalities required to support the Mission Act as verified and confirmed by hospital Bio-medical staff and the Office of Information and Technology (OI&T). The new technology in the Vyntus One as well as its Windows 10 operating system, is designed to improve quality of patient care and increase productivity and efficiency of clinician staff. Due to increased workload/demand for PFTs, the Vyntus One will ensure accuracy in results and will improve patient care in a timely manner. CareFusion's set of software applications called Sentry Suite is designed to improve quality of patient data and increase clinician productivity and efficiency in Pulmonary and Cardiopulmonary diagnostic testing.

Additionally, The James A. Haley currently owns medical device equipment with Sentry Suite software installed; the Bio-Medical Department has built server for Sentry Connect software which will interface with the Computerized Patient Record System (CPRS) and into the Electronic Medical Record (EMR) database. The Vyntus One will connect to this existing server/database. Historical patient data already exists on the existing server which also connects to out-patient clinics (CBOCs) and the CPRS/EMR database. The Vyntus One system will enhance connectivity, solve database/system failures and allow secure test data transfers from offsite clinics into the hospital's CPRS/VISTA database.

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CareFusion through its authorized Service-Disabled Veteran-Owned Small Business (SDVOSB) distributors (Solvat Services, LLC and The Janz Corporation) is the manufacturer of the brand name Sentry Suite software which is already in-place and in-use at James A. Haley VA Hospital and its out-patient clinics. Any additional equipment/upgrades are only available from this manufacturer. Use of any other manufacturer equipment will not interface with currently used Sentry Connect software and will not allow for the transfer of existing historical patient data within the CPRS/EMR. The inability of brand name equal equipment to transfer existing data can put in jeopardy the care, health and well-being of veteran-patients; thereby, making brand name (Vyntus One) essential in meeting the Government's need.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

- a. Date(s) market research conducted: 6/17/18 & 8/30/18
- b. Companies/organizations contacted as part of your market research (including names, titles, and contact information):

CAREFUSION RESPIRATORY TECHNOLOGIES
22745 SAVI RANCH PARKWAY
YORBA LINDA, CA 92887
Ph: 714-331-2321 / 800-561-7556
Email: Gmb-RespOrders@carefusion.com
Contact: John Mairs, 714-922-7468

MGC Diagnostics
350 Oak Grove Parkway
St. Paul, Minnesota, USA 55127-8599
Ph: 770-329-5183 /800-333-4137
Email: support@mgcdiagnostics.com
Contact: Mark Yenney, RRT III Senior Sales Consultant for Georgia & Florida

Quick Medical GS
30200 SE 79th Street, Suite 120
Issaquah, WA 98027
Ph: 425-222-4441/425-222-5963
Email: lindsey.tarter@quickmedical.com
Contact: Lindsey Tarter, Assistant Manager for Inside Sales

Sources Sought emailed to all VIP and GSA SDVOSB/VOSBs on 8/27/2019.

7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:

CareFusion GSA FSS: 36F79718D0508, expires 07-31-2023
Required items: 24
Items on FSS contract: 16
Open Market items: 08

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Of the required 24 items, 16 are listed on CareFusion GSA schedule; price reasonableness for those items has been determined by GSA. Pricing for the 08 remaining open market items were found to be fair and reasonable based on price analysis of same items available commercially to the private section in the open market (below price comparison chart pertains).

ITEM PRODUCT #	COMMERCIAL ITEM PRICING (\$) EACH	GOVERNMENT ITEM PRICING (\$) EACH	SAVINGS TO THE GOVERNMENT (\$) EACH
31788-001	68,100.00	51,000.00	17,100.00
32924-001	1,100.00	1,100.00	0.00
V-892590-13	369.74	369.74	0.00
31802-001	90,200.00	66,297.00	23,903.00
V-859140-13	6,070.00	4,000.00	2,070.00
V-577090	9,330.00	9,330.00	0.00
V-577092	8,000.00	8,000.00	0.00
V-577400-13	675.00	675.00	0.00

Based on price analysis showing Government savings of \$43,073.00 per system, the Contracting Officer anticipates and considers cost to be fair and reasonable and provides best value to the Government.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Sources Sought emailed to all VIP and GSA SDVOSB/VOSBs on 8/27/2019

Responses received: Two SDVOSB distributors of brand name product.

- Solvet Services, LLC
- The Janz Corporation

One SDVOSB distributor of brand name equal product.

- Bravo, Inc.

One VOSB distributor of brand name equal product.

- Solcon, Inc. (dba: Quick Medical GS)

Bravo, Inc is the distributor of a brand name equal product MGC PFT System. Bravo originally responded to sources sought stating their product could meet salient characteristics outlined within the sources sought and Statement of Need; however, after reconsideration, Bravo, Inc. provided confirmation that the MGC System was unable to meet all salient characteristics due to its inability to interface with currently used Sentry Suite system software. According to Bravo, the VA hospital would have to purchase the MGC System software Breezeconnect/Brizesuite that would work independently of the Sentry system; therefore, interface and transfer of existing data would not be feasible.

Solcon, Inc (dba: Quick Medical GS) holds GSA Schedule (V797D-60687). Quick Medical responded to sources sought with a brand name equal product EasyOne Pro Lab by ndd Medical Technologies. According to Quick Medical the Sentry Suite software from Vyair/CareFusion currently used at the James A. Haley VA Hospital limits their ability to connect and interface with current stored data. Pro Lab will work with EasyOne Connect Software by ndd. Accordingly, their ndd devices connects

through an HL7, XML or PDF interface and can be customized to the VA's needs. This would require a change in software systems. This interface will allow for bidirectional or unidirectional communication with any external system. The PDF could also be integrated into the Sentry Suite if Vyaire/CareFusion could import a PDF into their system. Solcon's technology is a bit different than Vyaire, but has been around for 10+ years.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

None, other than those outlined in paragraphs 5 and 8.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

SDVOSB brand name product distributors (Vyntus ONE PFT System)

Solvat Services LLC

345 Dourcet Rd, Ste 212
Lafayette, LA 70503
(337) 296-1406

Janz Corporation

6950 Americana Pkwy, Ste F
Reynoldsburg, OH 43068
(614) 759-7700

SDVOSB brand name equal product distributor (MGC Platinum Elite Series Body Plethysmographs)

Bravo, Inc

1811 SE 5th Avenue
Cape Coral, FL 33990
(239) 471-8127

VOSB brand name equal product distributor (EasyOne Pro Lab by ndd Medical Technologies)

Solcon, Inc. (dba: Quick Medical GS)

30200 SE 79th Street, Suite 120
Issaquah, WA 98027
(888) 345-4858

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

Potential actions that could be undertaken to remove the barriers to competition as identified in this justification would be conducting a cost analysis to identify PFT equipment and the associated cost to replace existing PFT system with a new product whose software can interface with other, if not all, PFT equipment software currently used in the industry. The key element of such a cost analysis would be the interface of one manufacturer's software with other manufacturer software; with this said, to procure equipment that does otherwise, would simply place the VA hospital in the

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same situation, whereas only one brand name product or sole source will serve as the sole provider of the PFT requirement; thereby, ultimately culminating in other than full and open competition.

- 12. Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Name: DELIA E. PALOS, RRT
Title: PFT Program Leader
Facility: James A. Haley VA Hospital & Clinics

Date

13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

- a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

LESLIE HAWKINS
Contracting Officer, Commodities-Contracting
NCO-8 RPO East, Tampa, FL

9/12/2019

Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

JOHNNY B. JONES
Branch Chief, Commodities-Contracting
NCO-8 RPO East, Tampa, FL

09/12/2019

Date