

DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

WatchPAT Unified home sleep testing probe, Watch Pat Temper Proof Bracelet, Watch Pat Body Position & Snore Microphone, Watch Pat 200 Kit, Adhesive Set for SBP Sensor, Central Plus Add-on Kit with RESBP, Pneumo- Opt UPAT Probes

(Medical Service)

1. **CONTRACTING OFFICERS TECHNICAL REPRESENTATIVE (COTR):** VANTHCS will appoint one (1) COTR for this contract. When service is requested, the contractor will always contact the COR Tamira Dyers 214-857-1517

2. **SCHEDULING ARRANGEMENTS:** Except by special alternative arrangement, scheduled delivery will be provided only during Contractor's normal working hour's local site time. Upon acceptance of this contract, the Contractor shall immediately contact the COR Eric Wikoff at 214-857-1517 to schedule mutually agreeable delivery times.

3. **SCOPE OF WORK:**
 - a. Delivery. All preparations necessarily required to be ready WatchPAT Unified home sleep testing probe, Watch Pat Temper Proof Bracelet, Watch Pat Body Position & Snore Microphone, Watch Pat 200 Kit, Adhesive Set for SBP Sensor, Central Plus Add-on Kit with RESBP, Pneumo- Opt UPAT Probes for operation (bar code and delivery).

 - b. Post installation inspection.

COR will verify that required specifications are met and testing will be performed as necessary to meet VA and vendor requirements.

All installation work shall be coordinated through the VA Healthcare System Biomedical Engineering Section. Existing VA networking components will be utilized. Locations of workstations will be coordinated through VA Sleep Medicine Center and Biomedical Engineering. User training for VA physicians and clinical staff shall be provided upon delivery. Minimum one year full service warranty required. This is to include parts, labor, travel cost, software upgrades, and any other industry standard features. The product must meet IT, PAC's requirements for compatibility, security, and privacy. Must meet or exceed all radiological industry safety standards.

Upon receiving a maintenance and repair call from VANTHCS, the Contractor shall make a return telephone call for within 2 hours. The Contractor will restore the equipment to FULL PERFORMANCE within forty-eight (48) hours of the original call. The Contractor shall notify the COTR of the existence or development of any defects in the equipment covered under this contract which the Contractor considers he/she is not responsible for under the terms of the contract (such as operator misuse). Training and support and preventative maintenance and educational courses to be provided on-site as indicated.

The vendor will provide all resources required to ensure a smooth transition, in accordance with the contract requirements.

4. **DESCRIPTION OF PROVIDED EQUIPMENT:**
 - a. **WatchPAT Unified home sleep testing probe:**

- The PAT® signal is measured from the fingertip by recording finger arterial pulsatile volume changes.
- Based on PAT® technology, the non-invasive EndoPAT system comprises a measurement apparatus that supports a pair of modified plethysmographic bio-sensors. The unique feature of the PAT® bio-sensors is that they impart a uniform sub-diastolic pressure field to the distal two thirds of the fingers including their tips. Applying the pressure in this way is extremely important as it:
 - Prevents distal venous blood pooling, that can induce a veno-arteriolar vasoconstriction reflex.
 - Unloads arterial wall tension which generates a greater dynamic range of the measured PAT® signal.
 - Fixates the PAT® bio-sensor to the finger, which reduces movement artifact

b. **WatchPAT Unified home sleep testing Body Position & Snore Sensor Technology:**

- The integrated sensor is powered by the WatchPAT™ device and does not require a battery. It is automatically activated by the WatchPAT™ device when plugged into the Snore & Body position port.
- The snore sensor is an acoustic decibel detector. It uses a very sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a small analog voltage that provides a clear, reliable indication of the presence of these sounds.
- The body position sensor uses a 3-axis accelerometer that provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit).
- The integrated Snoring & Body position sensor is an accessory of the WatchPAT™ home care device for use with patients suspected to have sleep related breathing disorders. The integrated sensor monitors the snoring level, which aids in the evaluation of the severity of sleep related breathing disorders, and the body position which aids in the evaluation of the type of sleep related breathing disorders

c. **SPECIFICATIONS:**

Snoring Sensor Technology		Sensitive microphone
Body Position Sensor Technology		3-axis Accelerometer
Signal Amplitude		0-3.3 V
Connector Type		1 mm medical safety connector plug from Plastics1 <i>Wire Length:</i> 3.2 foot (100 cm)
Physical Size		1.3 inch diameter (32 mm diameter)
Weight		12 gr
Warranty		6 months
Temperature	<i>Operation</i>	0 to 40 OC
<i>Storage</i>		-20 to 40 OC
<i>Transport</i>		-20 to 60 OC

(Medical Equipment)

Humidity	<i>Operating, Storage & Transport</i>	0% – 93% (non-condensing)
Atmospheric pressure	<i>Operating & Storage</i>	10 – 15 psi
	<i>Transport</i>	8 – 15 psi

5. **EXCLUSIONS** (unless otherwise quoted) :

- a. Modifications or corrections to the work scope dictated by concealed conditions encountered in the performance of the work and not indicated by the drawings, or specifications.
- b. Modification or corrections to installation room or supplied power.

6. **PERSONNEL CLEARANCES AND PRIVACY CONSIDERATIONS:** The Contractor will ensure that their personnel and subcontractor personnel meet the privacy standards as set forth by HIPAA (Health Insurance Portability and Accountability Act of 1996) with respect personal and confidential information that they may come upon, while servicing medical equipment.

7. **PATIENT HEALTH INFORMATION (PHI) AND INDIVIDUALLY IDENTIFIABLE INFORMATION (III):**

This system does contain Patient Health Information (PHI) and Individually Identifiable Information (III). No VA data will leave the VA Facility. If a hard drive or any other electronic storage device needs to be replaced, the device will be given to the ISO. After destruction of the data by degaussing, the device may be returned to the vendor for inventory control if so requested. The repair of this system will be supervised by a VA employee in BioMed to assure data does not leave the facility. The COR is responsible to assure that no VA data leaves the facility and an employee supervises repair. No Security & privacy training is needed by the vendor because the repair will be supervised. No other security statement is needed.

8. **DOCUMENTATION:** Contractor will provide the COTR with individual written reports which describe the maintenance and repair service performed on the equipment under warranty in sufficient detail so as to be acceptable by field inspectors of the Joint Commission and other inspecting bodies. This shall include a list of all parts replaced, all service performed as well as a statement that the equipment is operating per manufacturer's specifications after repair. The service report will be signed by the contractor's service technician, and by designated VANTHCS personnel.

- a. Prior to award, bidder must have a facility to include personnel, test equipment, parts inventory, training certificates, licenses and technical documentation available for inspection by VA Medical Center personnel and be able to show written evidence to technical qualifications of personnel, test equipment (and calibration documentation) licenses and availability of parts. Parts availability must be written documentation from either the equipment manufacturer or authorized parts supplier. In either case, bidder must be able to show the availability of parts to him/her within 24 hours after initial call. For contracts for maintenance and repair services form

other than the original manufacturer or a designated representative, the Contractor will be fully responsible for obtaining all technical documentation necessary to fulfill contractual obligations.

- b. The Contractor warrants that the services to be performed under this contract will be performed in a good workmanship manner and shall conform to the standards of the industry. This warranty is given expressly and in place of all other warranties, expressed or implied, statutory or otherwise, and is the only warranty given by the Contractor.
 - c. Warranty items that expire during the contract period will be added to the contract as appropriate.
9. **NEGLIGENCE CLAUSE:** When services and parts are required as a result of accident, abuse, misuse or negligence by other than the Contractor or his representative, and are not included as a part of PM inspection or service calls, such needs will be reported to the Contracting Officer's representative along with estimates of charges. The Contracting Officer and Representative will evaluate these needs and authorize appropriate action. The parts will be installed under the terms of the contract and each invoice is to include a legible itemized list of labor charges and parts costs. The government will incur no charges for service and parts including glassware due to accident, abuse, misuse or negligence by the contractor or his representative.
10. **RECORDS MANAGEMENT:** All records (administrative and program specific) created during the period of the contract belong to VA North Texas Health Care System(VANTHCS) and must be returned to VANTHCS at the end of the contract or destroyed in accordance to the VHA Record Control Schedule (RCS)10-1. NARA RM Language Clause to be included in contracts:
- a. Citations to pertinent laws, codes and regulations such as 44 U.S.C Chapter 21 , 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
 - b. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
 - c. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government 'IT' equipment and/or Government records.
 - d. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
 - e. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract or identified in the RCS 10-1.
 - f. The Government Agency owns the rights to all data/records produced as part of this contract.
 - g. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
 - h. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].

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- i. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.
- j. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under or relating to this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

11. END OF CONTRACT: Contractor guarantees that all equipment covered in this contract shall meet or exceed manufacturer's performance specifications at the contract expiration date.