

STATEMENT OF WORK

TITLE OF PROJECT:

ETCo2 Capnography upgrade to Spacelabs monitoring equipment for ED, IR, ICU, GU/ENDO Departments at the Syracuse VA Medical Center, Syracuse, NY

BACKGROUND:

Urgent and emergent airway management is often required outside of an operating room. It is critical that VA have both functional equipment and appropriate individuals who respond to the airway management needs of a given patient and are trained to perform airway management. Competence in airway management must be demonstrated and cannot be assumed based solely on job title, which includes physicians.

Use of Capnography ETCo2 equipment allows VA Clinical professionals to monitor the concentration or partial pressure of carbon dioxide in the respiratory gases of the lungs during anesthesia and intensive care for patients who will undergo or are currently have esophageal intubation. The VA Syracuse VA Medical Center is seeking to upgrade its current ETCo2 (Capnography) Monitoring equipment and acquire additional components as necessary to continue providing safe patient monitoring during procedures that use moderate sedation with the most current capnography equipment spacelabs is able to provide. Equipment and accessories to be provided must integrate and be compatible with existing Spacelabs ETCo2 configuration.

TYPE OF CONTRACT:

Firm-Fixed-Price

PERFORMANCE PERIOD:

The contractor shall complete the work required under this SOW within 60 Days or less from date of award, unless otherwise directed by the Contracting Officer (CO). If the contractor proposes an earlier completion date, and the Government accepts the contractor's proposal, the contractor's proposed completion date shall prevail. Work at the Government site shall not take place on Federal holidays or weekends unless directed by the CO.

PLACE OF PERFORMANCE / DELIVERY:

ATTN: Carol Agan, RN
Department of Veteran Affairs
Syracuse VA Medical Center
800 Irving Avenue
Syracuse, NY 13210

INFORMATION SECURITY CONSIDERATIONS:

The Certification and Accreditation (C&A) requirements do not apply and a Security Accreditation Package is not required.

All VA sensitive information shall be protected at all times in accordance with local security field office System Security Plans (SSP's) and Authority to Operate (ATO)'s for all systems/LAN's accessed while performing the tasks detailed in this SOW.

Invoicing

All vendors invoicing VA are required to use the Tungsten Network (Formerly OB-10) e-Invoicing system to submit invoices for payment. It is the responsibility of the vendor to have an active OB10 account established prior to invoicing.

For OB10 registration and/or additional information, please use:

<http://www.tungsten-network.com/US/en/veterans-affairs/>

SCOPE:

1. Introduction of Required Specifications:

- 1.1.1 Purpose: The purpose of this Statement of Work (SOW) is to outline the tasks and responsibilities of the awarded contractor in relation to the delivery of the requested ETCO2 modules, associated accessories and subsequent trade-in of Government owned equipment.
- 1.1.2 Primary Goals: The new ETCO2 modules will add existing functionality to the current Government owned patient monitors. The ETCO2 modules is designed to measure the concentration of carbon dioxide in a gas mixture and to aid in determining the patient's ventilatory, circulatory, and metabolic status.
- 1.1.3 Industry Standards: Unless otherwise stated, all equipment must be held to current industry standards for such equipment as present within the current market for telemetry system equipment, supplies, and related services.

1.2 Definitions:

- 1.2.1 ETCO2 Module: Also known as a "Capno" (Capnography) module measures the concentration of carbon dioxide in a gas mixture and to aid in determining the patient's ventilatory, circulatory, and metabolic status.
- 1.2.2 OEM: Original equipment manufacturer.
- 1.2.3 Depot Support: No cost biomed spares are shipped to the hospital at the cost of the Contractor. The hospital is responsible for the cost of shipping the equipment in need of repair to the Contractor's headquarters.

1.3 Equipment Requirements:

- 1.3.1 ETCO2 (Capno) Modules:
 - Must be compatible with existing Spacelabs patient monitors

- Must continuously measure ETCO2 (minimum CO2 and respiration rate)
- Must automatically compensate for ambient barometric pressure
- Must compensate for the presence of increased levels of nitrous oxide and oxygen
- Must automatically detect sample line occlusions

1.3 Delivery:

- 1.3.1 Delivery of ETCO2 modules and associated accessories is 30 days after Contractor acknowledgment of order.
- 1.3.2 Delivery is FOB Destination to Syracuse VAMC.

1.4 Support Features:

- 1.4.1 Telephone Support: Must include 24x7x365 Unlimited Telephone Support, 24x7 Go-Live Clinical Support by Telephone per Department, 24x7 Ongoing Clinical Support by Telephone per Department for the life of the system.

1.5 Warranty:

- 1.5.1 Equipment Warranty: The equipment contained in this contract comes with a standard one year warrant that begins at clinical acceptance. Additionally, the equipment comes with 4 years of depot support
- 1.5.2 Third Party Product Warranty: Any third part products contained in this contract come with a standard 1 year warranty that starts at the time of installation. After this time period the hospital is responsible for maintenance of these items with the OEM.
- 1.5.3 Supply and Accessory Warranty: Customer can return supplies and accessories that are new with unopened packaging within 90 days with no restocking fee. Return of supplies and accessories after 90 days will not be accepted.

1.6 Trade-In:

- 1.6.1 Trade-in for existing Government owned equipment is included in this contract. Once the Syracuse VAMC has identified and relocated trade-in equipment to a safe area, taken off the property book (if applicable), and trade-in equipment form is properly completed Spacelabs will ensure the equipment is removed and processed IAW local policies and regulations.

1.7 Exclusions:

- 1.7.1 Asbestos testing or abatement is not the responsibility of the Contractor.
- 1.7.2 The contractor will not work in a bio-hazardous, radioactive, toxic, or other high-risk environment.
- 1.7.3 The Contractor will not provide structural, mechanical or electrical drawings.

Product Descriptions, Items Numbers and Quantity are listed below:

IR

Line	Description	Item Number	Qty.
1	Capnography Module	92517	3
2	English Language	92517-1	3
3	Capnography Module, base unit	92517-A *	3
4	Integrated Module Housing (IMH)	91493 *	3
5	Depot Support Plan. Unit price	999-9999-42	4

	is per year. Monitoring Products only.		
6	Trade in discount, monitoring items. REQUIRES the completion and return of the Trade-in Equipment Form on page 9 with your purchase order.	7000-0001-999	1
7	Adds two additional waveforms to an Ultraview SL2200, SL2400, SL2600 or SL2800	040-1523-00 *	3
8	Roll Stand, Quick Release with Drop-In Backplate	016-0940-00	1
9	Universal Power Supply Holster, Rollstand Mounted	016-0760-00 *	1
10	Adapter Plate, Quick Release (for use with 91370/91369/91367)	016-0946-00	1
11	Patient Monitoring Operations Manual, CD-ROM, English	084-1101-03	1
12	Installation	999-9999-97	1

ED

Line	Description	Item Number	Qty.
1	Capnography Module	92517	2
2	English Language	92517-1	2
3	Capnography Module, base unit	92517-A *	2
4	Depot Support Plan. Unit price is per year. Monitoring Products only.	999-9999-42	4
5	Trade in discount, monitoring items. REQUIRES the completion and return of the Trade-in Equipment Form on page 9 with your purchase order.	7000-0001-999	1
6	Patient Monitoring Operations Manual, CD-ROM, English	084-1101-03	1

ICU

Line	Description	Item Number	Qty.
1	Capnography Module	92517	3
2	English Language	92517-1	3
3	Capnography Module, base unit	92517-A *	3
4	Depot Support Plan. Unit price is per year. Monitoring Products only.	999-9999-42	4
5	Trade in discount, monitoring items. REQUIRES the completion and return of the Trade-in Equipment	7000-0001-999	1

	Form on page 9 with your purchase order.		
6	Patient Monitoring Operations Manual, CD-ROM, English	084-1101-03	1

ENDO

Line	Description	Item Number	Qty.
1	Capnography Module	92517	11
2	English Language	92517-1	11
3	Capnography Module, base unit	92517-A *	11
4	Integrated Module Housing (IMH)	91493 *	11
5	Depot Support Plan. Unit price is per year. Monitoring Products only.	999-9999-42	4
6	Ultraview SL, Refurbished	R-91369	1
7	SL2400 Compact Monitor, Refurbished	R-91369-24	1
8	English Language, Refurbished	R-91369-1	1
9	Six Waveforms, Refurbished	R-91369-06	1
10	Perioperative, Refurbished	R-91369-D	1
11	Data Shuttle, Refurbished	R-91369-Q	1
12	Recorder, Refurbished	R-91369-U	1
13	Ultraview SL Command Module	91496	1
14	English Language	91496-1	1
15	Non-Invasive Parameter Set	91496-A*	1
16	Advanced Multiview Arrhythmia (MVII)	91496-H*	1
17	Nellcor SpO2	91496-N*	1
18	Adult/Neonatal Respiration	91496-R*	1
19	ST Segment Analysis	91496-S*	1
20	Integrated Module Housing (IMH)	91493 *	1
21	Depot Support Plan. Unit price is per year. Monitoring Products only.	999-9999-42	4
22	Roll Stand, Quick Release with Drop-In Backplate	016-0940-00	1
23	Universal Power Supply Holster, Rollstand Mounted	016-0760-00 *	1
24	Adapter Plate, Quick Release (for use with 91370/91369/91367)	016-0946-00	1
25	TruLink ECG Cable, shielded, 5-Lead Spacelabs Monitors to combiner, 305 cm /10 ft, AAMI**	700-0008-57	1
26	TruLink ECG Leadwire Set, Reusable, 5-Lead DIN shielded with combiner, pinch, 74 cm/29 in, AAMI**	700-0006-37	1
27	Nellcor DS-100A finger sensor, adult, reusable, OxiMax (each)	690-0003-01 *	1

<u>Depth</u>	17.8 cm (7 in)
<u>Weight</u>	0.8 kg (1.7 lb)
<u>Carbon Dioxide</u>	<p>Sidestream — FiO₂ and ETCO₂ are displayed after one breath and have a continuously updated breath average. ET will typically decrease below nominal value (ET_{nom}) when respiration rate (RR) exceeds the RR threshold (RR_{th}) according to the following formula:</p> <p>CO₂: $ET = ET_{nom} \times 125/RR$ for $RR_{th} > 125$</p> <p>Mainstream - ETCO₂ will be within specification for all respiration rates up to 150 bpm</p> <p>Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101</p>
<u>Range</u>	0 to 120 mmHg (0 to 16 kPa), 15%
<u>Resolution</u>	1 mmHg (0.1 kPa), 0.1%
<u>Measurement Rise Time</u>	<200 msec typically
<u>Accuracy</u>	±(0.2 vol% + 2% reading)
<u>Values</u>	Inspired/expired
<u>Gas Cross Effects</u>	<0.2% (O ₂ , N ₂ O, anesthetic agents)
<u>Respiratory Rate</u>	<p>Measurement based on CO₂ waveform; breath detection is based on a 1% change in CO₂ level</p> <p>Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101</p>
<u>Range</u>	1 to 150 BPM
<u>Accuracy</u>	±1 BPM
	<i>Apnea</i>
<u>Range</u>	20 to 45 seconds
<u>Resolution</u>	5 seconds
<u>Accuracy</u>	±1 second

<u>Warm Up</u>	<30 seconds following power on or a change in the operating mode between sidestream and mainstream for concentration reporting and full accuracy specification
<u>Sample Line Flow Rates</u>	50 ml/min □ 10 ml/min
<u>Total System Response</u>	Time Sidestream: <3 seconds Mainstream: <1 second
<u>CO2 Waveform Scales</u>	Selectable at 0 to 120 mmHg, 0 to 100 mmHg, 0 to 80 mmHg, 0 to 60 mmHg, 0 to 40 mmHg, 0 to 15 kPa, 0 to 12.5 kPa, 0 to 10 kPa, 0 to 7.5 kPa, 0 to 5 kPa, 0 to 15%, 0 to 12.5%, 0 to 10%, 0 to 7.5%, 0 to 5%
<u>Waveform Speeds</u>	Selectable at 25, 12.5, 6.25, 3.12, or 1.56 mm/second
<u>Measurement Units</u>	%, mmHg, kPa for CO2; BPM for respiration rate
<u>Alarms</u>	User-selectable; respiration rate (high and low limits), EtCO2 (high and low limits), MINCO2 (high limits), and apnea
<u>Gas Calibration</u>	Calibration from external gas mixture
<u>Occlusion</u>	Automatically detects sample line occlusions
<u>Suspend Sampling</u>	In suspend mode, sensors continue to operate but pumps stop and waveform and numeric zones are cleared

Classification

<u>MDD</u>	Class IIb
<u>EN 60601-1</u>	Class I Type BF defibrillator proof; device is not affected by patient defibrillation.
<u>CISPR11</u>	Group 1, Class B Suitable for use in domestic establishments connected to a low-voltage supply network.

Electrical Specifications

Power supplied by monitor.

Environmental Requirements

Operating

<u>Temperature</u>	0° to 50° C (32° to 122° F)
<u>Ambient Humidity</u>	<4 kPa H ₂ O (non-condensing), 95% RH at 30° C
<u>Atmospheric Pressure</u>	394 to 900 mmHg (52.5 to 120 kPa)

Storage

<u>Temperature</u>	-40° to 70° C (-40° to 158° F)
<u>Ambient Humidity</u>	5 to 100% RH (condensing), 100% RH at 40° C* *After condensation, store the unit for more than 24 hours in an environment with relative moisture content below 95% RH (non-condensing)
<u>Atmospheric Pressure</u>	0 to 11,760 meters (0 to 38,000 feet) (0 to 150 mmHg)

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