

# Notice of Intent to Certify Sole Source

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**To:** Interested Parties

**From:** Stacy Baldwin  
Agency Procurement Officer

**Date:** March 7, 2016

**Re:** Sole Source Certification Number **SS5017** for **Bravo pH Recorders and Calibration Stand**

**Contact Email Address:** [solesource@umc.edu](mailto:solesource@umc.edu)

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## Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5017** for **Bravo pH Recorders and Calibration Stand**, please be advised that UMMC intends to award the purchase of the **Bravo pH Recorders and Calibration Stand** to **Covidien** as the sole source provider of the **Bravo pH Recorders and Calibration Stand**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

## Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

## Schedule

<b>Task</b>	<b>Date</b>
First Advertisement Date	March 7, 2016
Second Advertisement Date	March 14, 2016

Response Deadline from Objectors	March 24, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before April 21, 2016

## Project Details

**1. Describe the commodity that the agency is seeking to procure:**

The University of Mississippi Medical Center (UMMC) seeks to purchase two additional Bravo pH Recorders with a Calibration Stand. The Adult Gastroenterology service is expanding their motility service. A GI motility specialist has joined the staff to provide testing, staffing competency and resident training. The Pediatric and Adult practice are currently sharing equipment. The increase in patient volume is creating a waiting list due to only two recorders being available at present within the organization.

The requested recording equipment is used to gather data in a wireless environment. Bravo pH monitoring is capsule-based and used to identify the presence of acid reflux. Data is collected over several days, which allows the doctor to evaluate reflux symptoms by determining the frequency and duration of acid flowing back up into the esophagus. The test is used to confirm if the patient's symptoms are caused by gastroesophageal reflux disease (GERD).

Bravo pH monitoring is unique because of its catheter-free design. By using a miniature pH capsule attached to the esophagus, pH data from the esophagus can be wirelessly transmitted to a small recorder worn on a shoulder strap or waistband.

**2. Explain why the commodity is the only one (1) that can meet the needs of the agency:**

The Bravo recorders are the only capsule wireless devices available to measure the pH of the esophagus. The equipment will allow patients to be scheduled without coordinating or delaying a care plan. The Adult service cannot grow with the existing equipment owned by the Pediatric service. These recorders are compatible with existing software.

**3. Explain why the source is the only person or entity that can provide the required commodity:**

Covidien is the sole provider for the wireless recorders, existing software and license purchased by the organization. See supporting letter from **Covidien**, Attachment A.

**4. Explain why the amount to be expended for the commodity is reasonable:**

The estimated amount to be expended is for the purchase of the **Bravo pH Recorders and Calibration Stand** is \$15,000. This amount is within the expected price range for these products.

**5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:**

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

### **Submission Instructions and Format of Response from Objecting Parties**

Interested parties who have reason to believe that the **Bravo pH Recorders and Calibration Stand** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **Covidien**. The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Thursday, March 24, 2016, at 3:00 p.m. (Central Time) to [solesource@umc.edu](mailto:solesource@umc.edu). Responses may be delivered via email to [solesource@umc.edu](mailto:solesource@umc.edu). UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact [solesource@umc.edu](mailto:solesource@umc.edu).

Attachment A: Vendor Correspondence

Attachment B: Objection Certification



Dear Andrea

This letter is to confirm Given Imaging as the sole source manufacturer of the ManoScan® high resolution manometry system and the Bravo® capsuled-based pH monitoring system.

ManoScan acquisition software incorporates unique capabilities including anatomical model data visualization of the esophagus with real time pressure profiles of Upper Esophageal Sphincter (UES), Esophageal Body and Lower Esophageal Sphincter, (LES). ManoView™ analysis software provides the eSleeve™ tool to measure sphincter barrier pressure, as well as graphical pointers to locate LES, UES, and Pressure Inversion Point (PIP) quickly and reliably. ManoScan catheters utilize a proprietary tactile-array pressure sensing technology that is unique to the ManoScan system. These catheters are designed, manufactured, serviced and supported by Given Imaging.

Given Imaging owns multiple patents on the ManoScan system related to software visualization and sensor technology. Patents for the ManoScan System are outlined in the table below.

Product	Patent #.	Title
ManoScan Z A200	8,306,290	"Diagnostic system for display of high-resolution physiological data of multiple properties"
ManoScan SW	8,075,502	"Visualization of values of a physical property detected in an organism over time"
	8,306,604	"Method of measuring and displaying the position of radio-graphically contrasted material within luminal body organs"
ManoScan AR SW	8,075,502	"Visualization of values of a physical property detected in an organism over time"
ManoView SW	8,075,502	"Visualization of values of a physical property detected in an organism over time"
	8,306,604	"Method of measuring and displaying the position of radio-graphically contrasted material within luminal body organs"
ManoView AR SW	8,075,502	"Visualization of values of a physical property detected in an organism over time"
HRM 3D Catheters	7,944,008	"Suspended membrane pressure sensing array"

Note: There are multiple competitive products sold in the US with claims of High Resolution Manometry, (HRM). These competitive products are different from the ManoScan System in that they do not provide unique features such as anatomical model data visualization software features nor a proprietary tactile-array pressure sensing technology.

Bravo® pH monitoring utilizes a miniature pH capsule attached to the esophagus, which collects and transmits pH data wirelessly to a small recorder worn on a shoulder strap or waistband. Information is collected over multiple days, which allows the doctor to evaluate reflux symptoms by determining the frequency and duration of acid flowing back up into the esophagus.

Given Imaging owns the patent on the Bravo capsule-based pH system related to software visualization. The patent for the Bravo pH system is outlined in the table below.

Product	Patent #.	Title
Bravo	6,285,897	"Remote physiological monitoring system"

Thank you for your interest in the ManoScan high resolution manometry and Bravo pH monitoring systems. If you should need additional materials or have questions, please feel free to contact me.

Bart Bedford

Capital Sales Specialist  
[Barton.Bedford@covidien.com](mailto:Barton.Bedford@covidien.com)  
 Phone: 205-234-9328  
 Mobile: 205-234-9328

Attachment B

**SUBMITTED IN RESPONSE TO  
Sole Source Certification No. SS5017  
Accepted until March 24, 2016, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

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Objector Name  
Objector's title

\_\_\_\_\_  
Date