

## Alaris™ IV Pumps

### Justification for Other than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs (VA)  
Office of Acquisition Operations  
Strategic Acquisition Center  
10300 Spotsylvania Ave, Suite 400  
Fredericksburg, VA 22408
2. Description of Action: The proposed action is for a brand name, 3-year Firm-Fixed Price Requirements type contract that includes decentralized orders for Alaris™ Brand Infusion (IV) Pumps to include related software and server packages. The proposed effort is in support of Veterans Health Administration (VHA), Procurement and Logistics Office who provides Life Cycle Management support for Alaris™ Brand Infusion IV Pumps to 78% (133 of 170) of the VA Medical Centers that will be replacing equipment due to expiring service life within the next 36 months.
3. Description of Supplies or Services: The Alaris™ Pump module is large volume infusion pumps that helps continuously or intermittently deliver fluids, medications, blood and blood products to adult, pediatric or neonatal patients. Clinicians can attach up to four IV infusion modules, allowing four independent infusions on a single pump unit. The IV pumps are designed to deliver solutions (typically) through intravenous (IV), epidural, and /or subcutaneous routes at pre-established accurate flow rates. The proposed action is to provide replacement of Alaris™ Pump module with software and related equipment to those centers listed in Table 1 which are currently only using the Alaris™ Pump with forecasted replacement quantities.

Table 1

Centers	VISN
(405) White River Junction VT	1
(650) Providence, RI	1
(402) Togus ME	1
(689) Connecticut HCS (Westhaven)	1
(518) Bedford, MA	1
(523) Boston HCS (Boston)	1
(608) Manchester, NH	1
(631) Northampton, MA	1
(528A5) Canandaigua, NY	2
(528A8) Albany, NY	2
(528A6) Bath, NY	2
(528) Buffalo, NY	2
(526) Bronx, NY	2
(528A7) Syracuse, NY	2

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Centers	VISN
(630) New York HHS (Brooklyn)	2
(632) Northport, NY	2
(561) New Jersey HCS (East Orange)	2
(620) Hudson Valley HCS (Castle Point, Montrose)	2
(460) Wilmington DE	4
(542) Coatesville, PA	4
(642) Philadelphia, PA	4
(503) Altoona, PA	4
(562) Erie, PA	4
(595) Lebanon, PA	4
(646) Pittsburgh HCS (Pittsburgh PA)	4
(693) Wilkes-Barre, PA	4
(529) Butler, PA	4
(540) Clarksburg, WV	5
(688) Washington DC	5
(517) Beckley, WV	5
(512) Maryland HCS (Baltimore MD)	5
(613) Martinsburg, WV	5
(637) Asheville, NC	6
(659) Salisbury, NC	6
(558) Durham, NC	6
(565) Fayetteville, NC	6
(590) Hampton, VA	6
(652) Richmond, VA	6
(658) Salem, VA	6
(509) Augusta, GA	7
(619) Central Alabama HCS (Montgomery AL)	7
(521) Birmingham, AL	7
(557) Dublin, GA	7
(508) Atlanta, GA	7
(534) Charleston, SC	7
(679) Tuscaloosa, AL	7
(544) Columbia, SC	7
(672) San Juan, PR	8
(573) N. Florida/S. Georgia HCS (Gainesville FL)	8
(546) Miami, FL	8
(673) Tampa, FL	8
(548) West Palm Beach, FL	8
(516) Bay Pines, FL	8
(675) Orlando, FL	8
(603) Louisville, KY	9

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Centers	VISN
(626) Tennessee Valley HCS (Nashville TN)	9
(614) Memphis, TN	9
(596) Lexington, KY	9
(506) Ann Arbor, MI	10
(538) Chillicothe, OH	10
(757) Columbus, OH	10
(541) Cleveland, OH	10
(552) Dayton, OH	10
(610) Northern Indiana HCS (Marion, IN)	10
(515) Battle Creek, MI	10
(553) Detroit, MI	10
(655) Saginaw, MI	10
(583) Indianapolis, IN	10
(537) Chicago (Westside), IL	12
(578) Hines, IL	12
(585) Iron Mountain, MI	12
(607) Madison, WI	12
(676) Tomah, WI	12
(695) Milwaukee, WI	12
(556) North Chicago, IL	12
(550) Illiana HCS (Danville IL)	12
(589) Kansas City, MO	15
(589A4) Columbia, MO	15
(589A5) Eastern Kansas HCS	15
(589A7) Wichita, KS	15
(657A4) Poplar Bluff, MO	15
(657A5) Marion, IL	15
(657) St. Louis, MO	15
(502) Alexandria, LA	16
(586) Jackson, MS	16
(520) Biloxi, MS	16
(564) Fayetteville, AR	16
(667) Shreveport, LA	16
(580) Houston, TX	16
(598) Central Arkansas HCS (Little Rock AR)	16
(629) New Orleans, LA	16
(671) South Texas HCS (San Antonio TX)	17
(519) West Texas HCS (Big Spring TX)	17
(756) El Paso, TX	17
(549) North Texas HCS (Dallas TX)	17
(740) Texas Valley Coastal Bend HCS (Harlingen TX)	17

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Centers	VISN
(504) Amarillo HCS (Amarillo TX)	17
(674) Central Texas HCS (Temple TX)	17
(501) New Mexico HCS (Albuquerque NM)	18
(649) Northern Arizona HCS (Prescott AZ)	18
(678) Southern Arizona HCS (Tucson AZ)	18
(644) Phoenix, AZ	18
(442) Cheyenne WY	19
(635) Oklahoma City, OK	19
(554) Eastern Colorado HCS (Denver CO)	19
(575) Grand Junction, CO	19
(660) Salt Lake City HCS (Salt Lake City UT)	19
(623) Muskogee, OK	19
(666) Sheridan, WY	19
(653) Roseburg HCS (Roseburg OR)	20
(668) Spokane, WA	20
(663) Puget Sound HCS (Seattle WA)	20
(687) Walla Walla, WA	20
(531) Boise, ID	20
(648) Portland, OR	20
(640) Palo Alto HCS (Palo Alto CA)	21
(662) San Francisco, CA	21
(459) VA Pacific Islands HCS (Honolulu HI)	21
(570) Central California HCS (Fresno CA)	21
(612) Northern California HCS (Martinez CA)	21
(654) Sierra Nevada HCS (Reno NV)	21
(593) Southern Nevada HCS (Las Vegas NV)	21
(605) Loma Linda, CA	22
(600) Long Beach HCS (Long Beach CA)	22
(691) Greater Los Angeles HCS (Los Angeles CA)	22
(664) San Diego HCS (San Diego CA)	22
(618) Minneapolis, MN	23
(656) St. Cloud, MN	23
(636) Omaha, NE	23
(636A6) Des Moines, IA	23
(636A8) Iowa City, IA	23
(438) Sioux Falls SD	23
(568) Black Hills HCS (Fort Meade SD)	23

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The brand name items required for this contract are listed in Table 2, Alaris™ Product List. The total estimated cost is \$ [REDACTED].

Table 2

ALARIS™ Part Number: Description	Forecasted Replacements
8015: ALARIS™ PC UNIT 8015 - W 802.11 G/B	7,200
8100: ALARIS™ PUMP MODULE 8100 V8.5.29.0	9,000
8110: ALARIS™ SYRINGE MODULE 8110 V8	225
8120: ALARIS™ PCA MODULE 8120 V8	900
8300: ALARIS™ ETCO2 MODULE V8	900
8600: ALARIS™ AUTO-ID MODULE	300
8650: ALARIS™ AUTO-ID HANDHELD SCANNER	300
SVR PKG1: Server Package (Pre-loaded Alaris™)	51
GUARDRAILS-ETC021: GUARDRAILS-ETC021-SITE LICENSE FEE	900
GUARDRAILS-LVP1: GUARDRAILS LVP LICENSE FEE	9,000
GUARDRAILS-PCA1: GUARDRAILS PCA LICENSE FEE	900
GUARDRAILS-SYR1: GUARDRAILS SYR LICENSE FEE	225
GUARDRAILS-MX-8015: GUARDRAILS SUITE MX-8015	7,200
SMARTSERVICE1: SMARTSERVICE IMPLEMENTATION < 250 POC UNITS	36
SMARTSERVICE2: SMARTSERVICE IMPLEMENTATION 251 - 749 POC UNITS	15
SMARTSERVICE3: SMARTSERVICE IMPLEMENTATION 750 + POC UNITS	3
SVR-SERVICES: FLAT FEE FOR FACILITY/DATA CENTER IMPLEMENTATION	51
SVR-SERVICES2: SERVER IMPLEMENTATION SERVICES- ADDITIONAL CONNECTIVITY INTO EXISTING ALARIS™ SYSTEM MANAGER-REMOTE	51
ALARIS™ SVR PKGV3: ALARIS™ SYSTEMS MANAGER (MODEL 8015)	7200
DEDICATED ALARIS PRE-LOADED SERVER PACKAGE	51
SERVER ADMINISTRATION FEE (ANNUAL FEE)	51
BIOMEDICAL ENGINEERING USER TRAINING	51
CLINICAL END USER TRAINING	51

Total Forecasted Replacements is based on inventory replacement data for various configurations of Alaris™ Pumps with software and related equipment.

4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C. 3304(a)(1) as implemented by Federal Acquisition Regulation (FAR) 6.302-1(c), "Only One Responsible Source and no Other Supplies or Services will Satisfy Agency Requirements, Application for Brand-Name Description."

5. Rationale Supporting Use of Authority Cited Above: The products identified in Table 2, have been determined to be the primary IV Pumps with related software and server packages for those specified facilities (Table 1) currently using the Alaris™ IV Pumps

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100% throughout the facility. The Alaris™ brand IV pumps is the only FDA approved modular pump marketed in the USA. The modular approach allows for optimal clinical flexibility as the pumps can be configured on-the-fly in the hospital from single or up to four channels depending on the critical nature of the patient's needs. The modular capability is required to allow the operation of the Patient Controlled Analgesic (PCA), Syringe, ETCO2 and Bar Code Quality Assurance (QA) modules which are attached and utilize the same "brain" found on the main pump.

Only one alternate brand infusion pump was found to be able to provide a capability similar to the modular configuration. The alternate infusion pump provides for attaching up to five additional modules by using the process of daisy chaining. This process requires the clinician to connect the power cords into the back of each unit; however each unit still requires its own brain, which requires you to have to program each separately. Unlike the alternate brand infusion pump, the Alaris™ infusion pump utilizes only one brain unit that runs the four pumps which attach like an erector set by snapping together. This also allows for more economical purchasing as the "modular approach" to usage can be taken so that administration sets and accessories already stocked to maintain the correct mix of modules in response to patient needs with no extra functionality not being utilized. The alternate infusion pump does not allow for the modules on hand to attach to the pump, nor is it Federal Information Processing Standard Publication (FIPS) certified.

The NIST requires private manufacturers and/or vendors to comply with the FIPS security accreditation program ensuring that any sensitive but unclassified information will be protected. The Alaris™ pumps are FIPS PUB 140-2, Level 2 certified, which is a U.S. government computer security standard used to approve cryptographic modules. Security Level 2 improves upon the physical security mechanisms by requiring features that show evidence of tampering, including tamper-evident coatings or seals that must be broken to attain physical access to the plaintext cryptographic keys and critical security parameters (CSPs) within the module, or pick-resistant locks on covers or doors to protect against unauthorized physical access. Without the FIPS validation the device could not connect to the network.

Market research revealed that only the Alaris™ brand is currently FIPS certified with the modular capability which is required for the operation of the Patient Controlled Analgesic (PCA), Syringe, ETCO2 and Bar Code Quality Assurance (QA) modules currently on hand.

The goal with this acquisition is to provide medical device users for the facilities identified with a means to procure the specified makes and models of technical equipment for replacement during life cycle management of Alaris™ IV Pumps.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section (Section 8) of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. Additionally, the proposed action will be synopsisized on the Federal Business Opportunities Page in accordance with FAR 5.201

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and the approved Justification will be made available with the published solicitation in accordance with FAR 6.302-1(c).

7. Actions to Increase Competition: The Government will continue to conduct market research to ascertain if there are advance technology changes in the market place that would enable future actions to be competed. Additionally, in order to remove or overcome barriers to competition in future acquisitions, the agency will work with the program office to perform additional market research to consider if alternate solutions can be considered.

8. Market Research: Market research was conducted and concluded that there are alternate manufacturers for this product. However, while these companies' manufacturer similar products it has been concluded that due to the required modular approach and wireless updates to drug library on individual infusion pumps the Alaris™ IV Pumps is the only option for replacing the equipment at the specified facilities. Only the Alaris™ brand infusion pump was found to be FIPS 140-1 and FIPS 140-2 validated to allow connection to the network with the ability to provide a modular approach which allows the attachment of the required PCA, Syringe, ETCO2 and QA modules.

The VetBiz.gov database was queried using the following search criteria: 339112 NAICS Code, and keywords "Alaris Infusion Pumps". This query yielded eight matches; see Table 3.

Table 3


Table 3 VetBiz Search Results		
Vendor	Carries Alaris Pumps	Socio-Economic
1ST AMERICAN MEDICAL DISTRIBUTORS, INC.	No	SDVOSB
AvKARE, Inc	No	SDVOSB
MEDICAL PLACE INC	No	VOSB
PERFORMANCE BIOMEDICAL LLC	No	VOSB
Rome Corporation	No	SDVOSB
TIGER SOLUTIONS INTERNATIONAL, LLC	No	SDVOSB
Vanguard Global Solutions, Inc.	No	SDVOSB




This research revealed that no SDVOSB/VOSB could provide Alaris™ IV Pumps since they are manufactured by only one company who is Becton Dickinson (BD)/CareFusion. Each vendor was contacted and they stated they could not provide the Alaris™ IV Pump. This was confirmed with the manufacturer, at which point they indicated that they currently have no authorized resellers or distributors. As a result of the market research, only the Alaris™ brand infusion pump was found to be FIPS certified with the FDA approved modular capability with only the original equipment manufacturer being able to meet the needs of the government.


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9. Any Other Facts Supporting this Justification: Outside of the original equipment manufacturer, three companies expressed an interest in this procurement. One can provide the Alaris™ brand IV pump, but not the services while the other two could not provide the modular capability.

10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

  
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 Deputy Program Manager

11. Fair and Reasonable Cost Determination: I hereby determine that the anticipated price to the Government for this contract action will be fair and reasonable based on:

- a. Comparison of the proposed prices to the historical prices paid, whether by the Government or other than the Government for the same or similar items.
- b. Comparison with competitive published price lists, published market prices of commodities, similar indexes, and discount or rebate arrangements.
- c. Comparison of proposed prices with an Independent Government Cost Estimate.

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


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 Contracting Officer



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### Approval

Based on the foregoing justification, I hereby approve the acquisition of brand name Alaris™ IV Infusion Pumps and server packages from BD/CareFusion, in the estimated total amount of \$[REDACTED], on an other than full and open basis, pursuant to the authority cited in FAR 6.302-1(c), Only One Responsible Source and no Other Supplies or Services Will Satisfy Agency Requirements, subject to availability of funds, and provided that the services and commodities herein described have otherwise been authorized for acquisition.



Head of Contracting Activity  
Strategic Acquisition Center