DELTA COUNTY Memorial HOSPITAL

Capital Expenditure Request (CER) Worksheet

Date:	12/16/2020
Department:	Urology
Manager:	Diane Dockter
Capital Description:	CystoNephro Videoscope

PROJECT EXPENSE:	
Total Project **Budget**: Includes equipment, interfaces, shipping, installation, facility modifications, etc.	$0.00
Total Project **Cost**: Includes equipment, interfaces, shipping, installation, facility modifications, etc.	$20,511.95
Total Project **Variance**:	$20,511.95

NEED:

Check all that apply:

- ☒ Necessary to meet regulatory requirements, patient care is jeopardized without
- ☐ Equipment upgrade, enhances productivity
- ☒ New service, business development

Have you?

- ☒ Involved affected employees?
- ☒ Involved affected physicians?

Equipment:

Function:
CystoNephro Videoscope is used in the clinic to view the lining of the bladder and urethra.

Benefit:

Detection of abnormalities or tumors. A second videoscope will allow scopes to be scheduled back to back, creating more efficient scheduling. Currently, due to the 30 minutes required for cleaning and sterilizing the scope, scope procedures can't be scheduled back to back. Approximately 120 scopes were performed in 2020.

Additional Operating Costs: ****(Please identify additional costs such as additional staff time and training, supplies, maintenance agreements, etc.)*

None.

Life Expectancy:

10 years.

PURCHASE:

Is the equipment available through the hospital's purchasing agreements?

☒ Yes
☐ No -- Justification:

Vendor Comparison:

	Vendor 1	Vendor 2	Vendor 3
Vendor Name	Olympus		
Vendor Address	3500 Corporate Pkwy. Center Valley, PA		
Vendor Contact	Bert Bair		
Vendor Phone	303-325-1456		
Price	$20,511.95		
Additional Costs	$0.00		
Vendor reputation	Great		
Vendor previously used	Yes		
Equipment reputation	Great		
Price protection period	March 15, 2021		
Service availability – including bio-med arrangements	Yes		
Ongoing service and repairs	Yes		
Warranty	Yes		
Installation and down time	N/A		
Demonstration date	Have one		

Vendor Selected: Olympus

Criteria:

Same as videoscope currently being used in the clinic.

*** ***Please attach copy of research, price quotations and other supporting documentation.***

Olympus America Inc.
3500 Corporate Parkway
P.O. BOX 610
Center Valley, PA 18034-0610

TEL: (800) 848-9024
FAX: (800) 228-4963

bert.bair@olympus.com
www.olympusamerica.com

Quote Number: Q-01021152

Please refer to this number on all correspondence
Effective Date: December 15, 2020

Expiration Date: March 15, 2021

Customer Information

Contact Name: FELICIA HEINZ

Contact Email: fheinz@deltahospital.org

Account Name: DELTA COUNTY MEMORIAL HOSPITAL

Customer Address: 1501 E 3RD ST
DELTA, Colorado
81416-2815
Customer Number: 20004926
(Sold To)

Olympus Information

Representative: Bert Bair
Phone: (303) 325-1456
Email: bert.bair@olympus.com

Cage code: 32212
DUNS#: 017018859
Tax ID: 11-2416961

Payment Terms: Net 30 subject to Olympus credit approval
F.O.B.: Shipping point, unless otherwise mutually agreed upon in writing
Tax: Applicable taxes are not included in this quote and are the responsibility of the customer

Comments

#	Item Type	Model And Description	Kit Component(s)	Qty	List Price	Contract Price	Unit Price	Total Price
1	New	**CYF-VH** : CYF-VH HD Flex CystoNephro Videoscope		1	$27,006.60	$20,492.70	$20,492.70	$20,492.70

* DENOTES OPEN MARKET ITEM
Pricing may be based on a local agreement or the following contract(s):
Premier PP-OR-1458 URO Tier 1

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CONFIDENTIAL AND PROPRIETARY - All information contained on this quotation is confidential and proprietary to Olympus

DELTA COUNTY MEMORIAL HOSPITAL

Signature: _____

Name: _____

Title: _____

Effective Date: _____

Purchase Order #: _____

Total List Price: (Before Trade-Ins)	$27,006.60
Total Net Price: (Before Trade-Ins)	$20,492.70
Total Trade-In Value:	$0.00
Sub Total:	$20,492.70
Freight:	$19.25
Grand Total:	**$20,511.95**

I. Olympus Standard Terms and Conditions apply to this quote, unless otherwise mutually agreed upon in writing
II. Errors & Omissions Excepted. Price quotes and the total package prices are for the quoted items only.
III. Changes and additions to, or deletions from this quote may cause pricing adjustments.
IV. Service manuals and additional operator manuals are not included and may be ordered by contacting the Customer Care Center at (800) 848 9024.
V. If freight charge is included, the freight charge may not necessarily reflect the exact charge paid by Olympus to the carrier due to the volume incentive discount agreements entered into between Olympus and carrier, unless otherwise mutually agreed upon in writing.

Based on the products purchased, the following terms may apply:

ScopeLocker storage product: Please take note of the ScopeLocker's specifications and dimensions and carefully measured the space where the ScopeLocker will be installed to ensure a good and proper fit. By submitting payment and/or a purchase order for any ScopeLocker, customer acknowledges and agrees that Olympus' standard return goods policy does not apply. ScopeLockers may only be returned if they have been delivered to the customer damaged. Customer is responsible for noting and reporting any external shipping damage prior to signing the carrier's receipt form for the ScopeLocker. Once customer signs the carrier's receipt form for the ScopeLocker, it is understood that the customer has inspected the shipment and has found no evidence of external shipping damage. Customer has seven (7) days after customer's receipt of the ScopeLocker to notify Olympus of any internal shipping damage which was undetectable at time of product receipt. Only returns with a valid Return Merchandise Authorization (\"RMA\") number issued by Olympus will be accepted and eligible for return. All authorized returns must be sent prepaid to Olympus or its designee and the RMA number must be prominently displayed on the shipping carton and all paperwork. Merchandise returned with proper RMA identification, with all accompanying items and manuals (as shipped to customer), shall be credited at the original customer's purchase price. No returns will be accepted more than 14 days from date of invoice. Credits will be given against customer's account; no cash refunds will be issued.

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Dear Valued Customer:

This letter is provided on behalf of Olympus Medical Systems Corporation (OMSC) and is intended to provide information about certain flexible endoscopes manufactured by OMSC that your institution may be using. OMSC has undertaken a review of past changes to the company's flexible endoscopes and has decided to take a number of actions as discussed below.

As you may know, not every modification to a medical device requires the submission of a new premarket notification (commonly referred to as a "510(k)") to FDA. In accordance with FDA regulations and guidance, it is up to the manufacturer to determine if a change is significant, thereby triggering the need to submit a new

510(k) to FDA, or if the change is minor and may be documented in the manufacturer's quality system.

OMSC made certain changes to its flexible endoscopes in the past and analyzed those changes using then- available FDA guidance. In some cases, OMSC determined, at that time, a change required a new 510(k); in other cases, the company determined that a change did not trigger the need for a new 510(k) submission.

OMSC recently conducted a retrospective review of past changes to its portfolio of flexible endoscopes (from 1991 through 2018), applying current FDA guidance for assessing device modifications, including FDA's 2017 guidance on this topic. That review validated our current process and found that the company has been appropriately assessing changes to its endoscopes over the past several years. However, following the review, OMSC decided that as a result of some earlier changes (all of which were implemented between 1991 and 2013), it would submit "catch up" 510(k)s for certain endoscope models and discontinue sales for other models.

At the end of this letter is a list of models affected by this review that you have purchased.

Patient safety remains our top priority. OMSC has and will continue to conduct regular post market surveillance according to applicable standards and guidance, including review and investigation of complaints and adverse events. Currently, we are not aware of any signals that would suggest these devices pose unacceptable risks to patients or users versus the benefits that you have come to trust and rely upon. Consequently, at this time, we do not intend to recall or take other corrective actions for these devices. Of course, we recommend that you follow all instructions for such devices, including the device reprocessing instructions, and report to Olympus and/or the FDA any product malfunctions or complaints.

OMSC has presented to FDA the findings of this review as well as the following plan of action developed by OMSC. For those models that the company intends to continue selling in the United States, OMSC will be submitting new 510(k)s to FDA. For other models, OMSC has discontinued new sales but will continue to service devices already in use until the end-of-service date, as indicated immediately below.

Sincerely,

Ross D. Segan, MD, MBA, FACS Chief Medical Officer
Olympus Corporation

Model and Description
CYF-VH : CYF-VH HD Flex CystoNephro Videoscope