Olympus Quality Information Sheet 1

Product Name (Item No.)	TJF-Q180V Qty: 1	Originator QIS No.	C2011-SJ-000417
Serial/Lot No.	● Serial No ○ Lot No : 2001062	Sales-BC QIS No.	n/a
Concern	Observing extremely difficult materials (patient debris and/or plastic stent materials) under the elevator.	Manufacturing-BC QIS No.	

Originator Information	Customer Information	
Originator: OAI	Name of Customer: Virginia Mason Medical Center	User Name: Patty Carroll
Originating Date: (yr/mo/day) 2011/1/27	Address: 1100 9th Ave, Seattle, WA 98101 United States	
	Tel.#: 206-583-6440	Fax #: unk

Product / Repair Part Information

● Purchased ○ Loaner ○ Other ○ Demo ○ Stock		CDS METHODS (Methods, Materials):
Frequency of use: unk	Date Occurred: (yr/mo/day) 2011/1/19	Cleaning: unk Disinfection: unk
Date of purchase: (yr/mo/day) 2010/11/18	Date of Initially Reported: (yr/mo/day) 2011/1/19	Sterilization: unk

Occurrence Information

○ Receipt Inspection ● Operation ○ Demonstration ○ Reprocessing ○ Repair ○ Commissioning ○ Preparation for use ○ Other	Has concern occurred before? ○ Yes How many times? n/a ● No Previous QIS No.? n/a

Description of Concern: Describe handling method and concern (Please supply sample picture if possible) ☐ Attachments

Customer Problem Report states, " Patty reported to me that they are observing extremely difficult materials (patient debris and/or plastic stent materials) under the elevator, back where the old scopes used to have the elevator wire channel. Virginia Mason does ERCP volumes among the highest in the country, which makes them an expert on such observations. They would like to know if there are other facilities complaining of excess debris that is difficult to remove under the elevator, now that they cannot flush the elevator wire channel because it is sealed. This is being experienced on all four TJF-Q180V scopes purchased. Please investigate this potential phenomenon and report back. Thank you."

Combined Products: n/a

☐ Exchange ☐ Repaired ☐ Charge	☐ Free of Charge ☐ Awaiting QIS Response ☒ No Action	Location of Item: ○ Attached ○ Not Return ● Dispatch by separate cover	Answer Required: ○ Yes ● No
Date: (yr/mo/day) 2011/1/27		Print Name: Candis Maninang	Signature: Cmaninang

Investigation Summary/Result and Decision/ Request to Manufacturing - BC: ○ Attachments

The device referenced was not returned to Olympus for evaluation. The exact cause of the users experience could not be conclusively determined.

● Complaint ○ Inquiry ○ Other	Response by Manufacturing BC is required? ○ Yes ● No If GIR is issued response is GIR form	GIR? ○ Yes ● No GIR No:	Location of Item: ○ Attached ● Not Return ○ Dispatch by separate cover

Date Investigated: (yr/mo/day)	Print Name:	Signature:
2011/2/11	Mia Zhang	Mia Zhang

OAI/OE Entry Only

No	Phenomenon(s)	Part(s)	Cause(s)
1	Others [N1]	Unknown [Z01]	Others [620]

Exhibit 304 - 001

OLYMPUS

CUSTOMER PROBLEM REPORT

Section 1 – General Information (Required Information)				**SO No.:**
Date Reported: 1/19/11		**Quantity:** 1		**RMA No.:**
Device Model: TJF-Q180V		**Serial/Lot No.:** 2001062		**Metrix No.:**
Hospital Name: Virginia Mason Medical Center			**Dept:** Endoscopy	
Hospital Address: (Street, City, State, & Zip)	1100 9th Ave., Seattle, WA 98101			
Repair Approver Contact: (First & Last Name)	Patty Carroll		**Title:** Endoscopy Nurse Manager	
Phone No.: (206) 583-6440		**Fax No.:**	**E-mail:** patricia.carroll@vmmc.org	
Report Taken By (OAI): (First & Last Name)	Mike Johnson		**Title:** MP Representative	

Section 2 – Event Information (Required Information) **Note: N/A means *Not Applicable* to the event**				
Hospital Contact: (First & Last Name) Patty Carroll			**Title:** Infection Control Supervisor	
Phone No.: (206) 583-6440		**Fax No.:**	**E-mail:** patricia.carroll@vmmc.org	
Did the device fail during a procedure/operation? Date(s) of Event: 1/19/11			☐ Yes	☐ No ☒ N/A
Type of procedure being performed: ERCP				☐ N/A
Was it a diagnostic or therapeutic procedure?			☐ Diagnostic	☒ Therapeutic
Any image loss? If yes, check all *applicable* boxes below. ☐ Total loss ☐ Intermittent loss ☐ Still visible			☐ Yes	☐ No ☒ N/A
Any patient/customer injury? Please give description below.			☐ Yes	☐ No ☒ N/A
Was the procedure completed?			☐ Yes	☐ No ☒ N/A
Was the same device used to complete the procedure? If no, please list the Device Model No. & Serial No. used:			☐ Yes	☐ No ☒ N/A
Was any other equipment replaced during the procedure? If yes, please list the Device Model No(s). & Serial No(s). used:			☐ Yes	☐ No ☒ N/A
Will the device be returned to Olympus for evaluation? If yes, provide: Ship Date: Tracking No.:			☐ Yes	☒ No ☐ N/A
If no, explain: No repair/evaluation needed				
Event Description: Please be as detailed as possible (including reprocessing method). Patty reported to me that they are observing extremely difficult materials (patient debris and/or plastic stent materials) under the elevator, back where the old scopes used to have the elevator wire channel. Virginia Mason does ERCP volumes among the highest in the country, which makes them an expert on such observations. They would like to know if there are other facilities complaining of excess debris that is difficult to remove under the elevator, now that they cannot flush the elevator wire channel because it is sealed. This is being experienced on all four TJF-Q180V scopes purchased. Please investigate this potential phenomenon and report back. Thank you.				
Investigation Results: Please include all findings.			☐ Repaired	☐ Replaced

Complaints
Sent by: Ana Tan/West/Corp/OAI

01/27/2011 03:07 PM

To Candis Maninang/Consultant/West/Corp/OAI@OAI
cc Grace Tan/West/Medical/OAI@OAI, Ana.Tan@olympus.com
bcc
Subject Fw: QA Problem Report

Hi Candis,

Please document as a P.MDR. Thank you.

-Ana

---- Forwarded by Ana Tan/West/Corp/OAI on 01/27/2011 03:08 PM ----

Patrick Garvey/West/Medical/OAI

01/27/2011 01:58 PM

To complaints@olympus.com
cc
Subject Fw: QA Problem Report

Team,

Please enter this complaint in the system. Please note that there is a requirement in the manual that the elevator raiser must be angled to a 45 degree angle during reprocessing.

PG

---- Forwarded by Patrick Garvey/West/Medical/OAI on 01/27/2011 01:57 PM ----

Mike Johnson/West/Medical/OAI

01/27/2011 12:49 PM

To Patrick Garvey/West/Medical/OAI@OAI
cc
Subject QA Problem Report

Patrick,

Please see problem report:

Please feel free to call me for further details if needed. Thank you!

MJ

Mike Johnson
Olympus America, Inc.
(800) 645-8100, ext. 106416 Voice Mail
(206) 579-5539 Mobile

www.olympusamerica.com CustomerProblemReport~VMMC~TJF-Q180V~1-19-11.doc

SJC Product Complaints
Call Report

entered: Patrick Garvey on 01/31/2011 at 10:54 PM
modified: Patrick Garvey on 01/31/2011 at 10:57 PM

Parent Document:

Calling Information		Call Log	
Author:	Patrick Garvey	Complaint No.:	C2011-SJ-000417
Contact Name:	Patty Carroll	Call Date:	01/31/2011
Contact Company:	Virginia Mason Medical Center 18810 165th Place NE Woodinville, WA 98072 United States	○ Face to Face ● Phone	
Phone:	206-583-6440		
Fax:	425-488-0897		

Call Discussion Notes

1/31/11 1533: Called and spoke with Ms. Patty Carroll. She said that they were still intermittently finding occurrences of patient or stent debris underneath the elevator on their TJF-180V. She said that they were using an introducer with a syringe to clean the area, and were paying extra attention to cleaning this area during reprocessing. She described the steps they performed during manual reprocessing, followed by processing in an AER. She said that they carefully cleaned the channels. She said that on a few occialsions they had noted debris in the suction container prior to performing a procedure. She said that they have instructed their technicians to test the scopes prior to the procedures, and instructed them not to use the scope if there is any evidence of debris. She said that there had been no reports of any infections associated with this matter, nor cross contamination.

Ms. Carroll stated that they were now keeping a log as part of their QA practices, so that they could identify if there was an issue and whom had reprocessed the device. She confirmed that they had received training on the reprocessing of the device when they first received it, and said that both Alicia Krist and Mike Johnson had followed on with them.

Thanked Ms. Carroll for her information. She requested that RA send her an e-mail so that she could contact RA if she needed to follow up.

Will send e-mail address to customer. The call ended.

Is Follow Required?: ● Yes - Followup is required ○ No

Followup Information		Action	
Action For:	Patrick Garvey	Status:	Closed
Due Date:	01/31/2011	☐ Call Back ☐ Conduct Meeting ☐ Conduct Presentation ☐ Fax Information	☐ Schedule Meeting ☐ Schedule Presentation ☐ Write Letter ☐ Write Proposal
Complete Date:	01/31/2011	☐ Research for Info Other:	

Action Detail

Subject:	Sent e-mail to customer.

Previous Call Reports

Complaint: C2011-SJ-000417 [01/31/2011] 1/31/11 1533: Called and spoke with Ms. Patty Carroll. She said that they were still intermittently finding occurrences of patient or stent debris underneath the elevator on their TJF-180V. She said that they were using an introducer with a syringe to clean the area, and were paying extra attention to cleaning this area during reprocessing. She described the steps they performed during manual reprocessing, followed by processing in an AER. She said that they carefully cleaned the channels. She said that on a few occialsions they had noted debris in the suction container prior to performing a procedure. She said that they have instructed their technicians to test the scopes prior to the procedures, and instructed them not to use the scope if there is any evidence of debris. She said that there had been no reports of any infections associated with this matter, nor cross contamination.

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Thanked Ms. Carroll for her information. She requested that RA send her an e-mail so that she could contact RA if she needed to follow up.

Will send e-mail address to customer. The call ended.

OLYMPUS

MEMORANDUM

Date: February 8, 2011

To: Complaint File

From: Mia Zhang

Subject: C2011-SJ-000417

This memo is to note that upon evaluation, the user's report of "observing patient debris and/or plastic stent materials under the elevator" does not meet the requirements of a reportable adverse event. This matter was noted prior to procedure. There were no reports of infections or cross contamination associated with this incidence, and there was no allegation of device malfunction. The user facility had a good reprocessing process in place and had implemented some practices to improve its current process. Additionally, an Olympus Endoscope Support Specialist is following up with the facility to monitor this incidence. Therefore, this event will be downgraded to a product complaint.

P58201A Instrument History 2/09/11

Item#..: TJF-Q180V Serial#: 2001062
Legacy Item#.: VIDEO DUODENOSCOPE W/NBI,
Factory#.....:
Old Ser/Item.: / N2551240
3rd Prty Auth:
P.O. Number..:

	Legacy	BPCS	JDE
Bill-to.....:	000000	100000	00062002
Ship-to.....:	0000000	0020	00102905

Bill-To Info.:
VIRGINIA MASON MEDICAL CENTER (OED BT)
ACCOUNTS PAYABLE- TERRY GARLAND
P.O. BOX 900
SEATTLE WA 98111
Ship-To Info.:
VIRGINIA MASON MEDICAL CENTER 45S
1201 TERRY AVENUE
SEATTLE WA 98101
Remark1.....:
Remark2.....:

Reference.....:
Contract#.....: 00015027
Contract Balance: 86,781.69-
Cap Amount.....: 806,747.17
Cap Val Exceeded:
Cntr Type/Rte Cd: BBB / OCR
Pre-Approval Amt: 0
Equipment Type..: Sale
Olympus Asset...: N Regular Sale
Pend Status.....:
Bill To/2nd Addr: 00062002
Due Back Date...:
Orig. Sale Date.: 11/18/2010
Last Ship Date..: 11/18/2010
First Rep. Date.:
Last Rep. Date..:
Inactive Date...:
Replacement Date:

F3=Exit F6=Contract Type F8=Print F9=Second Page F10=ShipTo Inq. F22=Clear

Candis Maninang/Consultant/West/Corp/OAI
01/27/2011 04:57 PM

To Mike Johnson/West/Medical/OAI@OAI
cc complaints@olympus.com
bcc
Subject Re: QA Problem Report - P.MDR(C2011-SJ-000417)

Dear Mike Johnson,

Thank you for taking the time to report this matter to Regulatory Affairs. We appreciate you bringing this matter to our attention. We have opened complaint number (C2011-SJ-000417) to document this report, and will carefully investigate this matter.

If you have any concerns or questions regarding this report, please contact us at 1-800-258-5187, and ask for Regulatory Affairs.

Sincerely,
Patrick Garvey, RRT
Director, Regulatory Affairs & Quality Assurance
Olympus America, Inc.
National Service Center
2400 Ringwood Avenue
San Jose, California 95131
Tel 1-408-935-5086
Toll-Free 1-800-258-5187, ext. 5086
Fax (408) 935-5010
patrick.garvey@Olympus.com

Complaints

----- Forwarded by Ana Tan/West/Corp/OAI on 01/27/2011 03:08 PM -----

Patrick Garvey/West/Medical/OAI
01/27/2011 01:58 PM

To complaints@olympus.com
cc
Subject Fw: QA Problem Report

Team,

Please enter this complaint in the system. Please note that there is a requirement in the manual that the elevator raiser must be angled to a 45 degree angle during reprocessing.

PG

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Mike Johnson/West/Medical/OAI

01/27/2011 12:49 PM

To Patrick Garvey/West/Medical/OAI@OAI
cc
Subject QA Problem Report

Patrick,

Please see problem report:

Please feel free to call me for further details if needed. Thank you!

MJ

Mike Johnson
Olympus America, Inc.
(800) 645-8100, ext. 106416 Voice Mail
(206) 579-5539 Mobile

www.olympusamerica.com

CustomerProblemReport~VMMC~TJF-Q180V~1-19-11.doc

Candis Maninang/Consultant/West/Corp/OAI
01/27/2011 04:59 PM

To Mia Zhang/West/Corp/OAI@OAI
cc Patrick Garvey/West/Medical/OAI@OAI, Connie Tubera/West/Medical/OAI@OAI, Ana Tan/West/Corp/OAI@OAI
bcc
Subject Fw: QA Problem Report- P.MDR(C2011-SJ-000417)

Hi Mia,
Please review the P.MDR(C2011-SJ-000417), "OBSERVING EXTREMELY DIFFICULT MATERIALS (PATIENT DEBRIS AND/OR PLASTIC STENT MATERIALS) DURING PROCEDURE."
Thanks,

Candis Maninang
Regulatory Affairs & Quality Assurance
Olympus America Inc.
National Repair Service Center
2400 Ringwood Avenue
San Jose, CA 95131
Tel# 408.935.5041
Fax# 408.935.5081
candis.maninang@olympus.com

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01/27/2011 03:07 PM

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cc Grace Tan/West/Medical/OAI@OAI, Ana.Tan@olympus.com
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01/27/2011 01:58 PM

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Mike Johnson/West/Medical/OAI

To Patrick Garvey/West/Medical/OAI@OAI

01/27/2011 12:49 PM

cc

Subject QA Problem Report

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MJ

Mike Johnson
Olympus America, Inc.
(800) 645-8100, ext. 106416 Voice Mail
(206) 579-5539 Mobile

www.olympusamerica.com

CustomerProblemReport~VMMC~TJF-Q180V~1-19-11.doc

OLYMPUS

January 27, 2011

Patty Carroll, Infection Control Supervisor
OR Department
Virginia Mason Medical Center
1100 9th Ave
Seattle, WA 98101

Dear Ms. Carroll:

Reference: Record Number: C2011-SJ-000417
Dated: 01/19/2011
Product/Model: TJF-Q180V Serial Number: 2001062
Reported Concern: Observing extremely difficult materials (patient debris and/or plastic stent materials) under the elevator.

Thank you for contacting Olympus Regulatory Department about your product referenced above, which was the subject of your complaint. This letter is in response to your contact. An investigation will commence to identify the phenomenon you are experiencing. If additional information is needed for this investigation, you will be contacted.

Thank you for trusting Olympus with your endoscope needs. If you need further assistance with this issue, please call Olympus Regulatory Department on our toll-free number, 1(800) 538-2239. This number is available for messages, 24 hours per day, 7 days per week.

For service, repairs and returns related issues, please call our National Service Center Customer Service toll-free line at 1 (800) 537-5739. A representative will be more than happy to assist you with any additional inquires you may have.

Sincerely,

Candis Maninang
Administrator, Regulatory Affairs

OLYMPUS AMERICA INC.
2400 Ringwood Avenue, San Jose, CA 95131-1700
TELEPHONE (408) 935-5000

OLYMPUS

February 16, 2011

Patty Carroll, Infection Control Supervisor
Infection Control Department
Virginia Mason Medical Center
1100 9th Ave
Seattle, WA 98101

Dear Ms. Carroll:

Reference: Record Number: C2011-SJ-000417
Dated: 01/19/2011
Product/Model: TJF-Q180V Serial Number: 2001062
Reported Concern: Observing extremely difficult materials (patient debris and/or plastic stent materials) under the elevator.

Thank you for contacting Olympus Regulatory Department about your product referenced above. It has come to our attention that we have not, to this date received your product for evaluation at our facility. To better serve you, we request that you send the product to us, so we can investigate the phenomenon you are experiencing.

Please send unit/product for evaluation/repair to:

Olympus America, Incorporated
Attention: Regulatory Affairs
2400 Ringwood Avenue
San Jose, CA 95131-1700

Please be advised that an RMA (Return Material Authorization) Number must accompany product. The number may be obtained by requesting it through your Sales Representative or by calling our Call Customer Center in New York at 1.800.848.9024. In the event that the product is not returned, we will deem this complaint closed.

Thank you for trusting Olympus with your endoscope needs. If you need further assistance with this issue, please call Olympus Regulatory Department on our toll-free number at 1.800.537.5739.

Sincerely,

Ana Tan
Administrator, Regulatory Affairs

OLYMPUS AMERICA INC.
2400 Ringwood Avenue, San Jose, CA 95131-1700
TELEPHONE (408) 935-5000

OLYMPUS®

COMPLAINT DECISION TREE

Model: TJF-Q180V	**Complaint Number:** CZ011-SJ-000417
Serial Number/Lot Number: 2001062	**RMA Number:** n/a
Service Order Number: n/a	**Invoice Number:** n/a

1. Is the request for service, evaluation, or credit associated with any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of an Olympus medical device after it has been released for distribution? Examples of complaints include, but are not limited to:
   - An allegation that an Olympus-branded or Olympus-distributed medical device failed during procedure.
   - A user or patient claim to be injured while using an Olympus-branded or Olympus-distributed medical device.
   - Requests for servicing or repair involving an asserted or suspected deficiency of the Olympus-branded or Olympus-distributed medical device, or failure to meet specifications.
   - An allegation of inadequacy in device labeling.

☑ A. Yes[1,2]. Process as per 102P.01	☐ No. Go to 2.

2. Has there been a request to return an Olympus or Olympus-distributed product for evaluation, service or credit?

☒ A. Yes: Go to 3	☐ B. No: Stop. Process does not apply.

3. Is there a written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device that is manufactured or distributed by Olympus America?

☑ A. Yes. Process as per 102P.01	☐ No. Stop. Process does not apply.

Initial Assessment: Print Name: Candis Manirang	Signature & Date: cmanirang 1/27/11
Post Investigation Assessment: Print Name: Iraj Zeijvali	Signature & Date: 2/17/11

[1] Note: If any report references failure during use, or any sort of adverse or potentially adverse event has occurred, the report must be communicated to RA, even if there has been misuse or abuse of the device.
[2] Keywords or phrases that indicate a complaint investigation is required include: procedure, operation, during a case, cecum, stomach, esophagus, mucus membrane, colon, vocal chords, lung, ERCP, EMR, TURP, bile duct, pancreas, larynx, trachea, oropharynx, nasopharynx or other anatomical structures. Keywords or phrases that indicate a complaint involving cross contamination (and mandatory RA investigation) include pancreatitis, pseudomonas, staphylococcus, bacilli, HIV, hepatitis, MRSA or other infectious agents or processes.

11F418 / V06
CN: 0908007

OLYMPUS®

MDR DECISION TREE

Model: TJF-Q180V	**Complaint Number:** C2011-ST-000417
Serial No./Lot No.: 2001062	**RMA Number:** n/a
Service Order Number: n/a	**Invoice Number:** n/a

1. Is there a complaint linked to an Olympus medical device, where it is alleged that the device may have caused or contributed to a
   1. Death, or
   2. Serious injury (e.g. perforation, chemical injury), or
   3. A malfunction, which if it were to recur, may cause death or serious injury, or
   4. Cross contamination of a patient or patients? [1]

☐ A. Yes: Follow process as per 102P.01.
☐ C. Unknown: Reassess following device evaluation. Proceed to question 2.
☒ B. No: Proceed to question 2.

2. Was it alleged that there was a loss of device function, which was reported to result in the unexpected termination of a procedure or significantly complicated the patient's course of treatment by:
   - Necessitating the completion of the procedure with another device, or
   - Necessitating in prolonged hospitalization, or
   - Necessitating a significantly prolonged procedure, or
   - Necessitating in additional procedure(s) to retrieve a foreign object that may not be safely passed through a natural orifice?

☐ A. Yes: Follow process as per 102P.01. Proceed to question 3.
☒ No: Proceed to question 3.

3. Did the report involve an alleged complete loss of image during a therapeutic procedure? [2]

☐ A. Yes: Follow process as per 102P.01. Proceed to question 4.
☒ B. No: Proceed to question 4.

4. Did the report involve an alleged complete loss of image during a diagnostic procedure that resulted in the procedure being completed with another device, resulted in prolonged hospitalization or a significantly prolonged procedure or involved an additional procedure(s) to retrieve a foreign object that may not be safely passed through a natural orifice? [3]

☐ A. Yes: Follow process as per 102P.01. Proceed to question 5.
☒ B. No: Proceed to question 5.

5. Did the report involve a likely cross contamination of a patient or user?

☐ A. Yes: Follow process as per 102P.01. Proceed to question 6.
☒ B. No: Proceed to question 6.

6. Did the report involve an unexpected emission of smoke or electrical arcing in a clinical setting, or result in persons initiating fire emergency procedures?

☐ A. Yes: Follow process as per 102P.01. Proceed to question 7.
☒ B. No: Proceed to question 7.

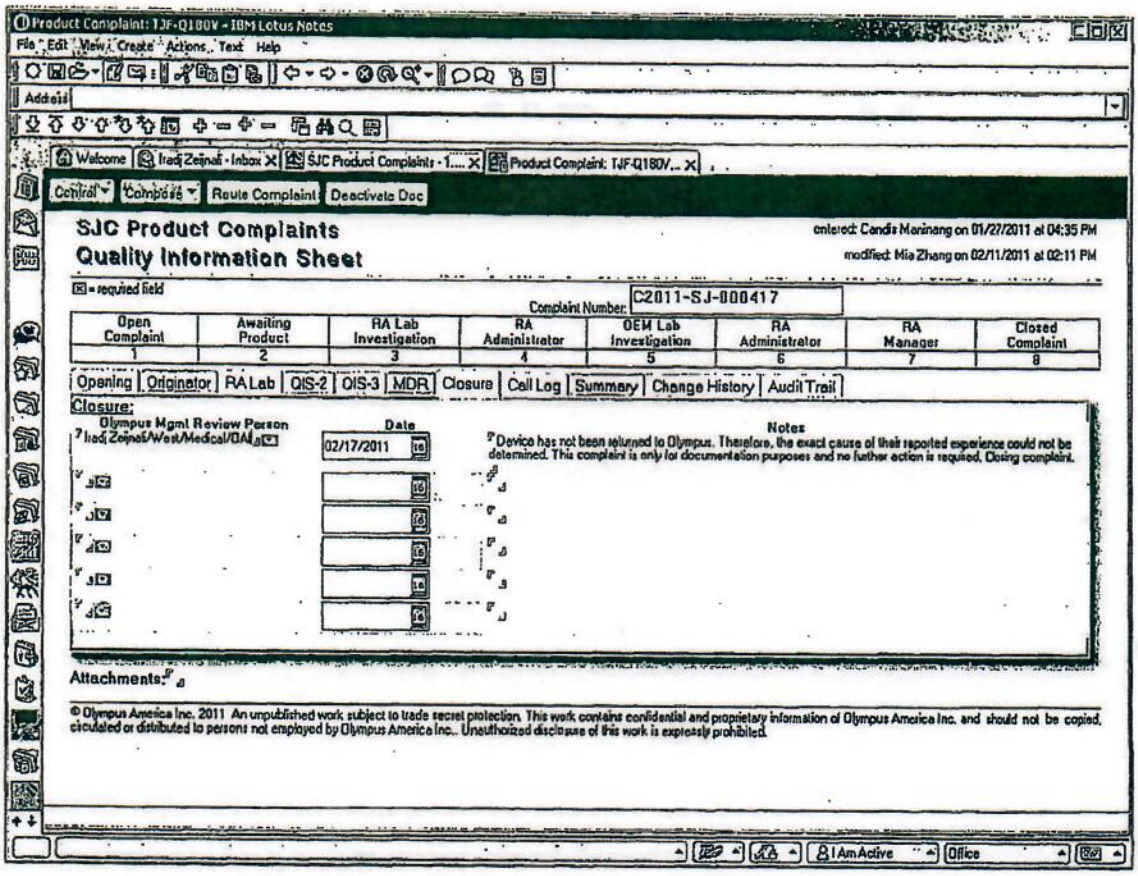
7. If the event is determined to possibly be MDR reportable by means of this decision tree, is the reported event exempted from MDR reporting per an Alternate Summary Reporting (ASR) Agreement, or other agreement with FDA following a Field Corrective Action (FCA)?

☐ A. Yes: Do not follow process as per 102P.01. Follow terms of ASR/FCA agreement. Document complaint in appropriate files.
☐ B. No: File as a MDR as per 102P.01.
☑ C. Not applicable. Does not meet MDR reporting requirements.

1/26/11

Initial Assessment: Print Name: Janis Maninang	Signature & Date: Maninang 1/27/11
Post Investigation Assessment: Print Name: Ivaj Zejnali	Signature & Date: 2/17/11

[1] Note: If death, injury, malfunction or cross contamination is associated with a report of user error, the answer to question #1 must still be "Yes."
[2] Note: The term therapeutic may include procedures that began as purely diagnostic.
[3] Note: Total loss of image during a diagnostic procedure, in the absence of other criteria which require filing as an MDR, are not reportable.


Product Complaint: TJF-Q180V - IBM Lotus Notes
File Edit View Create Actions Text Help
Address
Welcome
Iradj Zeinali - Inbox
SJC Product Complaints - 1....
Product Complaint: TJF-Q180V...
Central
Compose
Route Complaint
Deactivate Doc
SJC Product Complaints
Quality Information Sheet
entered: Candis Maninang on 01/27/2011 at 04:35 PM
modified: Mia Zhang on 02/11/2011 at 02:11 PM
= required field
Complaint Number: C2011-SJ-000417
Open Complaint 1
Awaiting Product 2
RA Lab Investigation 3
RA Administrator 4
OEM Lab Investigation 5
RA Administrator 6
RA Manager 7
Closed Complaint 8
Opening
Originator
RA Lab
QIS-2
QIS-3
MDR
Closure
Call Log
Summary
Change History
Audit Trail
Closure:
Olympus Mgmt Review Person
Iradj Zeinali/West/Medical/OAI
Date
02/17/2011
Notes
Device has not been returned to Olympus. Therefore, the exact cause of their reported experience could not be determined. This complaint is only for documentation purposes and no further action is required. Closing complaint.
Attachments:
© Olympus America Inc. 2011 An unpublished work subject to trade secret protection. This work contains confidential and proprietary information of Olympus America Inc. and should not be copied, circulated or distributed to persons not employed by Olympus America Inc.. Unauthorized disclosure of this work is expressly prohibited.
I Am Active
Office

OLYMPUS

Quality Information Sheet Packing Slip

Product Name (Item No.)	TJF-Q180V TJF-Q180V
serial/Lot No.	2001062
Concern	Observing extremely difficult materials (patient debris and/or plastic stent materials) under the elevator.

Originator QIS No.	C2011-SJ-000417
Sales-BC QIS No.	n/a
Manufacturing-BC QIS No.	

FEB 17 2011