

# Production Order: 500000285217



Production Order Document  
Production Order Qty: 100

PC

Sheet: 1 of 1

## Material: SA0155-01 Rev F

Material Type: ZFRT Description: Edwards Flex Shaft Commander 155885 Order Type: ZSTD  
 Production Version: 7987 Project Phase:  
 Plant / Business Unit: 1213 / AC5

\* Contact ME or QE prior to running. This is for a mandrel study.

NC-28746

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials																	
50	KITTING3  Kitting Devices    Kitting Devices	<p>Kitting Devices                      Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP                      Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>X031 9:30pm 30NOV23</u>                      Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>KAD2 5:00pm 04DEC23</u>                      Record Dryer Shelf #: <u>N/A</u></p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>MM0179-01</td> <td>D <u>D</u></td> <td>PC</td> <td>100</td> <td><u>0000372345</u></td> <td><u>100</u></td> </tr> <tr> <td>MM1536-01</td> <td>B <u>B</u></td> <td>PC</td> <td>100</td> <td><u>0000371063</u></td> <td><u>100</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0179-01	D <u>D</u>	PC	100	<u>0000372345</u>	<u>100</u>	MM1536-01	B <u>B</u>	PC	100	<u>0000371063</u>	<u>100</u>	N/A	N/A	30NOV23 TRD
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																		
MM0179-01	D <u>D</u>	PC	100	<u>0000372345</u>	<u>100</u>																		
MM1536-01	B <u>B</u>	PC	100	<u>0000371063</u>	<u>100</u>																		

Notes: DA 2564, 2511, 2484.

N/A

N/A

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N/A	N/A	RM0158-01	E	<u>Z</u>	PC	40	<u>N/A</u> <u>57559</u>	<u>N/A</u> <u>100</u>		
		1000-1153-01	A	<u>A</u>	PC	119	<u>N/A</u> <u>84034</u>	<u>N/A</u> <u>200</u>		
		1000-2053-01	A	<u>A</u>	PC	100	<u>N/A</u> <u>0000268040</u>	<u>N/A</u> <u>115</u>		
		MM1537-02	A	<u>A</u>	PC	100	<u>N/A</u> <u>0000271023</u>	<u>N/A</u> <u>500</u>	<u>N/A</u>	<u>N/A</u>
		TL0167-02	E	<u>E</u>	PC	14	<u>N/A</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>
		TL0165-05	J	<u>J</u>	PC	1	<u>N/A</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>
		TL0165-03	J	<u>J</u>	PC	1	<u>N/A</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>
							<u>N/A</u>			

Notes:

N/A  
N/A  
N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	141967-01	02	02	PC	100	79448	103	N/A		
		RM7349-02	C	C	PC	109	80022	119	N/A		
		RM7348-01	C	C	PC	100	77351	150	N/A		
		RM4001-01	B	B	PC	25	81962	100	N/A		
		RM0607-01	D	D	PC	12	70558	70	N/A	N/A	N/A
		RM0498-01	C	C	PC	100	0000176394	94	N/A		
		RM0009-04	I	I	PC	1	72289	Bulk	N/A		
		RM0009-04	I	I	PC	1	72289	Bulk			

Notes:

N/A  
N/A  
N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1538-01	A	A	PC	100	N/A	Bulk			
							0000271052	100			
							N/A	N/A			
		MM1537-01	A	A	PC	200	0000271034	500			
							N/A	N/A			
		MM0177-01	C	C	PC	100	0000268423	100			
							N/A	N/A			
		MM0180-01	E	E	PC	100	0000275690	108			
							N/A	N/A	N/A	N/A	N/A
		MM0178-01	E	E	PC	100	0000271050	170			
							N/A	N/A			
		MM0176-01	D	D	PC	100	0000271030	100			
							N/A	N/A			
		MM0074-01	G	G	PC	100	0000276843	104			
							N/A	N/A			

Notes:

N/A  
N/A  
N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
100	CATASY01  Catheter Assembly 1  	Line Clearance Perform Line Clearance and Heat Gun Setting	100	0	01Dec23	KL95
	Line Clearance  Confirmation Reqd(Milestone )					
150	CATASY01  Catheter Assembly 1  	Major and Minor Mandrel Assembly	100	0	07Dec23	PM96 AF54
	Major and Minor Mandrel Assembly					
<b>Notes:</b>						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
200	CATASY01 Catheter Assembly 1 	Loading Braid Stock	100	0	07Dec23	AL34 VP62
	Loading Braid Stock					
	Confirmation Reqd(Milestone )					
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	100	0	07Dec23	LM4b SXII

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Trim Braid Wire at Proximal End  Confirmation Reqd(Milestone )  N/A					
300	CATASY01  Catheter Assembly 1    Insert Cut Hypo Tube  Insert Cut Hypo Tube  Confirmation Reqd(Milestone )	Insert Cut Hypo Tube	100	0	07Dec23 VVL25 S010	
350	CATASY01  Catheter Assembly 1	Load Tubing	100	0	07Dec23 C497 C786	
Notes: N/A N/A N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Load Tubing  Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
400	<b>CATASY01</b> Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone )	Reflow	100	0	07Dec23	PM96 AX05 AF54
450	<b>CATASY01</b> Catheter	FEP Removal	100	0	07Dec23	PM96 AF54 OS21 SG88
<b>Notes:</b>						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 1 					
	FEP Removal					
	Confirmation Reqd(Milestone )					
N/A		N/A	N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1 	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 84K77 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	97	EW-1 DF-1 FM-1	07DEC23 M/34 TD45	MU78
	In-process Inspection and Rework					
	Confirmation Reqd(Milestone )					
N/A	N/A	N/A	N/A	N/A	N/A	N/A
<b>Notes:</b>						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
550	CATASY01 Catheter Assembly 1  Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone )	Remove Heat Shrink & Mandrel	97	0	07Dec23	HL85
600	CATASY01 Catheter Assembly 1  Distal Tip Assembly Confirmation	Distal Tip Assembly	95	MAH-11	07Dec23	MMD-Z

## **Notes:**

N/A

N/A

NIA

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N/A	Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
650	CATASY01 Catheter Assembly 1 	Loading Heat Shrink	95	0	01Dec23	ML38
	Loading Heat Shrink					
	Confirmation Reqd(Milestone )					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: <u>0521</u> Cal Due: <u>31 May 24</u> TMI: <u>2083C</u> Cal Due: <u>31 May 24</u> TMI: <u>0386</u> Cal Due: <u>31 May 24</u> TMI: <u>0936A</u> Cal Due: <u>31 May 24</u>	95	0	01Dec23	ML38
	Tipping					
Notes:						
N/A						
N/A						
N/A						

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	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
750	CATASY01 Catheter Assembly 1 	<p>Tip Inspection/ Flash Removal Material Consumed:</p> <p>Part #: RMH001-01 Batch #: 81962 Qty: N/A      Part #: RM0607-01 Batch #: 70558 Qty: N/A      Part #: N/A Batch #: N/A Qty: N/A      Part #: N/A Batch #: N/A Qty: N/A      Part #: N/A Batch #: N/A Qty: N/A</p>	015	0	07Dec23	MM02 HT73
	Tip Inspection/ Flash Removal					
	Confirmation Reqd(Milestone )					
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	014	ACD-1	07Dec23	ML65
Notes:						
N/A						
N/A						
N/A						

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N/A	Major Mandrel Removal  Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
850	CATASY01  Catheter Assembly 1  	Cut to Length Record DIM05 gage result for the first 5 parts at the start of operation: 1. <u>Passed</u> 2. <u>Passed</u> 3. <u>Passed</u> 4. <u>Passed</u> 5. <u>Passed</u>	94	0	① 04Dec23 07Dec23	VX44
900	QUALITY1  Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	N/A	N/A	N/A	N/A
Notes:						
N/A						
N/A						
N/A						

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① AT39 07Dec23



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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review  Confirmation Reqd(Milestone )	<p>Re-Inspect after re-work.</p> <p>Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information:</p> <p>TMI: 0700-01 Cal Due: 31 May 24</p> <p>TMI: N/A Cal Due: N/A</p> <p>Material Consumed:</p> <p>Part #: 1000-1153-01 Batch #: 84871 Qty: N/A</p> <p>Part #: RM4001-01 Batch #: 81962 Qty: N/A</p> <p>Part #: Rm0107-01 Batch #: 70558 Qty: N/A</p> <p>Part #: RM0158-01 Batch #: 57559 Qty: N/A</p> <p>Part #: N/A Batch #: N/A Qty: N/A</p>	93	#605-1	07Dec23 04Dec23 ①	MV33 ML46 PP40 XL91
950	QUALITY1  Quality Inspection & Review	<p>Quality Inspection &amp; Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information:</p> <p>TMI: N/A Cal Due: N/A</p> <p>Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A  
N/A  
N/A

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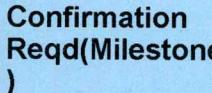
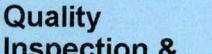
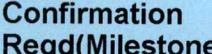
DAT39 07 Dec 23

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 <b>Quality Inspection &amp; Review</b>  <i>N/A</i>	TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30Sep25</u> TMI: <u>0692</u> Cal Due: <u>30Sep25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	71	DIS(SP)HHT STR-HHT DIS-HHT 16 16	07Dec23 04Dec23 ①	Y936
1000	 <b>QUALITY1</b> <b>Quality Inspection &amp; Review</b>  <b>Quality Inspection &amp; Review</b>  <i>N/A</i>	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31MAY24</u> Record Length Gage Information: TMI: <u>0889D</u> Cal Due: <u>30SEP24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30SEP24</u>	72	LT-III MIS-1 ④ ① ⑤	04Dec23 07Dec23	KL67

Notes:

*N/A*  
*N/A*  
*N/A*

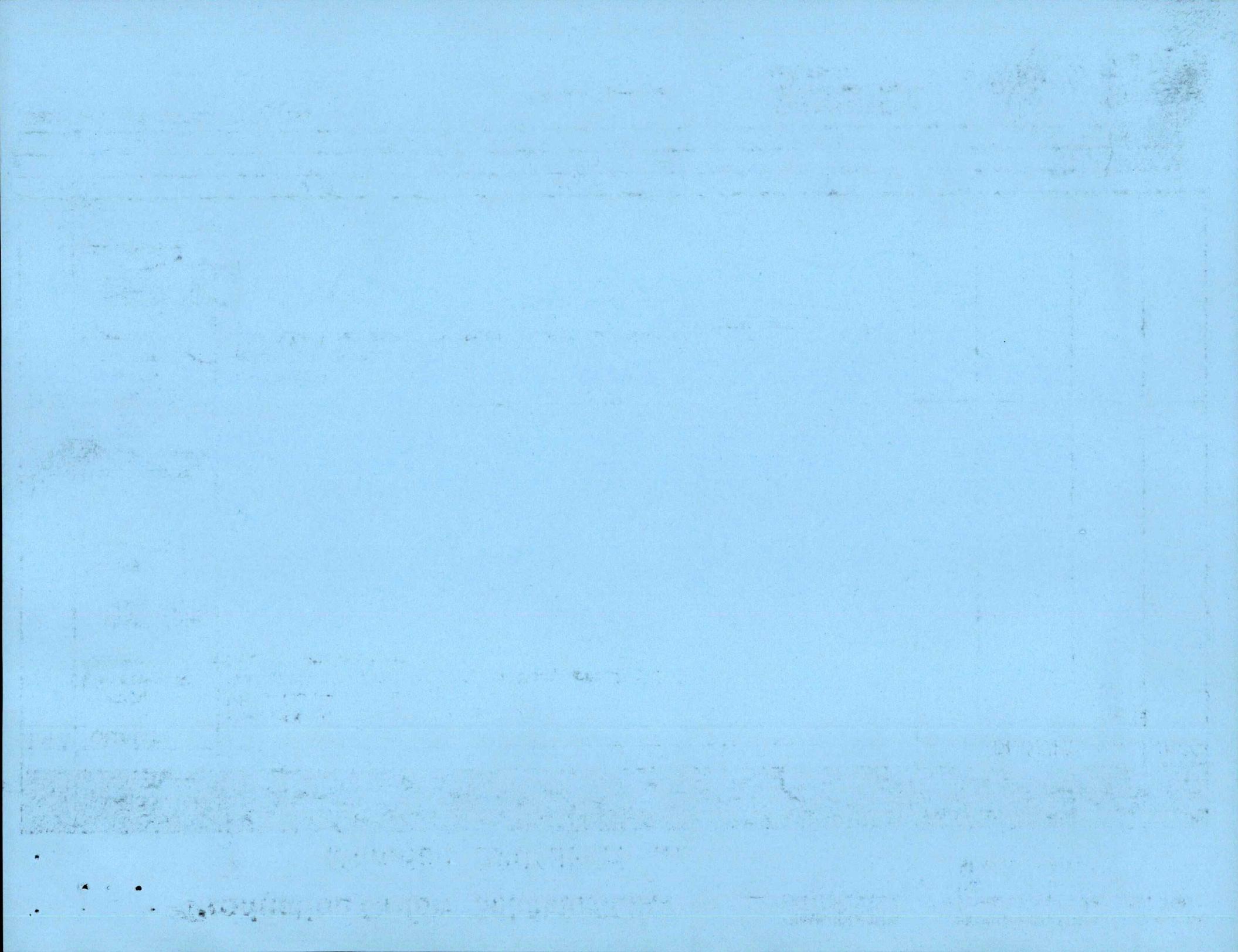
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*① AT39 07DEC23*
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N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	<b>QUALITY1</b> Quality Inspection & Review  Quality Inspection & Review Confirmation Reqd(Milestone )	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	① 50 60 60	Del - 1 Disc - 1 VD - 1 (TT) 9	05 Dec 23 12 13	SV43
1100	<b>CATASY01</b> Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>KP02</u> <u>07 Dec 23</u>	N/A	N/A	07 Dec 23	KP02

Notes:

 N/A  
 N/A  
 N/A

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1100	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
1150	PACKINT1  Packing assembly    Package  Confirmation Reqd(Milestone )	Package Package, Label, and Ship Finished Parts	60	O  OPFeb24	AP10  AP10	

Notes:

N/A AP10 OPFeb24

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**Batch Number:** 0000285217

**By:** APW

**Date:** 09 Feb 24

**Reviewed By:**

RB29

**Date:**

09 Feb 24

**Notes:**

N/A APW 09 Feb 24

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CREGANNA MEDICAL

**GANNA MEDICAL** is part of **EASTON** to **22 Nov 2023** **5228** **Part B-23**

**DEVIATION A** **1228** **11/21/23**

DEVIATION AUTHORIZATION NUMBER:	2484
* See attached email extension to 24 SEP 23	<u>1512</u>
VALIDATION FORM Began to	23 OCT 2023
	21512

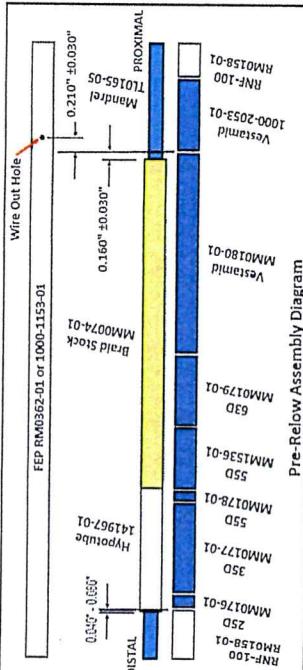
Requestor Name: Udhesh Kapadnis

Requestor Name: Udhesh Kapadnis		Revision
Document Number Affected		
3107610		L

Deviation From:

QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050:  
Current QIP3107610 does not state to inspect for the correct extrusion configuration.

Wire Out Hole



## Deviation To:

This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050. See instructions attached to this DA.

CONTROLLERS

**Justification:** Recently it has been found that operators are incorrectly assembling MM0179-01 and MM1536-01. The event documents in NC-26390, and NC-26426. Only few of experienced inspectors can detect finished unit that contains incorrect extrusion configuration, and inexperienced inspectors may not which potential non-conformance unit sent to customer. Interim correction action has been implemented at OP 250, 300, 350 to detect unit built with out of oriented extrusions. This DA is adding another layer of inspection at final QC inspection to avoid incorrect

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 2023	N/A

Risk Assessment

**RISK ASSESSMENT:** Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:  
Control Plans    Yes    No   FMEA's    Yes    No   Validations    Yes    No

<sup>1</sup>For a discussion of the effects of the above without controls see Boero and Gómez, 1993.

**Corrective Action Required:**  Yes  No

**If no, explain:** No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect extrusion assembly defects

**Training Required:**  Yes  No **If no, explain:**

Title	Approval Name	Approval Signature	Date
Mgr. Quality Engineering	Hai Nguyen		25 Jul 2023
Mgr. Manufacturing Engineering	Jake Stanislowski		25 Jul 2023
Mgr. Operations	Matthew Benson		25 Jul 2023

FM0002.RevF Deviation Authorization

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① UK55, 23 July 2023

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DA | 2484  
2468 ①

#### Description/Objectives of Training:

DA- Inspection at final QC, Op#1050.

#### Group Training Record

##### Procedure:

- 100% inspection at Op#1050 per the instructions below.
- Inspect 1 part at a time.
- Inspection is focused on the correct MM0179-01 and MM1536-01 assembly.
- Use the example MM0179-01 and MM1536-01 fixture for inspection. (See image 1)  
① **MM0179-01** **MM1536-01** **type connection TS12** **10AUG23**



Image- 1

##### Step 1:

- Visually locate the MM0180-01 (Vestamid) transition to MM0179-01 on the completed part approximately 9.75" from the distal end using magnification light 2.25X minimum.
- Align the fixture MM0179-01 extrusion proximal end to the Vestamid transition on completed part. (See image 2)



Image- 2

- Visually verify the MM0179-01 distal end of the fixture is approximately at the same location on the completed part. (See image 3)

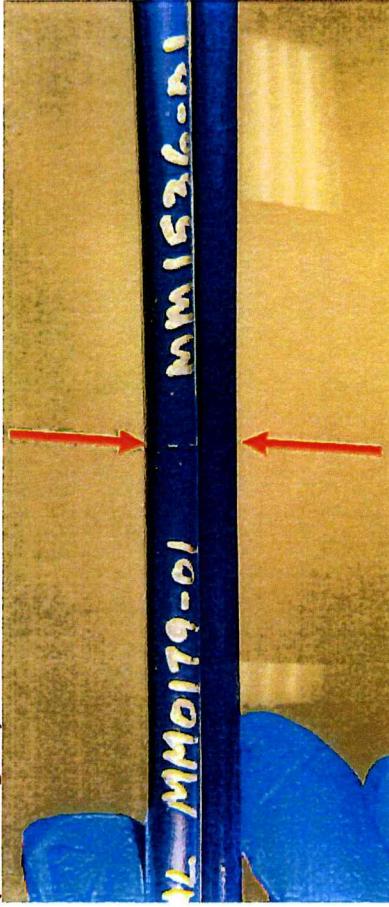


Image- 3

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, move to Step 2.

CONTROLLED COPY

- Step 2:**

  - Visually verify the MM1536-01 distal end of the fixture is approximately at the same location on the completed part. (See image 4)

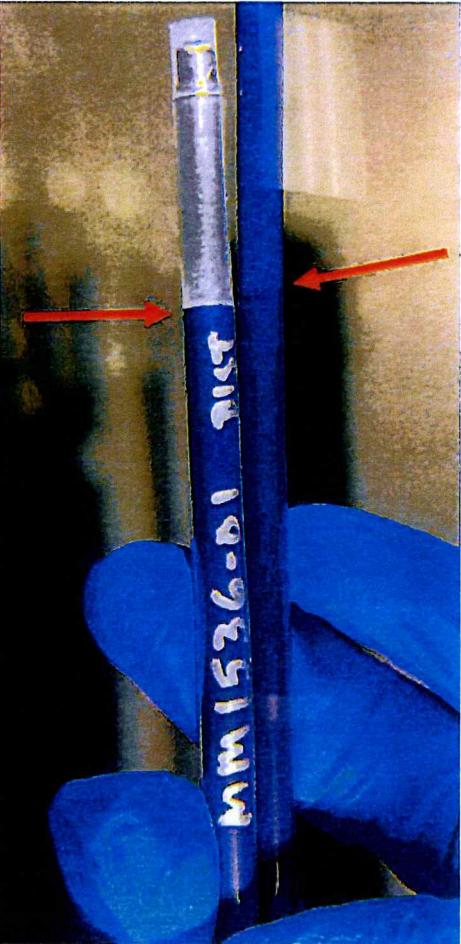


Image-4

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
  - If the part transition is aligned, the part passes inspection.
  - Use Image 5 as a guide for GOOD and BAD extrusion transition alignment.

<b>1</b>	<b>GOOD PART</b>	<b>MM0179-01</b>	<b>MM1536-01</b>
<b>2</b>		<b>MM1536-01</b>	<b>MM0179-01</b>
<b>3</b>		<b>MM0179-01</b>	<b>MM0179-01</b>
<b>4</b>		<b>MM1536-01</b>	<b>MM1536-01</b>

Image - 5

## **Shad, Trevor**

---

CONTROLLED COPY

**From:** Nguyen, Hai  
**Sent:** Thursday, August 24, 2023 1:48 PM  
**To:** Shad, Trevor  
**Subject:** RE: DA2484 extension - Due today

Thank you again Trevor!

**From:** Shad, Trevor <trevor.shad@te.com>  
**Sent:** Thursday, August 24, 2023 1:29 PM  
**To:** Nguyen, Hai <hai.nguyen@te.com>  
**Subject:** DA2484 extension - Due today  
**Importance:** High

I, Hai Nguyen TE#393596, extend DA2484 to 24SEP23 on this day 24AUG23.

Regards,

Trevor Shad  
Document Control  
Devices - Trenton Lane, MN



[EMAIL](mailto:Trevor.Shad@te.com) [Trevor.Shad@te.com](mailto:Trevor.Shad@te.com)

te.com



Extend until 06/09/2023 5228 10/01/23  
 Extend to 05/09/2023 5228 31/08/2023

CONTROLLED COPY

## DEVIATION AUTHORIZATION FORM

Requestor Name: Udhesh Kapadnis	
Document Number Affected	Revision
3107610	M

Deviation From:	Deviation To:
<b>QIP3107610, Section 7.0 Inspection Requirements OP1000:</b>	<ul style="list-style-type: none"> <li>Operation 1000: This DA allows Dim 5 and Dim 7 length to be inspected using "Catheter Tip Inspection System TM12288" instead of TM150713-Tab (Dim 5) and calibrated Caliper (Dim 7) See attached TMV1982 section 8.0 for reference.</li> <li>Dim 5 and Dim 7 inspection must perform prior to leak testing.</li> <li>Operation 1000: This DA allows attribute data for Dim 5 and Dim 7 to be recorded in same SAP ROS in OP950.</li> </ul>
<b>Current QIP3107610 section 7.0 OP 1000 does not state to inspect Dim 5 and Dim 7 length dimensions (TM150713-Tab for Dim 5 and Calibrated Caliper for Dim 7 are performed at OP950)</b>	
<b>Dim 5 and Dim 7 are inspected and recorded in SAP ROS in OP950 (variable and attribute data).</b>	

**Justification:** The current methodology to inspect Dim 5 and Dim 7 of Flex Commander shaft is performing at OP950 as per QIP3107610 using TM150713-Tab and calibrated caliper. After implementing of reline balancing project in May 2023, it has been observed that many tasks for one operator at OP950 and this one operator could not keep up with multiple inspections. To reduce workload and ensuring product quality is not compromising, it was determined Dim 5 and Dim 7 are to be inspected at OP1000 by using "Catheter Tip Inspection System TM12288". The Catheter Tip Inspection System has been approved per NOC EDW0098. This DA allows Flex Commander tip inspection by using Catheter Tip Inspection System at OP1000 while pending for QIP3107610 updating. Required number of attribute data points for Dim 5 and Dim 7 will be recorded in SAP ROS OP950.

SA0155-01 Edwards Flex Commander Shaft Inspection Requirement				
Test/Specification	Dimensions	Sampling	Equipment	
101396	<b>5 Distal Tip Length: Attribute Shoulder to distal end Record summary PASS/FAIL</b>	0.12" +/- 0.02"	100%	Catheter Tip Inspection System TM12288
101057	<b>7 Distal Pull Ring Length: Attribute Distal of Pull ring Mid Window Record summary PASS/FAIL</b>	0.050" +/- 0.025"	100%	Catheter Tip Inspection System TM12288

Part Number Affected	End Date:	Revision
SA0155-01	07 Oct 2023	H
08 Sept 2023	07 Oct 2023	N/A

**Risk Assessment:**

Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:

Control Plans  Yes  No FMEA's  Yes  No Validations  Yes  No

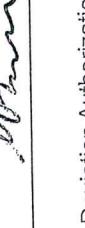
Details (if any): N/A

If yes to any of the above, what controls are being put in place to mitigate the risk.

**CONTROLLED COPY****Corrective Action Required:**  Yes  No

**If no, explain:** No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. QIP3107610 is being updated for Catheter Tip Inspection System at OP1000.

**Training Required:**  Yes  No **If no, explain:**

Title	Approval Name	Approval Signature	Date
Mgr. Quality Engineering	Hai Nguyen		08 Sep 2023
Mgr. Manufacturing Engineering	Jake Stanislowski		08 SEP 2023
Mgr. Operations	Matthew Benson		08SEP2023

FM0002.RevF

Deviation Authorization

## DEVIATION AUTHORIZATION FORM

<b>Requestor Name:</b> Krishna Selvaraj		
<b>Document Number Affected</b>	<b>Revision</b>	
Doc #3005206 (MPI0238)	BP	
<b>Deviation From:</b> <b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b> Using a laser micrometer, check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.		
<b>Deviation To:</b> <b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b> Using a laser micrometer at <b>OPER900 (TMI0700-01)</b> , check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.		

**Justification:**

TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable.  
 TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TM10602 issue is resolved.

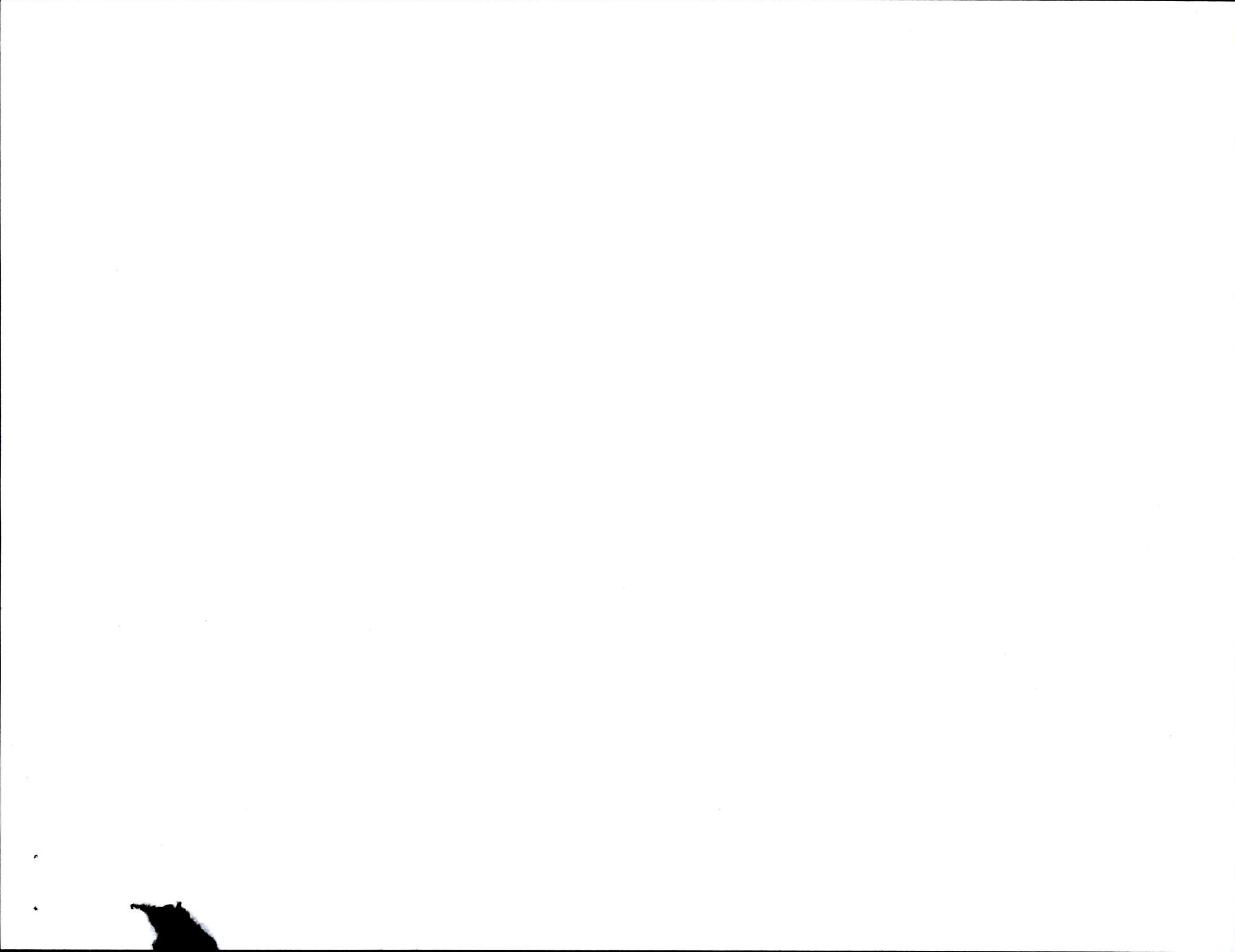
<b>Part Number Affected</b>	<b>Revision</b>	
SA0155-01	H	
<b>Start Date:</b> 16 Nov 23 <b>End Date:</b> 15 DEC 23 <b>Lot Number:</b> N/A		
<b>Risk Assessment:</b> Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No    FMEAs <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No    Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A If yes to any of the above, what controls are being put in place to mitigate the risk – N/A		
<b>Corrective Action Required:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>If no, explain:</b> This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.		
<b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, explain:</b> N/A		
<b>Title</b>	<b>Approval Name</b>	<b>Approval Signature</b>
Engineering Manager	Jake Stanislowski	
Quality Manager	Jay Zabel	
Operations Manager	Matthew Benson	
<b>Date</b>	16 Nov 2023	
<b>Date</b>	16 Nov 2023	
<b>Date</b>	16 Nov 2023	



**Document No:** 5105589  
**FM5104665 Rev:** C  
**Document Type:** Manufacturing Form  
**Title:** SA0155-01 Reflow Log Sheet Form

**PRODUCTION ORDER#** 500000285217

OP 400





Document No: 5105589  
FM5104665 Rev: C  
Document Type: Manufacturing Form  
Title: SA0155-01 Reflow Log Sheet Form

**PRODUCTION ORDER#** 500000285217

OP 400



Document No: 5106073  
Rev: E  
Document Type: Manufacturing Form  
Title: SA0155-01 Visual Rework Form

PO #: 500000285217

OP #: 500 Shift #: 2

Total Parts Reworked:		12	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		4
EW	Exposed Wire		9
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks	N/A	N/A
VD	Voids	N/A	N/A
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

MV78 04 Dec 13

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 5106073  
Rev: E  
Document Type: Manufacturing Form  
Title: SA0155-01 Visual Rework Form

PO #: 500000285217

OP #: 500 Shift #: 2nd

Total Parts Reworked:		14	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		2
EW	Exposed Wire		14
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks	N/A	N/A
VD	Voids	N/A	N/A
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		MY34 SV46	04 Dec 23
		04 Dec 23	04 Dec 23

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

PO #: 500000285217OP #: 750 Shift #: 2

Total Parts Reworked:		5	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		2
DIM07 US / WC	DIM07 Undersized (Window Closed)		2
EH	Exposed Hypotube		1
n/a	n/a	n/a	n/a
Inspected By (Sign and Date):		HT72 04 Dec 23	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

PO #: 500000285217

OP #: 750 Shift #: 2<sup>nd</sup>.

Total Parts Reworked:		8	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		7
DIM07 US / WC	DIM07 Undersized (Window Closed)		1
EH	Exposed Hypotube	N/A	N/A
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Mmo 2	04Dec23

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

**PRODUCTION ORDER#** 500000286217

OP 800



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000185217

OP #: 900 Shift #: 2nd

Total Parts Reworked:		27	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	NA	0
EH	Exposed Hypotube		2
EW	Exposed Wire		6
MP	Micropores	NA	0
SCR	Scratch		18
SKV	Skive Marks		1
VD	Voids	NA	0
DIM01 US	DIM01 OD Undersized	NA	0
DIM06 US	DIM06 OD Undersized		2
DIM06 OS	DIM06 OD Oversized		1
DIM09 US	DIM09 OD Undersized	NA	0
Inspected By (Sign and Date):		<i>Mil</i>	04 Dec 23

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 50000285217OP #: 900 Shift #: 2

Total Parts Reworked:		19	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	N/A	N/A
EW	Exposed Wire	11	2
MP	Micropores	N/A	N/A
SCR	Scratch		18
SKV	Skive Marks	/	/
VD	Voids	N/A	N/A
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	N/A	N/A
DIM06 OS	DIM06 OD Oversized	/	/
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		PP40 04 Dec 23	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

Maximum Force Reached During Tensile Test (10 samples accepted from final inspection for each lot shall be selected and tensile tested)																
Sample # -->	1	2	3	4	5	6	7	8	9	10	Avg	St Dev	K	Calculated Lower bound	Min Spec	Pass / Fail
Seg A	23.37	25.54	26.72	27.07	29.37	25.85	26.77	24.13	27.29	27.92	26.403	1.7634376	4.378	18.6826701	8.542	PASS
Seg B	58.9	63.1	58.88	60.52	64.98	56.75	57.26	57.33	55.72	58.35	59.179	2.9182318	3.981	47.5615193	8.542	PASS
Seg C	76.84	75.89	75.68	78.46	77.58	79.14	76.89	74.85	79.45	78.21	77.299	1.5367675	2.911	72.8254697	8.542	PASS

All Force Values are recorded in Pound-Force and Distance is in Inches  
Specification for lower bound is 38N was converted to 8.542lbf  
First Peak Force was collected during test and has been included in the raw data file ( this information will not be captured / summarized in the DA due to it is not required to used for DA acceptance.

### EDW Commander Flex - Bend and Tensile Strength Testing

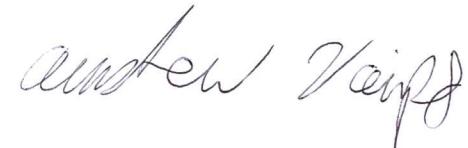
LOT #: 500000285217

Date:08DEC23

Inspector Name:Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24


08 Dec 23