

# Production Order: 500000300504



Production Order Document  
Production Order Qty: 500  
PC  
Sheet: 1 of 1

## Material: SA0155-01 Rev F

Material Type:	ZFRT	Description: Edwards Flex Shaft Commander 155885	Order Type: ZSTD
Production Version:	7988		Project Phase:
Plant / Business Unit:	1213 / AC5		

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	KITTING3  Kitting Devices  	<p>Kitting Devices Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP</p> <p>Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>Am 68 12:00pm 27 Jun 24</u></p> <p>Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>Am 68 11:30pm 28 Jun 24</u></p> <p>Record Dryer Shelf #: <u>N/A</u></p>	N/A	N/A	24/04/24	LH70

Notes: DA 2594, 2484, 2564

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
NP N/A	RM0158-01	E	<u>E</u>	PC	200	<u>58497</u>	<u>N/A</u>	<u>100</u>		
							<u>N/A</u>	<u>N/A</u>		
	RM0009-04	I	<u>I</u>	PC	1	<u>79169</u>	<u>Bulk</u>			
							<u>N/A</u>	<u>Bulk</u>		
	RM0009-04	I	<u>I</u>	PC	1	<u>79169</u>	<u>Bulk</u>			
							<u>N/A</u>	<u>Bulk</u>		
	MM1538-01	A	<u>A</u>	PC	500	<u>000028970</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
							<u>N/A</u>			
	MM1537-01	A	<u>A</u>	PC	1000	<u>0000284209</u>	<u>1000</u>			
							<u>N/A</u>	<u>N/A</u>		
	1000-2053-01	A	<u>A</u>	PC	500	<u>0000278830</u>	<u>500</u>			
							<u>N/A</u>	<u>N/A</u>		
	MM1537-02	A	<u>A</u>	PC	500	<u>0000288401</u>	<u>500</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	TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u> <u>N/A</u>	Bulk				
		J	<u>J</u>	PC	5	<u>N/A</u> <u>N/A</u>	Bulk				
		J	<u>J</u>	PC	5	<u>N/A</u> <u>N/A</u>	Bulk				
		02	<u>02</u>	PC	500	<u>85793</u> <u>N/A</u>	509				
		C	<u>c</u>	PC	543	<u>82863</u> <u>N/A</u>	500	N/A	N/A	N/A	N/A
		C	<u>c</u>	PC	500	<u>82886</u> <u>N/A</u>	500	N/A	N/A		
		B	<u>B</u>	PC	125	<sup>①</sup> <u>92823</u> N/A <u>82819</u>	N/A	N/A			
		D	<u>D</u>	PC	56	<u>74662</u>	100				

Notes:

N/A

N/A

N/A

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① KPO2 30 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A N/A		RM0498-01	C	C	PC	500	N/A <u>0000275492</u>	N/A 401		
		RM0362-01	E	E	PC	594	N/A <u>SD236</u>	N/A 600		
		MM0177-01	C	C	PC	500	N/A <u>0000284208</u>	N/A 500		
		MM0180-01	E	E	PC	500	N/A <u>0000287541</u>	N/A 571		
		MM0178-01	E	e	PC	500	N/A <u>0000276174</u>	N/A 500	N/A	N/A
		MM0176-01	D	D	PC	500	N/A <u>0000281411</u>	N/A 500		
		MM0074-01	G	G	PC	500	N/A <u>0000297031</u>	N/A 509		
							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
NA	NA	NA	NA	NA	NA	NA
100	CATASY01 Catheter Assembly 1  Line Clearance Confirmation Reqd(Milestone )	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	29Jun24	P146
150	CATASY01 Catheter Assembly 1  Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	29Jun24	AM47 SP34 YK40

Notes: *NA*

*NA* *NA*

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
MP	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
200	CATASY01  Catheter Assembly 1  	Loading Braid Stock	500	0	29 Jun 24	MV150 P767 LH445
250	CATASY01  Catheter Assembly 1  	Trim Braid Wire at Proximal End	500	0	29 Jun 24	DV39 C019 AJ65
<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
	Trim Braid Wire at Proximal End  N/A Confirmation Rreqd(Milestone )	N/A	N/A	N/A	N/A	N/A
300	CATASY01 Catheter Assembly 1   Insert Cut Hypo Tube  Insert Cut Hypo Tube  Confirmation Rreqd(Milestone )	Insert Cut Hypo Tube	500	0	29 Jan 24	AIG5 RL47
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	29 Jan 24	CX63 BD64
Notes:						MA N/A MA

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 Load Tubing  Confirmation Reqd(Milestone)					
N/A						
400	<b>CATASY01</b> Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone)		500	0	29 Jan 24	AL07 SN67 PM 96
450	<b>CATASY01</b> Catheter	FEP Removal	500	0	29 Jan 24	PM 96
<b>Notes:</b>						

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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
500	CATASY01  Catheter Assembly 1    In-process Inspection and Rework Confirmation Reqd(Milestone )	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 87654 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	489	EL + 1 SKV + 1 SF - IIII EW - IIIK II III - IIIO OF - IIII OF - IIII II	LL61 VC09 CB81 TA36 29 Jan 24	
		N/A N/A N/A N/A	N/A	N/A	N/A	N/A
	Notes:					

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OPY46 29 Jan 24



Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
550	CATASY01  Catheter Assembly 1  	Remove Heat Shrink & Mandrel  Remove Heat Shrink & Mandrel  Confirmation Reqd(Milestone )	489	0	29 Jan 24	FBO1 PH59 AX82 VA96 R523
600	CATASY01  Catheter Assembly 1    Distal Tip Assembly  Confirmation	Distal Tip Assembly	482	JL - HHT MAH - HHT HHT - HHT H (1) 5	29 Jan 24	FBO1 DY29 PH59 AX82 VA96

Notes:

N/A

N/A

N/A

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① PH46 29 Jan 24

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## Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
MP	Reqd(Milestone )	~IA	~IA	~IA	~IA	~IA
650	CATASY01 Catheter Assembly 1   Loading Heat Shrink  Confirmation Reqd(Milestone )	Loading Heat Shrink	484	0	29JUN24	F B01 D Y29 P H59 A X82
700	CATASY01 Catheter Assembly 1   Tipping	Tipping Record Tipping Oven Information: TMI: <u>2083C</u> Cal Due: <u>31MAY24</u> TMI: <u>0936A</u> Cal Due: <u>31MAY24</u> TMI: <u>0521</u> Cal Due: <u>31MAY24</u> TMI: <u>0386</u> Cal Due: <u>31MAY24</u>	484	0	29JUN24	B160 STX48 HV36 RS23
Notes:		~IA				
		~IA				
		~IA				

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## Material: SA0155-01 Rev F

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
750	CATASY01 Catheter Assembly 1 	<b>Tip Inspection/ Flash Removal</b> <b>Material Consumed:</b> Part #: <u>Pnk4001-01</u> Batch #: <u>52823</u> Qty: <u>10</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u>	484	0	29Jan24	BIGO STX48 HV36
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	482	ACD-II (2)	Jan 24 29	BD64 KLES SS44 SS52

Notes:

N/A

N/A

N/A

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	Major Mandrel Removal  Confirmation Rreq(Milestone )		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>	482	0	29 Jan 24	SS52
900	QUALITY1  Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	0	0	0	0
Notes:		N/A				
		N/A				
		N/A				

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## Material: SA0155-01 Rev F

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: TMI: <u>0700-01</u> Cal Due: <u>31 may 24</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> Material Consumed: Part #: <u>PNU001-01</u> Batch #: <u>82823</u> Qty: <u>17</u> Part #: <u>PNU007-01</u> Batch #: <u>74662</u> Qty: <u>5</u> Part #: <u>1000-153-01</u> Batch #: <u>88728</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u></p>	428	<p>EHT+①</p> <p>EH-1</p> <p>DS-11</p> <p>DIS-LHT/11</p> <p>DEL-LHT</p> <p>LHT/111</p> <p>MAR-1</p> <p>WK-LHT</p> <p>Fm-LHT/111</p> <p>EW-LHT/111</p> <p>H707-111</p> <p>VD-154</p> <p>#90S-1</p> <p>#10S-1</p>	305 cm ~11	K155 KT27 SH04 XL91 MV33 PP40 ML65
950	QUALITY1  Quality Inspection & Review	<p>Quality Inspection &amp; Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

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① P4 26 29 Jan 24

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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>   <b>Confirmation Reqd(Milestone)</b>	TMI: <u>NA</u> Cal Due: <u>NA</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>	399	STP-1/HH DIS-(SP)HH DIS-HH HH HH 1 WK-1 MAR-1 DEL-11 (29)	30 Jan 24 30	0521 XL91
1000	 <b>Quality Inspection &amp; Review</b>   <b>Quality Inspection &amp; Review</b>   <b>Confirmation Reqd(Milestone)</b>	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>30May24</u> Record Length Gage Information: TMI: <u>088910</u> Cal Due: <u>30SCP24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30SCP24</u>	387	LT-HH HH ① + 1 OAL-1	30 Jan 24 30	5544 XL91

Notes:

NA  
NA  
NA

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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
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	20 27	SCR-1 Del-111 (TT) Del-11 SCR-1 EW-111 DIS-111 MEX-11 VD-11 SKV-1 RDG-1	30 Jan 24 (27)	SV43 KK83
1100	<b>CATASY01</b> Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): <u>KP02</u> <u>30 Jan 24</u>	N/A	N/A	30 Jan 24	KP02

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① Signed for Der Xiong  
KK83 30 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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	360	0	30 Jan 24 / Apr 10	AP10

**Notes:**

N/A AP10 30 Jan 24 /

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**Material: SA0155-01 Rev F**

**Batch Number:** 0000300504

**By:** APW

**Date:** 30 Jan 24

**Reviewed By:**

RB29

**Date:**

30 JAM 24

**Notes:**

N/A APW 30 Jan 24

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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, 23JU 2023

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**TE**

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 ~~MM1536-02~~ fixture for inspection. (See image 1)  
**① MM1536-01 type correction TS12 10AUG-23**

#### CONTROLLED COPY

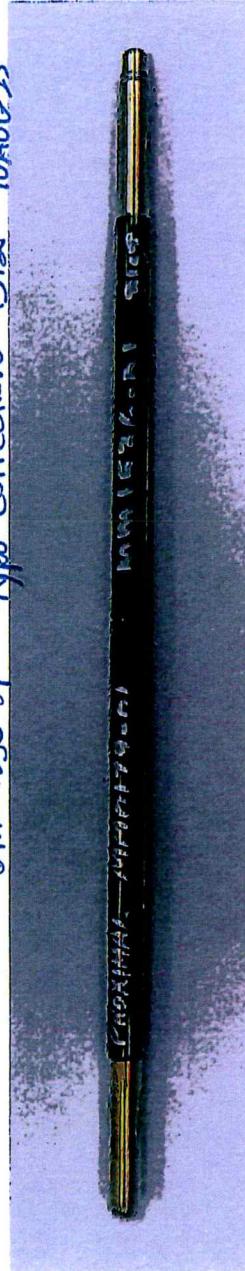


Image- 1

#### 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)

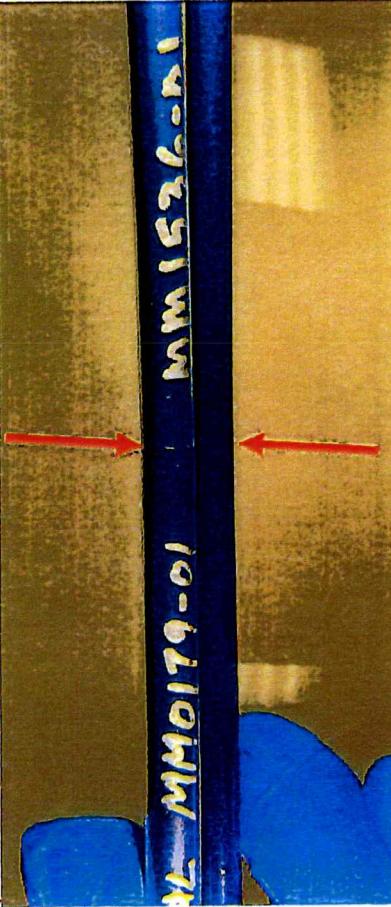


Image- 3

- 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.

**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)

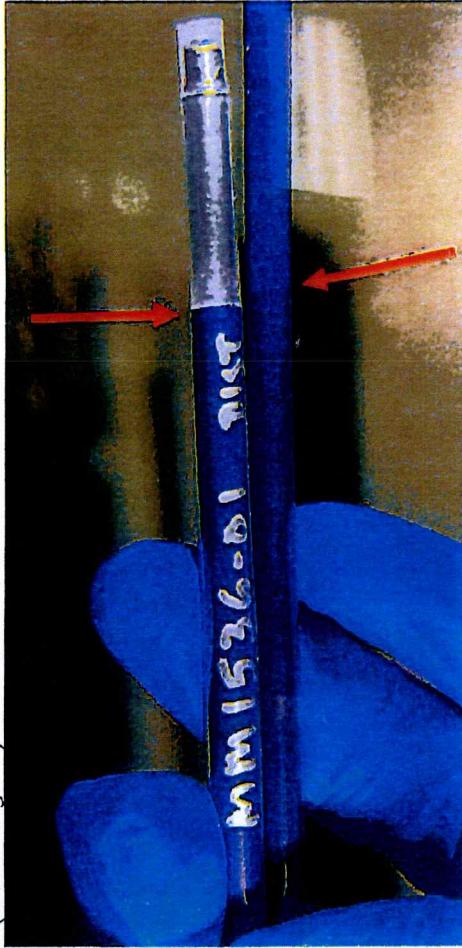


Image- 4

- 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>	MM0179-01	MM1536-01	<b>GOOD PART</b>
<b>2</b>	MM1536-01	MM0179-01	<b>MM0179-01 and MM1536-01 Wrong Order - BAD PART</b>
<b>3</b>	MM0179-01	MM0179-01	<b>Two MM0179-01 - BAD PART</b>
<b>4</b>	MM1536-01	MM1536-01	<b>Two MM1536-01 - BAD PART</b>

Image - 5

Entered to Hansel 3208 12/15/2023  
Entered to 13 Feb 2024 3208 Vagelis

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## DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj	
Document Number Affected	Revision
Doc #3005206 (MPI0238)	BP
Deviation From:	Deviation To:
<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>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.

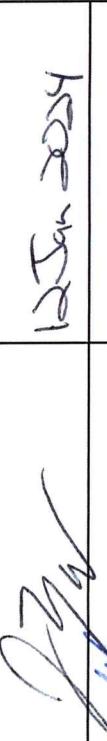
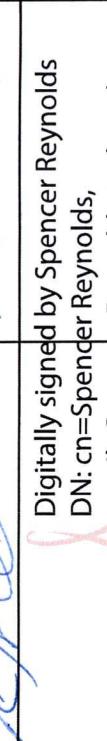
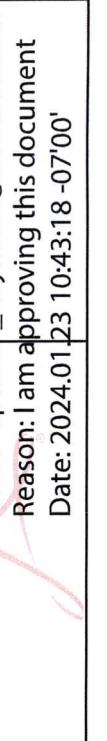
TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TMI0602 issue is resolved.

Part Number Affected	Revision		
SA0155-01	H		
Start Date:	End Date:	Lot Number:	
16 Nov 23	15 DEC 23	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 FMEA's <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 checked="" type="checkbox"/> Yes <input 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			
Title	Approval Name	Approval Signature	Date
Engineering Manager	Jake Stanislowski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023

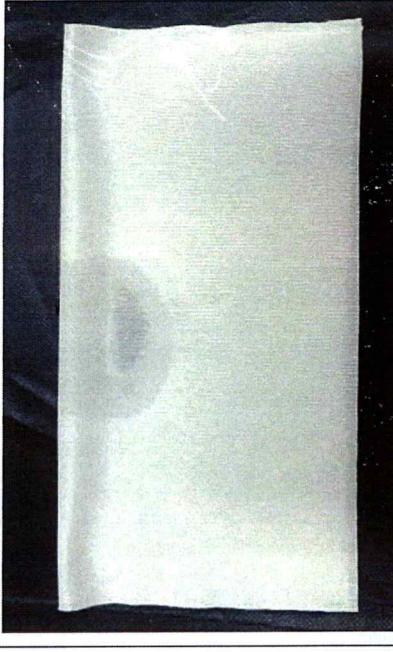


## DEVIATION AUTHORIZATION FORM

<b>Requestor Name:</b> Udhesh Kapadnis		
<b>Document Number Affected</b>	<b>Revision</b>	
3005206 (MP10238)	BQ	
SA0155-01 Router	F	
QIP3107610	N	
<b>Deviation From:</b> <ol style="list-style-type: none"> <li>1. Move SA0155-01 assemblies to OP900 for visual inspection and Rework after completing process at OP850-Cut to length.</li> <li>2. Perform visual inspection and rework at Op900 as per QIP3107610 Rev N.</li> </ol>		
<b>Deviation To:</b> <ol style="list-style-type: none"> <li>1. Move SA0155-01 assemblies to off-line 360° inspection system (TMI2434A) for visual inspection after completing process at OP850-Cut to Length.</li> <li>2. Perform visual inspection by using off-line 360° inspection system (TMI2434A) and verify defects per attached inspection instructions. Move SA0155-01 assemblies to OP900 for visual defect rework and 100% visual inspection per QIP3107610 Rev N.</li> </ol>		
<b>Justification:</b> <p>The purpose of this deviation is to collect the inspection data for only 3 standard production lots of SA0155-01 assemblies by using off-line 360° inspection system (TMI2434A). Data collected will be used to access 360° inspection system (TMI2434A) in-line implementation. See attached inspection instructions.</p> <p>Use of 360° Inspection system (TMI2434A) has very low risk to finished goods quality based on the 3108296 evaluations.</p>		
<b>Part Number Affected</b>	<b>Revision</b>	
SA0155-01	F	
<b>Start Date:</b>	<b>End Date:</b>	<b>Lot Number:</b>
12 Jan 2024	11 Feb 2024	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   FMEA's <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> N/A		
<b>If no, explain:</b> SA0155-01 lots run with DA for off-line use will provide data to assess 360° Inspection in-line use. Corrective action will be needed when 360° Inspection in-line is approved.		
<b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, explain:</b> N/A		

Title	Approval Name	Approval Signature	Date
Quality Manager	Jay Zabel		12 Jan 2024
Operations Manager	Matt Benson		18 Jan 2024
Engineering Manager	Jake Stanislawski		12 JAN 2024
Edwards Supplier Quality Engineer	<b>Spencer Reynolds</b>		<p>Digitally signed by Spencer Reynolds            DN: cn=Spencer Reynolds,            email=Spencer_Reynolds@edwards.com            Reason: I am approving this document            Date: 2024.01.23 10:43:18 -07'00'</p>

## Inspection Procedure

Step#	Written Instructions
1.	<p>Get a clean wipe and fold in half. Apply adequate amount (wet enough to wipe the stent area smoothly) of IPA on the top of the wipe.</p> 
2.	<p>Wrap the wet wipe around the distal end. Make sure there is no gap between the parts and the wipe.</p> 
3.	<p>Wipe the part from the distal end to the end of stent area. Rewrap the part using the dry area on the wipe.</p> 
4.	<p>Loads and aligns catheter with stop fixture on load station with the pull wire facing Upward direction.</p> 

5.	Press the green start button. Machine indexes catheter and inspects for defects.	
6.	Unload the catheter from unloading station.	
7.	Inspection results are displayed on the GUI monitor. Place inspected catheter on index fixture to align GUI defect results.	
8.	After aligning GUI defect result with index fixture, inspect defects per 3107610 SA0155-01 QIP for acceptance.	<ul style="list-style-type: none"> <li>• Take no action for result determined acceptable.</li> <li>• Use cleanroom tape to identify result determined rework.</li> <li>• Scrap catheter determined scrap.</li> </ul>



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500600300504

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	12:07pm	430	SN67	28Jan24	12:19pm	415	SN67	28Jan24	16
TM10942	44	12:30PM	430	KL45	28JAN24	12:42PM	415	KL45	28JAN24	13
TM10942	44	1:34pm	430	SN67	28Jan24	1:46pm	415	SN67	28Jan24	16
TM10942	44	1:58pm	430	SN67	28Jan24	2:10pm	415	SN67	28Jan24	16
TM10942	44	2:30 PM	430	AM47	28JAN24	2:42PM	415	AM47	28JAN24	16
TM10942	44	2:58pm	430	SN67	28Jan24	3:10pm	415	SN67	28Jan24	16
TM10942	44	3:23pm	430	SN67	28Jan24	3:35pm	415	SN67	28Jan24	16
TM10942	44	4:41PM	430	YK40	28Jan24	4:53PM	415	YK40	28Jan24	16
TM10942	44	5:00pm	430	CB58	28Jan24	5:12pm	415	CB58	28Jan24	16
TM10942	44	5:46 pm	430	SD34	28Jan24	5:58pm	415	SD34	28Jan24	16
TM10942	44	6:12 PM	430	PL22	28Jan24	6:24PM	415	PL22	28Jan24	6
TM10942	44	5:30pm	430	KL95	29Jan24	5:42pm	415	KL95	28Jan24	16



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

**PRODUCTION ORDER#** 500000300504

OP 400



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000300504

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	12:24pm	430	SN67	28Jan24	12:33pm	415	SN67	28Jan24	16
TM10745	44	1:50PM	430	AM47	28JAN24	2:02PM	415	AM47	28JAN24	16
TM10745	44	2:15 PM	430	AM47	28JAN24	2:27 PM	415	AM47	28JAN24	16
TM10745	44	2:45PM	430	AM47	28JAN24	2:57 PM	415	AM47	28JAN24	16
TM10745	44	3:13PM	430	PL22	28JAN24	3:25PM	415	PL22	28Jan24	16
TM10745	44	4:27PM	430	YK40	28Jan24	4:39PM	415	YK40	28Jan24	16
TM10745	44	4:55pm	430	CB58	28Jan24	5:07pm	415	CB58	28Jan24	16
TM10745	44	5:15pm	430	CB58	28Jan24	5:27 pm	415	CB58	28Jan24	16
TM10745	44	6:08pm	430	SN67	28Jan24	6:12pm	415	SN67	28Jan24	16
TM10745	44	5:05 pm	430	AF54	29Jan24	5:17 pm	415	AF54	29Jan24	16
TM10745	44	5:34am	429	KL95	29Jan24	5:36am	415	KL95	29Jan24	16
TM10745	44	6:05am	430	OS21	29Jan24	6:17am	415	OS21	29Jan24	16



Document No: 5105589

FM5104665 Rev: C

**Document Type: Manufacturing Form**

Title: SA0155-01 Reflow Log Sheet Form

**PRODUCTION ORDER#** 500000300504  
**OP 400** 50000030054 PY 46 30 Jan 24



Document No: 5106073

Rev: E

Document Type: Manufacturing Form

Title: SA0155-01 Visual Rework Form

PO #: 50000300504OP #: 500 Shift #: 3

Total Parts Reworked:		77	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		20
EW	Exposed Wire		50
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks		2
VD	Voids		5
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		VC09	28 JAN 24

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 #: 500000300504

OP #: 500 Shift #: 1st

Total Parts Reworked:		129	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	HHHHHH HHHHHH	29
EW	Exposed Wire	HHHHHH HHHHHH HHHHHH HHHHHH	65
MP	Micropores	N/A	N/A
SCR	Scratch		4
SKV	Skive Marks	HHH	7
VD	Voids	HHHHHH	24
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

CB81, LL61, UC09

29 Jan 24

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): 

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Page 1 of 1

PO #: 500000300504OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		82	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		16
DIM07 US / WC	DIM07 Undersized (Window Closed)		9
EH	Exposed Hypotube		23
N/A	Glue , stopper		34
Inspected By (Sign and Date):		STX 48	29 Jan 24

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# 500000200504

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10409	N/A	5:00PM	190F	KL4S	28JAN24	6:10PM	190F	KL4S	28JAN24	38
Tm10409	N/A	5:15am	190F	SS4H	29 Jan 24	6:25am	190F	SS4H	29 Jan 24	52
Tm12036	N/A	5:50am	190F	SS4H	29 Jan 24	7:00am	190F	SS4H	29 Jan 24	44
Tm10409	N/A	6:50am	190F	SS4H	29 Jan 24	8:00am	190F	SS4H	29 Jan 24	41
Tm12036	N/A	8:00am	190F	SS4H	29 Jan 24	9:10am	190F	SS4H	29 Jan 24	40
Tm10409	N/A	8:25am	190F	SS4H	29 Jan 24	9:35am	190F	SS4H	29 Jan 24	45
Tm12036	N/A	9:20am	190F	SS4H	29 Jan 24	9:30am	190F	SS4H	29 Jan 24	64
Tm10409	N/A	9:40am	190F	SS4H	29 Jan 24	10:50am	190F	SS4H	29 Jan 24	32
Tm102109	N/A	11:00am	190°F	KT217	29 Jan 24	12:10pm	190°F	KT217	29 Jan 24	41
Tm12036	② Tm12036	11:45am	190°F	KT217	29 Jan 24	12:50pm	190°F	KT217	29 Jan 24	45
Tm10409	N/A	12:15pm	190°F	KT217	29 Jan 24	1:20pm	190°F	KT217	29 Jan 24	32 ②
				N/A						② N/A 23
				KT217	29 Jan 24					

② KT217 29 Jan 24

① SS4H 29 Jan 24



**PO #:** 500000300504

OP #: 900 Shift #: 1st

Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

Title: SA0155-01 Dimensional/Visual Rework Form

P-146 29 Jan 22

Total Parts Reworked:		25 / 55	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		2
EH	Exposed Hypotube		9
EW	Exposed Wire		26
MP	Micropores		1
SCR	Scratch	 	100
SKV	Skive Marks		13
VD	Voids		34
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	N/A	N/A
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A

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):**



**PO #:** 500000300504

OP #: 900 Shift #: 2nd

Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

## Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		138	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		26
MP	Micropores		13
SCR	Scratch		130
SKV	Skive Marks		30
VD	Voids		18
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized	N/A	0
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0

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):**

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**PO #:** 500000300504

**OP #: 900 Shift #: 1st**

Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

## Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		20	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		3
EW	Exposed Wire		6
MP	Micropores		1
SCR	Scratch		21
SKV	Skive Marks		2
VD	Voids		5
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	N/A	N/A
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A

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.

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Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 5000003000504OP #: 900 Shift #: 2nd

Total Parts Reworked:		<u>52</u>	
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		16
SKV	Skive Marks	N/A	N/A
VD	Voids	11	2
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized	PP40 29 Jan 24	
DIM09 US	DIM09 OD Undersized	PP40 29 Jan 24	
<b>Inspected By (Sign and Date):</b>		PP40 29 Jan 24	

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):

PO #: 500000300504OP #: 900 Shift #: 2nd

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

<b>Total Parts Reworked:</b>		67	
<b>Router Code</b>	<b>Defect Failure Mode</b>	<b>Reworkable Defects (Tally)</b>	<b>Total Defects</b>
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		2
MP	Micropores	N/A	0
SCR	Scratch		12
SKV	Skive Marks	N/A	0
VD	Voids	N/A	0
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized	N/A	0
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
<b>Inspected By (Sign and Date):</b>		<i>Mu</i>	<i>29 Jan 24</i>

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):



**PO #:** 500000300504

OP #: 900 Shift #: 2

Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

**Title: SA0155-01 Dimensional/Visual Rework Form**

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):**

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Page 1 of 1



PO #: 500000300504 OP #: 900 Shift #: 2nd

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		48	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire	N/A	0
MP	Micropores	N/A	0
SCR	Scratch		15
SKV	Skive Marks		3
VD	Voids		1
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		16
DIM06 OS	DIM06 OD Oversized		7
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		<u>See H</u>	29 Jan 24

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	24.25	23.53	25.79	25.73	24.71	27.61	26.1	26	25.6	27.33	25.665	1.2628561	4.378	20.1362159	8.542	PASS
Seg B	62.88	54.54	62.51	67.51	54.72	60.16	67.23	62.76	54.32	61.68	60.831	4.9078156	3.981	41.2929859	8.542	PASS
Seg C	74.32	78.91	80.85	77.91	78.4	75.26	75.16	75.98	79.44	76.25	77.248	2.154988	2.911	70.9748299	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 #: 500000300504

Date: 30 JAN 24

Inspector Name: LUKASU C. TSHISHIMBI

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

30 JAN 24

