

# Production Order: 500000306369



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  
 Production Version: 7987  
 Plant / Business Unit: 1213 / AC5

Order Type: ZSTD

Project Phase:

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                      Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>XCS1 10:30AM 12Feb24</u>                      Record Time Extrusions First Exit Dryer (Initial/Time/Date):  <u>KD2 12:15PM 14Feb24</u>                      Record Dryer Shelf #: <u>N/A</u></p>	N/A	N/A	12FEB24	SA70																							
		<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>500</td> <td><u>0000294700</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> <tr> <td>MM1536-01</td> <td>B      <u>B</u></td> <td>PC</td> <td>500</td> <td><u>0000290560</u></td> <td><u>500</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	500	<u>0000294700</u>	<u>500</u>					<u>N/A</u>	<u>N/A</u>	MM1536-01	B <u>B</u>	PC	500	<u>0000290560</u>	<u>500</u>			
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																								
MM0179-01	D <u>D</u>	PC	500	<u>0000294700</u>	<u>500</u>																								
				<u>N/A</u>	<u>N/A</u>																								
MM1536-01	B <u>B</u>	PC	500	<u>0000290560</u>	<u>500</u>																								

Notes: DA 2484, 2564, 2594

N/A

N/A

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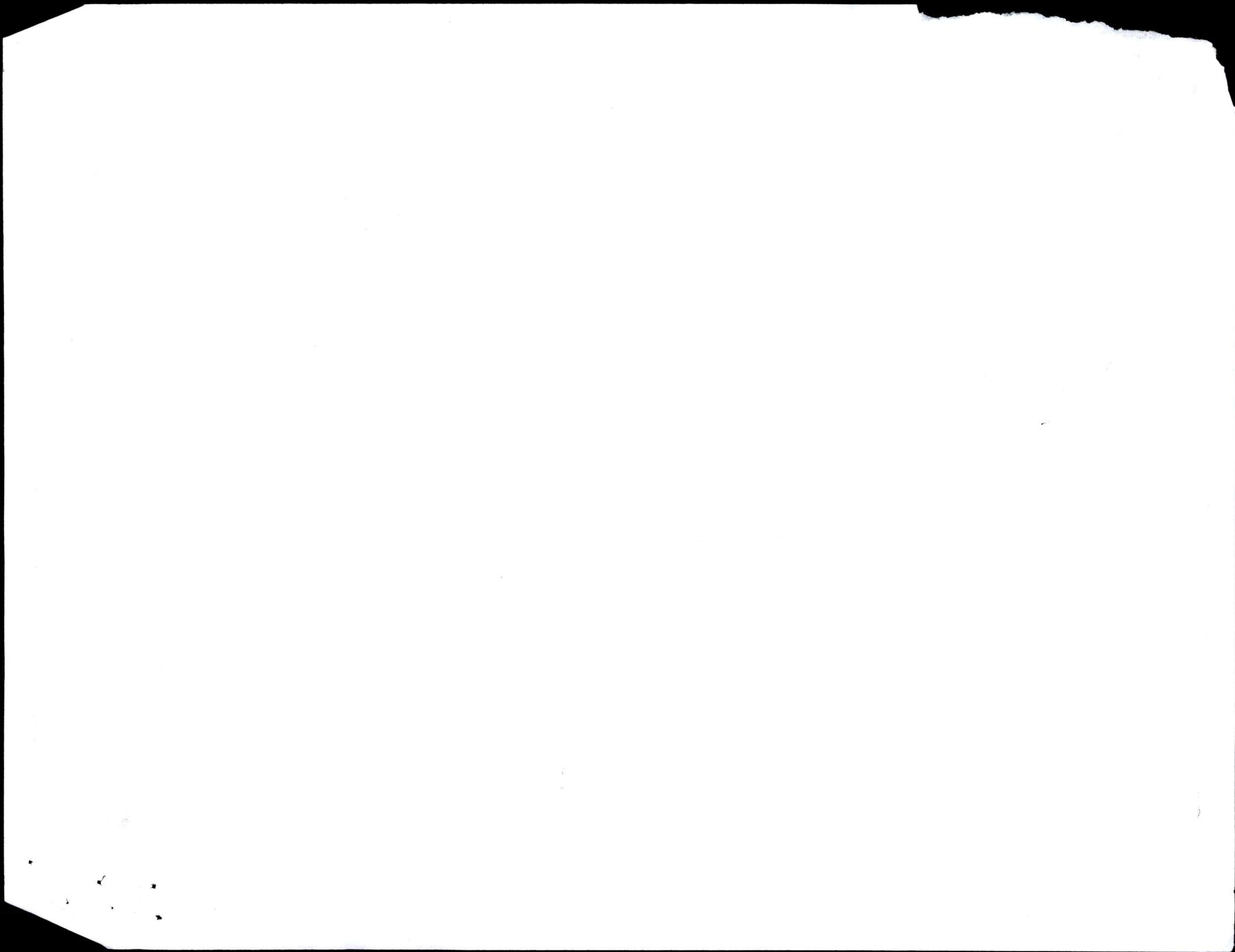
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<i>NP MA</i>		RM0158-01	E	<u>E</u>	PC	200	<u>N/A</u> <u>88018</u>	<u>N/A</u> <u>150</u>		
		1000-1153-01	A	<u>A</u>	PC	594	<u>N/A</u> <u>88693</u> <u>88626</u> <u>88222</u> <u>89089</u>	<u>N/A</u> <u>200</u> <u>200</u> <u>100</u>		
		1000-2053-01	A	<u>A</u>	PC	500	<u>0000287543</u>	<u>500</u>		
		MM1537-02	A	<u>A</u>	PC	500	<u>0000290571</u>	<u>500</u>		
		TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u>	<u>N/A</u>		
		TL0165-05	J	<u>J</u>	PC	5	<u>N/A</u>	<u>Bulk</u>	<i>N/A</i>	<i>N/A</i>
		TL0165-03	J	<u>J</u>	PC	5	<u>N/A</u>	<u>Bulk</u>	<i>N/A</i>	<i>N/A</i>
							<u>N/A</u>	<u>Bulk</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
<i>N/A</i>	<i>MA</i>	141967-01	02	<u>02</u>	PC	500	<u>87451</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
		RM7349-02	C	<u>C</u>	PC	543	<u>82870</u>	<u>400</u>	<u>82B68</u>	<u>100</u>	
		RM7348-01	C	<u>C</u>	PC	500	<u>84587</u>	<u>300</u>	<u>88523</u>	<u>250</u>	
		RM4001-01	B	<u>B</u>	PC	125	<u>89826</u>	<u>100</u>	<u>89828</u>	<u>100</u>	
		RM0607-01	D	<u>D</u>	PC	56	<u>71864</u>	<u>N/A</u>	<u>78845</u>	<u>66</u>	<i>MA</i>
		RM0498-01	C	<u>C</u>	PC	500	<u>0000287649</u>	<u>476</u>	<u>N/A</u>	<u>N/A</u>	<i>MA</i>
		RM0009-04	I	<u>I</u>	PC	1	<u>88992</u>	<u>Bulk</u>	<u>N/A</u>	<u>Bulk</u>	
		RM0009-04	I	<u>I</u>	PC	1	<u>88992</u>	<u>Bulk</u>			

Notes:

*MA*  
*MA*  
*MA*

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
MA N/A		MM1538-01	A	A	PC	500	N/A	Bulk			
							0000290562	500			
		MM1537-01	A	A	PC	1000	N/A	N/A			
							0000290561	1000			
		MM0177-01	C	C	PC	500	0000294697	60			
							N/A	500			
		MM0180-01	E	E	PC	500	0000294374	N/A			
							0000287541	200			
MA N/A		MM0178-01	E	E	PC	500	0000290565	300			
							N/A	500			
		MM0176-01	D	D	PC	500	0000288413	N/A			
MA N/A		MM0074-01	G	G	PC	500	0000303764	500			
							0000303764	22			
							0000292833	25			

**Notes:**

n/a

NA  
NA

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
100	CATASY01 Catheter Assembly 1  Line Clearance Confirmation Rreqd(Milestone )	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	14 Feb 24	V078
150	CATASY01 Catheter Assembly 1  Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	14 Feb 24	CL30 ST23 Y014 PM196 NK62 AF54
Notes:						MA MA N/A

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N/A	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
200	CATASY01  Catheter Assembly 1  	Loading Braid Stock	500	0	14Feb24	CL05 DR35 M450
250	CATASY01  Catheter Assembly 1  	Trim Braid Wire at Proximal End	500	0	14Feb24	AS31 EP32 VP62 LM46

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MA	Trim Braid Wire at Proximal End  Confirmation Reqd(Milestone )		N/A	N/A	N/A	N/A
300	CATASY01  Catheter Assembly 1    Insert Cut Hypo Tube  Confirmation Reqd(Milestone )	Insert Cut Hypo Tube	500	0	14 Feb 24 ①	ny35 ST96 VV2S LMUB CY97 MFTRN AL34K
350	CATASY01  Catheter Assembly 1	Load Tubing	500	0	14 Feb 24	SF23 GS22 V078 AL34 CY97

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① P46 ① P46 15 Feb 24 signed for cy97

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## Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Load Tubing Confirmation Reqd(Milestone )		MA	MA	MA	MA
400	CATASY01 Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone )	Reflow	500	0	14 Feb 24	Sy47 SA85 Dm96 NK62 AX05 AF54
450	CATASY01 Catheter	FEP Removal	500	0	14 Feb 24	Dm96 AF54
Notes:						MA MA MA

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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				
500	CATASY01  Catheter Assembly 1  In-process Inspection and Rework  Confirmation Reqd(Milestone )  N/A	In-process Inspection and Rework Material Consumed: Part #: 100-1153-0 Batch #: 88693 Qty: 10 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 Part #: N/A Batch #: N/A Qty: N/A	490	EW-HH-HH OF-HH-HH HH-EW EW-HH (10)	14Feb24	LL61 CB81 VC09 R66 TD25
		N/A	N/A	N/A	N/A	
		N/A	N/A	N/A	N/A	
		N/A	N/A	N/A	N/A	
		N/A	N/A	N/A	N/A	

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① P446 14 Feb 24

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## Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap City & Desc.	Date Comp.	Initials
550	CATASY01  Catheter Assembly 1  	Remove Heat Shrink & Mandrel  Remove Heat Shrink & Mandrel  Confirmation Reqd(Milestone )	490	0	14Feb24	VAP6 FB01 RS23 AX82 DY29 LL61 Y936
600	CATASY01  Catheter Assembly 1    Distal Tip Assembly  Confirmation	Distal Tip Assembly	476	DL - MAH - HTP MAH - HTP (14)	15Feb24	VAP6 FB01 AX82 PH59 PY46 TRN DY29 SV46

### Notes:

N/A

N/A

N/A

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① PY46 15 Feb 24  
Late entry

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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	476	0	14Feb24 DY29 ML356	FBO1
	Loading Heat Shrink					
	Confirmation Reqd(Milestone )					
700	CATASY01 Catheter Assembly 1  	Tipping Record Tipping Oven Information: TMI: 0986A Cal Due: 31/MAY/24 TMI: 0283C Cal Due: 31/MAY/24 TMI: 0386 Cal Due: 31/MAY/24 TMI: 0521 Cal Due: 31/May/24  Tipping	476	0	14Feb24 HV36 ML38	STR48

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	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>Rm4001-01</u> Batch #: <u>89826</u> Qty: <u>N/A</u> Part #: <u>Rm0607-01</u> Batch #: <u>71864</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>	476	0	14Feb24	STX48 Hv36 mm02
800	CATASY01  Catheter Assembly 1  	Major Mandrel Removal	468	ACD-HH 111	14Feb24	SSH44 SC88

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	Major Mandrel Removal  Confirmation Rreq(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>Pass</u> 2. <u>Pass</u> 3. <u>Pass</u> 4. <u>Pass</u> 5. <u>Pass</u>	467	X5 U/S -1	14Feb24	PY46 Y936 ML65
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	HT72 ML65 XN26
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	 <b>Quality Inspection &amp; Review</b> <b>Confirmation Reqd(Milestone )</b> Re-Inspect after re-work. 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>P04001-01</u> Batch #: <u>49826</u> Qty: <u>17</u> Part #: <u>7000-1153-01</u> Batch #: <u>88693</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>	414	EW-4HT #6US-III #9DS-III Dis-4HT DS-III #10S-1 #5US-III #7DS-III #6OS-III WB-1 MAR-III ACD-III DEC-III SKU-(53) FM-11 EH-III	15 Feb 24	P146 KL67 XL91 MV33 PP40 PX35	
950	<b>QUALITY1</b> <b>Quality Inspection &amp; Review</b> Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: <u>S0713B</u> Cal Due: <u>12 APR 24</u> Record Caliper Information:	N/A	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

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N/A	 <b>Quality Inspection &amp; Review</b>   <b>Confirmation Reqd(Milestone)</b>	<p>TMI: <u>0733</u> Cal Due: <u>30 APR 24</u>          Record DIM02 Go/No-Go Gage Information:          TMI: <u>0691</u> Cal Due: <u>30 SEP 25</u>          TMI: <u>0692</u> Cal Due: <u>30 SEP 25</u>          Record DIM02 Inspection Results N = 54:          Pass: <u>54</u> Fail: <u>0</u></p>	391	STR-1H1111 DIS-1H1(SP) DIS-HH1111 (23)	15 Feb 24 (23)	PY46 KL67 XL91 Y936			
1000	 <b>QUALITY1</b>  <b>Quality Inspection &amp; Review</b>   <b>Quality Inspection &amp; Review</b>   <b>Confirmation Reqd(Milestone)</b>	<p>Quality Inspection &amp; Review          Leak Test          Record Inspection Data in SAP ROS          Record Leak Tester Information:          TMI: <u>1056</u> Cal Due: <u>31 MAY 24</u>          Record Length Gage Information:          TMI: <u>0889D</u> Cal Due: <u>30 SEP 24</u>          Record Calibrated Ruler Information:          TMI: <u>0629</u> Cal Due: <u>30 SEP 24</u></p>	384	LT-HH1 +① OAL-1 (7)	15 Feb 24 (7)	SS44 KL67 XL91 Y936			
<b>Notes:</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 2px;">N/A</td> <td style="text-align: center; padding: 2px;">N/A</td> <td style="text-align: center; padding: 2px;">N/A</td> </tr> </table>							N/A	N/A	N/A
N/A	N/A	N/A							

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(OPY46 15 Feb 24)

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N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1  Quality Inspection & Review  	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	300	SCR - M7 111(M) FM - II (TT) SKV - III DIS - II DISC - II BP - I  (PB)	15 Feb 24	SJ43
1100	CATASY01  Catheter Assembly 1  	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): GS85 15 Feb 24	N/A	N/A	15 Feb 24	GS85
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	366	0 16 Feb 24	AP10 16 Feb 24	AP10

Notes:

N/A AP10 16 Feb 24

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**Batch Number:** 0000306369

**By:** AP10

**Date:** 16 Feb 24

**Reviewed By:**

RB29

**Date:**

16 feb 24

**Notes:**

N/A AP10 16 Feb 24

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

FM0002.RevF Deviation Authorization

**CONTROLLED COPY**

(1) UK55, 23JW 2023



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 **MM0179-01** **MM1536-02** **Type Connection TS12** **10AUG-23**

##### CONTROLLED COPY

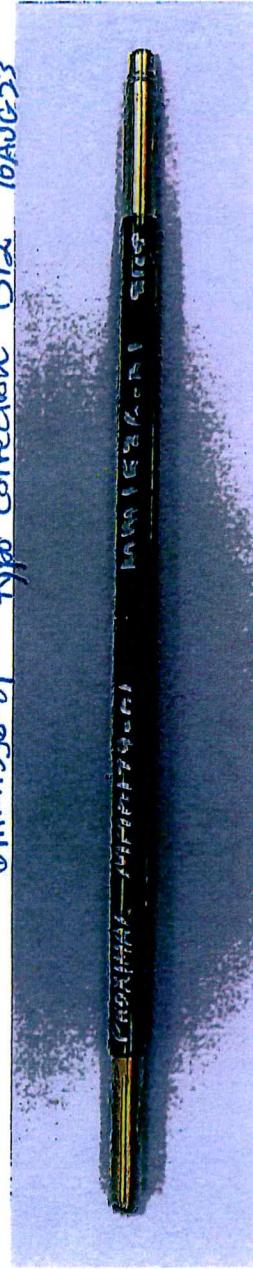


Image- 1

##### 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)

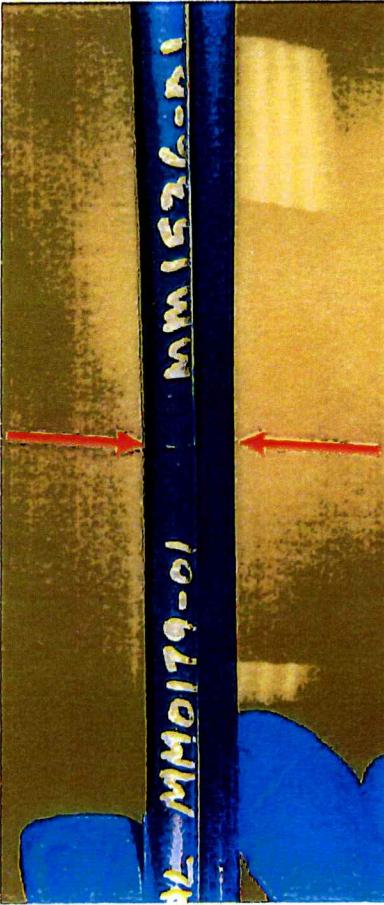


Image- 3

- 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)

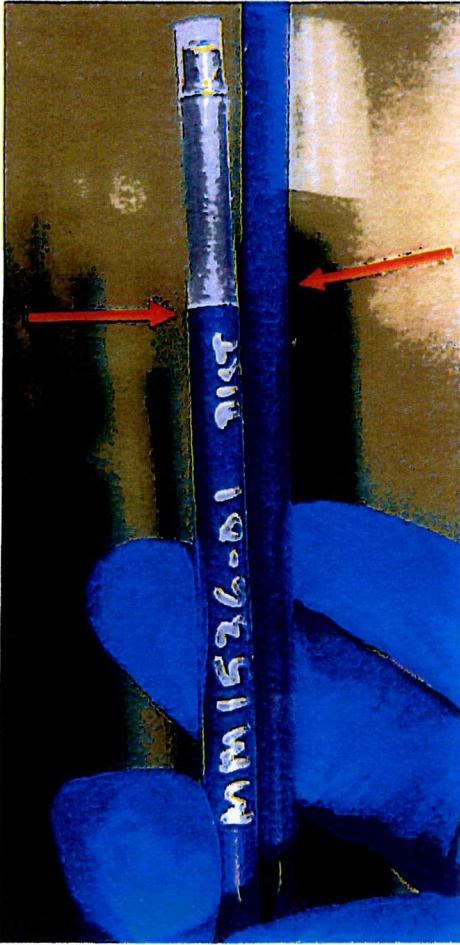


Image- 4  
Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.

- 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  <b>GOOD PART</b>	MM1536-01
<b>2</b>	MM1536-01	MM0179-01
<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

## 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.	

### **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.

<b>Part Number Affected</b>	<b>Revision</b>		
SA0155-01	H		
<b>Start Date:</b>	<b>End Date:</b>		
16 Nov 23	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      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> 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>	<b>Date</b>
Engineering Manager	Jake Stanislawski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023

Extd to 10/Jan/2024 DA28 Rev004

## DEVIATION AUTHORIZATION FORM

**Requestor Name:** Udhesh Kapadnis

Document Number Affected	Revision
3005206 (MPI0238)	BQ
SA0155-01 Router	F
QIP3107610	N

**Deviation From:**

- Move SA0155-01 assemblies to OP900 for visual inspection and Rework after completing process at OP850-Cut to length.
- Perform visual inspection and rework at Op900 as per QIP3107610 Rev N.

**Deviation To:**

- Move SA0155-01 assemblies to off-line 360° inspection system (TMI2434A) for visual inspection after completing process at OP850-Cut to Length.
- 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.

**Justification:**

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. Use of 360° Inspection system (TMI2434A) has very low risk to finished goods quality based on the 3108296 evaluations.

Part Number Affected	Revision
SA0155-01	F

Start Date:	End Date:	Lot Number:
12 Jan 2024	11 Feb 2024	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

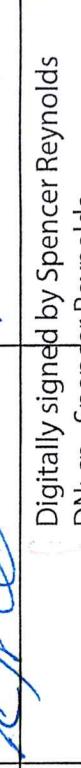
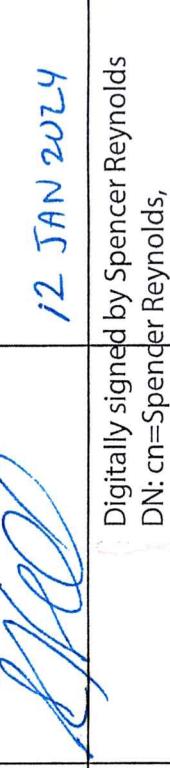
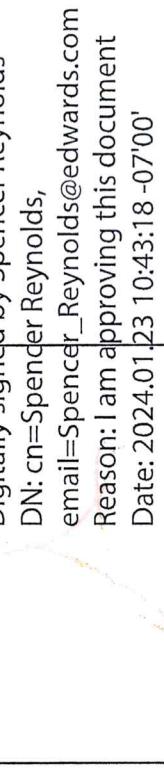
If yes to any of the above, what controls are being put in place to mitigate the risk  
 N/A

**Corrective Action Required:**  Yes  No  N/A

**If no, explain:**

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.

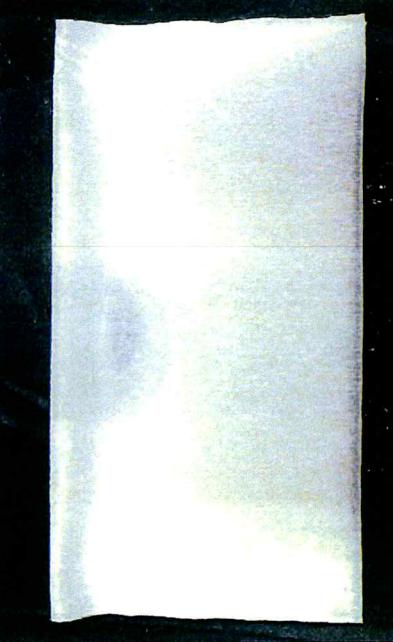
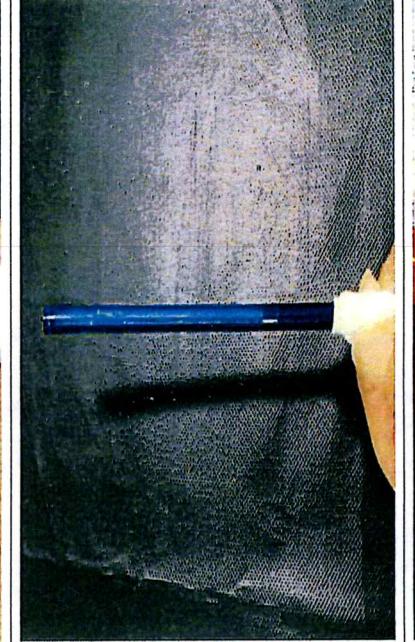
Training Required:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<b>If no, explain:</b> N/A

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>

**CONTROLLED COPY**

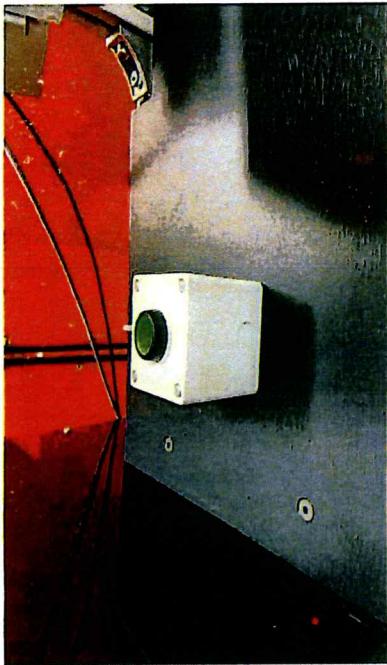
## Inspection Procedure

### CONTROLLED COPY

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> 

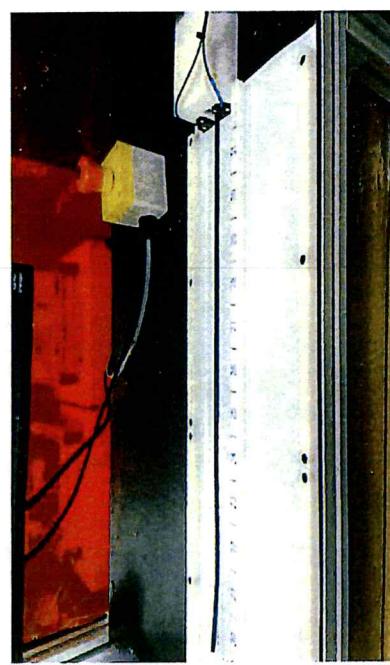
**CONTROLLED COPY**

Press the green start button. Machine indexes catheter and inspects for defects.



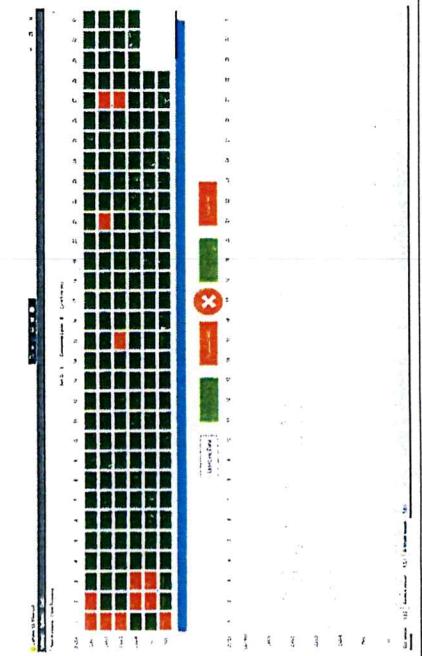
5.

Unload the catheter from unloading station.



6.

Inspection results are displayed on the GUI monitor. Place inspected catheter on index fixture to align GUI defect results.



7.

After aligning GUI defect result with index fixture, inspect defects per 3107610 SA0155-01 QIP for acceptance.

- Take no action for result determined acceptable.
- Use cleanroom tape to identify result determined rework.
- Scrap catheter determined scrap.



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER#: 500000306369

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	1:25AM	429	Sy47	14Feb24	1:37AM	415	Sy47	14Feb24	15
Tm10745	44	1:57AM	429	SH85	14 Feb 24	2:09AM	415	SH85	14 Feb 24	16
Tm10745	44	5:20am	430	NK62	14Feb24	5:32am	415	NK62	14Feb24	16
Tm10745	44	5:45am	430	TA36	14Feb24	5:57am	415	TA36	14Feb24	16
Tm10745	44	6:05AM	430	0521	14Feb24	6:17AM	415	0521	14Feb24	16
Tm10745	44	6:25AM	430	0521	14Feb24	6:37AM	415	0521	14Feb24	16
Tm10745	44	7:40am	430	AX05	14Feb24	7:52am	415	AX05	14Feb24	16
Tm10745	44	8:20AM	430	0521	14 Feb 24	8:32AM	415	0521	14 Feb 24	16
Tm10745	44	8:45AM	430	0521	14Feb24	8:57AM	415	0521	14Feb24	16
Tm10745	44	9:12am	430	AX05	14Feb24	9:24am	415	AX05	14Feb24	16
Tm10745	44	9:35am	428	AX05	14Feb24	9:47am	415	AX05	14Feb24	16
Tm10745	44	10:12am	430	AX05	14Feb24	10:24am	415	AX05	14Feb24	16



PRODUCTION ORDER#: 500000306369

OP 400

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



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

PRODUCTION ORDER#: 500000306369

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	1:17AM	428	SH85	14Feb24	1:26 AM	415	SH85	14Feb24	16
Tm10942	44	1:42AM	429	SH85	14Feb24	1:54AM	415	SH85	14Feb24	16
Tm10942	44	5:33AM	430	NK62	14Feb24	5:45AM	415	NK62	14Feb24	16
Tm10942	44	5:55AM	429	TA36	14Feb24	6:07AM	415	TA36	14Feb24	16
Tm10942	44	6:20AM	428	OS21	14Feb24	6:32AM	415	OS21	14Feb24	16
Tm10942	44	7:00AM	430	OS21	14Feb24	7:12AM	415	OS21	14Feb24	16
Tm10942	44	7:55AM	430	AX05	14Feb24	8:07AM	415	AX05	14Feb24	16
Tm10942	44	8:28AM	428	KL95	14Feb24	8:40AM	415	KL95	14Feb24	16
Tm10942	44	8:55AM	430	AX05	14Feb24	9:07AM	415	AX05	14Feb24	16
Tm10942	44	9:20AM	427	KL95	14Feb24	9:32AM	415	KL95	14Feb24	16
Tm10942	44	9:48AM	430	OS21	14Feb24	10:00AM	415	OS21	14Feb24	16
Tm10942	44	10:50AM	430	NK62	14Feb24	11:02AM	415	NK62	14Feb24	16

OP416 15 Feb 24 correction for SH85



PRODUCTION ORDER# 500000306369

OP 400

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

00521 14 feb 24



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

**PO #:** 5000000306369      **OP #:** 50

OP #: 500 Shift #: 1

**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):



**PO #:** 500000306369

OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

**Document Type: Manufacturing Form**

**Title: SA0155-01 Tipping 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):**

PO #: 5000003060369OP #: 750 Shift #: 2<sup>nd</sup>

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		13	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		10
DIM07 US / WC	DIM07 Undersized (Window Closed)	N/A	N/A
EH	Exposed Hypotube		3
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Mmo3	14 Feb 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#** 500000306369

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10409	N/A	8:00am	190°F	KLSS	14 Feb 24	9:10 am	190°F	KLSS	14 Feb 24	43
TM12036	N/A	8:35am	190°F	SSHH	14 feb 24	9:45am	190°F	SSHH	14 feb 24	35
TM10409	N/A	9:20am	190°F	SSHH	14 feb 24	10:30am	190°F	SSHH	14 feb 24	37
TM12036	N/A	9:55am	190°F	SSHH	14 feb 24	11:05am	190°F	SSHH	14 feb 24	53
TM10409	N/A	11:40pm	190°F	KLSS	14 Feb 24	12:50pm	190°F	KLSS	14 Feb 24	97
TM12036	N/A	12:05pm	190°F	SSHH	14 feb 24	1:15 pm	190°F	SSHH	14 feb 24	42
TM12036	N/A	2:40 pm	190°F	SSHH	14 feb 24	3:50pm	190°F	SSHH	14 feb 24	63
TM10409	N/A	4:33pm	190°F	SG88	14 Feb 24	5:43PM	190°F	XL91	14 Feb 24	50
TM10409	N/A	6:36pm	190°F	SG88	14 Feb 24	7:46PM	190°F	SG88	14 Feb 24	48
				N/A	14 Feb 24					
				SG88						

① P446 14 Feb 24



Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

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

**PO #:** 500000306369    **OP #:** 900    **Shift #:** 1

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.

① 6155 14 Feb 24

**Data Uploaded for Engineering Review (Check):**

- CONFIDENTIAL -

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Status CURRENT Effective 5/8/2023



Document No: 6102619  
Rev: B  
Document Type: Manufacturing Form  
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000306369 OP #: 900 Shift #: 2

Total Parts Reworked:		50	
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		5
MP	Micropores	N/A	0
SCR	Scratch		① 45 49
SKV	Skive Marks		
VD	Voids		
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized		
DIM09 US	DIM09 OD Undersized		
Inspected By (Sign and Date):		DX35 14 Feb 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):

OPY46 15 Feb 24 correction for DX35



Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

Title: SA0155-01 Dimensional/Visual Rework Form

**PO #:** 500000306369    **OP #:** 900    **Shift #:** 2

Total Parts Reworked:		51	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		2
EH	Exposed Hypotube	N/A	N/A
EW	Exposed Wire		12
MP	Micropores	N/A	N/A
SCR	Scratch		83
SKV	Skive Marks	N/A	N/A
VD	Voids		5
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized	N/A 14 Feb 24	
DIM09 US	DIM09 OD Undersized	HT72	
Inspected By (Sign and Date):		HT72 14Feb24	

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

Status CURRENT Effective 5/8/2023



**PO #:** 500000306369    **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

Status CURRENT Effective 5/8/2023



Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

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

**PO #:** 500000306369

**OP #: 900 Shift #: 2 NO**

Total Parts Reworked:		68	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	/	1
EW	Exposed Wire		8
MP	Micropores	N/A	N/A
SCR	Scratch		82
SKV	Skive Marks	N/A	N/A
VD	Voids		5
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		24
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):**

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Status CURRENT Effective 5/8/2023

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	30.27	26.19	28.53	28.87	33.98	26.69	29.35	25.34	28.34	23.98	28.154	2.8260738	4.378	15.7814487	8.542	PASS
Seg B	66.74	77.3	76.85	72.25	66.13	68.92	71.3	73.37	74.2	70.37	71.743	3.8367986	3.981	56.4687049	8.542	PASS
Seg C	91.36	81.94	77.65	81.36	77.76	91.62	77.57	83.98	76.24	84.18	82.366	5.5538079	2.911	66.1988652	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 #: 500000306369

Date: 15FEB2024

Inspector Name: AUGUSTINE JAH

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24



15 FEB 2024