Production Order: 500000294239

Material: SA0155-01 Rev F

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

Material Type: ZFRT

Description: Edwards Flex Shaft Commander 155885

Order Type: ZSTD

Production Version: 7987

Project Phase:

Plant / Business Unit: 1213 / AC5

NC - 29096

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	KITTING3 Kitting Devices Kitting Devices	Kitting Devices Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP Record Time Extrusions Enter Dryer (Initial/Time/Date): Am68 5:00pm 05Jan24 Record Time Extrusions First Exit Dryer (Initial/Time/Date): ①~~Am68 9:30Am~~ Am68 9:30Am 06Jan24 Record Dryer Shelf #: N/A	N/A	N/A	4JAN24	JH70

Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used
MM0179-01	D	D	PC	500	0000276172	500
					N/A	N/A
MM1536-01	B	B	PC	500	0000281412	500

Notes: DA2564, 2484
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

① Am68 06Jan24

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
							N/A	N/A				
		RM0158-01	E	E	PC	200	81054	100				
							N/A	N/A				
		1000-1153-01	A	A	PC	594	867411 86781 86780	200 200 200				
N/A	N/A	1000-2053-01	A	A	PC	500	0000287543 0000278880	400 100				
		MM1537-02	A	A	PC	500	0000276175	500				
							N/A	N/A	N/A	N/A	N/A	N/A
		TL0167-02	E	E	PC	70	N/A	Bulk				
							N/A	Bulk				
		TL0165-05	J	J	PC	5	N/A	Bulk				
							N/A	Bulk				
		TL0165-03	J	J	PC	5	N/A	Bulk				
							N/A	Bulk				

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	141967-01	02	02	PC	500	85502	525	N/A	N/A	N/A	N/A
							N/A	N/A				
		RM7349-02	C	C	PC	543	82673	582				
							N/A	N/A				
		RM7348-01	C	C	PC	500	82883	600				
							N/A	N/A				
		RM4001-01	B	B	PC	125	82824	200				
							N/A	N/A				
		RM0607-01	D	D	PC	56	78316	65				
							N/A	N/A				
		RM0498-01	C	C	PC	500	0000287519	450				
							N/A	N/A				
		RM0009-04	I	1	PC	1	① ~~87421~~ 82971 ~~87471~~	Bulk				
							N/A	Bulk				
		RM0009-04	I	1	PC	1	87921	Bulk				

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

① CB58 12Jan24

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
							N/A	Bulk				
		MM1538-01	A	A	PC	500	0000271052	500				
							N/A	N/A				
		MM1537-01	A	A	PC	1000	0000281413	1000				
							N/A	N/A				
		MM0177-01	C	C	PC	500	0000278966	500				
N/A	N/A						N/A	N/A				
		MM0180-01	E	E	PC	500	0000275691	500	N/A	N/A	N/A	N/A
							N/A	N/A				
		MM0178-01	E	E	PC	500	0000271050	500				
							N/A	N/A				
		MM0176-01	D	D	PC	500	0000281411	500				
							0000271036	40				
		MM0074-01	G	G	PC	500	0000286932	518				
							0000286923	26				

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

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 Confirmation Reqd(Milestone)	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	07Jan24	CBSB
150	CATASY01 Catheter Assembly 1 Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly .	500	0	07Jan24	SD34 YK40 SNM7

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

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 Confirmation Reqd(Milestone)	Loading Braid Stock .	500	0	07Jan24	MC17 SC10
250	CATASY01 Catheter Assembly 1	Trim Braid Wire at Proximal End .	500	0	07Jan24	P967 AL65 RZ22 TRN RL41

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Trim Braid Wire at Proximal End Confirmation Reqd(Milestone)	N/A	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	07Jan24	ALL2 RL47 PL22 TRN BD64
350	CATASY01 Catheter Assembly 1	Load Tubing .	500	0	07Jan24	BD64 CX63

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

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	CATASY01 Catheter Assembly 1 Reflow Confirmation Reqd(Milestone)	Reflow .	500	0	07Jan24	ALG7 CD19 ~~AR02~~ ① SN67
450	CATASY01 Catheter	FEP Removal .	500	0	07Jan24	AM47 JC92 SD34

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

① AR02 06 Jan 24

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Assembly 1 FEP Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	YK40
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 #: 86741 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 Part #: N/A Batch #: N/A Qty: N/A	475	FM-III DH-III OF-IIII EW-IIII II (25)	08 Jan 24	PT09 AR02 BI60 KK54 YK95
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

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 .	468	MAH-ЖНI IDB-1 (9)	08Jan24	PT09 MH10 CD19 TRN SC16 MH10 YK95
600	**CATASY01** Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly .	468	0	08Jan24	PT09

Notes:	N/A
	N/A
	N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
650	CATASY01 Catheter Assembly 1 Loading Heat Shrink Confirmation Reqd(Milestone)	Loading Heat Shrink .	468	0	08Jan24	PTOQ LH45
700	CATASY01 Catheter Assembly 1 Tipping	Tipping Record Tipping Oven Information: TMI: 0336 Cal Due: 31May24 TMI: 0936A Cal Due: 31May24 TMI: 0521 Cal Due: 31May24 TMI: 2083C Cal Due: 31May24	468	0	08Jan24	YH40 HV36

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500 PC

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 Tip Inspection/ Flash Removal Confirmation Reqd(Milestone)	Tip Inspection/ Flash Removal Material Consumed: Part #: RM0607-01 Batch #: 78316 Qty: N/A Part #: RM4001-01 Batch #: 82824 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	468	0	08Jan24	PT09 BI60 HV36 DY49
800	CATASY01 Catheter Assembly 1	Major Mandrel Removal .	459	ADC-IIIIIII ~~9~~ (1) (9)	08Jan24	KL45 TRN SN67 YK40 ~~AI65~~ SS44

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

(1) KL45 08Jan24

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500
PC

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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 Confirmation Reqd(Milestone)	Cut to Length Record DIM05 gage result for the first 5 parts at the start of operation: 1. Pass 2. Pass 3. Pass 4. Pass 5. Pass	459	0	08 Jan 24	RL45 AL42 TRN 5552
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

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	Re-Inspect after re-work. Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: 0700-01 Cal Due: 31 May 24 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: RM0607-01 Batch #: 78316 Qty: N/A Part #: RM4001-01 Batch #: 82824 Qty: N/A Part #: RM0158-01 Batch #: 81054 Qty: N/A Part #: 1000-1153-01 Batch #: 86781 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	448	SCR-1 EW-1 DIS-MM1 FM-11 DL-1 (11)	08 Jan 24	YJS LS46 YK95 PY46
950	QUALITY1 Quality Inspection & Review	Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: N/A Cal Due: N/A Record Caliper Information:	N/A	N/A	N/A	N/A

Notes: N/A N/A N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	TMI: N/A Cal Due: N/A Record DIM02 Go/No-Go Gage Information: TMI: 0691 Cal Due: 30Sep25 TMI: 0692 Cal Due: 30Sep25 Record DIM02 Inspection Results N = 54: Pass: 54 Fail: 0	409	#905 - 11 DIS - ~~||||~~ 11 (SP) STR - ~~||||~~ ~~||||~~ 11 DIS - ~~||||~~ ~~||||~~ ~~||||~~ 111 (39)	08Jan24	4267 8116 PL22 P146
1000	QUALITY1 Quality Inspection & Review Quality Inspection & Review Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: 1056 Cal Due: 31May24 Record Length Gage Information: TMI: 0889D Cal Due: 30Sep24 Record Calibrated Ruler Information: TMI: 0629 Cal Due: 30Sep24	384	LT - ~~||||~~ ~~||||~~ 111 SCR - ~~||||~~ (TT) DEL - 1111 (TT) FM - 11 (TT) VD - 1 (25)	08Jan24	CB58

Notes: N/A

N/A

N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

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	QUALITY1 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 ~~370~~ 346	FB- IIII EW-1 MEX-III SKV-II SCR-IIII IIII VD-IIII FM-1 DL-IIII Del-II ① ~~II~~ #505-1 Dis-1 DT-1 STN-1 FL-1 ~~GMR~~ GMI-1	08 Jan 24	SV43 XN26 KL45
1100	CATASY01 Catheter Assembly 1 Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): GS85 08 Jan 24	N/A	N/A	08 Jan 24	GS85

Notes: N/A
N/A
N/A

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

① SV43 09 Jan 24
② SV43 09 Jan 24

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

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

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
1150	PACKINT1 Packing assembly Package Confirmation Reqd(Milestone)	Package Package, Label, and Ship Finished Parts	346	0	10 Jan 24	APIO

Notes: N/A APIO 10 Jan 24

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

CREGANNA MEDICAL is part of TE connectivity

Production Order: 500000294239

Material: SA0155-01 Rev F

Production Order Document
Production Order Qty: 500
PC

Batch Number:	0000294239
By:	ADO
Date:	10 Jan 24

Reviewed By:	RBZG
Date:	12 JAN 24

Notes:	N/A ADO 10 Jan 24

Date Printed: 04.01.2024 / 18:24:30

SA0155-01

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Extend to 30 Jan 2024 JZ28 12/15/23

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CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: 2484

* See attached email extension to 24SEP23 TSK 24AUG23

Extend to 22Nov2023 JZ28 10/16/23

Extend to 21Dec2023 JZ28 11/17/2023

DEVIATION AUTHORIZATION FORM

Extend to 23Oct2023 JZ28 21Sep23

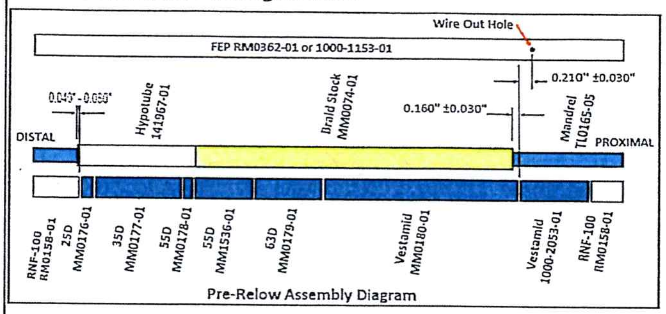
Requestor Name: Udhesh Kapadnis

Document Number Affected	Revision
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.



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.

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 assembly defects.

Part Number Affected	Revision
SA0155-01	H

Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 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.

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:**

① UK55, 23JW 2023

CREGANNA MEDICAL is part of TE

DA	2484 ~~2468~~ ①

Group Training Record

Description/Objectives of Training:
DA- Inspection at final QC, Op#1050.

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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~~ ② fixture for inspection. (See image 1)

② MM1536-01 typo correction TS12 10AUG23

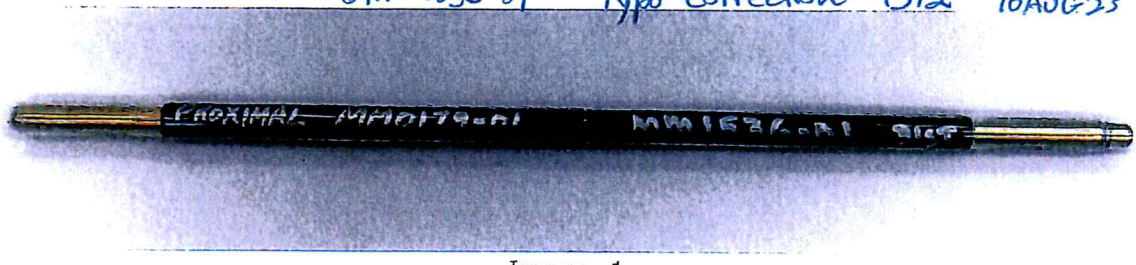

Image- 1

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)

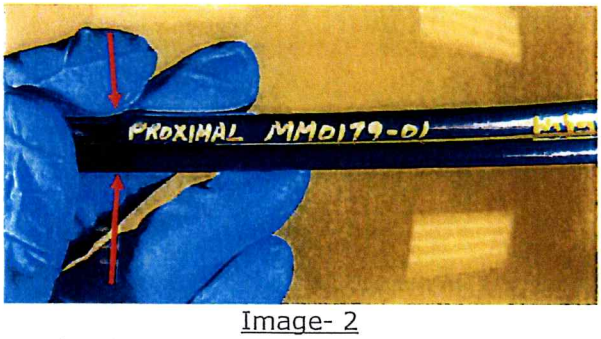

Image- 2

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

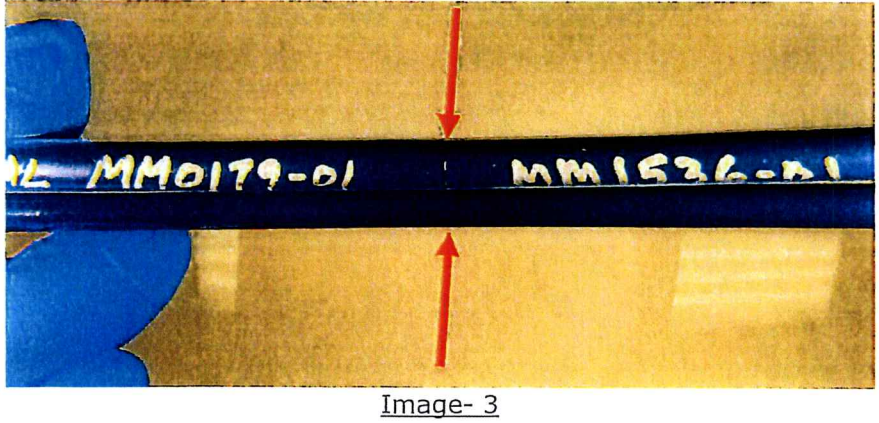

Image- 3

- 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.

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)

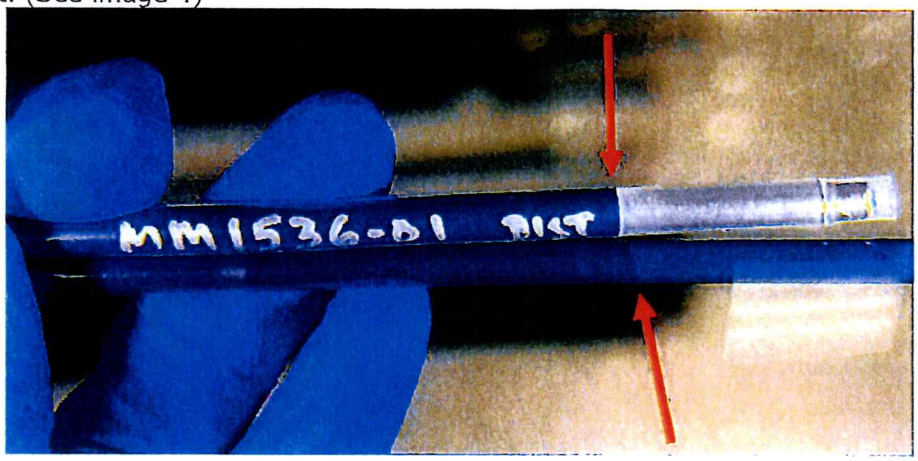

Image- 4

- 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.

Image – 5

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

Extend to 14 Jan 2024 1228 12/12/2023

CREGANNA MEDICAL is part of TE

DEVIATION AUTHORIZATION NUMBER: DA2564

CONTROLLED COPY

DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj

Document Number Affected	Revision
Doc #3005206 (MPI0238)	BP

Deviation From:	Deviation To:
Doc #3005206 (Flex Commander MPI0238): OPER850.11: 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.	**Doc #3005206 (Flex Commander MPI0238): OPER850.11:** Using a laser micrometer **at OPER900 (TMI0700-01)**, 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

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

If no, explain: This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.

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

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

PRODUCTION ORDER# 5000002947239

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	10:20am	430	cm99	06Jan24	10:32am	415	cm99	06Jan24	16
TM10942	44	10:47am	430	cm99	06Jan24	10:57am	415	cm99	06Jan24	16
TM10942	44	11:16am	430	cm99	06Jan24	11:28am	415	cm99	06Jan24	16
TM10942	44	11:42am	430	cm99	06Jan24	11:54am	415	cm99	06Jan24	16
TM10942	44	12:11pm	430	cm99	06Jan24	12:12pm	415	cm99	06Jan24	16
TM10942	44	1:30 PM	430	RL47	06 Jan 24	1:42 PM	415	RL47	06 Jan 24	16
TM10942	44	2:33pm	430	YKHO	06Jan24	2:45pm	415	YKHO	06Jan24	16
TM10942	44	3:02 PM	430	RL47	06 Jan 24	3:14 PM	415	RL47	06 Jan 24	16
TM10942	44	4:46 Pm	430	SD34	06 Jan 24	4:58 pm	415	SD34	06 Jan 24	16
TM10942	44	5:37 PM	430	RL47	06 Jan 24	5:49 PM	415	RL47	06 Jan 24	16
TM10942	44	6:27pm	430	CD19	06Jan24	6:39pm	415	CD19	06Jan24	16
TM10942	44	7:06am	430	cm99	07Jan24	7:18am	415	cm99	07Jan24	16

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

PRODUCTION ORDER# 5000002942 39

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	8:16am	430	cm99	07Jan24	8:28am	415	cm99	07Jan24	16
Tm10942	44	9:41 AM	430	RVL6	07Jan24	9:53 AM	415	RVL6	07Jan24	16
			N/A	cm99	07Jan24					

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

PRODUCTION ORDER# 5000002942 39

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	10:32am	430	cm99	06Jan24	10:44am	415	cm99	06Jan24	16
Tm10745	44	11:01am	430	cm99	06Jan24	11:13am	415	cm99	06Jan24	16
Tm10745	44	11:34am	430	cm99	06Jan24	11:46am	415	cm99	06Jan24	16
Tm10745	44	11:58am	430	cm99	06Jan24	12:10pm	415	cm99	06Jan24	16
Tm10745	44	12:23pm	430	SN67	06Jan24	12:35pm	415	SN67	06Jan24	16
Tm10745	44	1:22pm	430	RL47	06Jan24	1:34pm	415	RL47	06Jan24	16
Tm10745	44	1:46pm	430	RL47	06Jan24	1:58pm	415	RL47	06Jan24	16
Tm10745	44	2:07pm	430	SD34	06Jan24	2:18pm	415	SD34	06Jan24	16
Tm10745	44	2:47pm	438	SN67	06Jan24	2:59pm	415	SN67	06Jan24	16
Tm10745	44	3:23pm	430	SN67	06Jan24	3:35pm	415	SN67	06Jan24	16
Tm10745	44	4:24pm	430	RL47	06Jan24	4:36pm	415	RL47	06Jan24	16
TM10745	44	5:02pm	430	SD34	06Jan24	5:14pm	415	SD34	06Jan24	16

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

PRODUCTION ORDER# 5000002942 39

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	5:22PM	430	RL47	~~06 JAN 23~~ 06 Jan 24 (2)	5:34PM	415	RL47	~~06 JAN 23~~ 06 Jan 24 (2)	16
TM10745	44	5:47PM	430	AL42	~~06 JAN 23~~ 06 Jan 24 (2)	5:59PM	415	AL42	~~06 JAN 23~~ 06 Jan 24 (2)	16
TM10745	44	6:18PM	430	RL47	~~06 Jan 24~~ 06 Jan 24 (2)	6:30PM	415	RL47	~~06 Jan 24~~ 06 Jan 24 (2)	16
TM10745	44	7:36AM	430	SN67	~~07 JAN 23~~ 07 Jan 24 (1)	7:48AM	415	SN67	~~07 JAN 23~~ 07 Jan 24 (1)	16
TM10745	44	8:37AM	430	SN67	07 Jan 24	8:49AM	415	SN67	07 Jan 24	16
TM10745	44	9:45AM	430	PV16	07 Jan 24	9:57AM	415	PV16	07 Jan 24	4

N/A 07 Jan 24 cm99

(1) SN67 07 Jan 24

(2) PV 08 Jan 24 correction for ~~RL07~~ (2), AL42 ; RL47

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

PO #: 5000002944239 OP #: 500 Shift #: 3

Total Parts Reworked:		205	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	𝍸 𝍸 𝍸 𝍸	25
EH	Exposed Hypotube	𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸	40
EW	Exposed Wire	𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸	85
MP	Micropores	N/A	N/A
SCR	Scratch	𝍸 𝍸 𝍸	18
SKV	Skive Marks	𝍸 𝍸	15
VD	Voids	𝍸 𝍸 𝍸	22
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		LS46. AR02	07 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 #: 500000 294239 **OP #: 500** **Shift #:** 3

Total Parts Reworked:		37	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	IIII	4
EW	Exposed Wire	~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ ~~IIII~~ II	27
MP	Micropores	N/A	N/A
SCR	Scratch	II	2
SKV	Skive Marks	I	1
VD	Voids	III	3
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		AR02	06 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: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 5000002944239 **OP #: 750** **Shift #:** 1st

Total Parts Reworked:		21	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
DIM07 OS / WO	DIM07 Oversized (Window Open)	𝍸 𝍸 |	11
DIM07 US / WC	DIM07 Undersized (Window Closed)	N/A	N/A
EH	Exposed Hypotube	111	3
		𝍸 11	7
Inspected By (Sign and Date):		DY29 08 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): ☒

TE connectivity

Document No: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 500000294239 **OP #: 750** **Shift #:** 3

Total Parts Reworked:		170	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
DIM07 OS / WO	DIM07 Oversized (Window Open)	[tally marks]	67
DIM07 US / WC	DIM07 Undersized (Window Closed)	[tally marks]	18
EH	Exposed Hypotube	[tally marks]	54
GD/AB	Glue Damage / Air Bubbles	[tally marks]	31
Inspected By (Sign and Date):		BI60 08 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): ☑

CREGANNA MEDICAL is part of TE connectivity

Document No: FM5104661
Rev: B
Document Type: Manufacturing Form
Title: SA0155-01 Annealing Log Sheet Form

5000002942391

PRODUCTION ORDER# ~~5000002942391~~ (1) KL95 08Jan24

(1)

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10409	N/A	7:12Am	190°F	YK40	07Jan24	8:22Am	190°F	YK40	07Jan24	31
TM12036	N/A	8:08Am	190°F	YK40	07Jan24	9:18Am	190°F	YK40	07Jan24	38
TM10409	N/A	9:51Am	190°F	YK40	07Jan24	~~10:5~~ 11:01Am	190°F	YK40	07Jan24	36
TM12036	N/A	10:39Am	190°F	YK40	07Jan24	11:49Am	190°F	YK40	07Jan24	35
TM10409	N/A	11:36Am	190°F	YK40	07Jan24	12:46pm	190°F	YK40	07Jan24	32
TM12036	N/A	12:12pm	190°F	YK40	07Jan24	1:22pm	~~1:00pm~~ 190°F (1)	YK40	07Jan24	30
TM10409	N/A	1:30pm	190°F	AE65	07 Jan 24	2:40pm	190°F	AE65	07 Jan 24	21
TM12036	N/A	2:30pm	190°F	AE65	07 Jan 24	3:40 pm	190°F	AE65	07 Jan 24	30
TM10409	N/A	5:50pm	190°F	CD19	07Jan24	6:06 pm	190°f	CD19	07 Jan24	53
TM10409	N/A	4:50am	190°f	SS44	08Jan24	6:00am	190°f	SS44	08Jan24	91
TM10409	N/A	6:05am	190°f	SS44	08Jan24	7:15am	190°f	SS44	08Jan24	62
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	N/A	N/A	N/A	N/A	N/A	N/A

(1) YK40 07Jan 24

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

PO #: 5000004294239 OP #: 900 Shift #: 3

Total Parts Reworked:		121	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	11	2
EH	Exposed Hypotube	𝍸 1	6
EW	Exposed Wire	𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 1111	34
MP	Micropores	N/A	N/A
SCR	Scratch	𝍸 𝍸 𝍸 𝍸 𝍸 1111	29
SKV	Skive Marks	𝍸 𝍸 𝍸 𝍸 𝍸 1	26
VD	Voids	𝍸 111	8
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	𝍸 𝍸 11	12
DIM06 OS	DIM06 OD Oversized	1111	4
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		LS46, KX54, VY35 07JAN24	

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 #: 5000002942239 **OP #: 900** **Shift #:** 1st

Total Parts Reworked:		136	
Router Code	**Defect Failure Mode**	**Reworkable Defects (Tally)**	**Total Defects**
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	𝍸 1	11
EW	Exposed Wire	𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸	50
MP	Micropores	N/A	N/A
SCR	Scratch	𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸 𝍸	90
SKV	Skive Marks	N/A	N/A
VD	Voids	𝍸 𝍸 𝍸 1	21
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
Inspected By (Sign and Date):		PY46D429, KT47 K155 08Jan24	

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	25.15	25.73	24.98	24.01	26.7	27.2	25.75	24.74	24.67	25.35	25.428	0.960067	4.378	21.2248261	8.542	PASS
Seg B	59.83	56.67	63.62	53.84	62.86	56.16	57.83	61.65	62.66	56.94	59.206	3.377363	3.981	45.7607171	8.542	PASS
Seg C	83.9	79.61	76.19	78.53	80.09	83.94	83.44	78.56	80.47	77.25	80.198	2.766252	2.911	72.1454399	8.542	PASS

EDW Commander Flex - Bend and Tensile Strength Testing

LOT #: 500000294239
Date: 09 JAN 24
Inspector Name: Javier Olivares
Equipment ID: TMI0311B
Cal Due Date: 27 OCT 24

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.

J001 09 jan 24

TE MEDICAL

REWORK/REINSPECTION WORK ORDER FORM

Customer: Edwards Lifesciences	PO No.: N/A
Description: Flex Commander	TE Medical Lot No.:294239
Customer P/N: 155885	Returned Quantity: 384
TE Medical P/N: SA0155-01	Other: N/A
RMA #:	NC or CAPA #: NC29096

Will the rework have adverse effects on the product? ☒ No ☐ Yes (Provide justification of rework and how it was concluded).

There will be no product rework allowed for this NC. There will be no adverse effect on the products as quality inspectors are certified to perform 100% visual inspection per existing Quality Inspection Plan (QIP3107610)

Special Instructions:

1. QE/ Technician: to complete training per special instructions before sorting activity. Attach training record to NC before closing.
2. Inspectors: to perform the line clearance per MPI0230 prior to re-inspection of each lot.
3. Inspectors: to verify lot quantity prior to performing re-inspection of the affected lots. Contact Quality if count discrepancy found.
4. Inspectors: to perform 100% dimensional inspection of Dim5 using calibrated Flex Shaft Tip Go/No Go gauge TMI50713 and Vernier Caliper for DIM7. Defective units to be identified with defect type.
5. DA Inspector: to perform 100% visual inspection using visual guideline doc #3107585, before moving good units to Packaging. Contact Quality to remove hold in SAP.
6. QC Operator: Confirm lots in SAP to reflect final accept/reject quantities from 200% inspection activities.
7. Accepted units can be sent to Packaging and onward to Shipping.

Note: The scrap unit(s) will be documented within this Form and may be used for Engineering study (Quality Engineer is to collect scrapped parts)

Process	Qty	Initials	Equipment Number and Cal Due Date if applicable	Comments
Dimension inspection	384	PY46	(1) TM12050-12 ~~N/A~~ TM150713	N/A
Reworked (if necessary)	N/A	N/A	N/A	N/A
AQL Sampling	N/A	N/A	N/A	N/A
Total accepted	384	PY46	[redacted]	N/A
Total failed / scrapped	0	PY46		N/A
Other	N/A	N/A		N/A

(1) PY46 09 Jan 24

TE MEDICAL

REWORK/REINSPECTION WORK ORDER FORM

Note: Fill in the table below if components were replaced during the rework process. This form will be filed along with the original LHR.

Component(s) Used				Component(s) removed/scrapped			
P/N	Rev.	Lot No.	Qty.	P/N	Rev.	Lot No.	Qty.
N/A P146 09Jan24							

Process Time	Hour(s)	Initials	Comments
Re-work hours (± .25 hrs)	.5	P146	N/A
Final Rework/Re-Inspection/Re-Test hours (± .25 hrs)	N/A	N/A	N/A

Re-work/Re-inspection/Re-Test Performed By: P146 Date: 09Jan24

Final Rework/Re-inspection/Re-Test Reviewed By: N/A Date: N/A

Disposition of Reject Material (unit that does not meet the acceptance criteria after rework/inspection):

☐ Scrap to Bin

☒ Scrap to ~~R & D~~ ENGINEERING AB25 09Jan2024

Scrap Disposition by (Name, Date & Sign): Alphonso Bahn 09Jan 2024