



One Venture Infinite Possibilities

Monthly Technical Review – 16 Aug 2018

Agenda



1. Review of last MTR minutes & action items
2. First Pass Yield
 - Overall Results & individual instrument results
 - Instrument > targets (does not meet Waters targets or having downtrend)
 - Categories failure mode into material, tooling, fixtures, testers, workmanship, others
 - Improvement actions & effectiveness
3. Manufacturing readiness
 - Training review and competencies updates
 - Tooling & Fixtures updates
 - Testers updates
 - Documentation (ASP, TSP updates)
4. Quality (trending, analysis of issues (repeated case), updates / actions taken)
 - Suppliers
 - LAR
 - SCAR
 - Audit schedules, audit results, findings and closure
 - In Process
 - NCR
 - CAPA
 - Quality alerts
 - Customers & field complaints
 - QMS updates
5. Others
 - ECO, TMD
 - AOB

Review Of Last MTR Minutes

Action Items from Previous Meeting		
Description	Responsible	Due Date
Waters Documentation (ASP/TSP): GES to complete the ECO and OESR raised for the Waters ASP/TSP. Waters ASP: 16 out of 134 Documents need to update. Update: Waters TSP: 40 out of 59 Documents review completed , total 11 OESR pending to release GES redlined 16 ASP, WPPL is currently reviewing the ASP	WPPL – Desmond	Q2'18 Q4'18
iBSM/QSM FPY Action Plan: Report on spike of 0.3ml/min flow rate accuracy failures (lower spec limit – 0.297ml/min) on QSM (186017000) in Apr 2018. Update: 24-Jul-18: GES Engineering to add-in Jul 2018 data and to provide the report in next update.	Venture – Chan Myae	Q2'18
Waters RMA return: Waters MRB/RMA Process flow has been revised . May'18, June'18 and July'18 report has been physically reviewed under new format. Disposition will be provided by WPPL once completed.	WPPL QA – Wan Jing	Aug'18
Detector FPY Action Plan: Ram-Ray Valley Energy failure on Detector Final Test To check with Hamamatsu the SN range's outgoing report/data to compare for any relevance on the failure observed in 247500 models. Report update to provide in next meeting. Update: 16-Aug-18: Refer to report from Engineering	Venture – MiMi	Aug'18
FTN Firs Pass Yield Venture Engineering to submit OESR for the reported on Needle Seal Force failure 24 Jul 18: Completed, OESR submitted on June 25, 2018, Waters replied to revise the FSD for Sample Syringe Decay Failure if sufficient number of data points from both Singapore and Milford. To monitor the timeline completion of the document.	WPPL/Venture – Engineering Lwin/Desmond	Aug'18

Review Of Last MTR Minutes



Action Items from Previous Meeting

Description

Responsible

Due Date

Feedback/Complaint:

Mar'18: Pin Bent on J12 Instrument No. Affected: 186179100

24-May-18: Proposed a plastic dust cover/plug to cover the exposed connector to avoid damage during shipment/prior installation and prevent any deformed connectors ship out. Submitted the dust cover quotation to WPPL for approval on 04-Apr-18.

Status:

Venture marked up the TSP to add-in the dust cover and submit to Waters for approval

**WPPL Ops –
Desmond**

Q4'18



Feedback/Complaint:

Mar'18: Feedback/Complaint – Day1 Failure, DSP cable detached for 186015000

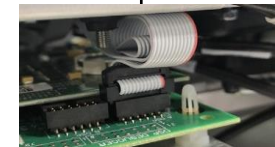
Update:

Work Instruction for iBSM-Plus (186015082) - Completed

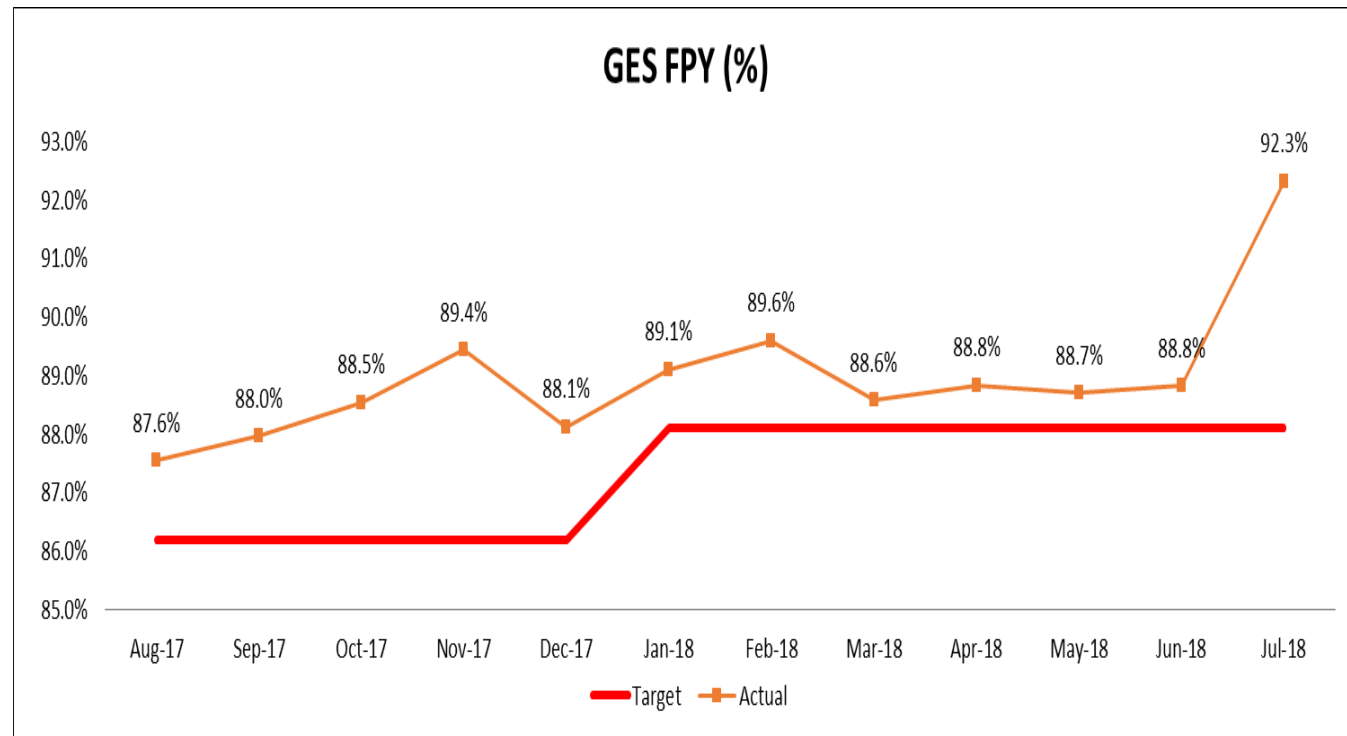
[Work Instruction for iBSM \(186015000\) - For Waters Approval](#)

**WPPL Ops –
Desmond**

**Q2'18
Q3'18**



GES		
Period	Target	Actual
Aug-17	86.2%	87.6%
Sep-17	86.2%	88.0%
Oct-17	86.2%	88.5%
Nov-17	86.2%	89.4%
Dec-17	86.2%	88.1%
Jan-18	88.1%	89.1%
Feb-18	88.1%	89.6%
Mar-18	88.1%	88.6%
Apr-18	88.1%	88.8%
May-18	88.1%	88.7%
Jun-18	88.1%	88.8%
Jul-18	88.1%	92.3%



➤ For Jul 2018, 8 instruments failed their respective FPY Target. (186015008, 186015017, 186002475, 186015029, 186247500, 186017006, 186015085, 186015082)

➤ DTS models are not included in overall FPY

Data Analysis

First Pass Yield (FPY) – Data Tabulation By Instruments in month July 2018

Material Number	Instrument Description	Product Group	2018 Target	May-18	Jun-18	Jul-18	Total Units Tested	Total Units Passed	Total Units Not Passed	Total Units Adjusted Passed	Total Units Change Component
186001863	ALLIANCE COLUMN HEATER	Column Heater	99%	NP	NP	NP	0	0	0	0	0
186001791	ALLIANCE COLUMN HEATER/COOLER	Column Heater	99%	NP	100.0%	100.0%	3	3	0	0	0
186001500	BREEZE COLUMN HEATER	Column Heater	99%	100.0%	100.0%	100.0%	5	5	0	0	0
186015011	ACQUITY UPLC 30cm COL HT	Column Heater	99%	100.0%	100.0%	100.0%	50	50	0	0	0
186186301	ALLIANCE Column Heater (Blue)	Column Heater	99%	99.5%	99.5%	100.0%	176	176	0	0	0
186179100	ALLIANCE Column Heater Cooler (Blue)	Column Heater	99%	100.0%	99.5%	100.0%	225	225	0	0	0
186017008	ACQUITY ARC 30cm Column Heater	ARC Column Heater	98%	100.0%	100.0%	100.0%	40	40	0	0	0
186017009	ACQUITY ARC 30cm Column Heater/Cooler	ARC Column Heater	97%	100.0%	100.0%	100.0%	55	55	0	0	0
186015010	ACQUITY HTCH	Column Heater	94%	100.0%	100%	100.0%	30	30	0	0	0
186015042	ACQUITY HTCH-A	Column Heater	93%	95.9%	93.0%	97.8%	183	179	4	4	0
186002441	TEMP CONTROLLER MODULE II	Controller Module	97%	100.0%	100.0%	100.0%	32	32	0	0	0
186002449	PRESSURE CONTROLLER MODULE II	Controller Module	99%	100.0%	100.0%	100.0%	16	16	0	0	0
186015007	ACQUITY UPLC Column Mgr-Right Inlet	Column Manager	96%	80.0%	100.0%	100.0%	8	8	0	0	0
186015008	ACQUITY UPLC Column Htr/Clr	Column Manager	90%	NP	NP	75.0%	4	3	1	0	1
186015009	ACQUITY UPLC Column Mgr-Left Inlet	Column Manager	100%	NP	100.0%	100.0%	3	3	0	0	0

NP – No Production



Data Analysis

First Pass Yield (FPY) – Data Tabulation By Instruments in month July 2018

Material Number	Instrument Description	Product Group	2018 Target	May-18	Jun-18	Jul-18	Total Units Tested	Total Units Passed	Total Units Not Passed	Total Units Adjusted Passed	Total Units Change Component
186015043	ACQUITY UPLC CM-A	Column Manager	82%	74.1%	82.4%	82.4%	153	126	27	26	1
186015049	ACQUITY UPLC CM-AUX	Column Manager	87%	87.5%	89.3%	90.6%	32	29	3	3	0
186015045	ACQUITY UPLC CH-30A	Column Manager	92%	100.0%	94.7%	100.0%	28	28	0	0	0
186015038	ACQUITY ACTIVE COLUMN MANAGER	Column Manager	95%	100.0%	100.0%	NP	0	0	0	0	0
186015039	ACQUITY AUXILIARY COLUMN MANAGER	Column Manager	86%	NP	100.0%	100.0%	3	3	0	0	0
186015017	FTN Sample Manager H-Class	FTN	55%	NP	50.0%	54.4%	68	37	31	30	1
186015046	FTN Sample Manager I-Class	FTN	45%	NP	41.3%	60.0%	10	6	4	2	2
186002475	ALLIANCE 2475 MULTICHANNEL FLR DETECTOR	Detector	94%	75.0%	100.0%	75.0%	4	3	1	1	0
186015029	ACQUITY UPLC FLR DETECTOR	Detector	97%	87.2%	77.1%	85.4%	41	35	3	3	0
186247500	ACQUITY 2475 FLR Detector Blue	Detector	90%	78.9%	81.25%	87.9%	33	29	4	4	0
186017006	ACQUITY ARC Detector	ARC Detector	95%	76.2%	92.31%	93.8%	16	15	1	1	0
186015000	UPLC I-CLASS BSM	iBSM	56%	NP	63.0%	57.7%	26	15	11	9	2
186017000	ACQUITY ARC QSM	ARC QSM	52%	52.1%	58.4%	52.3%	109	57	52	47	5

NP – No Production





Data Analysis

First Pass Yield (FPY) – Data Tabulation By Instruments in month July 2018

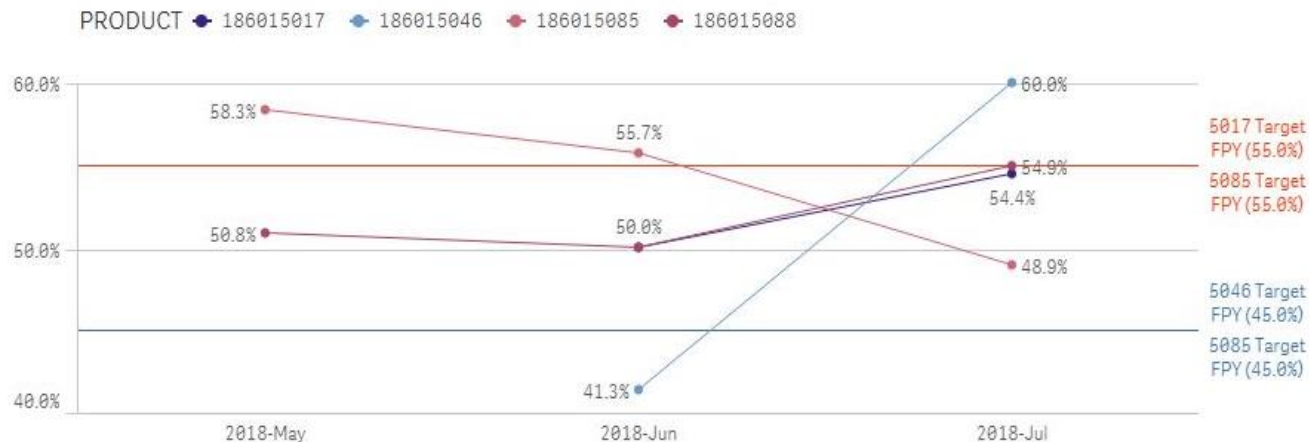
Material Number	Instrument Description	Product Group	2018 Target	May-18	Jun-18	Jul-18	Total Units Tested	Total Units Passed	Total Units Not Passed	Total Units Adjusted Passed	Total Units Change Component
186015088	ACQUITY I-Class FTN Plus	FTN PLUS	45%	50.0%	50.0%	54.9%	51	28	23	23	0
186015085	ACQUITY H-Class FTN Plus	FTN PLUS	55%	58.3%	55.7%	48.9%	92	45	47	47	0
186015082	ACQUITY UPLC I-Class BSM Plus	BSM PLUS	56%	44.3%	47.6%	45.3%	64	29	35	33	2
186017014	ACQUITY ARC BIO 30CM COLUMN HEATER	Column Heater	98%	NP	100.0%	100.0%	5	5	0	0	0
186017015	ACQUITY ARC BIO 30CM COLUMN HEATER/COOLER	Column Heater	97%	NP	100.0%	NP	0	0	0	0	0

Individual 2018 targets for Bifrost Models (186015088, 186015085 & 186058082) were copied from the common FTN/iBSM Models (186015046, 186015017 & 186015000).

Data Analysis

First Pass Yield (FPY) – First Pass Yield Discussion on FTN – 186015017, 186015046, 186015085, 186015085

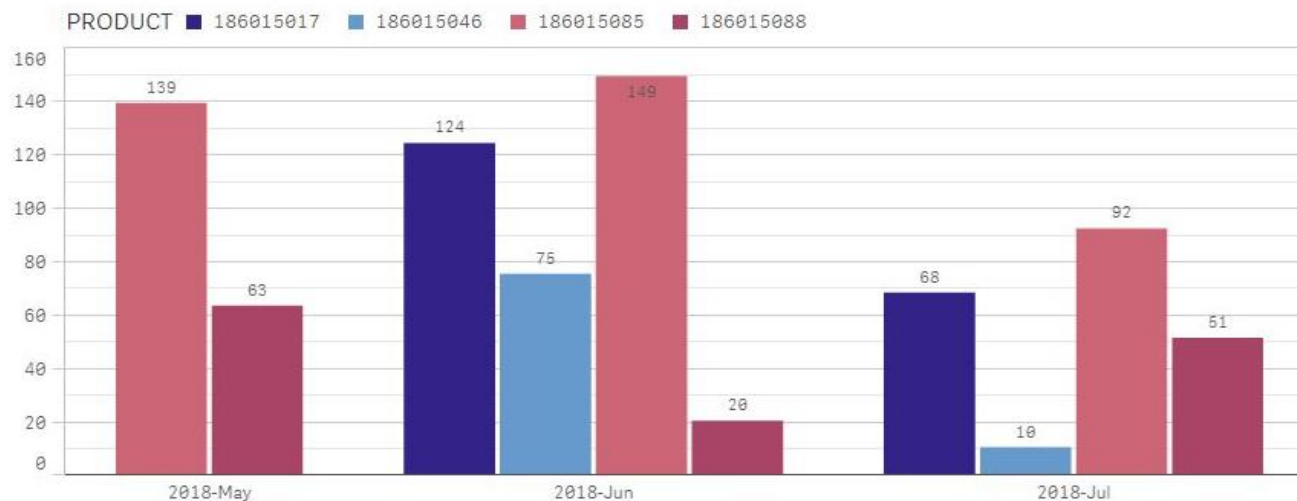
First Pass Yield For - 186015017, 186015046, 186015085, 186015088



July - 2018

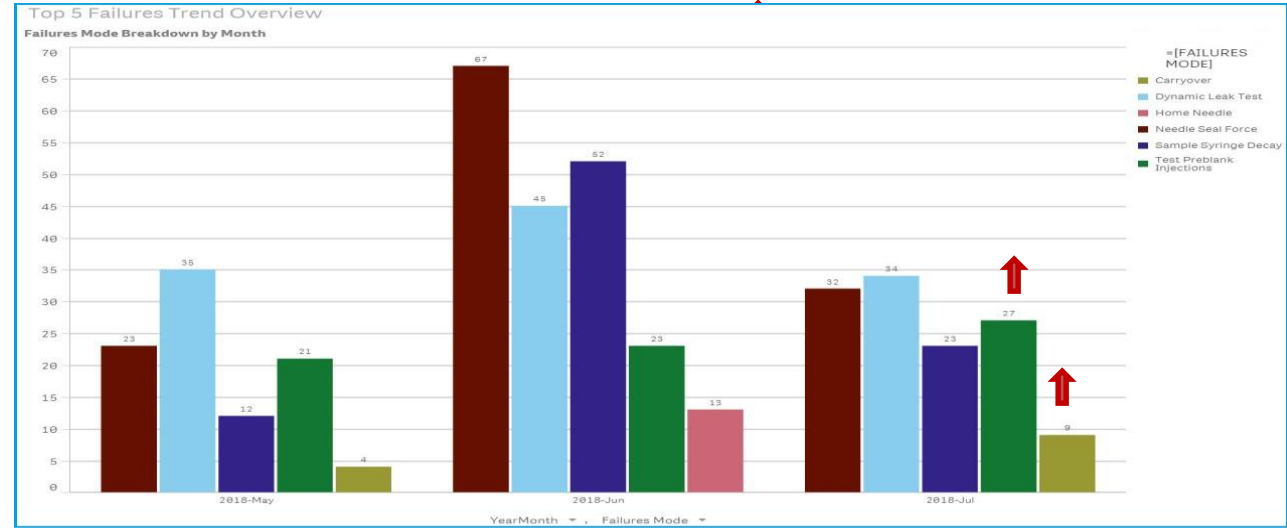
- 5017 – 54.4%
- 5046 – 60.0%
- 5085 – 48.9%
- 5088 – 54.9%

Total Units tested breakdown by Products



Data Analysis

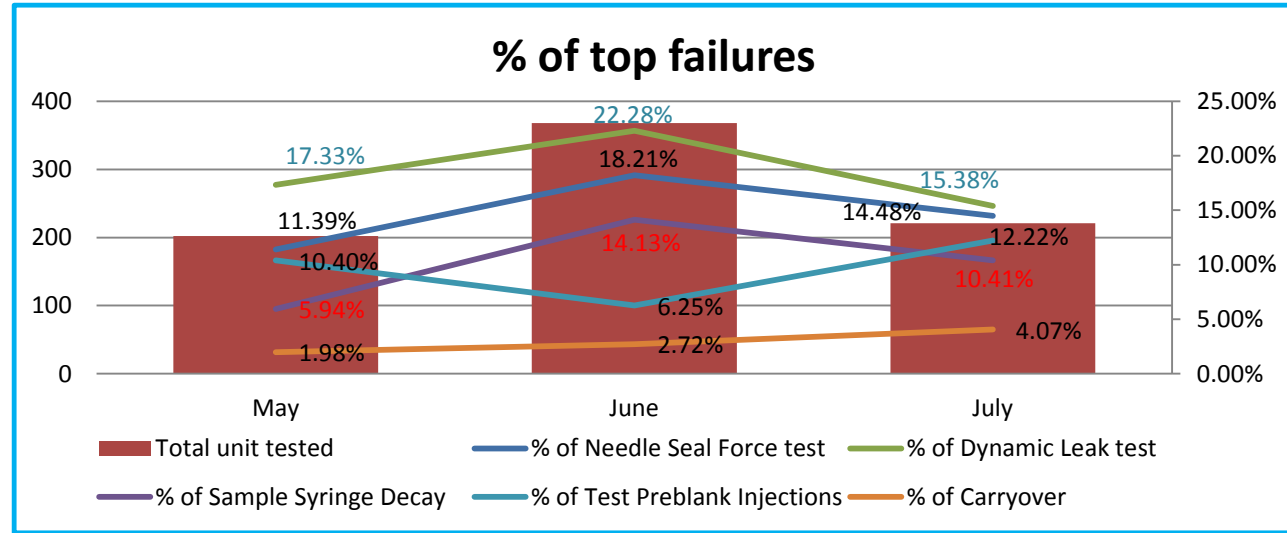
First Pass Yield (FPY) – First Pass Yield Discussion on FTN – 186015017, 186015046, 186015088, 186015085



Total FTN units tested – 221 units

Overall top 5 failures of FTN models are..

- Dynamic Leak test (x34)
- Needle Seal Force test (x32)
- Test Preblank Injections (x27)
- Sample Syringe Decay test (x23)



In July 2018, Failure down trends of

- Dynamic Leak Test
- Needle Seal Force Test
- Sample Syringe Decay are observed compared to June 2018.

In July 2018, Failure up trends of

- Test preblank injections
- Carryover are observed compared to June 2018.



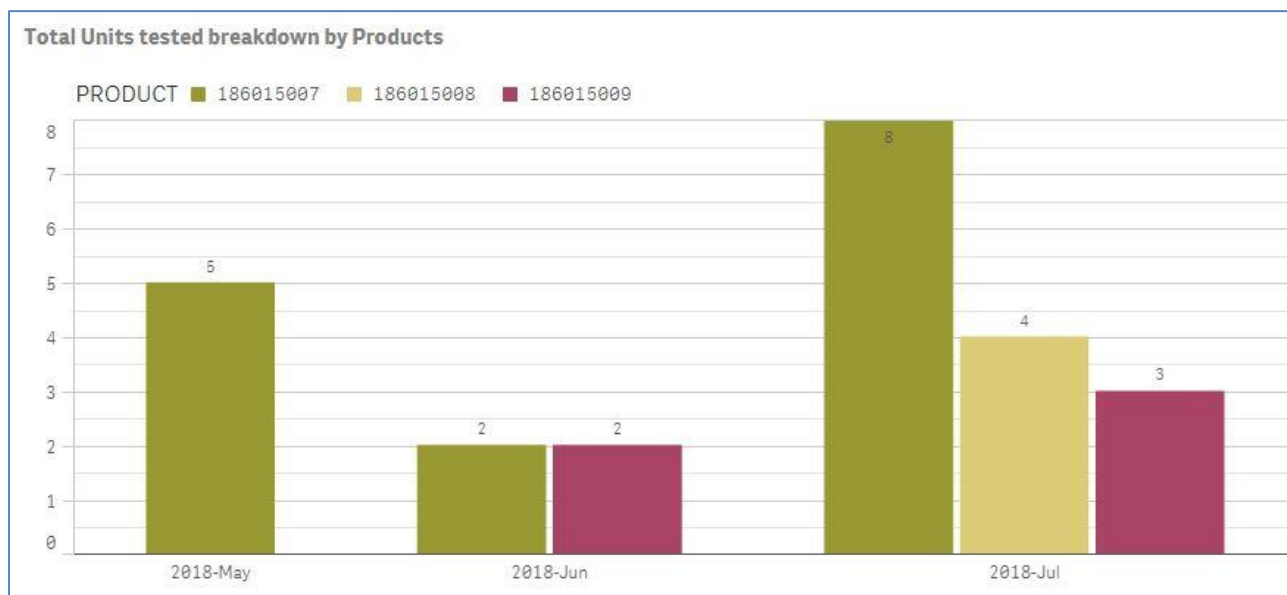
First Pass Yield Discussion on FTN

- 186015017, 186015046, 186015085 & 186015088

Investigation/ Possible Root Cause	Action Plan/Corrective Action/Improvement	Owner	Status
<u>Top Failures occurred are</u> 1. Dynamic Leak test (x34) 2. Needle Seal Force test (x32) 3. Test preblank injections (x27)	<u>1.Dynamic Leak Test (x34)</u> ▪ (x1) Needle leakage – material issue and rejected in Aug. ▪ (x2) Test sequence Error - no fault found. Retested. ▪ (x3) Test tubing Fitting – (x2) loose fitting and (x1) wear & tear ▪ (x5) Column Error - Failure related to column manager blockage ▪ (x11)Re-prime & Retested – No fault found. Retested. ▪ (x12) Pump error - error due to BSM unresponsive, leakage at pump seal. <u>2. Needle Seal Force test (x32)</u> ▪ (x1) Test sequence Error - No fault found. Retested. ▪ (x11) Re-installed and retested. ▪ (x20) Retested –Retested and passed. <u>3. Test preblank injections (x27)</u> ▪ (x1) Seat port tubing- replaced & verification in progress. ▪ (x1) communication test & (x1) pump error (BSM unresponsive) Retested. ▪ (x8) empower errors & (x8) re-prime/retest – no fault found & retest. ▪ (x8) column error – Column blockage. Primed and retested. <u>Improvement Plan</u> <u>Dynamic Leak test</u> - TE16 (x2) ,TE13-(x3) and TE15 (x5) pump error. TE13 has been changed BSM seal, vent valve and check valve. TE16 has been changed BSM seal. TE15 is being monitored to be changed BSM seal. <u>Needle seal force test</u> – studying on the causes of seal wash assembly re-installed helped to pass the failure. <u>Test preblank injections</u> - TE13-(x3) of column error. It has been changed column 4.	Khalip/Lwin HC Tan EiLwin Ruby Ei Lwin	Closed Ongoing Closed

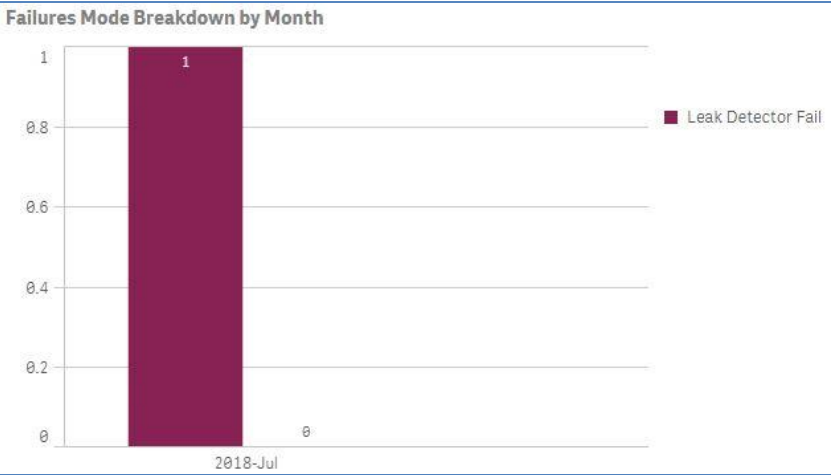
Data Analysis

First Pass Yield (FPY) – First Pass Yield Discussion on Acquity Column Manager – 186015007, 186015008, 186015009



First Pass Yield Discussion on Acquity Column Manager

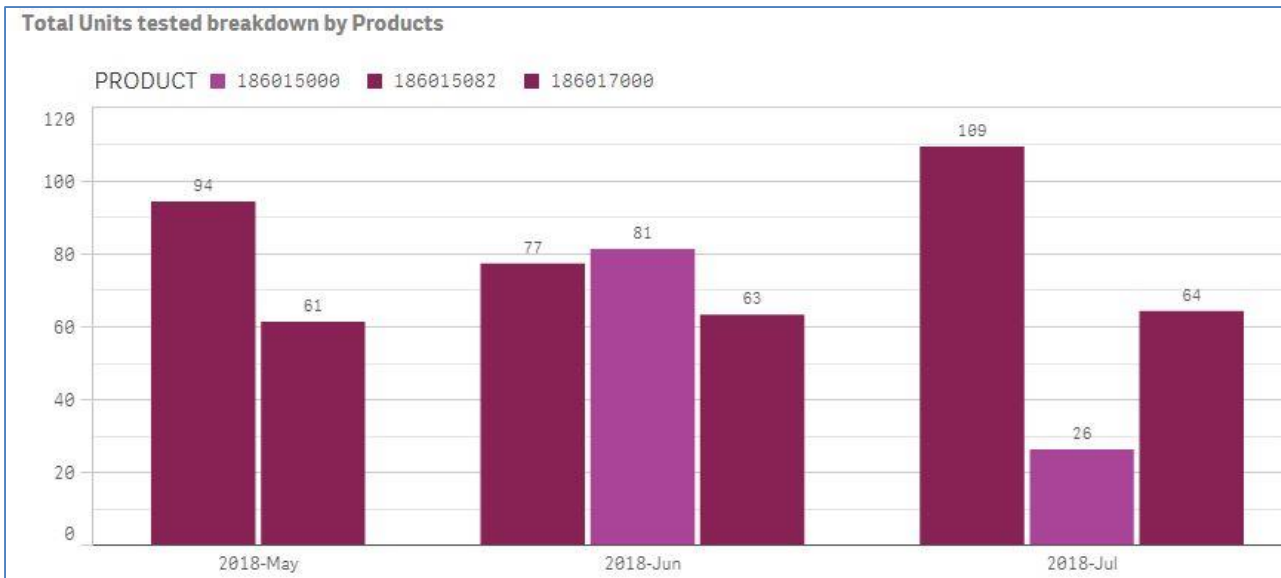
– 186015007, 186015008, 186015009



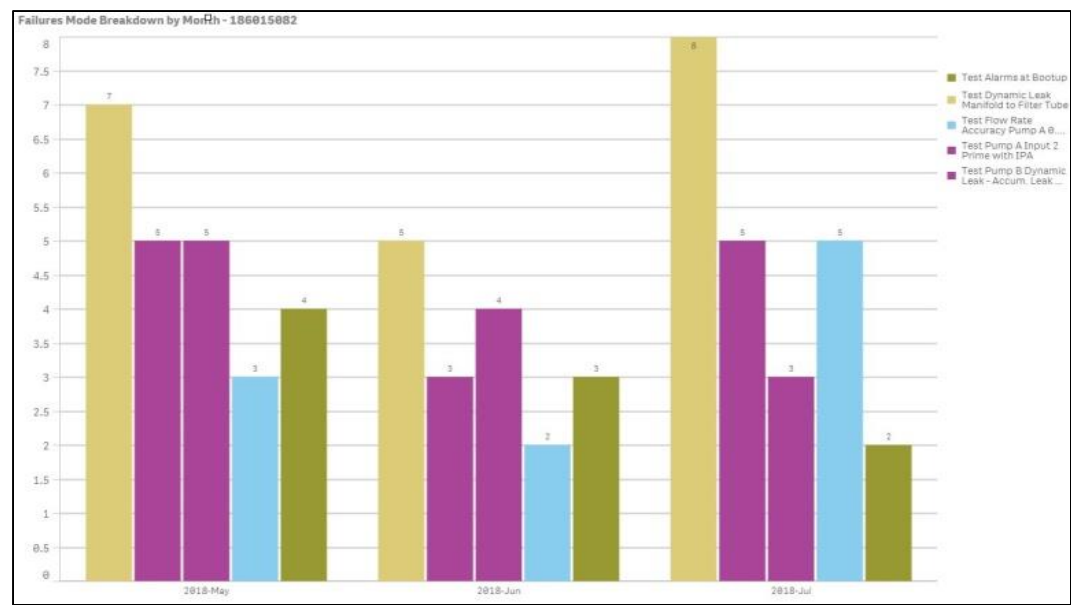
Investigation/Possible Root Cause	Action/Corrective Action/Improvement	Owner	Status
Production is seeing 75% yield on model 186015008 in Jul 2018 (Failure – 1Qty)	Troubleshooting Replaced PCB (W1210000389-R) Remark: No voltage on pin 2&3 of leak detector connector on PCBA if compared to good PCBA Supplier: CEI Board has been returned to CEI.	Chan	Closed

Data Analysis

First Pass Yield (FPY) – First Pass Yield Discussion on iBSM, iBSM Plus and QSM
– 186015000, 186015082, 186017000

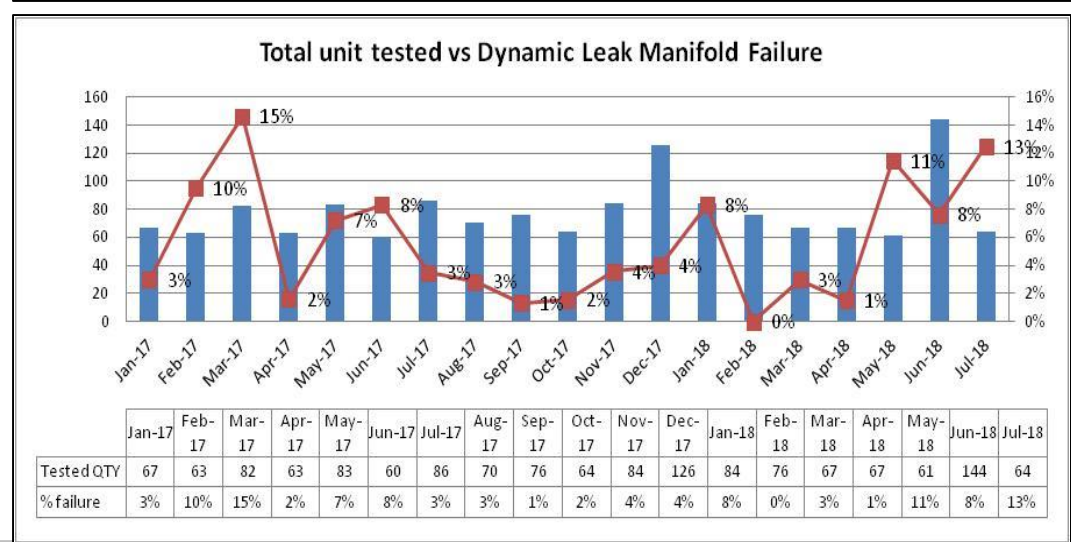


First Pass Yield Discussion on iBSM Plus– 186015082



Overall top 5 failures of i-BSM Plus

1. Dynamic Leak Manifold to Filter Tube - x8
2. Pump A Input 2 Prime with IPA –x5
3. Flow Rate 0.5ml/min – x5
4. Pump B Dynamic Leak Accum– x3
5. Test Alarms at Bootup – x2

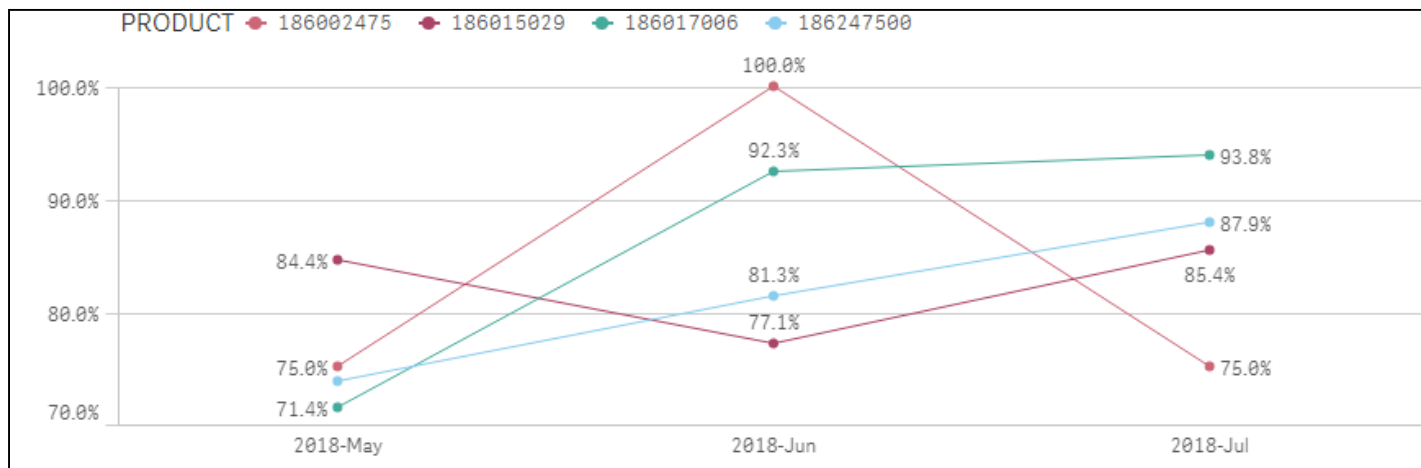




Investigation/Possible Root Cause	Action/Corrective Action/Improvement	Owner	Status
- Dynamic Leak Manifold to Filter Tube - x8 - Pump A Input 2 Prime with IPA –x5 - Flow Rate 0.5ml/min – x5 - Pump B Dynamic Leak Accum– x3 - Test Alarms at Bootup – x2	<u>Dynamic Leak Manifold to Filter Tube - x8</u> Retightened tubing connected to test tube –x7 Retest – X1 <u>Improvement Plan</u> ✓ Implemented test tube change frequency as monthly -26 Jul 18 - (No failure up to 10 Aug) - both 186015000 & 186015082 ✓ Swap test tube ends after half month - 10 Aug 18 <u>Pump A Input 2 Prime with IPA –x5</u> Reconnected pump solenoid cable & Retest – x1 Retightened In-Line Filter SS Frit - x3 Retest – x1 <u>Flow Rate 0.5ml/min – x5</u> Empty Beaker & zero scale – x2 Retest –x3 <u>Pump B Dynamic Leak Accum– x3</u> Retightened check valve – x2 Retest –x1 <u>Test Alarms at Bootup – x2</u> Reconnected cable vent valve –x2	Chan	Open Monitoring “Dynamic leak manifold to filter tube failure”

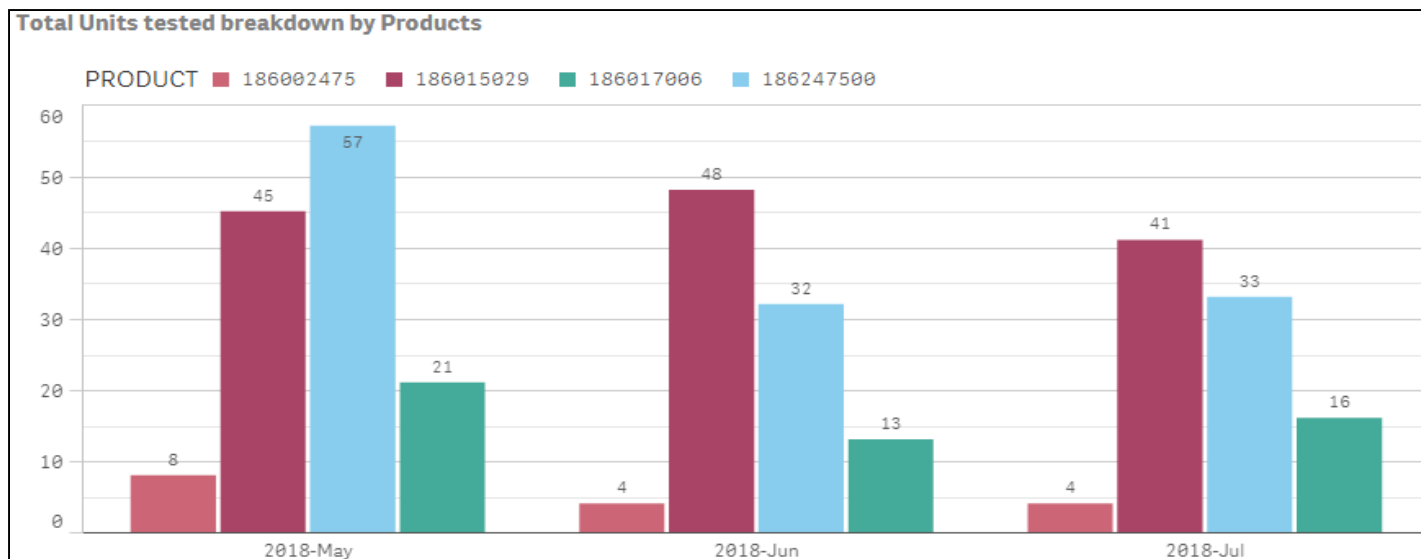
Data Analysis

First Pass Yield (FPY) – First Pass Yield Discussion on Detector
– 186015029, 186017006 and 186247500



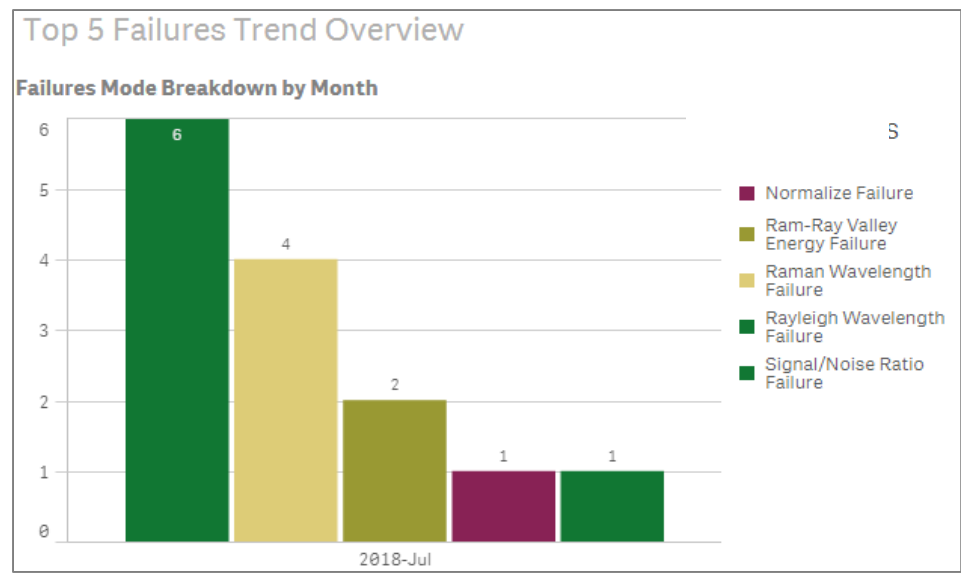
July - 2018

- 2475 – 75.0%
- 247500 – 87.9%
- 7006 – 93.8%
- 5029 – 85.4%



First Pass Yield Discussion on Detector

- 186015029, 186017006, 186247500, 186002475



186015029	18602475/186247500	186017006
1) Ram-Ray Valley Energy- x2 Swap PMT-x2 2) 2. Rayleigh Wavelength - x3 Swap Flow Cell -x3 *No rejects, failed PMTs & flow cells were used in another UUTs and passed	1. Raman Wavelength - x3 Swap Flow Cell -x2 2. Rayleigh Wavelength - x3 Swap Flow Cell -x2 *No rejects, failed flow cells were used in another UUT and passed	Raman Wavelength - x1 Swap Flow Cell -x1



Data Analysis

First Pass Yield (FPY) – First Pass Yield Discussion on Detector
– 186015029, 186017006, 186247500, 186002475

Investigation/ Possible Root Cause	Action Plan/Corrective Action/Improvement	Owner	Status
<u>Follow up on month of June' Top Failure:</u> Ram-Ray Valley Energy (5029)	Report Summary for Ram-Ray Valley Energy Failutre in 5029 model (Refer to the attached slides for details) * 2 failures on Month of Jul-18 No failure occured till 2nd weeks of Aug <u>Improvement/Action Plan</u> Continue to monitor this failure for the following months	MiMi	Open

Manufacturing Readiness

Tooling & Fixtures Updates



Dashboard Tracker 2018												
Criticality	JAN		FEB		MAR		APR		MAY		JUN	
	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down
1	4	0	4	0	4	0	4	0	4	0	4	0
2	25	0	25	0	25	2	25	2	25	0	25	0
3	18	0	18	0	18	0	18	1	18	1	18	0
Total:	47	0	47	0	47	2	47	3	47	1	47	0

Criticality	JUL		AUG		SEP		OCT		NOV		DEC	
	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down	Total Tester	Tester Down
1	4	0	4		4		4		4		4	
2	25	2	25		25		25		25		25	
3	18	1	18		18		18		18		18	
Total:	47	3	47		47		47		47		47	

Remarks:

1. FTN, TE83064-16, down on 02Jul18, 1 day.

Due to BSM high leakage, replace seal on both Primary and Accumulator pump B.

2. FTN, TE83064-13, down on 11Jul18, 1 day.

Due to Column 4 in Column Manager Blockage, replaced column

3: FTN, TE83064-13, down on 23Jul18 to 26Jul18, 4 days.

Due to severe leakage at BSM pump A accumulator and pump B primary. replace seal on both Primary and Accumulator pump

Criticality

1 = standard tester

2 = multiple tester but will affect output when down

3 = unique tester



Quality - Suppliers

Key Suppliers (Top 10) Monthly Overall Quality Performance – LAR (running 12 months)

No	Supplier	Commodity	LAR Target	2017					2018						
				Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
1	ATRONIX INCORPORATED	CABLE HARNES	99.8%	100%	100%	100%	100%	100%	100%	91.7%	100%	100%	100%	100%	100%
2	CMTI PTE LTD	CABLE HARNES	99.8%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
3	CEI CONTRACT MANUFACTURING LTD	PCBA	99.8%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
4	SL POWER ELECTRONICS CORP	POWER SUPPLY	99.8%	85.7%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
5	WATERS TECHNOLOGIES CORPORATION	METAL	99.8%	100%	100%	100%	98.9%	100%	100%	100%	100%	100%	100%	100%	100%
6	SHENZHEN BAITENG TECHNOLOGY	METAL	99.8%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
7	TREND SINGAPORE WEST PTE LTD	METAL	99.8%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
8	METAL COMPONENT ENGINEERING LIMITED	METAL	99.8%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
9	MRPC/JPI	PLASTIC	99.8%	100%	96.3%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
10	FU YU CORPORATION LIMITED	PLASTIC	99.8%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Remarks: All Supplier meet the LAR for the month of July 2018.



Not meeting target



Quality - Suppliers

Key Suppliers (Top 11) Monthly Overall Quality Performance – LRR(Line Reject Rate) (running 12 months)

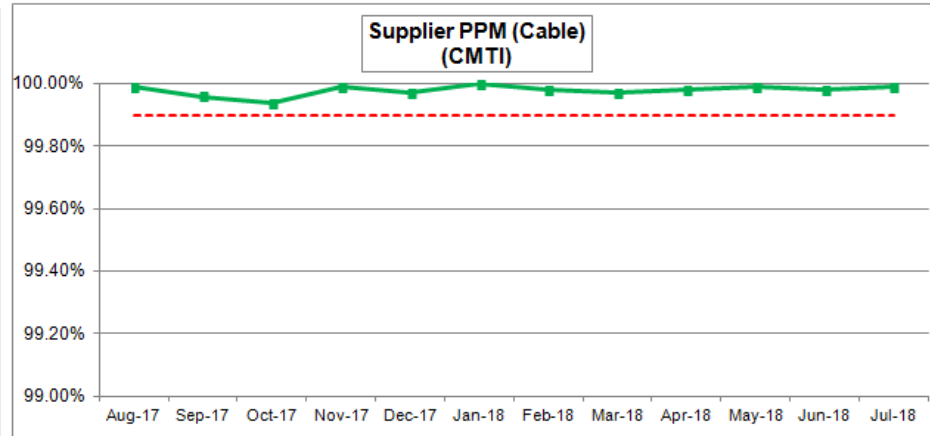
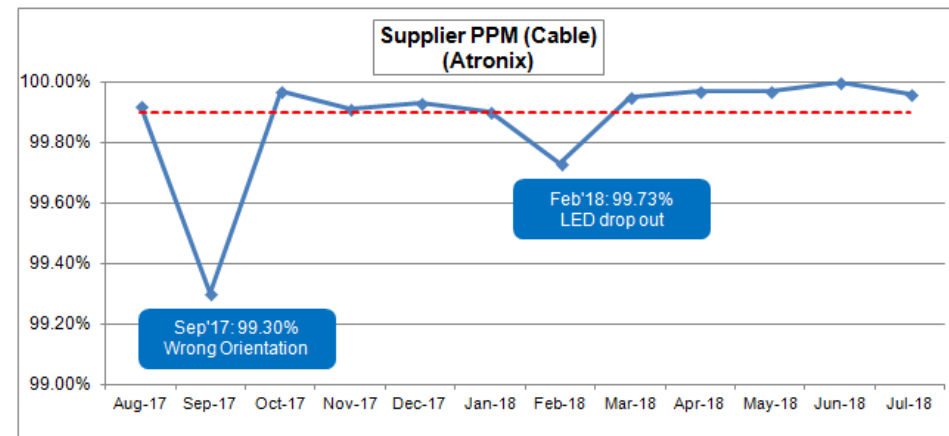
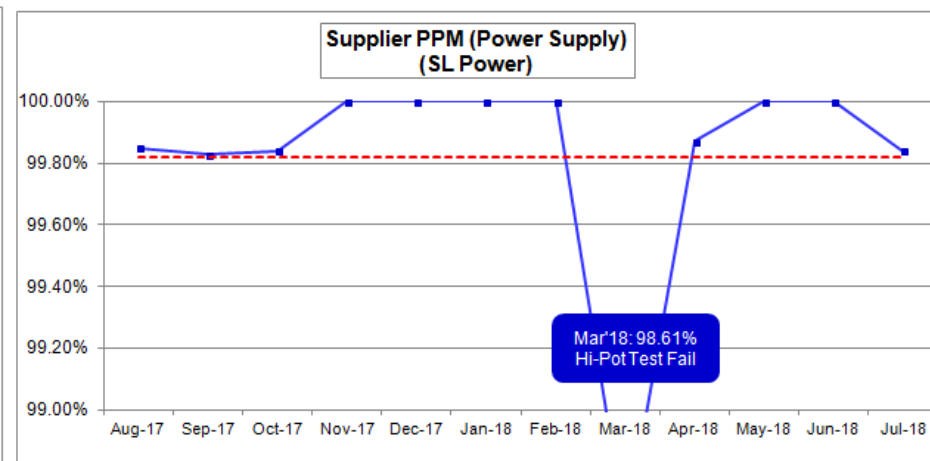
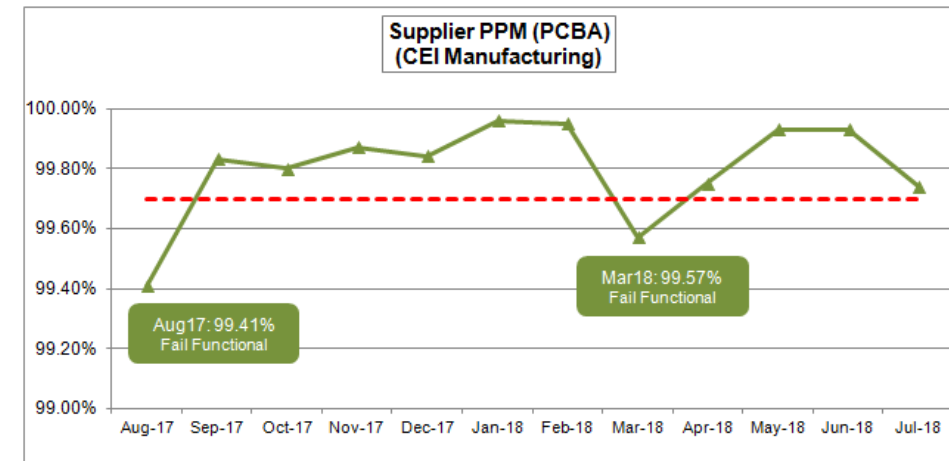
				Year 2017					Year 2018						
S/N	Supplier	Commodity	Target	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
1	ATRONIX INCORPORATED	CABLE HARNES	99.90%	99.92%	99.30%	99.97%	99.91%	99.93%	99.90%	99.73%	99.95%	99.97%	99.97%	100.00%	99.96%
2	CMTI PTE LTD	CABLE HARNES	99.90%	99.99%	99.96%	99.94%	99.99%	99.97%	100.00%	99.98%	99.97%	99.98%	99.99%	99.98%	99.99%
3	CEI CONTRACT MANUFACTURING LTD	PCBA	99.70%	99.41%	99.83%	99.80%	99.87%	99.84%	99.96%	99.95%	99.57%	99.75%	99.93%	99.93%	99.74%
4	SL POWER ELECTRONICS CORP	POWER SUPPLY	99.80%	99.85%	99.83%	99.84%	100.00%	100.00%	100.00%	100.00%	98.61%	99.87%	100.00%	100.0%	99.84%
5	WATERS TECHNOLOGIES CORP	METAL	99.82%	99.84%	99.84%	99.83%	99.47%	99.68%	99.87%	99.83%	99.91%	99.93%	99.80%	99.93%	99.85%
6	SHENZHEN BAITENG TECHNOLOGY	METAL	99.82%	99.90%	99.85%	99.89%	99.90%	99.90%	99.91%	99.98%	99.97%	99.98%	99.91%	99.93%	99.92%
7	TREND SINGAPORE WEST PTE LTD	METAL	99.82%	99.85%	99.84%	99.87%	99.89%	99.87%	99.93%	99.90%	99.87%	99.88%	99.89%	99.92%	99.85%
8	METAL COMPONENT ENGINEERING LIMITED	METAL	99.82%	99.87%	99.86%	99.86%	97.50%	99.89%	99.89%	99.93%	99.96%	99.96%	99.93%	99.91%	99.93%
9	MRPC Northeast Division	PLASTIC	99.82%	99.88%	99.99%	99.99%	99.98%	99.93%	99.98%	99.95%	99.97%	99.97%	99.96%	99.99%	99.96%
10	FU YU CORPORATION LIMITED	PLASTIC	99.82%	99.96%	99.98%	99.99%	98.63%	99.94%	99.97%	99.94%	99.91%	99.96%	99.92%	99.65%	99.88%
11	GES SINGAPORE	PCBA	99.70%	99.81%	100.00%	99.93%	100.0%	100.0%	100.0%	99.93%	100.0%	99.94%	100.0%	100.0%	100.0%

Not meeting target

Set Target Acceptance Rate for Yr 2018

Quality - Suppliers

Key Suppliers (Top 10) Monthly Overall Quality Performance – LRR(Line Reject Rate)
(running 12 months)

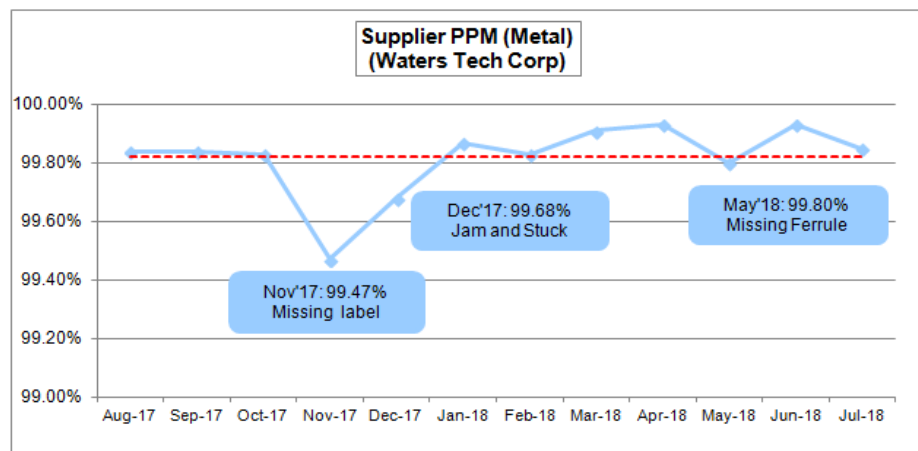
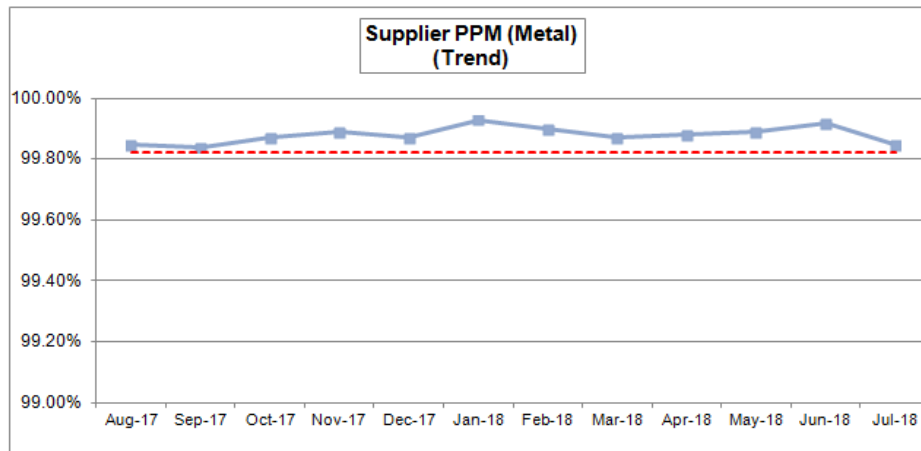
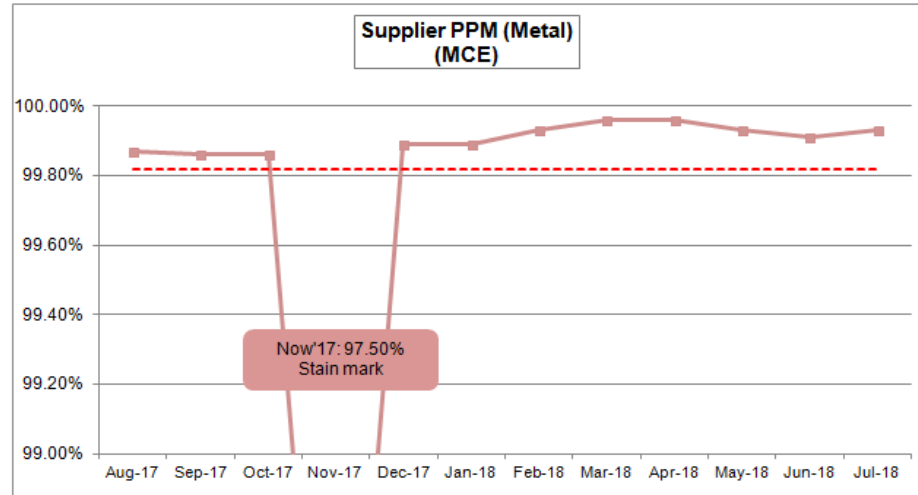
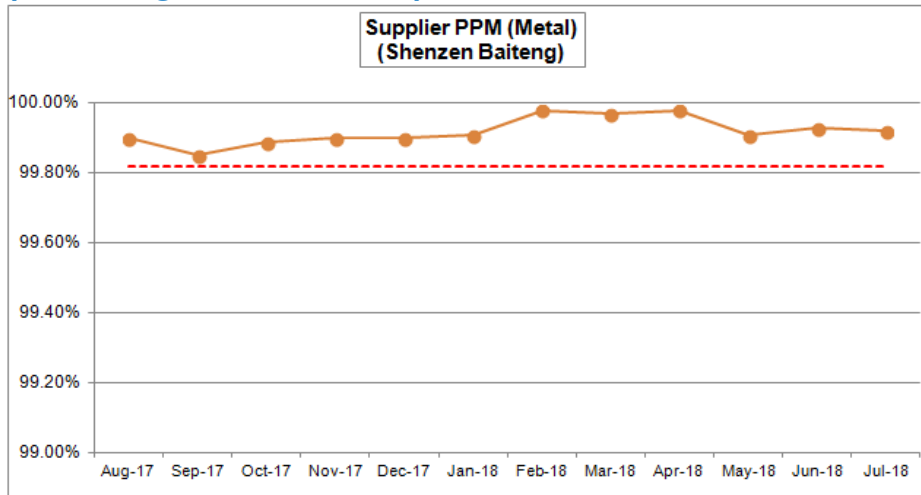


Remarks:

Above supplier (CEI, SL Power, Atronix and CMTI) meet the target acceptance rate in month of Jul 2018.

Quality - Suppliers

Key Suppliers (Top 10) Monthly Overall Quality Performance – LRR(Line Reject Rate)
(running 12 months)

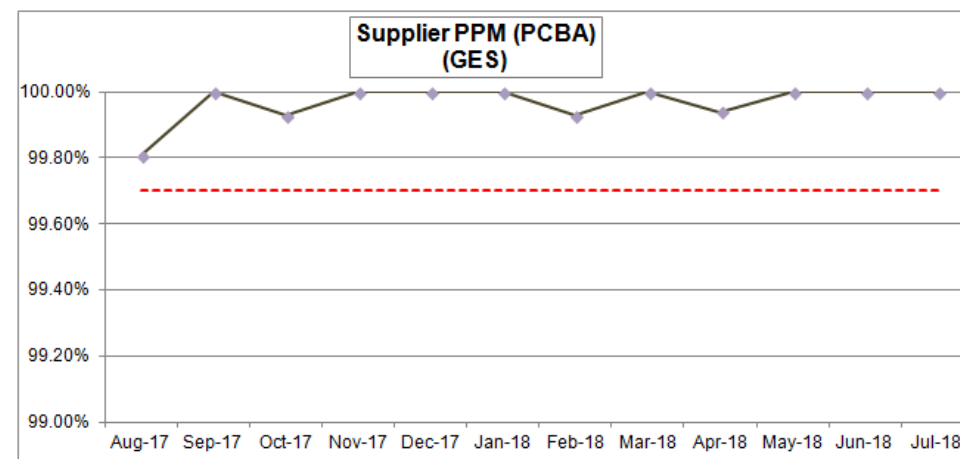
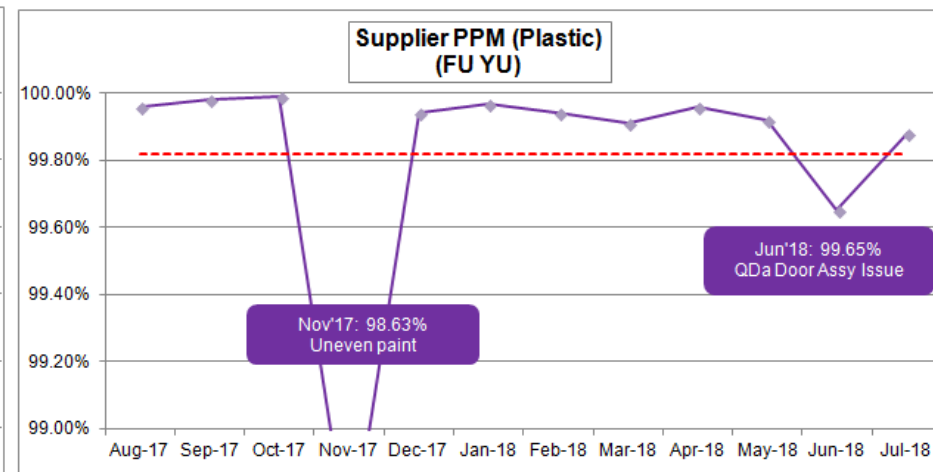
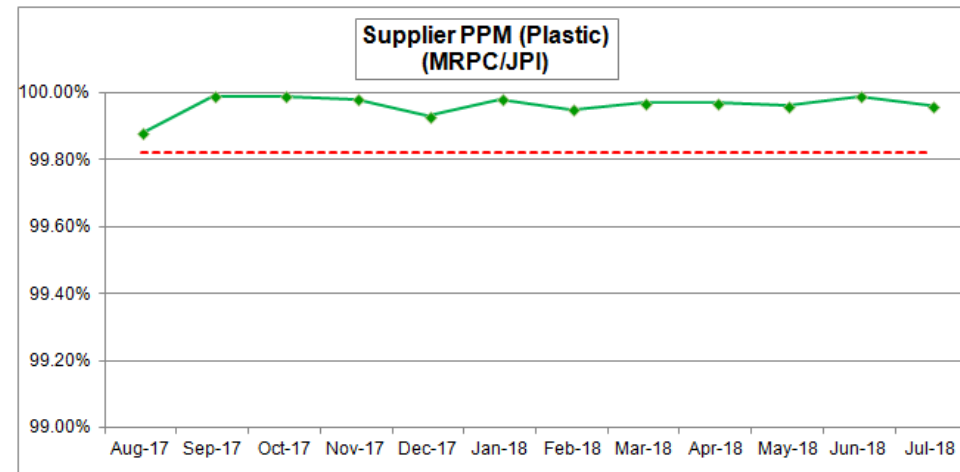


Remarks:

Above suppliers (Shenzhen Baiteng, MCE ,Trend and Waters Tech) meet the target acceptance rate in month of Jul 2018.

Quality - Suppliers

Key Suppliers (Top 10) Monthly Overall Quality Performance – LRR(Line Reject Rate)
(running 12 months)



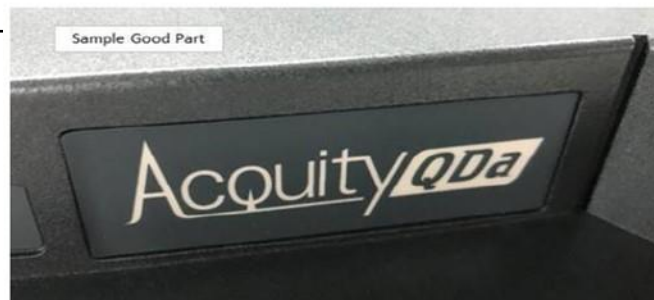
Remarks:

Above suppliers (MRPC, Fu Yu and GES PCBA) meet the target acceptance rate in month of Jul 2018.

Data Analysis

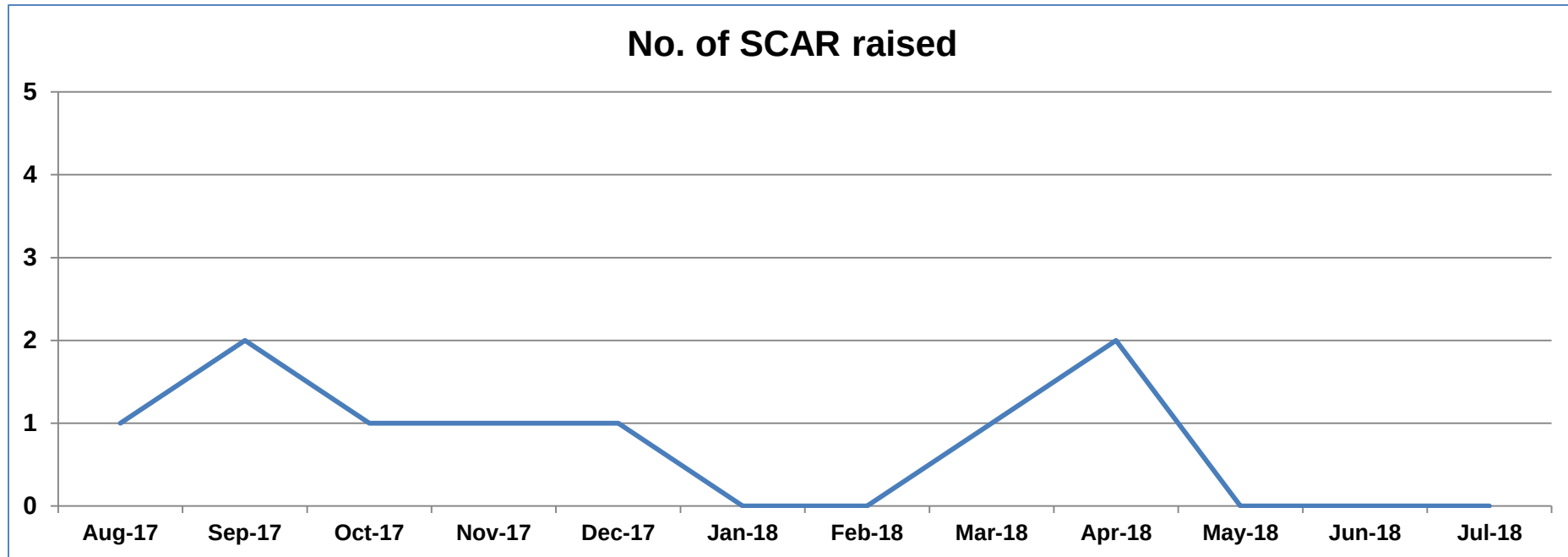
Key Suppliers Performance –FuYu

Supplier	Failure Mode / Issue	Action Plan	Person-In-Charge	Target Date	Status
FuYu	<u>Jun'18 Issue:</u> Part No: W1289008550-R Part Description: COVERS ASSEMBLY (QDa) Defect: Fitting Problem (Badge cannot slot in) Reject: 28pcs	<u>Actions:</u> 1. Received FA result from supplier last 15 May and informed the slot is within spec. Closed 2. GES measured the mating part (badge) also within spec, since this is also used for other model (FTN). Closed 3. FuYu sorted on hand Qty (Store) last 01Jun with all 28pcs suspected to be reject. Closed 4. FuYu proposed a method to assemble the badge using a tool to press the badge in and was evaluated by GES/WPPL. Closed 5. Deviation Request was rejected as the ASP states that to fix the badge into the door. As the tool can also be way to fix it. Closed 6. Report provided by supplier FuYu 27Jul and continue to follow up. Open 7. Wimslow mentioned a fixture that can help FuYu if the badge can fit properly. TBD	Martin/Suzhen	TBD	Open



Quality - Suppliers

Key Suppliers (Top 10) Monthly Overall Quality Performance – SCAR
(running 12 months)



	2017					2018						
Items	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
No. of SCAR raised	1	2	1	1	1	0	0	1	2	0	0	0
Status	Closed	Closed	Closed	Closed	Closed	NA	NA	Closed	Closed	NA	NA	NA

Remarks:

No SCAR was issued Jul 2018.

Quality - Suppliers

Audit Schedule



Supplier Audit 2018											
Jan-18		Feb-18		Mar-18		Apr-18		May-18		Jun-18	
Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual

Jul-18		Aug-18		Sep-18		Oct-18		Nov-18		Dec-18	
Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual	Plan	Actual
						FUYU ShenZhen Bai Teng				Trend	

Remarks:

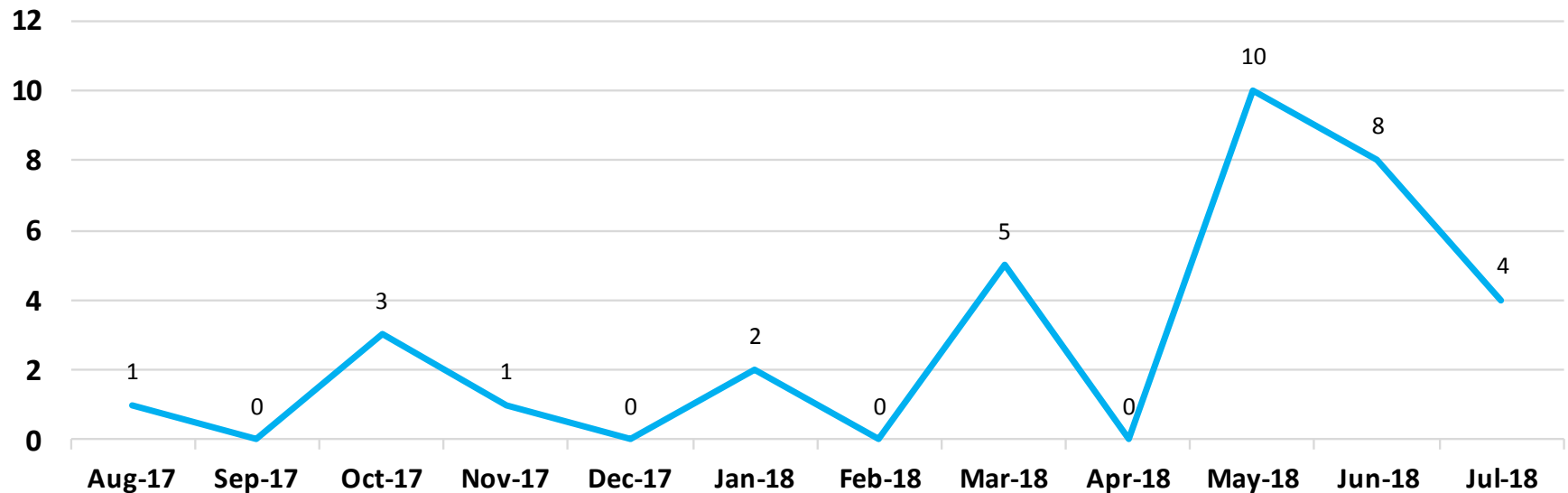
There are 3 vendors (FuYu, Trend and ShenZhen Bai Teng) recommend for on site audit for year 2018.

Quality Issues

Non Conformance Report (NCR) (running 12 months)



Non Conformance Report



	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
NCR	1	0	3	1	0	2	0	5	0	10	8	4
Status	Closed	NA	Closed	Closed	NA	Closed	NA	Closed	Closed	Closed	Open	Open

Remarks:

June-18

- NCMR rejected that failed in First Pass Yield – Open

July-18

- NCMR rejected that failed in First Pass Yield – Open

Quality Issues (Process)

Non Conformance Report (NCR) – NCR Update



Jul'18 - FPY (186015082) Test stop flow Input Open – Fail (Supplier: CEI Pte LTD)

Failure Mode / Issue	Action Plan	Owner	Target Date	Status
Part No: W1210000422/F-R Part Description: Personality Board Reject Rate: 1/ 200 = 0.50% SN: 020618036C NCMR No. 50000135759 RMA No. 26269	1. Checked cable connection - Okay 2. Replace personality board - Pass 3. Retest failed board to another unit - Fail (same failure) 4. Board return to CEI for verification <i>** part returned to Supplier, Monitor the reject for any repeated case for next month</i>	Chan Dette	31-Aug-18	Open

Jul'18 - FPY (18605082) Test Flow rate accuracy Pump A 2ml/min FAIL (Supplier: DJ Instrument)

Failure Mode / Issue	Action Plan	Owner	Target Date	Status
Part No: W1279001951/D-R Part Description: XDUCER PRESSURE FLEX CABLE 20K PSI Reject Rate: 1/ 292 = 0.34% SN: 278480 NCMR No. 50000136083	1. Test Flow rate accuracy Pump A 2ml/min FAIL 2. Check tube connection - OK 3. Changed transducer - PASS 4. Retest transducer to another unit – FAIL <i>** part returned to Supplier, Monitor the reject for any repeated case for next month</i>	Chan Min	31-Aug-18	Open



PREVIOUS MONTHS UPDATE

Quality Issues (Process)

Non Conformance Report (NCR) – NCR Update



Jun'18 - FPY (186015029) Serial Number cannot Scan (Supplier: CEI Pte LTD)

Failure Mode / Issue	Action Plan	Owner	Target Date	Status
Part No: W1210000691-R Part Description: ASSY PCB 3V CCPU FLR Reject Rate: 1/ 80 = 1.25% SN: 030218117C NCMR No. 50000134414 RMA No. 26138	1. Re-download firmware, still failed to scan serial no 2. Replace Serial cable, still failed 3. Replaced CPU , passed 4. Board to return to Supplier <i>** part returned to Supplier, Monitor the reject for any repeated case for next month</i>	MiMi Dette	Aug-18	Closed (No reject for as of 15 Aug'18)

Jun'18 - FPY (186017006) LCD No Display (Supplier: Hantronix)

Failure Mode / Issue	Action Plan	Owner	Target Date	Status
Part No: W1279002640-R Part Description: ASSY DISPLAY LCD WHITE LED BACKLIGHT Reject Rate: 1/ 38 = 2.63% SN: 7C209401D119 NCMR No. 50000134410	1. Verify the unit confirm no display 2. Check for any loose connection - OK NO problem 3. Replaced with New LCD - Unit is PASS 4. Re-verify the defective LCD into another unit – FAIL 5. LCD return to Supplier <i>** part returned to Supplier, Monitor the reject for any repeated case for next month</i>	MiMi Min	Aug-18	Closed (No reject for as of 15 Aug'18)

Jun'18 - FPY (186015082) Test degasser pressure fail (Supplier: IDEX Rheodyne)

Failure Mode / Issue	Action Plan	Owner	Target Date	Status
Part No: W1725000459/F-R Part Description: ASSY PCB DEGASSER QSPI MULTI-PERS Reject Rate: 1/ 14 = 7.14% SN: 140021927 NMCR No. 50000134985	Test Degasser Pressure Fail Verification: Check cable connection - OK Changed degasser PCBA - Pass	Chan Dette	Aug-18	Closed (No reject for as of 15 Aug'18)

Quality Issues (Process)

Non Conformance Report (NCR) – NCR Update

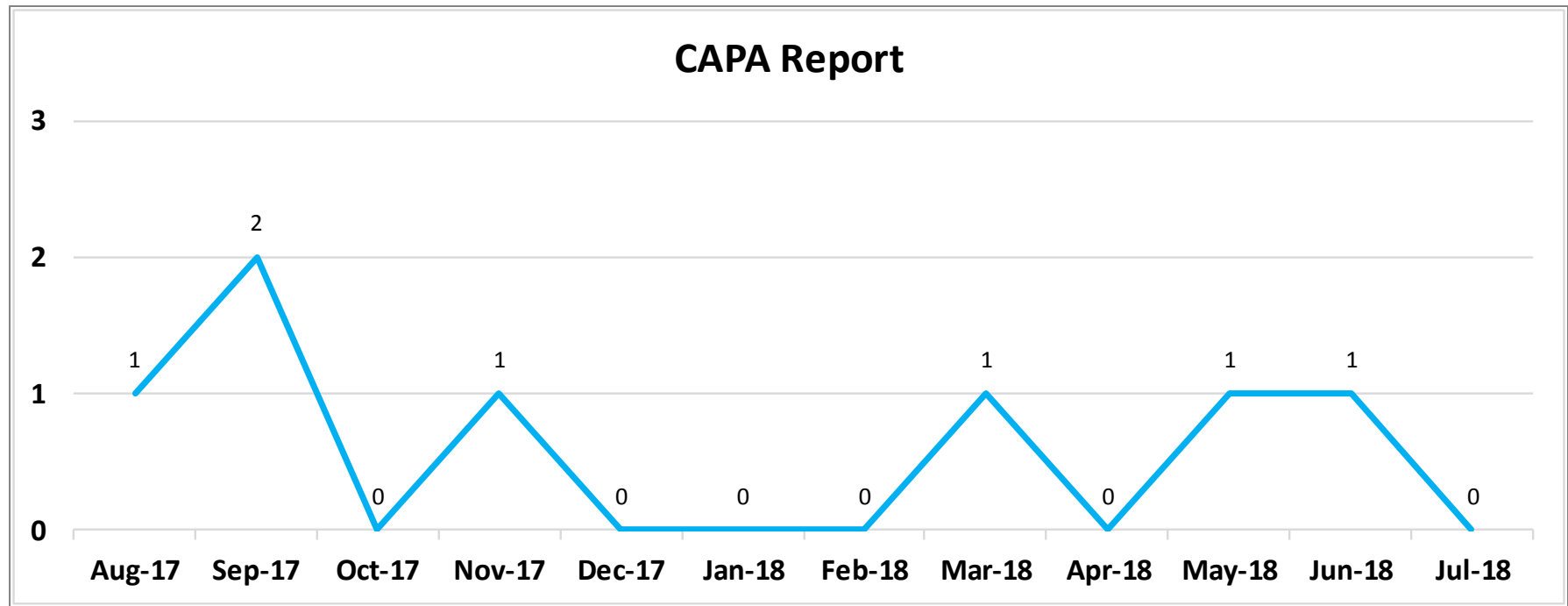


Jun'18 - FPY (186015082) Test dynamic pump B Fail – Primary (Supplier: PERFORMANCE SEALING INC.)

Failure Mode / Issue	Action Plan	Owner	Target Date	Status
Part No: W1425001037-R Part Description: HP SEAL DUAL SPRING * Pump A Dynamic Leak x1 ** Test dynamic pump B Fail x2 Reject Rate: 3/ 564 = 0.35% NCMR No. 50000134967	<u>Test dynamic pump B Fail – Primary</u> 1.Check for loose cables and tubing - All Okay 2.Re-tighten Inline Filter SS Frit – Retest Failed 3.Re-tighten Check Valve- Retest Failed 4. Replace Check Valve-Failed 5. Replace new seal-Passed Retest the HP seal to another unit - Fail <u>Dynamic Leak Pump Accumulator Leak Rate Failed</u> 1.Check for loose cables and tubing - All Okay 2.Re-tighten Inline Filter SS Frit – Retest Failed 3.Re-tighten Check Valve- Retest Failed 4. Replace Check Valve-Failed 5. Replace new seal-Passed Retest the HP seal to another unit - Fail <i>** part returned to Supplier, Monitor the reject for any repeated case for next month</i>	MiMi Sunny	Aug-18	Closed (No reject for as of 15 Aug'18)

Quality Issues

Corrective And Preventive Actions (CAPA) (running 12 months)



	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
CAPA	1	2	0	1	0	0	0	1	0	1	1	0
Status	Closed	Closed	NA	Closed	NA	NA	NA	Closed	NA	Closed	Open	NA

Remarks:

1 CAPA open for month of June 2018

No CAPA received for month of July 2018

Quality Issues

CAPA Update:

June'18: FRU Serial Number with extra "0":

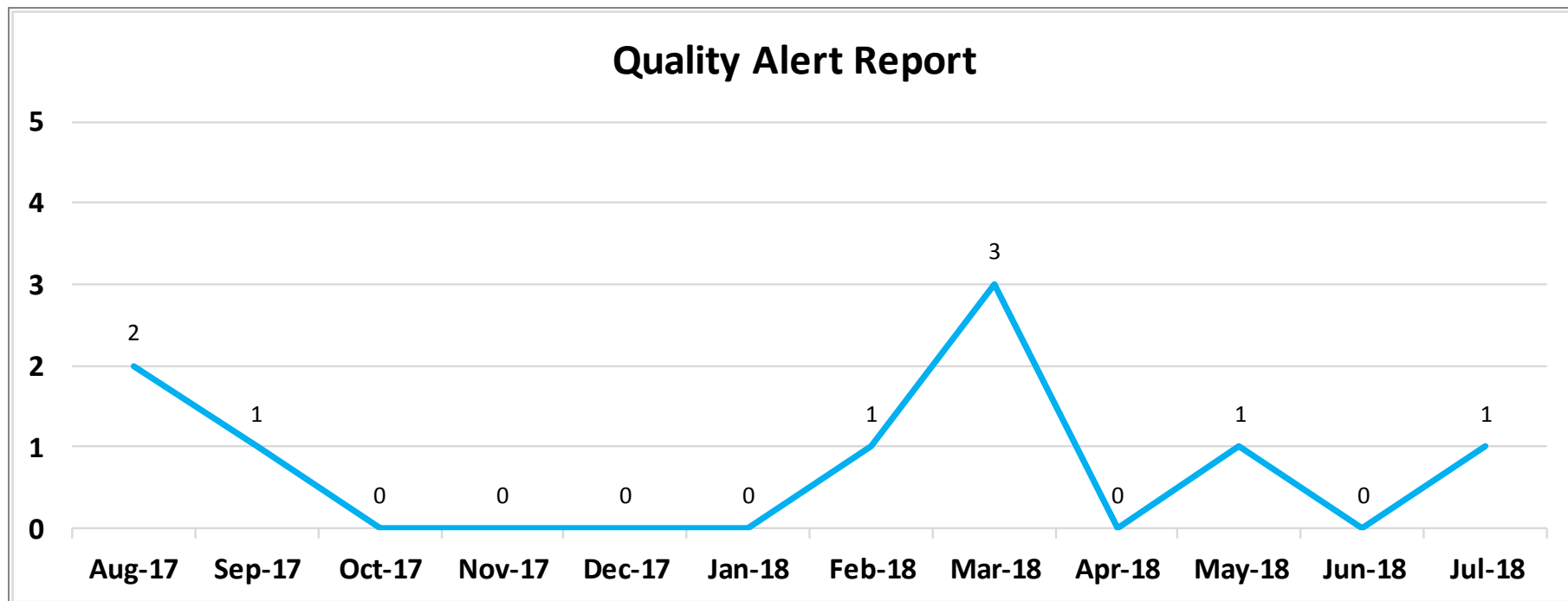
Reject/ Feedback/Complaint	Root Cause	Action Plan : Analysis/Containment /Corrective/Preventive	Owner	Target Date for Closure	Status
WPPL feedback that affected FRU Part Number label found to have extra "0" and offset printing. Issued: CAPA 18-010	Due to manual key in in the Production personnel forgot to remove the extra "0" during label printing.	Action Implemented/Plans: 1. Venture when to Schenker Warehouse to rework the remaining FRU that was affected. Closed 2. Revision of Work Instruction to indicate the method of printing the label. Closed 3. List all the spares/FRU list that used PN W1615004290B01-R and W1024343/7-R. Closed 4. Verify the purpose of the labels for all the FRU's and Spares for built, packing and shipment. Closed 5. Request to standardized the label format and label required per FRU/Spares. Open Status: Summary proposal has been submitted to Waters for review and approval. – July 2018	Dette	Q3'18	Open



Waters PO, P/N and Total
Qty is manually key-in by
Production

Quality Issues

Quality Alert Trending (running 12 months)



	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
Quality Alert	2	1	0	0	0	0	1	3	0	1	0	1
Status	Closed	Closed	NA	NA	NA	NA	Closed	Closed	NA	Closed	NA	Closed

Remarks:

Jul'18 – QA Alert for Clip and Gasket Mis-alignment

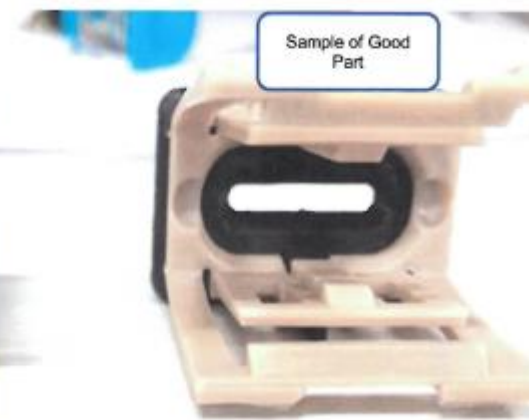
Quality Issues

Quality Alert Update:



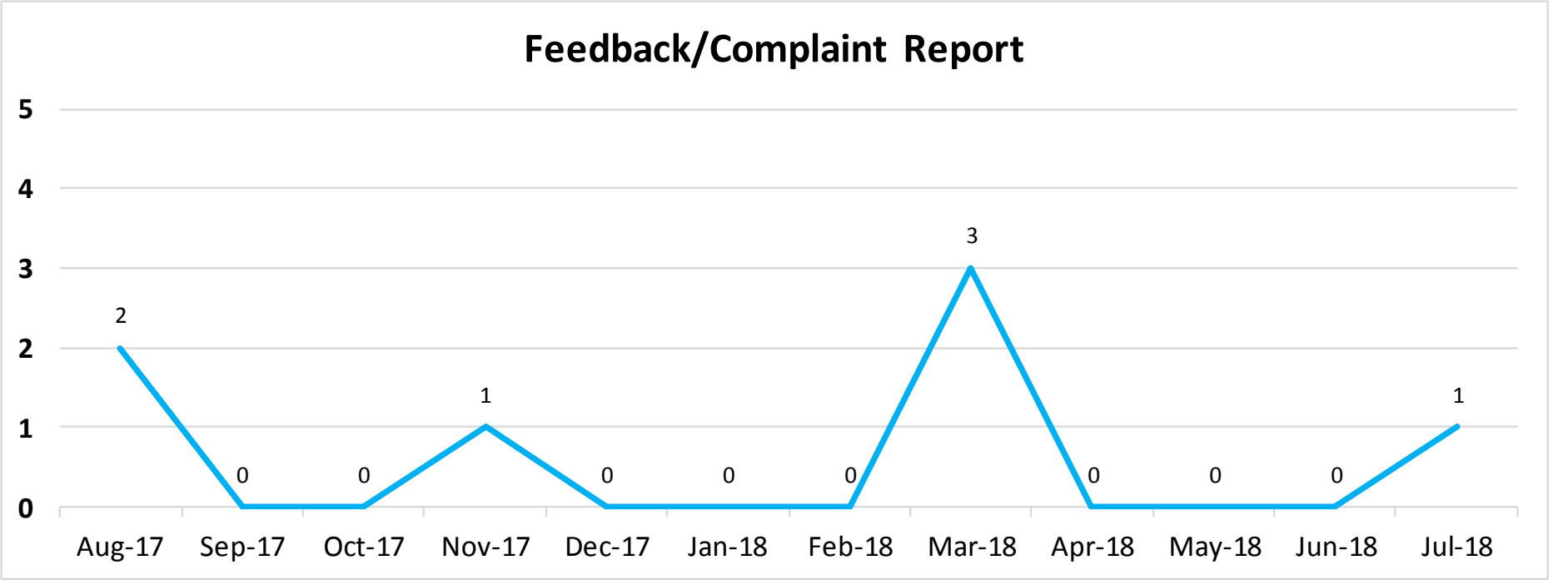
July'18: Quality Alert – PN 289010458 (Trough Clip) with mis-aligned and excess material (Gasket)

Reject/ Feedback/Complaint	Root Cause	Action Plan : Analysis/Containment /Corrective/Preventive	Owner	Target Date for Closure	Status
Due to recent cases of instruments failing Functional Failures (Pre-Heater Test).	Undetermined. Continue follow up with supplier	1. Issued Quality Alert to Production, Incoming and Outgoing Quality Inspectors / Leaders for awareness of the issue. Production to check for any excess burr/material from the gasket.	QME team	31-Jul-18	Closed



Quality Issues

Feedback/Complaint Trending (running 12 months)



	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
Feedback	2	0	0	1	0	0	0	3	0	0	0	1
Status	Closed	NA	NA	Closed	NA	NA	NA	Open	NA	NA	NA	Closed

Remarks:

Mar-18: 2 Open Items - Refer to slide 4 (Action Items from Previous Meeting)
July-18: 1 Feedback received (Refer to next slide)

July'18: Over tightening of head bolt issue (iBSM 186015000)

Reject/ Feedback/Complaint	Root Cause	Action Plan : Analysis/Containment /Corrective/Preventive	Owner	Target Date for Closure	Status
WPPL feedback that field feedback from Bill (Milford) regarding overtightening of head bolt issue Affected Instrument No.: 186015000 Converted SN: M17BUR346M	Not Applicable Verification Base from the serial number provided M17BUR346M, the suffix "M" indication the unit was built in US. If the unit will base from the serial number before conversion M17BUR346, the unit is not built in Venture, as the last unit built for 2017 i-Class BSM is M17BUR133G – Completed	Analysis: - What is the torque settings and requirements for assembly of accumulator Pump A? There have 2 assembly process on the Pump Head required torque settings. - Secure head assembly to mechanics assembly with two screws. (Torque setting 33 in/lbs) - Torque both head screws sequentially and incrementally to 60 in/lbs, then to 80 in/lbs and then to 98 in/lbs. (Torque settings 60 in/lbs, 80 in/lbs, 98 in/lbs) - What is the torque settings and requirements for assembly of accumulator Pump A on the instruments? from ASP 279002450, Slide the Actuators to the chassis and tighten(16x) screws on the instruments. (Torque setting 7 in/lbs) This feedback will be closed and no further action needed from Venture.	Dette	Aug'18	Closed

Any Other Business

Temporary Manufacturing Deviation (TMD)



TMD Update: 2 TMD is still open for Waters LC

TMD Tracker 2017-2018	
No. of TMD Closed	No. of TMD Open
25	2

TMD Number	TMD Date Received	Originator	Part Number	Expiration Date	Description	Start Serial No	Remarks
10515 v00	28-Jun-18	Randy Ryder	279000533 (THERMOELEC TRIC HEATER/COOL ER)	31-Dec-18	This deviation would allow use of the nonconforming material associated with Part # 279000533 revision G for production builds with dimensional defects for specification 3.660" +/- 0.005" (Zone D8) and specification 5.000" +/- 0.005" (Zone D6) - Parts did not measure within tolerance.	186001791 - 186015011 -	To monitor any issue (Fitting Problem) found on the Production line and include the TMD inside the DHR if found related to the issue.
TMD Number	TMD Date Received	Originator	Part Number	Expiration Date	Description	Start Serial No	Remarks
10508	04-Jun-18	Joe Gately	289008457 Degasser, Single, SST Stented	30-Sep-18	The drawings for the following list of materials contains a requirement that the packaging of the part to contain verbiage "WATERS CRITICAL CLEAN per 735001035" be on their label to assist in identification' per design spec 735001035 Section 7.2. Currently these parts do not comply to this labelling requirement. This TMD will allow the receipt of these parts until such time as the labelling can be added to the packaging. This TMD supersedes TMD010043 V02.	186017000 A16VQS001G	This TMD will be implemented by the incoming inspection and procurement teams and applies to Milford and Venture/GES. Waters purchasing and Supplier Quality will need to work with the above suppliers to implement the specified labelling "WATERS CRITICAL CLEAN per 735001035".



End of Report