



Monthly Technical Review (Dec 2018 Data)

Flex CFT

23 Jan 2019

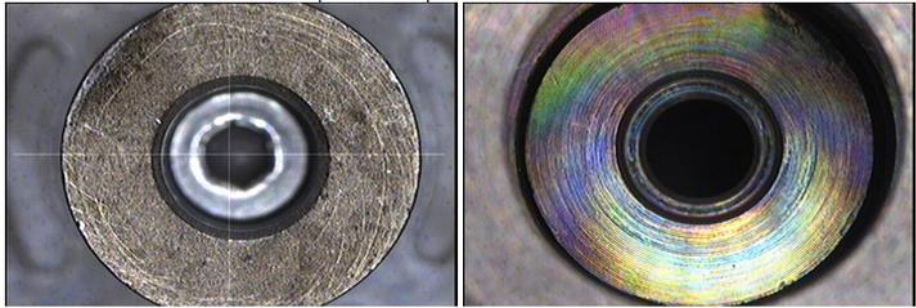
Agenda

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)
 - Improvement actions & effectiveness (if any)
3. Manufacturing readiness
 - Training review and competencies updates (na for this session)
 - Manufacturing Engineering Issues / Updates
 - Test Engineering Issues / Updates
 - TMD Updates
4. Quality (trending, analysis of issues (repeated case), updates / actions taken)
 - Suppliers
 - LAR
 - SCAR
 - Audit (schedules, audit results, findings and closure etc)
 - In Process
 - NCR
 - CAPA
 - Quality alerts
 - Customers & field complaints
 - QMS updates (na for this session)
5. Others
 - AOB

Review Of Last MTR Minutes

Description	Responsible	Due Date
<u>1) Quality Plan update</u> • 11Nov: Quality Plan to include the Arc Detectors. • 21Dec: update is in progress by WPPL. • 21Dec: Flex would like to propose to exclude “ISO 9001” from the Quality Plan. Flex QMS to send explanation why Flex proposes so. • 17 Feb: Flex to review Waters draft and get back to Waters. • 15 Jun: draft was sent back to WPPL • 21 Jul: WPPL and Flex will discuss the Draft Quality Plan comments on 27th Jul. • 15 Sep: Flex sent proposed draft Quality Plan on 10 Aug 2017 . Pend WPPL review. • 18 Dec: Flex reviewing the updated draft Quality Plan received on 14 Dec 2017. • 20 Mar: Quality Plan pending update on DHR content requirement and adding new model (QSM Plus) • 21 Jan: Quality Plan – Final stage of review is completed. Flex is to response WPPL.	Flex	TBA

Review Of Last MTR Minutes

Description	Responsible	Due Date
2) GPV (WAT270524) 15 Sep: after using the corrected lot, 1 failed out of more than 500u tested. 20 Sep: Parker's FA report- no indication of metallic fragments from the screw thread cutting process in the armature was found. (Refer to below photo cut from Prelim FA). The part will be returned to Flex for control build.  21 Nov: pend Parke to return GPV after FA to Flex. 18 Dec: 3 x RMA, Pend update from Parker 15 Jan: Request Flex stop checking with Parker until further notice as Parker is relocating the factory 20 Feb: Flex can start to peruse outstanding issues with Parker 20 Mar: RMA#14671 (01pc) - produced after corrective action. Flex is query Idex on the findings reported by Idex's FA report. 20 Mar: pursuing the other outstanding's reports 17 Apr: WPPL informed the triggering is 15000ppm. 14 Aug: Jan to Aug PPM – see next slide. 18 Sep: Implemented GBP Threadless armature. (TMD010532). 18 Sep: 1st SN: H18SM7376A PN 186269505) and H18SM4478A (186269506) for Alliance for WAT270524 15 Oct: 1st SN: 186015080 (H18QSP885A) and 186015018 (H18QSM607A) for QSM and QSM Plus for 279001810 15 Oct: Parker Oven Change S/N 146380 (WAT270524) and S/N 58188 (279001810) 15 Oct: Tjreadless armature PPM, please refer to next 2 slides 20 Nov: .‘additional testing’ GPV in focus. 18 Dec: 200pcs of Alliance GPV under TMD consumed. 2u failed. 21 Jan: Flex to closely monitor failure and report out GPV failures weekly.	Parker / Flex	On-going

Review Of Last MTR Minutes

PPM for Alliance GPV (PN WAT270524, threadless armature) (Target: 15k PPM) – update till WW02’19

Month	186269505 and 186269506 Qty Build	Qty GPV Failure	% Failed	PPM	GPV SN	Instrument SN	Remarks	
18-31 Aug -18	183	2	1.09%	10,929	(1) 145527 (2) 145530	(1) H18SM4527A (2) H18SM4532A	(1) Inlet D no solvent flow (2) Inlet C no solvent flow	TMD (Threadless Armature) implemented for Alliance.
Sep-18	484	5	1.03%	10,331	(1) 146402 (2) 146424 (3) 146426 (4) 146599 (5) 146568	(1) J18SM4723A (2) J18SM4728A (3) J18SM4810A (4) J18SM7565A (5) J18SM4847A	(1) Wire came off during assy (2) Inlet B no solvent flow (3) Inlet B no solvent flow (4) Inlet A no solvent flow (5) Inlet B no solvent flow	
Oct-18	508	7	1.38%	13,780	(1) 146872 (2) 147137 (3) 145371 (4) 147362 (5) 147359 (6) 147265 (7) 147286	(1) K18SM7602A (2) K18SM4209A (3) K18SM4268A (4) K18SM4248A (5) K18SM4275A (6) K18SM4287A (7) K18SM4309A	(1) Inlet C no solvent flow (2) Inlet C no solvent flow (3) Inlet A no solvent flow (4) Inlet B no solvent flow (5) Inlet B no solvent flow (6) Inlet B no solvent flow (7) Inlet B no solvent flow	
Oct-18	22	1	4.55%	45,455	(1) 147449	(1) K18SM4384A	(1) Inlet B no solvent flow	remarks; 22pcs additional tested 1st received
Oct-18	24	0	0.00%	-	-	-	-	remarks: 56u shipped from Milford under TMD
Nov-18	32	3	9.38%	93,750	(1) 147223 (2) 147148 (3) 147220	(1) L18SM4414A (2) L18SM4411A (3) L18SM4409A	(1) Inlet B no solvent flow (2) Inlet B no solvent flow (3) Inlet B no solvent flow	remarks: 56u shipped from Milford under TMD
Nov 18	463	1	0.22%	2,160	(1) 148141	(1) L18SM4733A	(1) Inlet D no solvent flow	
Dec 18	120	2	1.67%	16,667	(1) 146845 (2) 146754	(1) M18SM7746A (2) M18SM4908A	(1) Inlet D no solvent flow (2) Inlet B no solvent flow	
Dec 18	413	3	0.73%	7,264	(1) 148261 (2) 148451 (3) 148580	(1) L18SM4869A (2) M18SM4061A (3) M18SM7902A	(1)Inlet B no solvent flow (2) Inlet C and D no solvent flow (3) Inlet D no solvent flow	
Jan 19 (WW01)	91	2	2.20%	21,978	(1) 148733 (2) 148844	(1) M18SM4137A (2) M18SM4228A	(1) Inlet B and C reverse (2) Inlet D no solvent flow	
Jan 19 (WW02)	131	1	0.76%	7,634	(1) 148930	(1) A19SM4243A	(1) Inlet B and C no solvent flow	
NOTE 1 : On 18 Aug 2018, TMD010532(Threadless Armature) implemented for Alliance. • 1st GPV SN : 145274 • 1st SN for 186269505: H18SM7376A • 1st SN for 186269506: H18SM4478A								
NOTE 2 : On 30 Oct 2018, 56pcs under TMD 010576 V00 implemented • SN K18SM4365A to L18SM4417A								
NOTE 3a : Additional testing at Parker (1st 22u of GPV received from Parker) • SN K18SM4344A to K18SM4364A - for 22pcs with additional testing NOTE 3b: On 29 Oct 2018, started using the lot after CA implementation in Parker • 1st GPV SN : 147540 • 1st SN L18SM4418A								
NOTE 4 : On 30 Nov 2018, 120pcs under TMD 010576 V01 implemented • 1st SN for 186269505: L18SM7737A • 1st SN for 186269506: L18SM4887A								

Summary (up to WW02’19):
- Additional testing – 8/ 1120u (0.71%) failed

Review Of Last MTR Minutes

PPM for QSM GPV (PN 279001810, threadless armature) (Target: 15k PPM) – update till WW02’19

Month	Qty Build (Instrument)	Qty used (GPV)	Qty Failure	% Failed	PPM	GPV SN	Instrument SN	Remarks
27-31 Aug-18	32	64	0	0.00%	-	-	-	-
Sep-18	127	254	3	1.18%	11,811	(1) 58329 (2) 58232 (3) 58336	(1) J18QSM632A (2) J18QSM633A (3) J18QSM638A	(1) Test compositional accuracy & high pressure test (2) Test input B prime with MeOH (3) Test input D prime with MeOH
Oct-18	192	384	33	8.59%	85,938	(1) 58287 (2) 58203 (3) 58196 (4) 58282 (5) 58268 (6) 58192 (7) 58195 (8) 58200 (9) 58191 (10) 58190 (11) 58421 (12) 58395 (13) 58198 (14) 58410 (15) 58393 (16) 58400 (17) 58409 (18) 58433 (19) 58703 (20) 58685 (21) 58751 (22) 58394 (23) 58419 (24) 58237 (25) 58740 (26) 58669 (27) 58355	(1) J18QSM640A (2) K18QSM667A (3) K18QSM667A (4) J18QSM657A (5) K18QSM670A (6) J18QSM662A (7) J18QSM663A (8) J18QSM663A (9) J18QSM664A (10) K18QSM668A (11) K18QSP006A (12) K18QSP011A (13) K18QSP014A (14) K18QSP024A (15) K18QSP054A (16) K18QSP028A (17) K18QSP028A (18) K18QSP028A (19) K18QSP057A (20) K18QSM679A (21) K18QSP070A (22) K18QSP054A (23) K18QSP037A (24) K18QSP037A (25) K18QSP081A (26) K18QSP090A (27) K18QSP051A	(1) Compositional Accuracy test failed - AC 90%, AC 10% (2) Failed Test Input D Prime with MeOH (3) Compositional Accuracy test failed - BD 90% (4) Compositional Accuracy test failed - BD 90%, BD 10% (5) Channel D Prime fail - No flow (6) Compositional Accuracy test failed - BD 90%, BD 10% (7) Compositional Accuracy test failed - BD 10% (8) Compositional Accuracy test failed - BD 90%, AC 10% (9) Test input B prime with MeOH (10) Test input B prime with MeOH (11) Test compositional accuracy & high pressure test (12) Test input B prime with MeOH (13) Test input B prime with MeOH (14) Test input B prime with MeOH (15) Test Input B Prime with MeOH (16) Test Input D Prime with MeOH (17) Test Input B Prime with MeOH (18) Input C Prime with MeOH (19) Test Input B Prime with MeOH (20) Input Line A Prime with MeOH (21) Input Line B Prime with MeOH (22) Test Input D Prime with MeOH (23) Test Input B Prime with MeOH (24) Test Input D Prime with MeOH (25) Failed Compositional Accuracy and High Pressure Test (26) Test Input D Prime with MeOH (27) Test Input D Prime with MeOH
Oct-18	18	36	0	0.00%	-	-	-	-
Nov-18	191	382	1	0.26%	2,618	(1) 59484	(1) L18QSM722A	(1) Test Input A Prime with MeOH
Dec-18 (WW49)	229	458	1	0.22%	2,183	(1) 59987	(1) M18QSP393A	(1) Test input C prime with MeOH
Jan-19 (WW01)	51	102	0	0.00%	-	-	-	-
Jan-19 (WW02)	20	40	0	0.00%	-	-	-	-

NOTE 1 : On 27 Aug 2018, TMD010532 (Threadless Armature) implemented for QSM/QSM Plus.

- 1st GPV SN : 57688
- 1st SN for 186015018 : H18QSM607A
- 1st SN for 186015080 : H18QSP885A

NOTE 2 : On 30 Oct 2018, phased in GPV with additional testing at Parker

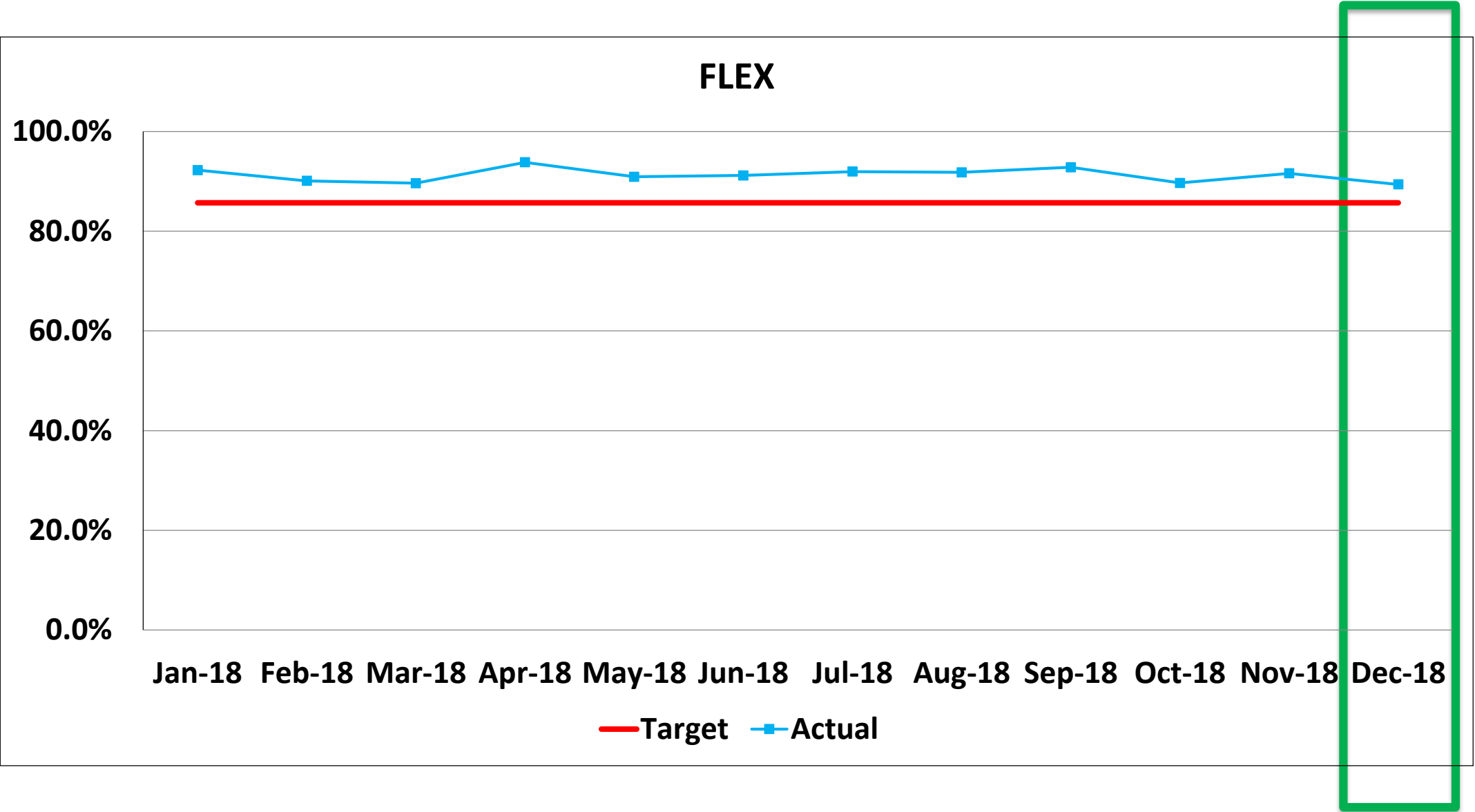
- 1st GPV SN : 58999
- 1st SN for 186015080 : K18QSP146A

Summary (up to WW02’19):

- Additional testing – 2/ 1018u (0.20%) failed

First Pass Yield

Overall



Period	Target	Actual
Jan-18	85.7%	92.2%
Feb-18	85.7%	90.1%
Mar-18	85.7%	89.6%
Apr-18	85.7%	93.8%
May-18	85.7%	90.9%
Jun-18	85.7%	91.2%
Jul-18	85.7%	92.0%
Aug-18	85.7%	91.8%
Sep-18	85.7%	92.8%
Oct-18	85.7%	89.7%
Nov-18	85.7%	91.6%
Dec-18	85.7%	89.4%

NOTE : FPY target is revised upward to 85.7% from 81.7% wef Jan 2018.
NOTE: with Alliance Carry Over test failure wef Oct 2018

First Pass Yield (with Carry over test failure)

Models 186002998,
186015034, 186269505
and 186269506 did not
meet target

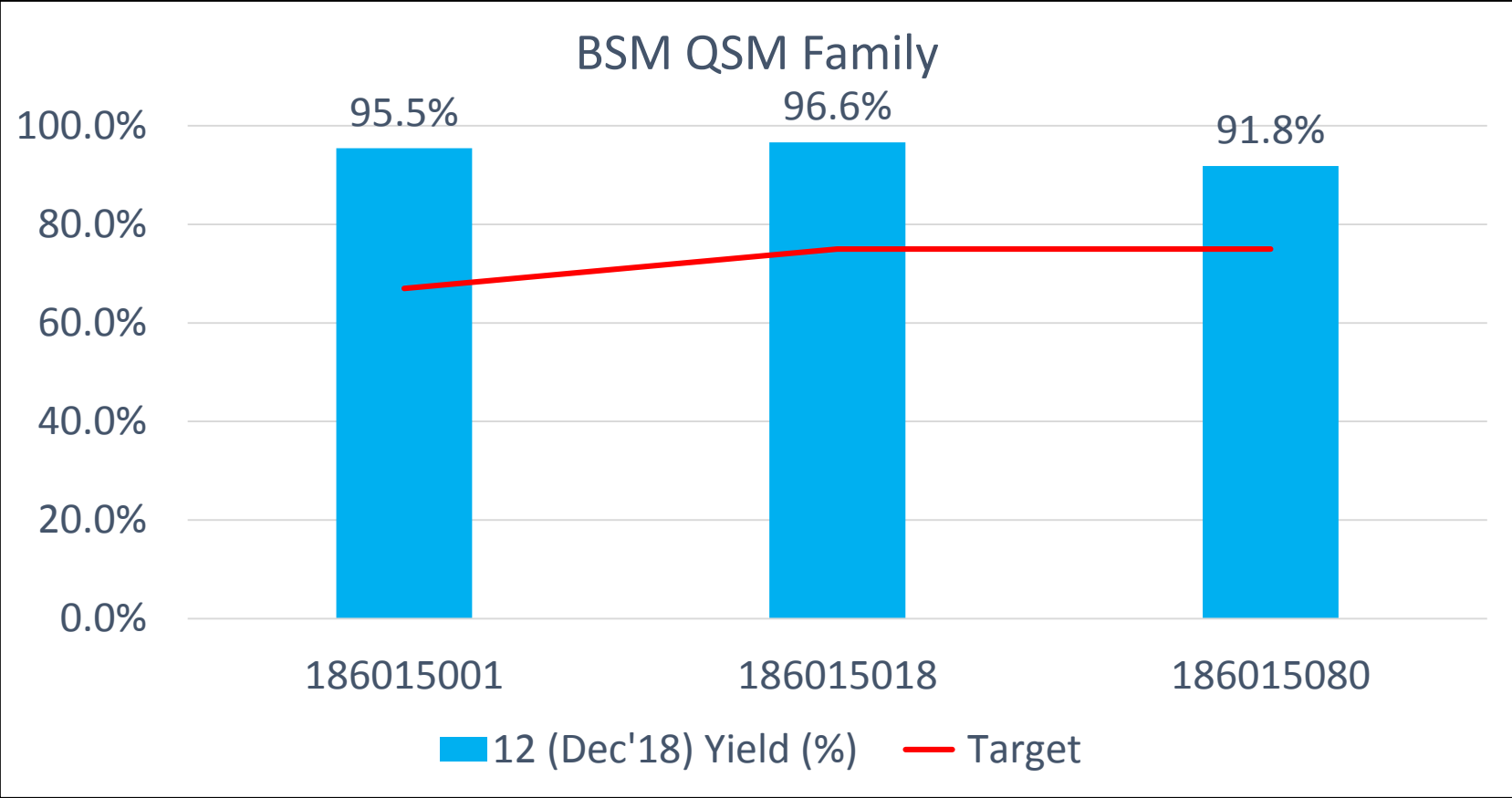
By Instruments

Material Number	Instrument Description	Product Group	Product Class	Target	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
186002487	2489 UV/Visible Detector	Detector	HPLC	92%	100.0%	100.0%	100.0%	97.0%	100.0%	100.0%	98.1%	97.5%	95.8%	100.0%	100.0%	94.7%
186002998	2998 Photodiode Array Detector	Detector	HPLC	79%	63.0%	50.0%	88.9%	89.3%	72.2%	69.0%	83.3%	84.2%	85.0%	67.9%	91.7%	75.6%
186248900	2489 UV/Visible Detector	Detector	HPLC	94%	98.8%	97.2%	98.7%	98.5%	96.9%	95.4%	98.1%	96.2%	100.0%	97.0%	97.4%	97.4%
186299800	2998 Photodiode Array Detector	Detector	HPLC	81%	86.0%	58.3%	80.5%	87.3%	85.2%	91.5%	88.7%	89.3%	88.6%	87.7%	91.2%	82.7%
186015031	ACQUITY TUV (with TC)	Detector	UPLC	91%	95.7%	98.8%	98.6%	92.9%	94.1%	98.4%	98.0%	97.5%	98.9%	95.9%	96.7%	96.4%
186015032	ACQUITY PDA (with TC)	Detector	UPLC	83%	78.8%	70.4%	83.9%	85.7%	84.1%	84.2%	83.9%	83.5%	94.4%	91.7%	87.5%	92.5%
186015033	ACQUITY eλ PDA (with TC)	Detector	UPLC	80%	78.3%	74.1%	84.7%	87.2%	91.4%	76.6%	81.8%	80.4%	86.4%	87.5%	85.3%	88.9%
186015034	ACQUITY UPC2 PDA Detector	Detector	UPLC	88%	88.9%	0.0%	66.7%	100.0%	83.3%	75.0%	87.5%	0.0%	0.0%	100.0%	75.0%	80.0%
186015053	ACQUITY PDA Detector w/TaperSlit	Detector	UPLC	89%	0.0%	0.0%	100.0%	0.0%	80.0%	0.0%	100.0%	100.0%	0.0%	75.0%	100.0%	0.0%
186017002	ACQUITY Arc 2489 UV/Vis Detector	Detector	UPLC	94%	97.9%	97.5%	95.6%	100.0%	100.0%	96.4%	100.0%	100.0%	100.0%	100.0%	100.0%	96.7%
186017003	ACQUITY Arc 2998 PDA Detector	Detector	UPLC	79%	88.7%	0.0%	73.5%	97.4%	89.6%	95.1%	88.2%	86.5%	91.4%	82.8%	87.5%	83.6%
WAT207000	ASSY, HPLC PUMP, M515	Pump	HPLC	97%	97.3%	100.0%	100.0%	95.8%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	95.5%	0.0%
186001515	1515 ISOCRATIC HPLC PUMP	Pump	HPLC	99%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	87.5%	100.0%	0.0%
186001525	1525 BINARY HPLC PUMP	Pump	HPLC	98%	100.0%	94.7%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
186001825	1525 MICRO W/DEGASSER	Pump	HPLC	100%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86%	93.2%	89.5%	86.0%	91.8%	86.3%	88.5%	88.0%	88.5%	89.4%	84.1%	82.6%	81.0%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	86%	88.1%	86.2%	87.5%	91.8%	85.7%	88.0%	88.7%	89.4%	87.8%	83.9%	84.7%	80.1%
186015001	ACQUITY Binary Solvent Manager	BSM	UPLC	67%	100.0%	100.0%	100.0%	96.7%	100.0%	100.0%	90.6%	87.5%	89.5%	93.5%	81.8%	95.5%
186015018	ACQUITY QSM	QSM	UPLC	75%	95.8%	95.7%	97.4%	98.0%	100.0%	98.0%	96.8%	95.6%	90.3%	81.5%	91.7%	96.6%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	Detector	UPLC	94%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.0%	0.0%	96.6%	0.0%	0.0%
186017013	ACQUITY Arc Bio 2998 PDA Detector	Detector	UPLC	79%	76.5%	0.0%	0.0%	0.0%	100.0%	0.0%	83.3%	0.0%	0.0%	62.5%	0.0%	85.7%
186015080	ACQUITY QSM PLUS	Detector	UPLC	75%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	84.0%	97.0%	91.8%

New Product – WPPL recommends to monitor FPY for at least 6 months.

First Pass Yield

QSM/BSM Family FPY (Dec 2018 data)

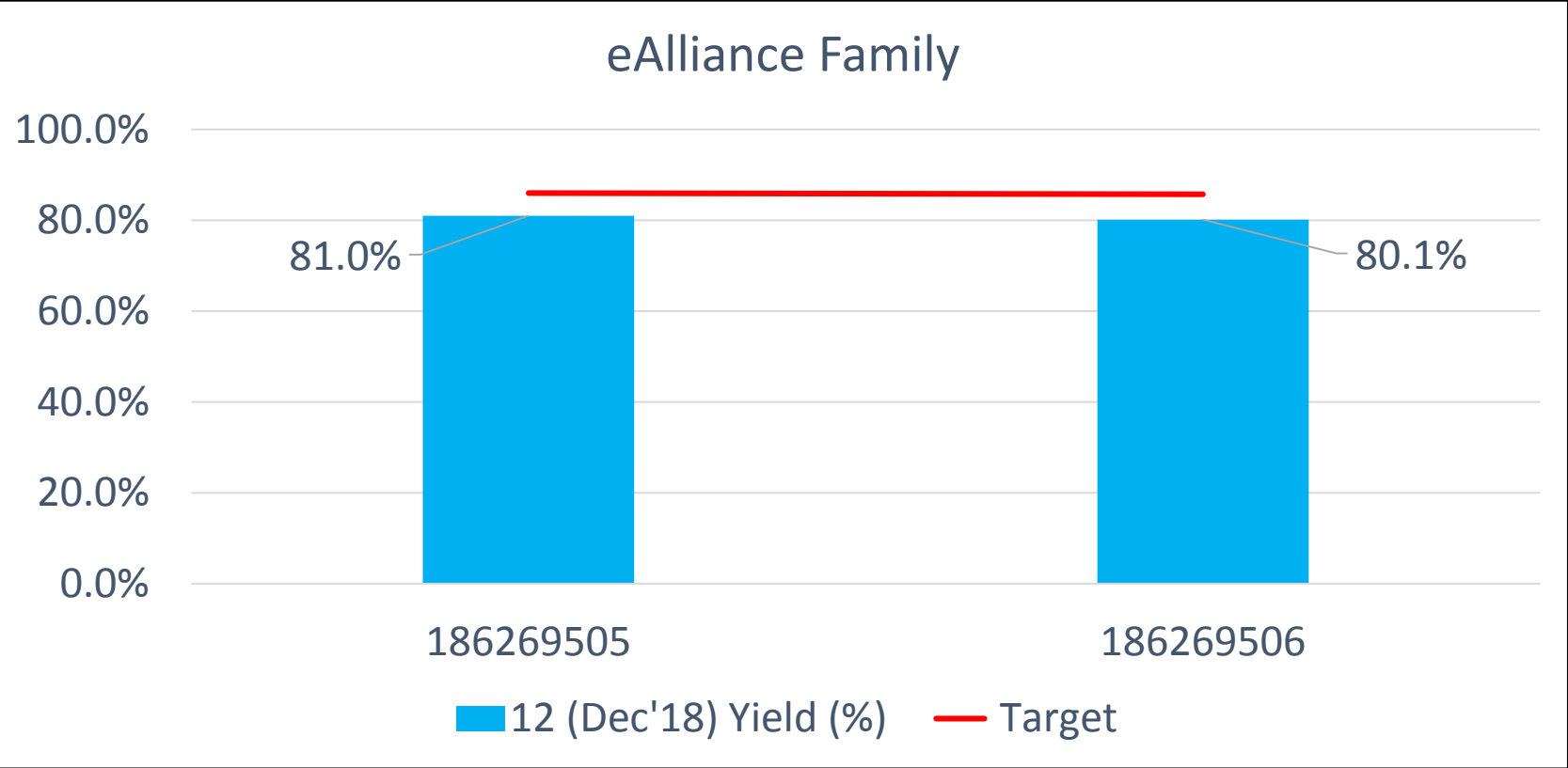


**All meet
target**

Material Number	Instrument Description	Product Group	Product Class	Target	Total Units Tested	Total Units Passed	Total Units Fail	12 (Dec'18) Yield (%)
186015001	ACQUITY Binary Solvent Manager	BSM/QSM Family	UPLC	67.0%	22	21	1	95.5%
186015018	ACQUITY QSM	BSM/QSM Family	UPLC	75.0%	119	115	4	96.6%
186015080	ACQUITY QSM PLUS	BSM/QSM Family	UPLC	75.0%	110	101	9	91.8%

First Pass Yield

Alliance Family FPY (Dec 2018 data)



**Both models
did not meet
target**

Material Number	Instrument Description	Product Group	Product Class	Target	Total Units Tested	Total Units Passed	Total Units Fail	12 (Dec'18) Yield (%)
186269505	e2695 Separations Module w/o HC	eAlliance Family	HPLC	86.0%	221	179	42	81.0%
186269506	e2695 Separations Module w/HC	eAlliance Family	HPLC	85.7%	312	250	62	80.1%

First Pass Yield

Alliance 186269505 (Dec 2018 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Carry over test			Injector Adjustment Test			Leak Detection Procedure		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
Jul '18	133	10	7.5%	▲	4	3.0%	▼	5	3.8%	▼
Aug '18	104	3	2.9%	▼	5	4.8%	▲	4	3.8%	▬
Sep '18	141	6	4.3%	▲	6	4.3%	▼	6	4.3%	▲
Oct '18	82	3	3.7%	▲	3	3.7%	▼	4	4.9%	▲
Nov '18	69	0	0.0%	▬	6	8.7%	▲	5	7.2%	▲
Dec '18	221	16	7.2%	▲	8	3.6%	▼	8	3.6%	▼

Debug Breakdown / Finding	Dec '18	Debug Breakdown / Finding	Dec '18	Debug Breakdown / Finding	Dec '18
Replaced blank(9)	15	Fine Tune Screw of Sensor Bracket	8	Re-tighten WAT270409	2
Reseat & realign injector	1			Re-tighten WAT078565	2
				Re-tighten 430001336	3
				Re-tighten 430001194	1

First Pass Yield

Alliance 186269505 (Dec 2018 data) – Top 3 failures

	Carry over test	Injector Adjustment Test	Leak Detection Procedure
Analysis / Comment	New skid# used for: 1. WATH-405024113-C: ASSY, HOUSING, MIDDLE, SEAL PACK: Skid # 531077967 Used on 06-Dec to 11-Dec 18 2. WAT-405024115-B : ASSY, HOUSING, TOP, SEAL PACK : Skid # 531077966 Used on 06-Dec - 12 Dec 18 3. WAT-WAT033276-07-SEAL : used on 04-Dec to 08-Dec 18	- Injector subassembly test as per WAT043815 that set the Down count Stream from 85 to 125 steps and Seal Width LSL > 60 steps. - Final test as per WAT271129 that Seal top at 38 to 50 and width 60 to 90. - As per TSP WAT271129, step 19.4 Seal Width Adjustment is part of the test procedure, - Currently Flex is recording this adjustment as an event - Flex will not record this adjustment as an event from Jan 2019 onwards (discussed in Dec 2018 MTR meeting)	- No visible leak observed by the technician. - Tightened the connection per TSP WAT271129, retest passed. - All 21 tubings are tightened by a 36in-lb torque wrench.
Root Cause / Possible Root Cause	- Not able to established root cause / related to 'new skids used'. related issues as part from failed UUT is/are able to pass to another unit.	NA	- Root Cause is still not established.
Corrective Action	- Continue good practices as below: 1. Use gloves for handling samples. 2. Preparation samples 70:30 every 3 days. 3. Replace Post Blank (9), Manual Prime, Needle Adjustment, Compression Test and Retest Carrover Test to recover Carry over test failures.	NA	NA
Effectiveness	NA. Continue to monitor for spike.	NA	 /

First Pass Yield

Alliance 186269506 (Dec 2018 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Carry over test			Leak Detection Procedure			Injector Adjustment test		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
Jul'18	425	45	10.6%	▼	17	4.0%	▲	18	4.2%	▼
Aug'18	320	22	6.9%	▼	13	4.1%	▲	14	4.4%	▲
Sep'18	343	15	4.4%	▼	15	4.4%	▲	17	5.0%	▲
Oct'18	448	8	1.8%	▼	21	4.7%	▲	23	5.1%	▲
Nov'18	451	5	1.1%	▼	24	5.3%	▲	23	5.1%	—
Dec'18	312	21	6.7%	▲	15	4.8%	▼	15	4.8%	▼

Debug Breakdown / Finding	Dec'18	Debug Breakdown / Finding	Dec'18	Debug Breakdown / Finding	Dec'18
Replaced blank(9)	19	Re-tighten 430001194	4	Fine Tune Screw of Sensor Bracket	15
Realign injector & retest	1	Re-tighten 430001336	2		
Reseat & realign injector	1	Re-tighten WAT078565	3		
		Re-tighten WAT270409	5		
		Leak not visible, replaced tubing 430001194 (TUBE ASSY, SAMP LOOP, 100ul, 2)	1		

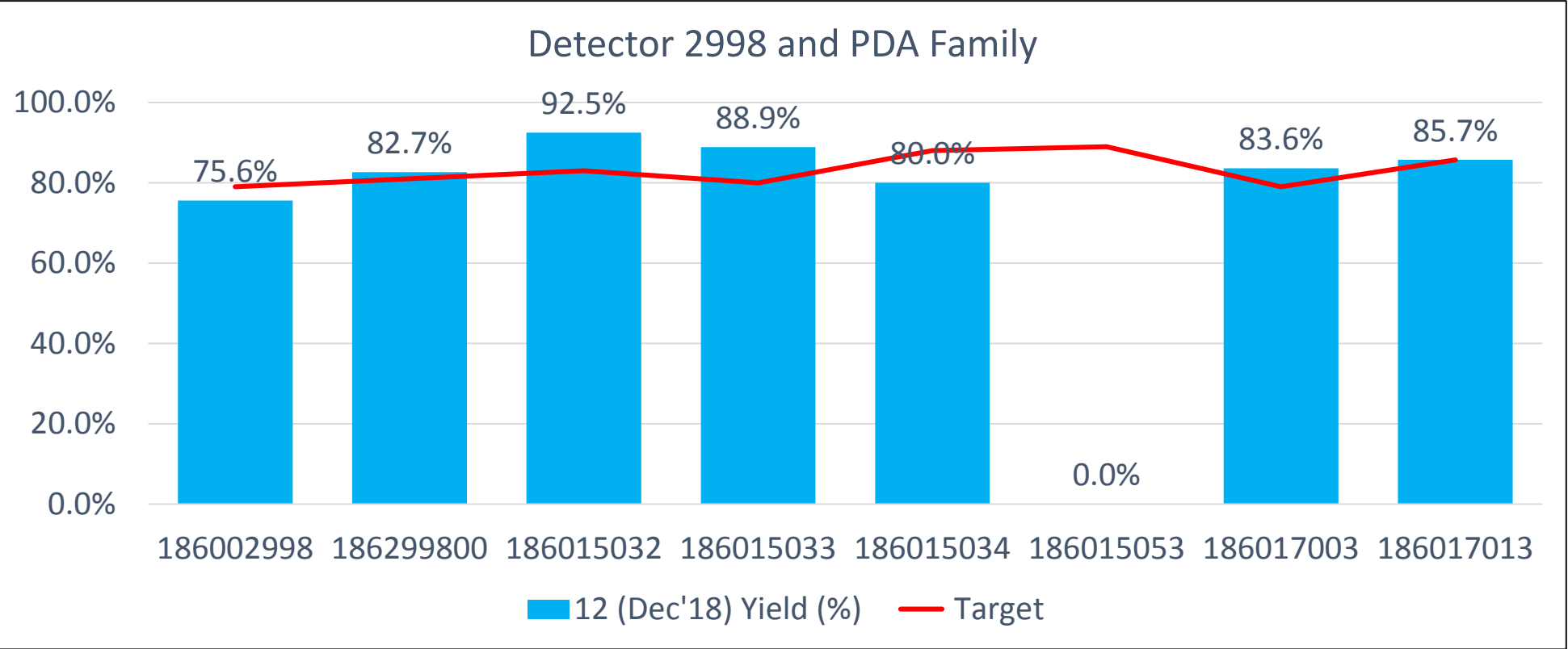
First Pass Yield

Alliance 186269506 (Dec 2018 data) – Top 3 failures

	Carry over test	Leak Detection Procedure	Injector Adjustment test
Analysis / Comment	New skid# used for: 1. WATH-405024113-C: ASSY, HOUSING, MIDDLE, SEAL PACK: Skid # 531077967 Used on 06-Dec to 11-Dec 18 2. WAT-405024115-B : ASSY, HOUSING, TOP, SEAL PACK : Skid # 531077966 Used on 06-Dec - 12 Dec 18 3. WAT-WAT033276-07-SEAL : used on 04-Dec to 08-Dec 18	- No visible leak observed by the technician. - Tightened the connection per TSP WAT271129, retest passed. - All 21 tubings are tightened by a 36in-lb torque wrench.	- Injector subassembly test as per WAT043815 that set the Down count Stream from 85 to 125 steps and Seal Width LSL > 60 steps. - Final test as per WAT271129 that Seal top at 38 to 50 and width 60 to 90. - As per TSP WAT271129, step 19.4 Seal Width Adjustment is part of the test procedure, - Currently Flex is recording this adjustment as an event - Flex will not record this adjustment as an event from Jan 2019 onwards (discussed in Dec 2018 MTR meeting)
Root Cause / Possible Root Cause	- Not able to established root cause / related to 'new skids used'. related issues as part from failed UUT is/are able to pass to another unit.	- Root Cause is still not established.	NA
Corrective Action	- Continue good practices as below: 1. Use gloves for handling samples. 2. Preparion samples 70:30 every 3 days. 3. Replace Post Blank (9), Manual Prime, Needle Adjustment, Compression Test and Retest Carrover Test to recover Carry over test failures.	NA	NA
Effectiveness	NA. Continue to monitor for spike.	NA	NA

First Pass Yield

Detector 2998 and PDA Family FPY (Dec 2018 data)



**186002998 and
186015034 not
meet target**

Material Number	Instrument Description	Product Group	Product Class	Target	Total Units Tested	Total Units Passed	Total Units Fail	12 (Dec'18) Yield (%)
186002998	2998 Photodiode Array Detector	Detector 2998 and PDA Family	HPLC	79.0%	45	34	11	75.6%
186299800	2998 Photodiode Array Detector	Detector 2998 and PDA Family	HPLC	81.0%	202	167	35	82.7%
186015032	ACQUITY PDA (with TC)	Detector 2998 and PDA Family	UPLC	83.0%	80	74	6	92.5%
186015033	ACQUITY eλ PDA (with TC)	Detector 2998 and PDA Family	UPLC	80.0%	63	56	7	88.9%
186015034	ACQUITY UPC2 PDA Detector	Detector 2998 and PDA Family	UPLC	88.0%	15	12	3	80.0%
186015053	ACQUITY PDA Detector w/TaperSlit	Detector 2998 and PDA Family	UPLC	89.0%	0	0	0	N/A
186017003	ACQUITY Arc 2998 PDA Detector	Detector 2998 and PDA Family	UPLC	79.0%	61	51	10	83.6%
186017013	ACQUITY Arc Bio 2998 PDA Detector	Detector 2998 and PDA Family	UPLC	85.7%	7	6	1	85.7%

First Pass Yield

Detector 186002998 (Dec 2018 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Communication Failed			Noise failed			Failed to initialize		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
Jul'18	30	2	6.7%	▼	2	6.7%	▼	0	0.0%	▬
Aug'18	19	2	10.5%	▲	0	0.0%	▬	1	5.3%	▲
Sep'18	20	1	5.0%	▼	1	5.0%	▲	0	0.0%	▬
Oct'18	28	3	10.7%	▲	4	14.3%	▲	0	0.0%	▬
Nov'18	12	1	8.3%	▼	0	0.0%	▬	0	0.0%	▬
Dec'18	45	7	15.6%	▲	2	4.4%	▲	1	2.2%	▲

Debug Breakdown / Finding	Dec'18	Debug Breakdown / Finding	Dec'18	Debug Breakdown / Finding	Dec'18
Retest without doing anything	7	Retest without doing anything	2	Component faulty,replaced 210000404 (ASSY, PCB 2998 PDA PERSONALITY)	1

First Pass Yield

Detector 186002998 (Dec 2018 data) – Top 3 failures

	Top 1	Top 2	Top 3
	Communication Failed	Noise failed	Failed to initialize
Analysis / Comment	-Retest the UUT. - One tester has 4 test ports and if a UUT has failed for Comm, the other 3 UUTs will also fail for Comm failure. In short, all the 4 UUTs will fail Communication. - Failure at random station. - Tester in used for validation of new PDAIni.txt (validation run start from 05 Nov 2018 to 13 Dec 2018)	Retest and pass	- UUT Not Able to Initialize (DSP Failed) - replaced by another good board the UUT able to proceed to initialize. - Off-line verified using KGU (s/n:B13998443N) Communication with DSP failed (message on screen: Charge Amp not found).
Root Cause / Possible Root Cause	-Soft Failure. - This is considered as event(Re-run test due to test equipment issue etc) as part of Final Test. Production need to perform re-test as per final test procedure.	- soft failure. - Low priority to work on this failure.	- PCBA 210000404 faulty.
Corrective Action	- To minimize COMM Failure: - daily clearing of DHCP Server before usage. - restarting computer after clearing DHCP Server. - IPN Switches manual trigger (works as expected - able to ON/OFF UUT).	NA	- RTV to Flex Senai.
Effectiveness	- Can only minimize the soft failures as failure not related to Instrument workmanship or faulty part.	NA	NA

First Pass Yield

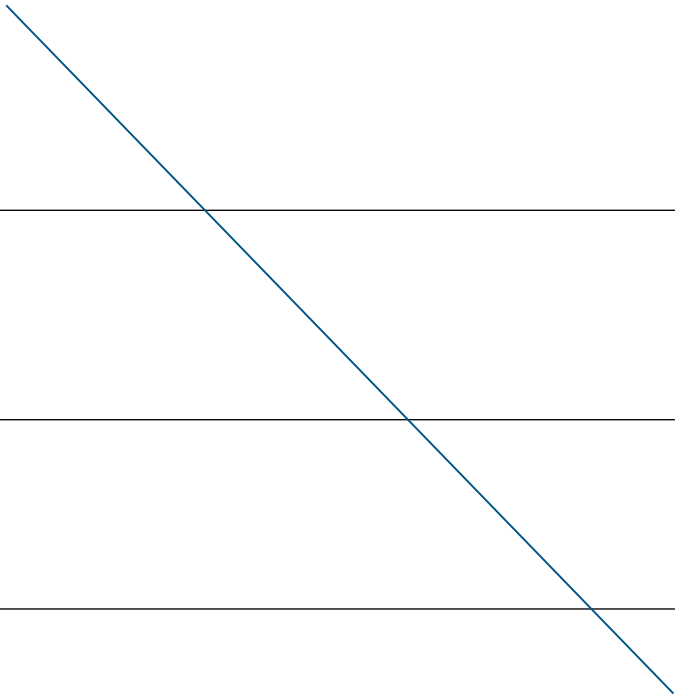
Detector 186015034 (Dec 2018 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Drift failed			Communication failed			NA		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
Jul'18	8	0	0.0%		0	0.0%			0.0%	
Aug'18	0	0	#DIV/0!		0	#DIV/0!			#DIV/0!	
Sep'18	0	0	#DIV/0!		0	#DIV/0!			#DIV/0!	
Oct'18	8	0	0.0%		0	0.0%			0.0%	
Nov'18	4	1	25.0%		0	0.0%			0.0%	
Dec'18	15	1	6.7%		1	6.7%			0.0%	

Debug Breakdown / Finding	Dec'18	Debug Breakdown / Finding	Dec'18	Debug Breakdown / Finding	Dec'18
Retest without doing anything	1	Retest without doing anything	1	NA	

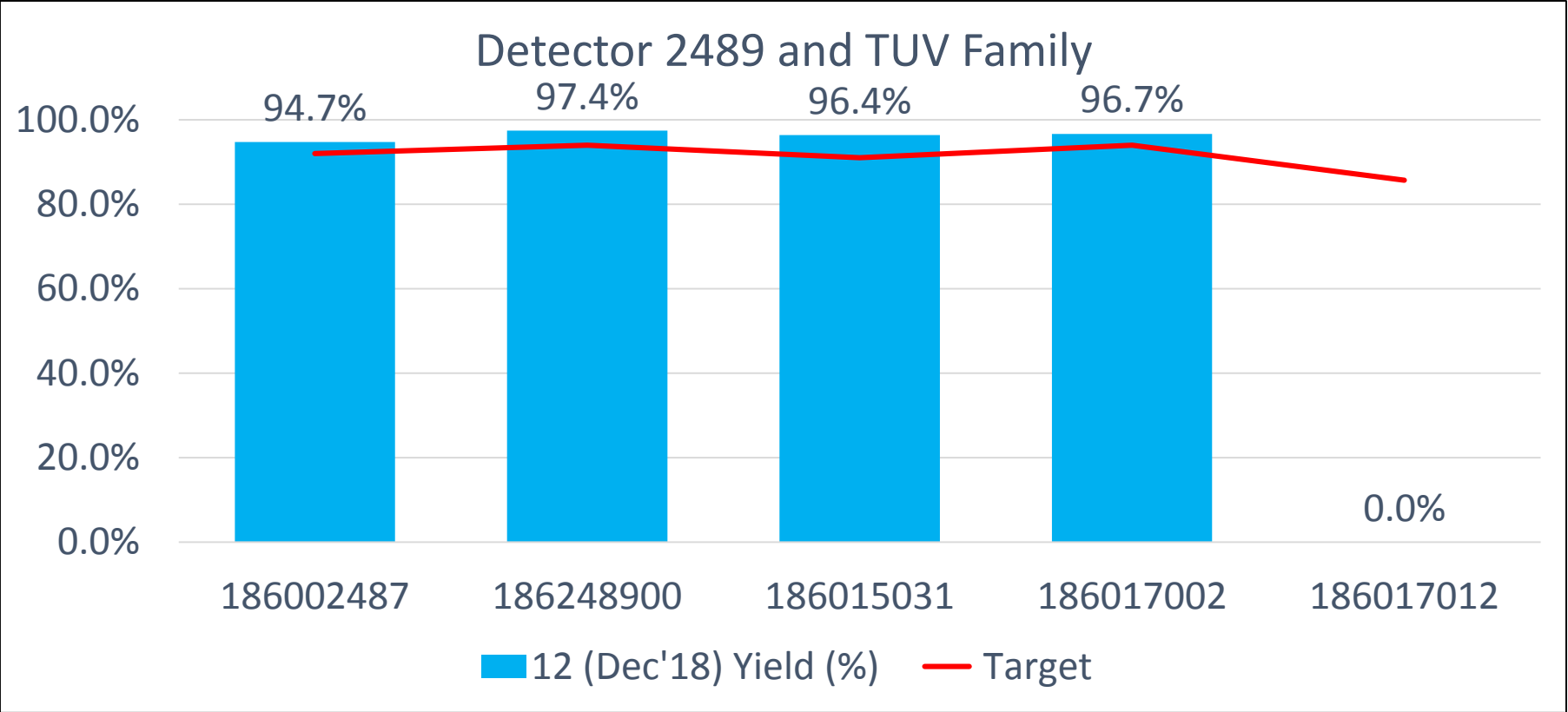
First Pass Yield

Detector 186015034 (Dec 2018 data) – Top 3 failures

	Top 1	Top 2	Top 3
	Drift failed	Communication failed	NA
Analysis / Comment	Retest and pass	Retest and pass	
Root Cause / Possible Root Cause	Random/soft failure. Low priority to work on this failure.	Random/soft failure. Low priority to work on this failure.	
Corrective Action	NA	NA	
Effectiveness	NA	NA	

First Pass Yield

Detector 2489 and TUV Family FPY (Dec 2018 data)

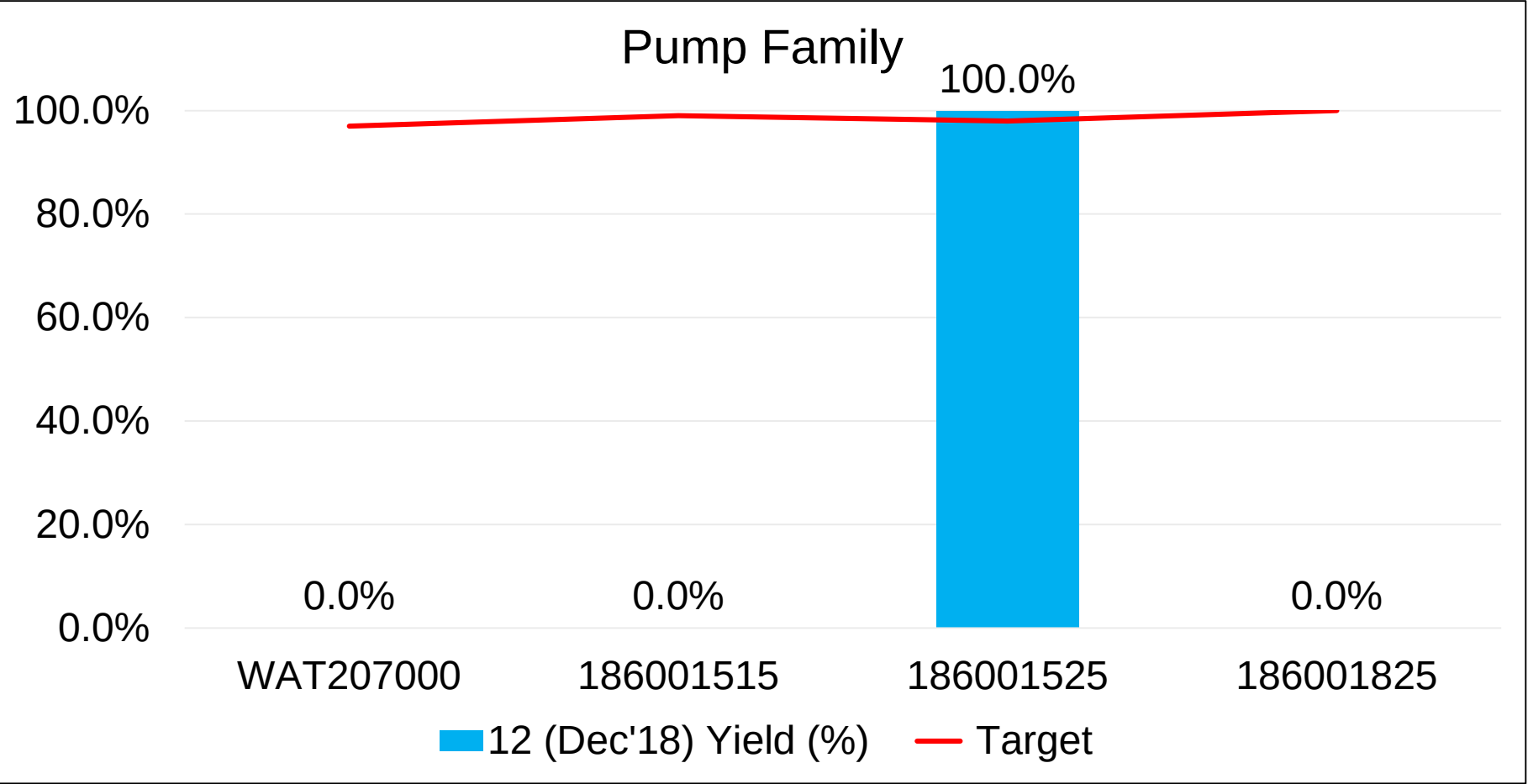


All meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Total Units Tested	Total Units Passed	Total Units Fail	12 (Dec'18) Yield (%)
186002487	2489 UV/Visible Detector	Detector 2489 and TUV Family	HPLC	92.0%	57	54	3	94.7%
186248900	2489 UV/Visible Detector	Detector 2489 and TUV Family	HPLC	94.0%	388	378	10	97.4%
186015031	ACQUITY TUV (with TC)	Detector 2489 and TUV Family	UPLC	91.0%	55	53	2	96.4%
186017002	ACQUITY Arc 2489 UV/Vis Detector	Detector 2489 and TUV Family	UPLC	94.0%	90	87	3	96.7%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	Detector 2489 and TUV Family	UPLC	85.7%	0	0	0	N/A

First Pass Yield

Pump Family FPY (Dec 2018 data)



All meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Total Units Tested	Total Units Passed	Total Units Fail	12 (Dec'18) Yield (%)
WAT207000	ASSY, HPLC PUMP, M515	Pump Family	HPLC	97.0%	0	0	0	N/A
186001515	1515 ISOCRATIC HPLC PUMP	Pump Family	HPLC	99.0%	0	0	0	N/A
186001525	1525 BINARY HPLC PUMP	Pump Family	HPLC	98.0%	8	8	0	100.0%
186001825	1525 MICRO W/DEGASSER	Pump Family	HPLC	100.0%	0	0	0	N/A

TMD Updates

TMD summary

TMD Tracker 2018		
Total TMD Received	No of TMD closed	No of TMD open
28	22	6

TMD - OPEN

Originator: Matt Franklin	Date: 17-Dec-2018	TMD #: TMD010367	v 05
Lab Office: AKT	Notify: Tom Chase, Eugene Tan	Requester: Tom Chase	
P/N(s): 415002619; 415002125 415002122		P/N COVER, FLOW CELL, ID; COVER, FLOWCELL, BLUE Desc.: COVER, FLOWCELL, BLUE	
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 30-Jun-2019	Expiration Detail: N/A	
Risk Assessor: Matt Franklin	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): - Flow Cell Covers (415002619, 415002122 and 415002125) are secured to the Flow Cell using 4 Screws (WAT270393). The Flow Cell Cover has 4 boss features with holes, in which the screws are installed into. - One of these features has been cracking when installing the screw. The feature closest to the opening in the cover is always the feature to crack (see attachment B for location). The 3 other features seem to accept the screw without cracking. - Both the hole feature and the screw measure within specification. This TMD is needed to use a smaller screw in this one feature while root cause is determined.			

Implementation Plan (<i>describe who, when, how of implementation</i>): Upon approval, the listed screw can be used in place of screw WAT270393, in the one feature closest to the opening in the flow cell (as described in the TMD Description). This TMD impacts Milford and Singapore Production. A cross functional team, including representatives from Manufacturing, Supplier Quality, Purchasing and Design will be working with the supplier to determine root cause and implement corrective actions. This TMD will no longer be needed and will be closed following successful implementation of corrective actions.
--

Status : Active.
 Flex has put up PO to buy the ‘smaller’ screws to support up to Jun 2019.

TMD - OPEN

Originator: Joe Gately	Date: 24-Sep-2018	TMD #: TMD010508	v 01
Lab Office: AKX	Notify: Kris Bujold, Monica Collins,	Requester: Ken Voisine	
P/N(s): See below	P/N See Below Desc.:		
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 30-Jun-2019	Expiration Detail: N/A	
Risk Assessor: Joe Gately	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): 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 labeling requirement. This TMD will allow the receipt of these parts until such time as the labeling can be added to the packaging. This TMD is being extended in order to give the supply chain adequate time to implement the labeling changes.			
Implementation Plan (<i>describe who, when, how of implementation</i>): This TMD will be implemented by the incoming inspection and procurement teams and applies to Milford and the contract manufacturers Venture/GES and Flextronics. Waters purchasing and Supplier Quality will need to work with the above suppliers to implement the specified labeling "WATERS CRITICAL CLEAN per 735001035". The duration of this TMD is to allow the supply chain time to implement the proper labeling per the 735001035 specification.			

Status : active

TMD - OPEN

Originator: BOB LINCOLN	Date: 19-Sep-2018	TMD #: TMD010554	v 00
Lab Office: SP1	Notify: See Implementation Plan	Requester: RANDY RYDER	
P/N(s): WAT270817	P/N FAN, 92MM X 25MM, 49 CFM Desc.:		
Expiration Type: ☐ Date or ☒ Qty/Lot	Expiration Date: N/A	Expiration Detail: 1612 pc by 31 JAN 2019	
Risk Assessor: BOB LINCOLN	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): WAT270817 rev 08 Purchase Specification called out a wire length of 255mm from fan frame to outside edge of connector. Rev 09 inadvertently calls out the same length from fan frame to *inside* edge of connector, which is now standard dimensioning for Waters but added 15mm length to the wiring. Initial samples of rev 09 were built to the original length, which is acceptable for use, but not in conformance with rev 09, which is now in effect. This TMD authorizes the use of these fan assemblies in production, rather than scrapping them. An ECR will be enacted to adjust the specified length back to the prior length. The dimension line will be restored to the outer edge of connector as before.			
Implementation Plan (<i>describe who, when, how of implementation</i>): Flextronics has 500 pc, and Venture has 743 pc, of fan assemblies labeled rev 09, but with the original wire length (255mm to the outer edge of connector, 240mm to the inner edge), rather than the slightly longer length that is specified in rev 09. They will build these into production units and use up this stock. Milford also has 369 pc of rev 08 which are to be used up, as their length is acceptable. This TMD will remain in effect until 31 Jan 2019, when the 1,612 pc are expected to be consumed. ECR 9224831 is being written for a permanent correction to the deviation.			

Status : active

Part inventory / plan:

Date	Inventory	
	rev 9	rev 10
19 Nov 2018	379	0
15 Mar 2019	262	500

262pcs – to sell to other site

In progress:
 Niu Niu(Flex) requested Jie Hui (WPPL) to request TMD extension.

TMD - OPEN

Originator: Lim Shaynee	Date: 25-Sep-2018	TMD #: TMD 010563	v 00
Lab Office: SP1	Notify: Eugene Tan, Tim Norton	Requester: Tim Norton	
P/N(s): 415002438		P/N Desc.: INSULATION, BOTTOM, DETECTOR, 2489	
Expiration Type: ☐ Date <i>or</i> ☒ Qty/Lot	Expiration Date: N/A	Expiration Detail: 3000 pcs	
Risk Assessor: Lim Shaynee	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): Flex received molded part, 415002438, supply by Rand Whitney where the rev letter molded into the part (rev D) does not match with the current rev level stated in the print (rev F).			

Status : active
(approx. 3k
part and
expect to last
till 31 May
2019)

Implementation Plan (<i>describe who, when, how of implementation</i>): To allow Flex receive the part 415002438 from Rand Whitney with the part molded with rev D. Rand Whitney to declare exposure of issue including, where applicable, part numbers, part descriptions, serial numbers, and date codes of affected material.
--

TMD - OPEN

Originator: Matt Franklin	Date: 17-Dec-2018	TMD #: TMD010578	v 01
Lab Office: AKA	Notify: Eugene Tan, Michelle Trobec	Requester: Matt Franklin	
P/N(s): WAT212043		P/N Desc.: RETAINER, FRIT	
Expiration Type: ☒ Date <i>or</i> ☐ Qty/Lot	Expiration Date: 30-May-2019	Expiration Detail: N/A	
Risk Assessor: Matt Franklin	TMD Category: Nonconforming Part		
Reason for Deviation <i>(describe why deviation is needed):</i> WAT212043 RETAINER, FRIT is mostly used in Singapore for the Alliance Seal Pack. Some parts are used in Milford Kitting for replacement Kits. These parts have been manufactured by the same supplier (MRPC) for over 20 years without any major customer complaint or known functional issues. These parts are on Dock-to-Stock from the supplier (MRPC). Recently, these parts were purchased directly from the Contract Manufacturer's stock (Flex) rather than from the supplier (MRPC) which caused these parts to be inspected by Milford IMA. These parts were rejected (QR 1899378) for the defects listed in the Deviation Description. This TMD is needed to accept the use of these parts until a Manufactured As Is (MAI) document can be completed and released.			
Implementation Plan <i>(describe who, when, how of implementation):</i> This TMD impact both Milford and Singapore CM (Flex) manufacturing sites. Upon approval of this TMD the WAT212043 RETAINER, FRIT can be used in both Milford and Singapore manufacturing sites, with the listed defects. In Milford, MRB is to release parts from QR 1899378 Incoming Inspection, for both Milford and Singapore, will take into account the allowed deviation for future inspection lots. The SQE will initiate and push to completion the MAI documentation.			

Status : active
(WAT212043 use in Seal Pack assy)

TMD - OPEN

Originator: Denise Soter	Date: 07-Jan-2019	TMD #: TMD010584	v 01
Lab Office: AKA	Notify: See Implementation Plan	Requester: Keith Lavallee	
P/N(s): See Appendix A		P/N Desc.: See Appendix A	
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 31-Jan-2019	Expiration Detail: N/A	
Risk Assessor: Lisa McNamara	TMD Category: Nonconforming Part		
Reason for Deviation (<i>describe why deviation is needed</i>): This reason for this TMD is WPPL notified Milford that product containing 415000680 ELBOW, DRAIN, 1/8 NPT TO BARBED was nonconforming because of undersized threads resulting in the elbow protruding above flush in the 415000358 CUP, COLUMN HEATER/COOLER DRAIN. All material in Milford was contained on QR#1975013. Additionally, the replacement lot of material had flashing which is not acceptable per the drawing specification. This TMD will allow both conditions as detailed below. This TMD is being modified to clarify the Implementation Plan.			

Status : active
 Supplier will deliver parts from new mold after this TMD expiry date 31 Jan 2019.

Implementation Plan (<i>describe who, when, how of implementation</i>): Upon approval of this TMD: - Milford: P/N 289005705 on QR#1975013 will be dispositioned as use-as-is and released from MRB. - All instruments and kits that were already assembled or packaged and released to a Distribution center are to be used as is with the undersized threads of the 415000680 ELBOW, DRAIN, 1/8 NPT TO BARBED. - Milford, Thar, Flex and Venture: All new incoming lots of 415000680 ELBOW, DRAIN, 1/8 NPT TO BARBED with flashing less than 0.060 inch are to be accepted and moved into inventory per this TMD and would not required tracking through consumption of the accepted material. - Milford, Thar, Flex and Venture: All sites to remove 415000680 ELBOW, DRAIN, 1/8 NPT TO BARBED from Dock-to-Stock status.

Manufacturing Engineering Issues / Updates

ECO Update for 2018 / 2019

ECO Tracker 2018

ECO Tracker 2018			
Total ECO Received	No. of ECO closed	No. of ECO Open	Remarks
169	155	14	5 : ECO yet to receive 3 : Awaiting effective date 6: Future effective date

ECO Tracker 2019

ECO Tracker 2019			
Total ECO Received	No. of ECO closed	No. of ECO Open	Remarks
06	00	06	1 : ECO yet to receive 5 : Future effective date

ASP / TSP Check and Changes Implementation

In Progress

Complete

Overall ASP/ TSP compliance check Status

Compliance check

120/
120

Redlining documents
(*Only applicable docs)

120/
120

Changes Implementation

84/
120

ASP/ TSP Compliance Check status :

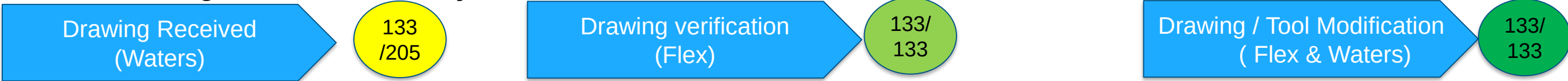
Product Family	ASP/ TSP	ASP/TSP Compliance Check			ASP/TSP Changes Implementation			
		Total	Completed Review	% Status	Complete Implementation	Pending Implementation	% Status	Remarks
eAlliance	ASP	26	26	100%	26	0	100%	- Completed.
	TSP	10	10	100%	10	0	100%	- Completed
BSM/QSM	ASP	12	12	100%	11	1	92%	- 1 ECO Pending Receive
	TSP	3	3	100%	3	0	100%	- Completed (ECO9225995)
TUV Detectors	ASP	19	19	100%	11	8	58%	- 8 Redlining submitted to WPPL.
	TSP	6	6	100%	6	0	100%	- Completed
PDA Detectors	ASP	26	26	100%	7	19	27%	- 19 Redlining submitted to WPPL
	TSP	1	1	100%	1	0	100%	- Completed
Pump	ASP	14 *	14 *	100%	6	8	43%	- 3 X Redline on Word format - 5 X Redline on PDF format
	TSP	3	3	100%	3	0	100%	- Completed

- Submitted the compliance check findings to Waters.
- All redlining documents completed and submitted to Waters.
- For Pump total ASP are 16. But to review 2 ASP, the next production run is in Dec'18. As there is no volume currently the quantity reflected as 14.

Drawing Verification Activity for Jigs/Fixtures/Tooling

 In Progress
 Complete

Overall Status for Drawing Verification Activity



Drawing Verification status :

No	Category of Tooling	Total number of Tools identified	Total number of Tools (with Drawings) Received from Waters	% of Drawings received	Total number of Tools (with Drawings) completed Review by Flex	% Reviewed of received drawings	Total number of Tools (with Drawings) Pending Drawing/ Tool Modification	Remarks
1	Customized tool	205	133	65.8%	133	100%	NA	-3x new tooling added to Seal pack assembly in Jun 18. Seal Press Fixture 999044857 Press Fixture 999044863 Holding Fixture 999044874 -35 X drawings from Key-point. --22 X verification review done.
2	Off the Shelf tool	26	NA	NA	NA	NA	NA	No action required
3	Obsoleted	4	NA	NA	NA	NA	NA	No action required.
	Total	232						

Training review and competencies updates

- NA -

Test Engineering Issues / Updates

TESTER DASH BOARD

Downtime Summary from 21 Nov 2018 to 19 Dec 2018 . (Refer to attached Dashboard)

Date	Tester	Problem	Root Cause	Action Taken	Status
09 Jul 2018	BSM / QSM Final Tester (TE82943-13)	Electronic Weigh Balance s/n: 12326184 – Display showing Error 1	Electronic weigh balance faulty (Unable to get a stable reading)	1. Ensure that the bubble spirit level is okay. 2. Re-Zero the weighing balance but to no avail. 3. Ensure that balance stability is not influence by breeze or vibration. 4. Remove weighing pan, Re insert the pan and Re-zero but no avail. 5. Press and hold the Re-Zero key until balance display CAL. Release the RE-Zero Key. Display shows "Error 1". 7. WPPL Yee Hwa follow-up to vendor - To be replace by spare unit 3rd WK Nov 2018 8. Return to Flex 05 Dec 2018 and arrange calibration by 10 Dec 2018 Calibration completed by vendor 13 Dec 2018 10. Target Calibration report to review and submit to Flex by 18 Dec 2018 Target Release to Prod by 18 Dec 2018	Close 18 Dec 2018
03 Oct 2018	Hipot Cable	Intermittent Pass / Fail	1. S02 , HV Lead Set, high & low, 1m	1. Raise OESR 2. Request for quotation for 2 cables 3. Issue PO 09 Oct 2018 . 4. Cable arrived and installed	Close 22 Nov 2018
15 Nov 2018	TE82943-14	Not able to Boot-up until Windows OS	1. Suspect to be defective Mother Board or HDD	1. Raise OESR 2. Off the CPU and restart. 3. Not able to boot-up to Windows OS 4. Display can reach until Bios only 5. Suspect to be Motherboard or HDD. 6. Request for replacement Workstation PC and reconfiguration 7. Replaced Power Supply Unit. 8. Reformat TE8243-14 HDD and reconfigured with SS. 9. Test one good UUT and reviewed data from SS& is OK. 10. Release for Prod'n	Close 22 Nov 2018

Data Analysis – Quality Issues

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

S/N	LAR / Month	Commodity	Target	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
1	BAITENG	Sheet Metal	96%	99%	100%	100%	100%	100%	100%	100%	100%	97%	100%	100%	100%
2	CMTI	Cable & Harnesses	96%	100%	100%	100%	100%	100%	100%	88%	100%	88%	100%	100%	100%
3	JCC	Machining	96%	100%	100%	100%	50%	82%	100%	100%	100%	100%	100%	100%	100%
4	Technimetal		96%	81%	100%	100%	100%	95%	96%	100%	100%	100%	100%	100%	100%
5	WPC		96%	94%	100%	100%	100%	100%	95%	100%	100%	100%	93%	97%	100%
6	B&E		96%	100%	100%	100%	100%	100%	100%	99%	100%	100%	100%	100%	100%
7	Fuyu	Plastics	96%	96%	100%	100%	93%	100%	100%	100%	100%	100%	100%	100%	100%
8	MRPC		96%	100%	100%	100%	100%	100%	100%	100%	100%	98%	100%	100%	100%
9	FLEXTRONICS SHAH ALAM SDN BHD	PCBA	96%	100%	99%	98%	100%	100%	100%	97%	100%	100%	100%	98%	99%
10	CEI		96%	NA	NA	NA	NA	NA	NA	100%	NA	100%	100%	100%	100%

Remarks:

1) NA

Data Analysis – Quality Issues

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

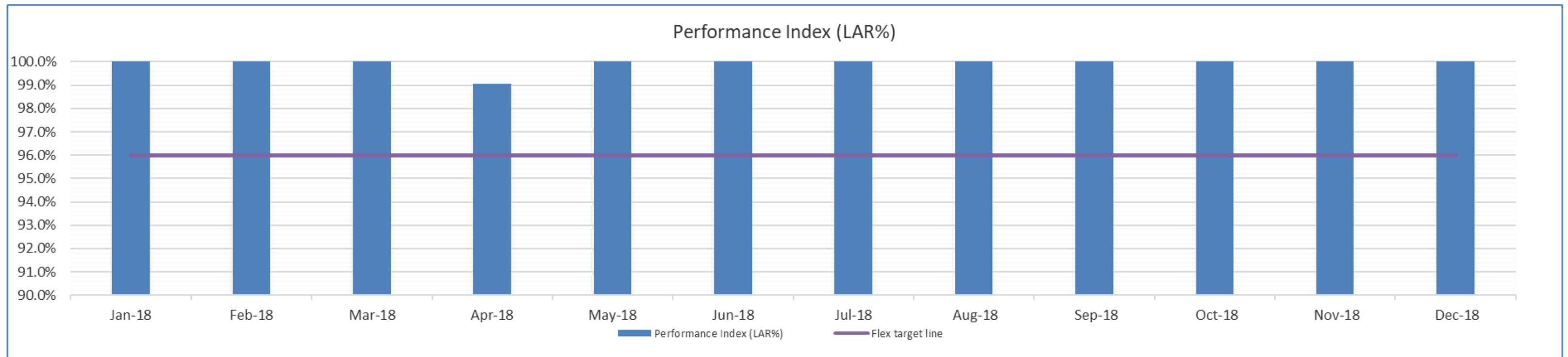
Vendor score below 96% LAR target

No	Supplier	Rejected Lot / Total Lot Received	LAR (%)	Part Number	Part Description	Defect Description	Disposition
1	NA	NA	NA	NA	NA	NA	NA

2. Data Analysis – Lot Acceptance Rate (LAR)

WATERS Machine shop Quality performance

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Performance Index (LAR%)	100.0%	100.0%	100.0%	99.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
No of lot inspected	78	65	68	105	81	89	80	73	92	96	63	90
No of lot accepted	78	65	68	104	81	89	80	73	92	96	63	90
Flex target line	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%



Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – dPPM

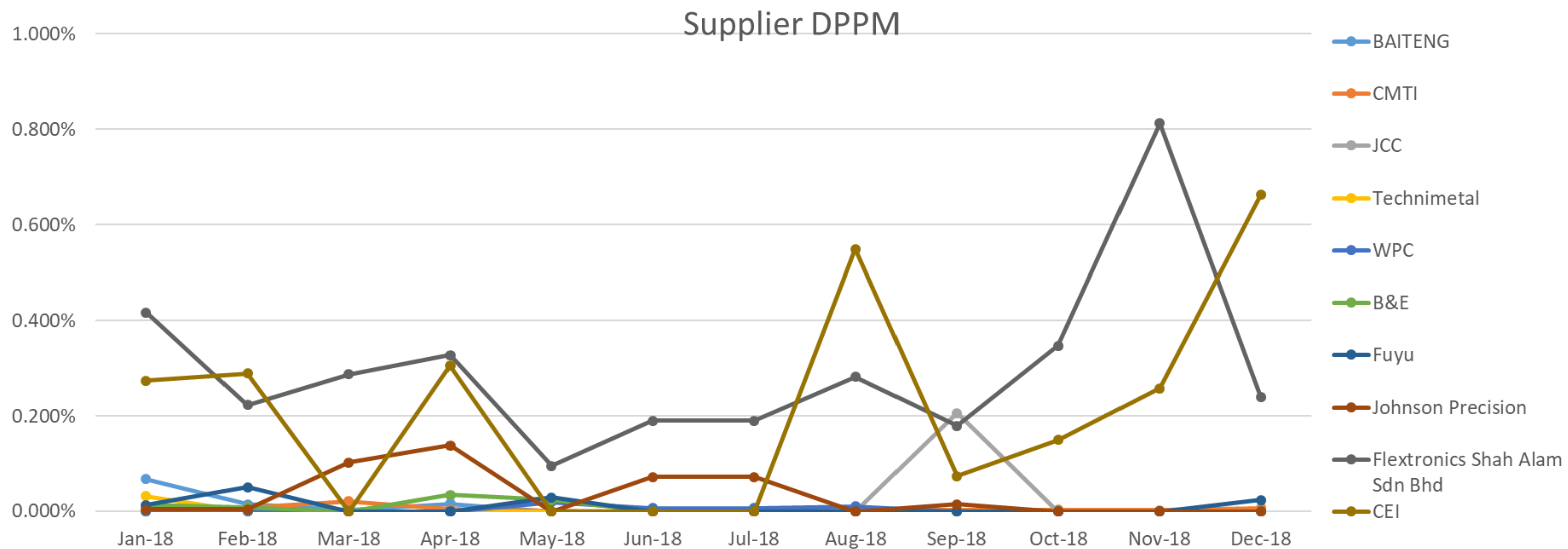
S/N	DPPM / Month	Target	Jan-18	Feb-18	Mar-18	'Apr-18	'May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
			%	%	%	%	%	%	%	%	%	%	%	%
1	BAITENG	0.500%	0.068%	0.015%	0.004%	0.016%	0.000%	0.000%	0.000%	0.000%	0.003%	0.000%	0.000%	0.000%
2	CMTI	0.500%	0.000%	0.008%	0.021%	0.004%	0.001%	0.000%	0.013%	0.005%	0.002%	0.003%	0.002%	0.007%
3	JCC	1.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.206%	0.000%	0.000%	0.000%
4	Technimetal	1.000%	0.032%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
5	WPC	1.000%	0.000%	0.000%	0.000%	0.000%	0.019%	0.007%	0.000%	0.010%	0.000%	0.000%	0.000%	0.000%
6	B&E	1.000%	0.013%	0.008%	0.000%	0.035%	0.024%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
7	Fuyu	1.000%	0.013%	0.051%	0.000%	0.000%	0.029%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.024%
8	Johnson Precision (MRPC)	1.000%	0.004%	0.004%	0.102%	0.139%	0.000%	0.072%	0.000%	0.000%	0.015%	0.000%	0.000%	0.000%
9	Flextronics Shah Alam Sdn Bhd	0.500%	0.417%	0.223%	0.288%	0.327%	0.095%	0.190%	0.245%	0.282%	0.179%	0.347%	0.812%	0.240%
10	CEI	1.000%	0.274%	0.289%	0.000%	0.305%	0.000%	0.000%	0.166%	0.549%	0.074%	0.150%	0.258%	0.662%

Remarks:

NA – No receipt of delivery

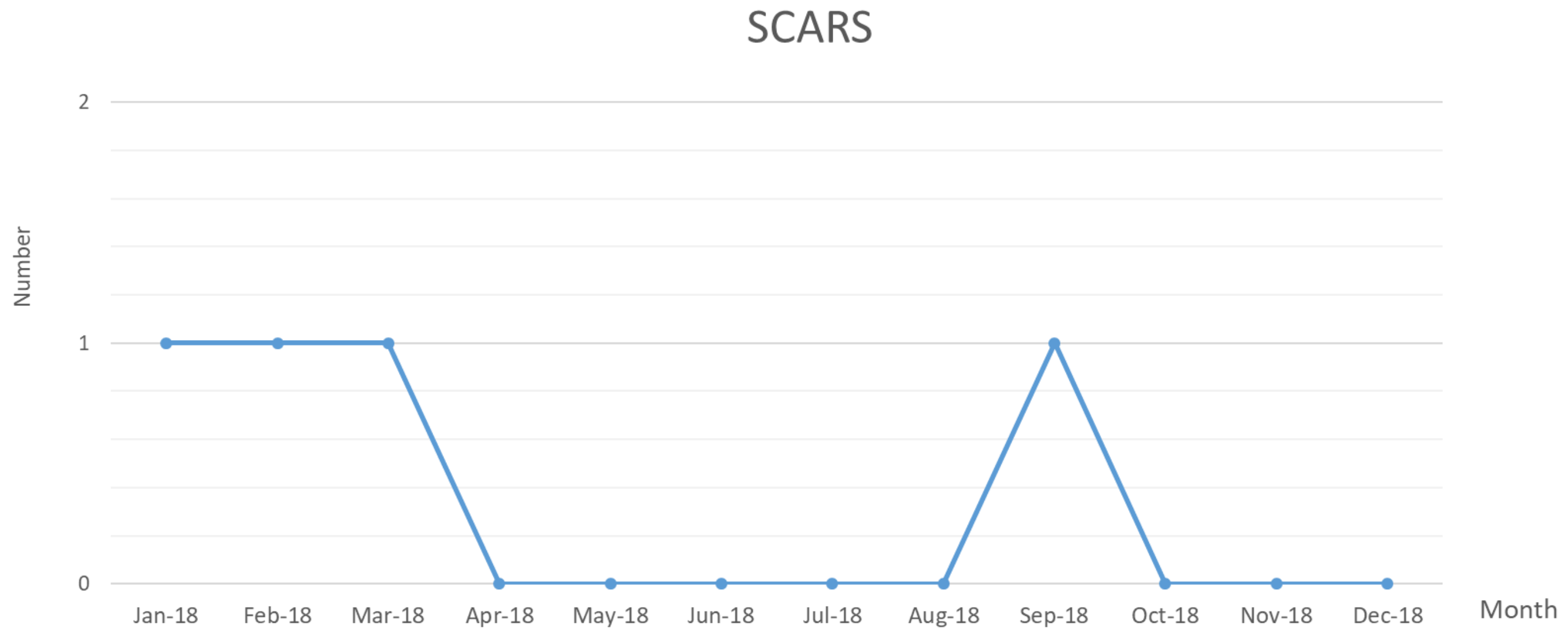
Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – dPPM



Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – SCARS



Data Analysis – Quality Issues

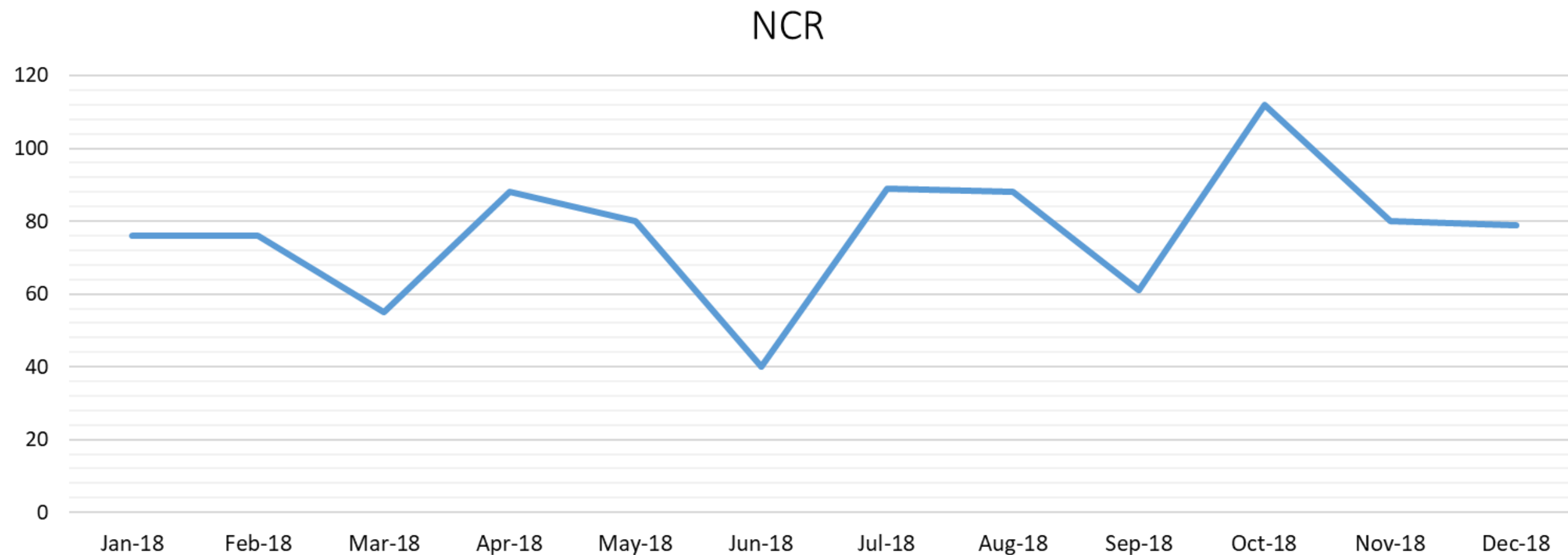
Quality Issues (Supplier) – SCAR Update / Action Taken on Supplier Sep '18 – Wrong connector

No	Supplier	Failure Mode / Issues	Action Plan	Owner	Target Date	Status
1	FLEXTRONICS SHAH ALAM SDN BHD	CA Number: CAR-SKW-00000052 CA issued date: 11-Sep-18 Part No: WAT-700005238-A Product: Part Description: SPARE, ASSY, PCB, PERSONALITY ACQUITY TUV Defect: The field service engineer found a problem on spare part 700005238 under serial no. 170118073M (engineering part no.210000414) with incorrect connector at location J28. The connector populated is male and it should be female. This connector is also used on 210000415 board.. Reject Qty: 1 pc Root Cause: 1. Based on the investigation with reference to RMA board, the wrong connector is used for another customer part which is produced by Senai. 2. The kitting date for the affected WO (210000414)-12pcs was done on 21st January 2018 while the other customer WO kitting was done on 9th November 2017 and 14th February 2018. This can conclude the kitting for the affected WO and the other customer was not done on the same day and there is long gap in between affected Waters's WO and the other customer's WO but somehow suspected there might be left over connector at kitting area from the other customer's kitting activity which was not returned to the store. It might be mixed during the kitting for the affected WO due to the similar physical. As for the current practice there is no line clearance or line buy-off done at the kitting area, which might be causing the kitting operator to overlook if any non-related component from the previous kitting activity available at that area. 3. As for the point of detection, can be divided into 4 stations as per below: a. Post Wave Inspection-The inspection document did not emphasize on the female and male differentiation checking criteria. b. ICT or FCT-No test coverage to differentiate the male and female connector. c. FVMI-The inspection document did not emphasize on the female and male differentiation checking criteria. d. FQA- The inspection document did not emphasize on the female and male differentiation checking criteria.	<u>Flex Senai</u> 1. To include actual picture of the RF connector and highlight the good connector in the inspection diagram and critical component checklist (CCL) for model 2100000414 & 210000415.-Done (05/10/18) 2. To generate Kitting line clearance form (SEN-MAT4033-00), to have a proper line clearance buy-off to avoid having component belong to other WO. -Done (2/11/18) Preventive Action: <u>Flex Senai</u> 1. To identify any other Waters model being populated with the RF connector and generate the retrospective review. -Done (24/09/18) 2. To modify the wave pallet to have a poke yoke clamp and update the Handload Process Manufacturing Assembly Instruction. -Done (03/12/18) 3. To update the Kitting line clearance form(SEN-MAT4033-00) into the Kitting Store Operation Procedure (SEN-MAT3008-00) and trained the related personal. -Done (04/12/18) <u>Flex Kallang</u> 1. PCBA spares received from Flex Senai to be packed at Flex Kallang. Done (07/12/18). Full package submitted. <u>Rejected on 04 Jan 19.</u> <u>Effectiveness check require for kitting line clearance form.</u> Target closure: 18 Jan 2019	Flex	08-Mar-19	Pending for closure

Data Analysis – Quality Issues

Quality Issues (Process - Material) – NCR (running 12 months)

	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
NCR	76	76	55	88	80	40	89	88	61	112	80	79



Data Analysis – Quality Issues

Quality Issues (Process - Material) – Repeated NCR / NCR Update

No	Supplier	Part No.	Part Description	Non-conformance	Defect Category	Non-Conformance Repeated		Rejected Qty	Out of Control Limit	Action Taken	Remark
1	AVNET ELECTRONICS MARKETING	WAT-WAT270148-00	ENCODER,HEDL-560	Non Conformance Description : Encoder unable to home	Test Failure	Nov'18	Dec'18	3	No	Failure Analysis Form WAT-RW-SKI05127 issued	Nov 18: 3 pcs
2	WATERS TECHNOLOGIES CORP.	WAT-405001338-B	NEEDLE,INJECTOR,M P35N	Non Conformance Description : Fail decay test spec ≤ 270 PSI	Test Failure	Nov'18	Dec'18	43	No	Under monitoring with P-chart	Nov 18: 7 pcs
3	PARKER HANNIFIN,PRECISION FLUIDICS DIVISION	WAT-WAT270524-02	GPV ASSEMBLY	Non Conformance Description : Inlet B, D no solvent flow during Solvent Inlet Plumbing Verification	Test Failure	Nov'18	Dec'18	5	No	Under monitoring with P-chart	Nov 18: 2 pcs
4	FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000355-F	ASSY, PCB, 2489 TUV PERSONALIT	Non Conformance Description : Display Malfunction	Test Failure	Nov'18	Dec'18	1	No	Under monitoring with P-chart	Nov 18: 1 pcs
5	FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000404-F	ASSY, PCB 2998 PDA PERSONALITY	Non Conformance Description : Failed to initialize	Test Failure	Nov'18	Dec'18	1	No	Under monitoring with P-chart	Nov 18: 1 pc
6	FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000416-K	ASSY, PCB 2690 FLUIDICS ROHS	Non Conformance Description : Needle malfunction failure during Rear Panel Test	Test Failure	Nov'18	Dec'18	1	Yes	Under monitoring with P-chart	Nov 18: 5 pcs
7	LAIRD TECHNOLOGIES (SEA) PTE LTD	WATH-289001192-D	ASSY, ENGINE, HEATER/COOLER	Non Conformance Description : Sample temp h/w faulty (3) during Heater/Cooler Test	Test Failure	Nov'18	Dec'18	1	No	Under monitoring with P-chart	Nov 18: 1 pc
8	WATERS TECHNOLOGIES CORP.	WATH-289003207-M	ASSY, CARTRIDGE, I2V, PLATE CL	Non Conformance Description : Failed Dynamic Leak Test	Test Failure	Nov'18	Dec'18	1	No	Under monitoring with P-chart	Nov 18: 1 pc

Data Analysis – Quality Issues

Audit Schedules

Supplier Audit Schedule 2018											
JAN		FEB		MAR		APR		MAY		JUN	
Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
N/A	N/A	N/A	N/A	+Season Malaysia	+Season Malaysia	*Greenpac	*Greenpac	N/A	N/A	*Armstrong Industrial	*Armstrong Industrial
Supplier Audit Schedule 2019											
JUL		FEB		MAR		APR		MAY		JUN	
Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
+CMTI *Flextronics Shah Alam		+B AND E Precision *Season Malaysia		+Kunshan Jieh Chueng Industrial *Tron Marketing *Zephyr Silkscreen Co.		+Fu Yu Corporation *Xcel Industrial Supplies		N/A	N/A	+Trend Singapore West *Hardware Speciality	

Remarks:

* – Common supplier

+ - Process Audit

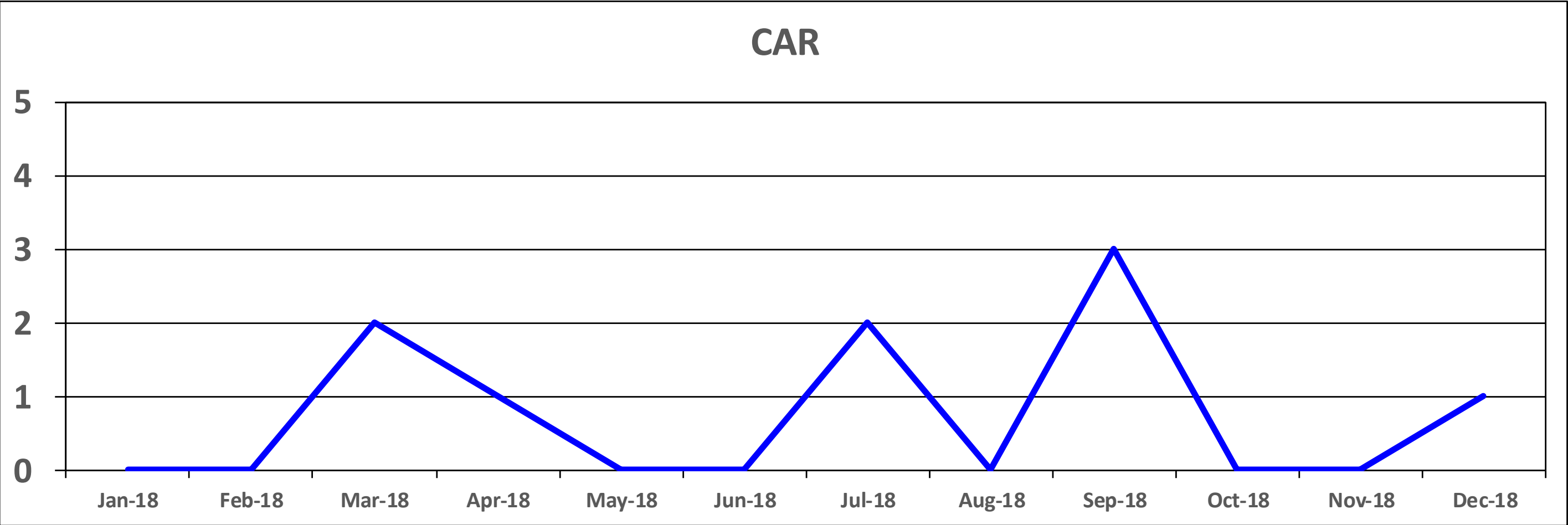
Data Analysis – Quality Issues

Audit Results, Findings and Closures

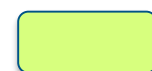
Armstrong Industrial Corporation Limited					
Category	Findings	Open	Close	Target to Close by	Status Update
NC	0	NA	NA	Dec-18	Closed

CAR Trending

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
CAR	0	0	2	1	0	0	2	0	3	0	0	1
Open	0	0	0	0	0	0	0	0	2	0	0	1
Closed	0	0	2	1	0	0	2	0	1	0	0	0



Product Family	Jan '18	Feb '18	Mar '18	Apr '18	May '18	Jun '18	Jul' 18	Aug '18	Sep' 18	Oct' 18	Nov' 18	Dec' 18	Remarks
Alliance	-	-	1	1	-	-	-	-	-	-	-	-	CAR 18-003: Mar'18 - 20u of PN 700001219 (Degasser Spare) were built with 289012691 (CHAMBER, DEGASSER, STENTED) instead of 289000622,(ASSY, DEGASSER, CHAMBER). – Closed CAR 18-007: Apr'18 - Collapse tubing of the red tube 430000922 – Closed
Detector	-	-			-	-	1	-	1	-	-	-	CAR 18-015: Jul'18 - DHR for Identification and Traceability - Closed CAR 18-018: Aug'18 – Incorrect front door label found on new PDA installed. – Open (CA extended, pend closure)
Solvent Manager	-	-	1		-	-	1	-	-	-	-	-	CAR 18-004: Mar'18 – Richport issue – Closed CAR 18-014: Jul'18 - Chassis Gasket Torn Defects found during DTS Inspection – Closed
PUMP	-				-	-	-	-	-	-	-	-	
Spares	-				-	-	-	-	1			1	CAR 18-019: Aug'18 - Window is not secured to holder. – Closed CAR 18-021: Sep'18 – PCBA 210000414 found Incorrect connector at location J28. – Open (CA extended, pend closure) CAR 18-025: Dec'18 - Alliance Enhancement kit package problem 700011805) – Open (final package to submit by 25 Jan 2019)



Closed



Open

Mislabeled PDA front door label

CAPA extended.
Pend closure.

Problem Statement	Investigation/ Possible Root Cause	Corrective Action/ Improvement Action																																																
Reported Date: 13 Aug 2018 Product: PN 186015032 (ACQUITY PDA) SN: D18UPD241A Qty: 1u Problem: Mislabeled PDA front door label seen at customer site in UK, pasted TUV Detector instead of PDA Detector. Manufacturing Date: Apr 2018	<u>Containment Actions:</u> <table><tr><th>Category</th><th>Containment Action</th><th>Result</th></tr><tr><td>Material Screening</td><td>1. Raw Material: All Detector labels inside Supermarket screened. 2. WIP/FG: All Detector instruments, including FG Stores, were screened to verify the product label.</td><td>No defect found. Refer to supporting slides</td></tr><tr><td>Training/Briefing</td><td>1. Production, FQA inspector and PQE (EA) were briefed about this Mislabeled issue. 2. Raised Q-Alert for Main Line Assy, Final test, FVMI and FQA</td><td>1. Completed by Ivy Marges on 14 Aug 2018 and Chua Kim Seng on 29 Aug 2018. 2. Completed by Ivy Marges on 13 Aug 2018.</td></tr><tr><td>IQA/SM</td><td>1. Raise Q-alert for briefing to SM and IQA to change the DTS for 2x parts to Inspection mode.</td><td>Completed by Ivy Marges on 03 Sep 2018.</td></tr></table> <u>Investigation:</u> <table><tr><th>Process</th><th>4M</th><th>Possible Cause</th><th>Found</th><th>Possible Cause Result? (Yes/No)</th><th>Opportunity for Improvement? (Yes/No/NA)</th></tr><tr><td>All</td><td>Man</td><td>1. Untrained Resources</td><td>1. Verified the production personnel were trained</td><td>No</td><td>No</td></tr><tr><td>Super mart</td><td>Material</td><td>1. Part mix-up due to too close to location. 2. No slot in KTE box for label</td><td>1. Part bins were located far away. Checked the inventory and no mix up was observed. 2. Designated KTE box with designated slot for label with P/N</td><td>No</td><td>Yes</td></tr><tr><td>Assembly /Test</td><td>Method</td><td>1. Part mix up during assembly</td><td>1. No mixed part observed 2. Assembly process is through One piece flow 3. Part kitting is through KTE for each instrument</td><td>No</td><td>Yes</td></tr><tr><td>Inspection</td><td>Method</td><td>1. Not checked as part of check list</td><td>1. Checklist is available at FVMI with picture of Label 2. Checklist is available at FQA with picture of Label</td><td>No</td><td>No</td></tr><tr><td>Packing</td><td>Method</td><td>1. Did not followed the procedure</td><td>1. There was one instance of standalone material transaction on PDA product label requested on the same day. It is possible that Super mart might have issued a wrong label. 2. There was no detection as inspection of product label is not part of current check list and requirement to check label prior to pack into Box. 3. Unable to interview and confirm the fact as packing operator has left the company.</td><td>Yes</td><td>Yes</td></tr></table>	Category	Containment Action	Result	Material Screening	1. Raw Material: All Detector labels inside Supermarket screened. 2. WIP/FG: All Detector instruments, including FG Stores, were screened to verify the product label.	No defect found. Refer to supporting slides	Training/Briefing	1. Production, FQA inspector and PQE (EA) were briefed about this Mislabeled issue. 2. Raised Q-Alert for Main Line Assy, Final test, FVMI and FQA	1. Completed by Ivy Marges on 14 Aug 2018 and Chua Kim Seng on 29 Aug 2018. 2. Completed by Ivy Marges on 13 Aug 2018.	IQA/SM	1. Raise Q-alert for briefing to SM and IQA to change the DTS for 2x parts to Inspection mode.	Completed by Ivy Marges on 03 Sep 2018.	Process	4M	Possible Cause	Found	Possible Cause Result? (Yes/No)	Opportunity for Improvement? (Yes/No/NA)	All	Man	1. Untrained Resources	1. Verified the production personnel were trained	No	No	Super mart	Material	1. Part mix-up due to too close to location. 2. No slot in KTE box for label	1. Part bins were located far away. Checked the inventory and no mix up was observed. 2. Designated KTE box with designated slot for label with P/N	No	Yes	Assembly /Test	Method	1. Part mix up during assembly	1. No mixed part observed 2. Assembly process is through One piece flow 3. Part kitting is through KTE for each instrument	No	Yes	Inspection	Method	1. Not checked as part of check list	1. Checklist is available at FVMI with picture of Label 2. Checklist is available at FQA with picture of Label	No	No	Packing	Method	1. Did not followed the procedure	1. There was one instance of standalone material transaction on PDA product label requested on the same day. It is possible that Super mart might have issued a wrong label. 2. There was no detection as inspection of product label is not part of current check list and requirement to check label prior to pack into Box. 3. Unable to interview and confirm the fact as packing operator has left the company.	Yes	Yes	1)Include barcode for the 6 label part number and scan into Flex-flow as poke yoke prior to paste the label to Instrument at Chassis assembly station. As of 12 Dec 2018 – 8 of 11 models implemented label verification. To be completed by CK Tan by 19 Dec 2018. 2) Enhance check list to include Inspection for the product label at final step prior to pack instrument into box at Packing station and Add “Remarks” field in the checklist to indicate, if any finding. To train all affected personnel on new check list. Completed by Gary Lai on 17 Sep 2018. 3) Product Label photo pasted in KTE Slot for easy check of correct label. Completed by Anil on 14 Sep 2018. 4)To study the feasibility of “Pick & Scan” using barcode scanner during material pick(1:1 issuance) TBD. 5) To train all production personnel on NCMR procedure, SKW-QMD2006-00. Completed by ST Wong on 02 Oct 2018. (Briefing conducted followed by Q-Alert – Completed by KS Chua on 21 Sep 18)
	Category	Containment Action	Result																																															
	Material Screening	1. Raw Material: All Detector labels inside Supermarket screened. 2. WIP/FG: All Detector instruments, including FG Stores, were screened to verify the product label.	No defect found. Refer to supporting slides																																															
Training/Briefing	1. Production, FQA inspector and PQE (EA) were briefed about this Mislabeled issue. 2. Raised Q-Alert for Main Line Assy, Final test, FVMI and FQA	1. Completed by Ivy Marges on 14 Aug 2018 and Chua Kim Seng on 29 Aug 2018. 2. Completed by Ivy Marges on 13 Aug 2018.																																																
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Observation from production line

CAPA extended.
Pend submit final package.

Problem Statement	Investigation/ Possible Root Cause	Corrective Action/ Improvement Action
<u>Reported Date:</u> 29 Nov 2018 <u>Product:</u> PN 186299800 <u>SN:</u> L18998760A & L18998761A <u>Qty:</u> 2x <u>Problem:</u> During Line walk Desmond Ann (WPPL) observed the product label for 186299800 not tally with the label displayed on the KTE box. <u>Manufacturing Date:</u> 28 Nov 2018	<u>Containment Actions:</u> The 2x of 186299800 at main line and 1x of 186299800 at supermarket were replaced immediately – Completed by Anil Kumar on 28 Nov 18 Verified other models and found all units using correct KTE boxes . No abnormality found Completed by KS Chua on 28 Nov 18 <u>Investigation:</u> There was a shortage of KTE boxes for 186299800 model with the increased detectors recovery plan and supermarket was in the process of creating additional KTE boxes. On that day, supermarket person used 186248900 KTE box to place 186299800 parts. This practice was immediately stopped. Briefing was done to both supermarket and production personnel.	1. To conduct briefing to production and supermarket personnel-Completed by Anil Kumar on 28 Nov 18 2. To verify other models for shortage of KTE boxes-Completed by Anil Kumar on 28 Nov 18. No shortage of KTE boxes. 3. To create sufficient KTE boxes for 299800 based on production schedule. To be completed by : Anil Kumar Target Date : 03 Dec 18

700005238 - Incorrect connector at location J28

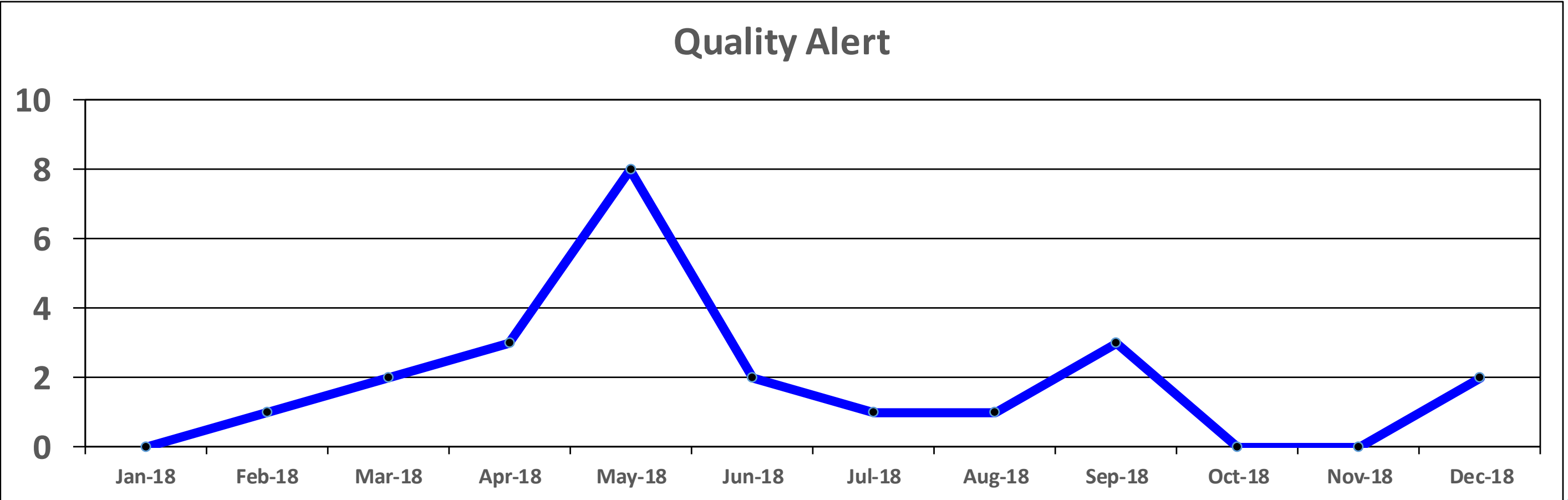
CAPA extended.
Pend closure.

Problem Statement	Investigation/ Possible Root Cause	Corrective Action/ Improvement
Reported Date: 21 Aug 2018 Product: 700005238 (spare part number for 210000414) SN: 170118073M (engineering part no.210000414) Qty: 1u Problem: Incorrect connector at location J28. The connector populated is male and it should be female. This connector is also used on 210000415 board. Manufacturing Date: Jan 2018	<u>Containment Actions:</u> 1. Purge notice raised for PCBA part number 210000414 & 210000415 and raw material part number 323000395. Screened through WIP, FG, RMA and raw material. Result: All OK. Completed on 23 Aug 2018 2. Quality alert generated on the wrong connector to create awareness to the inspection operator and trained the related personal. Completed on 21 Aug 2018 <u>Investigation:</u> 1. Based on the investigation with reference to RMA board, the wrong connector is used for another customer part which is produced by Senai. 2. The kitting date for the affected WO (210000414)-12pcs was done on 21st January 2018 while the other customer WO kitting was done on 9th November 2017 and 14th February 2018. This can conclude the kitting for the affected WO and the other customer was not done on the same day and there is long gap in between affected Waters's WO and the other customer's WO but somehow suspected there might be left over connector at kitting area from the other customer's kitting activity which was not returned to the store. It might be mixed during the kitting for the affected WO due to the similar physical. As for the current practice there is no line clearance or line buy-off done at the kitting area, which might be causing the kitting operator to overlook if any non-related component from the previous kitting activity available at that area. 3. As for the point of detection, can be divided into 4 stations as per below: a. Post Wave Inspection-The inspection document did not emphasize on the female and male differentiation checking criteria. b. ICT or FCT-No test coverage to differentiate the male and female connector. c. FVMI-The inspection document did not emphasize on the female and male differentiation checking criteria. d. FQA- The inspection document did not emphasize on the female and male differentiation checking criteria.	<u>Corrective Action</u> 1. To include actual picture of the RF connector and highlight the good connector in the inspection diagram and critical component checklist (CCL) for model 2100000414 & 210000415. Completed on 05 Oct 2018 2. To generate Kitting line clearance form (SEN-MAT4033-00), to have a proper line clearance buy-off to avoid having component belong to other WO. Completed on 02 Nov 2018 <u>Preventive Action:</u> Flex Senai Action 1. Identified other Waters model being populated with the RF connector and generated retrospective review. Completed on 24 Sep 18 2. Modified the wave pallet to have a poke yoke clamp and update the Handload Process Manufacturing Assembly Instruction. Completed on 03 Dec 18 3. Updated the Kitting line clearance form(SEN-MAT4033-00) into the Kitting Store Operation Procedure (SEN-MAT3008-00) and trained the related personal. Completed on 04 Dec 18 Flex Kallang Action 1. PCBA Spares are to be packed by Flex Kallang. The following PCBA Spares Part numbers are impacted: 700009329, WAT270919, 700005238, 700005420 and 700003761 Completed on 07 Dec 2018

In Process - Quality Alert

Quality Alert

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Quality Alert	0	1	2	3	8	2	1	1	3	0	0	2
Open	0	0	0	0	0	0	0	0	2	0	0	2
Closed	0	1	2	3	8	2	1	1	1	0	0	0



In Process - Quality Alert

Quality Alert Update

Dec'18:

Q-Alert Notice raised for IQA to do 100% inspection for 10 lots, to check for possible part mixed-up.

Q-Alert Notice		It is the Area/department representatives to retain Q-Alert Notice.	
EFFECTIVE DATE : FlexQ - On File			
Date	: 03 Jan 2019	Document No	: WAT-RW-SKI05099
Customer	: Waters Corporation	Document Rev	: B
Project Part Number	: 186269505, 186269506 700011805, 700011808	☐ New	☐ In House Originated
Affected Part Number	: WATH-279003850-D	☒	Customer/Supplier Feedback
Initiated by	: Ivy Marges		
Description / Sketches/Diagram :			
Issue: Customer feedback 1u wrong part packed in 700011805 - Kit, Alliance e2695 Enhancement Expected: 279003850 Wrong: WAT221-02			
1. IQA to do 100% inspection for 10 lots. 2. To verify no wrong part received. To reject if wrong part found.			

In Process - Quality Alert

Quality Alert Update

Dec'18:

Q-Alert Notice raised to Production.

> For Material Handler – to ensure to kit part from the correct part location

> For Spare Packing – to check PN 279003850 is correct before pasting label with Waters logo

Q-Alert Notice		It is the Area/department representatives to retain Q-Alert Notice.	
EFFECTIVE DATE : FlexQ - On File			
Date	: 18 Dec 2018	Document No	: WAT-RW-SKI05101
Customer	: Waters Corporation	Document Rev	: A
Project Part Number	: WAT-S-700011805	☐ New	☐ In House Originated
		☒ Customer/Supplier Feedback	
Affected Part Number	: WATH-279003850-D		
Initiated by	: Ivy Marges		
Description / Sketches/Diagram: Issue: Customer feedback lu wrong part packed in 700011805 - Kit, Alliance e2695 Enhancement Expected: PN 279003850 Wrong: WAT221-02 > Handload Process Instruction for 700011805 (Doc # WAT-RW-SKI04776) to update from rev C to D where; For PN: 279003850, not to paste label with Waters logo (as per below):  Instead, Flex Flow to scan the barcode on the supplier label (as per below):  > Before the ASP 700011805 (Doc # WAT-RW-SKI04776) released and implemented, Production to take note of below: Material Handler – to ensure to kit part from the correct part location Spare Packing – to check PN 279003850 is correct before pasting label with Waters logo			

In Process - Quality Alert

Quality Alert Update

Sep'18:

Q-Alert Notice raised for IQA and Supermart to be alert for possible mixed-up label. Also for IQA to take note and to change Product label part numbers in Dock-to-Stock to Inspection Mode.

Q-Alert Notice	It is the Area/department representatives to retain Q-Alert Notice.														
EFFECTIVE DATE : FlexQ - On File															
Date : 03 Sep 2018Document No : WAT-RW-SKI04937 Customer : Waters CorporationDocument Rev : A Project Part Number : 186015031, 186015032, 186015033, 186015034, 186015053 186017003, 186017013, 186299800, 186017002, 186017012, 186248900 ☐ New☐ In House Originated ☒ Customer/Supplier Feedback Affected Part Number : WATH-615003779-D, WATH-615004414-D, WATH-615004415-D WATH-615003951-E, WATH-615003737-E, WATH-615004496-B Initiated by : Ivy Marges															
Description / Sketches/Diagram : Issue: Customer feedback one unit of 186015032 (Instrument SN: D18UPD241A) has a wrong product label pasted on unit.															
<table><tr><th>Product label PN</th><th>Expected label content</th></tr><tr><td>WATH-615003779-D</td><td>PDA Detector</td></tr><tr><td>WATH-615004414-D</td><td>2998 PDA Detector</td></tr><tr><td>WATH-615004415-D</td><td>2489 UV/Vis Detector</td></tr><tr><td>WATH-615003951-E</td><td>PDA e2_s Detector</td></tr><tr><td>WATH-615003737-E</td><td>TUV Detector</td></tr><tr><td>WATH-615004496-B</td><td>PDA TS Detector</td></tr></table>	Product label PN	Expected label content	WATH-615003779-D	PDA Detector	WATH-615004414-D	2998 PDA Detector	WATH-615004415-D	2489 UV/Vis Detector	WATH-615003951-E	PDA e2 _s Detector	WATH-615003737-E	TUV Detector	WATH-615004496-B	PDA TS Detector	• IQA and Supermart to be alert for possible mixed-up label. • IQA to take note to change Product label part numbers in Dock-to-Stock to Inspection Mode. • Request IQA to monitor.
Product label PN	Expected label content														
WATH-615003779-D	PDA Detector														
WATH-615004414-D	2998 PDA Detector														
WATH-615004415-D	2489 UV/Vis Detector														
WATH-615003951-E	PDA e2 _s Detector														
WATH-615003737-E	TUV Detector														
WATH-615004496-B	PDA TS Detector														

In Process - Quality Alert

Quality Alert Update

Sep'18:

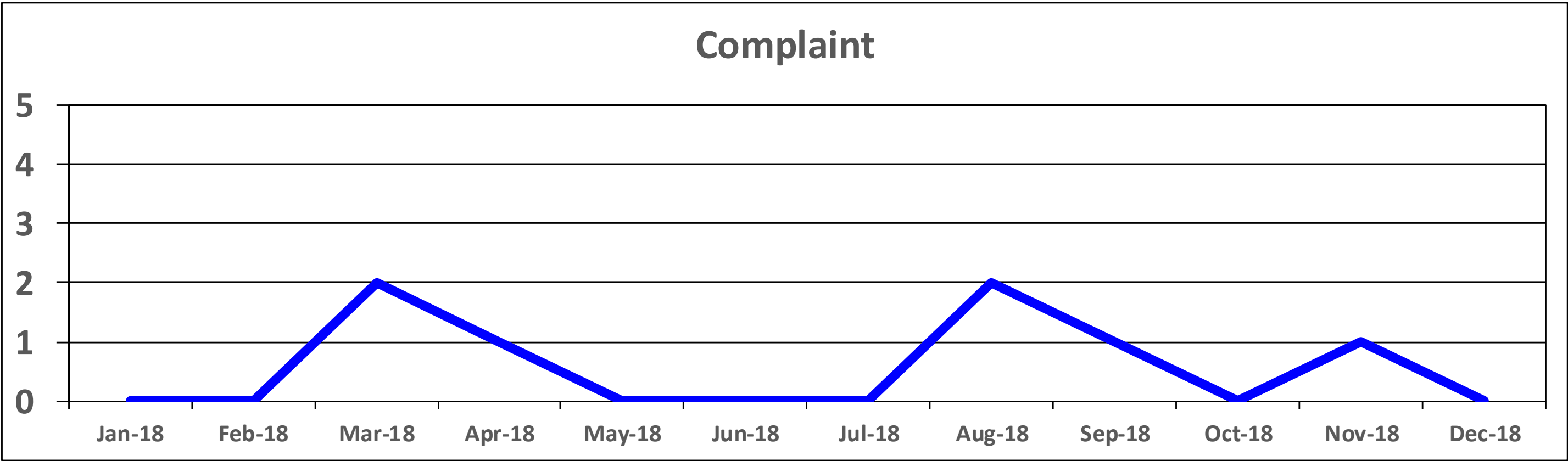
Q-Alert Notice raised to all Production personnel for proper execution when non conforming material detected as per NCMR procedure.

Q-Alert Notice		It is the Area/department representatives to retain Q-Alert Notice.	
EFFECTIVE DATE : FlexQ - On File			
Date : <u>18 Sep 2018</u>		Document No : <u>WAT-RW-SKI04953</u>	
Customer : <u>Waters Corporation</u>		Document Rev : <u>A</u>	
Project Part Number : <u>Applies to all Project Part number</u>		☐ New ☐ In House Originated	
Affected Part Number : <u>Applies to all Part number</u>		☒ Customer/Supplier Feedback	
Initiated by : <u>Ivy Marges</u>			
Description / Sketches/Diagram : <u>Problem:</u> One label was requested from store from the line. Not able to trace what happened to the original label. <u>Referring to Nonconforming Material Procedure (SKW-QMD2006-00)</u>		<u>Definition:</u> 4.5.4 Material – Material is a term that is generically used for components, manufacturing materials, in- process devices, finished devices, and returned devices. 4.5.14 Defective Part Trigger Form – This is a form use for tagging on nonconformance material to act as a traveler tag. The tag shall be dispose off together with the nonconformance material. <u>Execution (what operator needs to do):</u> 6.1.2 When Nonconforming Material is detected, proper identification is important to prevent mix-ups and inadvertent distribution or further use. The following forms of identification and segregation (or equivalent) are required: 6.1.2.1 NC Labels or forms attached to the nonconforming material; • Note: NC labels can be a DPTF. <u>Execution (what NC writer will do):</u> 6.2.1 Nonconforming material is entered and processed in FlexQ.	

Customer & Field Complaints

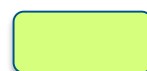
Customer & Field Complaints Trending

Month	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Complaint	0	0	2	1	0	0	0	2	1	0	1	0
Open	0	0	0	0	0	0	0	1	1	0	1	0
Closed	0	0	2	1	0	0	0	1	0	0	0	0



Customer & Field Complaints

Product Family	Month	Jan'18	Feb'18	Mar'18	Apr'18	May'18	Jun'18	Jul'18	Aug'18	Sep'18	Oct'18	Nov'18	Dec'18	Total Feedback	Remarks
Alliance	Field Feedback	-	-	2	1	-	-	-	-	-	-	-	-	3	Mar'18 - Solaris Pharma Corporation 2695EB Alliance SN K17SM4227A & M17SM4930A: start up failures –closed Mar'18 - Solvent Filter (WAT025531) rusty issue –closed Apr'18 - 2695 Red Tube OFI -430000922 -poor cut issue summary –closed
Detector	Field Feedback	-	-	-	-	-	-	-	1	-	-	-	-	1	Aug'18 – Incorrect front door label found on new PDA installed. – open (CA extended, pend closure)
Solvent Manager	Field Feedback	-	-	-	-	-	-	-	-	-	-	-	-	0	NA
PUMP	Field Feedback	-	-	-	-	-	-	-	-	-	-	-	-	0	NA
Spares	Field Fieldback	-	-	-	-	-	-	-	1	1	-	1	-	3	Aug'18 - Window is not secured to holder. – Closed Sep'18 - Incorrect connector at location J28. – Open (CA extended, pend closure) Nov'18 - Alliance Enhancement kit package problem 700011805 – Open. Final Package to submit by 25 Feb 2019.



Closed



Open

QMS Update

NA

- 1. Needle (PN 405001338) evaluation updates and selective photos under 40x magnification**
- 2. eDHR update**
- 3. MTR Field Data**

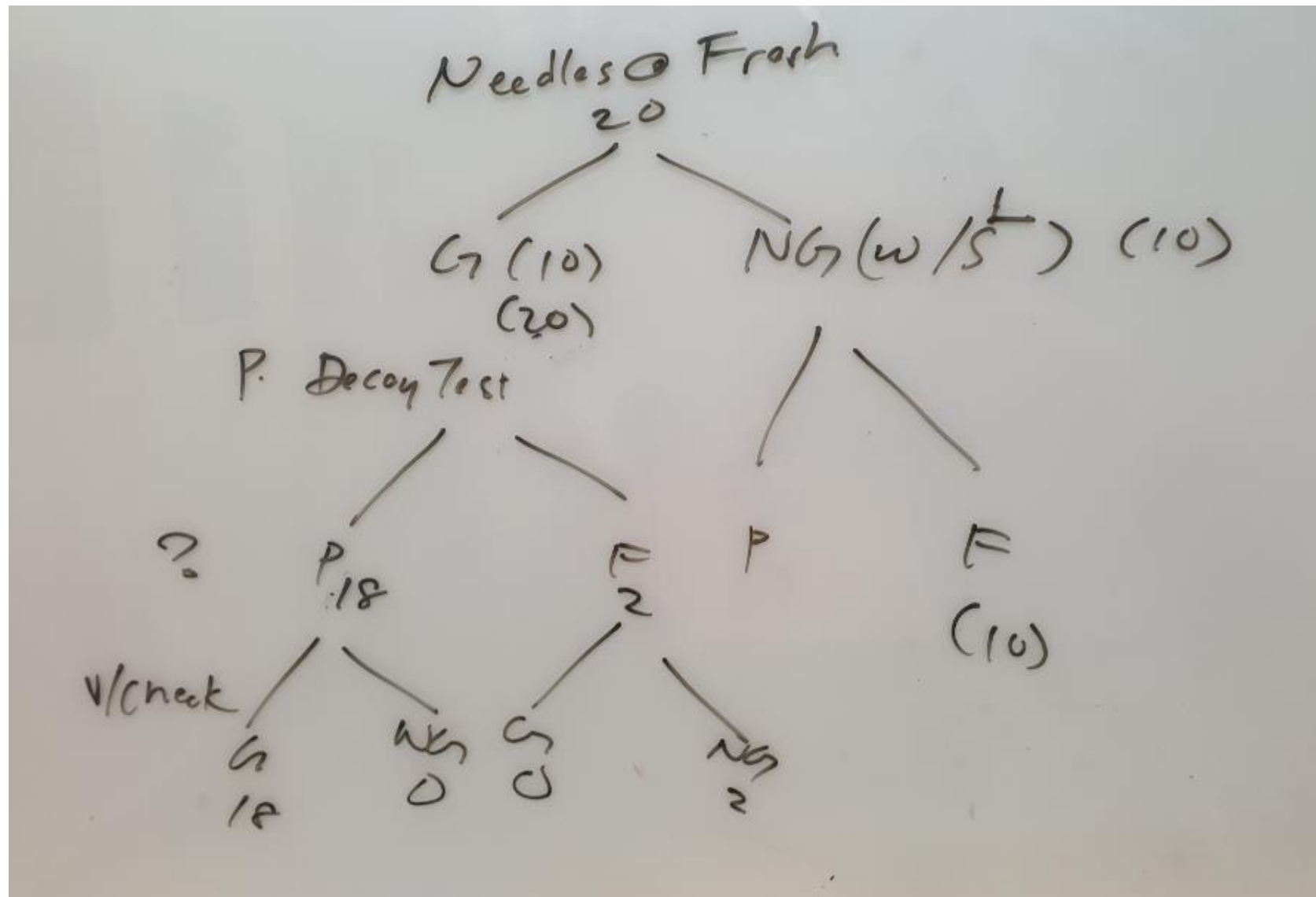
Evaluation of 405001338 Needle

17 Jan 2019

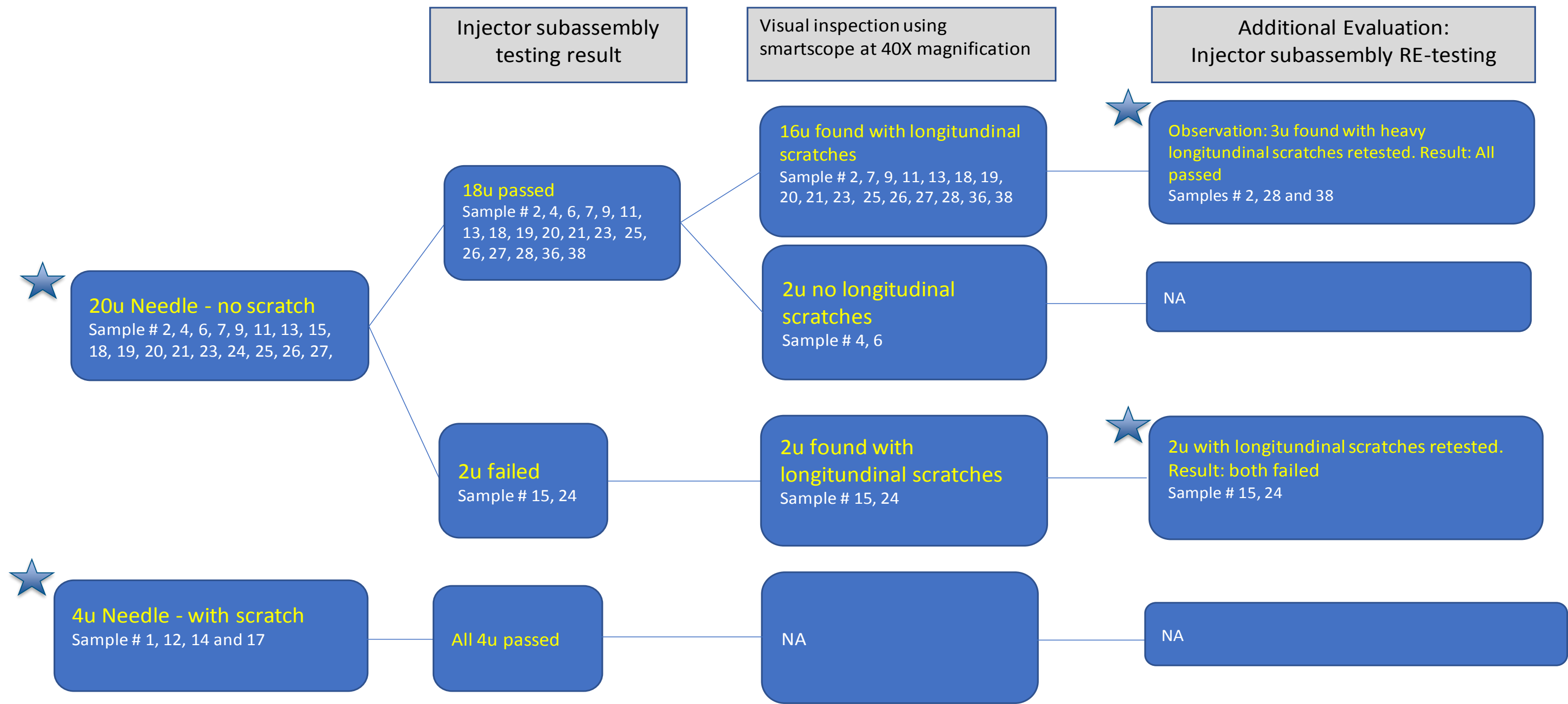
405001338 Needle

Background:

- On 11 Jan 2019 evening, Eugene provided a base (guideline), to evaluate on the 10% failures reported at Alliance Injector Sub-assy in WW01-2019.



405001338 Needle – Summary of Evaluation



★ Refer to next few slides for the smart scope images

405001338 Needle

Comments (from evaluation):

- Needle (before assy) - About 50% of the needles found with scratches when checked under 40x magnification.
- Needle (after assy) - Majority of the known good (no scratches) fresh needle are found with longitudinal scratches after testing.
- Needle without scratches before assy → 2 / 20 Failed Decay Testing.
- Needle with scratches before assy → 0/4 Failed Decay Testing.

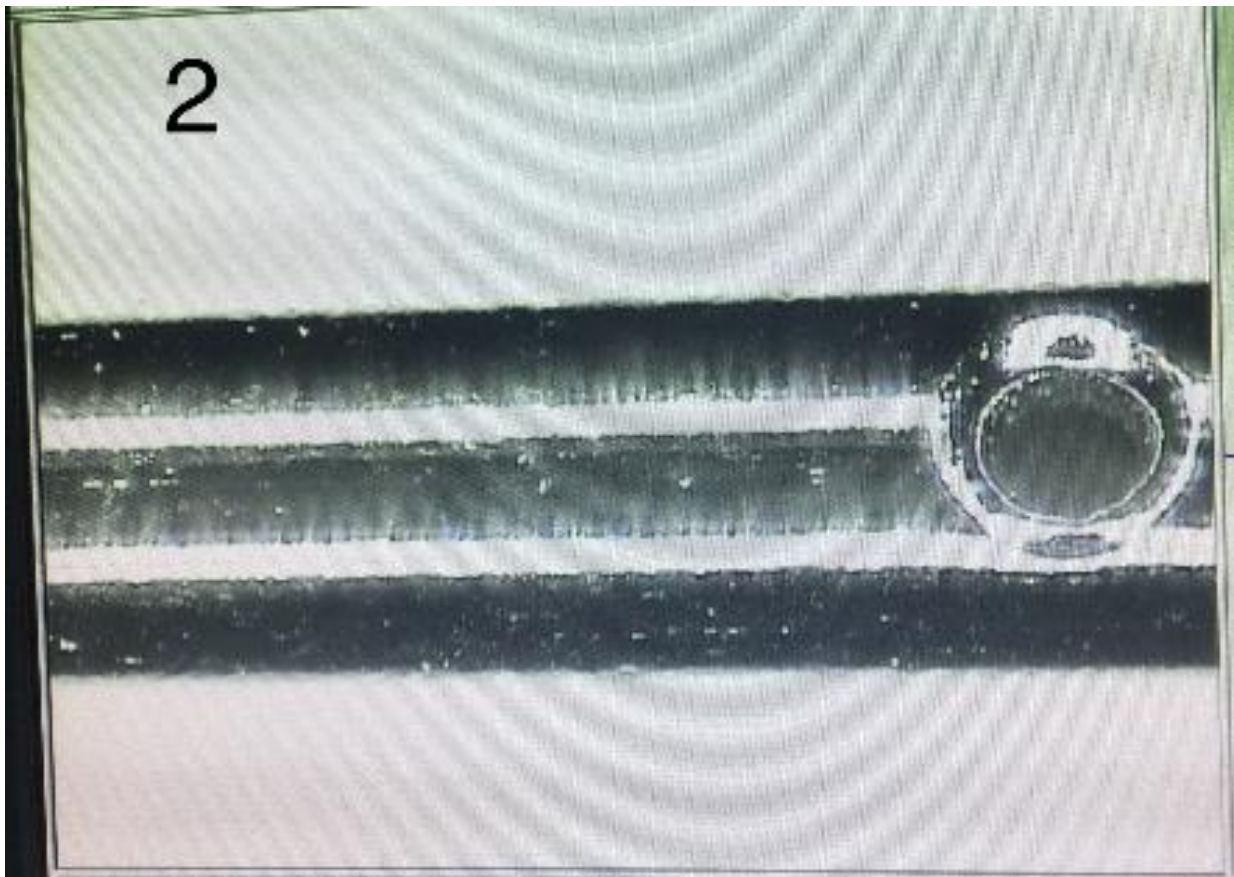
Action still in -progress:

- “Rough surface” observed inside the holes on Seal Pak components, checked under 25x magnification, for 3 out of 5 parts, at Flex premise.
- Working with suppliers (Keypoint and Yangbum).

405001338 Needle – scratch observed after assembly

Before Evaluation:

Visual – No scratch (40x mag)



No longitudinal scratches observed

After Evaluation:

Visual - Scratch observed (40x mag)

Decay Test – PASS

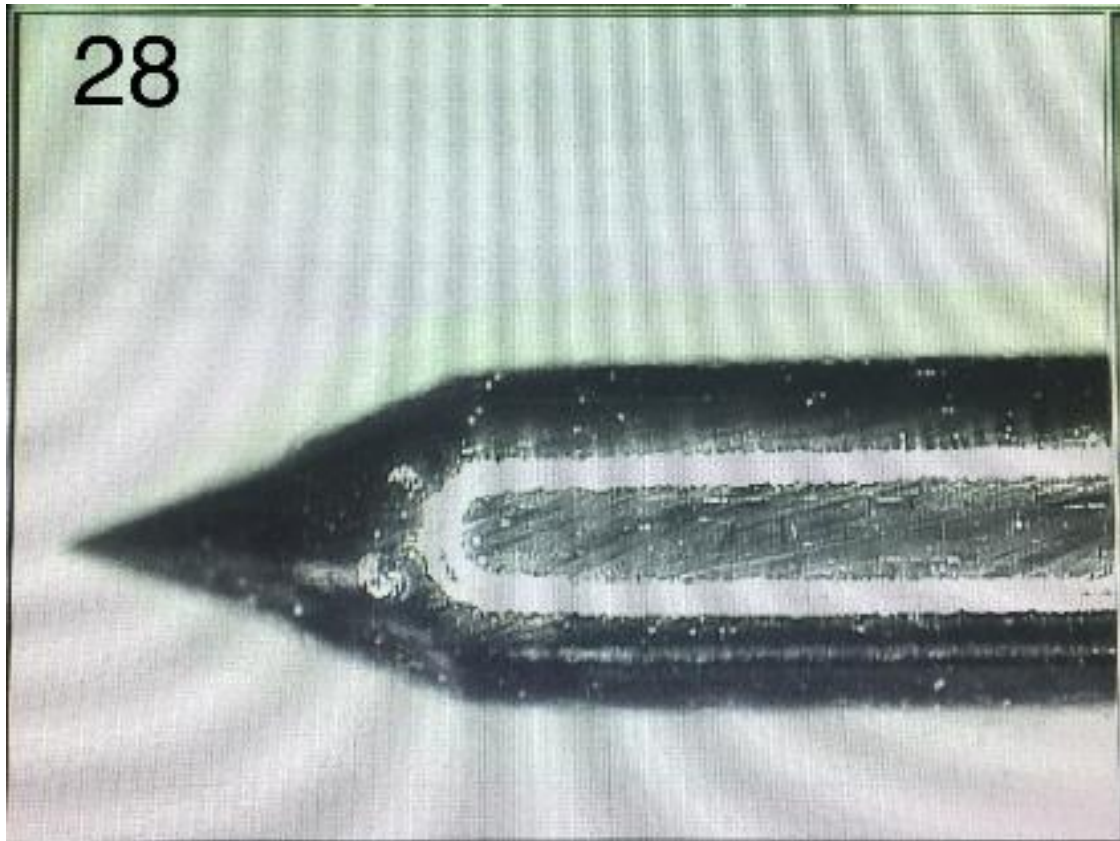


Longitudinal scratches observed

405001338 Needle –scratch observed after assembly

Before Evaluation:

Visual – No scratch (40x mag)



No longitudinal scratches observed

After Evaluation:

Visual - Scratch observed (40x mag)

Decay Test – PASS



Longitudinal scratches observed

405001338 Needle – scratch observed after assembly

Before Evaluation:

Visual – No scratch (40x mag)

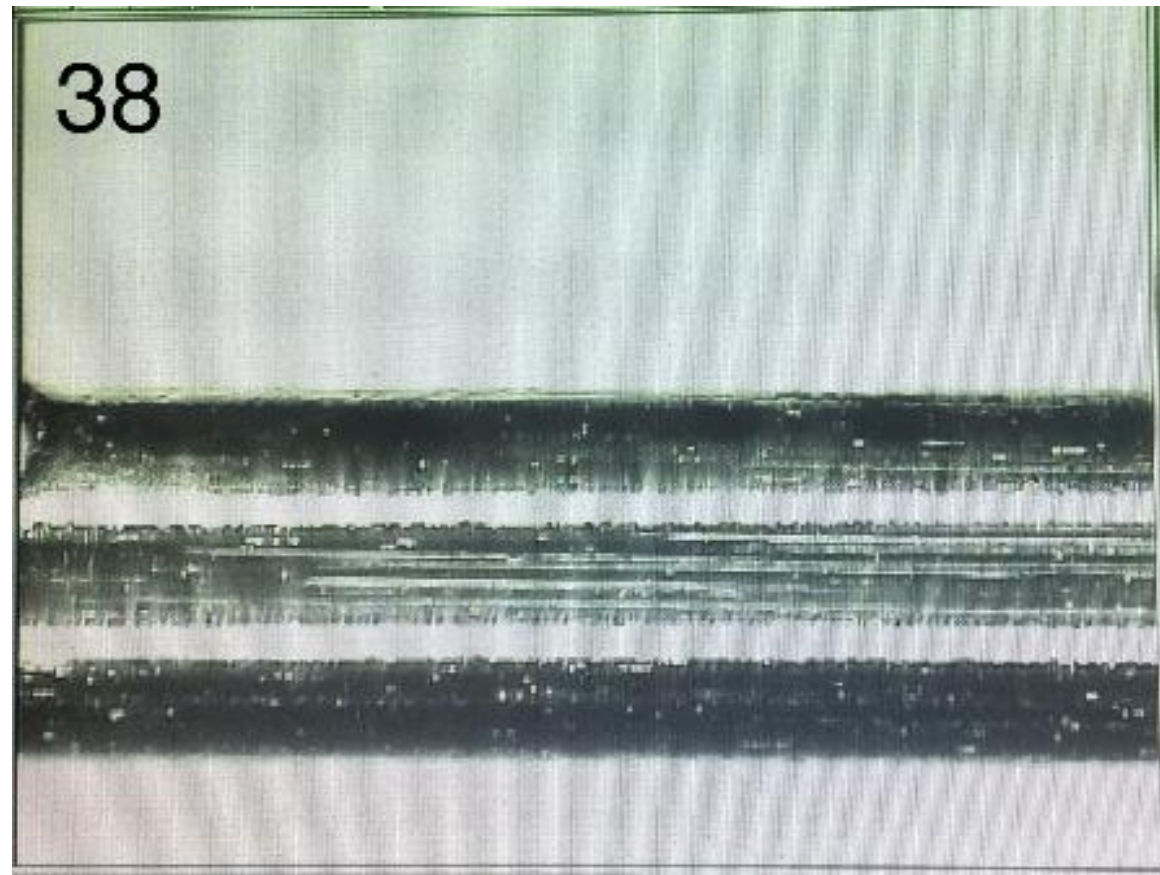


No longitudinal scratches observed

After Evaluation:

Visual - Scratch observed (40x mag)

Decay Test – PASS



Longitudinal scratches observed

405001338 Needle – scratch observed before and after assembly

Before Evaluation:

Visual – No longitudinal scratch



Before testing no longitudinal scratches (but 'slanted' scratches observed)

After Evaluation:

Visual – Longitudinal Scratch observed

Decay Test – **FAIL**

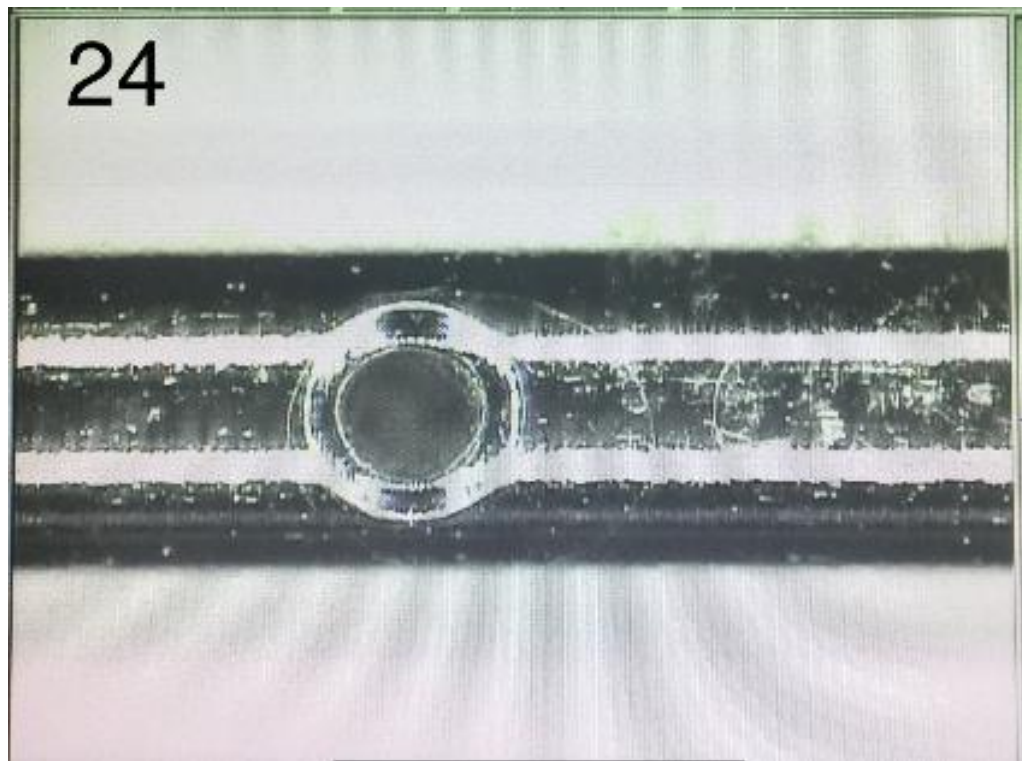


Longitudinal scratches observed

405001338 Needle – scratch observed before and after assembly

Before Evaluation:

Visual – No longitudinal scratch



Before testing, no longitudinal scratches observed but circular scratches observed near the needle hole as per above photo.

After Evaluation:

Visual – Longitudinal Scratch observed

Decay Test – **FAIL**



Longitudinal scratches observed

405001338 Needle – scratch observed before assembly

Before Evaluation:

Visual – Longitudinal scratch observed



Before testing, longitudinal scratches observed

After Evaluation:

Visual – did not perform check.

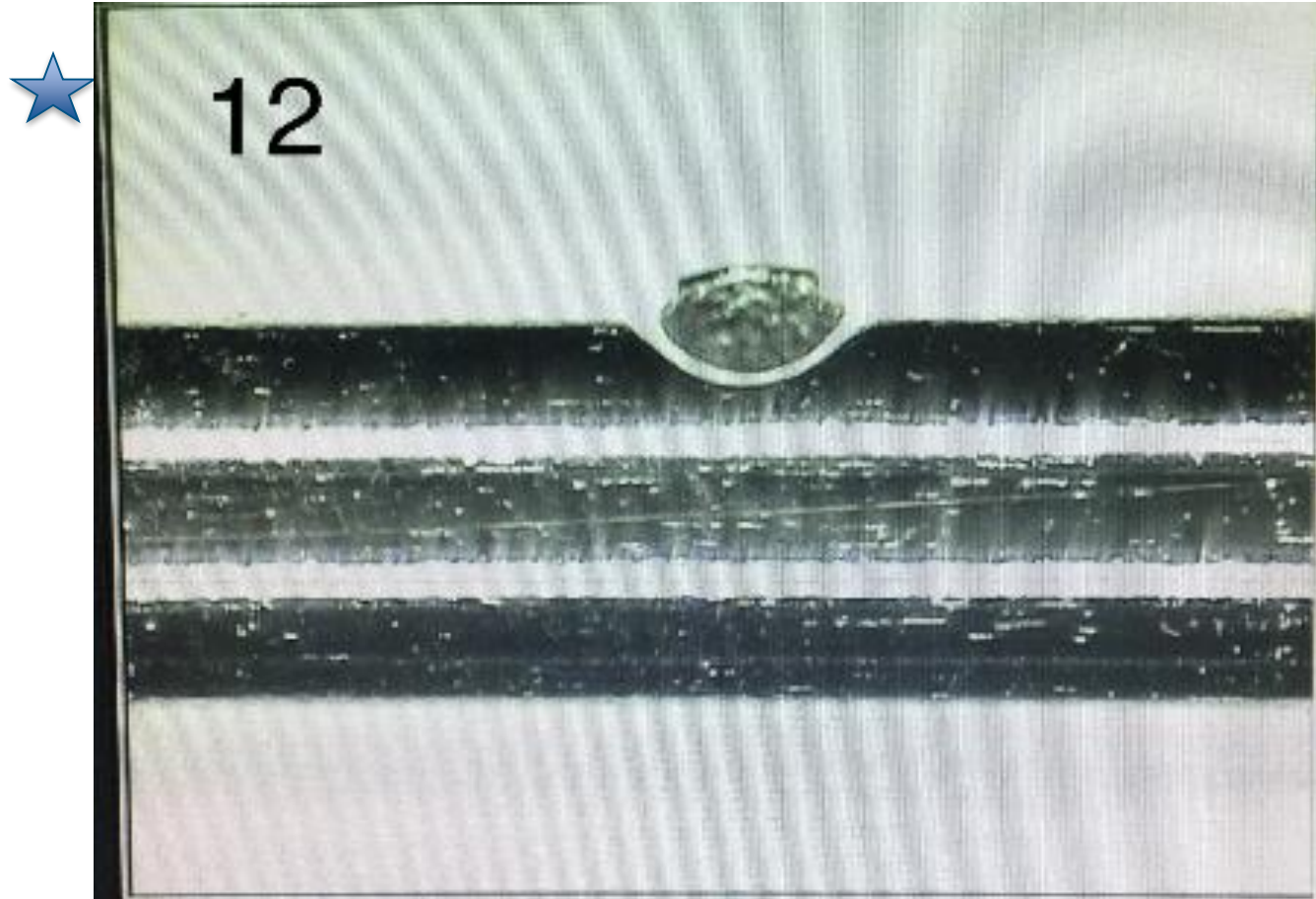
Decay Test – PASS

Did not remove needle from Assy

405001338 Needle – scratch observed before assembly

Before Evaluation:

Visual – Longitudinal scratch observed



Before testing, longitudinal scratches observed

After Evaluation:

Visual – did not perform check.

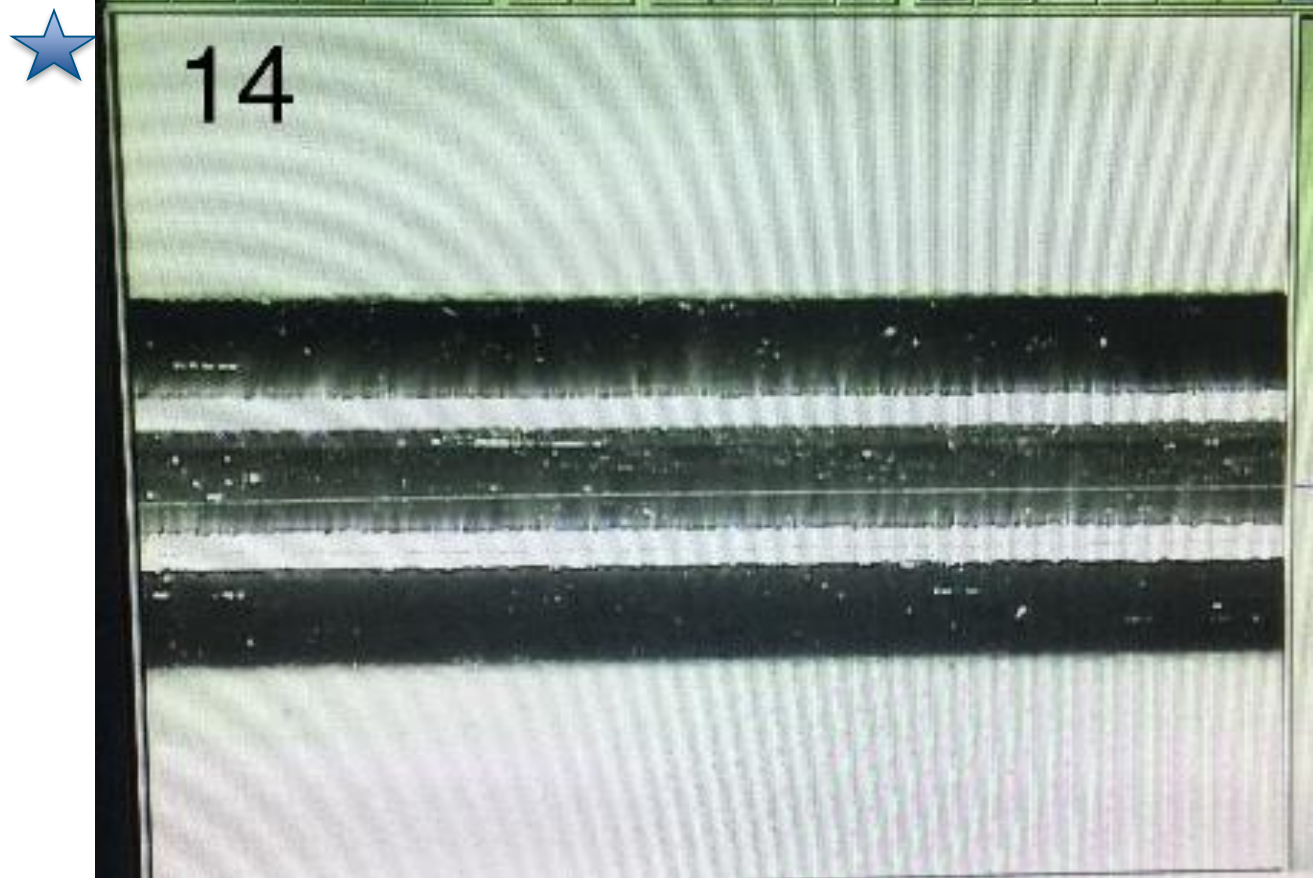
Decay Test – PASS

Did not remove needle from Assy

405001338 Needle – scratch observed before assembly

Before Evaluation:

Visual – Longitudinal scratch observed



Before testing, longitudinal scratches observed

After Evaluation:

Visual – did not perform check.

Decay Test – PASS

Did not remove needle from Assy

405001338 Needle – scratch observed before assembly

Before Evaluation:

Visual – Longitudinal scratch observed



Before testing, longitudinal scratches observed

After Evaluation:

Visual – did not perform check.

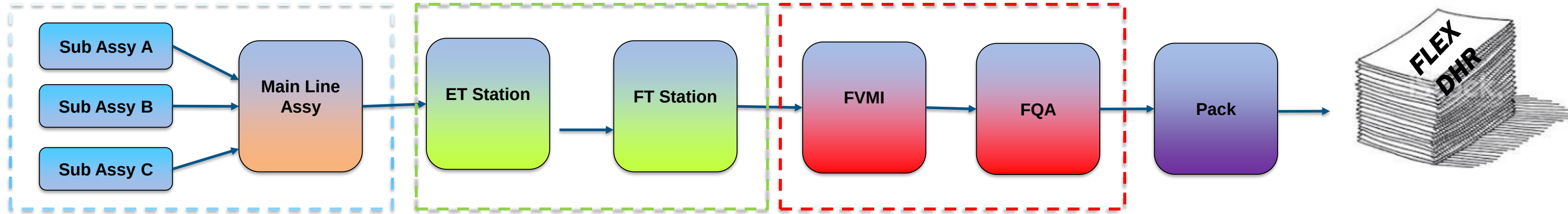
Decay Test – PASS

Did not remove needle from Assy

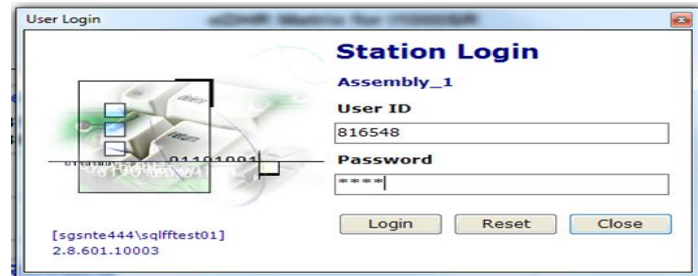


Waters Overall Continuous Improvement Plan - eDHR

22 Jan 2019



User control – Only certified user can access



Improve GDP

- Barcode scanning
- Data is less prone to GDP errors

Latest Revision of Work Instruction

- Ensure operator is referring to the correct Work Instruction (WI) (including Revision)

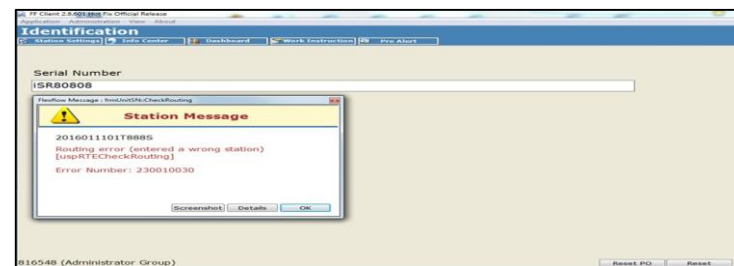
Time Sensitive Material Poka Yoke

- Automated checking for expiry date of Time Sensitive Material
- Lot number & expiration date will be recorded.

Essential Info Captured

- Technician Identity
- Date of Manufacturing
- Critical Part information
- Quality Checks and Quality Alert
- Test data (Dependent on customer access)
- Label Used

No Duplicate Serial Number

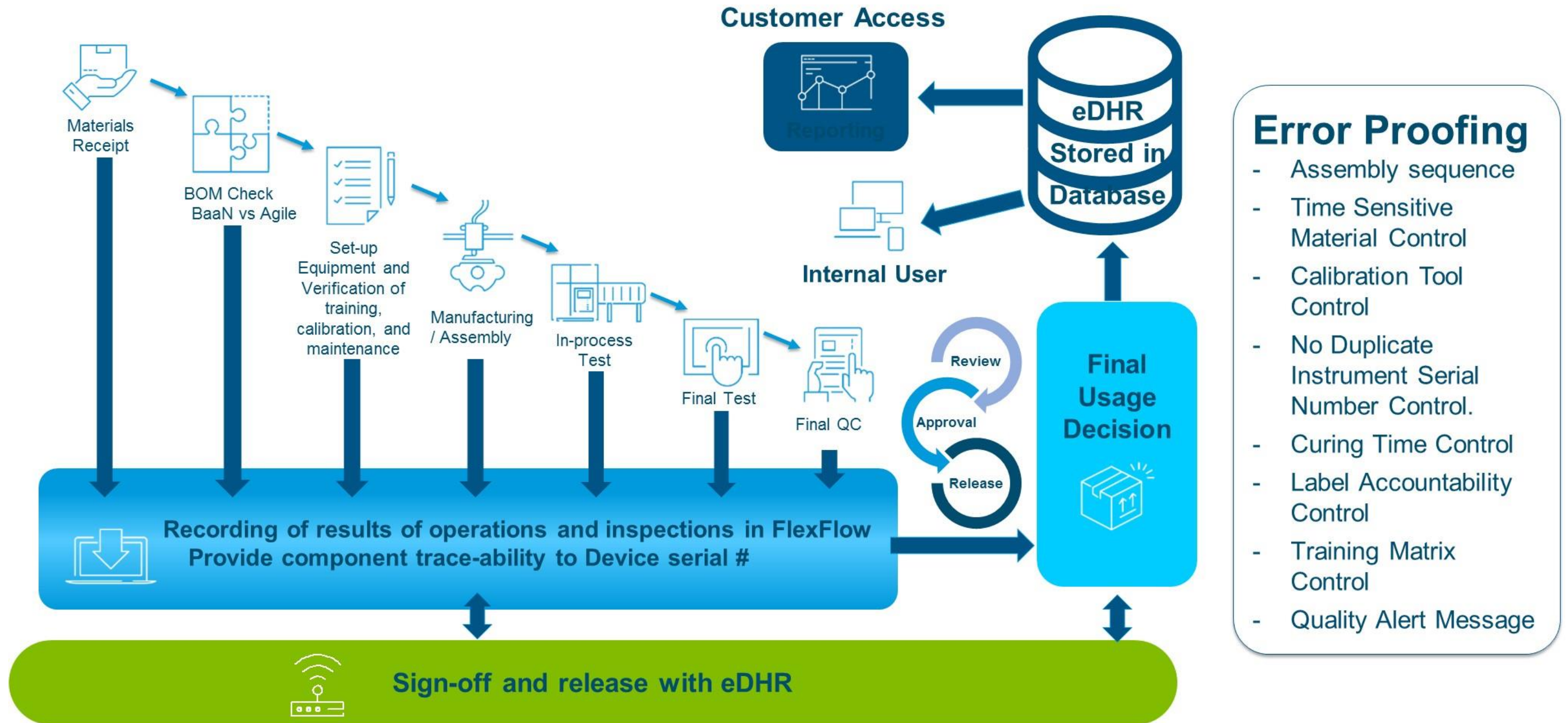


Curing Time Poka Yoke

- Control the curing start & end time

Calibrated Tools Poka Yoke

- Automated checking against due date of Calibrated equipment
- Calibration due date & Equipment ID will be recorded



SI No.	Activity	May'18	Jun'18	Jul'18	Aug'18	Sep'18	Oct'18	Nov'18	Dec'18	Jan'19	Feb'19	Mar'19	Apr' 19	May' 19
1	eDHR (Alliance) Project Kick Off Meeting with internal team.													
2	Identify requirements. Map details of manual DHR - Alliance													
3	Approval from IT for system readiness to implement eDHR													
4	IT to develop customized eDHR function into version 2.9													
Assembly records DHR to eDHR														
5	Creation of the eDHR matrix - Alliance			Plan	On-hold									
6	Identify requirements. Map details of manual DHR – BSM / QSM													
7	Share the details for further inputs – With WPPL													
8	Creation of the eDHR matrix - BSM / QSM													
9	Testing of eDHR matrix in test server													
10	Share the details for further inputs after test – With WPPL													
11	V & V – Protocol creation (User interface level validation)													
12	V & V – Protocol creation (Corp System level validation) *newly added													
14	V & V – Compilation of User inference & Corp System protocol													
15	V & V of the system – Protocol reports review with WPPL													
16	Finalize the eDHR matrix and validation reports with WPPL.													
17	Communication and training													
18	Go Live eDHR for QSM (in addition to manual DHR)													
19	Removal of manual DHR													

SI No.	Activity	May'18	Jun'18	Jul'18	Aug'18	Sep'18	Oct'18	Nov'18	Dec'18	Jan'19	Feb'19	Mar'19	Apr' 19	May' 19
Test reports from SigmaSure to eDHR shall be planned after QSM eDHR implementation														
1	Creation of proposal to pull test reports from SigmaSure to eDHR													
2	Review of networking and web storage of eDHR													
3	Review & Approval of feasibility by Waters													
4	System enhancement to allow SigmaSure access by eDHR													
5	Verification of test reports in eDHR													
6	Communication and training													
7	Go Live (in addition with test reports)													

MTR Field Data Nov 2018

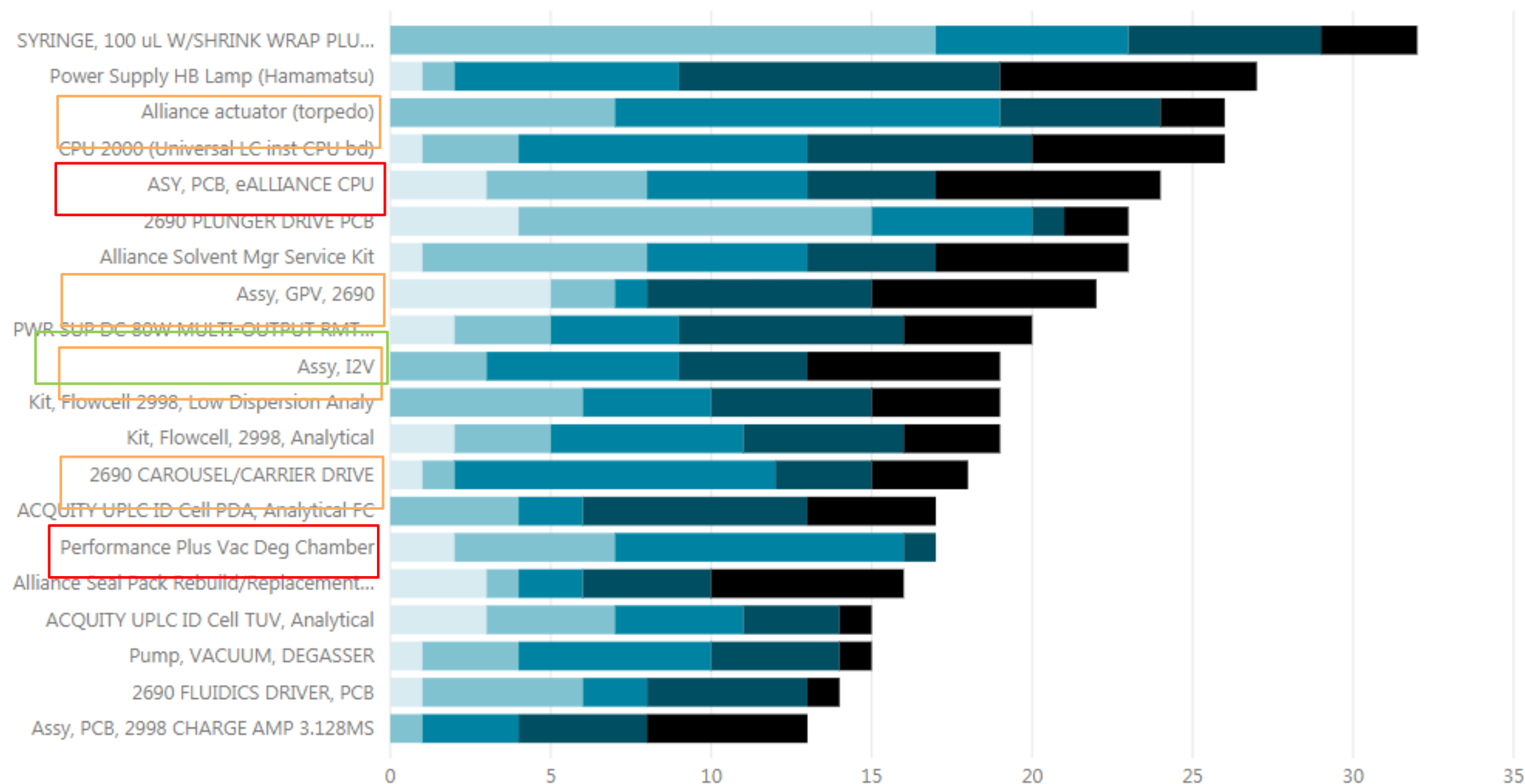
PIM Team

Jan 2019

Flextronics – Parts usage 0-90 days, Mfd Jul 2017 – Dec 2018

FSR count of 0-90 day level 4 part replacements

YrQtr Replaced 2017Q4 2018Q1 2018Q2 2018Q3 2018Q4



Milford Part

Waters Investigation

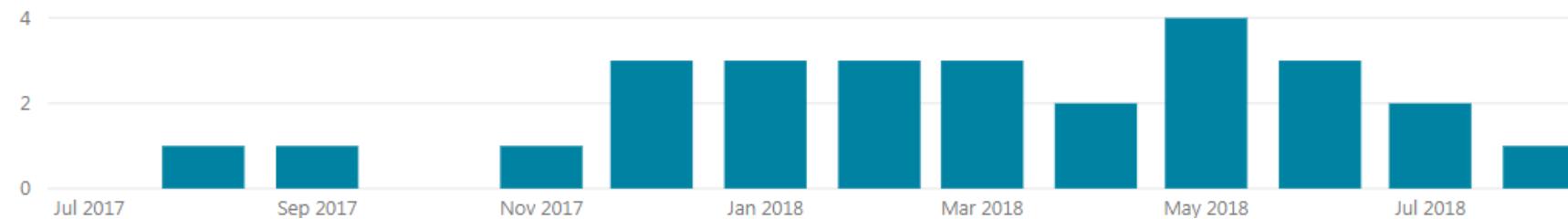
CMO Investigation
Requested

Level 4 part
replacements

Flextronics - Actions

- Product Improvement Management team now involved in Monthly Technical Reviews
- HB Lamp PSU (Hamamatsu) – 700002785 / 279001105

0-90 Day FSR count by DOM

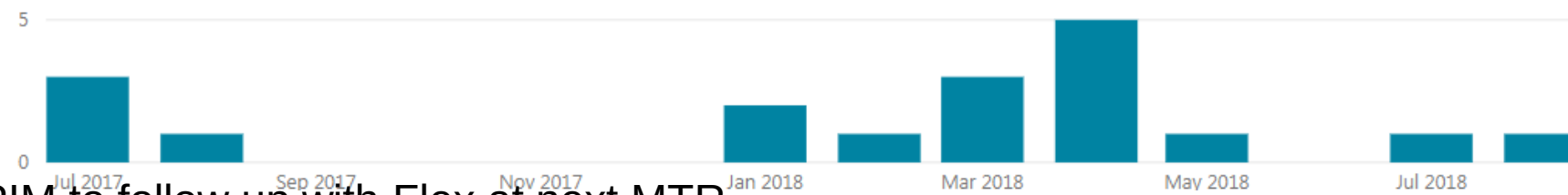


- PSU used across multiple lines, no field trend noted at this time, PIM follow up at next MTR

- Carousel Carrier – WAT270928 / WAT271290

- Need to understand cause of recent failures, parts requested for return and analysis

0-90 Day FSR count by DOM

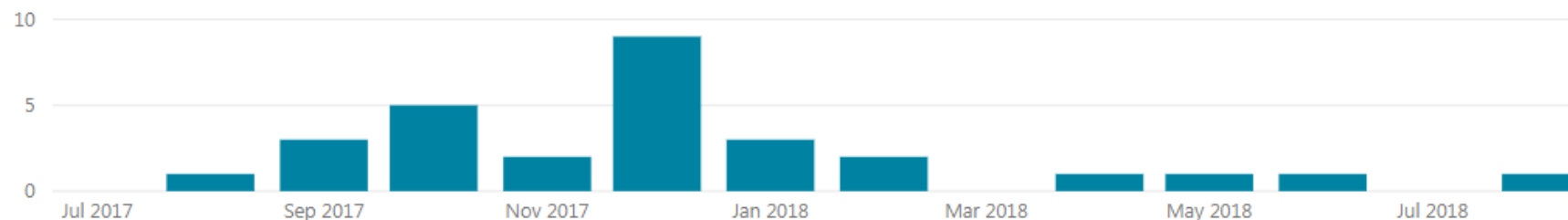


- PIM to follow up with Flex at next MTR

- Alliance Actuators – 700001031 / 289000527

- Failure analysis in process in Milford, plunger homing faults & motor loss sync errors reported

0-90 Day FSR count by DOM



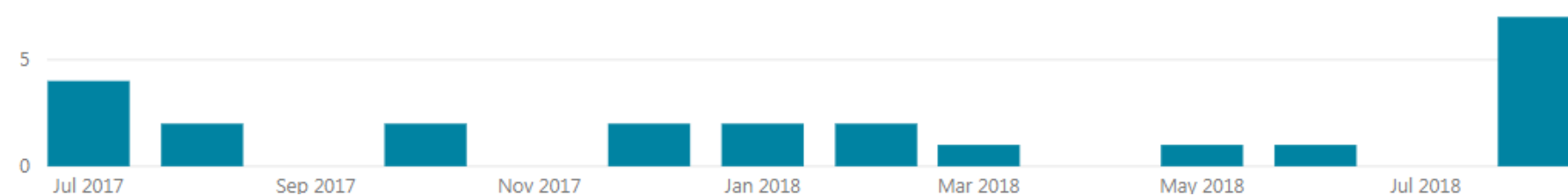
Failure charts
shown by DOM

CMO Investigation
Requested

Flextronics - Actions

- eAlliance CPU
 - Request Flex look into CPU usage during manufacture
 - Examine Flex Senai for any trends

0-90 Day FSR count by DOM





Waters

THE SCIENCE OF WHAT'S POSSIBLE.®

