Predictive Health Notification Alinity I Pipettor FE Pressure

ALINITY ci Immunoassay Analyzer

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PHN - Alinity IA Pipettor FE Pressure Spec Sheet for Apollo

References

APLM D000029930/A ICQ IA FE Pressure PHM Specs

Summary

To implement a Predictive Health Monitoring (PHM) algorithm for the Alinity-i analyzers that will detect a degrading pipettor pressure transducer or loss-of-connection to the controller board and associated loss of pressure monitoring before the customer begins experiencing an increase in pipetting errors and/or erratic results due to inaccurate pipetting.

PHN Descriptor	Alinity IA Pipettor FE Pressure
PHN Experience Code / Name	CC11 PHN_Alinity_IA; PHN_R1 Pipettor; FE Pressure CC21 PHN_Alinity_IA; PHN_R2 Pipettor; FE Pressure CCJ1 PHN_Alinity_IA; PHN_Sample Pipettor; FE Pressure
PHN KM Article Number/ Name	K82525012 PHN_Alinity IA: Front End (FE) Pressure
Skill Level	2- Advanced Service
Always On Package	Always On 01DP5- 01, 02, 03, 09, 80, 83, 84, 89
IDA Table	IDAQOWNER.ICQ_PMEVENTS
IDA Table Fields	MODULESN, LOGDATE_LOCAL, FRONTENDPRESSURE, PIPETTINGPROTOCOLNAME, PIPETTORMECHANISMNAME
Analysis Frequency	Daily
Data Required	Previous 1 day
Data Aggregation	None
Run Time Estimate	6 seconds (1 day, 32 instruments, 8,465 rows, 1 algorithm flag)
Flag Criteria	FE Pressure greater than 27,000 or less than 21,000
Probable Failure Modes	Pipettor pressure sensor. Pipettor board and connections.
Suppression Experience Codes	None
Applicable Work Done Codes (WDC)	R1: BB1* Fluid Aspiration, Dispense and Detection; R1 Probe; Multiple LLS / Pressure Monitoring Errors R2: BC1*: Fluid Aspiration, Dispense and Detection; R2 Probe; Multiple LLS / Pressure Monitoring Errors Sample: B31*: Fluid Aspiration, Dispense and Detection; Sample Probe; Multiple LLS / Pressure Monitoring Errors

Data Processing Steps

Data Processing Steps	
1	Query all data from the previous day for each pipettor/instrument combination (IDA Table: IDAQOWNER.ICQ_PMEVENTS).
2	Unique pipettors will be identified by PIPETTORMECHANISMNAME and MODULESN.
3	Exclude aspirations with: PIPETTINGPROTOCOLNAME = "NonPipettingProtocol"
4	Exclude pipettors that have less than 10 aspirations.
5	Summarize the data by calculating the number of aspirations in which FE pressure (FRONTENDPRESSURE) is less than 21,000 or greater than 27,000.
6	Flag any pipettor/instrument combination with 2% or more of its aspirations having FE pressure less than 21,000 or greater than 27,000. Note that the 2% is necessary to exclude occluded probes where the problem is resolved through a system flush.

Define Reusable Routine

Routine Details	
Routine Source	Define Reusable Routine
Routine Type	Oracle Procedure
Run Mode	Batch
Routine Invoke Command	PHM_ICQ_Pipettor_FE_PROC
Status	Disabled

Apollo Details	
Algorithm ID *	Alinity IA Pipettor FE Pressure - Generic
Algorithm Name *	Alinity IA Pipettor FE Pressure - Generic
Algorithm Description *	To detect degrading Pipettor Pressure Transducers through raised Front End (FE) pressure readings during aspiration.
Product Family *	Alinity IA
Algorithm Group *	Alinity Pipettor
Functional Area	N/A
Algorithm Category 1	N/A
Algorithm Category 2	N/A
Algorithm Category 3	N/A
Remaining Useful Life Value	7
Remaining Useful Life Unit	Day
Keep Results Num Days	14
Routine Details	
Routine Source	Define Reusable Routine
Routine Type	Oracle Procedure
Run Mode	Batch
Routine Invoke Command	PHM_ICQ_Pipettor_FE_PROC
Status	Disabled
Parameters	
Parameter Group Name	ICQ_FE_Pressure
Parameter Name	**Parameter Values**
ASPS	
IHN_LEVEL3_DESC	IHN_LEVEL3_DESC
MAX_VALUE	27000
MIN_VALUE	21000
PCTASPS	0.02
PIPMECHNAME	PIPMECHNAME
THRESHOLDS_COUNT	1
THRESHOLDS_DESCRIPTION	THRESHOLDS_DESCRIPTION

APPENDIX 1: CC11 PHN_Alinity_IA; PHN_R1 Pipettor; FE Pressure

Algorithm Code

```
SELECT
	evals.MODULESN
FROM
	(SELECT
		PM.MODULESN,
		COUNT(PM.PIPETTORMECHANISMNAME) AS ASPIRATIONS,
		SUM(CASE WHEN PM.FRONTENDPRESSURE > 27000 OR PM.FRONTENDPRESSURE <
21000
				THEN 1
				ELSE 0
			END) AS NUMFLAGS
	FROM
		IDAQOWNER.ICQ_PMEVENTS PM
	WHERE
		PM.LOGDATE_LOCAL >= TRUNC(SYSDATE) - 1
		AND PM.LOGDATE_LOCAL < TRUNC(SYSDATE)
		AND PM.FRONTENDPRESSURE IS NOT NULL
		AND PM.PIPETTINGPROTOCOLNAME != 'NonPipettingProtocol'
		AND PM.PIPETTORMECHANISMNAME = 'Reagent1PipettorMechanism'
	GROUP BY
		PM.MODULESN
	ORDER BY
		PM.MODULESN
	) evals
WHERE
	(evals.NUMFLAGS / evals.ASPIRATIONS) >= 0.02
	AND evals.ASPIRATIONS >= 10
```

Apollo Algorithm Details

(* is Mandatory)

Apollo Details	
Algorithm ID *	Alinity IA Pipettor R1 FE Pressure
Algorithm Name *	Alinity IA Pipettor R1 FE Pressure
Algorithm Description *	To detect degrading Pipettor Pressure Transducers through raised Front End (FE) pressure readings during aspiration.
Product Family *	Alinity IA
Algorithm Group *	Alinity Pipettor
Functional Area	N/A
Algorithm Category 1	N/A
Algorithm Category 2	N/A
Algorithm Category 3	N/A
Remaining Useful Life Value	7
Remaining Useful Life Unit	Day
Keep Results Num Days	14
Routine Details	
Routine Source	Use Reusable Routine
Reusable Routines	Alinity IA Pipettor FE Pressure - Generic
Run Mode	Batch
Status	Enable
ODS Routine Details	
ODS Routine Name	PHM_ODS_ICQ_PMEVENTS_PROC
Predictive Health Notification Details	
PHN Code	PHN_Alinity IA_CC11
Issue Description (Use Algorithm Name)	Alinity IA Pipettor R1 FE Pressure

Experience Code	CC11
Knowledge Management DB Articles	
KM Article ID	K82525012
KM Article	PHN_Alinity IA: Front End (FE) Pressure
Parameters	
Parameter Group Name	ICQ_FE_Pressure
Parameter Name	**Parameter Values**
ASPS	10
IHN_LEVEL3_DESC	Alinity IA Pipettor R1 FE Pressure
MAX_VALUE	27000
MIN_VALUE	21000
PCTASPS	0.02
PIPMECHNAME	Reagent1PipettorMechanism
THRESHOLDS_COUNT	1
THRESHOLDS_DESCRIPTION	Alinity IA Pipettor R1 FE Pressure
Chart Details	
Chart Title	Alinity IA Pipettor R1 FE Pressure
Chart Type	Line
Chart Threshold Parameter	ICQ_FE_Pressure-THRESHOLDS_COUNT
Group ID	Group 7
Chart X Axis Name	Date
Chart Y Axis Name	Threshold Count

APPENDIX 2: CC21 PHN_Alinity_IA; PHN_R2 Pipettor; FE Pressure

Algorithm Code

```
SELECT
	evals.MODULESN
FROM
	(SELECT
		PM.MODULESN,
		COUNT(PM.PIPETTORMECHANISMNAME) AS ASPIRATIONS,
		SUM(CASE WHEN PM.FRONTENDPRESSURE > 27000 OR PM.FRONTENDPRESSURE <
21000
				THEN 1
				ELSE 0
			END) AS NUMFLAGS
	FROM
		IDAQOWNER.ICQ_PMEVENTS PM
	WHERE
		PM.LOGDATE_LOCAL >= TRUNC(SYSDATE) - 1
		AND PM.LOGDATE_LOCAL < TRUNC(SYSDATE)
		AND PM.FRONTENDPRESSURE IS NOT NULL
		AND PM.PIPETTINGPROTOCOLNAME != 'NonPipettingProtocol'
		AND PM.PIPETTORMECHANISMNAME = 'Reagent2PipettorMechanism'
	GROUP BY
		PM.MODULESN
	ORDER BY
		PM.MODULESN
	) evals
WHERE
	(evals.NUMFLAGS / evals.ASPIRATIONS) >= 0.02
	AND evals.ASPIRATIONS >= 10
```

Apollo Algorithm Details

(* is Mandatory)

Apollo Details	
Algorithm ID *	Alinity IA Pipettor R2 FE Pressure
Algorithm Name *	Alinity IA Pipettor R2 FE Pressure
Algorithm Description *	To detect degrading Pipettor Pressure Transducers through raised Front End (FE) pressure readings during aspiration.
Product Family *	Alinity IA
Algorithm Group *	Alinity Pipettor
Functional Area	N/A
Algorithm Category 1	N/A
Algorithm Category 2	N/A
Algorithm Category 3	N/A
Remaining Useful Life Value	7
Remaining Useful Life Unit	Day
Keep Results Num Days	14
Routine Details	
Routine Source	Use Reusable Routine
Reusable Routines	Alinity IA Pipettor FE Pressure - Generic
Run Mode	Batch
Status	Enable
ODS Routine Details	
ODS Routine Name	PHM_ODS_ICQ_PMEVENTS_PROC
Predictive Health Notification Details	
PHN Code	PHN_Alinity IA_CC21

Issue Description (Use Algorithm Name)	Alinity IA Pipettor R2 FE Pressure
Experience Code	CC21
Knowledge Management DB Articles	
KM Article ID	K82525012
KM Article	PHN_Alinity IA: Front End (FE) Pressure
Parameters	
Parameter Group Name	ICQ_FE_Pressure
Parameter Name	**Parameter Values**
ASPS	10
IHN_LEVEL3_DESC	Alinity IA Pipettor R2 FE Pressure
MAX_VALUE	27000
MIN_VALUE	21000
PCTASPS	0.02
PIPMECHNAME	Reagent2PipettorMechanism
THRESHOLDS_COUNT	1
THRESHOLDS_DESCRIPTION	Alinity IA Pipettor R2 FE Pressure
Chart Details	
Chart Title	Alinity IA Pipettor R2 FE Pressure
Chart Type	Line
Chart Threshold Parameter	ICQ_FE_Pressure-THRESHOLDS_COUNT
Group ID	Group 7
Chart X Axis Name	Date
Chart Y Axis Name	Threshold Count

APPENDIX 3: CCJ1 PHN_Alinity_IA; PHN_Sample Pipettor; FE Pressure

Algorithm Code

```
SELECT
	evals.MODULESN
FROM
	(SELECT
		PM.MODULESN,
		COUNT(PM.PIPETTORMECHANISMNAME) AS ASPIRATIONS,
		SUM(CASE WHEN PM.FRONTENDPRESSURE > 27000 OR PM.FRONTENDPRESSURE <
21000
				THEN 1
				ELSE 0
			END) AS NUMFLAGS
	FROM
		IDAQOWNER.ICQ_PMEVENTS PM
	WHERE
		PM.LOGDATE_LOCAL >= TRUNC(SYSDATE) - 1
		AND PM.LOGDATE_LOCAL < TRUNC(SYSDATE)
		AND PM.FRONTENDPRESSURE IS NOT NULL
		AND PM.PIPETTINGPROTOCOLNAME != 'NonPipettingProtocol'
		AND PM.PIPETTORMECHANISMNAME = 'SamplePipettorMechanism'
	GROUP BY
		PM.MODULESN
	ORDER BY
		PM.MODULESN
	) evals
WHERE
	(evals.NUMFLAGS / evals.ASPIRATIONS) >= 0.02
	AND evals.ASPIRATIONS >= 10
```

Apollo Algorithm Details

(* is Mandatory)

Apollo Details	
Algorithm ID *	Alinity IA Pipettor Sample FE Pressure
Algorithm Name *	Alinity IA Pipettor Sample FE Pressure
Algorithm Description *	To detect degrading Pipetter Pressure Transducers through raised Front End (FE) pressure readings during aspiration.
Product Family *	Alinity IA
Algorithm Group *	Alinity Pipettor
Functional Area	N/A
Algorithm Category 1	N/A
Algorithm Category 2	N/A
Algorithm Category 3	N/A
Remaining Useful Life Value	7
Remaining Useful Life Unit	Day
Keep Results Num Days	14
Routine Details	
Routine Source	Use Reusable Routine
Reusable Routines	Alinity IA Pipettor FE Pressure - Generic
Run Mode	Batch
Status	Enable
ODS Routine Details	
ODS Routine Name	PHM_ODS_ICQ_PMEVENTS_PROC
Predictive Health Notification Details	
PHN Code	PHN_Alinity IA_CCJ1
Issue Description (Use Algorithm Name)	Alinity IA Pipettor Sample FE Pressure
Experience Code	CCJ1

Knowledge Management DB Articles	
KM Article ID	K82525012
KM Article	PHN_Alinity IA: Front End (FE) Pressure
Parameters	
Parameter Group Name	ICQ_FE_Pressure
Parameter Name	**Parameter Values**
ASPS	10
IHN_LEVEL3_DESC	Alinity IA Pipettor Sample FE Pressure
MAX_VALUE	27000
MIN_VALUE	21000
PCTASPS	0.02
PIPMECHNAME	SamplePipettorMechanism
THRESHOLDS_COUNT	1
THRESHOLDS_DESCRIPTION	Alinity IA Pipettor Sample FE Pressure
Chart Details	
Chart Title	Alinity IA Pipettor Sample FE Pressure
Chart Type	Line
Chart Threshold Parameter	ICQ_FE_Pressure-THRESHOLDS_COUNT
Group ID	Group 7
Chart X Axis Name	Date
Chart Y Axis Name	Threshold Count

APPENDIX 4: Algorithm Understanding Check – Algorithm Developer to Predictive Health Monitoring (PHM) Specialist Transition

Data Set Description

The data set for this understanding check was retrieved from the ICQOWNER.ODR_PMEVENTSICQ table within the BSQD1I database. Data was collected for all instruments between December, 1 2016 and February 28, 2017, inclusive. Data collection was limited to the SERIALNUMBER, PIPETTORMECHANISMNAME, FRONTEDNPRESSURE, PIPETTINGPROTOCOLNAME, and DATETIMESTAMP fields.

Data Set Retrieval

The following SQL code was used to retrieve the data set:

```
SELECT
	PM.SERIALNUMBER,
	PM.PIPETTORMECHANISMNAME,
	PM.FRONTENDPRESSURE,
	PM.PIPETTINGPROTOCOLNAME,
	PM.DATETIMESTAMP
FROM
	ICQOWNER.ODR_PMEVENTSICQ PM
WHERE
	TRUNC(PM.DATETIMESTAMP) >= TO_DATE('12/01/2016 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
	AND TRUNC(PM.DATETIMESTAMP) < TO_DATE('03/01/2017 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
```

Algorithm Developer Analysis

The following JMP script (JMP version 12.1.0) was used by the Algorithm Developer to analyze the data set and flag algorithm violations:

```
clear log();
include("JMPCreds_v1.jsl");

// Variables
// __user_name and __user_pw are utilized by the GetCreds function within JMPCreds_v1.jsl
time_start = Informat( "12/01/2016", "mm/dd/yyyy" );
time_end = Informat( "03/01/2017", "mm/dd/yyyy" );


// Database Credentials and Connectino to Database
GetCreds;
dbc = Create Database Connection(
	"DSN=BSQD1i;UID=" || __user_name || ";PWD=" || Hex To Char( __user_pw ) || ";
		DBQ=BSQD1I;		DBA=W;APA=T;EXC=F;FEN=T;QTO=T;FRC=10;FDL=10;LOB=T;RST=T;BTD=F;BNF=F;
		BAM=IfAllSuccessful;NUM=NLS;DPM=F;MTS=T;MDI=F;CSR=F;FWC=F;FBS=1000000000000;TLO=O;MLD=0;ODA=F;"
);


// SQL Queries
dt = Execute SQL( dbc,
	"SELECT
		t1.MODULESNDRM, t1.SERIALNUMBER, t1.DATETIMESTAMP, t1.PIPETTINGPROTOCOL,
		t1.PIPETTINGPROTOCOLNAME, t1.PIPETTORMECHANISM, t1.PIPETTORMECHANISMNAME,
		t1.FRONTENDPRESSURE
	FROM
		ICQOWNER.ODR_PMEVENTSICQ  t1
	WHERE
		(  (  ( t1.DATETIMESTAMP >= TO_TIMESTAMP('" || char( time_start ) || "', 'DDMONYYYY:HH24:MI:SS') )  AND
		( t1.DATETIMESTAMP < TO_TIMESTAMP('" || char( time_end ) || ":00:00:00', 'DDMONYYYY:HH24:MI:SS') )  )  ) ;",
	char(time_start) || "to" || char(time_end) || "_ICQ_FETable" );

// Close Connection
Close Database Connection(dbc);


dt << select where(
	dt:PIPETTINGPROTOCOL != 8
);

dt_sub = dt << Subset(
	( Selected Rows ),
```

```
		Output Table Name("Protocol_Filtered")
);

dt_sub << new column(
		"Date",
		numeric,
		nominal,
		Format( "m/d/y" ),
		Formula(
			num( Short Date( dt_sub:DATETIMESTAMP ) )
		)
);

dt_sum = dt_sub << Summary(
		Group( dt_sub:SERIALNUMBER, dt_sub:PIPETTORMECHANISMNAME, dt_sub:Date ),
		Min( dt_sub:FRONTENDPRESSURE ),
		Max( dt_sub:FRONTENDPRESSURE ),
		Freq( "None" ),
		Weight( "None" )
);

dt_sum << new column(
		"Flag_Status",
		character,
		continuous
);

for( i = 1, i <= NRow( dt_sum ), i++,
		if( Column( dt_sum, "N Rows" )[i] < 10,
			dt_sum:Flag_Status[i] = "LessThan10",
			if(	Column( dt_sum, "Min(FRONTENDPRESSURE)" )[i] >= 21000 &
				Column( dt_sum, "MAX(FRONTENDPRESSURE)" )[i] <= 27000,
				dt_sum:Flag_Status[i] = "good",
				dt_sum:Flag_Status[i] = "flagged"
			)
		)
);

dt_sum << Sort(
		Replace Table,
		By( :Flag_Status),
		Order( Ascending )
);
```

PHM Specialist Analysis

The following SQL code was used by the PHM Specialist to analyze the data set and flag algorithm violations:

```
SELECT
		evals.SERIALNUMBER,
		evals.PIPETTORMECHANISMNAME,
		evals.DAY,
		evals.MAXFEP,
		evals.MINFEP
FROM
		(SELECT
			PM.SERIALNUMBER,
			PM.PIPETTORMECHANISMNAME,
			TRUNC(PM.DATETIMESTAMP) AS DAY,
			MAX(PM.FRONTENDPRESSURE) AS MAXFEP,
			MIN(PM.FRONTENDPRESSURE) AS MINFEP,
			COUNT(PM.PIPETTORMECHANISMNAME) AS ASPIRATIONS,
			SUM(CASE WHEN PM.FRONTENDPRESSURE > 27000 OR PM.FRONTENDPRESSURE < 21000
					THEN 1
					ELSE 0
				END) AS NUMFLAGS
		FROM
			ICQOWNER.ODR_PMEVENTSICQ PM
		WHERE
			TRUNC(PM.DATETIMESTAMP) >= TO_DATE('12/01/2016 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
			AND TRUNC(PM.DATETIMESTAMP) < TO_DATE('03/01/2017 12:00:00 AM', 'mm/dd/yyyy hh:mi:ss am')
			AND PM.FRONTENDPRESSURE IS NOT NULL
			AND PM.PIPETTINGPROTOCOLNAME != 'NonPipettingProtocol'
		GROUP BY
			PM.SERIALNUMBER,
			PM.PIPETTORMECHANISMNAME,
```

```
                TRUNC(PM.DATETIMESTAMP)
        ORDER BY
                PM.SERIALNUMBER,
                TRUNC(PM.DATETIMESTAMP)
        ) evals
WHERE
        evals.NUMFLAGS >= 1
        AND evals.ASPIRATIONS >= 10
```

Algorithm Developer Analysis Output

The following 18 instrument (SERIALNUMBER) and pipettor (PIPETTORMECHANISMNAME) combinations were identified as violating the algorithm by the Algorithm Developer:

	SERIALNUMBER	PIPETTORMECHANISMNAME	Date	N Rows	Min(FRONTENDPRESSURE)	Max(FRONTENDPRESSURE)
1	AI01013	Reagent2PipettorMechanism	01/06/2017	30	24463	32008
2	CI00001	Reagent1PipettorMechanism	12/02/2016	255	0	0
3	CI00001	Reagent2PipettorMechanism	12/02/2016	77	0	0
4	CI00001	SamplePipettorMechanism	12/02/2016	149	0	0
5	CM00135	Reagent2PipettorMechanism	12/29/2016	157	23902	33299
6	IM00124	Reagent2PipettorMechanism	02/09/2017	119	23994	33299
7	IV00021	Reagent1PipettorMechanism	01/13/2017	1553	17305	24398
8	IV00022	Reagent2PipettorMechanism	12/02/2016	28	28395	28494
9	IV00022	Reagent2PipettorMechanism	12/05/2016	28	28415	28479
10	IV00022	Reagent2PipettorMechanism	12/07/2016	20	28434	28578
11	IV00022	Reagent2PipettorMechanism	12/08/2016	48	28418	28538
12	IV00022	Reagent2PipettorMechanism	12/09/2016	1090	28414	28596
13	IV00022	Reagent2PipettorMechanism	12/12/2016	352	28407	28577
14	IV00022	Reagent2PipettorMechanism	12/13/2016	220	28055	28597
15	IV00022	Reagent2PipettorMechanism	12/14/2016	210	28437	28500
16	IV00022	Reagent2PipettorMechanism	12/15/2016	356	28292	28579
17	IV00037	Reagent1PipettorMechanism	12/20/2016	1387	20954	22790
18	Qi00118	Reagent2PipettorMechanism	12/28/2016	78	23516	33299

PHM Specialist Analysis Output

The following 18 instrument (SERIALNUMBER) and pipettor (PIPETTORMECHANISMNAME) combinations were identified as violating the algorithm by the PHM Specialist:

	SERIALNUMBER	PIPETTORMECHANISMNAME	DAY	MAXFEP	MINFEP
1	AI01013	Reagent2PipettorMechanism	01/06/2017 12:00:00 AM	32008	24463
2	CI00001	Reagent1PipettorMechanism	12/02/2016 12:00:00 AM	0	0
3	CI00001	Reagent2PipettorMechanism	12/02/2016 12:00:00 AM	0	0
4	CI00001	SamplePipettorMechanism	12/02/2016 12:00:00 AM	0	0
5	CM00135	Reagent2PipettorMechanism	12/29/2016 12:00:00 AM	33299	23902
6	IM00124	Reagent2PipettorMechanism	02/09/2017 12:00:00 AM	33299	23994
7	IV00021	Reagent1PipettorMechanism	01/13/2017 12:00:00 AM	24398	17305
8	IV00022	Reagent2PipettorMechanism	12/02/2016 12:00:00 AM	28494	28395
9	IV00022	Reagent2PipettorMechanism	12/05/2016 12:00:00 AM	28479	28415
10	IV00022	Reagent2PipettorMechanism	12/07/2016 12:00:00 AM	28578	28434
11	IV00022	Reagent2PipettorMechanism	12/08/2016 12:00:00 AM	28538	28418
12	IV00022	Reagent2PipettorMechanism	12/09/2016 12:00:00 AM	28596	28414
13	IV00022	Reagent2PipettorMechanism	12/12/2016 12:00:00 AM	28577	28407
14	IV00022	Reagent2PipettorMechanism	12/13/2016 12:00:00 AM	28597	28055
15	IV00022	Reagent2PipettorMechanism	12/14/2016 12:00:00 AM	28500	28437
16	IV00022	Reagent2PipettorMechanism	12/15/2016 12:00:00 AM	28579	28292
17	IV00037	Reagent1PipettorMechanism	12/20/2016 12:00:00 AM	22790	20954
18	Qi00118	Reagent2PipettorMechanism	12/28/2016 12:00:00 AM	33299	23516

Algorithm Developer & PHM Specialist Output Comparison

Total # of Unique Instrument-Part-Days Tested	Total # of Algorithm Developer Flags	Total # of PHM Specialist Flags	Total # of Matched Flags (Algorithm Developer vs. PHM Specialist)
5,874	**18**	**18**	**18**

Understanding Check Summary

Based on the outputs from both the Algorithm Developer and PHM Specialist, the PHM Specialist's understanding of the delivered algorithm is confirmed. Both the Algorithm Developer and PHN Specialist analyzed the same data

set and got the same results. In particular, the SERIALNUMBER, PIPETTORMECHANISMNAME, and Date/DAY fields matched for all 18 instrument-part-day (SERIALNUMBER-PIPETTORMECHANISMNAME-Date/DAY) combinations. This means that both the Algorithm Developer and PHM Specialist flagged the same 18 algorithm violations within the given data set. Furthermore, there were no mismatches between the output from the Algorithm Developer and the output from the PHM Specialist.

Note: Although not explicitly called out in the understanding check information above, as it was not part of the algorithm originally delivered by the Algorithm Developer, the additional 2% requirement to check for occluded probes was implemented, tested, and behavior confirmed by the PHM Specialist. Moreover, when applied to the understanding check data set described above, the 2% requirement reduced the number of algorithm flags to 16. Two instrument-part-day combinations had only 1flagged aspiration out of many; a proportion less than 2%.

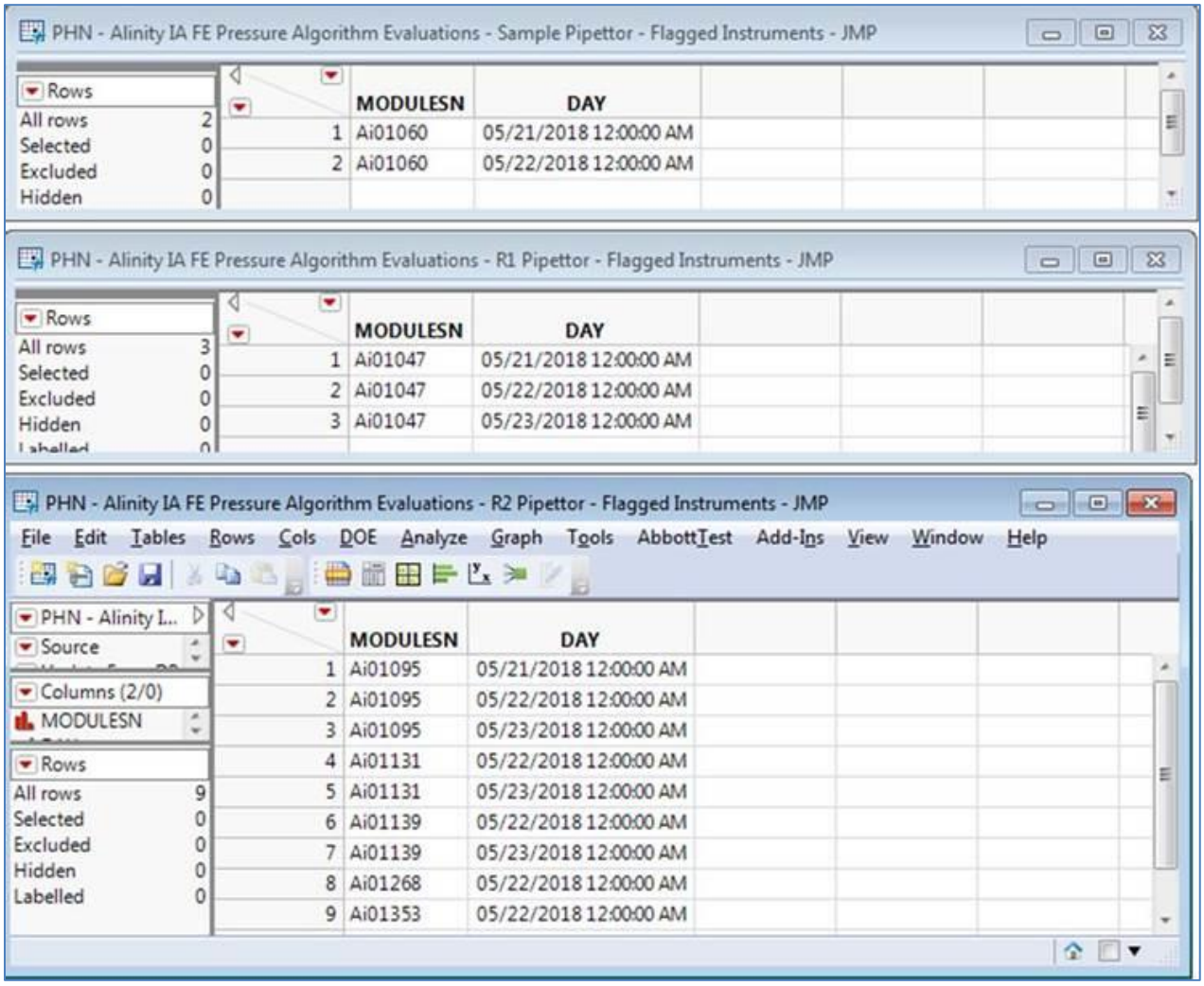
APPENDIX 5: Algorithm Transition to Apollo – PHM Specialist to Apollo Developer

Data Set Description

The data set for this transition was retrieved from the IDAQOWNER.ICQ_PMEVENTS table within the DABBTO database. Data was collected for all available instruments between May, 21 2018 and May 23, 2018, inclusive.

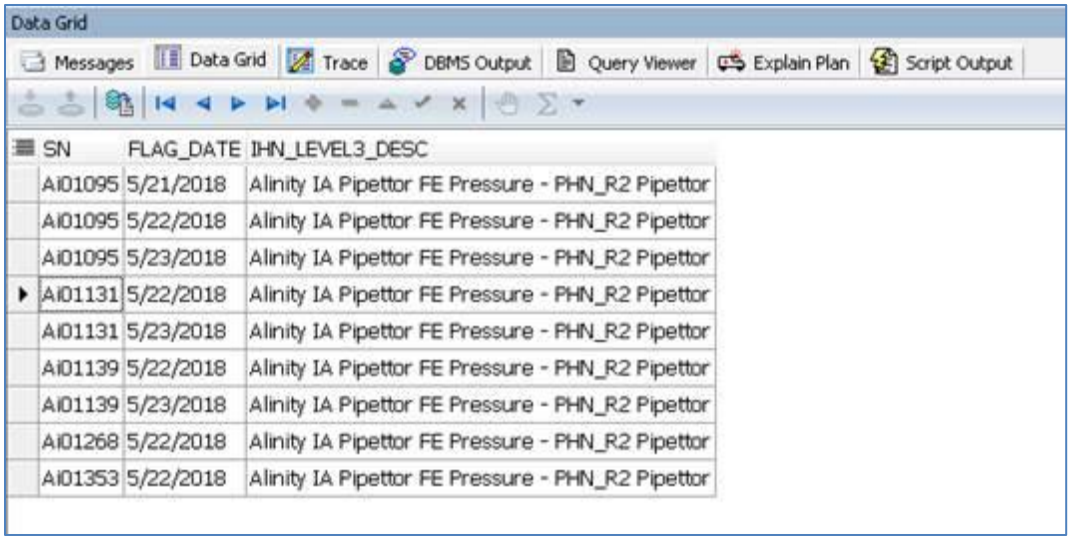
PHM Specialist Analysis Output

The following 14 instrument-days (MODULESN-DAY) were identified as violating the algorithm by the PHM Specialist:



Apollo Developer Analysis Output

The following 9 instrument-days (SN-FLAG_DATE) were identified as violating the algorithm by the Apollo Developer (note that where the Apollo Developer and PHM Specialist don't match is because the instruments do not exist in the Apollo environment, and therefore have no data to run the algorithm against):



SN	FLAG_DATE	IHN_LEVEL3_DESC
Ai01095	5/21/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01095	5/22/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01095	5/23/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01131	5/22/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01131	5/23/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01139	5/22/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01139	5/23/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01268	5/22/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor
Ai01353	5/22/2018	Alinity IA Pipettor FE Pressure - PHN_R2 Pipettor

Algorithm Transition Summary

Based on the outputs from both the Apollo Developer and PHM Specialist, the Apollo Developer's understanding of the delivered algorithm is confirmed. Both the Apollo Developer and PHM Specialist analyzed the same data set and got the same results (with the exception of the instruments not in Apollo as mentioned previously). In particular, the MODULESN/SN and DAY/FLAG_DATE fields matched. This means that both the Apollo Developer and PHM Specialist flagged the same algorithm violations within the given data set.