A Prognostic Health Monitoring Algorithm for Wash Aspirate Monitoring

ARCHITECT Immunoassay Analyzer

R&D Quality Engineering, Version 1.0

12/8/2014

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1. Purpose

To implement a Prognostic Health Monitoring (PHM) algorithm for ARCHITECT Immunoassay (IA) Analyzers that will detect degrading Wash Aspirate Monitoring (WAM) performance before the customer begins experiencing an increase in Error: 3700 unable to process test, (wash zone X) wash aspiration error for probe(s) (X), causing tests lost to exception or unplanned instrument down time.

2. Introduction

2.1 Scope

This document describes the recommended specifications for the WAM PHM alerts for the ARCHITECT i1000SR, i2000, and i2000SR IA Analyzers.

2.2 Notification Profiles

2.2.1 Max Temperature (Pattern A)

PHM Alert	Max Temperature (Pattern A)
Future PHM Alert Code	IHN01 WAM
Threshold	>= 5 consecutive values > 35C on a single wash zone probe
Platform	PL 115, 116 & 117 (ARCHITECT i1SR, i2, i2SR)
Data Source	WAM logs / Abbott Link / IDA
Notification	Daily Report / Instrument Serial Number
Analysis Frequency	Daily
Failure Prediction (RUL post-alert)	Percentiles[1] 25th = 0.72 days (17.3 hours) 50th = 2.6 days 75th = 10.0 days Mean = 6.1 days
Recommended Action	Replace ARC TUBING/SENS-WZ

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[1] This considers only cases when the algorithm precedes the failure event. As discussed below, the algorithm sometimes flags instruments at the same moment of failure, resulting in a RUL of 0. These values were dropped.

2.2.2 Ambient Temperature (Pattern B)

PHM Alert	Ambient Temperature (Pattern B)
Future PHM Alert Code	IHN01 WAM
Threshold	>= 2 consecutive values < 14C on a single wash zone probe
Platform	PL 115, 116 & 117 (ARCHITECT i1SR, i2, i2SR)
Data Source	WAM logs / Abbott Link / IDA
Notification	Daily Report / Instrument Serial Number
Analysis Frequency	Daily
Failure Prediction (RUL post-alert)	Percentiles[2] 25th = 0.275 days (6.6 hours) 50th = 6.1 days 75th = 43.6 days Mean = 19.3 days
Recommended Action	Replace ARC TUBING/SENS-WZ or cabling from thermistors to card cage.

2.2.3 Temperature Delta (Pattern C)

PHM Alert	Temperature Delta (Pattern C)
Future PHM Alert Code	IHN02 WAM
Threshold	>= 20 values < 3C on a single wash zone probe within an hour
Platform	PL 115, 116 & 117 (ARCHITECT i1SR, i2, i2SR)
Data Source	WAM logs / Abbott Link / IDA
Notification	Daily Report / Instrument Serial Number
Analysis Frequency	Daily
Failure Prediction (RUL post-alert)	Percentiles[3] 25th = 0.17 days (4.1 hours) 50th = 1.39 days 75th = 7.58 days Mean = 4.45 days
Recommended Action	Check for clogged probes and/or vacuum system issues

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[2] This considers only cases when the algorithm precedes the failure event. As discussed below, the algorithm sometimes flags instruments at the same moment of failure, resulting in a RUL of 0. These values were dropped.

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2.3   Overview

Dispense and aspiration of heated wash buffer solution into an RV during the wash process is monitored using WAM. WAM confirms that the wash buffer was dispensed and subsequently aspirated completely within the allotted time.

A normal wash aspiration produces a temperature profile with predictable characteristics. WAM determination is based on temperature measurements taken at 1 millisecond intervals from a thermistor located inside the Wash tubing approximately 11 inches from the probe tip.

Figure 1: Wash Zone Picture (ARCHITECT i2000 and i2000SR)
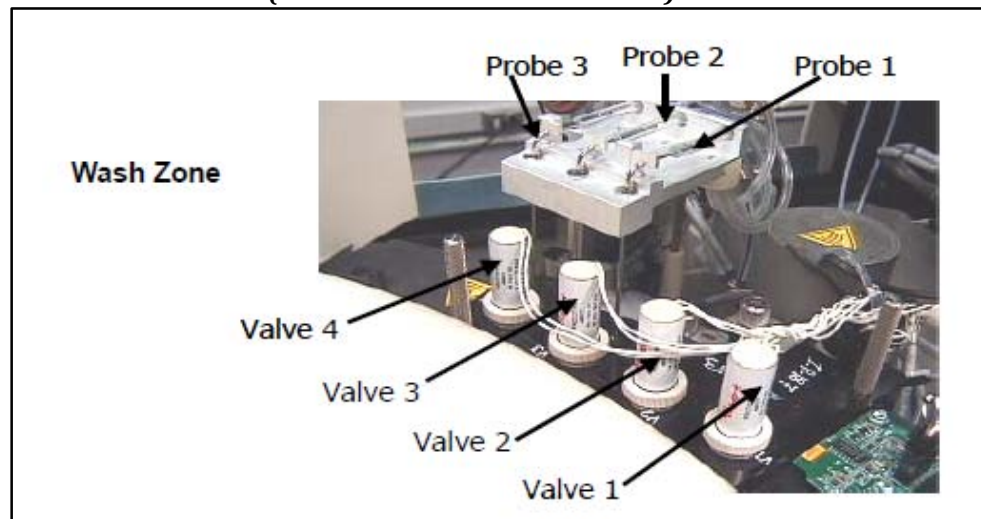
Figure 2: i2000SR WAM Temperature Channels

Wash Zone 1	Channel #	Wash Zone 2	Channel #
• Probe 1: Temperature Control Channel	6	• Probe 1: Temperature Control Channel	18
• Probe 2: Temperature Control Channel	10	• Probe 2: Temperature Control Channel	22
• Probe 3: Temperature Control Channel	14	• Probe 3: Temperature Control Channel	26

Figure 3: Wash Sequence (ARCHITECT i2000 and i2000SR)
The following is an overview of the events that occur during a normal Wash Zone cycle for the ARCHITECT i2000 and i2000SR platforms.

Process Path RV Position 1	Process Path RV Position 2	Process Path RV Position 3	Process Path RV Position 4
Buffer Dispensed for Final Volume of 400ul	Liquid Aspirated 500uL Buffer Dispensed Liquid Aspirated 1000uL Buffer Dispensed	Liquid Aspirated 1000uL Buffer Dispensed Liquid Aspirated 1000uL Buffer Dispensed	Liquid Aspirated x2
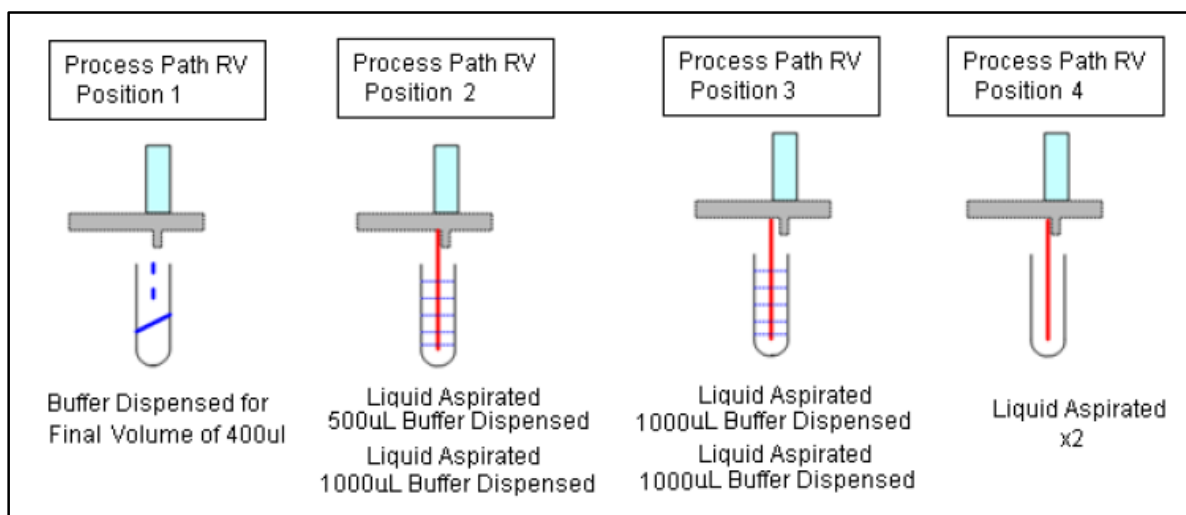
Before any washing begins, the Wash Zone Magnet pulls the microparticles to the side of the RV which prevents them from being aspirated out of the RV during the wash. Depending on the type of assay being run, a single RV may experience the wash cycle on Wash Zone 1 and 2, or just Wash Zone 2.

In the first position of the wash cycle:
- Buffer is dispensed into the RV via **valve 1** to reach a final volume of 400 uL

In the next position, two washes are performed on the RV:
- **WZ Probe 1** aspirates the buffer and the WAM value is recorded but ignored by software
- 500 uL of warm buffer is dispensed via **valve 2**
- **WZ Probe 1** aspirates the buffer and the WAM value is recorded and checked by software
- 1mL of warm buffer is dispensed via **valve 2**

In the next position another two washes are performed on the RV:
- **WZ Probe 2** aspirates the buffer and the WAM value is recorded and checked by software
- 1mL of warm buffer is dispensed via **valve 3**
- **WZ Probe 2** aspirates the buffer and the WAM value is recorded and checked by software
- 1mL of warm buffer is dispensed via **valve 3**

In the final position:
- **WZ Probe 3** aspirates the buffer and the WAM value is recorded and checked by software
- **WZ Probe 3** aspirates again, although the RV should not have liquid in it
- The WAM value is recorded but ignored by software

Wash Sequence (ARCHITECT i1000SR):
The wash sequence for the ARCHITECT i1000SR platform is the same as the wash sequence for the ARCHITECT i2000 and i2000SR listed above with one difference. Whereas the i2000 and i2000SR have two wash zones, the i1000 only has one. This means that, depending on the type of assay being run, a single RV may pass through the single i1000 Wash Zone once or twice.

WAM - Creating a Temperature Profile:
- As the wash aspiration probe descends into the reaction vessel, vacuum is applied causing ambient air to be drawn through the tubing. This results in a *small decrease* in temperature sensed by the thermistor.
- As heated buffer is aspirated from the RV and drawn into the tubing, the temperature sensed by the thermistor *rises* abruptly.
- When the RV is empty and the probe is clear, free-flowing air over residual buffer droplets result in evaporative cooling. This is sensed by the thermistor as a *drop* in temperature.

• In a normal aspiration, the magnitude of evaporative cooling is substantial. The resulting *temperature drop,* from evaporative cooling, is compared to a pre-determined threshold. From this comparison, determination of failure or success of the aspiration is made.

Figure 4: Wash Manifold and Vacuum Assembly (ARCHITECT i2000 and i2000SR)

Wash Manifold and Vacuum Assembly
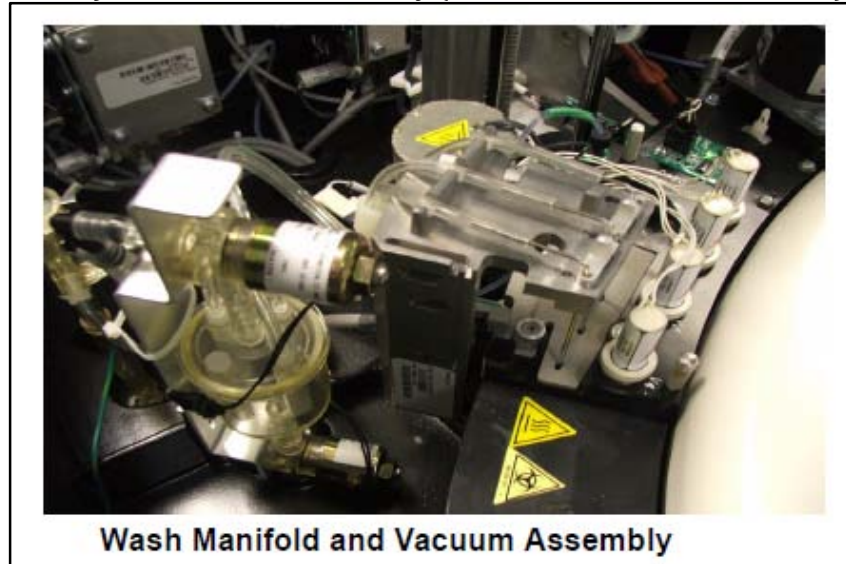
2.4   Abbreviations

ARC	ARCHITECT
AUC	Area Under Curve
CMIA	Chemiluminescent Microparticle Immunoassay
IA	Immunoassay
IDA	Instrument Data Analytics
IHN	Instrument Health Notification
PHM	Prognostic Health Monitoring
ROC	Receiver-Operating Characteristic
RUL	Remaining Useful Life
RV	Reaction Vessel
SCC	System Control Center
WAM	Wash Aspirate Monitoring
WZ	Wash Zone

3.   Data

3.1   Source

WAM Log:
The WAM log file is a useful troubleshooting tool. The information saved in the WAM log includes peak temperature read during aspiration, as well as the subsequent cooling magnitude. This log is uploaded to the enterprise via an AbbottLink connection. For instruments whose data is being collected in the Instrument Data Analytics (IDA) Database, the log data is also uploaded into the IDA where it can be accessed for evaluation.

3.2   Interpreting the WAM Log

To use the WAM Log Data, refer to P-216 WAM Log Interpretation in the *ARCHITECT i2000SR Service and Support Manual*. When reading a WAM Log, consider the following:
- Heating is performed by a Buffer Heater and controlled by a Temperature Controller Board
- Temperature is monitored by a thermistor in the Wash Zone Probe Tubing
- Maximum temperature is from warm Wash Buffer read by the thermistor during aspiration
- Subsequent cooling magnitude (TempDelta) is measured as air passes over the thermistor
- Temperature entries in the log are reported in degrees Celsius
- TempDelta readings greater than 1.25 are expected (1250)

Pre-processing algorithms must be applied to the raw WAM data in order to identify and eliminate empty process path positions and known air aspirations. This type of "data cleaning" is necessary for a meaningful analysis to be completed. The WAM log provides data for all 6 wash zone probes of an instrument by date/time stamp. However, there isn't always an RV present at every probe during every lockstep and known air aspirations exist (the second aspiration from probe 3 is always an air aspiration). Additionally, the 1st aspiration from Probe 1 of either wash zone is written to the WAM log, but ignored by the instrument. This is necessary because the volume of liquid aspirated is too low to acquire reliable thermistor readings, and indeed, temperature readings are quantitatively distinct from Probe 1 as compared to Probes 2 and 3. For this reason, the first aspiration of Probe 1 on either wash zone is eliminated from further analysis.

For example, in the WAM log pictured below, data is depicted for iSR02451 from Wash Zone 2. (Please note that while the log says WZ3, it is actually referencing WZ2. The WZ3 indication comes from an earlier version of system software when the instrument was designed with 3 wash zones. This is no longer the case as the instrument only has 2 wash zones.) The value in the "POSITION" columns is the Replicate ID that can be followed through all wash zone positions. If the "POSITION" value is "0" then there is no RV at that location. During the lockstep that begins at 3:32:44 PM, rep 5012954 is present at WZ2 Probe 1, no RV is present at Probe 2, and rep 5012936 is present at WZ2 Probe 3. Nine seconds later, at 3:32:53 PM, the second aspiration of that particular lockstep occurs. At this time, the same reps are still in the same positions. However, since no dispense occurs at Probe 3 between aspirations, the second set of values for Position 3 in this lockstep are much lower as they are air aspirations. At 3:33:02 PM (18 seconds after our initial time), we move 1 lockstep and now rep 5012954 is present at Probe 2.

Figure 5: WAM Log Example

EVENTDATE	MODULESNDRM	WASHZONEID	POSITION1	MAXTEMPPOSITION1	TEMPDELTAPOSITION1	POSITION2	MAXTEMPPOSITION2	TEMPDELTAPOSITION2	POSITION3	MAXTEMPPOSITION3	TEMPDELTAPOSITION3
05/22/2014 3:32:44 PM	ISR02451	3	5012954	30928	5383	0	29462	5424	5012936	33207	9535
05/22/2014 3:32:53 PM	ISR02451	3	5012954	31615	5034	0	28161	4989	5012936	28407	4115
05/22/2014 3:33:02 PM	ISR02451	3	5012958	30374	4206	5012954	34070	9515	0	27007	1798
05/22/2014 3:33:11 PM	ISR02451	3	5012958	31575	5314	5012954	33838	7224	0	27575	570
05/22/2014 3:33:20 PM	ISR02451	3	5012975	30295	4692	5012958	33609	6964	5012954	33564	6192
05/22/2014 3:33:29 PM	ISR02451	3	5012975	31495	5294	5012958	33612	6800	5012954	28411	5534

4. Alert

4.1 Current Thresholds Set in System Software

The below scores have thresholds set in the system software. If the threshold is violated, the analyzer will send one or more tests to exception.

4.1.1 ARCHITECT Software Thresholds

Score	Lower Threshold	Upper Threshold	Rule	Error Code
Temperature Delta	<= 1.25 C	N/A	1 violation, test sent to exception	3700
Temperature Delta	<= 1.25 C	N/A	10 violations in a row on the same wash zone probe, assay run stopped	3701

4.2 An Algorithm to Generate Predictive WAM Alerts

Retrospective analyses indicate that hard failures are preceded by several diagnostic patterns. A "hard failure" is defined as 10 Temperature Delta values of less than 1.2 C in a row on the same wash zone and probe. The below set of rules constitutes a PHM algorithm predictive of hard failure.

4.2.1 PHM Algorithm Rules for WAM

Marker Name	Score	Lower Threshold	Upper Threshold	Rule
Pattern A	Max Temperature	N/A	> 35 C	>= 5 consecutive violations on a single wash zone probe
Pattern B	Ambient Temperature	< 14 C	N/A	>= 2 consecutive violations on a single wash zone probe
Pattern C	Temperature Delta	N/A	< 3.0 C	>= 20 violations within 1 hour on a single wash zone probe

4.3   Root Cause

Wash aspiration failure can be caused by probe or tubing blockage, vacuum system malfunction or buffer dispense system malfunction. When troubleshooting WAM errors, consider the following questions as a guide to locate the root cause of the failure:

1. Is there an RV consistently under the Wash Zone?
- Verify RV loading and process path positioning

2. Is fluid dispensed into the RV?
- Inspect Buffer Dispense System

3. Is fluid aspirated by the Wash Zone Probe?
- Verify Vacuum System Operation

4. Is the Thermistor operational?
- Verify operation of Temperature System

In addition to predictive flagging of instruments for degrading WAM performance, the algorithm provides information regarding the most probable failure mode. If only one probe on one wash zone is being flagged, the below table presents the most common failure mode associated with each marker. However, if multiple probes or both wash zones are flagging, a faulty thermistor may not be the only issue. In this case, there may be additional issues associated with the instrument's vacuum system. Collaboration with the service organization is ongoing in order to narrow down the "Probable Failure Mode" when multiple probes and/or multiple wash zones are being flagged.

4.3.1   Probable Failure Modes by Pattern

Marker Name	Probable Failure Mode
Pattern A	ARC TUBING/SENS-WZ
Pattern B	ARC TUBING/SENS-WZ, or cabling from thermistors to card cage.
Pattern C	ARC TUBING/SENS-WZ, or Clogged Probe, Vacuum Issues, Dispense Issues, etc.

4.4   Recommended Action

An Instrument Health Notification can be sent then received by either the Service Organization or by a Customer. The recommendation for either party taking action is to follow the procedures in the ARCHITECT System Operations Manual in the Troubleshooting and Diagnostics section for Error 3700. Additionally, the following actions are *recommended specifically for the algorithm being flagged.*

o **For Pattern A**
- o Replace the ARC TUBING/SENS-WZ (part 08C94-87).
- o If flagging persists, perform all troubleshooting steps in Knowledge Management for EC3700.

o **For Pattern B**
- o Replace the ARC TUBING/SENS-WZ (part 08C94-87).
- o If after replacing the ARC TUBING/SENS-WZ (part 08C94-87) flagging persists, check the cabling that goes from the thermistors to the card cage.

- If flagging persists, perform all troubleshooting steps in Knowledge Management for EC3700.

- **For Pattern C in conjunction with A and/or B**
  - If flagging pattern C along with A and or B: Replace Thermistor tubing per pattern A and/or B. If pattern C continues to flag, then follow steps below for flagging pattern C.
- **For Pattern C alone**
  - Perform all troubleshooting steps in Knowledge Management for EC3700.
  - Perform ISA 116-129 (Vacuum Troubleshooting information)

5. Supporting Evidence

5.1 Algorithm Design Phase: Retrospective (Historical) Analysis

To identify predictive patterns, instruments exhibiting hard failure (*temp delta* <= 1.2 C for 10 consecutive replicates) in the last 90 days were queried from the IDA. This resulted in 147 total failure events. Next, the available time series for *maxtemp* and *tempdelta* was plotted for each failure event and examined systematically for diagnostic patterns.

Note: A temperature delta of 1.2 C (a truncated version of 1.25 C) was used for the analysis of the hard failure. The ARCHITECT software uses 1.25 C for the temperature delta lower threshold as seen in section 4.1.1. Any individual WAM temp delta that is less than 1.2 C will also be less than 1.25 C and will have an associated 3700 error code.

5.1.1 Pattern A

Description

In the historical dataset, Pattern A is characterized by a gradual or sharp increase in *maxtemp* occurring at a median of 3.08 days prior to hard failure. About 32% of all instruments with hard failures exhibited Pattern A. Two typical Pattern A examples are shown below.

Here, and throughout this document, figures present *maxtemp* in blue and *tempdelta* in red. *Ambient temperature* (when plotted) occupies a separate graph below the *maxtemp* and *tempdelta* series. Data are not averaged by day; each aspiration recorded in the WAM log is plotted. X-axes represent aspiration #, beginning arbitrarily at 0, corresponding to the first available data point. Vertical lines are added automatically by the algorithm to denote points of interest: flag times first, and hard failure times second. Traces are truncated at the moment of hard failure, and may not be visible by eye.

Figure 6: Example 1 of Pattern A
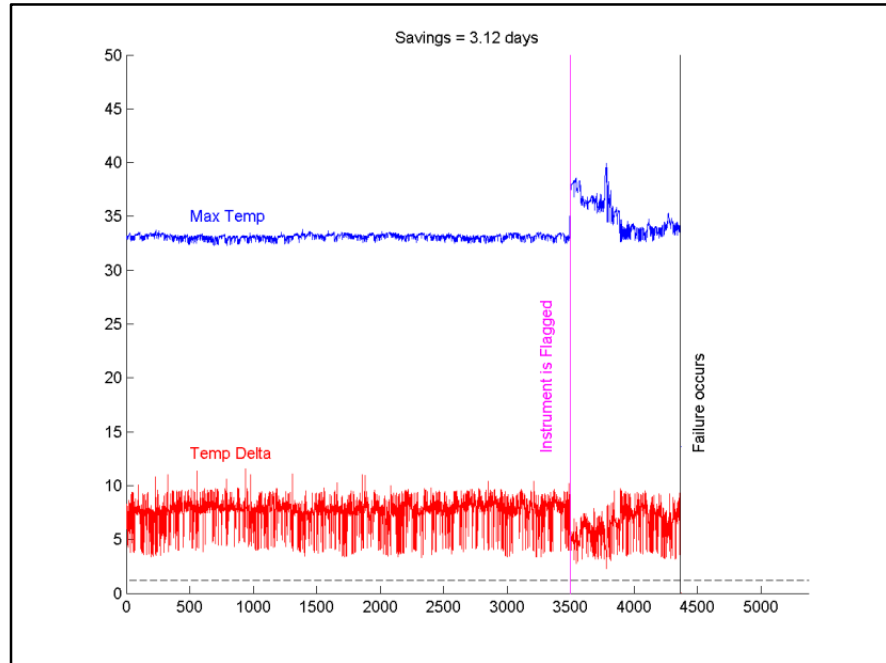
Figure 7: Example 2 of Pattern A
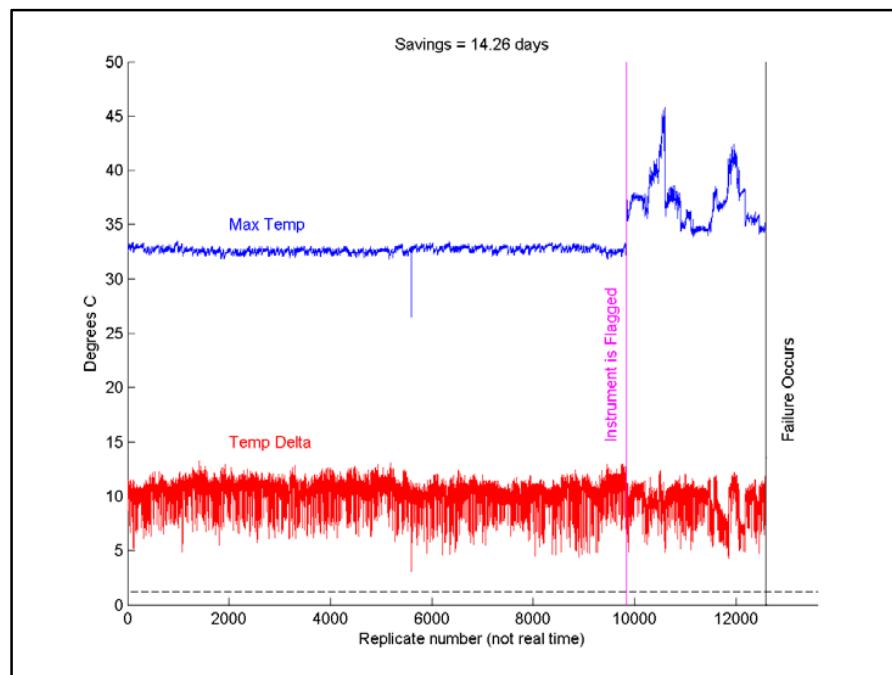
ROC Curve

The *receiver-operating characteristic* (ROC) quantifies the ability of an ideal observer to classify instruments using only *maxtemp* and a decision rule based on exceeding a particular value. In this historical analysis, the ROC curve expresses the extent to which Pattern A tends to occur when hard failures occur.

Mathematically, this compares the conditional probability:

$$Pr(\text{Pattern A} \mid \text{hard failure})$$

which is read: 'The probability of Pattern A occurring given that a hard failure occurred.'

$$to$$

$$Pr(\text{Pattern A} \mid \sim\text{hard failure})$$

which is read: 'The probability of Pattern A occurring given that a hard failure did not occur.'

To construct this curve, the *maxtemp* time-series from probes exhibiting hard failure were compared to that from probes not exhibiting hard failure. For each criterion k (from 0 to 50 C in 0.25 C increments), if *maxtemp* exceeded k for 5 consecutive aspirations[4], the probe was scored as "1", and "0" otherwise. If the algorithm was perfect, this classification scheme would exactly equal ground truth ("1" for probes with hard failures, "0" for probes without hard failures). This process yields a hit rate and false alarm rate for each criterion k. By varying $k,$ we find how often Pattern A occurs in the presence of hard failures, while gauging the best threshold value to use in the final algorithm.

The area under the ROC curve (AUC), a measure of classification efficacy, was 0.939. (A value of 0.5 would be equivalent to flipping a coin). A threshold of 35 C yielded the best compromise between sensitivity and specificity.

Figure 8: ROC Curve for Pattern A

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[4] Run lengths 1, 2, 5, 10, 20, and 50 were also tested. Run lengths greater than 10 resulted in lower ROC values; run lengths <= 10 were very similar; 5 was eventually chosen.
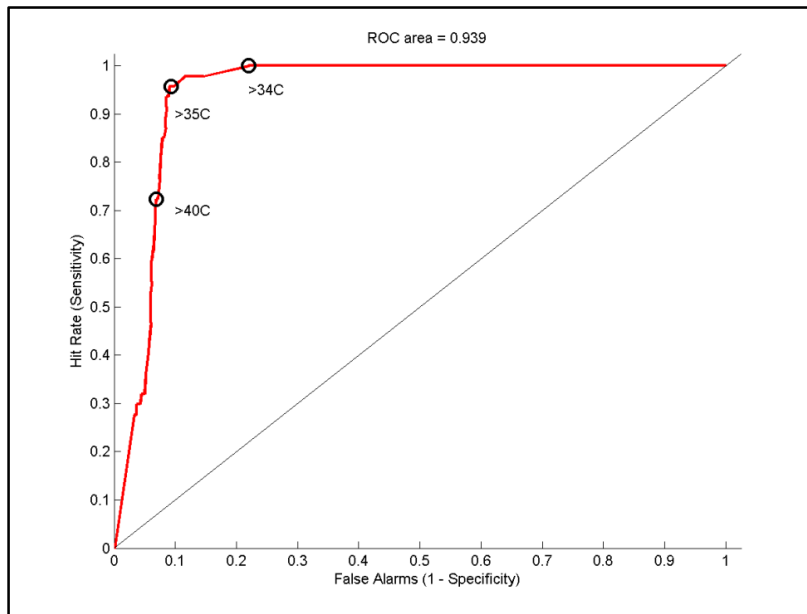
Remaining Useful Life (RUL)

Here, RUL refers to the temporal lag between when an instrument is flagged by Pattern A and when hard failure occurs. For Pattern A, the RUL distribution is below:

Figure 9: RUL Distribution for Pattern A (Histogram & Cumulative Distribution Function)
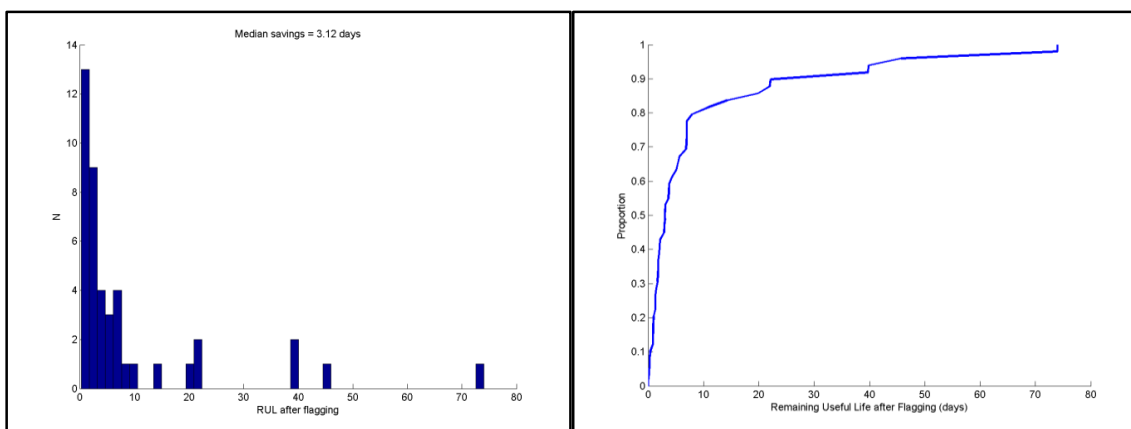
Root Cause

We identified instruments that 1) exhibited hard failure, 2) evidenced Pattern A, and 3) were serviced shortly after. The parts replaced for each failure event was recorded. There was an overwhelming tendency for Pattern A to result in replacement of the sensor or tubing (98%). Taking into account the fact that sensor/tubing replacement is also the most common response to WAM failures, Pattern A was found to result in this servicing event far more often than would be expected by chance (statistically significant by chi-square).

Figure 10: Contingency Analysis of Tubing/Sensor Replacement By Pattern
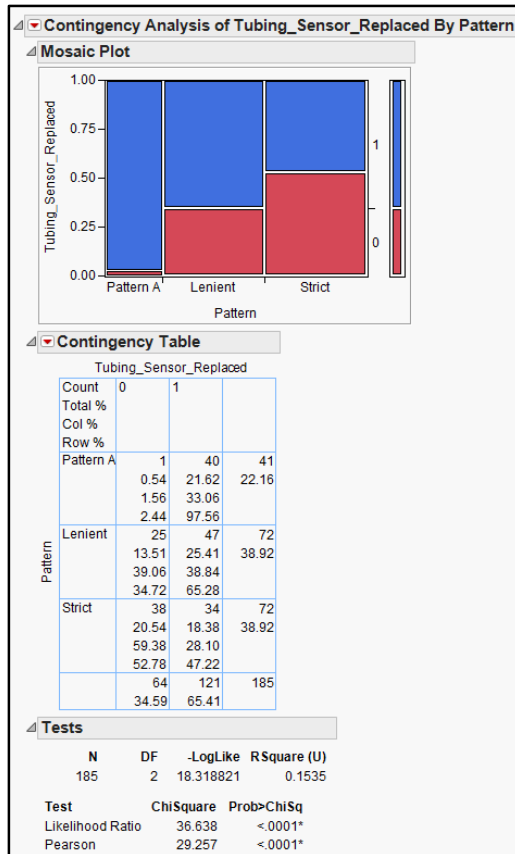
5.1.2   Pattern B

Description

Pattern B is characterized by a gradual or sharp decrease in *ambient temperature*. Ambient temperature is not saved to WAM logs, but can be easily recreated with the equation:

$$\text{Ambient temperature} = \text{MaxTemp} - \text{TempDelta}$$

About 8% of all instruments with hard failures exhibited Pattern B.

Figure 11: Example 1 of Pattern B
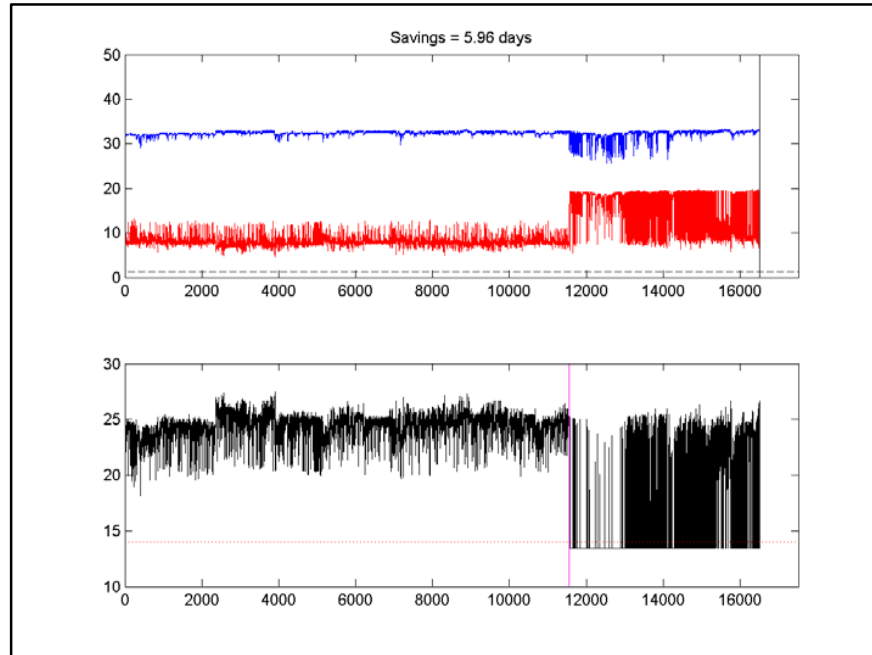

Figure 12: Example 2 of Pattern B
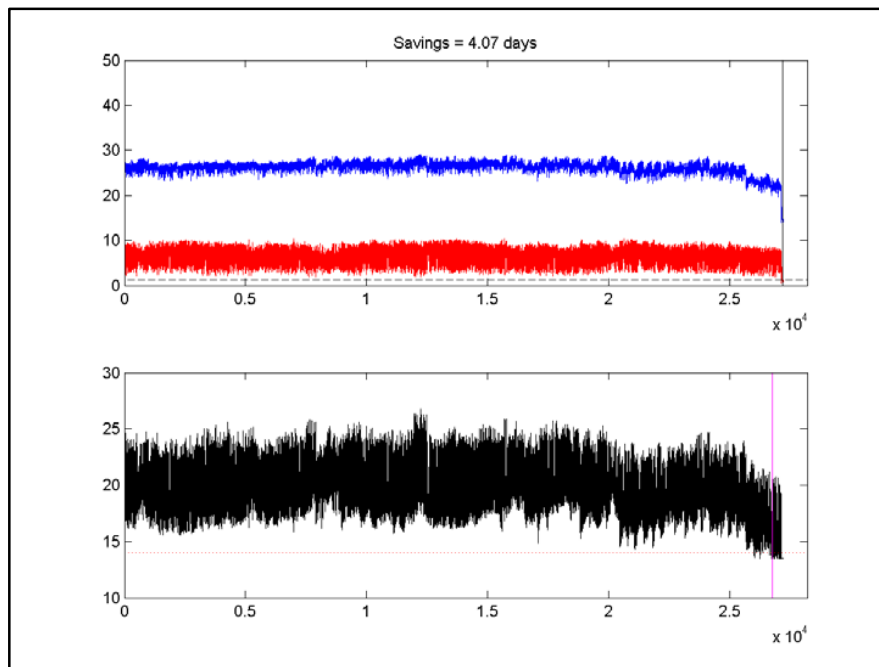
ROC Curve

To construct the ROC curve for Pattern B, the *ambient temperature* time-series from instruments exhibiting hard failure was compared to that from instruments not exhibiting hard failure, in the same manner as was described earlier for Pattern A. For each criterion k (from 0 to 50 C in 0.25 C increments), if *ambient temperature* exceeded k for 2 consecutive replicates, the instrument was scored as "1", and "0" otherwise. The hit rate and false alarm rate for each k was computed, and the area under the curve (AUC),

a measure of classification efficacy, was 0.98. A threshold of 14 C yielded the best compromise between sensitivity and specificity.

Figure 13: ROC Curve for Pattern B
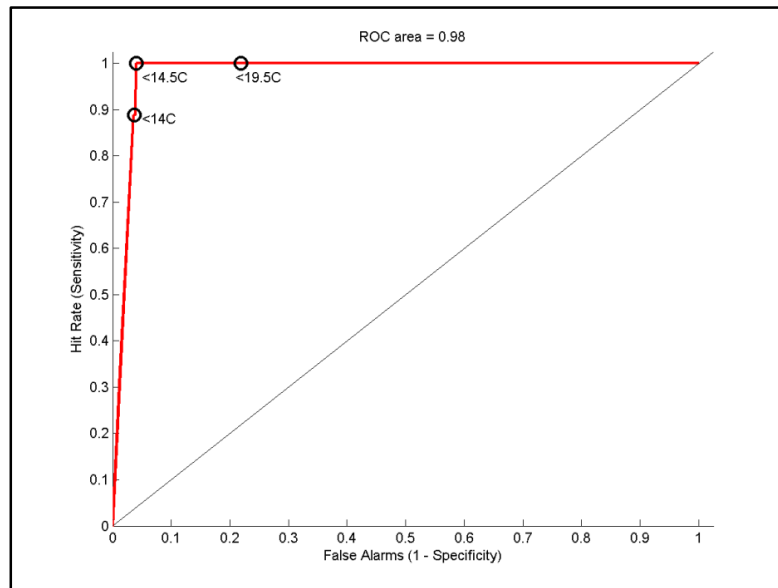
Remaining Useful Life (RUL)

The RUL distribution for Pattern B is below. The median RUL of 35 days is much longer than for Pattern A, but note also that Pattern B had much lower N than Pattern A in this historical dataset.

Figure 14: RUL Distribution for Pattern B (Histogram & Cumulative Distribution Function)
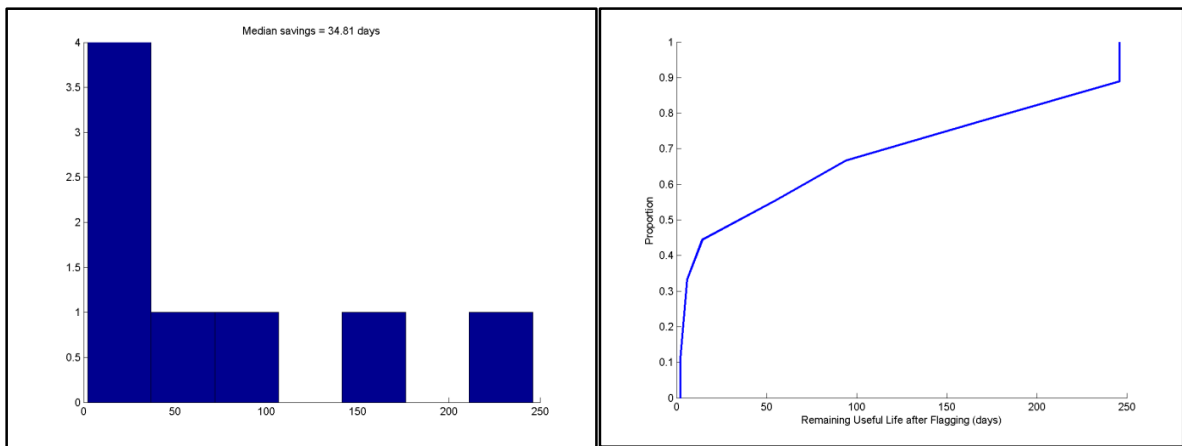
Root Cause

The root cause for Pattern B has not yet been ascertained, but intuition suggests a bad sensor due to:

1) Values of *ambient temperature* that are logically too low.
2) The existence of saturation events (see Pattern B example 1) common in failing sensors.

5.1.3   Pattern C

Description

Pattern C is an extension of a guideline in use by the service organization. Specifically, it is thought that when the number of TempDelta values < 3.5 C exceeded 10 in any 2 hour interval, the probe is trending towards a failure event. We investigated this analytically. For each probe in the historical database, we computed the *instantaneous rate* of TempDelta violations < X. Four values of X were assessed, including 2.5C, 3.0C, 3.5C, and 4.0C. This was accomplished through a sliding window of 1-hour duration. At each step, the program advances to the next TempDelta value occurring >= 1 hour later. The instantaneous rate for each window is then calculated as:

$$\text{Instantaneous Rate} = \text{\# violations / real time span}$$

In the below two examples, the violation rate is plotted in the lower panels. The probe is flagged when there are 20 violations within 1 hour of tempdelta < 3.0C.

Figure 15: Example 1 of Pattern C
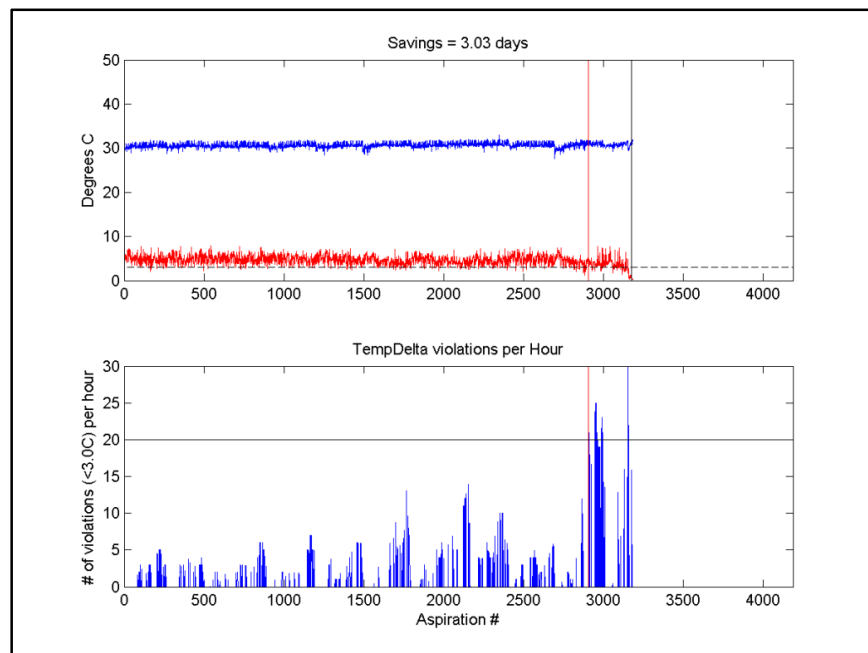
Figure 16: Example 2 of Pattern C
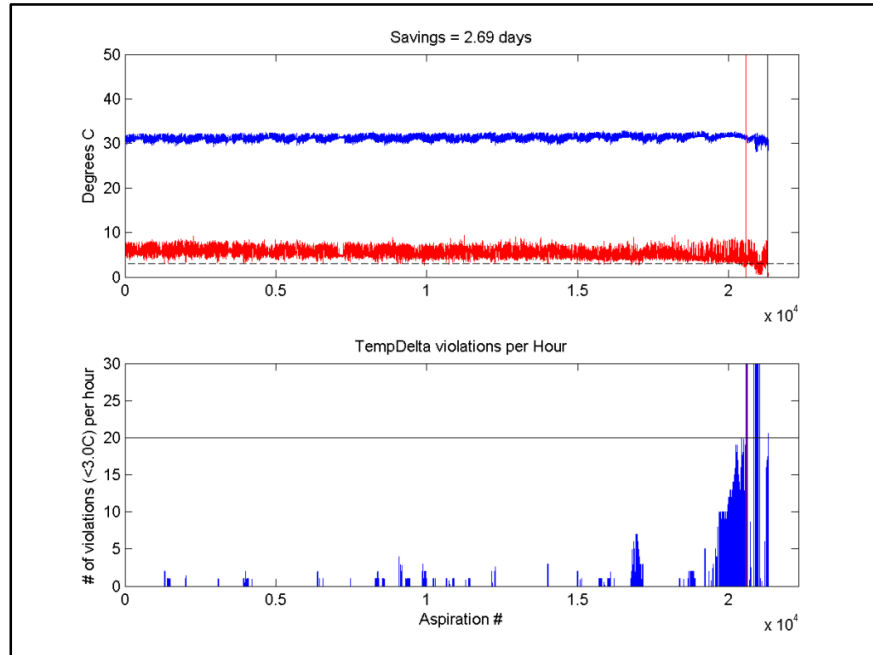
ROC Curve

To construct the ROC curve for Pattern C, the number of TempDelta readings < X within 1 hour was computed using a sliding window. This was computed for violation cutoff temperatures of 2.5C, 3.0C, 3.5C, and 4.0C. Next, we computed an ROC curve for *each* cutoff temperature by varying the threshold number of violations needed to flag for Pattern C. The ROC curve was traced out by varying the threshold violation rate from 0 to 500 (per hour) in steps of 1.0. The ROC curves for each cutoff temperature are below.

Figure 17: ROC Curve for Pattern C
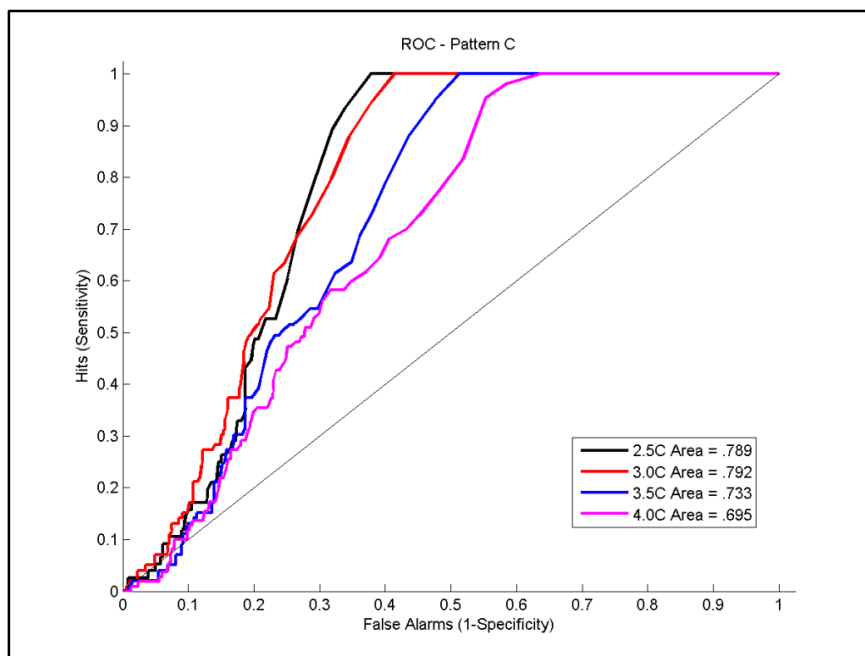
Numerically, the greatest classification accuracy was achieved using a cutoff temperature of 3.0C (see red trace above). Thus, 3.0C was chosen retained for future analyses. In the below, the ROC curve for a 3.0C cutoff is re-plotted, with specific violation thresholds indicated.

Figure 18: ROC Curve for Pattern C
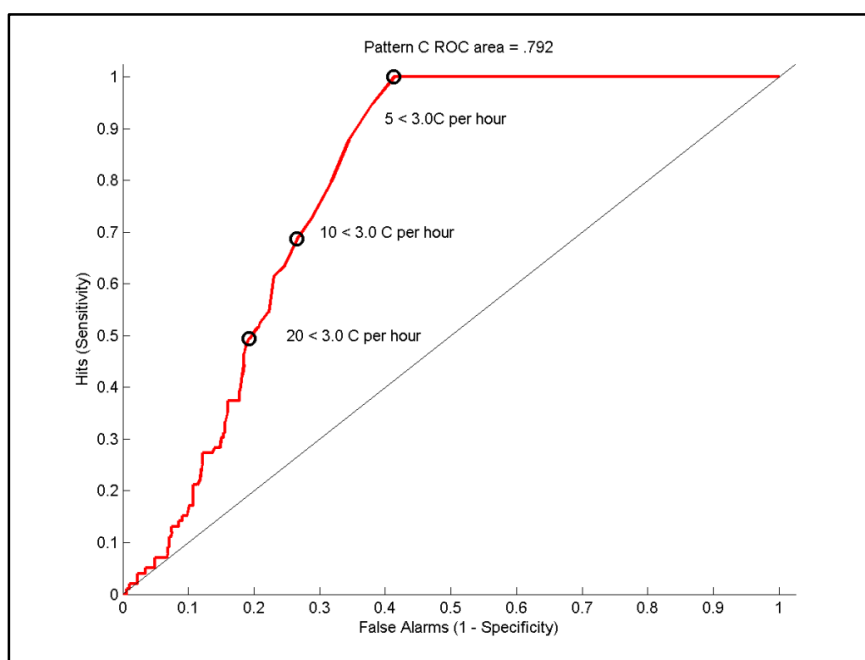
The ROC analysis suggests that using a threshold of 20 TempDelta readings < 3.0C within 1 hour leads to a hit rate of approximately 50% with about 80% specificity.

Remaining Useful Life (RUL)
Pattern C yielded a median RUL of 0.9 days. RUL distributions are plotted below.

*Figure 19: RUL Distribution for Pattern C (Histogram & Cumulative Distribution Function)*
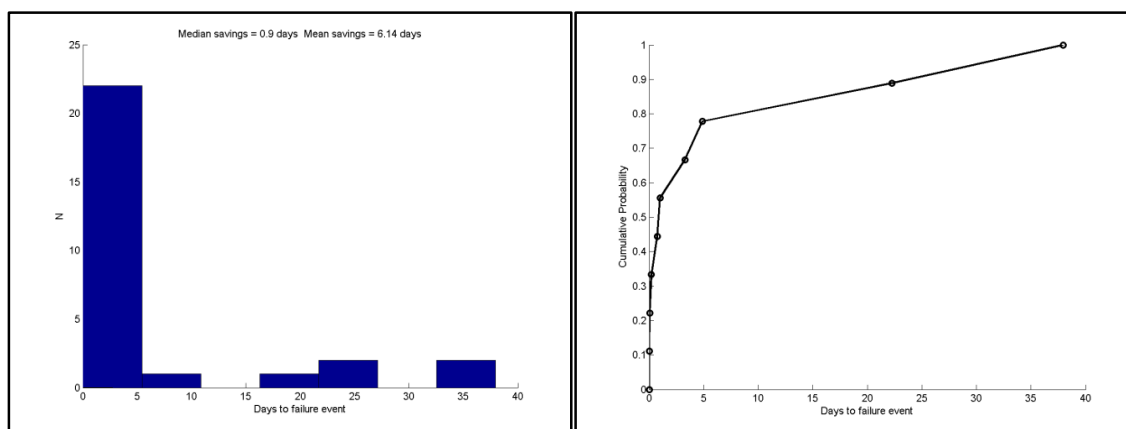
Root Cause
Like Patterns A and B, there is evidence to suggest that Pattern C sometimes, but not always arises in the presence of sensor and tubing issues. In the historical dataset, 15 probes that were flagged by Pattern C later had tickets opened. Of those, all reported servicing of the tubing/sensor assembly, but only 8

indicated likely cause. The service organization's expertise suggests that Pattern C may also indicate vacuum problems. Identifying root cause for Pattern C requires additional data and analysis and is the focus of ongoing investigation.

5.2   Algorithm Validation Phase: Prospective (Predictive) Analysis

The efficacy of this algorithm rests with its ability to identify instruments that will fail from those that will not. The historical analysis described above does not directly speak to this, as 1) the dataset was (necessarily) biased, and 2) the conditional probability of Pr(Pattern X | hard fail) is not, ultimately, of use to the service organization. Rather, a successful PHM algorithm addresses the converse conditional probability of Pr(hard fail | Pattern X). **It is important to appreciate that the below analysis is both qualitatively and quantitatively distinct from the historical analysis used during the algorithm design phase.** To ascertain the real-world predictive utility of Pattern A and B, two studies were conducted.

5.2.1   Study 1

We first conducted a real-world case study. On 8/6/2014, 1000 instruments were randomly selected from the IDA; the last 30 days of available data was obtained. From this, we identified a subset of 'imminent failure' instruments, characterized by:

a)   They were *currently* flagging for Pattern A or B (i.e., on 8/6/2014, the available data triggered the alert)
b)   A hard failure had *not yet occurred*.

<center>Pattern A flagged 21 instruments for imminent failure.</center>

<center>Pattern B flagged 11 instruments for imminent failure.</center>

The data for this subset of instruments were queried again on 9/3/2014 to assess whether or not they did indeed fail. This scenario approximates what the service organization might have experienced had the algorithm been in place.

Results:

There were several noteworthy observations.

1)   Patterns A and B often present in the vicinity of 3700 errors (single tempdelta < 1.2C) even when hard failures do not occur. We thus relaxed our assessment to include "soft failures" (2 consecutive aspirations with tempdelta < 1.2C). Currently, soft failures are sufficient for service to open a ticket via POM alert.
2)   There is evidence for 'customer intervention' in the absence of any hard or soft failure. Often, this follows the appearance of Pattern A or B, suggesting that customers were aware of a potential issue and serviced the instrument without opening a ticket (see examples below). This may lead to an artifactual reduction in ROC area. The extent to which this occurs is not known.
3)   Pattern A: of the 21 instruments flagged for imminent failure:
    a.   12 (57%) exhibited a hard or soft failure
    b.   4 (19%) appear to still be having issues (failure event still approaching)
    c.   2 (10%) exhibited evidence of customer intervention
    d.   3 (14%) returned to normal without any known intervention
4)   Pattern B: of the 11 instruments flagged for imminent failure:

a. 2 (18%) exhibited a hard or soft failure

b. 7 (64%) appear to still be having issues; this may not be surprising given that the RUL distribution for Pattern B is longer than for Pattern A

c. 2 (18%) returned to normal without any known intervention

5) Pattern C: the imminent failure analysis was not conducted on Pattern C

In the examples that follow, colored traces represent the initial dataset of 1000 instruments used to generate PHM alerts. Black traces continue with data queried after alerts were generated.

Figure 20: Predictive Analysis Example A1: Pattern A flags, instrument later fails
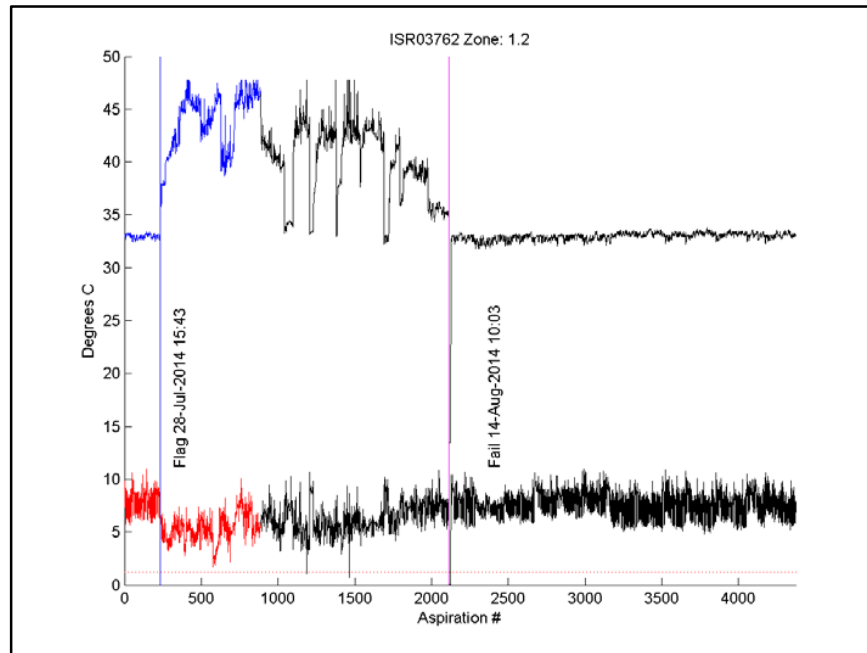
Figure 21: Predictive Analysis Example A2: Pattern A flags, instrument later fails
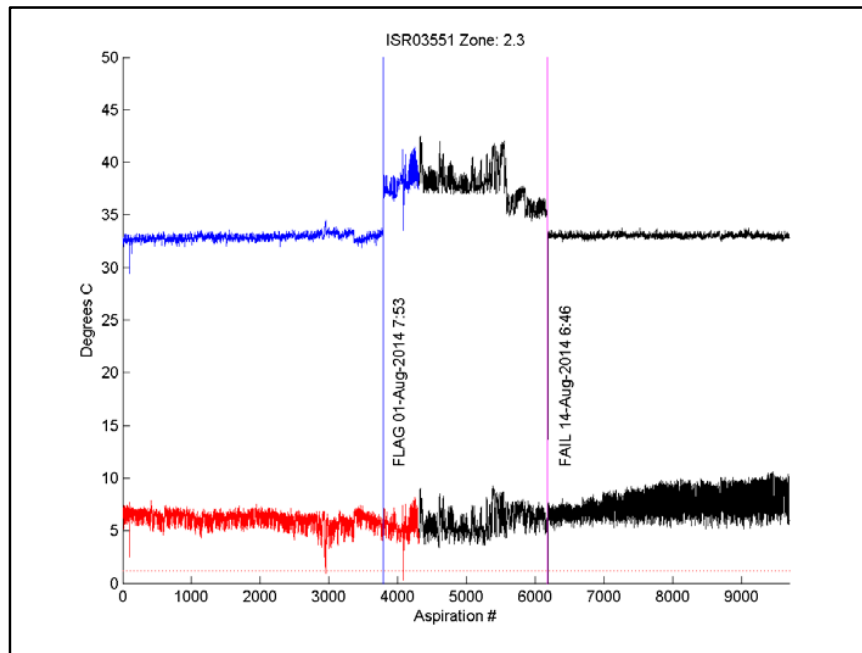
Figure 22: Predictive Analysis Example A3: Pattern A flags, instrument still having issues
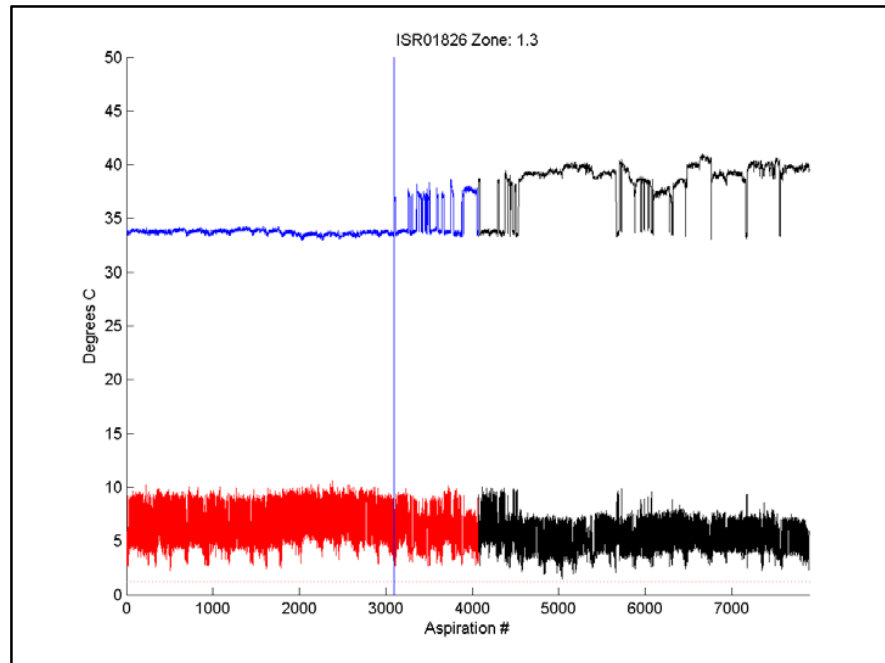
*Figure 23: Predictive Analysis Example A4: Pattern A flags, potential customer intervention*
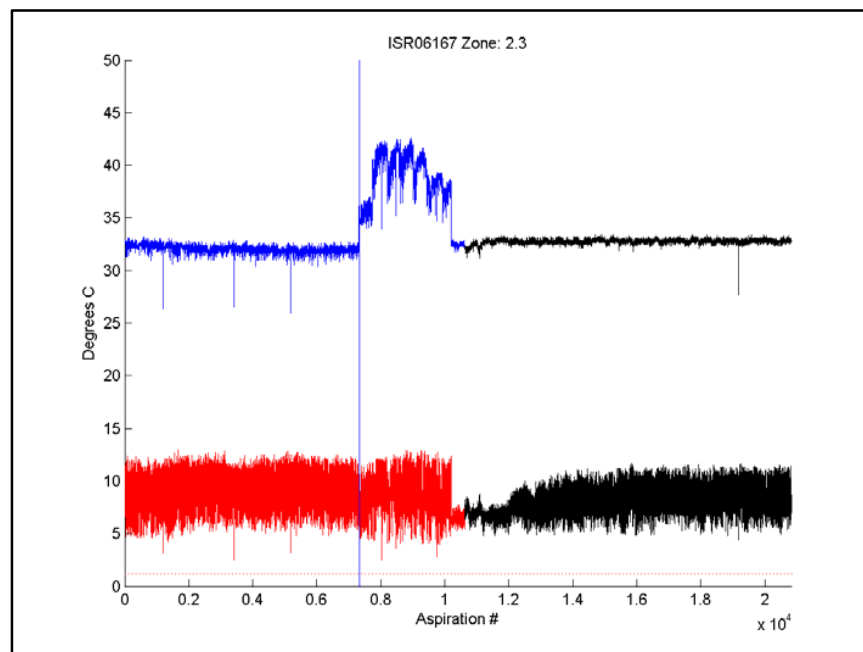
**Figure 24: Predictive Analysis Example B1: Pattern B flags, instrument later fails**
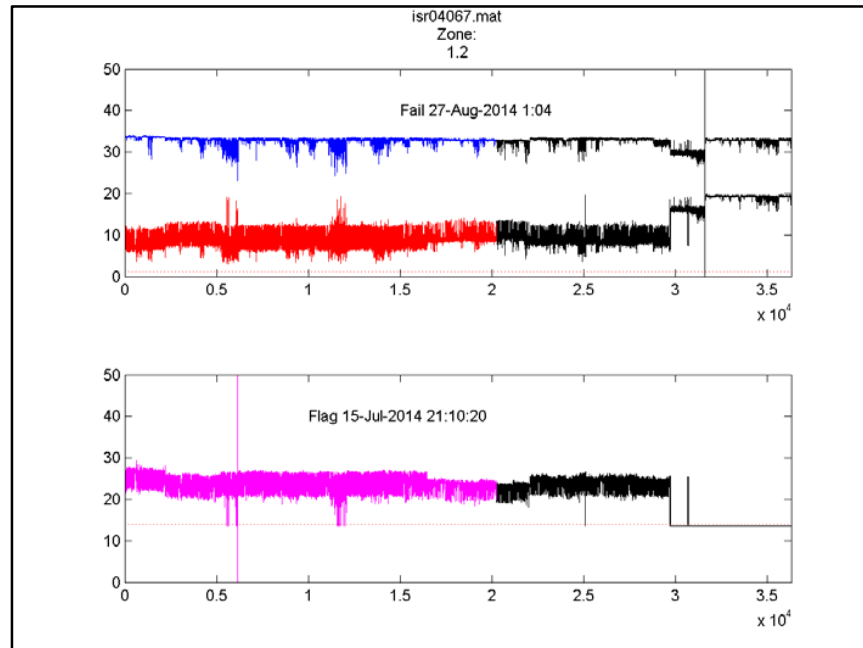
**Figure 25: Predictive Analysis Example B2: Pattern B flags, instrument still having issues**
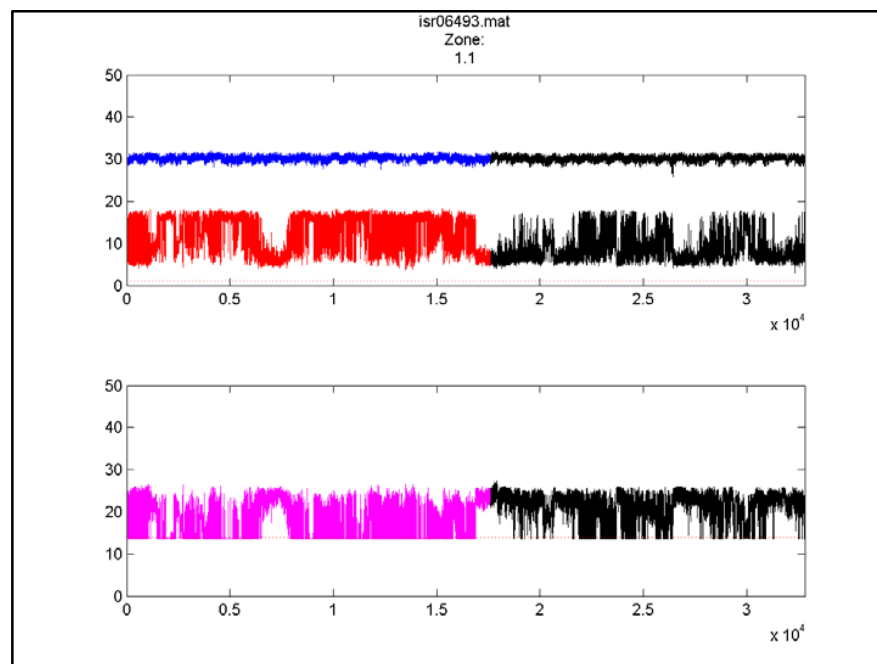
Figure 26: Predictive Analysis Example B3: Pattern B flags, issue resolved with no known intervention (potential False Alarm)
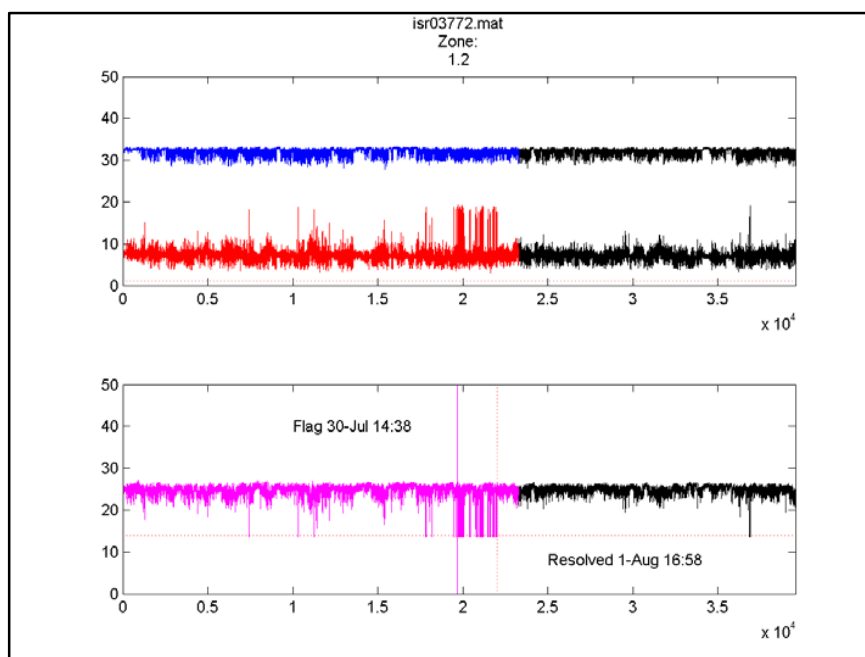
5.2.2 Study 2

We next used the same dataset of 1000 instruments to evaluate overall prognostic performance. Unlike the design phase, this study compares the converse conditional probabilities:

$$Pr(\text{hard fail} \mid \text{Pattern A})$$

which is read: "The probability of a hard failure given that Pattern A occurred"

to

$$Pr(\text{hard fail} \mid \sim\text{Pattern A})$$

which is read: "The probability of a hard failure given that Pattern A does not occur"

This comparison speaks directly to the utility of the algorithms for use in predicting failure events.

Overall performance

Over the ~30 days of data queried from 1000 randomly sampled instruments:

1) Pattern A flagged 172 probes. Of these, 108 (63%) exhibited a hard or soft fail. The remaining 38% consist of failure events that have not yet occurred and some number of false alarms.
2) Pattern B flagged 79 probes. Of these, 62 (79%) exhibited a hard or soft fail. As above, the remaining 22% consist of failure events yet to occur and some number of false alarms.
3) Pattern C flagged 88 probes. Of these, 50 (57%) exhibited a hard or soft fail. As above, the remaining 43% consist of failure events yet to occur and some number of false alarms.
   Please note that Pattern C **was not applied to Probe 1 of either wash zone**. The basis for this decision stems from two facts:
   a) The first aspiration of Probe 1 is recorded to the WAM log but is ignored by the instrument and does not play a role in generating any error codes.
   b) Probe 1 temperatures tend to be lower than Probes 2 & 3 and thus lead to more spurious Pattern C triggers than should otherwise occur.

Confusion Matrix

The table below indicates the number of probes flagged by the algorithm in the presence of a true hard failure, soft failure, or when no failure event occurred. Notably, of 137 hard failure events, 109 (80%) were detected by at least one rule. Conversely, of 4,782 probes that did *not* fail, only 420 (9%) were erroneously flagged by the algorithm. Of those, 83% were localized to Pattern C.

5.2.2 Confusion Matrix

		Flags				
		Pattern A	Pattern B	Pattern C	A or B or C	N
TRUTH	Hard Fail	68	49	50	109	137
	Soft Fail	107	62	108	187	253
	No Fail	65	16	347	420	4782

Remaining Useful Life (RUL)

Pattern A

Pattern A has a remaining useful life distribution with median = 2.93 days; as seen in the CDF function (below right), about 75% of failure events occur within ~10 days of the alert.

Figure 27: RUL Distribution for Pattern A (Histogram & Cumulative Distribution Function)
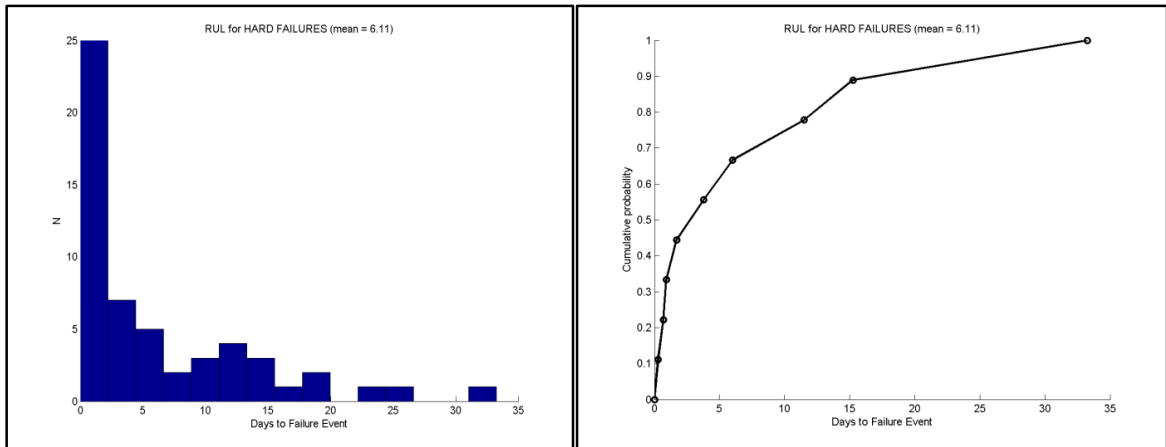
Pattern B

Despite Pattern B's strong ROC curve, many of its flagging events occur coincident with the failure event. Thus, it is accurate, but often does not provide much lead time. The below RUL distribution includes only 5 cases in which Pattern B flagged an instrument and it failed with RUL > 0.

Figure 28: RUL Distribution for Pattern B (Histogram & Cumulative Distribution Function)
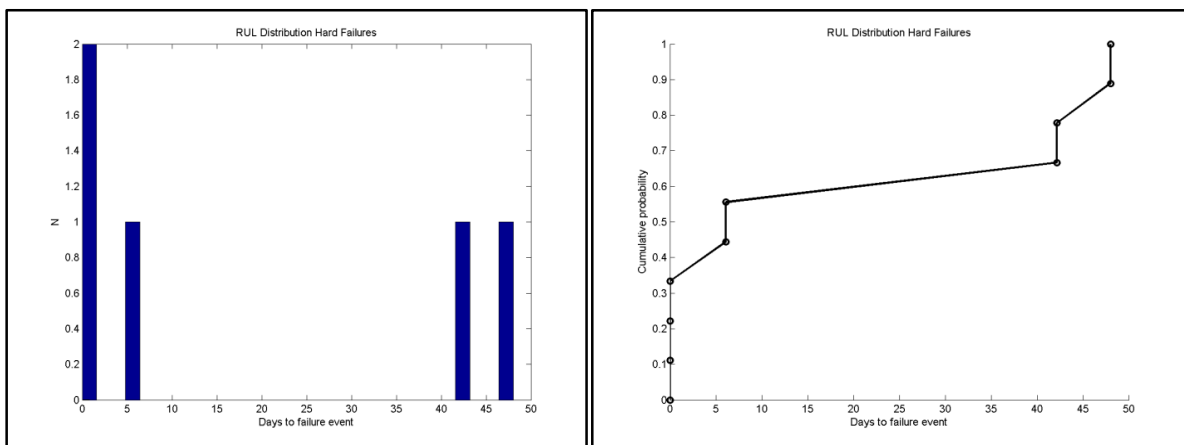
Pattern C

Pattern C yielded a median RUL of 1.39 days. As above, this excludes a small number of cases (n=6) in which the RUL estimate was 0, Pattern C having flagged coincident with the failure event.

Figure 29: RUL Distribution for Pattern C (Histogram & Cumulative Distribution Function)
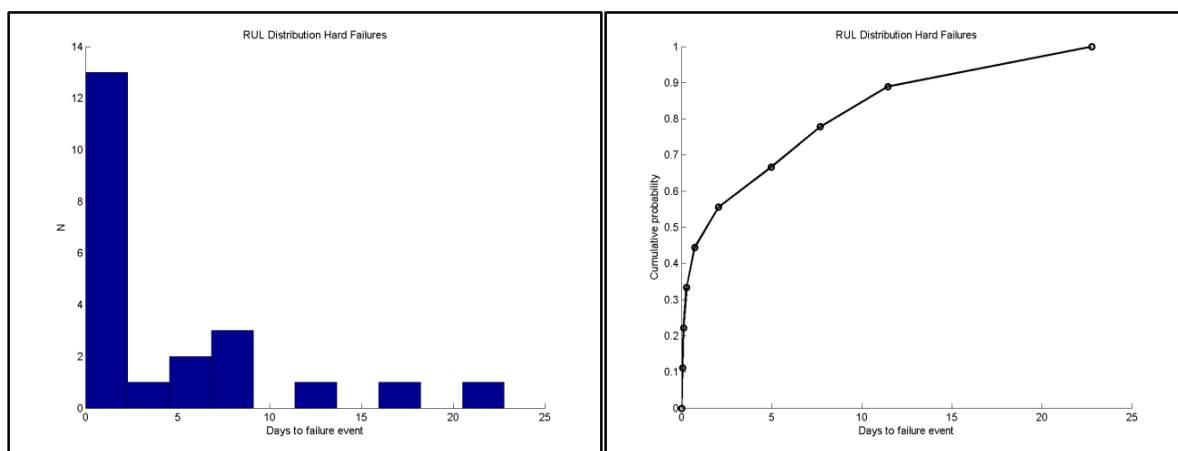
6. Benefits

The benefits of replacing WAM components when the algorithms predict an imminent problem can be summarized as follows:

a) Decrease in tests lost to exception due to 3700 errors
b) Decreased unplanned instrument downtime
c) Increased proactive service tickets
d) Decreased reactive service tickets
e) Increased customer satisfaction

7. Applicable Documents

7.1 Field Service Documents

ARCHITECT i2000/i2000SR Service and Support Manual
ARCHITECT i2000SR Field Service Training Manual
ARCHITECT i1000SR Service and Support Manual
ARCHITECT i1000SR Field Service Training Manual

7.2 System Requirement

PRD.D01-126: The ARCHITECT-IA system shall be capable of washing reaction vessels such that the average residual volume of wash buffer in cuvettes exiting a wash zone shall be at a volume of 9.0 ul or less with an SD of 2.0 ul.

PRD.D01-140: The ARCHITECT-IA system shall be capable of retaining an average of 92% or greater of the microparticles through two wash zones with a range of +/- 11.0% capture from the average. The test method controls must have a total range of </= 22.0%.

DHF-40000-000-02793 – Liquid Wash Management GDS13.D01: Temperature sensors located in the aspiration lines of each CMIA wash zone are used to detect clogs in the aspiration lines by measuring the air and liquid temperature during aspiration. During a normal aspiration, the aspirated liquid temperature gives a high temperature reading. Since the vacuum remains for an extended period of time after fluid has been evacuated, the reduced air temperature following aspiration, in conjunction with an evaporative cooling effect, produces a low temperature reading. A temperature delta greater than the set threshold indicates a good aspiration.

If vacuum is not present, processing cannot proceed. The controller module accordingly shuts down processing and notifies the ICW, informing the operator of the instrument status. If liquid is detected in the Wash reservoir, the entire vacuum system is suspect and processing cannot proceed. Again, processing of further tests ceases and the ICW and operator are informed. WAM (Wash Aspiration Monitoring) clog detection thermistor monitors the CMIA wash zone aspiration during processing. If the WAM detects a clog, processing will be stopped.

7.3 WAM Systems and Components
- WAM System
    - ARC TUBING/SENS-WZ: 08C94-87
    - ARC PROBE, WASH ZN: 08C94-35
- Vacuum System
    - PUMP, VACUUM: 7-77795-01
    - FILTER, VACUUM: 7-78475-01
    - VALVE, VACUUM: 7-76446-01
    - VALVE, DRAIN, VACUUM VESSEL: 7-76447-01
    - ASSY, VACUUM ACCUMULATOR, COMP: 7-200085-01
    - VACUUM VESSEL ASSEMBLY, WZ1: 7-77797-04
    - VACUUM VESSEL ASSEMBLY, WZ2: 7-77798-04
- Buffer Dispense System
    - 100UL BUFFER PUMP: 7-96343-01
    - 50UL BUFFER PUMP (WZ): 7-96346-01
    - VALVE, MANIFOLD KIT: 7-77612-03
    - HEATER, WZ BUFFER: 7-78306-02
    - WZ MANIFOLD: 7-96263-06
    - WZ MANIFOLD, FEP TIPS: 7-96176-05

7.4   Hazard Analysis

An excerpt from HA.D05 Hazard Analysis for Wash Zone:

Object Type	ID	Hazard Source	Hazard Cause	Module Assignment	Harm/Effect	Sev/Prob/Risk	Control Measures	Implementation and Verification	Risk Management Activity
Hazard Source	5340	**Incorrect Dispense of Wash Buffer volume**							
Hazard Cause	5341		Wash zone pump failure or pump performs only partial pump cycle	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design		
Mode of Control	839						Design	GDR46.D01 - ID 434 GDS12.D01 - ID 608, 618	
Mode of Control	1989						Design	SWRS OID 3686	
Hazard Cause	5342		Valve/Tubing/Connector failure resulting in dripping of wash buffer or formation of bubbles in fluidics lines	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Rare M	Design		
Mode of Control	841						Design	PRD.D01 - ID 148	
Mode of Control	842						Design	SWRS OID 1228	
Mode of Control	6064						Design	SWRS OID 1202	RMT Action02991
Hazard Cause	5343		Leaking wash zone manifold causes dripping of wash buffer and/or salt buildup	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling		
Mode of Control	2185						Labeling	ARCHITECT Operations Manual, Section 10, Troubleshooting and Diagnostics. Diagnostic procedures 2006, Wash Zone 1 Check, and 2007 Wash Zone 2 Check ARCHITECT Operations Manual, Section 9, Service and Maintenance/Maintenance, 6015 WZ Probe Cleaning - Manual	pNCR242437
Mode of Control	2186						Design	SWRS OID 1171, 1057	
Hazard Cause	5344		Wash buffer Low	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design		
Mode of Control	845						Design	GDR46.D01 - ID 438 GDS12.D01 - ID 608	
Mode of Control	846						Design	SWRS OID 283	
Hazard Cause	5345		Plugged wash buffer dispense probe.	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling		
Mode of Control	850						Labeling	ARCHITECT Operations Manual, Section 10, Troubleshooting and Diagnostics, procedures 2006 and 2007 wash zone dispense checks	
Mode of Control	851						Design	SWRS OID 1228	
Mode of Control	6065						Design	SWRS OID 1202	RMT Action02991
Hazard Source	5346	**Incorrect aspiration of wash buffer from reaction vessel**							

Hazard Cause	5347		Global vacuum failure - wash buffer is not aspirated from reaction vessel	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	853						Design	GDS13.D01 - ID 1090 GDS47.D01 - ID 1873
Hazard Cause	5348		Vacuum Failure - wash buffer is not aspirated - Single wash zone failure and/or individual wash head failure, position 4 of wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	855						Design	SWRS OID 1202
Hazard Cause	5349		Vacuum Failure - wash buffer is not aspirated - Single wash zone failure and/or individual wash head failure, positions 2 or 3 of Wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	856						Design	SWRS OID 1202
Hazard Cause	5350		Wash head drive mechanism failure	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	857						Design	GDR05.D01 - ID 539
Hazard Cause	5351		Probe/connector/ line leak resulting in loss of vacuum at the system level	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	858						Design	GDS13.D01 - ID 1090 GDS47.D01 - ID 1873
Hazard Cause	5352		Probe/ Connector/ line leak resulting in loss of vacuum at Wash Zone or at position 4 of each zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	860						Design	SWRS OID 1202
Hazard Cause	5353		Probe/ Connector/ line leak resulting in loss of vacuum at position 2 and/or position 3 of a wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	861						Design	SWRS OID 1202
Hazard Cause	5354		Plugged aspirate probe - position 4 of a wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling Protection	
Mode of Control	862						Labeling Protection	ARCHITECT Operations Manual, Section 9, Service and Maintenance.
Mode of Control	863						Design	SWRS OID 1202
Hazard Cause	5355		Plugged aspirate probe - position 2 and/or 3 of a wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling Protection	
Mode of Control	864						Labeling Protection	ARCHITECT Operations Manual, Section 9, Service and Maintenance.
Mode of Control	865						Design	SWRS OID 1202
Hazard Cause	5356		Wash aspiration probes plugged due to rapid buildup of proteinaceous material on the interior walls of probes at wash zone 1 after aspiration of the residual B12 pretreatment solution	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design	
Mode of Control	866						Design	SWRS OID 1202

Hazard Source	5357	**Aspirate probe carryover**							
Hazard Cause	5358		Aspirate probe penetration into fluid is too deep	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design		
Mode of Control	867						Design	GDS13.D01 - ID 1073 GDS47.D01 - ID 1856	
Hazard Cause	5359		Vacuum/valve failure causing incomplete or slow aspiration of wash buffer from reaction vessel -position 4 of each wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design		
Mode of Control	869						Design	SWRS OID 3696	
Hazard Cause	5360		Vacuum/valve failure causing incomplete or slow aspiration of wash buffer from reaction vessel -position(s) 2 and/or 3 of each wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design		
Mode of Control	870						Design	SWRS OID 4321	
Hazard Cause	5361		Probe/line partial blockage causing incomplete or slow aspiration of wash buffer from reaction vessel - position(s) 2 and/or 3 of each wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling Protection		
Mode of Control	871						Design	SWRS OID 1202	
Mode of Control	1986						Labeling Protection	M&D 6043 ARCHITECT Operations Manual, Section 9, AS Needed Maintenance	
Hazard Cause	5362		Probe/line partial blockage causing incomplete or slow aspiration of wash buffer from reaction vessel - position 4 of each wash zone	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling		
Mode of Control	872						Design	SWRS OID 1202	
Mode of Control	1987						Labeling	M&D 6043 ARCHITECT Operations Manual, Section 9, AS Needed Maintenance	
Hazard Cause	5363		Residual sodium hypochlorite >1PPM on aspirate probe from Maintenance and Diagnostic Procedure 6041.DD	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling		
Mode of Control	2217						Design	Design Verification protocol and report DV681.D01	
Mode of Control	2218						Labeling	M&D 6041 test procedure (6041.TP) and Form FN25.006 Label Content Review and Approval	
Hazard Source	5364	**Splashing during wash buffer dispense**							
Hazard Cause	5365		Buffer dispense velocity incorrect	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design		
Mode of Control	873						Design	GDS12.D01 - ID 602	
Mode of Control	1988						Design	SWRS OID 3686	

Hazard Cause	5366		Process path tolerance of reaction vessel /wash probe positioning incorrect	i2000 i2000SR	Incorrect or Delayed Patient Result	Major Improbable L	Design Labeling	
Mode of Control	874						Design	GDR05.D01 - ID 536
Mode of Control	875						Design	GDR05.D01 - ID 542
Mode of Control	876						Labeling	ARCHITECT Operations Manual, Section 10, Troubleshooting and Diagnostics, procedures 2006 and 2007 wash zone dispense checks

8. Appendices

8.1 Appendix A: RUL Validation

8.1.1 RUL Validation in the Field: Executive Summary

The RULs that service is observing in the field is in line with PHM's predictions reported in the design document. The primary disagreement seems to be the use of *mean* RUL vs the use of *median* RUL. When reconsidered and compared against the RULs currently observed (Tracking spreadsheet maintained by US Commercial Operations Smart Centers), the algorithms are working as expected. The below address several concerns.

8.1.2 Primer: The Cumulative Distribution Function (CDF)

As the analyses rely heavily on the CDF, it will be beneficial to briefly discuss what the CDF means. A CDF contains the same information as a histogram, but plotted differently. The histogram "bins" the data and indicates the N within each bin. The CDF indicates what percentage of the data in the histogram falls *at or below* a particular data. This is illustrated in simulated data below. The median is marked with a red line in each. In the CDF on the right, the horizontal line corresponds to the 50th percentile (median), which is 9.97.

Figure 1: Histogram (left) and CDF (right) for simulated data. Median marked with magenta lines.
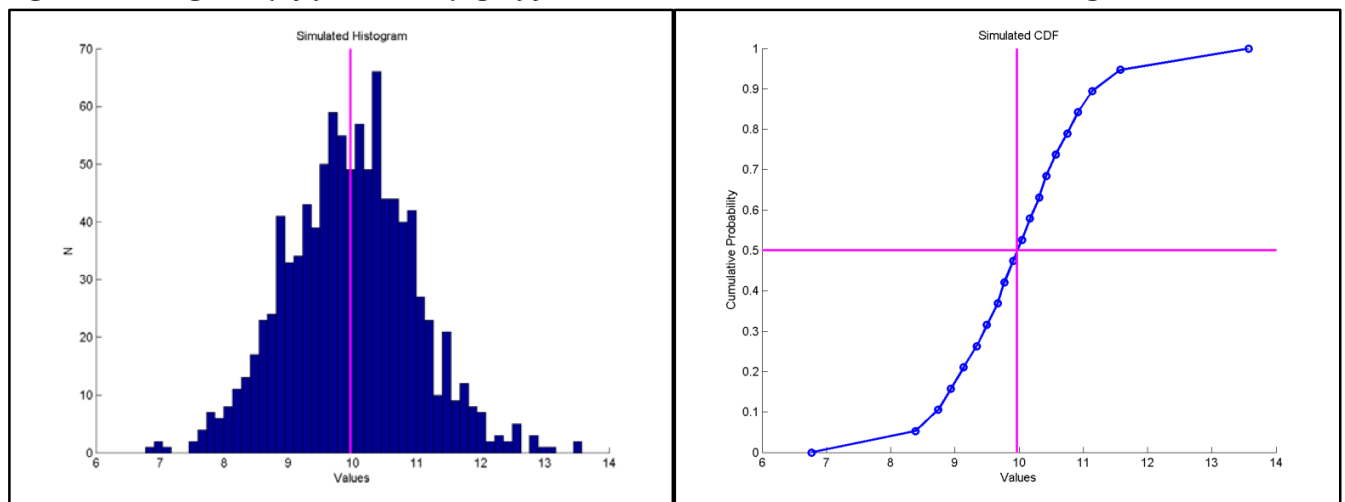
8.1.3 Specific Concerns

The mean RUL is inappropriate in our dataset

The mean RUL (e.g., for Pattern A, 6.1 days) is an inappropriate summary statistic, as the distributions exhibit large positive skew. With highly skewed distributions, the mean becomes less representative than the median (or 50th percentile) because it is highly sensitive to extreme values. The median, along with the 25th and 75th percentiles, are in the design document (section 2.2).

The RUL distribution presented in the design document *excluded* cases where the algorithm flags at the same moment as hard failure. This was done to answer the question: how much time will the algorithm buy us *when the flag occurs early enough to take action*. So, some of the instruments in Service's validation will seem to appear then disappear on the same day if customers take action. Including those cases reduces the mean RUL by at least 1 day. The median (50th percentile) is less affected by this. These cases are included in the plots below.

Below, the RUL distributions are re-plotted for each pattern *including* 0 values; the mean is marked with a red line, the median with a magenta line. Note the large separation. Also note that in every case, most of the failures occur within 1 day of the algorithm flag. From this, PHM would conclude that what service is observing is entirely consistent.

Figure 2: Pattern A. The cumulative distribution function (CDF) is plotted on the left, the histogram on the right. Magenta lines correspond to the median value, red lines to mean value.
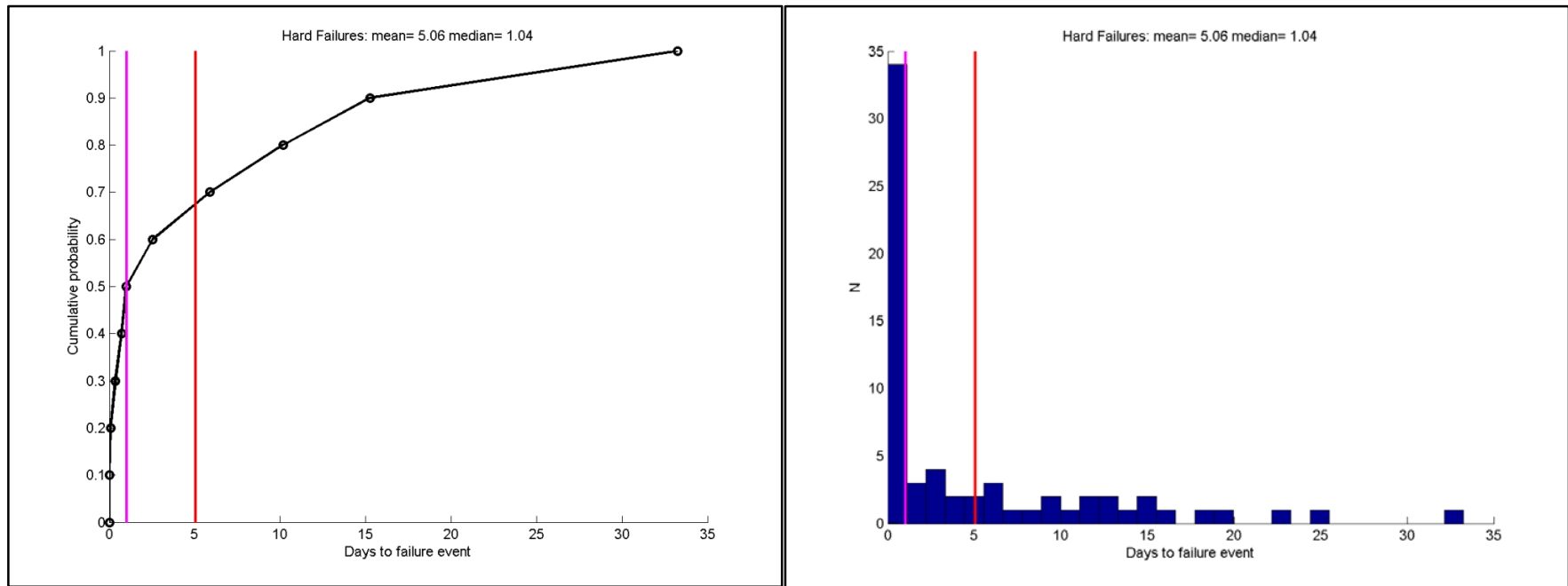
Comment: The difference between mean and median for Pattern A is quite large. Including RULs of 0 decreases the mean RUL from 6.1 to 5.06 days. The median changes as well, from 2.6 days to 1.04 days.

Figure 3: Pattern B. The cumulative distribution function (CDF) is plotted on the left, the histogram on the right. Magenta lines correspond to the median value, red lines to mean value.
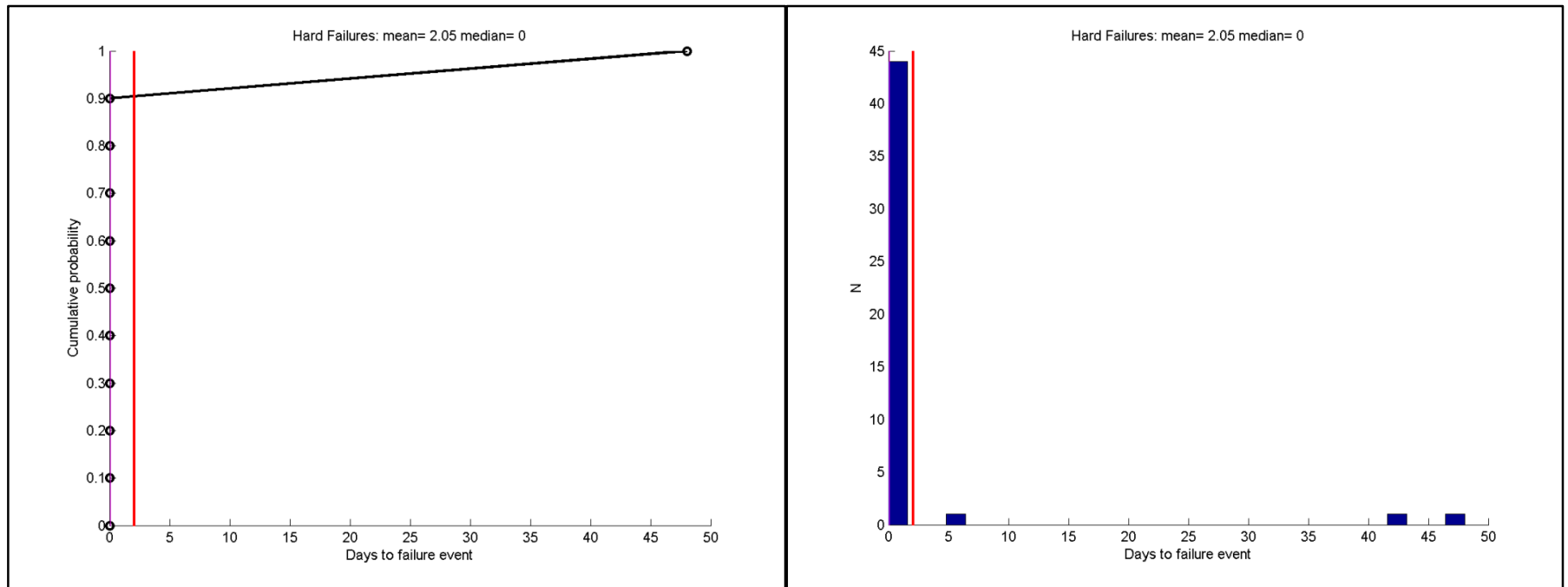
Comment: In the validation dataset of 1000 instruments, Pattern B had a RUL > 0 very rarely. Therefore, including those values leads to distributions that are arguably less informative.

Figure 4: Pattern C. The cumulative distribution function (CDF) is plotted on the left, the histogram on the right. Magenta lines correspond to the median value, red lines to mean value.
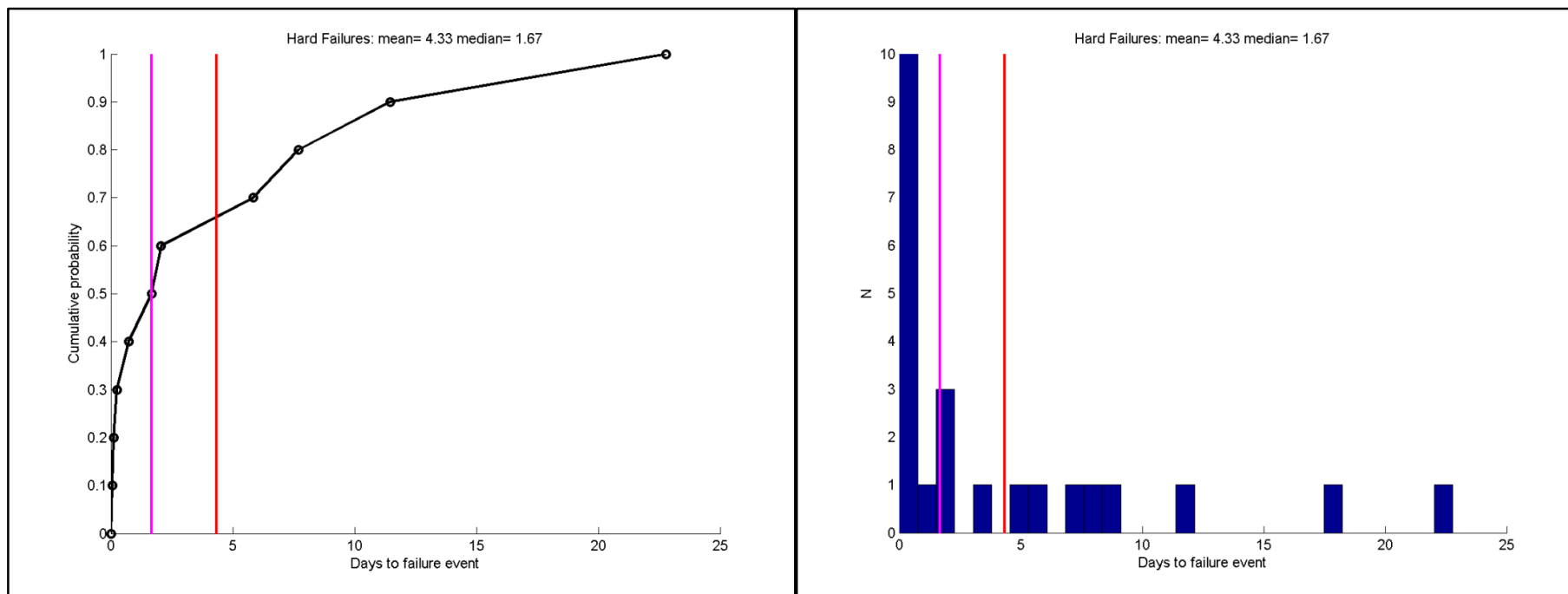

Comment: For Pattern C, including instruments with RUL = 0 does not alter the mean or median RUL much, but it is apparent that the mean and median are exceptionally different (4.33 vs. 1.67 days).

The small set of "let them run" instruments appears to be performing as expected.

Examination of Service's tracking spreadsheet suggests the following:

- Most instruments that disappear from the spreadsheet have had hard or soft failures, or customer intervention. There are comparably few that have no explanation.
- Instruments that cyclically appear and disappear from the spreadsheet are almost exclusively limited to Pattern C flags. It has been previously established that this makes sense.

Actual RUL from service's tracking spreadsheet is very close to specifications as described in the design document for Patterns A and B; Pattern C is somewhat different, but re-evaluatation at the 30-day mark is necessary (service only has 21 days, and therefore simply cannot have the later values PHM's database has). To compare quantitatively:

- For each "run" instrument, estimate the number of days flagging on the spreadsheet. For instruments appearing and disappearing, use the longest run.
- Grouped Service's actual RULs by which pattern was flagging, computed the CDFs, and overlay them on the CDFs from the section above (derived from PHM's analyses)
- If the algorithms are performing within specification, Service's CDFs (red) should approximate PHM's predictions (black). Note that Service only has 21 days, causing something known as "range restriction", so perfect overlap is impossible at this point.

Figure 5: Pattern A. Black CDF same as previous section and is derived from PHM's analyses. Red CDF estimated using service's tracking spreadsheet.
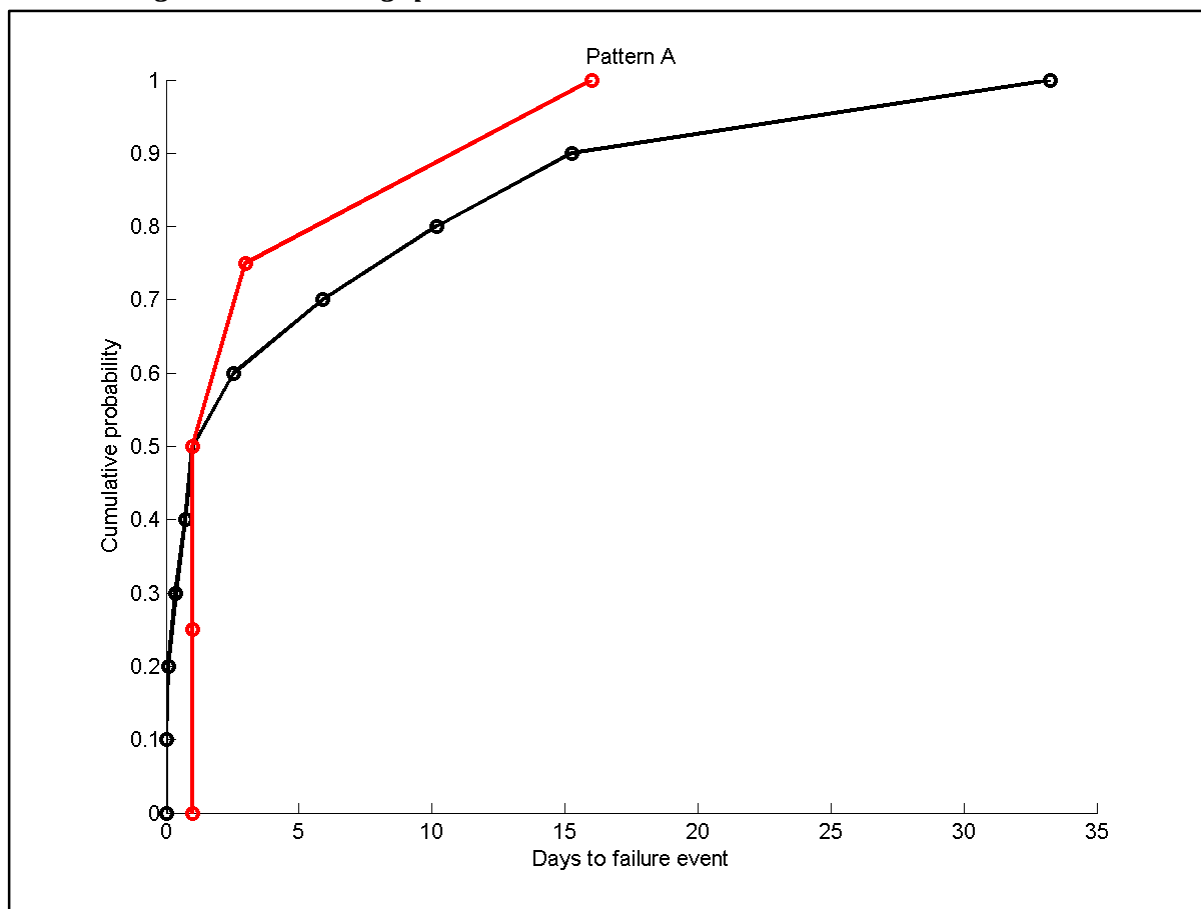
Comment: Given the small dataset from service, and also the fact that the red CDF only includes 21 days, whereas the black CDF includes more than a month, there is *exceptional* overlap. Note that the medians (50th percentiles) are nearly identical.

Figure 6: Pattern B. Black CDF same as previous section and is derived from PHM's analyses. Red CDF estimated using service's tracking spreadsheet.
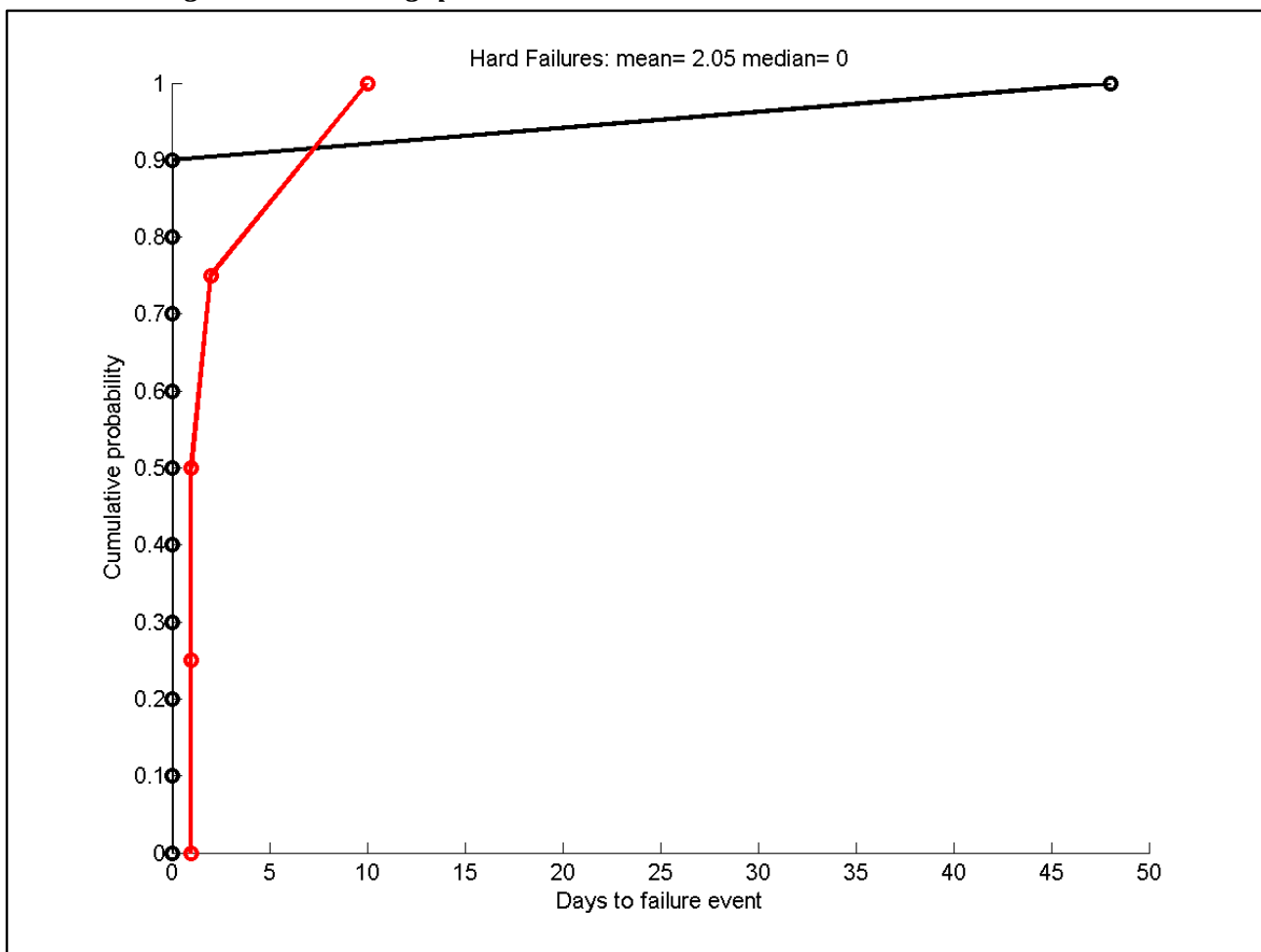
Comment: Again, the shapes of the CDFs are exceptionally close, even with such a small dataset. Also, the medians are again very similar.

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Figure 7: Pattern C. Black CDF same as previous section and is derived from PHM's analyses. Red CDF estimated using service's tracking spreadsheet.
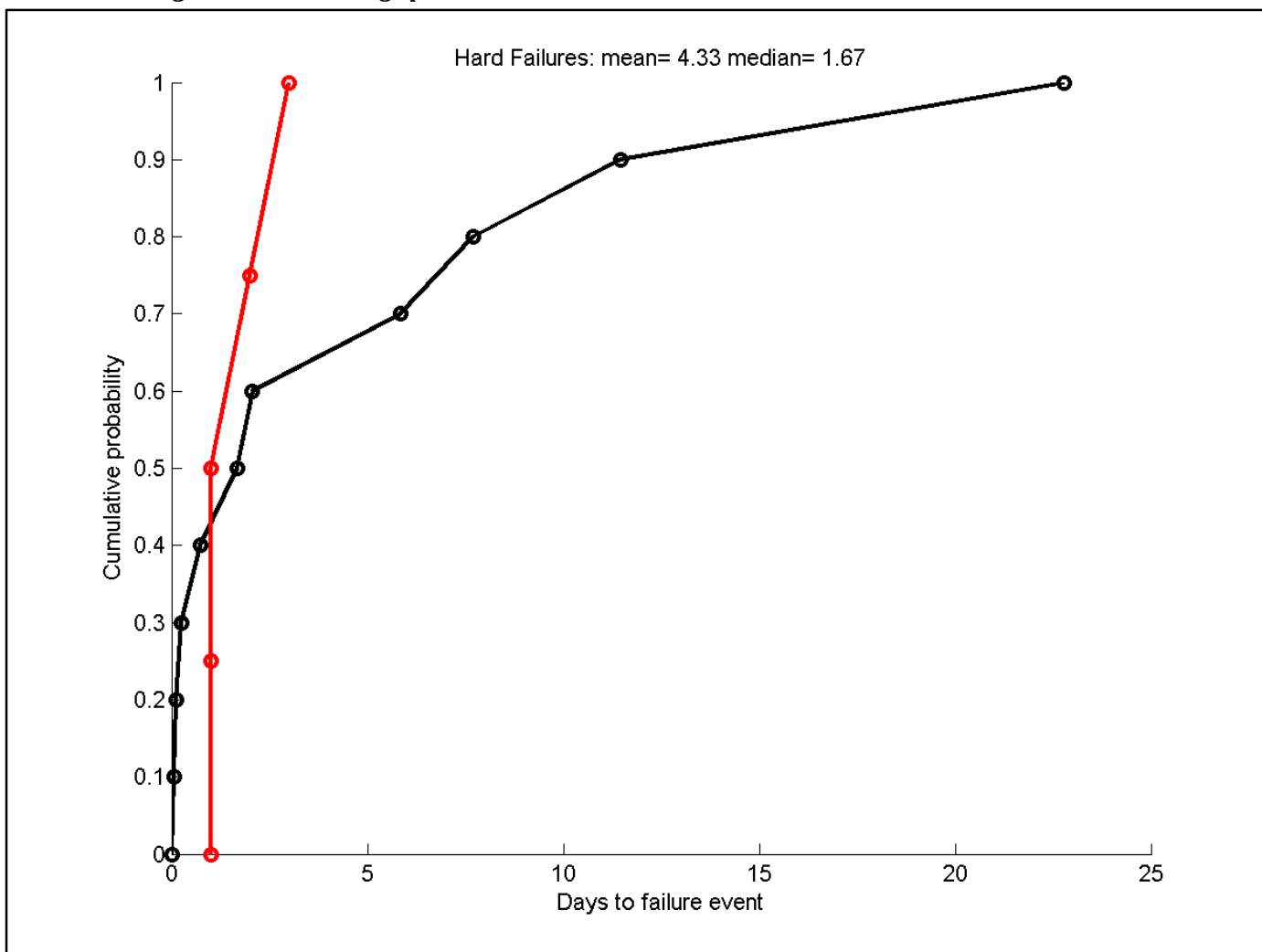

Comment: For Pattern C, there is noticeable mismatch between the design specification (black) and service's data (red), although for the 3rd time, the medians are very close. Further data is needed to evaluate further.

Table 1: Illustrates, very simply, the percentages of failures that should occur within N days. Pattern B is not included due to the extremely low N.

	Pattern A	
Days before failure	0-1	50%
	2-6	20%
	7-15	20%
	16-33	10%

	Pattern C	
Days before failure	0-2	60%
	3-6	20%
	7-11	10%
	12-23	10%

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8.2   Appendix B: Daily WAM Report

8.2.1   Report Example (USA Instruments Only)

USA - Patterns A, B
and C Violations Repo

8.2.2   Report JMP Script Example (AMTI, Europe, Japan, Latin America, USA and Worldwide)

WAM Scheduler
v2.jsl

8.2.3   Algorithms SQL Code (Worldwide Query)

```
rawdt1=Open Database(
"DSN=pabbto;UID="||username||";PWD="||pass_word||";FBS=100000000;",
"
SELECT
  ABC.COUNTRY,
  ABC.CITY,
  ABC.CUSTOMER,
  ABC.SN,
  ABC.WZPROBE,
  CASE WHEN MIN(ABC.FLAGDATEA) IS NOT NULL AND
          MIN(ABC.FLAGDATEB) IS NULL AND
          MIN(ABC.FLAGDATEC) IS NULL
          THEN MIN(ABC.FLAGDATEA)
          WHEN MIN(ABC.FLAGDATEB) IS NOT NULL AND
          MIN(ABC.FLAGDATEA) IS NULL AND
          MIN(ABC.FLAGDATEC) IS NULL
          THEN MIN(ABC.FLAGDATEB)
          WHEN MIN(ABC.FLAGDATEC) IS NOT NULL AND
          MIN(ABC.FLAGDATEA) IS NULL AND
          MIN(ABC.FLAGDATEB) IS NULL
          THEN MIN(ABC.FLAGDATEC)

        WHEN MIN(ABC.FLAGDATEA) IS NOT NULL AND
          MIN(ABC.FLAGDATEB) IS NOT NULL AND
          MIN(ABC.FLAGDATEC) IS NULL
          THEN LEAST(MIN(ABC.FLAGDATEA), MIN(ABC.FLAGDATEB))
          WHEN MIN(ABC.FLAGDATEB) IS NOT NULL AND
          MIN(ABC.FLAGDATEC) IS NOT NULL AND
          MIN(ABC.FLAGDATEA) IS NULL
          THEN LEAST(MIN(ABC.FLAGDATEB), MIN(ABC.FLAGDATEC))
          WHEN MIN(ABC.FLAGDATEC) IS NOT NULL AND
          MIN(ABC.FLAGDATEA) IS NOT NULL AND
          MIN(ABC.FLAGDATEB) IS NULL
          THEN LEAST(MIN(ABC.FLAGDATEC), MIN(ABC.FLAGDATEA))

          WHEN MIN(ABC.FLAGDATEA) IS NOT NULL AND
          MIN(ABC.FLAGDATEB) IS NOT NULL AND
```

```
                            MIN(ABC.FLAGDATEC) IS NOT NULL
                            THEN LEAST(MIN(ABC.FLAGDATEA), MIN(ABC.FLAGDATEB),
        MIN(ABC.FLAGDATEC)) END
                AS FLAGDATE,
                ABC.FLAGA,
                ABC.FLAGB,
                ABC.FLAGC
            FROM
              (SELECT
                            CASE WHEN MAX(A.FLAGA) = 'YES'
                                    THEN A.COUNTRY
                                    WHEN MAX(B.FLAGB) = 'YES'
                                    THEN B.COUNTRY
                                    WHEN MAX(C.FLAGC) = 'YES'
                                    THEN C.COUNTRY END
                            AS COUNTRY,
                            CASE WHEN MAX(A.FLAGA) = 'YES'
                                    THEN A.CITY
                                    WHEN MAX(B.FLAGB) = 'YES'
                                    THEN B.CITY
                                    WHEN MAX(C.FLAGC) = 'YES'
                                    THEN C.CITY END
                            AS CITY,
                            CASE WHEN MAX(A.FLAGA) = 'YES'
                                    THEN A.CUSTOMER
                                    WHEN MAX(B.FLAGB) = 'YES'
                                    THEN B.CUSTOMER
                                    WHEN MAX(C.FLAGC) = 'YES'
                                    THEN C.CUSTOMER END
                            AS CUSTOMER,
                            CASE WHEN MAX(A.FLAGA) = 'YES'
                                    THEN A.SN
                                    WHEN MAX(B.FLAGB) = 'YES'
                                    THEN B.SN
                                    WHEN MAX(C.FLAGC) = 'YES'
                                    THEN C.SN END
                            AS SN,
                            CASE WHEN MAX(A.FLAGA) = 'YES'
                                    THEN A.WZPROBEA
                                    WHEN MAX(B.FLAGB) = 'YES'
                                    THEN B.WZPROBEB
                                    WHEN MAX(C.FLAGC) = 'YES'
                                    THEN C.WZPROBEC END
                            AS WZPROBE,
                            MIN(A.FLAGDATEA) AS FLAGDATEA,
                            MIN(B.FLAGDATEB) AS FLAGDATEB,
                            MIN(C.FLAGDATEC) AS FLAGDATEC,
                            CASE WHEN MAX(A.FLAGA) = 'YES'
                                THEN 'YES'
                                ELSE 'NO' END
                            AS FLAGA,
                            CASE WHEN MAX(B.FLAGB) = 'YES'
                                THEN 'YES'
                                ELSE 'NO' END
                            AS FLAGB,
                            CASE WHEN MAX(C.FLAGC) = 'YES'
                                THEN 'YES'
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                          ELSE 'NO' END
                    AS FLAGC
            FROM
                  (SELECT
                          RAWA.COUNTRY,
                          RAWA.CITY,
                          RAWA.CUSTOMER,
                          RAWA.SN,
                          RAWA.WZPROBE AS WZPROBEA,
                          MAX(RAWA.FLAGA) AS FLAGA,
                          MIN(RAWA.FLAGDATEA) AS FLAGDATEA
                  FROM
                          (SELECT
                                  IA.AREA,
                                  IA.COUNTRYNAME COUNTRY,
                                  IA.CITY,
                                  substr(IA.CUSTOMERNAME,1,22) CUSTOMER,
                                  IA.CUSTOMERNAME CUSTOMER_NAME,
                                  WZA.MODULESNDRM AS SN,
                                  WZA.WASHZONEID || '.' || WZA.POSITION AS WZPROBE,
                                  WZA.EVENTDATE AS FLAGDATEA,
                                  WZA.MAXTEMP,
                                  CASE WHEN WZA.MAXTEMP > 35 AND
                                            LAG (WZA.MAXTEMP) OVER (PARTITION BY
WZA.MODULESNDRM, WZA.WASHZONEID, WZA.POSITION ORDER BY WZA.EVENTDATE) > 35 AND
                                            LAG (WZA.MAXTEMP, 2) OVER (PARTITION BY
WZA.MODULESNDRM, WZA.WASHZONEID, WZA.POSITION ORDER BY WZA.EVENTDATE) > 35 AND
                                            LAG (WZA.MAXTEMP, 3) OVER (PARTITION BY
WZA.MODULESNDRM, WZA.WASHZONEID, WZA.POSITION ORDER BY WZA.EVENTDATE) > 35 AND
                                            LAG (WZA.MAXTEMP, 4) OVER (PARTITION BY
WZA.MODULESNDRM, WZA.WASHZONEID, WZA.POSITION ORDER BY WZA.EVENTDATE) > 35
                                  THEN 'YES'
                                  ELSE 'NO' END
                                  AS FLAGA
                          FROM(
                          SELECT
                                    WA.MODULESNDRM,
                                    WA.EVENTDATE,
                                    WA.WASHZONEID - 1 AS WASHZONEID,
                                    '1' AS POSITION,
                                    WA.POSITION1 AS REPLICATEID,
                                    CASE WHEN WA.POSITION1 = LAG
(WA.POSITION1) OVER (ORDER BY WA.MODULESNDRM, WA.POSITION1, WA.WASHZONEID,
WA.EVENTDATE) AND
                                            WA.WASHZONEID = LAG
(WA.WASHZONEID) OVER (ORDER BY WA.MODULESNDRM, WA.POSITION1, WA.WASHZONEID,
WA.EVENTDATE) AND
                                            WA.EVENTDATE - 10 /(24*60*60) <
LAG (WA.EVENTDATE) OVER (ORDER BY WA.MODULESNDRM, WA.POSITION1, WA.WASHZONEID,
WA.EVENTDATE)
                                            THEN 'Probe 1 Second Temp'
                                          ELSE 'Probe 1 First Temp' END
                                    AS PIP_ORDER,
                                    WA.MAXTEMPPOSITION1/1000 MAXTEMP
                            FROM
                                    IDAOWNER.WASHASPIRATIONS WA
                            WHERE
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                                            WA.POSITION1 > 0 AND
                                            WA.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                            WA.EVENTDATE <= TRUNC(SYSDATE)

                            UNION ALL

                            SELECT
                                    WA.MODULESNDRM,
                                    WA.EVENTDATE,
                                    WA.WASHZONEID - 1 AS WASHZONEID,
                                    '2' AS POSITION,
                                    WA.POSITION2 AS REPLICATEID,
                                    'Probe 2' AS PIP_ORDER,
                                    WA.MAXTEMPPOSITION2/1000 MAXTEMP
                            FROM
                                    IDAOWNER.WASHASPIRATIONS WA
                            WHERE
                                    WA.POSITION2 > 0 AND
                                    WA.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                    WA.EVENTDATE <= TRUNC(SYSDATE)

                            UNION ALL

                            SELECT
                                    WA.MODULESNDRM,
                                    WA.EVENTDATE,
                                    WA.WASHZONEID - 1 AS WASHZONEID,
                                    '3' AS POSITION,
                                    WA.POSITION3 AS REPLICATEID,
                                    CASE WHEN WA.POSITION3 = LAG
(WA.POSITION3) OVER (ORDER BY WA.MODULESNDRM, WA.POSITION3, WA.WASHZONEID,
WA.EVENTDATE) AND
                                                WA.WASHZONEID = LAG
(WA.WASHZONEID) OVER (ORDER BY WA.MODULESNDRM, WA.POSITION3, WA.WASHZONEID,
WA.EVENTDATE) AND
                                                WA.EVENTDATE - 10 /(24*60*60) <
LAG (WA.EVENTDATE) OVER (ORDER BY WA.MODULESNDRM, WA.POSITION3, WA.WASHZONEID,
WA.EVENTDATE)
                                            THEN 'Probe 3 Second Temp'
                                        ELSE 'Probe 3 First Temp' END
                                    AS PIP_ORDER,
                                    WA.MAXTEMPPOSITION3/1000 MAXTEMP
                            FROM
                                    IDAOWNER.WASHASPIRATIONS WA
                            WHERE
                                    WA.POSITION3 > 0 AND
                                    WA.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                    WA.EVENTDATE <= TRUNC(SYSDATE)
                            ) WZA

                INNER JOIN IDAOWNER.IDAMODULEINFORMATION IA
                        ON
                        WZA.MODULESNDRM = IA.MODULESN AND
                        IA.CREATEDATE = (SELECT MAX(CREATEDATE) from
IDAOWNER.IDAMODULEINFORMATION where MODULESN = IA.MODULESN AND
                        CREATEDATE <= SYSDATE) AND
                        WZA.EVENTDATE > IA.EFFECTIVEFROMDATE AND
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                        WZA.EVENTDATE < IA.EFFECTIVETODATE
                  WHERE
                              NOT WZA.PIP_ORDER = 'Probe 3 Second Temp' AND
                              NOT WZA.PIP_ORDER = 'Probe 1 First Temp' AND
                              IA.AREA IS NOT NULL AND
                              IA.CUSTOMERNAME NOT LIKE '%ABBOTT%' AND
                              IA.CUSTOMERNAME NOT LIKE '%Flextronics%'
                  ) RAWA
            WHERE
                  RAWA.FLAGA = 'YES'
            GROUP BY
                  RAWA.COUNTRY,
                  RAWA.CITY,
                  RAWA.CUSTOMER,
                  RAWA.SN,
                  RAWA.WZPROBE
      ) A



      FULL JOIN



            (SELECT
                  RAWB.COUNTRY,
                  RAWB.CITY,
                  RAWB.CUSTOMER,
                  RAWB.SN,
                  RAWB.WZPROBE AS WZPROBEB,
                  MAX(RAWB.FLAGB) AS FLAGB,
                  MIN(RAWB.FLAGDATEB) AS FLAGDATEB
            FROM
                  (SELECT
                        IB.AREA,
                        IB.COUNTRYNAME COUNTRY,
                        IB.CITY,
                        substr(IB.CUSTOMERNAME,1,22) CUSTOMER,
                        IB.CUSTOMERNAME CUSTOMER_NAME,
                        WZB.MODULESNDRM AS SN,
                        WZB.WASHZONEID || '.' || WZB.POSITION AS WZPROBE,
                        WZB.EVENTDATE AS FLAGDATEB,
                        WZB.AMBIENTTEMP,
                        CASE WHEN WZB.AMBIENTTEMP < 14 AND
                              LAG (WZB.AMBIENTTEMP) OVER (PARTITION BY
WZB.MODULESNDRM, WZB.WASHZONEID, WZB.POSITION ORDER BY WZB.EVENTDATE) < 14
                              THEN 'YES'
                           ELSE 'NO' END
                        AS FLAGB
                  FROM(
                        SELECT
                              WB.MODULESNDRM,
                              WB.EVENTDATE,
                              WB.WASHZONEID - 1 AS WASHZONEID,
                              '1' AS POSITION,
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                                                        WB.POSITION1 AS REPLICATEID,
                                                        CASE WHEN WB.POSITION1 = LAG
(WB.POSITION1) OVER (ORDER BY WB.MODULESNDRM, WB.POSITION1, WB.WASHZONEID,
WB.EVENTDATE) AND
                                                        WB.WASHZONEID = LAG
(WB.WASHZONEID) OVER (ORDER BY WB.MODULESNDRM, WB.POSITION1, WB.WASHZONEID,
WB.EVENTDATE) AND
                                                        WB.EVENTDATE - 10 /(24*60*60) <
LAG (WB.EVENTDATE) OVER (ORDER BY WB.MODULESNDRM, WB.POSITION1, WB.WASHZONEID,
WB.EVENTDATE)
                                                        THEN 'Probe 1 Second Temp'
                                                      ELSE 'Probe 1 First Temp' END
                                                        AS PIP_ORDER,
                                                        (WB.MAXTEMPPOSITION1 -
WB.TEMPDELTAPOSITION1)/1000 AS AMBIENTTEMP
                                             FROM
                                                        IDAOWNER.WASHASPIRATIONS WB
                                             WHERE
                                                        WB.POSITION1 > 0 AND
                                                        WB.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                                        WB.EVENTDATE <= TRUNC(SYSDATE)

                                             UNION ALL

                                             SELECT
                                                        WB.MODULESNDRM,
                                                        WB.EVENTDATE,
                                                        WB.WASHZONEID - 1 AS WASHZONEID,
                                                        '2' AS POSITION,
                                                        WB.POSITION2 AS REPLICATEID,
                                                        'Probe 2' AS PIP_ORDER,
                                                        (WB.MAXTEMPPOSITION2 -
WB.TEMPDELTAPOSITION2)/1000 AS AMBIENTTEMP
                                             FROM
                                                        IDAOWNER.WASHASPIRATIONS WB
                                             WHERE
                                                   WB.POSITION2 > 0 AND
                                                   WB.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                                   WB.EVENTDATE <= TRUNC(SYSDATE)

                                             UNION ALL

                                             SELECT
                                                        WB.MODULESNDRM,
                                                        WB.EVENTDATE,
                                                        WB.WASHZONEID - 1 AS WASHZONEID,
                                                        '3' AS POSITION,
                                                        WB.POSITION3 AS REPLICATEID,
                                                        CASE WHEN WB.POSITION3 = LAG
(WB.POSITION3) OVER (ORDER BY WB.MODULESNDRM, WB.POSITION3, WB.WASHZONEID,
WB.EVENTDATE) AND
                                                        WB.WASHZONEID = LAG
(WB.WASHZONEID) OVER (ORDER BY WB.MODULESNDRM, WB.POSITION3, WB.WASHZONEID,
WB.EVENTDATE) AND
                                                        WB.EVENTDATE - 10 /(24*60*60) <
LAG (WB.EVENTDATE) OVER (ORDER BY WB.MODULESNDRM, WB.POSITION3, WB.WASHZONEID,
WB.EVENTDATE)
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                                                         THEN 'Probe 3 Second Temp'
                                                      ELSE 'Probe 3 First Temp' END
                                      AS PIP_ORDER,
                                      (WB.MAXTEMPPOSITION3 -
WB.TEMPDELTAPOSITION3)/1000 AS AMBIENTTEMP
                                 FROM
                                      IDAOWNER.WASHASPIRATIONS WB
                                 WHERE
                                      WB.POSITION3 > 0 AND
                                      WB.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                      WB.EVENTDATE <= TRUNC(SYSDATE)
                                 ) WZB

                INNER JOIN IDAOWNER.IDAMODULEINFORMATION IB
                        ON
                        WZB.MODULESNDRM = IB.MODULESN AND
                        IB.CREATEDATE = (SELECT MAX(CREATEDATE) from
IDAOWNER.IDAMODULEINFORMATION where MODULESN = IB.MODULESN AND
                        CREATEDATE <= SYSDATE) AND
                        WZB.EVENTDATE > IB.EFFECTIVEFROMDATE AND
                        WZB.EVENTDATE < IB.EFFECTIVETODATE
                          WHERE
                                      NOT WZB.PIP_ORDER = 'Probe 3 Second Temp' AND
                                      NOT WZB.PIP_ORDER = 'Probe 1 First Temp' AND
                                      IB.AREA IS NOT NULL AND
                                      IB.CUSTOMERNAME NOT LIKE '%ABBOTT%' AND
                                      IB.CUSTOMERNAME NOT LIKE '%Flextronics%'
                                  ) RAWB
                WHERE
                        RAWB.FLAGB = 'YES'
                GROUP BY
                        RAWB.COUNTRY,
                        RAWB.CITY,
                        RAWB.CUSTOMER,
                        RAWB.SN,
                        RAWB.WZPROBE
                ) B
        ON
        A.COUNTRY = B.COUNTRY AND
        A.CITY = B.CITY AND
        A.CUSTOMER = B.CUSTOMER AND
        A.SN = B.SN AND
        A.WZPROBEA = B.WZPROBEB




        FULL JOIN



                (SELECT
                        RAWC.COUNTRY,
                        RAWC.CITY,
                        RAWC.CUSTOMER,
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                                RAWC.SN,
                                RAWC.WZPROBE AS WZPROBEC,
                                MAX(RAWC.FLAGC) AS FLAGC,
                                MIN(RAWC.FLAGDATEC) AS FLAGDATEC
                    FROM
                    (SELECT
                            IC.AREA,
                            IC.COUNTRYNAME COUNTRY,
                            IC.CITY,
                            substr(IC.CUSTOMERNAME,1,22) CUSTOMER,
                            IC.CUSTOMERNAME CUSTOMER_NAME,
                            WZC.MODULESNDRM AS SN,
                            WZC.WASHZONEID || '.' || WZC.POSITION AS WZPROBE,
                            WZC.EVENTDATE AS FLAGDATEC,
                            WZC.TEMPDELTA,
                            CASE WHEN WZC.EVENTDATE - 1/24 < LAG
(WZC.EVENTDATE,19) OVER (PARTITION BY WZC.MODULESNDRM, WZC.WASHZONEID, WZC.POSITION
ORDER BY WZC.EVENTDATE)
                                    THEN 'YES'
                                    ELSE 'NO' END
                            AS FLAGC
                    FROM(
                    SELECT
                                WC.MODULESNDRM,
                                WC.EVENTDATE,
                                WC.WASHZONEID - 1 AS WASHZONEID,
                                '1' AS POSITION,
                                WC.POSITION1 AS REPLICATEID,
                                CASE WHEN WC.POSITION1 = LAG
(WC.POSITION1) OVER (ORDER BY WC.MODULESNDRM, WC.POSITION1, WC.WASHZONEID,
WC.EVENTDATE) AND
                                        WC.WASHZONEID = LAG
(WC.WASHZONEID) OVER (ORDER BY WC.MODULESNDRM, WC.POSITION1, WC.WASHZONEID,
WC.EVENTDATE) AND
                                        WC.EVENTDATE - 10 /(24*60*60) <
LAG (WC.EVENTDATE) OVER (ORDER BY WC.MODULESNDRM, WC.POSITION1, WC.WASHZONEID,
WC.EVENTDATE)
                                    THEN 'Probe 1 Second Temp'
                                    ELSE 'Probe 1 First Temp' END
                            AS PIP_ORDER,
                            WC.TEMPDELTAPOSITION1/1000 TEMPDELTA
                    FROM
                            IDAOWNER.WASHASPIRATIONS WC
                    WHERE
                            WC.POSITION1 > 0 AND
                            WC.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                            WC.EVENTDATE <= TRUNC(SYSDATE)

                    UNION ALL

                    SELECT
                            WC.MODULESNDRM,
                            WC.EVENTDATE,
                            WC.WASHZONEID - 1 AS WASHZONEID,
                            '2' AS POSITION,
                            WC.POSITION2 AS REPLICATEID,
                            'Probe 2' AS PIP_ORDER,
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                                        WC.TEMPDELTAPOSITION2/1000 TEMPDELTA
                        FROM
                                        IDAOWNER.WASHASPIRATIONS WC
                        WHERE
                                        WC.POSITION2 > 0 AND
                                        WC.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                        WC.EVENTDATE <= TRUNC(SYSDATE)

                        UNION ALL

                        SELECT
                                        WC.MODULESNDRM,
                                        WC.EVENTDATE,
                                        WC.WASHZONEID - 1 AS WASHZONEID,
                                        '3' AS POSITION,
                                        WC.POSITION3 AS REPLICATEID,
                                        CASE WHEN WC.POSITION3 = LAG
(WC.POSITION3) OVER (ORDER BY WC.MODULESNDRM, WC.POSITION3, WC.WASHZONEID,
WC.EVENTDATE) AND
                                                WC.WASHZONEID = LAG
(WC.WASHZONEID) OVER (ORDER BY WC.MODULESNDRM, WC.POSITION3, WC.WASHZONEID,
WC.EVENTDATE) AND
                                                WC.EVENTDATE - 10 /(24*60*60) <
LAG (WC.EVENTDATE) OVER (ORDER BY WC.MODULESNDRM, WC.POSITION3, WC.WASHZONEID,
WC.EVENTDATE)
                                                THEN 'Probe 3 Second Temp'
                                                ELSE 'Probe 3 First Temp' END
                                        AS PIP_ORDER,
                                        WC.TEMPDELTAPOSITION3/1000 TEMPDELTA
                        FROM
                                        IDAOWNER.WASHASPIRATIONS WC
                        WHERE
                                        WC.POSITION3 > 0 AND
                                        WC.EVENTDATE >= TRUNC(SYSDATE - 1) AND
                                        WC.EVENTDATE <= TRUNC(SYSDATE)
                        ) WZC

                INNER JOIN IDAOWNER.IDAMODULEINFORMATION IC
                        ON
                        WZC.MODULESNDRM = IC.MODULESN AND
                        IC.CREATEDATE = (SELECT MAX(CREATEDATE) from
IDAOWNER.IDAMODULEINFORMATION where MODULESN = IC.MODULESN AND
                        CREATEDATE <= SYSDATE) AND
                        WZC.EVENTDATE > IC.EFFECTIVEFROMDATE AND
                        WZC.EVENTDATE < IC.EFFECTIVETODATE
                WHERE
                        NOT WZC.PIP_ORDER = 'Probe 3 Second Temp' AND
                        NOT WZC.PIP_ORDER = 'Probe 1 First Temp' AND
                        IC.AREA IS NOT NULL AND
                        WZC.TEMPDELTA < 3 AND
                        IC.CUSTOMERNAME NOT LIKE '%ABBOTT%' AND
                        IC.CUSTOMERNAME NOT LIKE '%Flextronics%'
                ) RAWC
        WHERE
                RAWC.FLAGC = 'YES'
        GROUP BY
                RAWC.COUNTRY,
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                                RAWC.CITY,
                                RAWC.CUSTOMER,
                                RAWC.SN,
                                RAWC.WZPROBE
                    ) C
        ON
        A.COUNTRY = C.COUNTRY AND
        A.CITY = C.CITY AND
        A.CUSTOMER = C.CUSTOMER AND
        A.SN = C.SN AND
        A.WZPROBEA = C.WZPROBEC
        GROUP BY
                    A.COUNTRY,
                    B.COUNTRY,
                    C.COUNTRY,
                    A.CITY,
                    B.CITY,
                    C.CITY,
                    A.CUSTOMER,
                    B.CUSTOMER,
                    C.CUSTOMER,
                    A.SN,
                    B.SN,
                    C.SN,
                    A.WZPROBEA,
                    B.WZPROBEB,
                    C.WZPROBEC) ABC
    GROUP BY
        ABC.COUNTRY,
        ABC.CITY,
        ABC.CUSTOMER,
        ABC.SN,
        ABC.WZPROBE,
        ABC.FLAGA,
        ABC.FLAGB,
        ABC.FLAGC
",
"WORLDWIDE - Patterns A (MAXTEMP), B (AMBIENTTEMP) and C (TEMPDELTA) Violations
Summary"
);
```