A Prognostic Health Monitoring Algorithm for Daily Maintenance

ARCHITECT Clinical Chemistry (CC) and Immunoassay (IA) Analyzers

Global Service Offerings and Innovation

4/20/2016

Table of Contents

1.   Purpose

To implement a Prognostic Health Monitoring (PHM) algorithm for ARCHITECT Clinical Chemistry (CC) and Immunoassay (IA) Analyzers that will monitor daily maintenance procedures at a serial-number level.

2.   Introduction

2.1   Scope

This document describes the recommended specifications for Daily Maintenance Fail alerts for the ARCHITECT IA and CC analyzers.

2.2   Notification Profile

PHM Alert	Daily Maintenance Fail
Future PHM Alert Code	TBD by Service
Threshold	2 or more days with failed daily maintenance and > 0 PATIENT samples attempted.
Platform	ARCHITECT IA & CC (PL 115, 116, 117, 126, 127, 128)
Data Source	Maintenance Logs / Abbott Link / IDA
Notification	Daily Report / Instrument Serial Number

Analysis Frequency	Daily
Failure Prediction (RUL post-alert)	NA
Recommended Action	Complete daily maintenance / establish root cause for continued failures / service instrument

2.3   Overview

To ensure optimal system performance, a *daily maintenance procedure* is outlined for both the IA and CC analyzers.

For the CC system, daily maintenance includes:
- Flush sample and reagent lines
- Change water bath
- Add water bath additive
- Wash ICT probe with ICT cleaning fluid and ICT reference solution
- Drain and fill ICT reference cup

For the I2000/I2000SR systems, daily maintenance includes:
- Clean and condition sample pipettor probe
- Clean the probes, temperature tubing and sensors, and vacuum vessels in wash zone1 and 2
- Mix microparticle bottles on reagent carousel

For the I1SR system, daily maintenance includes:
- Clean outside of probes in wash zone
- Mix microparticle bottles on reagent carousel
- Dry vacuum pump filter

Failure to complete daily maintenance can lead to a variety of undesirable conditions, including air bubbles in tubing, particulate matter in water bath, dirty (contaminated) pipettor probes, and others. The daily maintenance procedures were specifically designed to enhance the reliability of the instrument and its results.

Unfortunately, daily maintenance is sometimes neglected, either because the customer elects to cancel the maintenance procedure ('user cancel'), or because some ongoing instrument issue prevents the daily maintenance procedure from completing ('failed'). Customers are able to run assays and report results despite these conditions.

The algorithm outlined herein defines a rule-set for monitoring customer's adherence to the daily maintenance procedure at a serial-number level.

3.   Data

3.1   Source

The algorithm makes use of several data tables:

Maintenance Logs

Maintenance logs are downloaded and parsed by AbbottLink daily. The relevant procedure codes for this algorithm are 6041 for IA instruments and 6070 for CC instruments. The MAINTENANCELOGS table in IDA stores a year's worth of maintenance procedures, but the RESULT field (having 'Complete','User Canceled', or 'Failed') is presented in the local language of the region the Instrument resides. Fortunately, the AbbottLink DRM table 'AED_MAINTENANCE' also stores maintenance log data, but with a RESULT field having only 'PASS' or 'FAIL' regardless of the local language. This algorithm uses the DRM database for maintenance logs to avoid translation.

Test Counts

The IDA tables RESULTS_CC and RESULTS_IA are used to compute the number of tests Instruments are reporting after failed or user canceled daily maintenance. As explained below, this is to ensure instruments with failed daily maintenance are only flagged if they are actively reporting tests. If no tests

are recorded, the instrument is not flagged. If querying from DRM, the table 'ASSAYCOUNT' in schema 'CPR' supersedes IDA tables.

AbbottLink last contact
The AbbottLink DRM database tables 'DEVICE_CONTACT' is used to ensure that instruments are currently able to upload to the IDA database. Instruments with failed daily maintenance are flagged only if it is certain that AbbottLink connectivity remains. If the last contact date is not recent, we cannot be sure that a daily maintenance has in fact been completed but not reported to IDA.

Error messages
The IDA table 'MESSAGES' stores error codes thrown by instruments, along with their time-stamp. The algorithm accesses this table to pull the error codes surrounding the last available failed or user canceled daily maintenance ($\pm$ 10 minutes around the time stamp of failed daily maintenance). This data is used to determine the most likely root cause for failed daily maintenance so that service professionals can better diagnose and solve the issue. If using DRM , the table AED_NOTIFICATION supersedes the IDA 'MESSAGES', as DRM tables are updated in real-time while IDA is updated daily.

4.   Alert

4.1   Current Thresholds Set in System Software

There are currently no alerts other than those immediately visible to the customer. Abbott representatives can access this data by pulling log files directly from AbbottLink, but this is a painstaking process and not a feasible solution.

4.2   An Automated Algorithm to Monitor Daily Maintenance

The algorithm follows the process as outlined below:

1) First, the algorithm identifies instruments whose last 6041 or 6070 daily maintenance message did *not* end in a completion. The below demonstrates this case for one example instrument, but in practice, all instruments are analyzed simultaneously.

MODULESNDRM	COMPLETIONDATE	PROCEDURE	RESULT
C803334	2016-03-11 07:44:10	6070 Daily Maintenance	Completed
C803334	2016-03-12 09:13:54	6070 Daily Maintenance	Completed
C803334	2016-03-14 08:11:09	6070 Daily Maintenance	Failed
C803334	2016-03-15 07:12:04	6070 Daily Maintenance	Failed
C803334	2016-03-16 08:24:14	6070 Daily Maintenance	Failed
C803334	2016-03-17 07:29:47	6070 Daily Maintenance	Failed
C803334	2016-03-17 07:36:17	6070 Daily Maintenance	Failed
C803334	2016-03-19 08:27:36	6070 Daily Maintenance	Failed
C803334	2016-03-19 08:43:40	6070 Daily Maintenance	Failed
C803334	2016-03-19 09:05:11	6070 Daily Maintenance	Failed
C803334	2016-03-19 09:18:40	6070 Daily Maintenance	Failed
C803334	2016-03-19 09:38:32	6070 Daily Maintenance	Failed

2) Second, the algorithm quantifies the extent of failed daily maintenance by calculating the number of days with Fail/User Cancel: The number of unique dates that experience a Fail or User cancel message since the last Completed daily maintenance. To be flagged, an Instrument must have > 1 day with attempted, but not completed daily maintenance. This will ignore Instruments that have just had a failed daily maintenance, or Instruments that had a failed daily maintenance in the past, but have stopped running. Anecdotal evidence suggests that many of these instruments recover and complete daily maintenance the next day; those that do not will still be flagged 24 hours later.

3) Third, the algorithm executes customized SQL queries to determine how many tests, if any, have been reported during the entire period of incomplete daily maintenance. For each instrument, the query counts REPLICATEIDs with PATIENT results beginning with the exact time stamp of the first failed/incomplete daily maintenance up until midnight of the current day. To be flagged, an instrument must have > 0 PATIENT results. In this way, instruments that are experiencing issues but not actively running are ignored.

4) Fourth, the algorithm executes additional customized SQL queries to pull error codes in the $\pm$ 10 minutes surrounding the last failed/canceled daily maintenance. The below demonstrates the most common error codes for a set of instruments with failed daily maintenance (the 5 most common are displayed in the columns 'EC1' to 'EC5'.

MODULESNDRM	EC1	EC2	EC3	EC4	EC5
C803334	0202	9096	3579	5507	NA
C801135	9096	3576	NA	NA	NA
C460793	9096	3579	5507	NA	NA
C802671	0202	9096	3003	NA	NA
C460474	9096	5508	NA	NA	NA
C401192	9096	5619	NA	NA	NA
C802852	0202	9096	7521	3579	5507
C803727	9096	5619	NA	NA	NA
ISR51198	0202	0115	0208	3100	NA

Please note that the error codes were queried and analyzed during algorithm development, but are *not* currently planned for use in production, due to limitations of the notification platform. However, the-end user is encouraged to manually examine error codes around daily maintenance failure and refer to the associated KM article for related information.

5) Finally, the AbbottLink last contact date is queried. To be flagged, an instrument must have had contact in the last day. Those that have not are ignored, as daily maintenance may have been completed but not reported to the database.

4.3   Root Cause

The error codes surrounding a failed daily maintenance can aid in determining root cause. Some error codes are common, but innocuous. For example, error code 9096 is defined in the Architect operations manual as below:

Error code: 9096

Error message received from *c* System (x).
x = Error code number and statuses

Probable cause	Corrective action
Low level informational message displaying the error number received from the *c* System processing module.	*Review logs*, page 10-14, for an error code that occurred at the same time as this message.

Others are much more descriptive; for example error code 7521 suggests water bath issues:

Error code: 7521

Run request denied, water bath temperature is out of range.

Probable cause	Corrective action
• Water in water bath is not circulating because the system was idle for an extended period of time.	Change water bath. Perform *daily* maintenance procedure *6070 Daily Maintenance*, page 9-23 or *as-needed* maintenance procedure *2134 Change Water Bath*, page 9-43.

A mapping of error codes, probable root cause, and recommended action can be found in the associated Knowledge Management (KM) article.

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:

a) Complete daily maintenance, if possible
b) Refer to the associated KM article for probable root cause and recommended action

5.   Benefits / Return on Investment

Both the customer and Abbott benefit from this alert. From the customer's standpoint, running assays under repeated failed daily maintenance can lead to future unplanned downtime, increased tests sent to exception, and overall dissatisfaction. This alert minimizes these problems and ensures that the procedures recommended for instrument reliability and confident results are followed.

From Abbott's standpoint, ensuring that customers perform daily maintenance helps us meet the 99% uptime guarantee. Customers who continually neglect their instruments are more likely to experience unplanned future downtime.