AFINION™ 2

AFINION 2 - POCT1-A Connectivity Protocol

Abbott Diagnostics
Technologies AS
Oslo, Norway

March 2020

AFINION™ 2 – POCT1-A Connectivity Protocol

CONTENTS

1   DOCUMENT INFORMATION

1.1   Updates from previous version of this protocol

Previous version: TP13/80/2094/2103/2722-15267 v. 1.0 - July 2019
This version: TP13/80/2094/2103/2722-15588 v. 1.0 - March 2020

Section 3.1.1	Added section; Connection Timing.
Section 3.1.4	- Clarified that measurement units of transmitted results match the measurement units used when showing results on the display. - Put unit overview in table - Added expiration date to observation results examples
Section 3.1.6	Corrected outdated parts in Device Event examples. Added possible values for EVT.run_type.
Section 4.2	Corrected maximum number of operators from 500 to 1000
Section 5.1	- Updated reference. - Fixed formatting consistency - Added software upgrade
General	Added new assay: HbA1c Dx

1.2   Scope

This document describes the implementation of the POCT1-A protocol in the Afinion 2 Analyzer (software version 21.07 and newer).

1.3   Definitions

POCT1-A	Point Of Care Testing standard
Observation Reviewer	Manages test results, quality assurance and quality control data. This task is normally performed by the data management system.

1.4   References

[1]   Point-of-Care Connectivity; Approved Standard (ISBN 1-56238-450-3) NCCLS, 2001.

2   DEVICE IDENTIFICATION

In POCT1-A a device is identified by the manufacturer's vendor ID, the name of the product and the ID of the particular unit. This information is transmitted at the start of a conversation in the "hello" message (see section 3.1.2).

The vendor ID for all devices manufactured by Abbott Diagnostics Technologies is: **ADTNOR**
The manufacturer name for devices manufactured by Abbott Diagnostics Technologies is:
Abbott Diagnostics Technologies
The device name for the Afinion 2 Analyzer is: **Afinion 2 Analyzer**
The device ID for Afinion 2 Analyzer is the same as the serial number of the device, e.g. 20012345.

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3 BASIC PROFILE

The POCT1-A standard [1] describes a basic profile that shall be supported by all devices that connect to an Observation Reviewer.
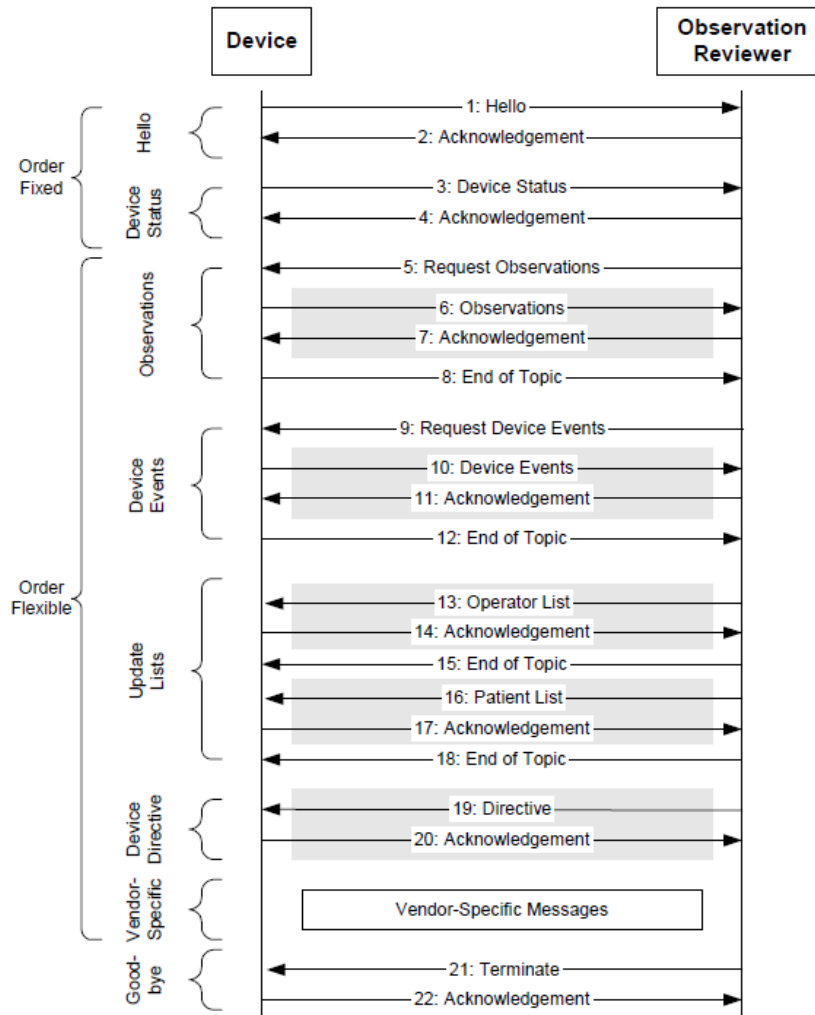
Message ID	Direction	Description
HEL.R01	Device->System	Hello message, initiate communication
ACK.R01	Device->System System->Device	Message ACK
DST.R01	Device->System	Device status message
REQ.R01	System->Device	Request data
OBS.R01	Device->System	Patient observation data
OBS.R02	Device->System	Control observation data
EOT.R01	Device->System System->Device	End of topic
ESC.R01	Device->System System->Device	Escape message
OPL.R01	System->Device	New operator list
OPL.R02	System->Device	Incremental operator list
DTV.R01	System->Device	Simple directive
DTV.R02	System->Device	Complex directive
DTV.ALERE.AXIS.LQCSET	System->Device	Liquid control lot information Add / clear list
DTV.ALERE.AXIS.DVCSET	System->Device	Device setup
ALERE.AXIS.LOCKSTATUS	Device->System	Lockout status.
DTV.AFINION.SWU	System->Device	Software upgrade directive
SWU.SEGMENT	System->Device	Software upgrade segment
END.R01	System->Device	Terminate conversation

3.1 Basic communication flow

The Afinion Analyzer supports the basic profile as described in [1], Appendix B. Device Messaging Layer Specification, section 4.

The communication is initiated by the instrument sending a "Hello" message to the observation reviewer followed by a "Device status" message telling the observation reviewer about any new device events or observations.

The observation reviewer may then decide to download the device events and new observations from the instrument and add or remove operators in the instrument and add information about new liquid QC lots.

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Figure 1: POCT1-A basic communication flow

3.1.1 Connection timing

The instrument initiates new connections periodically while idle. The delay time between normally terminated conversations is configurable via the Device Setup (**DTV.ALERE.AXIS.DVCSET**) directive (see section 5.3). The default delay time is 60 seconds.

The instrument will not initiate connections when not idle, i.e. while tests are running or while the instrument is running self-test.

If a new test is initiated by the user while a conversation is in progress, the conversation will be aborted by the instrument.

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3.1.2 Hello message

The hello message contains information about the device; manufacturer and device identification (see section 3), information about the device hardware and software version and information about which directives are supported by the device.
The hello message uses message type **HEL.R01**.

Example:
```xml
<HEL.R01>
  <HDR>
    <HDR.control_id V="1001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2007-01-24T23:54:53+0000" />
  </HDR>
  <DEV>
    <DEV.device_id V="20012345" />
    <DEV.vendor_id V="ADTNOR" />
    <DEV.manufacturer_name V="Abbott Diagnostics Technologies" />
    <DEV.hw_version V="HW6.2" />
    <DEV.sw_version V="21.09" />
    <DEV.device_name V="Afinion 2 Analyzer" />
    <DEV.market_configuration V="US" />
    <DCP>
      <DCP.application_timeout V="60" />
    </DCP>
    <DSC>
      <DSC.connection_profile_cd V="SA" />
      <DSC.topics_supported_cd V="DTV" />
      <DSC.topics_supported_cd V="D_EV" />
      <DSC.topics_supported_cd V="OP_LST" />
      <DSC.topics_supported_cd V="OP_LST_I" />
      <DSC.directives_supported_cd V="SET_TIME" />
      <DSC.directives_supported_cd V="LQC_SETUP" />
      <DSC.directives_supported_cd V="LQC_CLEAR" />
      <DSC.directives_supported_cd V="DEVICE_SETUP" />
      <DSC.directives_supported_cd V="SWU" />
      <DSC.max_message_sz V="32768" />
      <DSC.max_swu_image_sz V="15000000" />
      <DSC.max_swu_seg_sz V="60000" />
    </DSC>
  </DEV>
</HEL.R01>
```

3.1.3 Device Status

The device status message (message type **DST.R01**) contains information about the number of new (not yet transmitted) observations and device events as well as the date/time of the last registered observations and device events. It can also give an indication if an assay is locked and the status of the last software upgrade.

Example: Device reporting four new observations and one new event.
```xml
<DST.R01>
  <HDR>
    <HDR.control_id V="1002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2007-01-24T23:54:53+0000" />
  </HDR>
  <DST>
    <DST.status_dttm V="2007-01-24T23:54:53+0000" />
    <DST.new_observations_qty V="4" />
    <DST.new_events_qty V="1" />
    <DST.condition_cd V="R" SN="POCT1" SV="1" />
    <!--R if instrument is ready, P if one or more assays are locked -->
```

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```
        <DST.observations_update_dttm V="2007-01-24T23:54:53+0000" />
        <DST.events_update_dttm V="2007-01-24T23:54:53+0000" />
        <DST.operators_update_dttm V="2007-01-24T23:54:53+0000" />
        <DST.upgrade_status V="Success" />
      </DST>
    </DST.R01>
```

3.1.4   Observation results

Patient results requested by the observation reviewer are reported back using the **OBS.R01** message type.
Control results are reported back using the **OBS.R02** message.
Each run is sent as a separate observation message, with each result as a separate observation object.

The observation reviewer will request new results using the **REQ.R01** message. The observation reviewer can choose to either request new results (results that have not yet been successfully transferred) or request all results. This is done by setting the REQ.request_cd field to ROBS for new observations and RALL for all observations.

If both patient and control measurements are to be sent, the instrument will send the control measurements first and send patient measurements once all control measurements have been transferred.

If more than 10 observations are to be sent, the instrument will split the observations into messages containing up to 10 observations. Each message must be answered with an **ACK** message by the observation reviewer.

Afinion tests may present results in different units, depending on instrument settings. Units used for results transmitted via the POCT1-A interface will match the unit settings shown on the instrument's display. Units are configurable via the instrument's touchscreen user interface. The possible units for each assay type are shown below:

Assay	Analyte/Value	Allowed units
ACR	Alb	mg/L
	Creat	mmol/L, mg/dL
	ACR[1]	mg/g, mg/mmol
CRP	CRP	mg/L
HbA1c	HbA1c	IFCC[2], %, mmol/mol
	eAG[1]	mmol/L
HbA1c Dx	HbA1c	%
Lipid Panel	Chol	mg/dL, mmol/L
	Trig	mg/dL, mmol/L
	HDL	mg/dL, mmol/L
	LDL[1]	mg/dL, mmol/L
	non-HDL[1]	mg/dL, mmol/L
	Chol/HDL[1]	mg/dL, mmol/L

---

[1] Calculated value. This value may be sent along with a result, but QC lot information shall not be provided for these values.

[2] IFCC is not an option when results are transmitted from the instrument, but control lot information for the QC lockout functionality may be provided in this unit.

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Example: Observation reviewer requests new observations

```xml
<REQ.R01>
  <HDR>
    <HDR.control_id V="10036" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2016-06-10 11:37:46+02:00" />
  </HDR>
  <REQ>
    <REQ.request_cd V="ROBS" />
  </REQ>
</REQ.R01>
```

Example: Observation reviewer requests all observations

```xml
<REQ.R01>
  <HDR>
    <HDR.control_id V="10036" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2016-06-10 11:37:46+02:00" />
  </HDR>
  <REQ>
    <REQ.request_cd V="RALL" />
  </REQ>
</REQ.R01>
```

Example: One ACR, one HbA1c and one HbA1c Dx reading

```xml
<OBS.R01>
  <HDR>
    <HDR.control_id V="1012" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-10-04T09:00:20+0000" />
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS" />
    <SVC.observation_dttm V="2013-10-03T14:04:43+0000" />
    <SVC.status_cd V="NRM" />
    <SVC.reason_cd V="NEW" />
    <SVC.sequence_nbr V="2" />
    <PT>
      <PT.patient_id V="0" />
      <PT.patient_id2 V="" />
      <PT.patient_id3 V="" />
      <PT.patient_id4 V="" />
      <OBS>
        <OBS.observation_id V="ACR" SN="ADTNOR" />
        <!--Possible values ACR, HbA1c, CRP,Lipid Panel-->
        <OBS.value V="2.1" U="mg/mmol" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
      </OBS>
      <OBS>
        <OBS.observation_id V="Alb" SN="ADTNOR" />
        <OBS.value V="46.7" U="mg/L" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
      </OBS>
      <OBS>
        <OBS.observation_id V="Creat" SN="ADTNOR" />
        <OBS.value V="21.8" U="mmol/L" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
      </OBS>
    </PT>
    <OPR>
```

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```
        <OPR.operator_id V="102" />
      </OPR>
      <RGT>
        <RGT.name V="ACR" />
        <RGT.lot_number V="10164509" />
        <RGT.expiration_date V="2015-08" />
      </RGT>
    </SVC>
    <SVC>
      <SVC.role_cd V="OBS" />
      <SVC.observation_dttm V="2013-10-03T14:31:56+0000" />
      <SVC.status_cd V="NRM" />
      <SVC.reason_cd V="NEW" />
      <SVC.sequence_nbr V="3" />
      <PT>
        <PT.patient_id V="0" />
        <PT.patient_id2 V="" />
        <PT.patient_id3 V="" />
        <PT.patient_id4 V="" />
        <OBS>
          <OBS.observation_id V="HbA1c" SN="ADTNOR" />
          <OBS.value V="7.0" U="%" />
          <OBS.method_cd V="M" />
          <OBS.status_cd V="A" />
        </OBS>
      </PT>
      <OPR>
        <OPR.operator_id V="" />
      </OPR>
      <RGT>
        <RGT.name V="HbA1c" />
        <RGT.lot_number V="10167530" />
        <RGT.expiration_date V="2015-09" />
      </RGT>
    </SVC>
    <SVC>
      <SVC.role_cd V="OBS" />
      <SVC.observation_dttm V="2020-02-17T14:24:40+0000" />
      <SVC.status_cd V="NRM" />
      <SVC.reason_cd V="NEW" />
      <SVC.sequence_nbr V="4426" />
      <PT>
        <PT.patient_id V="PAM" />
        <PT.patient_id2 V="" />
        <PT.patient_id3 V="" />
        <PT.patient_id4 V="" />
        <OBS>
          <OBS.observation_id V="HbA1c" SN="ADTNOR" />
          <OBS.value V="5.69" U="%" />
          <OBS.method_cd V="M" />
          <OBS.status_cd V="A" />
        </OBS>
      </PT>
      <OPR>
        <OPR.operator_id V="" />
      </OPR>
      <RGT>
        <RGT.name V="HbA1c Dx" />
        <RGT.lot_number V="10204279" />
        <RGT.expiration_date V="2021-09" />
      </RGT>
    </SVC>
  </OBS.R01>
```

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Example: CRP and HbA1c Dx control reading. The observation message contains information about the control lot used in this control test.

```xml
<OBS.R02>
  <HDR>
    <HDR.control_id V="1003" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-10-04T14:09:09+0000" />
  </HDR>
  <SVC>
    <SVC.role_cd V="LQC" />
    <SVC.observation_dttm V="2013-10-04T13:23:00+0000" />
    <SVC.status_cd V="NRM" />
    <SVC.reason_cd V="NEW" />
    <SVC.sequence_nbr V="1" />
    <CTC>
      <CTC.name V="CRP" />
      <CTC.lot_number V="10156287" />
      <CTC.expiration_date V="2016-01" />
      <CTC.level_cd V="1" />
      <OBS>
        <OBS.observation_id V="CRP" SN="ADTNOR" />
        <OBS.value V="20" U="mg/L" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
        <OBS.normal_lo-hi_limit V="[13.0;23.0]" U="mg/L" />
      </OBS>
    </CTC>
    <OPR>
      <OPR.operator_id V="OPR" />
    </OPR>
    <RGT>
      <RGT.name V="CRP" />
      <RGT.lot_number V="10165569" />
      <RGT.expiration_date V="2015-10" />
    </RGT>
  </SVC>
  <SVC>
    <SVC.role_cd V="LQC" />
    <SVC.observation_dttm V="2020-02-17T15:11:24+0000" />
    <SVC.status_cd V="NRM" />
    <SVC.reason_cd V="NEW" />
    <SVC.sequence_nbr V="4427" />
    <CTC>
      <CTC.name V="HbA1c" />
      <CTC.lot_number V="10206618" />
      <CTC.expiration_date V="2022-01" />
      <CTC.level_cd V="1" />
      <OBS>
        <OBS.observation_id V="HbA1c" SN="ADTNOR" />
        <OBS.value V="5.96" U="%" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
        <OBS.normal_lo-hi_limit V="[5.26;6.54]" U="%" />
      </OBS>
    </CTC>
    <OPR>
      <OPR.operator_id V="" />
    </OPR>
    <RGT>
      <RGT.name V="HbA1c Dx" />
      <RGT.lot_number V="10204279" />
      <RGT.expiration_date V="2021-09" />
    </RGT>
  </SVC>
</OBS.R02>
```

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3.1.5   Conversation termination

A conversation is terminated when an **END.R01** message is sent by the observation reviewer.

Example:
```
<END.R01>
  <HDR>
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-03-11T14:00:05+01:00" />
  </HDR>
  <TRM>
    <TRM.reason_cd V="NRM"/>
  </TRM>
</END.R01>
```

If Afinion cannot process incoming messages (e.g. because an assay is starting), it will send an Escape message **ESC.R01** as a response to incoming messages:

```
<ESC.R01>
  <HDR>
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-03-11T14:00:05+01:00" />
  </HDR>
  <ESC>
    <ESC.esc_control_id V="100212"/>
    <ESC.detail_cd V="CNC"/>
    <ESC.note_txt V="Assay started"/>
  </ESC>
</ESC.R01>
```

3.1.6   Device events

Device events are sent from the instrument in the form of **EVS.R01** messages containing information about instrument events. These events are generated by the Afinion instrument whenever an error code is displayed on the screen.

The instrument will store events in local memory ready to be transmitted via POCT1-A whenever a request is made. An event can only be transmitted to the observation reviewer once.

The **EVS.R01** message described in the POCT1-A communication profile has been extended to include information that may be relevant to errors occurring during assay runs, such as assay type, lot number, run type and patient ID.

EVT.run_type
Possible values:
>   Pat
>   Qc

The observation reviewer requests device events by transmitting an **REQ.R01** message to the instrument with the REQ.request_cd field set to RDEV

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Example: Request for device events:

```
<REQ.R01>
  <HDR>
    <HDR.control_id V="10002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-07-10 15:25:07+02:00" />
  </HDR>
  <REQ>
    <REQ.request_cd V="RDEV" />
  </REQ>
</REQ.R01>
```

Example: Device events message:

```
<EVS.R01>
  <HDR>
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2014-08-03T14:20:05+01:00" />
  </HDR>
  <EVT>
    <EVT.description V="Information code #301"/>
    <EVT.event_dttm V="2014-08-02T13:23:05+01:00"/>
    <EVT.severity_cd V="N"/>
    <EVT.patient_id1 V="00112233" />
    <EVT.patient_id2 V="LASTNAME" />
    <EVT.patient_id3 V="FIRSTNAME" />
    <EVT.patient_id4 V="19700301" />
    <EVT.assay_type V="CRP" />
    <EVT.run_type V="Pat" />                <!-- Enum: Pat, Qc -->
    <EVT.cartridge_lot V="8011232451" />
    <OPR>
      <OPR.operator_id V="OPR1" />
    </OPR>
  </EVT>
  <EVT>
    <EVT.description V="Information code #201"/>
    <EVT.event_dttm V="2014-08-02T15:02:01+01:00"/>
    <EVT.severity_cd V="N"/>
    <EVT.patient_id1 V="554423234" />
    <EVT.patient_id2 V="LASTNAME" />
    <EVT.patient_id3 V="FIRSTNAME" />
    <EVT.patient_id4 V="19700301" />
    <EVT.assay_type V="HbA1c" />
    <EVT.run_type V="Pat" />
    <EVT.cartridge_lot V="8011232451" />
    <OPR>
      <OPR.operator_id V="OPR2" />
    </OPR>
  </EVT>
</EVS.R01>
```

4   SUPPORTED DIRECTIVES

4.1   Date / time

The observation reviewer may set the date and time of the instrument using the SET_TIME **DTV.R02** directive.

Note: Time zone information and leap second functionality is not supported by Afinion SW, so this information will be ignored if present.

The time format is *yyyy-mm-ddTHH:MM:SSZZZZ*

Time zone information may be included but will be ignored by the instrument.

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Example:

```xml
<DTV.R02>
  <HDR>
    <HDR.control_id V="10002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-07-10 17:39:26+02:00" />
  </HDR>
  <DTV>
    <DTV.command_cd V="SET_TIME" />
  </DTV>
  <TM>
    <TM.dttm V="2013-07-10T17:39:26+02:00" />
    <TM.accy V="0.5" />
  </TM>
</DTV.R02>
```

4.2   Operator list

The observation reviewer may download operator lists to the instrument during a conversation. The message types used for operator lists are **OPL.R01** and **OPL.R02**.
A list downloaded using **OPL.R01** will replace any previously stored operator information in the instrument. **OPL.R02** is used to either add or subtract operators to or from the instrument.

Note: These messages are not checked for content before they are applied to the database. Any message that would lead to the deletion of the last supervisor operator or a list replacement that contains no supervisor operators will be accepted. An instrument that has no supervisors cannot be configured in any way via the instrument GUI, which may be desirable in some settings. This is done intentionally in order for hospitals/DMS managers to have a way to avoid supervisor user misuse. This places a greater responsibility on the DMS to make sure this situation does not occur unintentionally.

A maximum of 1000 operators may be stored in the instrument. The instrument may take a long time to process large operator lists and thereby creating timeouts in the system. To avoid this, operator lists should be broken up into shorter segments (10 or less operators in each message). Incremental operator lists are recommended for instrument updates in order to minimize the amount of traffic and processor time needed.

To update an operator's privileges, the operator should be deleted from the instrument and then added with the new privileges.

An operator ID consists of 1 – 16 characters [0-9][A-Z]. Operator IDs are not case sensitive.

Operator access: Operator's access privileges are set using the method_cd and permission_level_cd parameters. Method_cd sets the assay types the user will be allowed to run. Multiple instances of this parameter can be used to set access to multiple assay types. The value ALL may be used to allow the user to access all assay types.

Permission level sets the operator level to either USER or SUPERVISOR. An operator of USER level will not have access to the instrument's settings panel.

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ACC.method_cd
Possible values:
> CRP
> HbA1c
> HbA1c Dx
> ACR
> Lipid Panel
> ALL

ACC.permission_level_cd
Possible values:
> USER
> SUPERVISOR

*Example: A new operator list is downloaded. This will overwrite the existing list in the instrument. Operator information may be split into multiple **OPL.R01** messages. Each list will be replied to with an **ACK.R01** message. An **EOT** message must be transmitted after the last **OPL.R01** message to signal the end of the data transfer.*

```xml
<OPL.R01>
  <HDR>
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-03-11T14:00:05+01:00" />
  </HDR>
  <OPR>
    <OPR.operator_id V="OPERATOR1"/>
    <ACC>
      <ACC.method_cd V="CRP"/>
      <ACC.method_cd V="HbA1c"/>
      <ACC.permission_level_cd V="USER"/>
    </ACC>
  </OPR>
  <OPR>
    <OPR.operator_id V="OPERATOR2"/>
    <ACC>
      <ACC.method_cd V="ALL"/>
      <ACC.permission_level_cd V="USER"/>
    </ACC>
  </OPR>
  <OPR>
    <OPR.operator_id V="OPERATOR3"/>
    <ACC>
      <ACC.method_cd V="ALL"/>
      <ACC.permission_level_cd V="SUPERVISOR"/>
    </ACC>
  </OPR>
</OPL.R01>
```

Example: Users "OPERATOR1" and "OPERATOR2" are removed and a new user, "OPERATOR4" is added. If OPERATOR4 already exists in the instrument it will be overwritten.

```xml
<OPL.R02>
  <HDR>
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-03-11T14:00:05+01:00" />
  </HDR>
  <UPD>
    <UPD.action_cd V="D" />
```

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```
<OPR>
  <OPR.operator_id V="OPERATOR1"/>
</OPR>
<OPR>
  <OPR.operator_id V="OPERATOR2"/>
</OPR>
</UPD>
<UPD>
<UPD.action_cd V="I" />
<OPR>
  <OPR.operator_id V="OPERATOR4"/>
  <ACC>
    <ACC.method_cd V="CRP"/>
    <ACC.method_cd V="Lipid Panel"/>
    <ACC.permission_level_cd V="USER"/>
  </ACC>
</OPR>
</UPD>
</OPL.R02>
```

5 VENDOR SPECIFIC DIRECTIVES

5.1 Insert QC lot information

QC lot information may be downloaded by the observation reviewer using the message type
DTV.ALERE.AXIS.LQCSET. The message contains a list of information about liquid QC lots. All transmitted
QC lot data is appended to the QC lot list stored in the instrument. If a QC lot already exists in the
instrument's database, the lot information will be overwritten.

A maximum of 100 control lots may be stored in the instrument. A message may contain up to 100 control
lots although because storing the data in the instrument will take some time, communication timeouts
may occur when very large lists are transmitted. It is therefore recommended that lists are split up into
smaller segments (<= 10 records).

The LQCSET message must include:
- Assay name [CRP, ACR, HbA1c, Lipid Panel]
- Lot number (8 – digit number).
- Control level [1,2]
- Expiration date yyyy-mm
- Expected range: The content of this depends on the assay type. Range information may be
  provided in any of the measurement units listed below. Any unit shown in section 3.1.4 may be
  used. An assay may contain both measured and calculated result values. Only measured values
  are to be transmitted as QC lot information.

Example: Information about one ACR CI control and one ACR CII control.

```
<DTV.ALERE.AXIS.LQCSET>
  <HDR>
    <HDR.message_type V="DTV.ALERE.AXIS.LQCSET" SN="ADTNOR" SV="1.0" />
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-03-11T14:00:05+01:00" />
  </HDR>
  <DTV>
    <DTV.command_cd V="LQC_SETUP" />
  </DTV>
```

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```
<LQC_SETUP>
  <name V="ACR" />
  <lot_number V="10155632" />
  <level_cd V="1" />
  <expiration_date V="2013-06" />
  <expected_range>
    <albumine>
      <valid_range V="[25;32]" U="mg/L"/>
    </albumine>
    <creatinine>
      <valid_range V="[2.4;3.1]" U="mmol/L"/>
    </creatinine>
  </expected_range>
</LQC_SETUP>
<LQC_SETUP>
  <name V="ACR" />
  <lot_number V="10155633" />
  <level_cd V="2" />
  <expiration_date V="2013-06" />
  <expected_range>
    <albumine>
      <valid_range V="[120;134]" U="mg/L"/>
    </albumine>
    <creatinine>
      <valid_range V="[22;28]" U="mmol/L"/>
    </creatinine>
  </expected_range>
</LQC_SETUP>
</DTV.ALERE.AXIS.LQCSET>
```

5.2 Clear QC lot information

The **DTV.ALERE.AXIS.LQCSET** directive may be used to clear all QC lot information from the instrument.

```
<DTV.ALERE.AXIS.LQCSET>
  <HDR>
    <HDR.message_type V="DTV.AFINION.LQCSET" SN="ADTNOR" SV="1.0" />
    <HDR.control_id V="10001" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-03-11T14:00:05+01:00" />
  </HDR>
  <DTV>
    <DTV.command_cd V="LQC_CLEAR" />
  </DTV>
</DTV.ALERE.AXIS.LQCSET>
```

5.3 Device setup

A special directive can be used to change the instrument settings from the DMS. The content of this message includes configuration of QC lockout and operator lockout as well as unit configurations. This message may be extended to include more configuration settings.

```
<DTV.ALERE.AXIS.DVCSET>
  <HDR>
    <HDR.control_id V="10002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-07-11 12:17:21+02:00" />
  </HDR>
  <DTV>
    <DTV.command_cd V="DEVICE_SETUP" SN="ADTNOR" SV="6.00" />
  </DTV>
  <DEVICE_SETUP>
    <operator_lockout>
      <!--Allow local operator lockout configuration? (0=No, 1=Yes)-->
      <allow_local V="1" />
```

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```xml
            <!--Operator session duration (minutes) [0,1440]-->
            <session_duration V="30" />
            <!--Operator lockout level (DIS=disabled,OPT=optional,REQ=required)-->
            <lockout V="REQ" />
        </operator_lockout>
        <qc_lockout>
            <!--Allow local QC lockout configuration? (0=No, 1=Yes)-->
            <allow_local V="1" />
            <assay>
                <assay_name V="CRP" /><!--Assay Name (ACR, CRP, HbA1c, HbA1c Dx, Lipid Panel)-->
                <!--Period setting-->
                <!--V=Lockout by (time,runs)-->
                <!--T=Lockout interval (# hours between required QC runs) (0,...)-->
                <!--W=Warning period (# hours remaining to trigger warning message)-->
                <timeout V="time" T="21" W="10" />
                <lockout_level V="1" /> <!--Lockout level (0=OFF, 1=CI or CII, 2=CI + CII)-->
                <!--Force lock. If set to 1, this will block the instrument from performing patient
                tests for the assay type-->
                <lock_assay V="0" />
            </assay>
            <assay>
                <assay_name V="ACR" />
                <timeout V="runs" T="19" W="5" />
                <lockout_level V="2" />
                <lock_assay V="0" />
            </assay>
            <assay>
                <assay_name V="HbA1c" />
                <timeout V="time" T="11" W="8" />
                <lockout_level V="0" />
                <lock_assay V="0" />
            </assay>
        </qc_lockout>
        <connection>
            <connect_dly V="60" /><!--Delay between connection attempts when the device is idle-->
        </connection>
        <user>
            <allow_result_discard V="1" /><!— Allow user to discard unwanted results. Enum: (0=Do
    not show discard button, 1=show discard button)-->
        </user>
    </DEVICE_SETUP>
</DTV.ALERE.AXIS.DVCSET>
```

5.4   Lockout status information

QC lockout and operator lockout status information is accessible through the use of the directive
ALERE.AXIS.LOCKSTATUS. The status message retrieved by sending a **REQ.R01** message with request_cd
DEVSTAT

Example: Request message
```xml
<REQ.R01>
  <HDR>
    <HDR.control_id V="10014" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-07-15 15:15:17+02:00" />
  </HDR>
  <REQ>
    <REQ.request_cd V="DEVSTAT" />
  </REQ>
</REQ.R01>
```

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Example status message

```xml
<ALERE.AXIS.LOCKSTATUS>
  <HDR>
    <HDR.control_id V="1003" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2013-07-15T15:15:18+0000" />
  </HDR>
  <qc_lockout>
    <assay>
      <name V="HbA1c" />
      <!--Lockout method: ENUM 0=Lockout by #hours, 1=Lockout by #runs-->
      <!--If 1, lockout_period and warning_period is #runs-->
      <!--If 0, lockout_period and warning_period is #hours-->
      <method V="0" />
      <!--Lockout period INTEGER (#hours or #runs between required control runs) (0,...)-->
      <lockout_period V="12" />
      <!--Warning period INTEGER (#hours or #runs remaining to show warning) (0,...)-->
      <warning_period V="9" />
      <!--Lockout level ENUM 0=OFF, 1=CI or CII, 2=CI and CII-->
      <lockout_level V="2" />
      <!--Force lockout ENUM (0=DISABLED, 1=ENABLED). When ENABLED, the instrument will not
run patient runs for the assay type. Set by DMS. -->
      <force_lockout V="0" />
      <!--Lockout status ENUM 1=Locked, 0=Unlocked-->
      <locked V="1" />
    </assay>
    <assay>
      <name V="HbA1c Dx" />
      <method V="0" />
      <lockout_period V="24" />
      <warning_period V="12" />
      <lockout_level V="2" />
      <force_lockout V="0" />
      <locked V="1" />
    </assay>
    <assay>
      <name V="CRP" />
      <method V="0" />
      <lockout_period V="25" />
      <warning_period V="12" />
      <lockout_level V="2" />
      <force_lockout V="0" />
      <locked V="1" />
    </assay>
    <assay>
      <name V="ACR" />
      <method V="1" />
      <lockout_period V="14" />
      <warning_period V="6" />
      <lockout_level V="1" />
      <force_lockout V="0" />
      <locked V="1" />
    </assay>
    <assay>
      <name V="Lipid Panel" />
      <method V="0" />
      <lockout_period V="15" />
      <warning_period V="5" />
      <lockout_level V="1" />
      <force_lockout V="0" />
      <locked V="1" />
    </assay>
  </qc_lockout>
  <operator_lockout>
    <!--Operator lockout level ENUM (0=DISABLED, 1=OPTIONAL, 2=REQUIRED)-->
    <lockout_level V="0" />
    <!--Operator login session length INTEGER (0,...)-->
    <login_time V="30" />
  </operator_lockout>
</ALERE.AXIS.LOCKSTATUS>
```

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5.5 Software upgrade

New software versions may be distributed remotely to the instrument using the software upgrade directive. The software image is downloaded in a series of segments. Each segment is checked by the device upon reception. Once all segments are downloaded, the upgrade may proceed.

The download is initiated by the observation reviewer by sending a document of type **DTV.AFINION.SWU** to the instrument. This message contains information about the total image size (DTV.image_size) and the maximum individual segment size (DTV.segment_size). Sizes are reported in number of bytes.

Example: Software upgrade directive

```
<DTV.AFINION.SWU>
  <HDR>
    <HDR.control_id V="10002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:26:42+01:00" />
  </HDR>
  <SWU>
    <SWU.image_size V="13164256" />
    <SWU.segment_size V="60000" />
    <SWU.auto_update V="1"/>
    <SWU.auto_restart V="1"/>
  </SWU>
</DTV.AFINION.SWU>
```

Parameters:
- **SWU.image_size:** The total image size in bytes. The maximum image size supported by the instrument is defined in **DSC.max_swu_image_sz** in the **HEL.R01** message.
- **SWU.segment_size:** The size of each individual segment in bytes. All segments are usually the same size except the final one. This parameter should reflect the largest transmitted segment size. The maximum segment size supported by the instrument is defined in **DSC.max_swu_seg_sz** in the **HEL.R01** message.
- **SWU.auto_update:** (1,0) If 1, the software upgrade will be performed with no user interaction required. The instrument will not show the software upgrade confirmation prompt after restart. If 0, the upgrade must be confirmed on the Afinion 2 touchscreen, similar to upgrading from a USB flash drive
- **SWU.auto_restart:** (1,0) If 1, the instrument will restart after the POCT1-A conversation has ended. The restart will trigger the software upgrade. If 0, the instrument will not reboot after ending the POCT1-A conversation. The next automatic nightly restart, or a user-initiated restart, will trigger the software upgrade.

If the request to download is accepted by the instrument, it will respond with an **ACK** message (type=AA). If the request is for some reason denied, the instrument will respond with an **ACK ERR** message (type=AE) with a note describing the reason the download was denied. Upon receiving an **ACK**, the observation reviewer will proceed to transmit the segments containing the software image.

Each segment is transmitted as an XML document of type **SWU.SEGMENT**. Each message contains a sequence counter ("seq"), starting at 1, and the size of the segment. The binary size of the segment in bytes is used, not the size of the BASE64 encoded text. Example: Since a BASE64 symbol is 6 bits, while a byte is 8 bits, a segment with size=60000 contains 60000 bytes of information, which equals 80000

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BASE64 symbols. The instrument will respond with an **ACK** after each segment. It is recommended for the observation reviewer to wait for the **ACK** before sending the next segment.

Example: Software upgrade segment and ACK response

System->Device:
```
<SWU.SEGMENT>
  <HDR>
    <HDR.control_id V="10003" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:26:43+01:00" />
  </HDR>
  <SEG size="60000" seq="1" crc="9299b456c">U2FsdGVkX19Z/L7AFzGm4dPbzwBh+b...</SEG>
</SWU.SEGMENT>
```

Device->System:
```
<ACK.R01>
  <HDR>
    <HDR.control_id V="1004" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:26:27+0000" />
  </HDR>
  <ACK>
    <ACK.type_cd V="AA" />
    <ACK.ack_control_id V="10003" />
  </ACK>
</ACK.R01>
```

System->Device:
```
<SWU.SEGMENT>
  <HDR>
    <HDR.control_id V="10004" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:26:43+01:00" />
  </HDR>
  <SEG size="60000" seq="2" crc="128bfc3ef">ajkxdWsbWGOnLLVdZFCUB7ALG4y/vFHN...</SEG>
</SWU.SEGMENT>
```

Device->System:
```
<ACK.R01>
  <HDR>
    <HDR.control_id V="1005" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:26:27+0000" />
  </HDR>
  <ACK>
    <ACK.type_cd V="AA" />
    <ACK.ack_control_id V="10004" />
  </ACK>
</ACK.R01>
```

...

System->Device:
```
<SWU.SEGMENT>
  <HDR>
    <HDR.control_id V="10224" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:29:45+01:00" />
  </HDR>
  <SEG size="15104" seq="222" crc=" e6568ec4">+YLKP0EJpP+m8OBFKRWajKKSg1Ww5+gA7...</SEG>
</SWU.SEGMENT>
```

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Device->System:

```
<ACK.R01>
  <HDR>
    <HDR.control_id V="1225" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:29:29+0000" />
  </HDR>
  <ACK>
    <ACK.type_cd V="AA" />
    <ACK.ack_control_id V="10224" />
  </ACK>
</ACK.R01>
```

If the instrument detects an error during the transfer, it will respond with an **ACK ERR** with a note detailing the problem. In case of CRC error detected by the instrument, the observation reviewer may resend the segment.

After all segments have been successfully transmitted to the instrument, the observation reviewer will finalize the download by sending an End of Topic (**EOT.R01**) message to the instrument.

Example

```
<EOT.R01>
  <HDR>
    <HDR.control_id V="10225" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-11-16T13:29:45+01:00" />
  </HDR>
  <EOT>
    <EOT.topic_cd V="SWU" />
  </EOT>
</EOT.R01>
```

The software download may take some time to complete. If the user starts a new assay run or reboots the instrument while the download is in progress, the download will be aborted and will have to be restarted.

Encoding

The software image segments are encoded as BASE64 with character set **[A-Z][a-z][0-9]+/**. The text string may include padding (=), but this is not required. The text string may not include newlines.

CRC

The checksum is calculated for each BASE64 segment and transmitted together with it. Before calculation, the BASE64 string needs to be stored in a byte array, where each BASE64 character is represented by one byte based on the ASCII character set ('A' = 65, 'z' = 122, '+' = 43, '/' = 47, etc.). The checksum is calculated using the CRC-32 algorithm. It uses the byte array and a 32-bit ANSI x3.66 CRC checksum table for the polynomial 0xEDB88320.