Alere Afinion 2 – POCT1-A Connectivity Protocol

No restriction

Doc ID: TP13/80/2094/2103/2722-14647
Master Doc ID: TP13/80/2094/2103/2722-13153
Version no.: 2.0
Authorised: 30.08.2016

Alere Technologies AS
Kjelsåsveien 161, P.O. Box 6863 Rodeløkka, NO-0504 Oslo, Norway

1 DOCUMENT INFORMATION

1.1 Scope

This document describes the implementation of the POCT1-A protocol in the Analyzer 2.

1.2 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.

1.3 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 4.1.1).

The vendor ID for all devices manufactured by Alere Technologies is: **ALERE.AXIS**
The manufacturer name for devices manufactured by Alere Technologies is: **Alere Technologies**
The device name for the Afinion Analyzer 2 is: **Alere Afinion 2 analyzer**
The device ID for Afinion Analyzer 2 is the same as the serial number of the device, e.g. 2012345.

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
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.

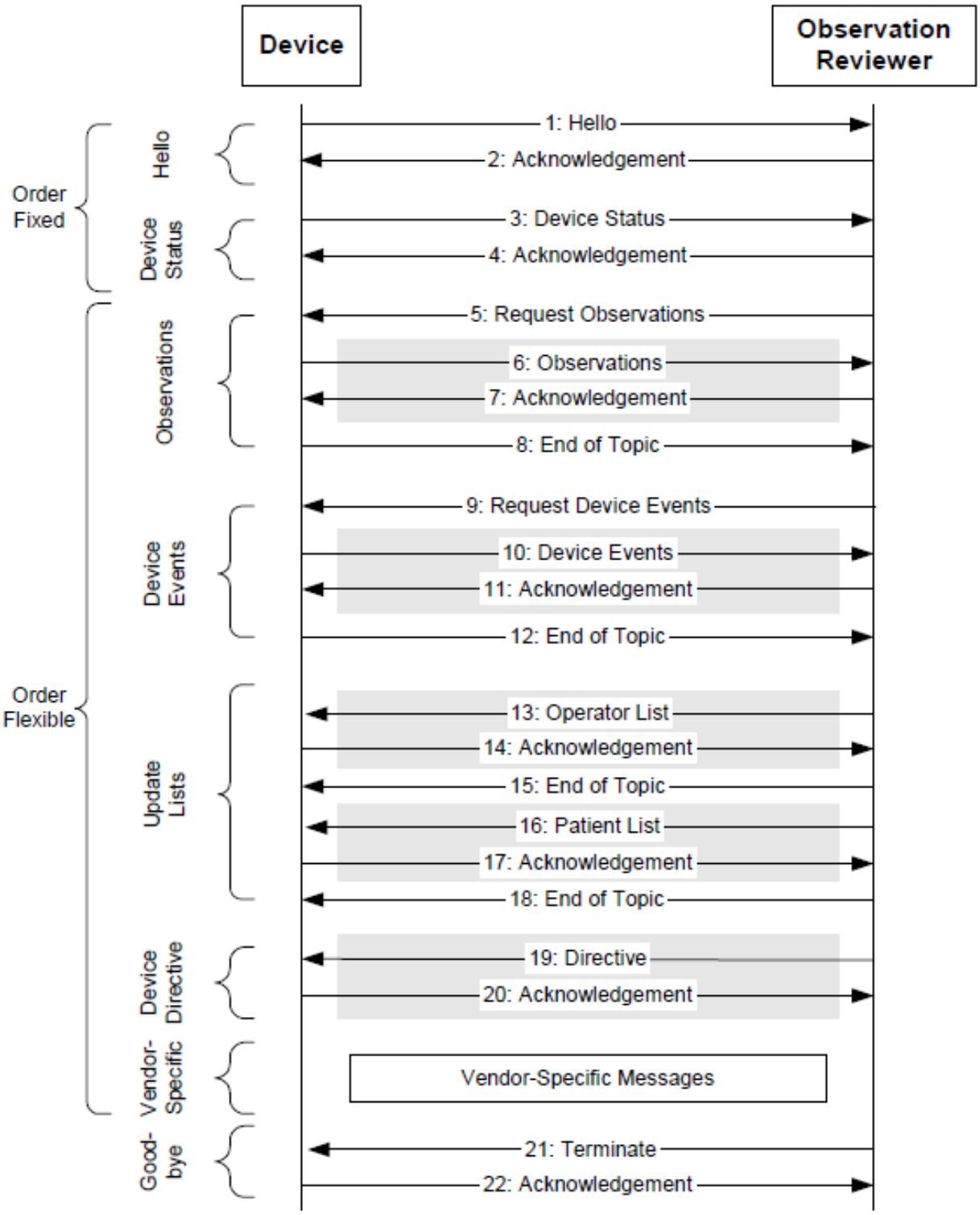

Figure 1: POCT1-A basic communication flow

3.1.1 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:

```
<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="21" />
    <DEV.vendor_id V="ALERE.AXIS" />
    <DEV.manufacturer_name V="Alere Technologies" />
    <DEV.hw_version V="HW1" />
    <DEV.sw_version V="1.00" />
    <DEV.device_name V="Alere Afinion 2 Analyzer" />
    <DEV.market_configuration V="Internal" />
    <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.max_message_sz V="32768" />
    </DSC>
  </DEV>
```

3.1.2 </HEL.R01>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.

Example: Device reporting four new observations and one new event.

```
<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="15" />
    <DST.new_events_qty V="0" />
    <DST.condition_cd V="R" SN="POCT1" SV="1" />
    <!--R if instrument is ready, P if one or more assays are locked -->
    <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>
</DST.R01>
```

3.1.3 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. The possible units for each assay type are shown below:

- ACR
  - albumin (allowed units: mg/L)
  - creatinine (allowed units: mmol/L, mg/dL)
  - ACR (allowed units: mg/g, mg/mmol)*
- CRP
  - crp (allowed units: mg/L)
- HbA1c
  - hba1c (allowed units: IFCC[1], %, mmol/mol)
  - eAG (allowed units: mmol/L)*
- Lipid Panel
  - Chol (allowed units: mg/dL, mmol/L)
  - Trig (allowed units: mg/dL, mmol/L)
  - HDL (allowed units: mg/dL, mmol/L)
  - LDL (allowed units: mg/dL, mmol/L)*
  - non-HDL (allowed units: md/dL, mmol/L)*
  - Chol/HDL (No unit)*

Example: Observation reviewer requests new observations

```
<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>
```

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

[1] 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.

Example: Observation reviewer requests all observations

```
<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 and one HbA1c reading

```
<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="ALERE.AXIS" />
        <!--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="ALERE.AXIS" />
        <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="ALERE.AXIS" />
        <OBS.value V="21.8" U="mmol/L" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
      </OBS>
    </PT>
    <OPR>
      <OPR.operator_id V="102" />
    </OPR>
    <RGT>
      <RGT.name V="ACR" />
      <RGT.lot_number V="10164509" />
      <RGT.expiration_date V="”” />
    </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="ALERE.AXIS" />
        <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="” />
    </RGT>
  </SVC>
</OBS.R01>
```

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

```
<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="ALERE.AXIS" />
        <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="” />
    </RGT>
  </SVC>
</OBS.R02>
```

3.1.4 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>
```

3.1.5 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 occuring during assay runs, such as assay type, lot number, run type and patient ID.

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

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="Error code #301"/>
    <EVT.event_dttm V="2014-08-02T13:23:05+01:00"/>
    <EVT.event_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="Error code #201"/>
    <EVT.event_dttm V="2014-08-02T15:02:01+01:00"/>
    <EVT.event_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

4.1.1 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.

Example:

```
<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>
```

4.1.2 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 500 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.

ACC.method_cd
Possible values:

- CRP
- HbA1c
- 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.*

```
<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.

```
<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" />
    <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

5.1.1 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 ut 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 4.1.3 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="ALERE.AXIS" 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>
  <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>
```

5.1.2 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="ALERE.AXIS" 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>
```

5.1.3 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="ALERE.AXIS" SV="6.00" />
  </DTV>
  <DEVICE_SETUP>
    <operator_lockout>
      <!--Allow local operator lockout configuration? (0=No, 1=Yes)-->
      <allow_local V="1" />
      <!--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, 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>
```

5.1.4 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

```
<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>
```

Example status message

```
<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="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>
```