DCA Vantage® Analyzer

Host Computer Communications Link

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General Information

This document applies to the DCA Vantage® Analyzer version 3.0 and greater software. The DCA Vantage Analyzer is a semi-automated, bench top system. It is designed to quantitatively measure the percentage of Hemoglobin A_{1C} in blood and low concentrations of albumin in urine (microalbuminuria), measure creatinine in urine, and calculate the albumin/creatinine ratio in urine. The DCA Vantage Analyzer is intended for professional use in a physician's office or hospital laboratory. Tests performed using the DCA Vantage Analyzer are intended for *in vitro* diagnostic use.

You can connect the DCA Vantage system to a host computer or laboratory Information System (LIS through either a serial connection or an Ethernet connection between instrument and host. You select the interface you want to use from the menus on the DCA Vantage Analyzer screen. The serial interface is compatible with the EIA-232-D Specification. The Ethernet interface is established through the instrument's RJ45 internet connection.

This document defines the data codes, transmission protocols, error recovery, and message content of communication between the DCA Vantage Analyzer (the instrument) and a laboratory computer (the host) using the ASTM protocol or the POCT1-A2 protocol.

Sections 1 through 7 describe the use of the ASTM standard. Sections 8 through 12 describe the use of the POCT1-A2 standard.

Communications Protocols

The DCA Vantage system supports the ASTM Specification E1381, Low-Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems. The system also supports the ASTM Specification E1394, Standard Specification for Transferring Information between Clinical Instruments and Computer Systems.

The DCA Vantage system uses the POCT1-A standard to link to a data manager and to hospital/laboratory information systems (LIS). The POCT1-A standard automates transmission of information including date and time, result, patient ID, and Operator ID.

For more information on configuring connectivity to an LIS from a DCA Vantage Analyzer, refer to the *DCA Vantage Operator's Guide* (English Part Number 06489264).

ASTM Messages

ASTM messages transferred from the DCA Vantage instrument to the host include:

- HbA_{1c} test result records
- Microalbumin/Creatinine test result records
- Filter Test Cartridge result records
- Control Test result records

ASTM messages transferred from the host to the DCA Vantage instrument include:

- Force Control remote commands
- Remote Lockout remote commands

POCT1-A2 Messages

The POCT1-A2 standard specifies two interfaces: one between the device and the data manager and one between the data manager and the LIS. The interface between the device and the data manager is called

the device interface. The DCA Vantage Analyzer supports bidirectional messaging between the DCA Vantage Analyzer and a data manager through the Device Messaging Layer (DML) Specification of the POCT1-A2 protocol. This document describes the DML communication of the DCA Vantage Analyzer.

The messages transferred over the device interface include the following:

- Patient observation messages
- Non-patient observation messages
- Device status messages
- Device event messages
- Operator lists
- Directives to the device from the data manager
- Acknowledgement and Escape messages
- Keep alive messages

NOTE: POCT1-A2, the default Ethernet connection protocol, requires a value in the patient_id field in the patient observation test record. In software version 4.0 and higher, you cannot clear the Enabled and Required options for the Patient Test Data Entry Setting for Patient ID. However, you can edit the value to another valid entry in the patient_ID field. Earlier versions of the DCA Vantage software used the ASTM protocol, which allows a blank patient_id field. You may still select ASTM as your Ethernet protocol. For detailed information, see Patient Observations (OBS.R01).

Using This Guide

The following table illustrates how this guide is organized:

If you want to learn about…	Then refer to…
ASTM general specifications and overview	Section 1, General Information
Low-level protocols, specifically the Physical Layer and Data Link Layer, used by ASTM	Section 2, ASTM and Low-Level Protocols
ASTM record structure and content, including test result message structure	Section 3, ASTM Record Structure and Content
ASTM Modes of operation	Section 4, ASTM Modes of Operation
Transmitting ASTM messages between the DCA Vantage Analyzer and the LIS host	Section 5, ASTM Transmit Use Cases
Interpreting Service Mode Data records	Section 6, ASTM Service Mode Data Records
Translating ASTM message fields	Section 7, Translation of ASTM Message Content
POCT1-A2 general specifications and overview	Section 8, POCT1-A2 Introduction
POCT1-A2 communication basics and data flow	Section 9, POCT1-A2 Communication Basics
POCT1-A2 message types	Section 10, POCT1-A2 Messaging Notes
POCT-A2 message examples	Section 11, POCT1-A2 Messaging Model
POCT1-A2 Reference information	Section 12, POCT1-A2 Reference Information

Related Documents

The following documents include instructions for configuring and operating the DCA Vantage Analyzer, as well as relevant standards:

Siemens *DCA Vantage Analyzer Operator's Guide*, English Part Number 06489264

"Low-Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems," Document Number ASTM E1381-95

"Standard Specification for Transferring Information between Clinical Instruments and Computer Systems" Document Number ASTM E1394-97

"POCT1-A2—Point-of-Care Connectivity; Approved Standard—Second Edition," Document Number POCT1-A2 ISO 11073-90101

ASTM and Low-Level Protocols

Low-level refers to the layers of the OSI communications model that deal with the physical and logical link connection, specifically to the Physical and Data Link layers of that model. The low-level protocols that the DCA Vantage system supports are largely defined by the ASTM 1381 standard. The exception to that is the establishment of an Ethernet physical link, which is a logical extension of that specification.

Conventions Used in the ASTM Sections of this Document

The following conventions appear in the ASTM sections of this document, particularly in the examples:

Convention	Description
<SYM>	A control character symbol, e.g., CR = carriage return, contained within a less than and greater than sign, indicate a single ASCII character. For instance, <CR> is used to represent the carriage return character, ASCII value 13.
<lowercase>	Lowercase characters between less than and greater than represent a variable name. For instance, "<last-name>^<first-name>" represents the patient's last name and first name separated by a component separator.
`L|1|N<CR>`	ASTM message records are shown using `Courier`, 9 point, bold font. The vertical bar character, |, ASCII 124, separates the fields in a record description. Multiple values within a field are separated by the Component Delimiter (the Caret, ^, ASCII 94).

Terminology Used in the ASTM Sections of this Document

The following terms are used throughout the ASTM sections of this document:

Term	Definition
Establishment Phase	The phase in the ASTM 1381 protocol that determines the direction of information flow between instrument and host. The sender requests to send by issuing an <ENQ>. The receiver accepts the request by issuing an <ACK>.
Filter Test	A test used to verify the optical performance of the instrument. These are also known as Optical tests.
Frame	A subdivision of an ASTM 1381 message. It is used to allow periodic communication between devices. A message containing 240 characters or less is sent in a single frame. Larger messages are broken up into multiple frames.
Host	Any laboratory computer system as defined by the ASTM 1381 standard. These computer systems typically collect reports from the instrument and/or send remote commands to the instrument.

Term	Definition
Instrument	The DCA Vantage Analyzer—a Clinical Laboratory Instrument as defined by the ASTM 1381 protocol. Also called a "device" or "system."
Message	A message is a collection of related information. It is the textual body of information that is transmitted between instrument and host during one session. Message can consist of many different types of records.
Pending Result	A result that is waiting to be transmitted to the host.
Session	A session is a total unit of communication activity between instrument and host as defined by the ASTM 1381 protocol. The session begins with the establishment phase and ends with the termination phase.
Termination Phase	This is the phase in the ASTM 1381 protocol during which the sender relinquishes its control of the communication link by issuing an <EOT>. After the termination phase, the communication link is returned to a neutral state.
Transfer Phase	This is the phase in the ASTM 1381 protocol during which the sender sends messages to the receiver.

Physical Layer

The Physical Layer refers to the point-to-point connection between the DCA Vantage Analyzer (the instrument) and a laboratory computer system (the host).

Serial Connection

Serial transmission between the instrument and the host is established through the instrument's serial port using a serial cable. The serial physical layer describes the mechanical and electrical connection for serial binary data bit transmission between instrument and computer system. The DCA Vantage system implements and complies with serial physical layer defined in the ASTM 1381 standard. For additional information about this layer, please refer to the standard.

Ethernet Connection

TCP/IP transmission between the instrument and the host is established through the instrument's Ethernet network adapter using an RJ45 connector. The DCA Vantage system supports only the instrument connecting to the host. This means that the host must listen for connections on a TCP/IP port and must accept the connection when the instrument tries to connect.

Data Link Layer

The Data Link Layer operates the same way, regardless of whether the physical connection is serial or Ethernet.

The DCA Vantage system implements and complies with the Data Link layer defined in the ASTM 1381 standard. For additional information about this layer, please refer to that standard.

The Data Link Layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery. Link connection and release establishes which system sends and which system receives. Delimiting and synchronism provide for framing of the data and recognition of frames. Sequence control maintains the sequential order of information across the connection. Error detection senses transmission and format errors. Error recovery attempts to recover from detected errors by retransmitting defective frames.

General Overview of Data Link

Specific information defining the data link layer is contained in the ASTM standard. This section provides an overview of the data link layer.

Information flows in one direction at a time. When one side wants to send a message to the other, it must first establish the direction of communication. The sender sends an enquiry character <ENQ>. If the receiver is ready to receive, it returns an acknowledgement character <ACK>. Once the direction is established, the sender sends a frame or sequence of frames to the receiver. Transmission frames contain framing characters, data content, and checksum. The receiver verifies the checksum and returns an acknowledgement to the sender.

Sample Data Link Transmission

The following is a sample transmission from instrument to host:

Direction	Term	Definition
		ESTABLISHMENT PHASE
Instrument to Host	<ENQ>	Request to establish direction
Host to Instrument	<ACK>	Request accepted, Direction established
		TRANSFER PHASE
Instrument to Host	<STX>	Start of Text, Start of frame
Instrument to Host	FN	Single digit Frame number (0 through 7)
Instrument to Host	Text	Data content of the message
Instrument to Host	<ETX>	End of Text, Transmission control character
Instrument to Host	Checksum	2 character checksum, Hex
Instrument to Host	<CR><LF>	End of Frame
Host to Instrument	<ACK>	Acknowledgement
		TERMINATION PHASE
Instrument to Host	<EOT>	End of transmission, Both sides return to Neutral state

ASTM Record Structure and Content

The low-level protocols define how messages are transferred between instrument and host. This section describes the actual content of the messages.

The record structure and content of DCA Vantage system messages sent over an ASTM link are defined by the ASTM 1394 specification. This section provides an overview of that structure. For a complete description of that structure, refer to the ASTM specification.

ASTM Message Structure

After the direction of communication is established between instrument and host, the sender sends a message to the receiver. The sender sends one message per transfer session. The message content is transferred in the text portion of the ASTM 1381 transmission frame.

Records within an ASTM Message

ASTM messages contain records. Records are separated by a carriage return character <CR>. All messages begin with a Message Header Record and end with a Message Terminator Record.

The following is an example of a simple message from instrument to host:

`H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||P||20060823235959<CR>L|1|N<CR>`

Fields within a Record

ASTM records contain fields. Fields are identified by their position within the record. Fields are delimited by the field separator character (vertical bar, |, ASCII 124). A field's position is obtained by counting the field delimiters from the front of the message. If a field has no value, its field delimiter appears directly after the previous delimiter. If the record has no additional fields with values, it is not necessary to provide the delimiters for those fields.

In the example:

`H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||P||20060823235959<CR>`

"H" is field 1, "\^&" is field 2, "DCA Vantage^01.00.00.00^A123456" is field 5, "P" is field 12, and "20060823235959" is field 14.

NOTE: In ASTM Records, the first field is always the record type.

Components within a Fields

An ASTM field can contain more than one value. Multiple values within a field are separated by the Component Delimiter (the Caret, ^, ASCII 94).

In the example:

`H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||P||20060823235959<CR>`

Field 5 contains "DCA Vantage^01.00.00.00^A123456". This field contains 3 values separated by the component delimiter.

Record Types

An ASTM message consists of a hierarchy of records of various types. In ASTM Records, the first field is always the record type. The DCA Vantage system uses the following record types:

- Message Header Record (H)
- Patient Record (P)
- Order Record (O)
- Result Record (R)
- Comment Record (C)
- Manufacturing Record (M)
- Message Terminator Record (L)

Message Header Record (H)

The Message Header record marks the beginning of a message. It contains information about the sender. It also defines the field, repeat field, component field, and escape delimiter characters. It is always the first record sent in a message.

Field #	Field Name	Definition
1	Record Type	H
2	Delimiter Definition	The 4 characters that follow the record type (H) define the delimiters potentially used in the message. The character immediately following the record type is the 1st field delimiter of the record and is used to define all field delimiters for the message. The 3 characters of the 2nd field define the repeat delimiter (\\), the component delimiter (^), and the escape delimiter (&).
4	Access Password	Required when the host sends a Remote Command Request to the instrument.
5	Sender Information	Sender Information is a component field. When the instrument sends this information, it is in the following format: "<product-code>^<software-version>^<serial number>".
12	Processing ID	This field indicates how the message is to be processed. P = Production (the message contains clinical results) D = Debugging (the instrument is in service mode)
14	Date and Time	This is the date and time of the message transmission. The format of this field is YYYYMMDDHHmmSS. Where YYYY is the 4 digit year, MM is the 2 digit month, DD is the 2 digit day of month, HH is the hour of day (0 through 23), mm is the minutes, and ss is the seconds.

Example record from instrument (clinical results):

`H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||P||20061002200015<CR>`

Message Terminator Record (L)

The Message Terminator record marks the end of a message. It is always the last record sent in a message.

Field #	Field Name	Definition
1	Record Type	L
2	ASTM Sequence Number	1
3	Terminator Code	N = Normal Termination

Example:

`L|1|N<CR>`

Patient Information Record (P)

The Patient information record contains information about a sample that applies to every record of that sample.

Field #	Field Name	Definition
1	Record Type	P
2	ASTM Sequence Number	1, 2, 3…
3	Patient ID	Practice Assigned Patient ID. (This field is not sent in Service Mode 1.)
6	Patient Name	Component Field: <last name>^<first name> (patient samples only, only if entered, not in Manufacturing Mode 1)(This field is not sent in Service Mode 1)

Example:

```
P|1|987654|||Doe^Jane<CR>
```

Test Order Record (O)

For the DCA Vantage system, this record is sent from the instrument to the host only to provide the instrument sequence number for the test result.

Field #	Field Name	Definition
1	Record Type	O
2	ASTM Sequence Number	1, 2, 3, ….
4	Instrument Specimen ID	From instrument to host, according to test type: • Patient results: 001 through 999 (sample sequence number), Reagent Lot Number "<sample sequence number>^<reagent lot number>" • Siemens Controls: Control Level ID, Control Lot Number, and Reagent Lot Number (for example, "C#1^9003^9012") (note upper case 'C').[1] For HbA$_{1c}$, C#1=Normal and C#2=Abnormal. For Microalbumin/Creatinine, C#1=Low and C#2=High. • Non-Siemens Controls: Control Level ID and Reagent Lot Number (for example, "c#1^^9012") (note lowercase 'c'). Level ID numbers go from 1 through 9. • Filter Test Cartridges and Service Filter Test Barcodes (standard number): "S<n>" where <n> is the test type (for example, "S1") (note uppercase 'S') (S1 = Procession and Drift test, S2 = Precision Only test, S3 = Normalization Factor test).[2] • Filter tests run through the menu (standard number): "s<n>" where <n> is the test type (for example, "s1") (note lower case 's').

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[1] The label for the type of control ("C" in the example) is language-dependent. If the language is French, the control type prefix is 'T'. If the language is German or Swedish, the prefix is 'K'. Otherwise, the prefix is 'C' as shown above.

Field #	Field Name	Definition
12	Action Code	Q = when control is run, else unused
26[3]	Report Types	F = Final
		C = Correction of previously transmitted results

Example for clinical specimen:
`O|1||018^9012||||||||||||||||||||||||F<CR>`

Example for control solution selected by bar code:
`O|1||C#1^9003^9012|||||||||Q|||||||||||||||F<CR>`

Example for control solution selected by menu:
`O|1||c#1^^9012|||||||||Q|||||||||||||||F<CR>`

Example for Filter Test Cartridge selected by bar code:
`O|1||S1||||||||||||||||||||||||F<CR>`

Example for Filter Test selected by menu:
`O|1||s1||||||||||||||||||||||||F<CR>`

Result Record (R)

Each Result record contains the result of a single test determination, as follows:

- HbA$_{1c}$ reagent assay results—one Result record per test.
- Microalbumin/Creatinine reagent assay results—three records for a patient result and two records for a control result.
- Precision and Drift filter test—two Result records per test.
- Precision test or MNF test—one Result record per test.

Result records are transmitted only from instrument to host. A Result record can never appear without a preceding Patient record. The following table lists and defines the fields in a Result record.

Field #	Field Name	Definition
1	Record Type	R
2	ASTM Sequence Number	1, 2, 3…
3	Universal Test ID	Clinical Mode: ^^^HbA1c ^^^Alb[4] ^^^Crt[5] ^^^Ratio[6] Run Standard Mode: ^^^Precision ^^^Drift MCRF [7]

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[2] The label for the Standard ("S" in the example) is language-dependent. If the language is Spanish, the Standard prefix for optical test results is 'E'. Otherwise, the prefix is 'S' as shown above.
[3] The Report Type field is transmitted when Service Mode is enabled or disabled.
[4] If an Alb is received, it is followed by a Crt. If it is not a control result, it is then followed by Ratio.

Field #	Field Name	Definition

4	Data or Measurement	Clinical Mode:
		   Test result value. [8]
		
		Run Standard mode (component field):
		   Precision test value = \<mean transmittance>^\<standard deviation>
		   Drift test value = \<mean transmittance>^\<drift>

5	Units	Clinical mode:
		   Units of measurement:
		   HbA_{1c} = "%"(For IFCC only, HbA_{1c}="mmol/mol")
		   Alb = "mg/L"
		   Crt = "mg/dL" or "mmol/L"
		   Ratio = "mg/g" or "mg/mmol"

6	Reference Range	Lower and Upper Patient Reference Range (for HbA_{1c} patient tests only) and Lower and Upper Expected Range Limits for Siemens Controls. Reference Ranges and Expected Ranges use the same units shown in Field 5. Format = 4.0 to 6.0
7	Abnormal result flags[9]	Instrument Measurement Range flags can appear on HbA1c, Alb, and Crt results, as follows: \< = Below instrument measurement range \> = Above instrument measurement range Reference Range flags can appear on patient HbA_{1c} results and on Siemens Control results (HbA_{1c}, Alb, and Crt only H = Above patient reference range or expected range of a control L = Below patient reference range or expected range of a control
9[10]	Result Status	F = Final Result C = Correction of previously transmitted results
11	Operator ID	Operator ID of the instrument user who performed the test (if known)[11] (not sent in manufacturing mode 1).
12	Date and Time	Date and Time the test analysis began

Example clinical result – HbA_{1c} below instrument measurement range:

`R|1|^^^HbA1c|2.5|%|4.0 to 6.0|<||F|||20061023112233<CR>`

Example clinical result – HbA_{1c} below reference range:

`R|1|^^^HbA1c|3.8|%|4.0 to 6.0|L||F|||20061023112233<CR>`

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[5] If the language is German, Norwegian, Danish, or Swedish, the Creatinine label is "Krt".

[6] If the language is German, the Ratio label is "Verhaeltnis".

[7] An MCRF result record is sent for a Microalbumin Normalization Factor (MNF) test.

[8] If Alb and/or Crt is out of range, the Ratio value is "---".

[9] The Result record does not indicate when values are user-corrected. Comment records following the Result records show user-correction parameters that were applied.

[10] The Result Status field is transmitted when Service Mode is enabled or disabled.

[11] Depending on the security mode of the instrument and the test performed, the operator may need to enter their Access Code to run the test. When the Access Code is entered, the corresponding Operator ID is automatically associated with the test. In other modes, Operator ID may be enabled as demographic data entry.

Example clinical result – HbA$_{1c}$ within normal range:

```
R|1|^^^HbA1c|5.3|%|4.0 to 6.0|||F|||20061023112233<CR>
```

Example clinical result – HbA$_{1c}$ above reference range:

```
R|1|^^^HbA1c|12.8|%|4.0 to 6.0|H||F|||20061023112233<CR>
```

Example clinical result – HbA$_{1c}$ above instrument measurement range:

```
R|1|^^^HbA1c|14|%|4.0 to 6.0|>||F|||20061023112233<CR>
```

Example clinical result – Microalbumin/Creatinine below instrument measurement range:

```
R|1|^^^Alb|5.0|mg/L||<||F|||20061023112233<CR>
R|1|^^^Crt|15|mg/dL||<||F|||20061023112233<CR>
R|1|^^^Ratio|---|mg/g||||F|||20061023112233<CR>
```

Examples of Filter Test Cartridge results:

```
R|1|^^^Precision|0.1379^0.00015|||||F|||20061023112233<CR>
R|1|^^^Drift|1.0019^0.0017|||||||||20061023112233<CR>
```

or

```
R|1|^^^Precision|0.1379^0.00015|||||F|||20061023112233<CR>
R|1|^^^MCRF|1.0019|||||||||20061023112233<CR>
```

Comment Records (C)

Comment records can be inserted anywhere between the message header record and the message terminator record. Patient records can be followed by up to 8 Comment records; control records can have up to 3 comments. Each comment record applies to the first non-comment record preceding it. Comment records have the following format:

Field #	Field Name	Definition
1	Record Type	C
2	ASTM Sequence Number	1, 2, 3…
3	Comment Source	I Clinical instrument system
4	Comment Text	1-to-many record specific text strings, separated by a component delimiter
5	Comment Type	G General/Free text comment

The DCA Vantage system uses comment records as follows:

- After the order record for patient tests, transmit GFR data and Comment information (if entered)

```
C|1|I|<age>^<gender>^<race>^<creatinine input>^<gfr
result>^<c1>^<c2>^<c3>^<c4>^<c5>^<c6>^<c6c7>^<c8>|G<CR>
```

- After HbA$_{1c}$ results, transmit User Correction Slope, User Correction Offset, Primary Reporting Unit, and eAG (when available and enabled). The eAG reporting unit is either "mg/dL" or "mmol/L".[12]

  Primary Reporting Unit Values:

  NGSP, mono-S, or IFCC; (If Japanese Mode = OFF)

  HbA1c(NGSP), JDS, or IFCC; (If Japanese Mode = ON)

  ```
  C|1|I|1.000^0.0 <units>^NGSP^< eAG-value><eAG-units|G<CR>
  ```

- After Microalbumin and Creatinine results, transmit User Correction Slope and Offset

  ```
  C|1|I|1.000^0.0 <units>|G<CR>
  ```

- After the order record for controls, transmit Comment Information (if entered,) (one for each comment entered) up to 3 comments).

  ```
  C|1|I|<c1>^<c2>^<c3>G<CR>
  ```

Manufacturer Information Record (M)

Manufacturer Information Records transmit custom data between instrument and host. The following table shows the general format of a Manufacturing Information Record:

Field #	Field Name	Definition
1	Record Type	M
2	ASTM Sequence Number	1, 2, 3…
3	MF1	Manufacturing Field 1
4	MF2	Manufacturing Field 2
…	…	…
14	MF12	Manufacturing Field 12

The DCA Vantage system uses the following Manufacturer Information Record:

- Remote Command request record (host to instrument)
- Remote Command response record (instrument to host)
- Error reports record (instrument to host)

Remote Command Request Record

The DCA Vantage system accepts remote commands only if the ASTM Message Header Record (H) provides the proper password. The proper password for Remote Command ASTM messages is "Service".

Manufacturer Information Records for Remote Command Requests contain the following data:

---

[12] eAG is not available in all countries.

Field	Definition
MF1	"C" Indicator for Remote Command Request
MF2	Remote command request type: "h" Force High Microalbumin/Creatinine Control "l" Force Low Microalbumin/Creatinine Control "a" Force Abnormal HbA$_{1c}$ Control "n" Force Normal HbA$_{1c}$ Control "s" Set Patient Lockout[13] "c" Clear Patient Lockout
MF3	The token specified by the host to identify the remote command request (unsigned 64-bit number)

Example – force normal HbA$_{1c}$ control:

M│1│C│n│9080<CR>

Remote Command Response Record

The instrument sends Remote Command Responses to the host in response to a Remote Command Request.

Manufacturer Information Records for Remote Command Responses contain the following data:

Field	Definition
MF1	D Indicator for Remote Command Response
MF2	Remote command response: "invalid login" User did not specify proper password in the ASTM Header record. "Invalid request" Remote command type requested was invalid. "pending" System is Busy. System will force the control when it is ready. "started" System started the requested operation. "completed" System completed the requested operation. "timeout" Timeout waiting for the operation to start. "error" Error occurred while processing the requested operation.
MF3	The token provided by the host to identify the remote command request.

Example – remote command completed:

M│1│D│completed│9080<CR>

---

[13] Using the ASTM protocol, a remote computer system can set or clear patient lockout. An operator with appropriate privileges can clear a lockout from the DCA Vantage Analyzer but cannot set it from the device.

Expected Responses to Remote Commands

The following table shows which responses can be received in response to a given remote command request:

Command	Invalid Login	Invalid Request	Pending	Started	Completed	Timeout	Error
Force a Control	Yes	No	Yes	Yes	Yes	Yes	Yes
Set Patient Lockout	Yes	No	Yes	No	Yes	No	No
Clear Patient Lockout	Yes	No	No	No	Yes	No	No
Unknown Command	Yes	Yes	No	No	No	No	No

Error Report

The Error report record contains the following data:

Field	Definition
MF1	E – Indicator for Error Report Record
MF2	Errors code

Example of "Error Report" Manufacturing record:

`M|1|E|30<CR>`

Test Result Message Structure

An ASTM Message is a collection of ASTM records as defined above. When the instrument sends test result messages to the host, there is a hierarchical order to the records, as follows:

Header Record
    Patient Record 1
        Test Order Record 1
            0 through 8 Comment Records (if entered)
            Result Record 1
    Message Terminator Record

ASTM Modes of Operation

The DCA Vantage system can operate in one of three modes, service mode disabled, service mode 1, and service mode 2. Test result messages sent from the instrument to the host differ based on the mode of operation. The following sections give an overview of these differences.

Service Mode Disabled

This is the default mode. If the service mode is disabled, the system creates a Customer message for the current test in progress. Customer messages have the following notable characteristics:

- Message Header Processing ID = P for Production.

- No manufacturing messages are sent to the host.

- Comment records are transmitted if the user entered text for patient demographics.

- Operator ID, if known, is sent in the Result Record.

Depending on the security mode of the instrument and the test performed, the operator might need to enter his or her Access Code to run the test. When the Access Code is entered, the corresponding Operator ID is automatically associated with the test. In other modes, Operator ID may be enabled as demographic data entry.

ASTM Message Transmit Use-Cases

This section describes use-cases that involve transmission of ASTM message between the DCA Vantage system and the LIS host. It also describes the messages transmitted during those use-cases.

HbA$_{1c}$ Test Results

HbA$_{1c}$ test results are transmitted from instrument to host after patient tests, control tests, or when the Transmit button is pressed during recall of an HbA$_{1c}$ test.

Service Mode Disabled

With Service Mode disabled, the device transmits the message to the host. The following is an example of such a transmission:

```
H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||P||20061002200015<CR>
P|1|987654|||Doe^Jane<CR>
C|1|I|age^39|G<CR>
O|1||018^9012||||||||||||||||||||||||F<CR>

R|1|^^^HbA1c|2.5|%|4.0 to 6.0|<||F|||20061023112233<CR>
C|1|I|1.000^0.0 %^NGSP|G<CR>
L|1|N<CR>
```

Microalbumin/Creatinine Test Results

Microalbumin/Creatinine test results are transmitted from instrument to host after patient tests or control tests, or when the transmit button is pressed during recall of one of these tests.

NOTE: When results are transmitted for control tests, field 6 of the Results Records for Albumin and Creatinine shows the Expected Range of the control.

Service Mode Disabled

```
H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||P||20061002200015<CR>
P|1|987654|||Doe^Jane<CR>
C|1|I|age^39|G<CR>

O|1||018^9012|||||||||||||||||||||||||F<CR>

R|1|^^^Alb|5.0|mg/L||<||F|||20061023112233<CR>

R|2|^^^Crt|15|mg/dL||<||F|||20061023112233<CR>

R|3|^^^Ratio|84.0|mg/g||||F|||20061002183420<CR>

C|1|I|1.000^0.0|G<CR>
L|1|N<CR>
```

Filter Test Results

Filter test results are transmitted from instrument to host after a Precision and Drift Filter test.

NOTE: Operator ID, if known, is transmitted in Fully Restricted or Restricted Plus access mode.

Service Mode Disabled

```
H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||D||20061002200015<CR>
P|1<CR>[14]
O|1||S1||||||||||||||||||||||||||F<CR>[15]
R|1|^^^Precision|0.7085^0.00026|||||F|||20061002183420<CR>[16]
R|2|^^^Drift|0.9981^0.0041|||||F|||20061002183420<CR>[17]
L|1|N<CR>
```

Remote Commands for an ASTM Link

Remote Command ASTM Message

The host can send a remote command request to the instrument.

```
H|\^&||password|hostdevice^hostversion|||||||P||20061002200015<CR>[18]
M|1|C|h|9080<CR> [19]
L|1|N<CR>
```

Remote Command Response ASTM Message

The instrument sends remote command responses to the host. The instrument returns the host-supplied token, so that the host can track the remote command.

```
H|\^&|||DCA Vantage^01.00.00.00^A123456|||||||D||20061002200015<CR>
M|1|D|completed|9080<CR>[20]
L|1|N<CR>
```

Translation of ASTM Message Content

The DCA Vantage instrument supports limited translation of its ASTM 1394-97 message fields. Due to the constraints of ASTM 1381-95, translation is limited to 7-bit ASCII characters. **Multi-byte characters are not supported**.

---

[14] There is no Patient ID and Name for Optic tests

[15] There are no comments for Optic tests

[16] The data field for Precision contains <mean-transmittance>^<standard-deviation>

[17] The data field for Drift contains <mean-transmittance>^<drift>

[18] Host must send a password with the remote command.

[19] In this example, the host supplied "9080" as token to track this request.

[20] The instrument returns the host-supplied token so that the host can track the remote command.

The DCA Vantage supports translation of the following fields:

Tag	English	Notes
UI_ASTM_BLACK	African American	GFR Race value. Comment record after patient result records if GFR was entered. **not translated**
UI_ASTM_CONTROL	C	Used in field 2 (instrument specimen ID) of the Order record for controls. This is the first character in the Control Level (e.g. C#1). **translated as follows:** 'T' if French, 'K' if German, Norwegian, Danish or Swedish
UI_ASTM_CREATININE	Crt	Used in field 3 (Universal test ID) of the Result record (e.g. "^^^Crt"). **translated as follows:** "Krt" if German, Norwegian, Danish, or Swedish
UI_ASTM_DEFAULT	Default	HbA$_{1c}$ calculation algorithm. Comment record after HbA$_{1c}$ result records. **not translated**
UI_ASTM_EXTCONTROL	c	Same as UI_ASTM_CONTROL. Lowercase is used to indicate External. **translated as follows:** 't' if French, 'k' if German, Norwegian, Danish or Swedish
UI_ASTM_FEMALE	Female	GFR Sex value. Comment record after patient result records if GFR was entered. **not translated**
UI_ASTM_MALE	Male	GFR Sex value. Comment record after patient result records if GFR was entered. **not translated**
UI_ASTM_MONO_S	mono-S	HbA$_{1c}$ calculation algorithm. Comment record after HbA$_{1c}$ result records. **not translated**
UI_ASTM_RATIO	Ratio	Used in field 3 (Universal test ID) of the Result record (e.g. "^^^Ratio"). **translated as follows:** "Verhaeltnis" if German
UI_ASTM_SELECTEDSERVICE	s	Same as UI_ASTM_SERVICE. Lowercase is used to indicate a menu run optical filter test. **translated as follows:** 'e' if Spanish.
UI_ASTM_SERVICE	S	Used in field 2 (instrument specimen ID) of the Order record for Optical Filter Tests. This is the first character of the test type (that is, S#1),. **translated as follows:** 'E' if Spanish.

Tag	English	Notes
UI_ASTM_WHITE	White	GFR Race value. Comment record after patient order record if GFR was entered. **not translated**
UI_ASTM_YEARS	Years	GFR Age units. Comment record after patient order record if GFR was entered. **not translated**

POCT1-A2 Introduction

POCT1-A2 is a communication standard maintained by the Clinical and Laboratory Standards Institute (CLSI) that connects Point-of-Care (POC) devices to Laboratory Information Systems (LIS) and Hospital Information Systems (HIS). The POCT1-A2 standard specifies two interfaces: one between device and data manager and one between the data manager and LIS/HIS. The interface between device and data manager is called the Device Interface, which uses the Device Messaging Layer (DML) Specification.

The following sections describe the DML communication of the analyzer. Messages exchanged between the device and data manager are in XML format.

Purpose

The following sections contain the requirements to support bi-directional information management communications between a DCA Vantage Analyzer and a data manager. This information is intended for software development and software validation engineers.

Scope

The following sections define the application level (messaging) layer between the DCA Vantage device and a data manager. They do not define the lower level communication protocols or other application-level communication protocols available with the DCA Vantage Analyzer, such as the ASTM interface.

This document is not intended to be a POCT1-A2 protocol requirements document and or a summary of such requirements. That protocol is described in the CLSI document POCT1-A2, Appendix B – Device Messaging Layer (DML) Specification.

You should be familiar with the POCT1-A2 specification.

Related Documents

ISO 11073-90101:2008(E) Point-of-Care Connectivity; Approved Standard – Second Edition, Vol. 26 No. 28, Appendix B -Device Messaging Layer (DML) Specification - (Clinical and Laboratory Standards Institute)

DCA Vantage Operator's Guide English, Siemens Part Number 06489264, Version 4

POCT1-A2 Definitions, Acronyms, and Abbreviations

The following table contains definitions, acronyms, and abbreviations used in this section:

Term	Definition
CLSI	Clinical and Laboratory Standards Institute (formerly NCCLS).
Conversation	A prescribed message flow between the device and a data manager using the POCT1-A2 DML protocol, having both an initialization phase and a termination phase. A conversation is the largest unit of messaging defined by the DML specification. It is made up of a series of exchanged topics. (Section 2.2).
Data Manager	A computer system that performs the function of POCT1-A2 Observation Reviewer. This system sits between clinical device and LIS, providing store and forward functionality for information received from the device.
Device	Point-of-Care device used to measure and/or record clinical observations.
DML	Device Messaging Layer (part of the POCT1-A2 standard).
Download	Data transfer operation when the data traffic is from the data manager to the device.
LIS/HIS	Laboratory Information System/Hospital Information System.
Object	An element included in a messaging topic.
Observation	A measured patient or control value or a calculated value If the DCA device is configured for POCT1 DML connection with a data manager, but it cannot connect to the data manager, it stores and flags ("buffers") the untransmitted patient and non-patient observations. When a connection is established, the DCA device tells the data manager how many observations have been buffered, and the data manager can then request them.
Observation Reviewer	The formal POCT1-A2 name for the data manager.
POCT	Point of Care Testing.
POCT1-A2	Point-of-Care Connectivity; Approved Standard – Second Edition.
Reagent Object	An optional segment of both patient and control test results. If the device does not have information for all of the required attributes, the reagent (RGT) segment is omitted.
Service Object	An object within a message that contains other objects related to the test ("service") being reported.
Topic	A collection of one or more objects. Each observation topic can contain numerous observation objects. If a topic sent by the data manager exceeds the device's max_message_sz attribute, the topic is broken into multiple messages, each of which is acknowledged by the device. After the last message is acknowledged by the device, the data manager must send an EOT message to conclude the topic.
Upload	Data transfer operation when the data traffic is from the device to the data manager.

POCT1-A2 Overview

DML is a bidirectional session and application-layer protocol which requires a robust and reliable lower-level transport. The DCA Vantage Analyzer supports and requires the use of TCP/IP as the low-level transport for POCT1 DML.

Because it uses a dedicated LAN connection, the DCA Vantage Analyzer supports and expects to operate in the DML protocol's Continuous Mode. Once Basic Profile communication is established, the data manager **must** send a START_CONTINUOUS directive to the device. This allows the device to send unsolicited observations and device status changes to the data manager.

The DCA Vantage Analyzer supports the following data transfers through its DML communications link:

- Hello message (HEL.R01)
- End of Topic Message (EOT.R01)
- Escape Message (ESC.R01)
- Request Observations Message (REQ.R01)
- HbA$_{1c}$ Results (OBS.R01 and OBS.R02)
- Microalbumin/Creatinine Results (OBS.R01 and OBS.R02)
- Start Continuous Directive (DTV.R01, command_cd "START_CONTINUOUS")
- Operator List Download - Full list only (OPL.R01)
- Device Status (DST.R01)
- Device Events (EVS.R01)
- Remote Command Directive (DTV.SIEM.DVCMD, command_cd = "<remote command>")
- Keep Alive (KPA.R01)
- Terminate Message (END.R01)

POCT1-A2 Communication Basics

This section describes the basic communication between the DCA Vantage Analyzer and data manager when using the POCT1-A2 DML protocol.

Network Connection

The DCA Vantage device supports POCT1-A2 DML communication only through a TCP/IP network connection. The data manager is required to listen on a TCP/IP port for a connection request from the device. Through the DCA Vantage Analyzer configuration menu, the operator must specify the data manager's network address (hostname or IP-address) and IP-port. Basic set-up of network connectivity is also required (that is, Subnet mask and Gateway).

When the DCA Vantage Analyzer shuts down, it sends a Terminate message, waits for the corresponding ACK, and then drops the TCP/IP connection. If the ACK is not received within the 60-second Application-level timeout, the DCA Vantage Analyzer drops the connection. When the DCA Vantage receives a Terminate message from the data manager, it sends an ACK message and drops the TCP/IP connection. It then tries to reestablish the connection every 10 seconds until the connection is reestablished.

Messaging Flow

This section provides an overview of the message flow between the DCA Vantage Analyzer and the data manager using the POCT1-A2 DML protocol. Refer to the DML specification for complete detail of this message flow.

A *conversation* is the largest unit of messaging defined by the DML specification. A conversation is a prescribed message flow between the device and the data manager, having both an initialization phase and a termination phase. A conversation is made up of a series of exchanged topics.

There are two forms of conversation: Basic Profile and Continuous. A Basic Profile conversation is initialized, information is exchanged, and then the conversation is terminated. A Continuous Mode conversation is initialized, and then a special directive is sent from the data manager to the device to place the conversation into Continuous Mode. The Continuous Mode conversation remains open so that the device can send device status changes, device events, and observations to the data manager as they occur.

The DCA Vantage Analyzer always operates in Synchronous mode. The DCA Vantage Analyzer does not support Asynchronous Acknowledgement of its Observation messages.

One POCT1-A2 messaging profile defines all conversations between DCA Vantage Analyzer and the data manager, but, depending on the status of the device and the data manager, different sets of messages can be communicated during a given conversation.

NOTE: Not all POCT1-A2 messages are appropriate for DCA Vantage Analyzer. Messages not used are not documented here.

Topics sent by the data manager that exceed the device's max_message_sz attribute must be broken into multiple messages, with DCA Vantage Analyzer acknowledging each well-formed message before the data manager sends the next message. When the DCA Vantage Analyzer acknowledges the last message, the data manager must send an EOT message to conclude the topic.

Basic Profile

Messaging in a Basic Profile conversation is largely driven by the data manager. After the conversation is initialized and device status sent, the data manager must initiate conversation topics to send information to or get information from the device. These topics can appear in any order. When all required communication is complete, the data manager sends a START_CONTINUOUS directive to the device to enter Continuous Mode.

Continuous Mode

After the data manager sends a START_CONTINUOUS directive to the device, continuous mode communication begins.

When in continuous mode, the device can send unsolicited observations, device events, and device status changes to the data manager. The data manager can send operator lists, directives, and vendor specific messages to the device.

In continuous mode, either side can send the Conversation Terminate message to end the conversation.

Conversation Flow

The following sections contain sample conversations flows.

Basic Profile Conversation Flow

The DCA Vantage Analyzer requires the data manager to place the conversation into continuous mode. The Basic Profile conversation accomplishes this, as shown in the following table:

Topic	From Device	From Data Manager	Description
Hello	HEL.R01		The device lets the data manager know that it is ready for communications.
		ACK.R01	
Device Status	DST.R01		The device manager tells the data manager its status.
		ACK.R01	
Observations		REQ.R01	Request observations
	OBS.R01		Observations
		ACK.R01	Acknowledge
	EOT.R01		End of Topic
Enter Continuous Mode Directive		DTV.R01	The data manager sends a directive to the device with the Directive. command_cd = "START_CONTINUOUS".
	ACK.R01		The device acknowledges the message after entering continuous mode.

Continuous Mode Conversation Flow

The following table shows a sample Continuous Mode conversation flow. The topics in this conversation can appear in any order and at any time:

Topic	From Device	From Data Manager	Description
Unsolicited Patient Observations	OBS.R01		The device sends an observation to the data manager.
		ACK.R01	The data manager acknowledges the message.
Unsolicited non-Patient Observations	OBS.R02		The device sends an observation to the data manager.
		ACK.R01	The data manager acknowledges the message.

Topic	From Device	From Data Manager	Description
Unsolicited Device Status	DST.R01		The device sends device status to the data manager whenever the device status changes.
		ACK.R01	The data manager acknowledges the message.
Update Lists		OPL.R01	The data manager sends "Complete Update" operator list message to the device (may send multiple messages if complete list does not fit in one message).
	ACK.R01		The device acknowledges the message (1 for each message).
		EOT.R01	The data manager sends End-of-topic to conclude Update List topic.
Remote Command		DTV.SIEM.DV CMD	The data manager sends a directive to the device to perform a remote command.
	ACK.R01		The device acknowledges the receipt of the directive.
Device Events	EVS.R01		The device sends a device event to the data manager to report the status of an Update Operator List Request or a Maintenance Complete Notification.
		ACK.R01	The data manager acknowledges the message.
Keep Alive		KPA.R01	The data manager sends a keep alive message to device.
	ACK.R01		The device acknowledges the message.
Good-bye	END.R01		The device requests to end the conversation.
		ACK.R01	The data manager acknowledges the message.
Good-bye		END.R01	The data manager requests to end the conversation.
	ACK.R01		The device acknowledges the message.

Error Handling

The DML specifies two types of errors, Protocol and Application, for which the Escape and Ack messages are used respectively:

- A Protocol error occurs when a message is malformed, with regard to the POCT1-A2, standard.

- An Application error occurs when the data is unacceptable.

This section specifies when the DCA Vantage Analyzer responds with an Escape and when it responds with an error acknowledgement.

Escape Messages

An Escape message indicates a Protocol error. Escape messages fall into one of the categories listed in the following table:

Message	Description
Escape: Cannot Complete Topic at This Time (CNC)	The device is not in a valid state for the message; for example, the device can not process an Operator List Update message when it is waiting for a reply or when it is busy running a test. The data manager should retry its request after receiving this form of escape message.
Escape: Unsupported Topic (TOP)	A message was received for an unsupported topic.
Escape: Other (OTH)	The device may return this type of Escape for a variety of reasons. When the device sends an OTH escape, the note_txt field contains further explanation about the exception (see Escape Message (ESC.R01)).
	Reasons for the OTH Escape message include:
	• The DCA Vantage Analyzer replies with this type of Escape when it receives an XML message that is not well-formed.
	• If a received message is larger than max_message_sz attribute specified in the Hello topic, then the DCA Vantage Analyzer interprets this as multiple not well-formed XML messages and sends this type of Escape message for each. To determine the number of replies sent, divide the size of the original message by max_message_sz attribute and round up to a whole integer.
	• Errors detected while processing an Operator List Update message. Indicates that the message received contained an error or cannot be supported

Ack (Acknowledgement)

An Ack message indicates either success or error. When indicating an error, the error_detail_cd qualifies the error into one of the categories listed in the following table:

Reply Message	Meaning
Ack: Object Sequence Error (100)	An object (<HDR>, <ACK>, or any required element of an object) is missing from a received message.
Ack: Required Field Missing (101)	A required field is missing from an object in the message.
Ack: Table Value Not Found (103)	The value of a coded field (CS, CV, CE) is not valid in received message.
Ack: Unsupported Field Value (200)	Directives are supported but a specific Directive received is not supported or understood.

Reply Message	Meaning
Ack: Unsupported Version ID (201)	The message version identifier is not supported. The version identifier must be "POCT1".
Ack: Application Internal Error (202)	Any error not explicitly covered by other specified categories.
Ack: Start Continuous Directive Accepted (300)	The Start Continuous directive was received and successfully processed.
Ack: Terminate Directive Accepted (301)	The Terminate directive was received and successfully processed.

POCT1-A2 Messaging Notes

This section provides special detail about DML topics that the DCA Vantage Analyzer supports.

Patient Test and Non-Patient Test Observation Messages

Basic Profile

When a connection is initially established, it is said to be using the *Basic Profile*. At that time, the device manager can request buffered observations from the device.

When the DCA Vantage Analyzer is configured for a POCT1 DML connection with a data manager, if it cannot connect to the data manager, it stores and flags ("buffers") the untransmitted patient and non-patient observations. When a connection is established, the DCA device tells the data manager how many observations have been buffered by using the new_observations_qty attribute of the Device Status object. The data manager can then request these observations by using a REQ.R01 message.

After all buffered observations have been received, the data manager places the conversation into continuous mode.

Continuous Mode

With the communications link operating in continuous mode, the DCA Vantage Analyzer can send unsolicited patient test observation messages (OBS.R01) and non-patient test observation messages (OBS.R02) to the data manager. Observation messages are sent either at the end of a test or when the operator sends a test from recall.

If an observation was never sent to the data manager, the reason_cd attribute for the Service object is set to "NEW". If an observation was previously sent to the data manager, the reason_cd attribute for the Service object is either "RES" (resend) or "EDT" (edited). For additional information, see *POCT1-A2 Point-of-Care Connectivity; Approved Standard—Second Edition*, Appendix B, Device Messaging Layer (DML) Specification, Table 49.

Observation Object Details

Each observation topic may contain numerous observation objects. The observation_id attribute of each object contains a unique identifier for the observation. A localized form of the ID always exists in the TRANSLTN child element of the observation_id attribute.

```
<OBS.observation_id V="Ratio" SN="SIEM" SV="1.0">
      <TRANSLTN V="Verhaeltnis"/>
</OBS.observation_id>
```

The following table lists the observation_id values that the DCA Vantage Analyzer provides:

Observation ID	Description
ALB	Microalbumin (measured – mg/L)
CRT	Creatinine (measured – mg/dL or mmol/L)
Ratio	Ratio between Microalbumin and Creatinine (patient test – calculated – mg/g or mg/mmol)
HbA$_{1c}$	Glycated hemoglobin (HbA$_{1c}$ test – measured - % or mmol/mol)
eAG	eAG is provided only when available[21] and enabled. (HbA$_{1c}$ test – calculated from HbA$_{1c}$ – mg/dL or mmol/L)
GFR	Glomerular Filtration Rate (HbA$_{1c}$ test – calculated from user-entered data – ml/min/1.73m^2)

When test results are transmitted within an observation object, the value attribute, OBS.value (type PQ) contains value and unit and the method_cd. The method code attribute (type CS) is set to M for Measured or C for Calculated.

HbA$_{1c}$, ALB, and CRT observation objects, when appropriate, contain normal_lo-hi_limit attributes. For HbA$_{1c}$ patient tests, the normal reference range is specified in the normal_lo-hi_limit attribute of the observation object. For Siemens Control tests, the expected range is specified in the normal_lo-hi_limit attribute of the observation object.

HbA$_{1c}$, ALB, and CRT observation objects, when appropriate, contain interpretation_cd attributes. If the measured value is outside the device reporting range, the interpretation_cd value is set to < or >. For HbA$_{1c}$ patient tests, if the measured value is outside the reference range, the interpretation_cd attribute is set to L or H. For control tests, if the measured value is outside the expected range, the interpretation_cd attribute is set to L or H.

Observation objects can have child Note objects to give additional information about the observation. Each note contains a name-value pair, separated by a caret. All names are in English. Values are transmitted using the selected language of the device, except where noted.

---

[21] eAG is not available in all countries.

The following table lists the names used in observation object notes:

Name	Value
Slope	User Correction Slope On HbA_{1c}, ALB, and CRT patient observations (if user correction was applied) max length = 5 characters format = x.xxx
Offset	User Correction Offset On HbA_{1c}, ALB, and CRT patient observations (if user correction was applied) max length = 12 characters format = x.xx.uuuuuuu where uuuuuuu = units (that is, % or mg/mmol)
Reporting Units	HbA_{1c} Primary Reporting Units On all HbA_{1c} observation objects (patient and non-patient) max length = 11 characters value – NGSP, mono-S, or IFCC, if Japanese Mode = OFF value – HbA1c(NGSP), JDS, or IFCC, if Japanese Mode = ON
Age	User-entered patient demographic for GFR On GFR patient observation objects max length = 3 characters numeric (integer) (years)
Gender	User-entered patient demographic for GFR On GFR patient observation objects max length = 6 characters Female or Male (not translated)
Race	User-selected patient demographic for GFR on GFR patient observation objects
Creatinine	User-entered patient demographic for GFR (plasma creatinine) On GFR patient observation objects max length = 12 characters numeric (integer)(mg/dL or umol/L)

Service Object Details

Service objects can have child Note objects that give additional information about the service. Each note contains a name-value pair, separated by a caret. All names are in English. Values are transmitted using the selected language of the device except where noted. The following table lists the names used in service object notes:

Name	Value
Comment<x>	Control Comment Values (x = 1 through 3) on Control test service objects (if enabled and entered) or Patient Comment Values (x = 1 through 8) on patient test service objects (if enabled and entered) max length = 24 characters text (user-entered)
Sample ID	Sample ID for patient test service objects (if enabled and entered) max length = 13 characters text (user-entered)
QCResult	When using a Siemens Control, the Non-Patient Observation Message Service object contains a note that provides the pass/fail result of the control test. max length = 1 character The value is P if the test passed and F if the result failed.

Device Status

When the conversation is originally established, the device sends a device status message to the data manager. That initial device status message indicates the device's current level of readiness in the condition_cd attribute. The condition_cd attribute values that the device supports are:

- B – the device is busy

- R – the device is ready

- L – the device is locked (the device cannot run any form of patient test)

- PH – the device is partially locked (cannot run HbA$_{1c}$ patient tests)

- PM – the device is partially locked (cannot run Microalbumin/Creatinine patient tests)

After the conversation is placed in continuous mode, the DCA Vantage Analyzer sends a new device status message any time its level of readiness changes.

POCT1 condition codes are defined in Table 25 of the POCT1-A2 specification, Appendix B. PH (Partial Hemoglobin A$_{1c}$) and PM (Partial Microalbumin/Creatinine) are vendor-specific codes.

Device Events

The DCA Vantage Analyzer does not buffer device events. For this reason, the Device Status message does not contain the DST.new_events_qty and DST.events_update_dttm attributes.

The DCA Vantage Analyzer does not support a request for device event messages from the data manager (REQ.R01 message with REQ.request_cd set to RDEV).

Device events (EVS.R01) are sent from the DCA Vantage Analyzer to the data manager only when the communications link is operating in continuous mode. Each EVS.R01 message contains one event.

Event descriptions are not translated.

Update Complete Device Events

At the end of an operator list update, the DCA Vantage Analyzer sends a device event to indicate the result of the update request. The following table lists the Update Complete device events:

severity_cd	Description
N	Operator List Update Succeeded
W	Operator List Update Failed – Internal Error
W	Operator List Update Failed – No Supervisors

Maintenance Complete Device Events

When maintenance is completed on the device, the device sends a maintenance complete device event to the data manager. The following table lists the maintenance-complete device events:

severity_cd	Description
N	Maintenance Complete – Precision and Drift Test
N	Maintenance Complete – Air Filter Changed
N	Maintenance Complete – Barcode Window Cleaned
N	Maintenance Complete – Cartridge Compartment Cleaned

Operator List

The data manager can create a new operator list for the DCA Vantage Analyzer by sending a Complete Update message (OPL.R01).

Like any other message sent by the data manager, operator lists are limited in size by the max_message_sz attribute provided in DCA Vantage Analyzer's Hello message. When a Complete Update operator list exceeds the max_message_sz, the data manager breaks the list down into a series of messages, each contained within the complete operator list topic, with the DCA Vantage Analyzer acknowledging each message of the topic as it is received. Once the data manager has sent all operator list messages, it must send an end-of-topic message (EOT.R01) to the device to indicate that the entire operator list has been sent. When the DCA Vantage Analyzer receives the end-of-topic message, it replaces its current operator list with the list that the data manager sent.

The following table is an example of how the Complete Update operator list topic could be used to create a new operator list of 100 operators using multiple messages. (The example assumes that the max_message_sz corresponds to 60 operators.) The DCA Vantage Analyzer accepts up to 1000 operators.

Message from Data Manager	DCA Vantage Analyzer Action
OPL.R01 (60 operators)	Store 60 operators in a temporary list.
OPL.R01 (40 operators)	Add a further 40 operators to the temporary list.
EOT	Replace the device's operator list with the contents of the temporary list. Prepare for next topic.

If the DCA Vantage Analyzer receives an operator list message when it is busy running a test, it rejects the update and returns an Escape message (ESC.R01) with a detail code of "CNC" (cannot complete).

If the DCA Vantage Analyzer receives an operator list message that violates any rule (see Escape Messages), it rejects the update and reverts to its previously stored list. At that point, DCA Vantage Analyzer sends an Escape message (ESC.R01) with a detail code of "OTH" (other) to the data manager. The data manager responds by not sending any remaining messages of the operator list topic.

The Access Control object is a component of the Operator List message. The permission_level_cd attribute of the Access Control object indicates what operations the user is allowed to perform on the device. At least one operator must have SUPERVISOR privilege. The following table maps permission levels supported by the DCA Vantage Analyzer to the operations allowed for that permission level:

Code	Value	Operations Allowed
1	SUPERVISOR	Can run test, Can run QC test, Can recall results, Can access setup
3	TRUSTED USER	Can run test, Can run QC test, Can recall results
4	USER	Can run test, Can run QC

At the end of an operator list update, the DCA Vantage Analyzer sends a device event to indicate the result of the update. See Device Events for details.

Directives

The DCA Vantage Analyzer supports the directives from the data manager shown in the following table:

Directive	Description
Message type DTV.R01, command_cd = "START_CONTINUOUS"	Puts the conversation into continuous mode.
Message type DTV.SIEM.DVCMD, command_cd = "FORCE_HIGH"	Instructs the device to force the operator to run a High Microalbumin/Creatinine control.
Message type DTV.SIEM.DVCMD. command_cd = "FORCE_LOW"	Instructs the device to force the operator to run a Low Microalbumin/Creatinine control.
Message type DTV.SIEM.DVCMD. command_cd = "FORCE_ABNORMAL"	Instructs the device to force the operator to run an Abnormal HbA_{1c} control.
Message type DTV.SIEM.DVCMD. command_cd = "FORCE_NORMAL"	Instructs the device to force the operator to run a Normal HbA_{1c} control.

SW_Version

The sw_version attribute appears in Device objects (DEV). This attribute contains the software version numbers for the device. The format of the DCA Vantage Analyzer sw_version attribute is "MM.mm.rr.BB" where:

MM = Major version number of the software (1 or more characters)

mm = Minor version number of the software (1 or more characters)

rr = Revision number of the software (1 or more characters)

BB = Build number of the software (1 or more characters)

Reagent Objects

The reagent object exists in both patient and Control test results. If the DCA Vantage Analyzer does not have information for all of the required attributes, the RGT segment of the results is omitted.

The reagent object has the following attributes, all of which are required:

name ("DCA HB1Ac" or "DCA A/C")
lot_number (up to 6 characters)
expiration_date (in the format YYYY-MM-DD)

POCT1-A2 Messaging Model

This section details the objects that comprise each of the messages and the attributes of the objects.

The following subsections define message objects and message topics (a collection of objects). Each section contains a description, object definition(s), and XML examples.

The object definitions use the format from the POCT1-A2 DML specification, where each definition contains an object name with its DTD name (for example, "Header (HDR)") followed by a list of object attributes.

The attribute definitions contain the name, the data type, and a brief description. HL7, version 3 attribute data types are indicated by braces { }. (Refer to POCT1-A2 protocol Annex A – DML data types).

Fields with a "+" sign are required.

Fields with a "-" sign are optional, unless a note specifies what is expected. In the object descriptions that follow, the columns generically are "DTD Name," "Data Type," and "Description." The rows indicate the object attributes.

POCT1-A2 General Messages

The POCT1-A2 defined messages that initiate and control the flow of a conversation are detailed in this section.

Header Object (all messages)

Header objects are sent at the beginning of all messages.

Header (HDR)

- message_type	{CV}	Used for vendor specific messages. See example below
+ control_id	{ST}	uniquely identifies the message in the conversation
+ version_id	{ST}	'POCT1'
+ creation_dttm	{TS}	Date and time the message was sent

Example:

```
<HDR>
    <HDR.control_id V="10001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2010-09-01T16:30:00-00:00"/>
</HDR>
```

Example, Siemens Specific:

```
<HDR>
    <HDR.message_type V="DTV.SIEM.DVRQC" SN="SIEM" SV="1.0"/>
    <HDR.control_id V="10001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2010-09-01T16:30:00-00:00"/>
</HDR>
```

Hello Topic (HEL.R01)

Hello Topic messages are sent from the device to the data manager to let the data manager know that the device is available for communication. The Hello Topic defines the device, its capabilities, the directives it supports, and the maximum message size.

NOTE: In the following examples, a notation such as "(1..1)" indicates an entity relationship; for example in the Hello Topic, "Device (DEV) (1..1) means that for every Hello Topic, there is one device object. An asterisk (*) in such an expression represents any number.

message type: 'HEL.R01'

Header (HDR)

Device (DEV) (1..1)

+ device_id	{ST}	"<vendor_id>^<model_id>^<serial_id>"
+ vendor_id	{ST}	"SIEM"
+ model_id	{ST}	"DCA Vantage"
+ serial_id	{ST}	Serial Number; for example, "A123456" (7 characters)
+ manufacturer_name	{ON}	'Siemens Healthcare Diagnostics'

+ hw_version	{ST}	hardware version[22]
+ sw_version	{ST}	software version number (in the format MM.mm.rr.BB)

Device Capabilities (DCP) (1..1)

+ application_timeout   {REAL}   Application-level timeout, fixed at 60 seconds

Device Static Capabilities (DSC) (1..1)

+ connection_profile_cd {CS}   'SA' (synchronous ack)
+ topics_supported_cd   {SET(CS)} D_EV, DTV, OP_LST
+ directives_supported_cd   {SET(CV)}START_CONTINUOUS and vendor specific
+ max_message_sz   {INT}   bytes (maximum message size is 16,000 bytes)

Example:

```
<HEL.R01>
      <HDR>
            <HDR.control_id V="10001"/>
            <HDR.version_id V="POCT1"/>
            <HDR.creation_dttm V="2010-09-01T16:30:00-00:00"/>
      </HDR>
      <DEV>
            <DEV.device_id V="SIEM^DCA Vantage^A123456"/>
            <DEV.vendor_id V="SIEM"/>
            <DEV.model_id V="DCA Vantage"/>
            <DEV.serial_id V="A123456"/>
            <DEV.manufacturer_name V="Siemens Healthcare Diagnostics"/>
            <DEV.hw_version V="1"/>
            <DEV.sw_version V="3.0.0.0"/>
            <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.directives_supported_cd V="START_CONTINUOUS"/>
                <DSC.directives_supported_cd V="FORCE_HIGH" SN="SIEM" SV="1.0"/>
                <DSC.directives_supported_cd V="FORCE_LOW" SN="SIEM" SV="1.0"/>
                <DSC.directives_supported_cd V="FORCE_ABNORMAL" SN="SIEM" SV="1.0"/>
                <DSC.directives_supported_cd V="FORCE_NORMAL" SN="SIEM" SV="1.0"/>
                <DSC.max_message_sz V="16000"/>
            </DSC>
      </DEV>
</HEL.R01>
```

Acknowledgement (ACK.R01)

Acknowledgement messages are sent by each side of the communication link to let the other side know that the previous message has been successfully received.

message type: 'ACK.R01'

---

[22] You can use the hardware version to distinguish between the various hardware configurations of the DCA Vantage. Hardware version "1" is for configurations that use MDOC technology; version "2" is for configurations that use SD card technology. Additional versions may be added in the future.

<u>Header (HDR)</u>

<u>Acknowledgement (ACK) (1..1)</u>
+ type_cd	{CS}	AA, AE (POCT1-A2 specification, table 13)
+ ack_control_id	{ST}	control_id of message being acknowledged
- note_txt	{ST}	description of error, for logging/presentation to user
- error_detail_cd	{CV}	(POCT1-A2 specification, see <u>Ack (Acknowledgement)</u> for

the list of error codes)

Example:

```
<ACK.R01>
    <HDR>
        <HDR.control_id V="4001"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:01-00:00"/>
    </HDR>
    <ACK>
        <ACK.type_cd V="AA"/>
        <ACK.ack_control_id V="10001"/>
    </ACK>
</ACK.R01>
```

Device Status (DST.R01)

The device status message is sent from the device to the data manager to convey the device's status information.

message type: 'DST.R01'

<u>Header (HDR)</u>

<u>Device Status (DST) (1..1)</u>
+ status_dttm	{TS}	time stamp (YYYY-MM-DDTHH:MM:SS)
+ new_observations_qty	{INT}	Number of new observations
+ condition_cd	{CV}	Level of readiness

Example:

```
<DST.R01>
    <HDR>
        <HDR.control_id V="10002"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:03-00:00"/>
    </HDR>
    <DST>
        <DST.status_dttm V="2010-09-01T16:30:03-00:00"/>
        <DST.new_observations_qty V="0"/>
        <DST.condition_cd V="PM" SN="SIEM" SV="1.0"/>
    </DST>
</DST.R01>
```

The DCA Vantage Analyzer does not buffer device events. For this reason, the Device Status message does not contain the DST.new_events_qty and DST.events_update_dttm attributes.

See <u>Device Status</u> for a list of condition codes (DST.condition_cd) that the DCA Vantage Analyzer supports.

End of Topic (EOT.R01)

The end of topic message can be sent by either side. This message indicates that a potentially multi-message topic has completed.

message type: 'EOT.R01'

Header (HDR)

End of Topic (EOT) (1..1)
+ topic_cd   {CV}   OPL
- update_dttm   {TS}   time stamp of list (YYYY-MM-DDTHH:MM:SS)
+ eot_control_id   {ST}   control ID of original message

Example:

```
<EOT.R01>
    <HDR>
        <HDR.control_id V="40054"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-12T10:35:30-00:00"/>
    </HDR>
    <EOT>
        <EOT.topic_cd V="OPL" />
        <EOT.eot_control_id V= "40052" />
    </EOT>
</EOT.R01>
```

Device Event (EVS.R01)

The Device Event message is sent from the device to the data manager to communicate the result of a Complete Update topic (OPL.R01) or the completion of a maintenance procedure.

message type: 'EVS.R01'

Header (HDR)

Device Event (EVT)(1..1)
+ description   {ST}   event description (see Device Events)
+ event_dttm   {TS}   time stamp (YYYY-MM-DDTHH:MM:SS)
+ severity_cd   {CS}   'W' (warning) or 'N' (note).

Operator (OPR)(1..1)
+ operator_id   {ST}   'REMOTE' (not translated)

Example:

```
<EVS.R01>
    <HDR>
        <HDR.control_id V="10010"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-06-16T01:23:45-05:00"/>
    </HDR>
    <EVT>
        <EVT.description V="Operator List Update Succeeded"/>
        <EVT.event_dttm V="2010-06-16T01:23:45-00:00"/> (YYYY-MM-DDTHH:MM:SS)
        <EVT.severity_cd V="N"/>
        <OPR>
            <OPR.operator_id V="REMOTE"/>
        </OPR>
    </EVT>
</EVS.R01>
```

Request (REQ.R01)

The Request message is sent from the data manager to the device to request specific action. The only request supported is the Request for Observation (ROBS) message that occurs before the conversation is placed in continuous mode.

message type: 'REQ.R01'

Header (HDR)

Request (REQ) (1..1)
+ request_cd   {CV}

Example:

```
<REQ.R01>
    <HDR>
        <HDR.control_id V="4006"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:09-00:00"/> (YYYY-MM-DDTHH:MM:SS)
    </HDR>
    <REQ>
        <REQ.request_cd V="ROBS"/>
    </REQ>
</REQ.R01>
```

Terminate Message (END.R01)

The Terminate message can be sent by either side to break the communication link.

message type: 'END.R01'

Header (HDR)

Termination (TRM) (1..1)
+ reason_cd   {CV}   Always "UNK" (Unknown)
- note_txt   {ST}   text message, for logging/presentation to user

Example:

```
<END.R01>
    <HDR>
        <HDR.control_id V="4006"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:09-00:00"/>
    </HDR>
    <TRM>
        <TRM.reason_cd V="UNK"/>
    </TRM>
</END.R01>
```

Keep Alive Message (KPA.R01)

The DCA Vantage Analyzer supports receiving keep alive messages.

message type: 'KPA.R01'

Header (HDR)

Example:

```
<KPA.R01>
    <HDR>
        <HDR.control_id V="4006"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:09-00:00"/>
    </HDR>
</KPA.R01>
```

Escape Message (ESC.R01)

The escape message can be sent by either side to tell the other side that the message received contained an error or can not be supported.

message type: 'ESC.R01'

Header (HDR)

Escape (ESC) (1..1)
+ esc_control_id   {ST}   The control_id of message the Escape is a response to
+ detail_cd   {CS}   OTH, TOP, CNC (see Escape Messages0)
- note_txt   {ST}   Further explanation that may be logged by the receiver

Example:

```
<ESC.R01>
    <HDR>
        <HDR.control id V="4006"/>
        <HDR.version id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:09-00:00"/>
    </HDR>
    <ESC>
        <ESC.esc control id V="10001"/>
        <ESC.detail cd V="OTH"/>
        <ESC.note_txt V="Operator ID is blank"/>
    </ESC>
</ESC.R01>
```

The note_txt attribute of the Escape message contains a string that describes the specific exception. This text can be used for diagnostics or can be placed in a log file.

The following table shows the text strings that the device uses. The note text in this table includes attributes, indicated by {0} and {1}. These attributes are variables that are filled in by the device according to the situation. For example, because the number of operators allowed on the device is 1000, the note text in the first message would read "Number of operators exceeds limit of 1000."

Escape Note Text
Number of operators exceeds limit of {0}.
Operator ID is blank.
Password (access code) is blank.
Operator ID {0} does not have exactly one Access Control object.
Operator ID {0} has invalid permission level of {1}.
Password (access code) {0} has invalid characters.
Operator ID {0} has invalid characters.
Password (access code) {0} is not unique within the list.
Operator ID {0} is not unique within the list.
Password (access code) {0} has {1} characters.
Operator ID {0} has {1} characters.

POCT1-A2 Observation Messages

The following sections detail objects used in Observation messages.

Patient Observations (OBS.R01)

Description: Patient observation messages are sent from the device to the data manager to transmit the results of a patient test. Results are transmitted either at the end of a test or when sent by the operator during patient test recall. Observation messages typically contain multiple observation objects. See Observation Object Details for more detail.

HbA_{1c} patient test results contain an "HbA1c" observation, an "eAG" observation (if available[23] and enabled), and a "GFR" observation (if entered).

Microalbumin and Creatinine patient test results contain an "ALB" observation, a "CRT" observation, and a "Ratio" observation.

NOTE: POCT1-A2, the default Ethernet connection protocol, requires a value in the patient_id field in the patient observation test record. For software version 4.0 and higher, you cannot clear the Enabled and Required options for the Patient Test Data Entry Setting for Patient ID. However, you can edit the value to another valid entry in the patient_ID field.

- If you recall a patient record, ensure that there is a value in the patient_id field before resending that record; otherwise, the record is not sent to the LIS.

---

[23] eAG is not available in all countries.

- Upon reconnect, the buffered observation count does not include blocked records.
- Earlier versions of the DCA Vantage software used the ASTM protocol, which allows a blank patient_id field. You may still select ASTM as your Ethernet protocol.

message type: 'OBS.R01'

Header (HDR)

Service (SVC) (1..1)
+ role_cd   {CS}   'OBS' (Patient Test Result)
+ observation_dttm   {TS}   measurement time stamp (YYYY-MM-DDTHH:MM:SS)
+ reason_cd   {CS}   "NEW", "RES", or "EDT"
- sequence_nbr   {INT}   device sample sequence number (1 through 999)

Patient (PT) (1..1)
+ patient_id   {ST}   up to 24 characters
- name   {PN}   with child elements FAM and GIV (each up to 16 chars)

Observation (OBS) (1..*)
+ observation_id   {CE}   Unique identifier (see Observation Object Details)
+ value   {PQ}   The value and unit component of the observation
+ method_cd   {CS}   "M" (Measured), or "C" (Calculated)
- interpretation_cd   {CS}   Interpretation Code (see Observation Object Details)
- normal_lo-hi_limit   {IVL<PQ>}   Reference Range Limits (HbA1c only)

Note (NTE) (0..*)
- text   {ST}   note about the observation (see Observation Object Details)

Operator (OPR) (0..1)
+ operator_id   {ST}   up to 16 characters

Reagent (RGT) (0..1)
+ name   {ST}   "DCA HbA1c" or "DCA A/C" (not translated)
+ lot_number   {CS}   up to 6 characters
+ expiration_date   {TS}   time stamp (YYYY-MM-DD). Material expiration date.

Note (NTE) (0..*)
- text   {ST}   Note about the service (see Service Object Details)

Example:

```
<OBS.R01>
    <HDR>
        <HDR.control_id V="10003"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:30:06-00:00"/>
    </HDR>
    <SVC>
        <SVC.role_cd V="OBS"/>
        <SVC.observation_dttm V="2010-09-01T16:29:54-00:00"/>
        <SVC.reason_cd V="NEW"/>
        <SVC.sequence_nbr V="123"/>
        <PT>
            <PT.patient_id V="1234567"/>
            <PT.name V="Patient Name">
                <FAM V="Name"/>
                <GIV V="Patient"/>
            </PT.name>
            <OBS>
```

```
                    <OBS.observation_id V="HbA1c" SN="SIEM" SV="1.0"/>
                        <TRANSLTN V="HbA1c"/>
                    </OBS.observation_id>
                    <OBS.value V="3.5" U="%"/>
                    <OBS.method_cd V="M"/>
                    <OBS.interpretation_cd V="L"/>
                    <OBS.normal_lo-hi_limit V="[4.0;6.5]" U="%"/>
                    <NTE>
                        <NTE.text V="Reporting Units^NGSP"/>
                    </NTE>
                </OBS>
            </PT>
            <OPR>
                <OPR.operator_id V="John Doe"/>
            </OPR>
            <RGT>
                <RGT.name V="DCA HbA1c"/>
                <RGT.lot_number V="9358"/>
                <RGT.expiration_date V="2012-05-31"/>
            </RGT>
            <NTE>
                <NTE.text V="Sample ID^1234567890123"/>
            </NTE>
            <NTE>
                <NTE.text V="Comment1^Male"/>
            </NTE>
        </SVC>
    </OBS.R01>
```

Reagent objects can be found in both patient and Control test results. If the device does not have information for all of the required attributes, the reagent (RGT) segment is omitted.

Non-Patient Observations (OBS.R02)

Description: Non-Patient Observation messages are sent from the device to the data manager to transmit control test results. Observation messages can contain multiple observation objects. See Observation Object Details for more detail.

HbA$_{1c}$ control test results contain an "HbA1c" observation.

Microalbumin and Creatinine control test results contain an "ALB" observation and a "CRT" observation.

message type: 'OBS.R02'

Header (HDR)

Service (SVC) (1..1)
+ role_cd	{CS}	'LQC' (Observation(s) from a liquid control quality test)
+ observation_dttm	{TS}	measurement time stamp (YYYY-MM-DDTHH:MM:SS)
+ reason_cd	{CS}	"NEW", "RES", or "EDT"
- sequence_nbr	{INT}	device sample sequence number (1 through 999)

Control/Calibration (CTC) (1..1)
+ name	{ST}	'Siemens HbA1c', "Siemens A/C", or "Other
- lot_number	{CS}	example '9012' (up to 10 characters)

- exp_date	{TS}	time stamp (YYYY-MM-DD). Control expiration date.
+ level_cd	{CV}	'1' through '9', 'L', 'H', 'A', or 'N'[24]

Observation (OBS) (1..*)

+ observation_id	{CE}	Unique identifier (see Observation Object Details)
+ value	{PQ}	stores value and units of the result
+ method_cd	{CS}	'M' (Measured)
- interpretation_cd	{CS}	Interpretation Code (see Observation Object Details)
- normal_lo-hi_limit	{IVL<PQ>}	Limits of the Expected Range (Siemens Controls Only)

Note (NTE) (0..*)

- text	{ST}	note about the observation (see Observation Object Details)

Operator (OPR) (0..1)

+ operator_id	{ST}	up to 16 characters

Reagent (RGT) (0..1)

+ reagent_name	{ST}	"DCA HbA1c" or "DCA A/C" (not translated)
+ lot_number	{CS}	up to 6 characters
+ expiration_date	{TS}	time stamp (YYYY-MM-DD). Material expiration date.

Note (NTE) (0..*)

+ text	{ST}	Notes about the QC Test (see Service Object Details)

Example:

```
<OBS.R02>
    <HDR>
        <HDR.control_id V="10015"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T17:23:14-00:00"/>
    </HDR>
    <SVC>
        <SVC.role_cd V="LQC"/>
        <SVC.observation_dttm V="2010-09-01T16:29:54-00:00"/>
        <SVC.reason_cd V="NEW"/>
        <SVC.sequence_nbr V="123"/>
        <CTC>
            <CTC.name V="Siemens HbA1c"/>
            <CTC.lot_number V="9012"/>
            <CTC.expiration_date V="2012-06-30"/>
            <CTC.level_cd V="1" SN="SIEM" SV="1.0"/>/>
            <OBS>
                <OBS.observation_id V="HbA1c" SN="SIEM" SV="1.0">
                    <TRANSLTN V="HbA1c"/>
                </OBS.observation_id>
                <OBS.value V="8.2" U="%">
                <OBS.method_cd V="M"/>
                <OBS.interpretation_cd V="H"/>
                <OBS.normal_lo-hi_limit V="[4.0;6.5]" U="%"/>
                <NTE>
                    <NTE.text V="Reporting Units^NGSP"/>
                </NTE>
            </OBS>
        </CTC>
```

---

[24] Use levels 1 through 9 for "Other" controls. L=Low, H=High, A=Abnormal, N=Normal.

```
                              <OPR>
                                    <OPR.operator_id V="John Doe"/>
                              </OPR>
                              <RGT>
                                    <RGT.name V="DCA HbA1c"/>
                                    <RGT.lot_number V="9003"/>
                                    <RGT.expiration_date V="2012-05-31"/>
                              </RGT>
                              <NTE>
                                    <NTE.text V=" QCResult^P "/>
                              </NTE>
                        </SVC>
                  </OBS.R02>
```

POCT1-A2 Operator List Message

The operator list message is sent from the data manager to the device to update the operator list in the device.

Operator List Topic (OPL.R01)

The DCA Vantage Analyzer supports only the "Complete Update" form of the Operator List message model. Operator IDs from table 40 of the POCT1-A2 specification are rejected.

Description: The operator list message is sent from the data manager to the device to update the operator list in the device.

message type: 'OPL.R01'

Header (HDR)

Operator (OPR) (1..*)
+ operator_id   {ST}   up to 16 characters

Access Control (ACC) (1..1)
+ method_cd   {CV}   always "ALL"
+ password   {ED}   access code, base-64 encoded[25]
+ permission_level_cd {CV}   see Access Control objects in Section 10.4

Example:

```
<OPL.R01>
    <HDR>
          <HDR.control_id V="40054"/>
          <HDR.version_id V="POCT1"/>
          <HDR.creation_dttm V="2010-09-12T16.32.45-00:00"/>
    </HDR>
    <OPR>
          <OPR.operator_id V="John Doe"/>
          <ACC>
                <ACC.method_cd V="ALL"/>
                <ACC.password ENC="B64"> cGFzc3dvcmQ=</ACC.password>
                <ACC.permission_level_cd V="1"/>
          </ACC>
```

---

[25] Operator access codes are a maximum of 13 characters. When encoded, a 13-character password is converted to 20 characters.

```
            </OPR>
      </OPL.R01>
```

POCT1-A2 Directive Messages

Directive messages are sent from the data manager to the device to request action from the device.

Start Continuous Directive (DTV.R01)

Description: The Start Continuous directive is sent from the data manager to the device. This directive causes the device to switch into Continuous mode.

message type: 'DTV.R01'

Header (HDR)

Directive (DTV) (1..1)
+ command_cd   {CV}   START_CONTINUOUS

Example:

```
<DTV.R01>
   <HDR>
        <HDR.control_id V="4050"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2010-09-01T16:32:45-00:00"/>
   </HDR>
   <DTV>
        <DTV.command_cd V="START_CONTINUOUS"/>
   </DTV>
</DTV.01>
```

Remote Command Directive (DTV.SIEM.DVCMD)

Description: A Remote Command directive is sent from the data manager to the device to direct the device to perform an operation.

message type: 'DTV.SIEM.DVCMD'

Header (HDR)
+ message_type   {CV}   DTV.SIEM.DVCMD
+ control_id   {ST}   Uniquely identifies message throughout the conversation
+ version_id   {ST}   'POCT1'
+ creation_dttm   {TS}   Date and time the message was sent (YYYY-MM-DDTHH:MM:SS)

Directive (DTV) (1..1)
+ command_cd   {CV}   "<remote command>", see Directives

Example:

```
<DTV.SIEM.DVCMD>
    <HDR>
            <HDR.message_type V="DTV.SIEM.DVCMD" SN="SIEM" SV="1.0"/>
            <HDR.control_id V="4050"/>
            <HDR.version_id V="POCT1"/>
            <HDR.creation_dttm V="2010-09-01T16:32:45-00:00"/>
    </HDR>
    <DTV>
            <DTV.command_cd V="FORCE_HIGH" SN="SIEM" SV="1.0"/>
    </DTV>
</DTV.SIEM.DVCMD>
```

POCT1-A2 Reference Information

Time Stamps

The string form of the date-time value uses HL7 encoding rules. Refer to the POCT1-A2 Protocol Annex A – DML data types for a description of the HL7 rules.

Format is YYYY-MM-DDTHH:MM:SS+/-ZZ:ZZ but time stamps that represent dates and not times (for example,. expiration dates) are in YYYY-MM-DD format.

The device does not support time-zones. All time zone indicators in time stamps (+/-ZZ:ZZ) are sent as "-00:00".

Character Sets

All messages use the XML UTF-8 encoding.

Valid characters for operator password (access code) on the DCA Vantage Analyzer include: Upper case letters A through Z and numbers 0 through 9.

Valid characters for operator ID on the DCA Vantage Analyzer include: Upper case letters A through Z, numbers 0 through 9, and apostrophe.

Control_id Attribute

The control_id attribute that appears in the Header object uniquely identifies the message throughout the conversation.

For legibility, the data manager should use sequence numbers in the 1,000 (one thousand) range, while the DCA Vantage Analyzer generates sequence numbers in the 10,000 (ten thousand) range.

Conversation topics initiated by the DCA Vantage Analyzer use sequential numbers from 10001 to 20000 for the sequence, resetting to 10001 with the transmission following 20000. The sequence is also reset to 10001 whenever the communication link is restarted.

Message Timeouts

A timeout can occur whenever the device is waiting for a message from the data manager. This can occur when waiting for the next message in an update of the operator list or when waiting for an acknowledgement. If the DCA Vantage Analyzer detects a timeout, it terminates the current conversation and attempts to begin a new one. The DCA Vantage Analyzer message timeout is 60 seconds.