SIEMENS Healthineers

Atellica® VTLi
Immunoassay Analyzer

POCT1-A2 Communications Specification

11561588, 2021-09

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11561588, 2021-09

Contents

1.0 Introduction 5
1.1 Description 5
1.2 Purpose 5
1.3 Scope 5
1.4 Abbreviations and Definitions 5
1.5 References 7
2.0 Communication basics 7
2.1 Network connection 7
2.2 Communication content 7
2.2.1 Minimal set of conversation topics 7
2.2.2 Extended set of conversation topics 8
2.3 Messaging Profile 8
2.3.1 Basic Profile Conversation Flow 8
2.4 Error Handling 10
2.4.1 Escape 10
2.4.2 Error Acknowledge 11
2.4.3 Timeouts 11
3.0 Messaging model 12
3.1 Message field types 12
3.2 Messages 13
3.2.1 Header Object (all messages) 14
3.2.2 Hello Message (HEL.R01) 14
3.2.3 Acknowledgement Message (ACK.R01) 17
3.2.4 Device Status Message (DST.R01) 17
3.2.5 Request Message (REQ.R01) 18
3.2.6 Observation Topic (OBS.R01, OBS.R02) 19
3.2.7 End of Topic Message (EOT.R01) 31
3.2.8 Terminate Message (END.R01) 32
3.2.9 Escape Message (ESC.R01) 32
3.2.10 Device Events Topic (EVS.R01) 33
3.2.11 Operator List Topic (OPL.R01, OPL.R02) 35
3.2.12 Directive Messages (DTV.R01, DTV.R02, DTV.SIEM) 40
4.0 Appendix A – Timezone handling 48
5.0 Appendix B – Possible Atellica VTLi Settings 49
6.0 Appendix C – Possible DEVICE Events 50

1.0 Introduction

1.1 Description

POCT1-A2 is a communication standard maintained by the Clinical and Laboratory Standards Institute (CLSI) in order to connect Point-of-Care devices (POCD) to Laboratory and Hospital Information Systems (LIS/HIS). The interface between device and data manager is called the Device Interface which is implemented using the Device Messaging Layer (DML) Specification.

1.2 Purpose

This specification describes how to support bi-directional communications between the device and a data manager based on the POCT1-A2 communication standard. This information is intended for software developers and system integrators.

1.3 Scope

The following sections define the application level (messaging) layer between the Atellica VTLi and a data manager. They do not define lower level communication protocols.

Contents of this document based upon the Point-of-Care Connectivity; Approved Standard – Second Edition (POCT1-A2 vol. 26) maintained by the Clinical and Laboratory Standards Institute (CLSI). It is assumed that the reader is familiar with that specification. Some information, figures and tables are taken directly from the POCT1-A2 specification to prevent the reader from having to refer back and forth between each document.

1.4 Abbreviations and Definitions

Abbreviation	Description
ACK	An acknowledgement message, sent from the Atellica VTLi to the data manager or vice versa
ANSI	American National Standards Institute (www.ansi.org).
ASCII	American Standard Code for Information Interchange (a character-encoding scheme originally based on the English alphabet).
CLSI	Clinical and Laboratory Standards Institute (formerly NCCLS).
DHCP	Dynamic Host Configuration Protocol (used to obtain network configuration data from a central server)
DML	Device Messaging Layer (part of the POCT1-A2 standard). Describes a complete messaging protocol to exchange results and quality information between a device and an Observation Reviewer.
DNS	Domain Name Server (used to translate domain and hostnames into the corresponding numeric IP address)
DTD	Document Type Definition.
EUI-64	Extended Unique Identifier (a numbering name space for MAC addresses managed by IEEE)
GMT	Greenwich Mean Time
HIS/LIS	Hospital Information System/Laboratory Information System
HL7	Health Level 7 (www.hl7.org) – an ANSI-accredited standards development organization focused on messaging to support the exchange of clinical and administrative health data.

Abbreviation	Description
IEEE	Institute of Electrical and Electronic Engineers
IP	Internet Protocol (part of TCP/IP)
MAC	Media Access Control address (a unique identifier assigned to network interfaces for communications on the physical network segment)
MRN	Medical Record Number
NAK	A not-acknowledged message, sent from the Atellica VTLi to the data manager or vice versa
NTP	Network Time Protocol (algorithms for synchronizing clocks of computer systems over data networks)
POC	Point-of-Care – the environment surrounding a patient.
POCD	Point-of-Care Device – an instrument used at the patient's side to measure and/or record a clinical observation.
POCT	Point-of-Care Testing
POCT1-A2	Point-of-Care Connectivity; Approved Standard – Second Edition
QA/QC	Quality Assurance/Quality Control
TCP/IP	Transmission Control Protocol/Internet Protocol – the foundation transport protocol of the Internet that provides reliable and bi-directional stream-oriented network communication.
UTC	Coordinated Universal Time (primary time standard by which the world regulates clocks and time; for most common purposes it is synonymous with GMT)
UTF-8	8-bit Unicode Transformation Format
XML	Extensible Markup Language – a meta language widely used for business-to-business data exchange

Term	Definition
Alert	Error or warning event on the Atellica VTLi
Atellica VTLi	The Atellica VTLi analyzer, part of the Atellica VTLi platform
Base64	Encoding scheme that represents binary data in an ASCII string format.
Data Manager	A system that performs the function of POCT1-A2 Observation Reviewer. This system is located between the POC Atellica VTLi and LIS/HIS, providing store and forward functionality for information received from the Atellica VTLi as well as QA/QC and other POC instrument and data management functions.
Device	Point-of-Care instrument used to measure and/or record clinical observations.
NULL	Indicates that a given field has no value (often used for required fields without an actual value or if the value is not determinable).
Observation	A measured patient or control value or a calculated value.
Observation Reviewer	The formal POCT1-A2 name for the data manager. Provides services to support the management of test results, quality assurance, quality control data and medical orders.
Questionnaire	Questionnaire provide an option for the user to enter manual input related to the measurement.

1.5 References

Ref. #	Title	Document ID
POCT1-A	Point-of-Care Connectivity; Approved Standard – Second Edition, Vol. 26 No. 28, Appendix B –Device Messaging Layer (DML) Specification - (Clinical and Laboratory Standards Institute)	ISBN-1-56238-616-6

2.0 Communication basics

This section describes the basic communication between Atellica VTLi and Observation Reviewer when using POCT1-A2 DML protocol.

2.1 Network connection

DML is a bi-directional session and application-layer protocol which requires a robust and reliable lower-level transport. The Siemens Atellica VTLi supports and requires the use of TCP/IP as the low-level transport for POCT1-A2 communication. The Observation Reviewer is required to listen on a TCP/IP port for a connection request from the Atellica VTLi.

2.2 Communication content

The content of a communication between the Atellica VTLi and an Observation Reviewer consists of the following elements.

Conversation	A prescribed flow of messages between the Atellica VTLi and Observation Reviewer, having both an initialization and a termination phase. A Conversation is made up of a series of “Topics”.
Topic	The flow of messages to exchange a complete set of data within a Conversation (e.g. Observations, Device Events). A Topic is composed of a series of “Messages”.
Message	The simplest element of data exchange between the Atellica VTLi and Observation Reviewer. Each Message is composed of one or more “Objects”.
Object	An Object is the smallest logical element of a message (e.g. Header, Observation, Order). Each Object is composed of one or more “Attributes”.
Attribute	An Attribute is the smallest named element of a message that contains data. Examples of attributes include “expiration date”, “value” and “permission level cd”.

2.2.1 Minimal set of conversation topics

POCT1-A2 requires a minimal set of supported conversation topics to be consistent with the standard. An Observation Reviewer communicating with the Atellica VTLi is required to support at least the following list of conversation topics.

1. Hello (see section 3.2.2)
2. Device Status (see section 3.2.4)
3. Observations (see section 3.2.6)
   3.1. Patient Tests (see section 3.2.6.1)
   3.2. Non-Patient Tests (QC measurements and e.g. Calibration Tests; see section 3.2.6.2)

4. Terminate (see section 3.2.8)

Of course all types of messages which are needed to control the conversation flow have to be supported also. These messages are:

- Acknowledgement (see section 3.2.3)
- Escape (see section 3.2.9)
- Request (see section 3.2.5)

2.2.2 Extended set of conversation topics

In addition to the minimum message set for POCT1-A2 compliance, the Atellica VTLi can handle the following conversation topics.

1. Device Events (see section 3.2.10)
2. Update Lists
   2.1. Operator List (see section 3.2.11)
3. Directives (see section 3.2.12)
   3.1. LOCK / UNLOCK Directive (see section 3.2.12.1)
   3.2. SET_TIME Directive (see section 3.2.12.2)
   3.3. Vendor-specific (see section 3.2.12.3)
4. Vendor-specific Data Exchange (see section 3.2.12.3)

2.3 Messaging Profile

The POCT1-A2 specification defines two forms of conversations: Basic Profile and Continuous Mode. A Basic Profile conversation is initialized, information is exchanged and then the conversation is terminated.

The Atellica VTLi supports Basic Message Flow communication. Continuous Mode is not supported.

The directive to place the conversation into Continuous Mode will be answered with a negative Acknowledge (see section 2.4.2). The with continuous mode associated message – Keep Alive will be answered with an Escape (see section 2.4.1)

Furthermore POCT1-A2 defines a second extension for the communication profiles called Asynchronous Mode. Communication in Asynchronous Mode allows sending the next messages of a topic before receiving the Acknowledgement for the current message. In Synchronous Mode the sending party has to wait for an Acknowledgement which verifies that the Message was received and understood properly.

The Atellica VTLi always operates in Synchronous Mode. Asynchronous acknowledgement of topic messages is not supported.

2.3.1 Basic Profile Conversation Flow

The following figure shows an example conversation between the Atellica VTLi and an Observation Reviewer. It will be assumed that there are new observations available for transmission and the conversation proceeds without any errors.

Topic	From Device	From Observation Reviewer	Description

Topic	From Device	From Observation Reviewer	Description
Hello	HEL.R01 →		A Device initiates this startup sequence by sending a Hello message to an Observation Reviewer.
		← ACK.R01	The Observation Reviewer sends a confirmation to start the communication.
Device Status	DST.R01 →		The Atellica VTLi transmits its status to the Observation Reviewer including the number of new observations and new device-events.
		← ACK.R01	Acknowledge.
Observations		← REQ.R01	The Observation Reviewer requests unsent Observations from the Atellica VTLi.
	OBS.R01/ R02 →		The Atellica VTLi sends one Observation in each message as long observations are available in the internal buffer (without acknowledging the request message).
		← ACK.R01	Acknowledge
	EOT.R01 →		The Atellica VTLi sends an End of Topic message to indicate that there are no more new observations to send.
Events		← REQ.R02	The Observation Reviewer requests unsent Events from the Atellica VTLi.
	EVS.R01 →		The Atellica VTLi sends 50 events per message as long new events are available.
		← ACK.R01	Acknowledge
	EOT.R01 →		The Atellica VTLi sends an End of Topic message to indicate that there are no more new events to send.
		← OPL.R01 / OPL.R02	The observation reviewer sends complete or incremental Lists of operators
	ACK.R01 →		Acknowledge
		← EOT.R01	End of Topic
		← DTV.R01	The observation reviewer sends Basic-Device-Directive if available
	ACK.R01 →		Acknowledge
		← DTV.R02	The observation reviewer sends The SET_TIME directive.
	ACK.R01 →		Acknowledge
Vendor specific messages (will be send if needed)			

Topic	From Device	From Observation Reviewer	Description
		← DTV.LOCK	The observation reviewer sends the LOCK-Directive
	ACK.R01 →		
		← DTV.UNLOCK	The observation reviewer sends the UNLOCK-Directive
	ACK.R01 →		Acknowledge
		← DTV.SIEM.SET_LQC_RANGE	The observation reviewer sends the SET_LQC_RANGE-Directive
	ACK.R01 →		Acknowledge
		← DTV.SIEM.DEACTIVATELOT	The observation reviewer sends the DEACTIVATE_LOT-Directive
	ACK.R01 →		Acknowledge
Terminate		← END.R01	The Observation Reviewer requests to end the conversation.
	ACK.R01 →		The Atellica VTLi acknowledges the termination request and quits the connection.

Topic ordering in POCT1-A2 is very flexible once the conversation startup sequence (table rows highlighted in red) has been successfully completed. The Observation Reviewer will assume control after conversation initiation and has to decide about topics that have to be processed as well as their ordering within the conversation whereas the Atellica VTLi must be prepared to handle topics in any order.

2.4 Error Handling

The POCT1-A2 standard specifies two types of errors, Protocol and Application, for which the Escape and Error Acknowledge messages are used respectively. A protocol error occurs when a message is malformed, with regard to the POCT1-A2 standard (e.g. not well-formed XML). An application error occurs when the data is unacceptable (e.g. invalid values in data fields). This section describes when the Atellica VTLi responds with an Escape and when it sends an error acknowledgement. The messages itself are explained in their respective sections.

2.4.1 Escape

An Escape message indicates a protocol error which fits into one of the following categories:

- Unsupported Topic (**TOP**; The Observation Reviewer starts a topic that the Atellica VTLi cannot handle – e.g. Patient List update. Not supported directives will cause an Error Acknowledge instead of an Escape message – see section 2.4.2.)
- Other (**OTH**; The Atellica VTLi may return this type of Escape for a variety of reasons. Further explanation of the exception is inserted in the note_txt field.)
  Reasons may be for example:
  - Not POCT1A-Standard conform messages. For example when a required field is missing.

2.4.2 Error Acknowledge

An Error Acknowledge indicates an Application Error. The error_detail_cd field qualifies the error into one of the following categories:

Code	Value	Description/Comment
102	Data type error	A message element is not of the type expected: e.g. a field that the receiver expects to be of type PQ is actually of type CV in the current message.
200	Unsupported field value	The field contained data of the wrong field value or a Directive received is not supported or understood, e.g. a PQ field contained a value without units or the Observation Reviewer sends a START_CONTINUOUS Directive.
201	Unsupported version id	The message version identifier (HDR.version_id) is not supported. It must always be “POCT1”.
202	Application internal error	Any error not explicitly covered by other specified categories.

2.4.3 Timeouts

2.4.3.1 Message Timeout

The default message timeout of the Atellica VTLi is 30 seconds. This means if the Atellica VTLi is waiting for data (e.g. an acknowledgement) from Observation Reviewer which doesn’t approach within this time the Atellica VTLi will terminate the current conversation (by sending a termination message) and attempt to begin a new one. The message timeout is configurable on the Atellica VTLi.

2.4.3.2 Connection Timeout

The connection timeout describes the time which the Atellica VTLi waits at longest for establishment of a valid TCP/IP-Connection. In cases of invalid IP-Addresses or network-problems a connection timeout will usually triggered much faster. The connection timeout is configurable on the Atellica VTLi.

2.4.3.3 Termination Message

In case the incoming message is invalid XML or contains no or an invalid Message_Id a Termination-Message will be send. Also in cases when a message is received that is not applicable to the current state. For example, an Operatorlist arrives right after a Hello-Message. The Observation-Reviewer can also send a Termination-Message at any time it deems necessary.

3.0 Messaging model

This section details the objects that comprise each of the messages and the attributes of the objects based on the POCT1-A2 information model.

3.1 Message field types

More detailed information about message field types can be found in the standard description (Annex A. Device Messaging Layer Data Types (Normative))
The table shown below describes the data types that may be found in messages.

Name	Symbol	Description
Encapsulated Data	ED	Data that is primarily intended for human interpretation or for further machine processing outside the scope of the POCT1-A2 specification. This includes unformatted or formatted written language, multimedia data or structured information as defined by a different standard (e.g. XML signatures.) Instead of the data itself, an ED may contain only a reference (e.g. a URL or other types of network resource name).
Character String	ST	Text data, primarily intended for machine processing (e.g. sorting, querying, indexing, etc.) Used for names, symbols, and formal expressions.) Note that the ST data type is a specialization of the ED data type when the ED media type is text/plain. At creation of CharacterString object all return characters (like \r\n) are replaced with white space characters. In this way the formatting is removed and Middleware does not have to cope with multiline strings.
Coded Simple Value	CS	Coded data consists of a code and display name. The code system and code system version is fixed by the context in which the CS value occurs. CS is used for coded attributes that have a single HL7-defined value set.
Coded Value	CV	Coded data consists of a code, display name, code system and original text. Used when a single code value must be sent.
Coded With Equivalents	CE	Coded data consists of a coded value (CV) and, optionally, coded value(s) from other coding systems that identify the same concept. Used when alternative codes may exist.
Person Name	PN	A name of a person. Person names usually consist of several name parts that can be classified as given, family, nickname etc. These parts can be provided using the following child elements: GIV (given name), MID (middle name), FAM (family name), PFX (prefix, e.g. “Dr.”), SFX (suffix, e.g. “Ph.D.”), DEL (delimiter character to separate components)
Organization Name	ON	A name of an organization. ON name parts are typically not distinguished, but may distinguish the suffix for the legal standing of an organization (e.g., “Inc.”, “Co.,” “B.V.”, “GmbH,” etc.) from the name itself.
Integer	INT	Number positive and negative, whole numbers, typically the results of counting and enumerating. The standard imposes no bounds on the size of integer numbers.
Real Number	REAL	Fractional numbers. Typically used whenever quantities are measured, estimated, or computed from other real numbers. The typical representation is decimal, where the number of significant decimal digits is known as the precision.
Physical Quantity	PQ	A dimensioned quantity expressing the result of measurement. It consists of a real number value and a physical unit. Physical quantities are often constrained to a certain dimension by specifying a unit representing the dimension (e.g. m, kg, s, kcal/d, etc.) However, physical quantities should not be constrained to any particular unit (e.g. should not be constrained to centimeter instead of meter or inch).

Name	Symbol	Description
Point in Time	TS	A time stamp. The string form of date-time value uses the HL7 encoding rules. Schematically this format can be illustrated as follows: YYYY-MM-DDTHH:MM:SS.SSSxOH:OM (where x has to be either "+" for GMT *plus* offset or "-" for GMT *minus* offset and OH/OM is the offset from GMT in hours and minutes). Use of variable precision (right to left truncation) is allowed (e.g. a date only field in the format of YYYY-MM-DD). The separator characters are required ("-", "T", ":", "."). In most cases the milliseconds including the leading "." will be omitted by the Atellica VTLi. A time stamp possibly can have a NULL value if unknown (using the "NULL" Attribute instead of "V").
Physical Quantity Interval	IVL<PQ>	A set of continuous values of an ordered quantity, with units. POCT1 imposes some restrictions on the allowed IVL<PQ> representations, in order to simplify parsing logic (refer to the POCT1-A2 specification for details).
Set Collection	SET<T>	An unordered collection of unique values of any type T.

The POCT1-A2 standard relies on the HL7 version 3 rules for encoding these data types as XML elements. In this scheme, values are encoded using XML elements which have attributes drawn from a common set. For example, the ST type can use the "V", "VT" and "PROB" attributes, while the CS type can use the "V", "DN", "VT" and "PROB" attributes. The attributes "VT" and "PROB" may be optionally used for all of the above mentioned data types when appropriate. For detailed information about the attributes for each data type refer to the POCT1-A2 specification.

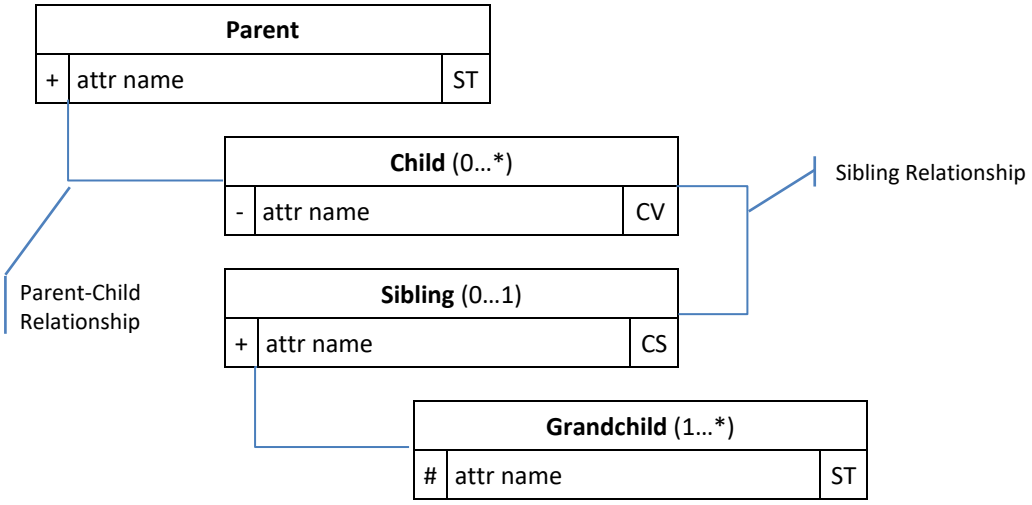
3.2 Messages

The attributes of objects are described in tables. The first column will contain symbols that indicate whether an attribute is required (+), optional (-) or required but maybe empty (#). The second column contains the attribute name while the third column holds its data type.

In a message model figure, object cardinality is noted as part of the object name. The following notation conventions are used for object cardinality:

- (0...1) – zero or one instance
- (0...*) – zero or more instances
- (1...*) – one or more instances
- The absence of a cardinality notation indicates one and only one instance.

The following figure illustrates the connector notation used to relate objects within a hierarchy:



All **values with decimal places have to use the decimal point** rather than any regional separator.
In order to support characters beyond the ASCII character set, the exchanged **messages** between the Atellica VTLi and an Observation Reviewer **must be encoded in UTF-8** format.

All messages shall contain the following XML header as the first line:
<?xml version="1.0" encoding="UTF-8"?>

3.2.1 Header Object (all messages)

Header objects are sent at the beginning of all messages. It is a mandatory component of every message (even vendor-specific) and must be included for POCT1-A2 compliance.

Header (HDR)			
-	message_type	CV	Used for vendor specific message. Values for this field may be found in the descriptions of each message. The message-type attribute will be a part of each message from the Atellica VTLi.
-	Encoding_chars	ST	Not supported
+	control_id	ST	Uniquely identifies the message within the conversation
+	version_id	ST	must be always "**POCT1**" for POCT1-A2 compliance
+	creation_dttm	TS	Date and time the message was sent

For the Atellica VTLi the control_id attribute shall contain a number. The Atellica VTLi generates sequence numbers in the 10000 (ten thousand) range. Conversation topics initiated by the Atellica VTLi use sequential numbers from 10001. The sequence is also reset to 10001 whenever the communication link is restarted.

Example:

```
<HDR>
    <HDR.control_id V="10001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2012-05-07T14:55:00-00:00"/>
</HDR>
```

Example for the header of a vendor-specific message (here for the Reagent List topic message of the Atellica VTLi;

```
<HDR>
    <HDR.message_type V="DTV.SIEM.SET_LQC_RANGE" SN="SIEM"/>
    <HDR.control_id V="10010"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2012-05-07T14:56:00-00:00"/>
</HDR>
```

3.2.2 Hello Message (HEL.R01)

The Hello Topic defines the Atellica VTLi, its capabilities, the directives it supports and the maximum message size. This is the first message sent from the Atellica VTLi to the Observation Reviewer that initiates a conversation.

Header (HDR)

Device (DEV)				Max Length
+	device_id	ST	SIEM^Atellica VTLi^<serial_id>	
+	vendor_id	ST	SIEM	
+	model_id	ST	Atellica VTLi	
+	serial_id	ST	<serial_id> In very exceptional cases, the analyzer serial id might not be known. In this case 'UNKNOWN' is transmitted as serial id.	
+	manufacturer_name	ON	Siemens Healthcare Diagnostics Inc.	
+	hw_version	ST	<hw_version>	
+	sw_version	ST	<sw_version>	
+	device_name	ST	Name of the device. Atellica VTLi devices will pass the analyzer id. The analyzer id is a logical name defined by the organization using the Atellica VTLi. Can be set via service software.	[1…30]
-	vmd_name	ST	**Not supported**	
-	vmd_id	ST	**Not supported**	

Device Capabilities (DCP) (0…1)			
+	application_timeout	REAL	Application-level timeout, default value is **30** seconds
-	vendor_specific	ED	**Not supported**

Device Static Capabilities (DSC) (0…1)			
+	connection_profile_cd	CS	"**SA**" (synchronous acknowledgements; only this value is applicable for the Atellica VTLi)
+	topics_supported_cd	SET(CV)	Supported message Topics (beyond the minimum for POCT1-A2 compliance; see list below)
+	directives_supported_cd	SET(CV)	Directive commands that the Atellica VTLi supports (see list below)
+	max_message_sz	INT	**PINF** – positive infinity – The Atellica VTLi accepts messages in each size. But for better usability it is strongly recommended to limit to size of messages. For example, only 50 operators per message.

The following Topics beyond the minimum for POCT1-A2 compliance are supported by the Atellica VTLi. Patient lists are currently not supported:

- D_EV = Device Events
- DTV = Directives
- OP_LST = Operator List
- OP_LST_I = Incremental Operator List

The list below contains the supported Directives:

- SET_TIME = Set Device Time
- LOCK = Lockout all testing functions on the device
- UNLOCK = Release Lockout (enable all testing functions on the Atellica VTLi)
- ACTIVATE_LOT = Activates or sets a Lot (vendor specific)
- DEACTIVATE_LOT = Deactivates an existing Lot (vendor specific)
- SET_CUSTOM_LQC_RANGE = Sets LQC-range values (vendor specific)

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<HEL.R01>
    <HDR>
         <HDR.message_type V="HEL.R01" />
        <HDR.control_id V="10001"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:00+01:00"/>
    </HDR>
    <DEV>
        <DEV.device_id V="SIEM^Atellica VTLi^<000001009>"/>
        <DEV.vendor_id V="SIEM"/>
        <DEV.model_id V="Atellica VTLi"/>
        <DEV.serial_id V="000001009"/>
        <DEV.manufacturer_name V="Siemens Healthcare Diagnostics Inc."/>
        <DEV.hw_version V="1.0"/>
        <DEV.sw_version V="1.0.0.0"/>
        <DEV.device_name V="EmergencyDept_1"/>
            <DCP>
                <DCP.application_timeout V="30"/>
            </DCP>
            <DSC>
                <DSC.connection_profile_cd V="SA"/>
                <DSC.topics_supported_cd V="D_EV"/>
                <DSC.topics_supported_cd V="DTV"/>
                <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="LOCK"/>
                <DSC.directives_supported_cd V="UNLOCK"/>
                <DSC.max_message_sz NULL="PINF"/>
            </DSC>
    </DEV>
```

```
</HEL.R01>
```

3.2.3 Acknowledgement Message (ACK.R01)

Acknowledgement messages are sent from both sides of the communication link in reply to a message from the other side. If the previous message has been successfully received the recipient has to send an Acknowledgement of the type Application Accept (AA), otherwise it has to be of the type Application Error (AE).

Header (HDR)

Acknowledgement (ACK)			
+	type_cd	CS	**AA** (Application Accept; message received successfully) or **AE** (Application Error; there was an error processing the received message)
+	ack_control_id	ST	control_id of the message being acknowledged.
-	note_txt	ST	Error description for logging or presentation to the user.
-	error_detail_cd	CV	A code indicating the type of error that occurred (see section 2.4.2 for possible values in case of an error). In case of success the value may be **0** but the attribute can be omitted because the AA already conveys success.

Example: (this could be the answer to the Hello message example shown above)

```
<?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
    <HDR>
        <HDR.control_id V="4001"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:01+01:00"/>
    </HDR>
    <ACK>
        <ACK.type_cd V="AA"/>
        <ACK.ack_control_id V="10001"/>
    </ACK>
</ACK.R01>
```

3.2.4 Device Status Message (DST.R01)

The Device Status message reports the current status of the Atellica VTLi including the number of new observations and Atellica VTLi events since the last transmission.

Header (HDR)

Device Status (DST)			
+	status_dttm	TS	The time that this status information was observed.
+	new_observations_qty	INT	The number of observations the Atellica VTLi has to report.
-	new_events_qty	INT	The number of events since the last sync.
+	condition_cd	CV	Level of readiness; possible values

			L (Locked; Analyzer is not capable of measurements due to one of the following reasons: upgrade failed, self-test failed, locked remotely), **P** (Partial Lock; Analyzer is capable of measurements, but at least one assay is unavailable due to e.g. LQC failed, LQC expired), **R** (Ready; Analyzer is ready to perform all available measurements).
-	observations_update_dttm	TS	Time of the last successful transmission of observations.
-	events_update_dttm	TS	Time the Atellica VTLi last successfully completed the Device Events Topic.
-	operators_update_dttm	TS	Time the Atellica VTLi last successfully completed the Operator List Topic.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<DST.R01>
    <HDR>
        <HDR.control_id V="10002"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:02-00:00"/>
    </HDR>
    <DST>
        <DST.status_dttm V="2012-05-07T14:55:02-00:00"/>
        <DST.new_observations_qty V="1"/>
        <DST.new_events_qty V="1"/>
        <DST.condition_cd V="R"/>
        <DST.observations_update_dttm V="2012-05-07T14:45-00:00"/>
        <DST.events_update_dttm V="2012-05-07T14:45:02-00:00"/>
        <DST.operators_update_dttm V="2012-05-07T14:45:04-00:00"/>
    </DST>
</DST.R01>
```

3.2.5 Request Message (REQ.R01)

The Request message is sent from the Observation Reviewer to request new observations (ROBS), Device Events (RDEV) or the extended device status (REDS). If the Device Status message indicated that there is no new data for transmission, the Observation Reviewer shall skip to the next topic or end the conversation by sending the Terminate message (see section 3.2.8).

Request messages are not acknowledged using the ACK message. Instead the Atellica VTLi will immediately send the requested data using the corresponding message.

Extended Atellica VTLi status (REDS) is not supported.

Header (HDR)

Request (REQ)			
+	request_cd	CV	A code denoting the information requested – possible values are **ROBS** (request Observations)

			RDEV (request Device Events) **REDS** (request Extended Device Status)

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<REQ.R01>
    <HDR>
        <HDR.control_id V="4003"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:04+01:00"/>
    </HDR>
    <REQ>
        <REQ.request_cd V="ROBS"/>
    </REQ>
</REQ.R01>
```

3.2.6 Observation Topic (OBS.R01, OBS.R02)

POCT1-A2 specifies two types of Observation messages, patient related and non-patient related. Patient related Observation messages contain the results of patient tests while non-patient related Observation messages are used for Calibration and QC test results. The message structure of both types distinguishes slightly and will be described in the subsections of this section.
The Atellica VTLi will send observations which are associated with only one patient per message. On message can contain more than one observation. Every transmitted Observation message has to be acknowledged by the Observation Reviewer. After finishing the data transfer the Atellica VTLi will send an End of Topic message (see section 3.2.7) to indicate that the topic has completed. If there are no new observations the Atellica VTLi immediately sends an End of Topic message.

The Atellica VTLi uses a hierarchical structure to arrange its result data. On top, there's the analysis result, representing the result of an entire analysis. This result can contain several cartridge measurements, which each represent the result of one specific cartridge. This cartridge measurement can, in turn, contain several target measurements, which each represent the result of a specific analyte for that cartridge.

Currently, the cartridge measurement and target measurement levels *can* be converted to a Patient/NonPatient Observation, following the following rules:

- **Cartridge:**
  - Successful cartridge measurements (either valid or invalid) with a qualitative (QL) cartridge result are translated into a single observation. This is only relevant for Patient Observations.
  - Invalid or aborted cartridge measurements are translated into a Patient / NonPatientService. In this case, a separate observation is created for each attached target measurement.
- **Target:** Target results are translated into observations when they are either valid/invalid;

3.2.6.1 Patient related Observation Messages (OBS.R01)

Patient related Observation messages are used to transfer patient test results to the Observation Reviewer. Multiple results can be included in a single message,

Note that ORDER and some fields are not supported.

Header (HDR)

Service (SVC) (1…*)			
+	role_cd	CS	Always "**OBS**" for patient related observations.
+	observation_dttm	TS	The date-time-stamp when the measurement was started.
-	status_cd	CS	Test conditions: **NRM** (Normal)
-	reason_cd	CS	**NEW** (Default, new observation), **RES** (Resend, when resend from the view results menu)
-	sequence_nbr	INT	**Not Supported**

Patient (PT)				**Max Length**
+	patient_id	ST	Unique patient identifier. The id that was scanned with the integrated barcode scanner or manual entry. When patient id entry is skipped a patient id with the following syntax is created: No Patient ID: <date-time>.	[1…50]
-	location	ST	**Not Supported.**	
-	name	PN	**Not Supported.**	
-	birth_date	TS	**Not Supported.**	
-	gender_cd	CS	**Always set to Unknown**	
-	weight	PQ	**Not Supported.**	
-	height	PQ	**Not Supported.**	

Observation (OBS) (1…*)			
+	observation_id	CE	Based on value of method_cd: • **M** Name of the analyte as shown on the results display of the Atellica VTLi. A cartridge may support multiple analytes. This results in multiple Observations. • **I** Is a non empty string with the following format:

			<QuestionID>.<SequenceNumber> ○ Question ID as shown in the questionnaire of the Atellica VTLi. ○ SequenceNumber this questionnaire sequence result as opposed to the other questionnaire sequence results. This results in multiple Observations. • **C** Cartridge type.
-	value	PQ	The observation result, if expressed quantitatively. This field is required when method_cd value is equal to "M". Due to a failure it is possible that a test may be completed with invalid observations. In these cases, the invalid result will not transmit the measured result value, but `NullCode.Unknown`. Also, a note on the service object will be used to indicate the cause of the failure. For rejected measurements, the measured value **is** transmitted.
-	qualitative_value	CV	The observation result, if expressed qualitatively. This field is required when method_cd value is equal to "I" or "C". Based on value of method_cd: • **I** The value will be <AnswerId> and not the predefined set according specification (see POCT1-A). Answer identification is a non-empty string. • **C** "**A**" is the qualitative value is **detected**. "**N**" is the qualitative value is **not detected**.
+	method_cd	CS	**M** (Measured), measurement by the analyzer. **I** (Input), manual input used for "Questionnaire". **C** (Calculated), used for cartridge QL results.
-	status_cd	CS	**A** if accepted by user and a valid result **D** if rejected by user

			U if unknown (in case measurement aborted without result.) **X** if accepted by user but invalid result
-	interpretation_cd	CS	**>** Above Absolute High Off Instrument Scale **H** Above high normal limit (if configured) **N** Normal **L** Below low normal limit (if configured)**<** Below Absolute Low Off Instrument Scale Exceeding the instrument scale has priority over exceeding the normal limit. So if both are exceeded, only the indication of the instrument scale is used. Note that the reporting of '<' and '>' by Atellica VTLi is configurable per assay. For example, an assay might be configured to return the result **0** (with interpretation_cd **N**) when the result lies below the instrument scale.
-	normal_lo_hi_limit	IVL<PQ>	Low and high limit range for normal tests (target ranges) Encoding rule examples: • [70;105] both are known • [70;+inf[only lower limit is known •]-inf;105] only upper limit is known
-	critical_lo_hi_limit	IVL<PQ>	**Not Supported**

Note[1] **(NTE)** (0…*)			
+	text	ST	Note about the observation If the result is invalid the reason for invalidness is transmitted via a Note using the following syntax: <timestamp>: <code> (<severity>): <description> <timestamp> in local time zone. <code> of the problem e.g. 1234 <severity>: Info, Warning, Error <description>: textual description in the local language For example: *06/17/2014 12:17:42: 554 (Error): Optical features not within specification.* If any other tags (these are errors, warnings or informational messages) are attached to the measurement, these are also added as notes to the

[1] For method_cd value I the cardinality is always 0.

			result.

Operator (OPR) (0…1)				**Max Length**
+	operator_id	ST	Unique identifier of the operator. For automatic internal processes "**AUTO**" is used by the Atellica VTLi.	[1…50]
-	name	PN	Operator name	[1…256]

Order (ORD) (1)				**Max Length**
+	universal_service_id	CE	Format: <cartridge type>_<version>	<cartridge_type> [1..30] <version> [1..10]
-	ordering_provider_id	ST	An identifier that uniquely identifies the provider who ordered this service	Na
-	order_id	CV	Uniquely identifies this service instance. This field may contain an order id, accession number or other such identifier.	na

Specimen (SPC) (0…1)			
+	specimen_dttm	TS	The moment of sample detected is taken. If the moment of sample detection is not known, the entire Specimen block is omitted.
-	specimen_id	CV	**Not Supported**
-	source_cd	CE	**Not Supported**
-	type_cd	CE	The selected sample type (or omitted when no sample type was selected). This can be one of the following: • BLDC: Blood Capillary when sample type *Fingerstick* was selected • BLDV: Blood Venous when sample type *Tube* or *TubeWholeBlood* was selected • PLAS: Plasma when sample type *TubePlasma* was selected

Reagent (RGT) (1)				**Max Length**
+	name	ST	Manufacturer's name for the	<Product name>

			cartridge lot. The following format is used here: <Product name> (REF=<Product id>), e.g. *HScTnI (REF=51223001039)*	[1…50] <Product id> [1…50]
+	lot_number	CS	Unique number to identify the lot.	[1…50]
+	expiration_date	TS	The date past which the reagent should not be used.	

Note (NTE) (1…2)			
+	Text	ST	Additional measurement identification. This contains the identification of the result and the level in the measurement: Analysis: <unique analysis id> – Cartridge Measurement: <sequence id>-<repeat number> e.g. *Analysis: ante0003_121123_0004 - Cartridge Measurement: 1-0* In case a measurement **with questionnaire** was executed, a second note with additional questionnaire identification will be added. This contains the identification of the questionnaire: Questionnaire type: <type> – Questionnaire version: <version> e.g. *Questionnaire type: Clinicade - Questionnaire version: 1*

Example measurement observation only:

```
<?xml version="1.0" encoding="utf-8"?>
<OBS.R01>
  <HDR>
    <HDR.message_type V="OBS.R01" />
    <HDR.control_id V="10678" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2012-11-23T10:09:36+01:00" />
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS" />
    <SVC.observation_dttm V="2012-11-23T10:06:19+01:00" />
    <SVC.status_cd V="NRM" />
    <SVC.reason_cd V="NEW" />
    <PT>
      <PT.patient_id V="Patient001" />
      <PT.gender_cd V="U" />
      <OBS>
```

```
        <OBS.observation_id V="cTnI" />
        <OBS.value V="21.9" U="pg/ml" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
        <OBS.interpretation_cd V="N" />
        <OBS.normal_lo-hi_limit V="]-inf;300]" />
      </OBS>
      <OBS>
        <OBS.observation_id V="cTnI" />
        <OBS.qualitative_value V="N" />
        <OBS.method_cd V="C" />
        <OBS.status_cd V="A" />
      </OBS>
    </PT>
    <OPR>
      <OPR.operator_id V="9889" />
      <OPR.name V=" Service" />
    </OPR>
    <ORD>
      <ORD.universal_service_id V="cTni_R3" />
    </ORD>
    <SPC>
      <SPC.specimen_dttm V="2020-07-02T09:57:10+02:00" />
      <SPC.type_cd V="BLDV" />
    </SPC>    <RGT>
      <RGT.name V="HScTnI (REF=51223001039)" />
      <RGT.lot_number V=" B64000-001" />
      <RGT.expiration_date V="2099-12-31T00:00:00+01:00" />
    </RGT>
    <NTE>
      <NTE.text V="Analysis: ante0003_121123_0004 - Cartridge Measurement: 1-
0" />
    </NTE>
  </SVC>
</OBS.R01>
```

Example measurement observation combined with questionnaire observations:

```
<?xml version="1.0" encoding="utf-8"?>
<OBS.R01>
  <HDR>
    <HDR.message_type V="OBS.R01" />
    <HDR.control_id V="10678" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2012-11-23T10:09:36+01:00" />
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS" />
    <SVC.observation_dttm V="2012-11-23T10:06:19+01:00" />
    <SVC.status_cd V="NRM" />
    <SVC.reason_cd V="NEW" />
    <PT>
      <PT.patient_id V="Patient001" />
      <PT.gender_cd V="U" />
```

```
      <OBS>
        <OBS.observation_id V="Aripiprazole" />
        <OBS.value V="21.9" U="pg/ml" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
        <OBS.interpretation_cd V="N" />
      </OBS>
      <OBS>
        <OBS.observation_id V="OlanzapineOral" />
        <OBS.value V="1.19" U="pg/ml" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
        <OBS.interpretation_cd V="N" />
      </OBS>
      <!-- Relation between selected drug and subsequent answers is
maintained by postfix in observation_id: '.0', '.1', etc. -->
      <OBS>
        <OBS.observation_id V="DrugType.0" />
        <OBS.qualitative_value V="AripiprazoleOral" />
        <OBS.method_cd V="I" />
      </OBS>
      <OBS>
        <OBS.observation_id V="Regimen.0" />
        <OBS.qualitative_value V="Daily" />
        <OBS.method_cd V="I" />
      </OBS>
      <OBS>
        <OBS.observation_id V="Dose.0" />
        <OBS.qualitative_value V="1.5mg" />
        <OBS.method_cd V="I" />
      </OBS>
      <OBS>
        <OBS.observation_id V="DrugType.1" />
        <OBS.qualitative_value V="OlanzapineOral" />
        <OBS.method_cd V="I" />
      </OBS>
      <OBS>
        <OBS.observation_id V="Regimen.1" />
        <OBS.qualitative_value V="Weekly" />
        <OBS.method_cd V="I" />
      </OBS>
      <OBS>
        <OBS.observation_id V="Dose.1" />
        <OBS.qualitative_value V="3.5mg" />
        <OBS.method_cd V="I" />
      </OBS>
      <!-- Etc, etc... -->
    </PT>
    <OPR>
      <OPR.operator_id V="9889" />
      <OPR.name V="Service" />
    </OPR>
    <ORD>
      <ORD.universal_service_id V="cTni_R3">
       </ORD>
```

```
    <SPC V="2012-11-23T10:06:19+01:00" />
    <RGT>
      <RGT.name V="BNP (REF=51223001039)" />
      <RGT.lot_number V=" B64000-001" />
      <RGT.expiration_date V="2099-12-31T00:00:00+01:00" />
    </RGT>
    <NTE>
      <NTE.text V="Analysis: ante0003_121123_0004 - Cartridge Measurement: 1-
0" />
    </NTE>
    <NTE>
      <NTE.text V="Questionnaire type: Clinicade – Questionnaire version: 1"
/>
    </NTE>
  </SVC>
</OBS.R01>
```

When method_cd has value “I” the question identification is postfixed by a sequence number. Multiple sequences of questions (“I” observations) can occur which are indicated by a unique index.

Observation messages of tests completed without observations will contain as much information as known. Some data may not be recorded at the time the failure occurs and will be omitted, so it is possible that not all objects and attributes are present in the Observation message (beyond the minimum required).

3.2.6.2 Non-Patient related Observation Messages (OBS.R02)

Non-patient related Observation messages are very similar to the patient-related messages. Instead of a patient object they contain a control/calibration object to determine the kind of test driven. As for patient-related observations control or calibration test results may be separated into multiple Observation messages depending on the amount of data to transmit.

Header (HDR)

Service (SVC) (1…*)			
+	role_cd	CS	**LQC** (Liquid QC), **EQC** (Electronic QC), **CVR** (Calibration Verification), **CAL** (Calibration), **PRF** (Proficiency)
+	observation_dttm	TS	The Time the observation was performed
-	status_cd	CS	Test conditions: **NRM** (Normal)
-	reason_cd	CS	**NEW** (Default, new observation), **RES** (Resend),
-	sequence_nbr	INT	**Not Supported**

Control/Calibration (CTC)				**Max Length**
+	name	ST	Identification of the calibration or control. LQC: Product description of the control fluid used to perform the test. The following format is used here:	<Product name> [1…50] <Product id> [1…50]

			<Product name> (REF= <Product id>), e.g. *CardioImmune XL Level 1 (REF= CAI-XL1)*	
-	lot_number	CS	The (vendor-specific) lot number of the control/calibration material.	[1…50]
-	expiration_date	TS	The expiration date for the reagent used for this test.	
-	level_cd	CV	The level indication as mentioned on the vial of the calibration / control material and used in the on-screen display and instructions.	
-	cal-ver_repetition	INT	Applicable for CAL and CVR tests to indicate if tests are repeated for a certain level. Starts counting with 1. Only applicable for calibration verification tests. If tests within a linearity sequence are repeated at a given level, this field indicates the repetition count for this particular test.	

Observation (OBS) (1…*)			
+	observation_id	CE	Name of the analyte as shown on the results display of the Atellica VTLi. A cartridge may support multiple analytes.
-	value	PQ	The observation result, if expressed quantitatively. Due to a failure it is possible that a test may be completed with invalid observations. In these cases, the invalid result will not transmit the measured result value, but `NullCode.Unknown`. Also, a note on the service object will be used to indicate the cause of the failure. For rejected measurements, the measured value **is** transmitted.
-	qualitative_value	CV	**Not Supported**
+	method_cd	CS	**M** (Measured)

-	status_cd	CS	**A** if accepted by user and a valid result **D** if rejected by user **U** if unknown (in case measurement aborted without result.) **X** if accepted by user but invalid result
-	interpretation_cd	CS	**N** Normal **<** Below Absolute Low Off Instrument Scale **>** Above Absolute High Off Instrument Scale Also see [3.2.6.1].
-	normal_lo_hi_limit	IVL<PQ>	Low and high limit range for normal tests (QC ranges) Encoding rules: [70;105] both are known; [70;+inf[only lower limit is known;]-inf;105] only upper limit is known
-	critical_lo_hi_limit	IVL<PQ>	Not Supported Low and high limit range outside which clinical review is required (Encoding rules see above)

Note (NTE) (0…*)			
+	text	ST	Note about the observation If the result is invalid the reason for invalidness is transmitted via a Note using the following syntax: <timestamp>: <code> (<severity>): <description> <timestamp> in local time zone. <code> of the problem e.g. 1234 <severity>: Info, Warning, Error <description>: textual description in the local language For example: *06/17/2014 12:17:42: 554 (Error): Optical features not within specification.* If any other tags (these are errors, warnings or informational messages) are attached to the measurement, these are also added as notes to the result.

Operator (OPR) (0…1)				**Max Length**
+	operator_id	ST	Unique identifier of the operator. For automatic internal processes "**AUTO**" is used by the Atellica VTLi.	[1…50]
-	name	PN	Operator name	[1…256]

Reagent (RGT) (1)				**Max Length**
+	name	ST	Manufacturer's name for the cartridge lot. The following format is used here: <Product name> (REF=<Product id>), e.g. *HScTnI (REF=51223001039)*	<Product name> [1…50] <Product id> [1…50]
+	lot_number	CS	The lot number of the reagent used.	[1…50]
+	expiration_date	TS	The date past which the reagent should not be used in the format	

Note (NTE) (1)			
+	text	ST	Note about the service. This contains the identification of the result and the level in the measurement: Cartridge: Analysis: <unique analysis id> – Cartridge Measurement: <sequence id>-<repeat number>

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<OBS.R02>
  <HDR>
    <HDR.message_type V="OBS.R02" />
    <HDR.control_id V="10011" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2014-06-17T11:10:47+02:00" />
  </HDR>
  <SVC>
    <SVC.role_cd V="LQC" />
    <SVC.observation_dttm V="2014-06-17T11:02:16+02:00" />
    <SVC.status_cd V="NRM" />
    <SVC.reason_cd V="RES" />
    <CTC>
      <CTC.name V="CardioImmune XL Level 1 (REF=CAI-XL1)" />
      <CTC.lot_number V="1234567890" />
      <CTC.expiration_date V="2099-01-31T00:00:00+02:00" />
      <CTC.level_cd V="Low" />
      <OBS>
        <OBS.observation_id V="cTnI" />
        <OBS.value V="113.7" U="pg/ml" />
        <OBS.method_cd V="M" />
        <OBS.status_cd V="A" />
        <OBS.interpretation_cd V="N" />
        <OBS.normal_lo-hi_limit V="[0.01234;123.4]" />
      </OBS>
    </CTC>
    <RGT>
      <RGT.name V="HScTnI (REF=51223001039)" />
```

```
      <RGT.lot_number V="B64000-001" />
      <RGT.expiration_date V="2099-12-31T00:00:00+02:00" />
    </RGT>
    <NTE>
      <NTE.text V="Analysis: 12345678_140617_0001 - Cartridge Measurement: 1-
0" />
    </NTE>
  </SVC>
</OBS.R02>
```

Observation messages of QC tests completed without observations will contain as much information as known. Some data may not be recorded at the time the failure occurs and will be omitted, so it is possible that not all objects and attributes are present in the Observation message (beyond the minimum required).

3.2.7 End of Topic Message (EOT.R01)

End of Topic messages can be sent by either side to indicate that a potentially multi-message topic has completed. All topics that possibly can maintain multiple messages have to be finished with an End of Topic message even if the actual topic only consisting of one message.
The receiver shall not answer this message with an acknowledgement but rather continue with the next topic.

Header (HDR)

End of Topic (EOT)			
+	topic_cd	CV	A code for the topic that has just been completed. Possible values are: **EVS** (End of the Device Events Topic) **OBS** (End of the Observation Topic) **OPL** (End of the Operator List Topic) **EDS** (End of the Extended Device Status Topic)
-	update_dttm	TS	A time stamp provided to indicate the date and time that the current list was valid.
-	eot_control_id	ST	A message control code from the header of the message to which this EOT is a response. If the current topic doesn't have a preceding request to respond to (like the Operator List topic for example) this attribute shall be omitted.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<EOT.R01>
    <HDR>
        <HDR.control_id V="10004"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:08-00:00"/>
    </HDR>
    <EOT>
        <EOT.topic_cd V="OBS" SN="POCT1" SV="1"/>
        <EOT.eot_control_id V="4003"/>
    </EOT>
```

```
</EOT.R01>
```

3.2.8 Terminate Message (END.R01)

The Terminate message will be send if a participant wants to end the current conversation. Usually the Observation Reviewer has to quit the conversation by sending this message when all topics are done. In rare cases the Atellica VTLi will send a Terminate message (e.g. an operator want to run a test during an ongoing conversation) (see section 2.4.3). Regardless of the side which sends the Terminate message the opposite has to confirm the request with an acknowledgement message.

Header (HDR)

Termination (TRM)			
+	reason_cd	CV	A code for the reason terminating the conversation. Possible values are: **NRM** (Normal) **ABN** (Abnormal, shall be specified in note_txt) **USR** (User request) **UNK** (Unknown)
-	note_txt	ST	An optional text message that may be logged or displayed.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<END.R01>
    <HDR>
        <HDR.control_id V="4005"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:10-00:00"/>
    </HDR>
    <TRM>
        <TRM.reason_cd V="NRM"/>
        <TRM.note_txt V="Normal conversation end"/>
    </TRM>
</END.R01>
```

3.2.9 Escape Message (ESC.R01)

The Escape message is a part of the error handling. Either side of the communication can send it if a protocol error was detected (see sections 2.4 and 2.4.1 for further details). The opposite participant must stop processing the current topic and move on to the next topic in the message flow when receiving an Escape message.

Header (HDR)

Escape (ESC)			
+	esc_control_id	ST	The message control code (control_id) from the header of the message to which this Escape is a response.
+	detail_cd	CS	A code indicating the reason for the Escape message. Following values are possible:

			CNC (Cannot complete topic at this time) **TOP** (Unsupported topic) **OTH** (Other reason – shall be qualified in note_txt)
-	note_txt	ST	Further explanatory text that may be logged or displayed by the receiver.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<ESC.R01>
    <HDR>
        <HDR.control_id V="10005"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:55:10-00:00"/>
    </HDR>
    <ESC>
        <ESC.control_id V="4005"/>
        <ESC.detail_cd V="OTH"/>
        <ESC.note_txt V="Could not complete topic because of an invalid structure of the incoming message."/>
    </ESC>
</ESC.R01>
```

3.2.10 Device Events Topic (EVS.R01)

Device Events messages are sent from the Atellica VTLi to the Observation Reviewer to communicate status (e.g. Battery status) or important events (e.g. Alerts such as device failures, workflow errors etc) information that possibly needs an intervention. They can also contain results of maintenance procedures or of requested operations from previous conversations (like operator list updates).
Like the Observation topic the Atellica VTLi Events topic can consist of multiple messages. Therefore an End of Topic message will be sent after transmission is completed even though sending only a single Atellica VTLi Events message. One Message can contain up to 50 single Atellica VTLi-Events.

Header (HDR)			

Device Event (EVT) (1…*)			
+	description	ST	Free text description of the event. The descriptions are provided in the same language as the configured default language of the Atellica VTLi. The full list of supported device events can be found in Appendix C – Possible DEVICE Events. For device events that are the result of errors/warnings on the Atellica VTLi, the following format is used for the description: #<code> (<description>): <details>
+	event_dttm	ST	Time the event occurred.
+	severity_cd	CS	An indication of the level of operator intervention. Possible Values are:

			C (Critical, operator intervention required to restore normal operation of the Atellica VTLi) **W** (Warning, encountered a situation that may affect the normal operation of the Atellica VTLi in the future) *Note: Value **N** (Note, an informational message that doesn't require any intervention) is not supported by Atellica VTLi.* For the mapping of analyzer application Alert Severity to POCT severity, see Figure 1.

Operator (OPR)				**Max Length**
+	operator_id	ST	Unique identifier of the operator. If no operator is logged in (e.g. operator authentication is turned off), "**AUTO**" is used by the Atellica VTLi.	[1…50]
-	name	PN	Operator name.	[1…256]

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<EVS.R01>
    <HDR>
        <HDR.control_id V="10005"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:56:00-00:00"/>
    </HDR>
    <EVT>
        <EVT.description V=" Analyzer has been locked by a remote user. "/>
        <EVT.event_dttm V="2012-05-07T12:03:00-00:00"/>
        <EVT.severity_cd V="W"/>
            <OPR>
                <OPR.operator_id V="AUTO"/>
            </OPR>
    </EVT>
    <EVT>
        <EVT.description V="#1003 (Barcode scanner): Unable to scan barcode"/>
        <EVT.event_dttm V="2012-05-07T12:12:00-00:00"/>
        <EVT.severity_cd V="W"/>
            <OPR>
                <OPR.operator_id V="OP123456"/>
                <OPR.name V="John Smith"/>
            </OPR>
    </EVT>
</EVS.R01>
```

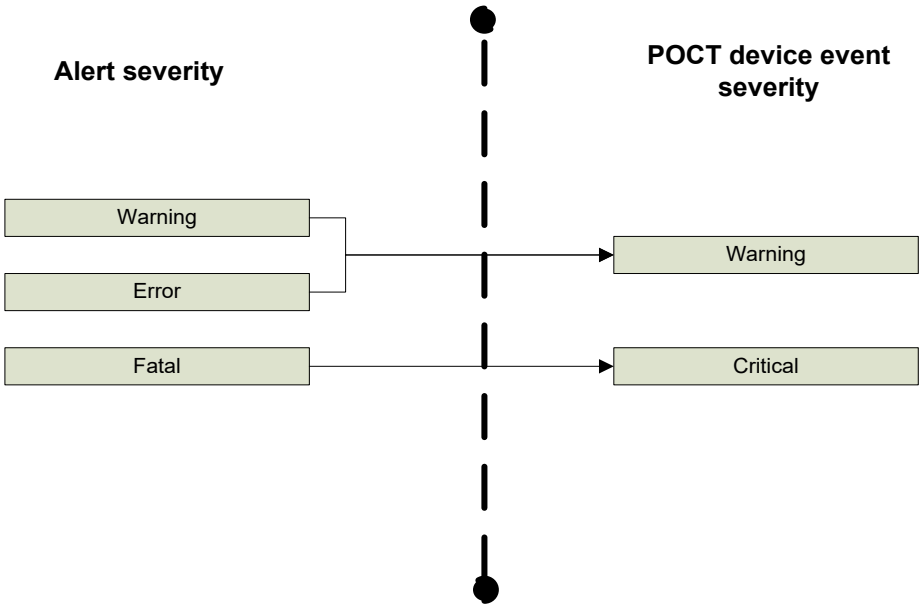


Figure 1 : Mapping of Atellica VTLi Alert severity to POCT device event severity

3.2.11 Operator List Topic (OPL.R01, OPL.R02)

The Atellica VTLi is able to store an operator list to assign particular users to measurements and maintenance tasks. To retrieve the initial list and possibly updates the Atellica VTLi supports the Operator List topic with both complete (OPL.R01) and incremental (OPL.R02) updates. New or updated lists have to be populated by the Observation Reviewer using this Operator List topic. The initial list for a new Atellica VTLi shall be send as a complete update (OPL.R01). Following list updates can be sent by either a complete or an incremental update while a complete update replaces the current operator list on the Atellica VTLi. The Observation Reviewer has to decide which method could be the best way for a particular transmission.

The Atellica VTLi accepts an unlimited number of operators. It would not be desirable to send all records in one message since that would end in a very large and unmanageable message. Therefore the topic shall be broken into multiple operator list messages with a maximum of 100 operators in each message. An Acknowledgement message will be sent from the Atellica VTLi for each Operator List message. Once the Observation Reviewer has completed it must send an End of Topic message to indicate that the entire operator list was sent.

If the Atellica VTLi receives an Operator List message that violates any rule specified in this section and the following subsections, it rejects all records in the particular message, but stores all operators acknowledged before in the Atellica VTLi database to allow using of the Atellica VTLi even if not all operators could be added.
At the point of an erroneous message the Atellica VTLi sends an error acknowledge message with further information about the failure within the fields error_detail_cd and note_txt field (see section 2.4.2). The Observation Reviewer responds by either sending an End of Topic to stop processing or skip the erroneous message and continue sending remaining messages of the Operator List topic.
The following list provides possible errors for the Operator List topic:

- Duplicate operators (more than one record with the same operator ID)
- Blank operator ID
- Invalid operator ID (e.g. too many or not allowed characters)

It is possible to restrict the access rights for particular users by using the Access Control object which is a part of the Operator List message. If this object is omitted for a specific user the permission level will be set to USER (see subsections 3.2.11.1 and 3.2.11.2 for details about the Access Control object).

3.2.11.1 Complete Operator List Messages (OPL.R01)

The Complete Operator List message is used to transfer a new user list from the Observation Reviewer to the Atellica VTLi. In most cases this is only required for new Atellica VTLis which never received an operator list or when changing the location of a Atellica VTLi to a new facility. To update an operator list the Incremental Operator List message described in the next section should be used instead of sending a complete list (except for large updates where many records changing).

On receipt of a Complete Operator List message, the Atellica VTLi will first delete all existing operators that have been received from the Observation Reviewer in the past. After this has been done, the new operators, contained in the message, will be added. When a Complete Operator List is distributed over multiple messages (because of the large amount of operators in this list) and these messages are sent within one conversation, only the first message will cause the POCT operators on the Atellica VTLi to be deleted. All subsequent parts of the list are then appended,

Header (HDR)

	Operator (OPR) (1…*)			**Max Length**
+	operator_id	ST	Unique identifier of the operator. Accepted characters: All alphanumeric (uppercase and lowercase). Also the following characters: dot(.), minus(-), underscore(_), exclamation mark(!), @-sign(@), hashtag(#), comma(,), slash(/), quote(‘) and space( ). Note: Only characters are available on the keypad of the Atellica VTLi may be used in the operator id.	[1…50]
-	name	PN	Operator name up to 255 characters	

	Access Control (ACC) (0…1)			**Max Length**
+	method_cd	CV	Always **ALL** for all analytic methods of the Atellica VTLi.	
-	password	ED	The user’s password to operate the Atellica VTLi. May be omitted or empty in case operator authentication with password is not enabled. Accepted characters: All alphanumeric (uppercase and lowercase). Also the following characters: dot(.), minus(-), underscore(_), exclamation mark(!), @-sign(@), hashtag(#), comma(,), slash(/), quote(‘) and space( ).	[0…50]
-	active_date	TS	The date after this certificate is valid.	
-	expiration_date	TS	The date on which this certificate expires.	
-	permission_level_	CV	A code indicating which operations the user is allowed to	

	cd		perform. Possible values are: 1 → Supervisor 2 → Key operator 3 → Trusted user 4 → User 5 → Service 6 → Training For the mapping to application rights in the analyzer application, see [Figure 2].	

Note (NTE) (0…*)			
+	text	ST	Not used. Textual description of the user privileges for displaying.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<OPL.R01>
    <HDR>
        <HDR.control_id V="4007"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:56:00-00:00"/>
    </HDR>
    <OPR>
        <OPR.operator_id V="OP123456"/>
        <OPR.name V="Atellica VTLi Supervisor"/>
            <ACC>
                <ACC.method_cd V="ALL"/>
                <ACC.password>ff12908feab</ACC.password>
                <ACC.permission_level_cd V="1"/>
            </ACC>
     </OPR>
</OPL.R01>
```

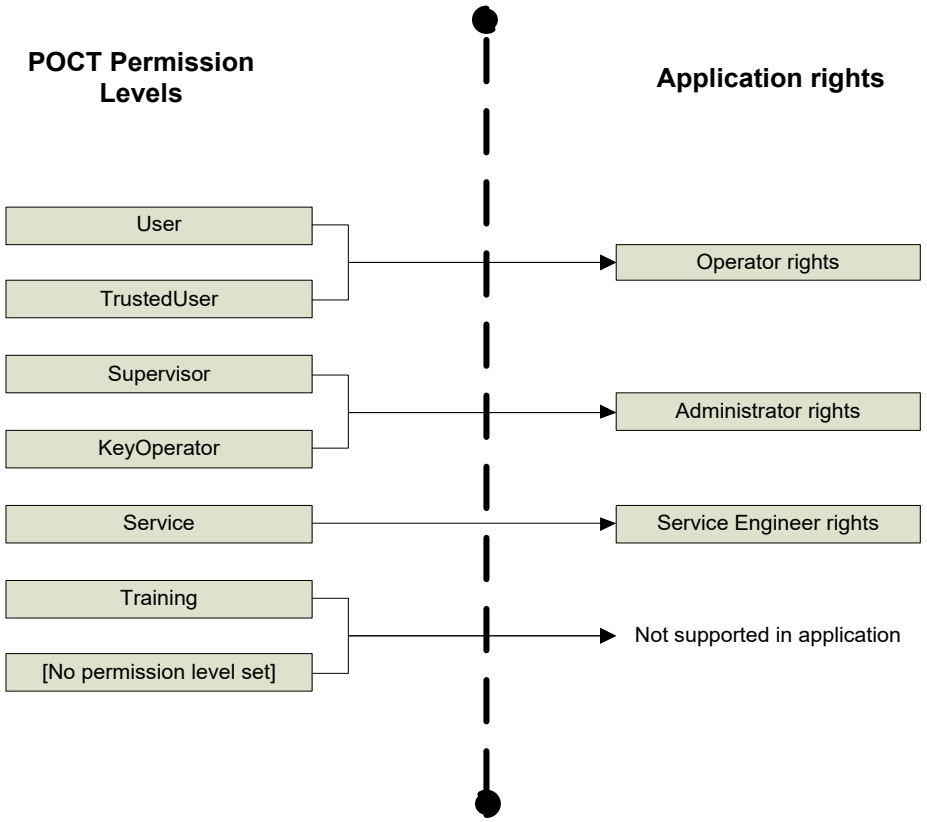


Figure 2: Mapping of POCT permission levels to Atellica VTLi rights

3.2.11.2 Incremental Operator List Messages (OPL.R02)

Incremental Operator List messages can be used to update an outdated operator list on the Atellica VTLi. They are very similar to Complete Operator List messages but allow sending only new and changed operators by an Observation Reviewer instead of transmitting a full list which must include all operators. (operators_update_dttm field in the Atellica VTLi Status message indicates prior operator list uploads; this field is omitted on Atellica VTLis which never received a list). To populate an initial operator list to a new Atellica VTLi the Complete Operator List message must be used.
A prior deletion of an already existing operator is not required (but possible) to change the record. Existing records will be replaced by the new entries. So an Observation Reviewer is not obligated to send two update actions (delete and insert) to change operator details on the Atellica VTLi.

Header (HDR)

Update Action (UPD) (1…*)			
+	action_cd	CS	What operation should be performed using the referenced data? Possible values are: **I** (Insert the specified entries into the associated list) **D** (Delete the specified entries from the associated list) Note: When using paired delete and insert operations to edit or replace an operator the Observation Reviewer must ensure the correct ordering of the actions (the delete action must be

			performed *before* the corresponding insert action, otherwise the recently edited record will be deleted from the Atellica VTLi instead of only changing its contents).

Operator (OPR) (1…*)				**Max length**
+	operator_id	ST	Unique identifier of the operator Accepted characters: All alphanumeric (uppercase and lowercase). Also the following characters: dot(.), minus(-), underscore(_), exclamation mark(!), @-sign(@), hashtag(#), comma(,), slash(/), quote(‘) and space( ).	[1…50]
-	name	PN	Operator name	[1…256]

Access Control (ACC) (0…1)				
+	method_cd	CV	Always **ALL** for all analytic methods of the Atellica VTLi.	
-	password	ED	The user’s password to access the described method. Accepted characters: All alphanumeric (uppercase and lowercase). Also the following characters: dot(.), minus(-), underscore(_), exclamation mark(!), @-sign(@), hashtag(#), comma(,), slash(/), quote(‘) and space( ).	[0...50]
-	active_date	TS	The date after this certificate is valid.	
-	expiration_date	TS	The date on which this certificate expires.	
-	permission_level_cd	CV	A code indicating which operations the user is allowed to perform. Possible values are: (Code; Value; Description) 1 → Supervisor 2 → Key operator 3 → Trusted user 4 → User 5 → Service 6 → Training For the mapping to application rights in the analyzer application, see [Figure 2].	

Note (NTE) (0…*)			
+	text	ST	Textual description of the user privileges for displaying.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<OPL.R02>
    <HDR>
        <HDR.control_id V="4007"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:56:00-00:00"/>
    </HDR>
    <UPD>
        <UPD.action_cd V="D"/>
            <OPR>
                <OPR.operator_id V="OP123456"/>
            </OPR>
    </UPD>
    <UPD>
        <UPD.action_cd V="I"/>
            <OPR>
                <OPR.operator_id V="OP123456"/>
                <OPR.name V="Atellica VTLi Supervisor"/>
                    <ACC>
                        <ACC.method_cd V="ALL"/>
                        <ACC.password>ff12908feab</ACC.password>
                        <ACC.permission_level_cd V="1"/>
                    </ACC>
                    <NTE>
                        <NTE.text V="Administrative Operator with all privileges"/>
                    </NTE>
            </OPR>
    </UPD>
</OPL.R02>
```

3.2.12 Directive Messages (DTV.R01, DTV.R02, DTV.SIEM)

Directive messages are sent from the Observation Reviewer to the Atellica VTLi in order to request an action. There are three types of Directive messages to fulfill various scenarios for sending commands with or without parameters to the Atellica VTLi. POCT1-A2 provides a set of pre-defined directives. Vendors have the possibility to specify own directives depending on the Atellica VTLi requirements. Not all POCT1-A2 directives are supported by the Atellica VTLi. This document only contains those that can be understood and executed.

Since directives consist of only one message send from the Observation Reviewer an End of Topic is not required. The Atellica VTLi will send either a positive or an error acknowledge to indicate the possibility to execute the command.
The result of a command execution will be answered directly by an ACK or NAK-Message.

Supported Directives are provided within the Hello message (see section 3.2.2) sent from the Atellica VTLi at the beginning of the conversation.

3.2.12.1 Basic Directive Messages (DTV.R01)

Basic Directives are the simplest form of sending commands to the Atellica VTLi. They only allow sending a simple command and cannot include any parameters.
The following basic-directives are supported:

- LOCK – Locks the Atellica VTLi for further measurements
- UNLOCK – Unlocks the formerly locked Atellica VTLi

Other sent directives will be answered by a NAK.

After a successful UNLOCK directive it may be that the analyzer is still not usable to perform patient tests e.g. if the analyzer is locked due to a self-test failure it cannot be solved by unlocking remotely. In this case the sending of another UNLOCK-Directive will be answered with a NAK (A NAK is only sent if the Atellica VTLi is locked due to another reason e.g. locked by self-test, if is already unlocked the Atellica VTLi will answer with an ACK). The problem should be solved by solving the self-test failure. The Atellica VTLi status will still indicate a LOCKED state.

Header (HDR)

Directive (DTV)			
+	command_cd	CV	A coded value representing the command for the Atellica VTLi to perform. Following basic directives are supported by the Atellica VTLi: **LOCK** - Lockout all testing functions on the Atellica VTLi. **UNLOCK** - Enable all testing functions on the Atellica VTLi. If the Atellica VTLi is already unlocked it will answer with a positive acknowledge.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<DTV.R01>
    <HDR>
        <HDR.control_id V="4011"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:56:00-00:00"/>
    </HDR>
    <DTV>
        <DTV.command_cd V="LOCK"/>
    </DTV>
</DTV.R01>
```

3.2.12.2 Complex Directive Messages (DTV.R02)

Complex and Vendor-specific Directive messages enhance Basic Directives to allow parameters to be communicated in addition to the simple command code. They include one or more parameter objects or elements as siblings of the Directive Object.

POCT1-A2 specifies one Complex Directive message which is used to set the device time from an Observation Reviewer. The Atellica VTLi is able to execute this directive and can set its internal clock with the provided information.

When setting a new time zone, the analyzer will need to reboot to be able to use this new information. This will result in the termination of the running conversation.

The Set Device Time directive has the following structure:

Header (HDR)

Directive (DTV) (1…1)			
+	command_cd	CV	**SET_TIME**

Time (TM) (1…1)			
+	dttm	TS	Observation Reviewer time stamp conforming to the TS data type rules including a valid time zone offset relative to UTC.
-	accy	REAL	**Not Supported**

Time Zone (TZ) (0…1)			
+	offset	ST	Atellica VTLi's local time zone offset, relative to UTC, if known. Format: "+hh:mm" or "+hh" (locations east of GMT) and "-hh:mm" or "-hh" (locations west of GMT)
-	label	ST	Atellica VTLi's local time zone label if known (e.g. "EST", "EDT").
-	new_dttm	TS	**Not Supported**
-	new_offset	ST	**Not Supported**
-	new_label	ST	**Not Supported**

Leap Second (LS) (0…1)			
+	cumulative	INT	**Not Supported**
-	new_dttm	TS	**Not Supported**
-	new_cumulative	INT	**Not Supported**

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<DTV.R02>
    <HDR>
        <HDR.control_id V="4012"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2012-05-07T14:56:00-00:00"/>
    </HDR>
    <DTV>
        <DTV.command_cd V="SET_TIME"/>
    </DTV>
    <TM>
        <TM.dttm V="2012-05-07T14:56:00-01:00"/>
```

```
  </TM>
   <TZ>
        <TZ.offset V="+01"/>
        <TZ.label V="CET"/>
        <TZ.new_dttm V="2012-03-24"/>
        <TZ.new_offset V="+02"/>
        <TZ.new_label V="CEST"/>
   </TZ>
</DTV.R02>
```

For more information about timezone handling, see [4.0].

3.2.12.3 Vendor-specific Messages (DTV.SIEM)

Vendor-specific messages extending the opportunities for bidirectional data exchange between Observation Reviewer and Atellica VTLi. They can be used for any information transfer that is not covered by one of the POCT1-A2 conversation topics. For this reason this approach involves creating new message types, models and flows. There are three rules apply to the creation of these messages and flows which are implemented in the vendor-specific messages provided by the Atellica VTLi:

- All messages must start with a Header Object specified in section 3.2.1 followed by zero or more message objects.
- The string content of the field “V” in message_type attribute of the Header Object shall indicate the vendor-specific content and/or purpose of the message. It may also indicate the vendor name. For messages differing in their internal structure different names shall be used. The field SN shall contain the vendor identifier.
- Vendor-specific exchanges shall be designed in terms of topics, with a clear message indicating the end of the current topic (e.g. an Acknowledgement or End of Topic message). Thus, each vendor-specific message flow is bounded which means that the flow has a well-defined start and end.

Vendor specific messages provided by the Atellica VTLi will be discussed in the following subsections.
To relieve implementation most of the message objects using the POCT1-A2 standard data types.

3.2.12.4 Activate-Lot-Directive (DTV.SIEM.ACTIVATELOT)

This directive activates a Lot. It can be used for all kinds of lots.

PREREQUISITE: For correct application of this function it is required that all lot id’s are unique!

When activating a lot, the following situations can occur:

- No lot with the specified lot id exists on the Atellica VTLi. In this case the lot is added and a positive acknowledge is returned;
- A lot with the same lot id already exists on the Atellica VTLi. In this case, no action is taken and a positive acknowledge is returned with a descriptive message. Note that this check is only performed on lot id, since the lot id is always unique. In other words, if (hypothetically) another lot with the same lot id but another product type already exists on the Atellica VTLi, this would lead to the same result (= no action and a positive acknowledge is returned).

Note that the product id is optional, but including it in lot related messages is the preferred way of working. When a cartridge lot is sent to the Atellica VTLi *without* a product id, the Atellica VTLi will not be able to link it to a specific assay. As a result, the cartridge lot will not be shown in the dashboard UI of the Atellica VTLi. The link will be established the first time the cartridge lot is used in a measurement (when the provided information is combined with the information in the cartridge's RFID). After this measurement, the cartridge lot *will* be visible in the UI.

Header (HDR)

Directive (DTV) (1…1)			
+	command_cd	CV	A coded value representing the command for the Atellica VTLi to perform. The command_cd for the ACTIVATELOT-Directive is: **ACTIVATE_LOT**

LOT (LOT) (1…1)				
-	product_id	ST	Unique ID that identifies the product to which the lot belongs	[1…50]
+	product_type	CS	Coded simple value representing the type of the Lot. Possible values are: **CARTRIDGE** – for cartridge lots **LIQUID_QC** – for liquid qc lots	
+	lot_id	ST	Unique ID that identifies the lot (/batch)	[1…50]

Example:

```
<DTV.SIEM.ACTIVATELOT>
        <HDR>
                <HDR.message_Type V="DTV.SIEM.ACTIVATE_LOT"/>
                <HDR.control_id V="4020"/>
                <HDR.version_id V="POCT1"/>
                <HDR.creation_dttm V="2001-11-01T16:32:43-08:00"/>
        </HDR>
        <DTV>
                <DTV.command_cd V="ACTIVATE_LOT"/>
        </DTV>
        <LOT>
                <LOT.product_id V="CAI-XL1"/>
                <LOT.product_type V="LIQUID_QC"/>
                <LOT.lot_id V="1234567890"/>
        </LOT>
</DTV.SIEM.ACTIVATELOT>
```

3.2.12.5 DeActivate-Lot-Directive (DTV.SIEM.DEACTIVATELOT)

This directive de-activates an existing Lot. It can be used for all kinds of lots.

When de-activating a lot, the following situations can occur:

- A lot with the specified lot id exists on the Atellica VTLi. In this case the lot is de-activated and a positive acknowledge is returned. Note that this check is only performed on lot id, since the lot

id is always unique. In other words, if (hypothetically) another lot with the same lot id but another product type already exists on the Atellica VTLi, this would lead to the same result (= lot will be de-activated and a positive acknowledge is returned).

- No lot with the specified lot id exists on the Atellica VTLi. In this case, no action is taken and a positive acknowledge is returned with a descriptive message.

Header (HDR)

Directive (DTV) (1…1)			
+	command_cd	CV	A coded value representing the command for the Atellica VTLi to perform. The command_cd for the Deactivate-Directive is: **DEACTIVATE_LOT**

LOT (LOT) (1…1)				
-	product_id	ST	Unique ID that identifies the product to which the lot belongs	[1…50]
+	product_type	CS	Coded simple value representing the type of the Lot. Possible values are: **CARTRIDGE** – for cartridge lots **LIQUID_QC** – for liquid qc lots	
+	lot_id	ST	Unique ID that identifies the lot (/batch)	[1…50]

Example:

```
<DTV.SIEM.DEACTIVATELOT>
        <HDR>
                <HDR.message_Type V="DTV.SIEM.ACTIVATE_LOT"/>
                <HDR.control_id V="4020"/>
                <HDR.version_id V="POCT1"/>
                <HDR.creation_dttm V="2001-11-01T16:32:43-08:00"/>
        </HDR>
        <DTV>
                <DTV.command_cd V="DEACTIVATE_LOT"/>
        </DTV>
        <LOT>
                <LOT.product_id V="CAI-XL1"/>
                <LOT.product_type V="LIQUID_QC"/>
                <LOT.lot_id V="1234567890"/>
        </LOT>
</DTV.SIEM.DEACTIVATELOT>
```

3.2.12.6 SetCustomLqcRange-Directive (DTV.SIEM.SETCUSTOMLQCRANGE)

The SetCustomLqcRange-Directive allows the set of custom defined ranges for liquid-QC. It is possible to send only 1 lot per message, but 1 message allows multiple targets with multiple levels.

Header (HDR)

Directive (DTV) (1…1)			
+	command_cd	CV	A coded value representing the command for the Atellica VTLi to perform. The command_cd for the SetCustomLqcRange-Directive is: **SET_CUSTOM_LQC_RANGE**

LOT (LOT) (1…1)				
-	product_id	ST	Unique ID that identifies the product to which the lot belongs	[1…50]
+	product_type	CS	Coded simple value representing the type of the Lot. Possible values are: **LIQUID_QC** – for liquid qc lots	
+	lot_id	ST	Unique ID that identifies the lot (/batch)	[1…50]

QCRANGES (QCRANGES) (1…1)

Target (TARGET) (1…*)			
+	TARGET	ST	Name of the target/analyte

Level (LEVEL) (1…*)				**Max Length**
+	level_cd	ST	Name of the level for the current range.	[1…50]
+	range	IVL<PQ>	Lower- and Upper-Limit of the current level Only closed limits are supported (ranges that include the limit values). Ranges that exclude the limit values are not supported by the embedded software, with the exception of positive/infinite values.	

Example:

```
<?xml version="1.0" encoding="utf-8"?>
<DTV.SIEM.SETCUSTOMLQCRANGE>
        <HDR>
                <HDR.control_id V="4003" />
                <HDR.version_id V="POCT1" />
                <HDR.creation_dttm V="2014-06-17T10:44:32+02:00" />
        </HDR>
        <DTV>
                <DTV.command_cd V="SET_CUSTOM_LQC_RANGE" />
        </DTV>
        <LOT>
```

```
            <LOT.product_id V="CAI-XL1" />
            <LOT.product_type V="LIQUID_QC" />
            <LOT.lot_id V="1234567890" />
        </LOT>
        <QCRANGES>
            <TARGET V="cTnI">
                <LEVEL>
                    <LEVEL.level_cd V="H" />
                    <LEVEL.range V="[5.00;50.00]" U="pg/ml" />
                </LEVEL>
                <LEVEL>
                    <LEVEL.level_cd V="L" />
                    <LEVEL.range V="[-10.00;-5.00]" U="pg/ml" />
                </LEVEL>
            </TARGET>
        </QCRANGES>
</DTV.SIEM.SETCUSTOMLQCRANGE>
```

4.0 Appendix A – Timezone handling

POCT timezones are fundamentally different than Windows timezones. Where Windows timezones specify a timezone schedule for the entire year (with Standard to Daylight time transition and Daylight to Standard time transition), POCT will only specify current timezone and the NEXT transition that will happen. The information containing the next transition is not handled by the Atellica VTLi, so the transition will only take effect on the analyzer **after** it has synchronized the time and timezone with the Observation reviewer at least once after the transition has occurred. The following scheme is used to map the POCT timezone to the Windows timezone:

Windows	**Which POCT fields are used**
Bias	The offset to UTC (*TZ.offset*) is converted to minutes and used here. The result is then negated, since Windows specifies the bias as the offset from the local time to UTC instead of the other way around.
StandardBias	This value is always '0'.
StandardName	The name associated with the Standard time (*TZ.label*). We use it to store the name associated with the current time (so before the next transition). Since POCT doesn't distinguish whether the current time is Standard or Daylight Savings Time (it only reports the next transition), this can mean that the Daylight Savings Time name is entered here. It is an optional field in the POCT message, so it can be left empty.
StandardDate	This will be empty
DaylightBias	This will be empty
DaylightName	This will be empty
DaylightDate	This will be empty

5.0 Appendix B – Possible Atellica VTLi Settings

Key	Value
PocAdminTelephoneNumber	Telephone number of the POC administrator. Possible values: Free text
OperatorIdEntryOption	Indicates which method is used by the operator to enter the operator id. Possible values: MANUAL/KEYBOARD
OperatorAuthenticationLevelOption	Indicates the operator authentication level. Possible values: NONE/ID/IDANDPASSWORD
PatientIdentification	Indicates which method is used on the Atellica VTLi for patient identification. Possible values: NONE/BARCODE
SoundEnabled	Indicates whether or not sound is enabled on the Atellica VTLi. Possible values: YES/NO
AutomaticLogoutTimeout	Timeout (in minutes) after which a user session is logged out when no activity was detected. Possible values: 10/15/30/60
DataOverwriting	Indicates whether or not data may be overwritten by the Atellica VTLi. Possible values: ALWAYS/CONFIRM/NEVER

6.0 Appendix C – Possible DEVICE Events

Error/Warning related Device events:

Code	Severity	Short description
1000	Warning	Power button failure
1001	Warning	Battery hardware failure
1002	Warning	Cradle hardware failure
1003	Warning	Barcode scanner hardware failure
1004	Warning	Cartridge hardware failure
1005	Warning	RFID reader hardware failure
1006	Warning	Sample detector hardware failure
1007	Warning	Cap hardware failure
1008	Warning	Temperature controller hardware failure
1009	Warning	Frame capturing hardware failure
1010	Warning	Measurement hardware failure
1011	Warning	Measuring unit hardware failure
1012	Warning	Coil calibration hardware failure
1013	Warning	Hardware failure during measuring unit power off
1014	Warning	Hardware failure during measuring unit power on
1015	Warning	Version info hardware failure
1016	Warning	Tilt sensor hardware failure
1017	Warning	Optics hardware failure
1018	Warning	Display hardware failure
1601	Warning	RFID format invalid
1602	Warning	RFID version not supported
1603	Warning	RFID could not be read
1604	Warning	Cartridge expired
1605	Warning	Cartridge already used
1606	Warning	Cartridge protocol not supported
1607	Warning	Cartridge type not expected
1608	Warning	Cartridge protocol invalid
1609	Warning	Sample detected on inserted cartridge
1800	Warning	Sample not detected within timeout
1801	Warning	Sample detected before temperature reached
1802	Warning	Cap not closed on time during sample detection
1803	Warning	RFID was already locked
1804	Warning	Sample added before questionnaire was finished
1805	Warning	Sample added before add sample instructions were shown
2600	Warning	Middleware communication failure
2650	Warning	Service software communication failure
2699	Warning	General communication failure
4051	Warning	No operators present detected during login
4052	Warning	Invalid operator id entered during login
4053	Warning	Inactive account detected during login
4054	Warning	Expired account detected during login
4055	Warning	Training account detected during login
4056	Warning	Invalid password detected during login
4057	Warning	Accounts with no permission level not supported

Code	Severity	Short description
9000	Critical	Fatal error
9001	Critical	Data access failure

Other Device Events:

Severity	Short description
Critical	Atellica VTLi locked remotely
Critical	Atellica VTLi locked due to failed self-test
Critical	Atellica VTLi locked due to failed tilt sensor self-test
Critical	Atellica VTLi locked due to failed software upgrade
Note	Atellica VTLi unlocked
Warning	Assay has been locked due to a failed QC test.
Warning	Assay has been locked due to a QC test that was out of range.