ADVANCED INSTRUMENTS

Osmo1®

Specification,
Laboratory Information System (LIS) Interface

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Chapter 1

Purpose

This document describes the bidirectional TCP/IP communication link between the Osmo1 and a laboratory information system (LIS) or host computer.
This document is intended for the information systems professional responsible for developing a middleware "driver" or application residing on the host computer.

Overview

The Osmo1 can be connected to an LIS or general-purpose computer to exchange information. The communication protocols supported by the Osmo1 software are CSLI[1] bidirectional and unidirectional protocols LIS2-A2 (record formats) and LIS01-A2 (low level protocol).

The communication link allows the host computer to transmit patient work orders to the Osmo1 and accept test results transmitted from the Osmo1. The host work orders provide sample information to the Osmo1 software, but do not select the parameters to be measured. The Osmo1 has only one possible measurement cycle.

The type of protocol used is selected from the **LIS/LAN** screen accessed from the **SETTINGS** menu in the Osmo1 user interface, as explained in the Osmo1 User's Guide.

The Osmo1 software can be configured to automatically transfer available results to the host or manually transfer results to permit the operator time to review the data and release the samples. In bidirectional mode, the Osmo1 system can request patient work order information from the LIS when needed.

The LIS may also initiate sending patient work order information to the Osmo1 in advance of sample runs. The information will be parsed and stored in the system for later use. An automatic request for patient information is generated when a system measurement cycle starts and no existing sample ID work order or patient demographic record exists in the system.

[1] – Clinical and Laboratory Standards Institute

Basic Operation

Bidirectional Mode

The Osmo1 can be configured to expect download of patient work orders from the LIS. In this mode the Osmo1 will receive work orders at any time and store them for matching with a sample presented for test. If no order is found, the Osmo1 will query the LIS for an order matching the sample presented. The Osmo1 will still send a result record even if no matching work order is found.

In this mode the Osmo1 will also respond to queries from the LIS. It will send back work orders and result records matching the appropriate fields in the query record.

Unidirectional Mode

The Osmo1 can be configured to send a result record without matching it to a patient work order. A default work order will be made up just to satisfy the LIS2-A2 protocol.

Automatic Mode

The Osmo1 can be configured to send a result record as soon as a test is completed without operator intervention. This mode will work with either the Bidirectional Mode or Unidirectional Mode as described above.

Manual Mode

The Osmo1 can be configured to require an operator to verify a result before it is sent to the LIS system. The operator uses the **Results** screen to verify the result and initiate the sending operation. This mode will work with either the Bidirectional Mode or Unidirectional Mode as described above.

Chapter 2

Low Level Protocol

Physical Layer

The Osmo1 is able to communicate with a LIS system via the TCP/IP protocol. All communications are expected to use the character bit sequence, structure, and parity sense definitions defined by the X3.15-1976 and X3.16-1976 ANSI[2] standards with signal levels and data transmission rates defined by the IEEE[3] 802.3 standard. Any speed 10 MB/s or higher is acceptable. The physical connection to the instrument is via a commercial RJ45F style connector located on the back of the instrument, and Category 5 cabling as defined by ANSI EIA/TIA 568A should be used. A hub or switch may be used to connect to a laboratory network or a connection may be made to a dedicated host computer utilizing a "cross-over" CAT-5 cable. In a deviation from the LIS01-A2 protocol, the Osmo1 may act as either the client or the server in establishing the TCP/IP connection. This is configurable from the **SETTINGS > LIS/LAN** screen. In the normal case where the Osmo1 is the client, the IP address and port (default 13003) of the host computer are configurable from the **SETTINGS > LIS/LAN** screen. In the case where the Osmo1 is setup to be the server, only the port number (default 13003) may be configured.

Data Link Layer

The Osmo1 uses the data link layer protocol described in LIS01-A2 to establish the connection and handle error and time out conditions. The three phases of this protocol are: Establishment, Transfer, and Termination, as described below. Either system may at any point be the sender; the other side is then the receiver. In *Unidirectional Mode* the Osmo1 is always the sender and the LIS system is always the receiver. When neither system is in the process of actively transferring data, the link is said to be in a neutral state.

Establishment Phase

The system with information to transmit initiates the Establishment Phase. This can only occur when the link is in the neutral state. A single <ENQ> character (ASCII decimal 5) is used to start this phase. The only valid responses to the <ENQ> character are <ACK> (ASCII decimal 6), <NAK> (ASCII decimal 21) or <ENQ>. If a <ACK> is received, the phase is complete and the initiating system becomes the sender. If a <NAK> is received, the other system is usually busy handling other requests. The initiating system will wait 10 seconds and try sending the <ENQ> again. The receiving system may also have data to transfer and may send the <ENQ> at the same time. This is called "line contention" and is handled differently in the Osmo1 than in the LIS

system. The Osmo1 will wait 1 second and then try the Establishment Phase again. The LIS system should wait a minimum of 20 seconds or until it sees the link being in the neutral state before trying the Establishment Phase again.

[2] – American National Standards Institute
[3] – Institute of Electrical and Electronics Engineers

Transfer Phase

While in the Transfer Phase the sender transmits messages to the receiver in frames. Each frame contains a maximum of 64,000 characters including frame overhead. While the LIS01-A2 standard states long messages may be sent by being broken up into multiple frames, the Osmo1 software is not currently configured to handle this situation. A frame starts with the <STX> character (ASCII Decimal 2), followed by a frame number which is a single digit from 0 to 7. The first frame in a Transfer begins with frame number 1 and is incremented until it reaches 7 when the next frame has a frame number of 0 and continues to increment as above. The frame number is used to distinguish between new and re-transmitted frames. The message part is terminated with the <ETX> character (ASCII decimal 3) followed by the checksum (see below) and <CR><LF>.

Checksum

The checksum makes it possible to determine if a frame is defective. It is encoded as two ASCII characters and is computed by adding the ASCII decimal values of all the characters in the frame starting with the frame number and ending with the <ETX> character. Only the least significant 8 bits are kept and are converted to hexadecimal digits making up the two ASCII characters.

Acknowledgement

The sender will wait for an acknowledgement from the receiver after each frame is sent. There is a timeout of 15 seconds on receiving the acknowledgement. If a timeout occurs, the Termination phase is entered and in the Osmo1, the entire message is re-queued for transmission. If a reply of <ACK> is received, the transmission was successful and a new frame may be sent. If a reply of <NAK> was received, there was an error during transmission or in the checksum calculation. The frame should be retransmitted for a total of 6 retries. If the limit of 6 occurs, the message should be re-queued for transmission. If a reply of <EOT> (ASCII decimal 4) is received, the receiver requests termination of the transmission. In the Osmo1 this causes the transmission to end and the message is re-queued as above.

Termination Phase

The sender transmits an <EOT> character to indicate all frames have been sent. Both the sender and the receiver consider the link to be in the neutral state after the exchange of the <EOT> character.

Chapter 3

Message Layer

The Message Layer describes content of messages based on the LIS2-A2 standard. Any restrictions and exemptions will be noted when applicable.

Message Content

The following limitations and specifications apply to the message content:

1) Allowed characters are in single byte, eight bit values (Latin-1 character set) in the decimal range 32 – 126 and 128 – 254 plus decimal values 7, 9, 11, 12, and 13. Some fields may be UTF8 encoded as noted below.
2) Maximum field length within a record will be noted in the detailed specification.
3) The Osmo1 as a Sender will always use the suggested delimiters of | as **Field** delimiter, \ as **Repeat** delimiter, ^ as **Component** delimiter and & as **Escape** character.
4) The Osmo1 as a Receiver will handle any other valid set of delimiters (see LIS2-A2 section 5.4).
5) The Osmo1 will not transmit any "null" values to indicate the value has not changed since the last transmission and will not use any received null values.
6) Any received fields not required by the Osmo1 will be ignored and will not be described in the detail sections below.
7) The following record types will not be sent by the Osmo1 and will be ignored if received: Comment (C), Scientific (S), and Manufacturer Information (M).
8) All date/time fields are specified as YYYYMMDDHHMMSS where HH is a specified as a 24 hour time.
9) Universal Test ID fields are used to indicate test type or Quality Control type.

Record Field Contents

In the examples below the overhead characters of <STX> and frame number at the front and checksum plus <CR><LF> at the end are not shown. Optional fields are noted as appropriate.

Header Record

The fields used in this record are as specified in LIS2-A2:

6.1: Record Type ID—**H** identifies the record as a message header record.

6.2: Delimiter Definition—the five Latin-1 characters immediately following the H record type ID define the delimiters to be used throughout the subsequent records of the message. The second character in the header record is the **Field** delimiter, the third character is the **Repeat** delimiter, the fourth character is the **Component** delimiter, and the fifth is the **Escape** character.

6.5: Sender ID—this text field defines the sender. In the Osmo1 this is the instrument type as well as the software version.

6.10: Receiver ID—this text field specifies the name of the receiver. Its purpose is to verify the transmission is indeed for the receiver. In the Osmo1 this is the word LIS.

6.12: Processing ID—Message processing: P=Production (patient test data). Q=Quality control.

EXAMPLE:

H|\^&|||Osmo1^V1.0|||||LIS||P|LIS2-A2|20161110082005<CR><ETX>

Patient Information Record

The fields used in this record are as specified in LIS2-A2:

7.1: Record Type ID—**P** identifies the record as a patient information record.

7.2: Sequence Number—Integer specifying the number of the patient record within the message.

7.3: Practice-assigned ID—Text field specifying a unique patient ID assigned by the practice. This field is optional.

7.4: Laboratory-assigned ID—Text field specifying a unique patient ID assigned by the laboratory. This field is optional.

EXAMPLE:

P|1|PracticeID|LabID<CR><ETX>

Test Order Record

The fields used in this record are as specified in LIS2-A2:

8.4.1: Record Type ID—**O** identifies the record as a test order record.

8.4.2: Sequence Number—Integer specifying the number of the order record for the patient. This will always be 1 for the Osmo1.

8.4.3: Specimen ID—Text field specifying a unique specimen ID assigned by the LIS. This field is optional, but if missing, the Instrument Specimen ID described below will be included. This field is UTF8 encoded.

8.4.4: Instrument Specimen ID—Text field specifying a unique specimen ID assigned by the instrument either from reading a barcode or as entered by an operator. This field is optional, but if missing, the Specimen ID described above must be included.

8.4.5: Universal Test ID—Text field containing up to four parts describing the test. In the Osmo1 case it will always be OSMO.

8.4.6: Priority Flag—Single character field specifying the priority of the test. The only codes recognized by the Osmo1 are **S** for STAT and **R** for routine. This field is optional and if missing, **R** will be assumed.

8.4.7: Requested/ordered Date and Time—Text field specifying the date/time of the order. This could be a time in the future and the system will not look for the specimen until after the time specified. This field is optional.

8.4.8: Specimen Collection Date and Time—Text field specifying the date/time of collecting the specimen. This field is optional.

8.4.10: Collection Volume—Text field specifying the volume of the specimen. If no unit is specified (with a component delimiter), the unit is assumed to be milliliters. This field is optional.

8.4.11: Collector ID—Text field specifying the ID of the specimen collector. This field is optional.

8.4.12: Action Code— Single character specifying the action to be taken when the order is received. See the definition of the codes in the LIS2-A2 document. This field is optional.

8.4.15: Date and Time Specimen Received—Text field specifying the date/time of receiving the order. This field is optional.

8.4.16: Specimen Descriptor—Text field specifying the type of the specimen. The Specimen Source is not used. This field is optional.

8.4.17: Ordering Physician—Text field specifying the name of the ordering physician. Parts of the name should be separated with component delimiters rather than space characters. This field is optional.

8.4.18: Physician's Telephone Number—Text field specifying the telephone number of the ordering physician. This field is optional.

8.4.19: User Field Number 1—Text field sent by the requestor and returned with the response. This field is optional.

8.4.21: Laboratory Field Number 1—Text field definable for any use by the laboratory. This field is optional.

8.4.23: Date and Time Results Reported—Text field specifying the date/time of reporting the order back with the result. The Osmo1 will always include this field in reports sent to the LIS.

8.4.26: Report Type— Single character specifying the type of the report. See the definition of the codes in the LIS2-A2 document. This field is optional.

EXAMPLE:

O|1|3MA005||^^^||20161110082002|20161110082002||0.000|||||20161110082002|||||| ||20161110082002|||<CR><ETX>

Result Record

The fields used in this record are as specified in LIS2-A2:

9.1: Record Type ID—**R** identifies the record as a result record.

9.2: Sequence Number—Integer specifying the number of the result record associated with the preceding test order record. This will always be the replicate number for the Osmo1.

9.3: Universal Test ID—Text field containing up to four parts describing the test. In the Osmo1 case it will contain one four letter code, always OSMO.

9.4: Measured Value—Integer osmolality value.

9.5: Units—Text field specifying the units for the preceding value. This will always be mOsm/Kg H2O for the Osmo1.

9.6: Result Status—Text field describing the status of the test. See the LIS2-A2 document for the possible codes. This field is optional.

9.7: Operator identification—Text field describing the identification of the operator who performed the test and possibly the identification of the test verifier separated by a component delimiter. This field is optional and if present is UTF8 encoded.

9.8: Date/Time of Start of Test—Text field describing the date/time the test was started.

9.9: Date/Time of End of Test—Text field describing the date/time the test finished.

9.10: Instrument Identification—Text field describing the serial number of the Osmo1.

EXAMPLE:

R|1|^^^OSMO|51|mOsm/Kg H2O||N|N|F||OperatorID|20161027142723||
17010095A<CR><ETX>

Request Information Record

This record may be used by the Osmo1 to request the order for a sample if not already present and may also be used by the LIS to request results from previously measured samples.

The fields used in this record are as specified in LIS2-A2:

11.1: Record Type ID—**Q** identifies the record as a request record.

11.2: Sequence Number—Integer specifying the sequence number of the request. This should always be 1 since only one request may be handled at a time.

11.3: Starting Range ID—Text field specifying the starting record to look up. It may have up to three components: the first must be the Patient ID (see sections 7.3 and 7.4) or blank, the second must be the Specimen ID (see sections 8.4.3 and 8.4.4) or blank. For Patient ID and Specimen ID a wildcard character of * may be used to indicate partial matches. This field MUST be present with at least a Patient ID or a Specimen ID (wildcard only is fine).

11.5: Universal Test ID—Text field containing up to four parts describing the test type requested. In the Osmo1 case it will contain one four letter code for test to be reported, always OSMO.

11.6: Nature of Request Time Limits—Text field specifying the base for the time request described below. An **S** specifies Specimen collect date and **R** specifies result test date. This field is optional and **R** is assumed if it is missing.

11.7: Beginning Request Results Date and Time—Text field specifying the oldest date/time to use in the look up. This field is optional and all times are assumed if missing.

11.8: Ending Request Results Date and Time—Text field specifying the newest date/time to use in the look up. This field is optional.

11.9: Requesting Physician Name—Text field specifying the name of the doctor requesting the result. This field is optional.

11.10: Requesting Physician Telephone Number—Text field specifying the telephone number of the doctor requesting the result. This field is optional.

11.11: User Field—Text field specifying any special instructions for the request. This field is optional.

11.13: Requesting Information Status Codes—Text field specifying the status of the request. See the LIS2-A2 document for the codes and their meaning. This field is optional.

EXAMPLE:

Q|1|A*^SP1^0|||R|20110517105358\|DoctorXYZ|123-456-7890|Extra||N
<CR><ETX>

Message Terminator Record

This record is used to signify the end of a message.

The fields used in this record are as specified in LIS2-A2:

12.1: Record Type ID—**L** identifies the record as a terminator record.

12.2: Sequence Number—Integer specifying the sequence number of the request. This should always be 1.

12.3: Termination Code—Single character specifying the status of the message. See the LIS2-A2 document for the possible code. This field is optional and an N for normal will be assumed if missing.

EXAMPLE:

L|1|N<CR>< ETX>

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