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EasyBloodGas™

LIS Interface

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LIS Interface

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The EasyStat and EasyBloodGas analyzer are for In Vitro Diagnostic Use.

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LIS Interface manual

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Introduction

The analyzer has the capability to communicate with a laboratory information system (LIS), based on the CLSI standards LIS02-A2 and LIS01-A2. The communication protocol is not a complete implementation of the standard, but covers those areas that will allow the analyzer to send test results to an LIS consistent with the requirements of the standard. The details of the communication are described in this document.

LIS Functions

The analyzer provides the central LIS function of remote access. Through an attached barcode reader or through the user interface, samples are assigned an ID and upon test completion, results are sent back to the laboratory computer. In addition, the LIS provides a means for configuring and testing the status of the LIS connection.

Communications Protocol

The CLSI communications protocol was designed specifically for medical devices and supports the transfer of an array of medical data. Information about this protocol can be found in publications produced by the CLSI – Designation: LIS02-A2 : "Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems" and Designation: LIS01-A2 : "Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems".

References:

(CLSI. Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems. CLSI document LIS01-A2 [ISBN 1-56238-665-4]. CLSI, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA, 2003.)

(CLSI. Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard–Second Edition.CLSI document LIS02-A2 [ISBN 1-56238-550-X]. CLSI 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA, 2004.)

Operational Overview

Barcoded Samples

The analyzer recognizes barcode labeled sample tubes using one of the following formats: Codebar, Code39, UPC and Interleaved 2 of 5. Barcodes must be no longer than 3.00 inches and have a line width of no less than 0.5mm. A maximum of 14 characters is allocated for the sample ID.

When the analyzer is in the LIS mode of operation a successfully read barcode will be displayed for confirmation at the "Run Sample" menu. If an ID is confirmed the program attaches the ID to the sample for subsequent transmission to the LIS.

Uploaded Test Results

As a test result becomes available a result record is composed, attached to its patient and order record and sent to the LIS.

Data elements in a result record include: sequence number, selected test, result value, units, abnormality flags, operator ID, result status, and time of result. A detailed description of the abnormality flags (Result Flags Code) is included later in this document.

Downloaded order and comment records are not supported. Uploaded comment records are not supported.

The Header Record in a result message will contain sufficient information to determine which analyzer is sending results information should there be more than one analyzer connected to the LIS.

Mechanical and Electrical Interfaces

A standard RS-232 interface cable with a DB9M termination is used to connect the analyzer's computer interface to the laboratory computer. If the laboratory computer connection is not standard RS-232, an interface adapter must be used. The interface uses standard voltage levels and electrical characteristics as defined in the EIA Standard RS-232.

Communications Interface

RS-232 Protocols

The default RS-232 protocols for the analyzer are: 2400 baud, 8 data bits, no parity, and 1 stop bit. The system cannot be configured to alternate settings.

Datalink Layer

The datalink layer supports the CLSI protocol LIS01-A2, Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems. These requirements include the means of establishing communication, error detection, error recovery and the formatting for sending and receiving messages.

Record Processing

The record processing layer specifies the content of the records in accordance with CLSI protocol LIS02-A2, Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems. These requirements define the hierarchical message structure, record and field composition and delimiters.

LIS Application Interface

Record Types

The instrument supports the following record types: Header Record, Patient Record, Order Record, Result Record and Terminator Record. The instrument ignores all other record types.

Record Processing

The tables below describe the contents of the supported fields within the records recognized by the analyzer. Downloaded transmissions apart from acknowledgement and error handling are ignored. A null is assigned to these fields on an upload.

Header Record

Field	Field Type	Download Requirement	Upload Requirement	Max Len	Description
1	Record Type	N	A	1	Required Field containing H
2	Delimiters	N	A	4	Default values: Field Delimiter | Repeat Delimiter \\ Component Delimiter ^ Escape Delimiter &
3	Message ID	N	A	1	Always '1'
5	Sender ID	N	A	10	Serial Number of device sending data
13	Version#	N	A	8	ASTM Protocol Version (LIS02-A2)
14	Date and Time	N	A	14	Date and time of transmission Formatted as YYYYMMDDHHMMSS.

Upload Requirements Field Legend:

N	Never
A	Always

Patient Record

Field	Field Type	Download Requirement	Upload Requirement	Max Len	Description
1	Record Type	N	A	1	Required Field containing P
2	Sequence Number	N	A	1	Starts with 1 for the first patient and is incremented by one for each patient in the transmission
3	Lab Assigned Patient ID	N	A	14	User entered Patient ID (must be numeric)

Upload Requirements Field Legend:

N Never

A Always

Order Record

Field	Field Type	Download Requirement	Upload Requirement	Max Len	Description
1	Record Type	N	A	1	Required Field containing O
2	Sequence Number	N	A	1	Starts with 1 for the first order record and is incremented by one for each additional order record for a patient
3	Specimen ID	N	A	14	Sample ID entered via barcode or interface. Identical to Field 3 of the Patient record
5	Universal Test ID	N	A	8	Contains four components. The first three are null. The fourth component indicates the battery of tests: "ES" on the EasyStat and "EBG" on the EasyBloodGas
8	Collection Time	N	O	14	Date and time of sample collection. Formatted as YYYYMMDDHHMMSS.
16	Sample Type	N	A	11	Indicates sample material: Blood, QC^xxxxxxxx, CAL

Upload Requirements Field Legend:

N	Never
O	Optional
A	Always

Result Record

Field	Field Type	Download Requirement	Upload Requirement	Max Len	Description
1	Record Type	-	A	1	Required Field containing R
2	Sequence Number	-	A	2	Starts with 1 for the first result and is incremented by one for each additional result within the order. Resets to 1 when the results of another order are transmitted.
3	Universal Test ID	-	A	9	Contains four components. The first three are ignored. The fourth component is the Manufacturer's Code (see Analytes Code Table)
4	Test Result	-	A	8	Floating point number if the number of decimal places is configured in the instrument to be greater than 0. An unreportable result is represented by "-E-" or "---"
5	Units of Measure	-	S	8	Configured by the operator for individual analytes
7	Abnormality Flags	-	S	30	Two character code to represent abnormal results (see Result Flag Code table). This field may have multiple components.
9	Result Status	-	A	1	Required field contains F
11	Operator ID	-	O	14	ID of operator running the test
13	Time Test Completed	-	A	14	Date and time of test completion. Formatted as YYYYMMDDHHMMSS.

Upload Requirements Field Legend:

A Always

O Optional

S Sometimes

Terminator Record

Field	Field Type	Download Requirement	Upload Requirement	Max Len	Description
1	Record Type	N	A	1	Required Field containing L
2	Sequence Number	N	A	1	Contains the value 1
3	Termination Code	N	A	1	Contains the value N

Upload Requirements Field Legend:

N	Never
A	Always

Result Flags Code

The following table defines the abnormality flags that may be embedded in a result record. A maximum of two flags may be included within any result record.

Flag	Description	Condition
AA	Air in Cal A	Air bubble was detected in A Calibration Fluid
AB	Air in Cal B	Air bubble was detected in B Calibration Fluid
AC	Air in Rinse	Air bubble was detected in the Rinse Fluid
AD	Cal A mV Drift	Two subsequent Cal A mV measurements differ by more than a specified amount
AS	Air in Sample	Air bubble was detected in Sample Fluid
BC	Cal B or C mV	Cal B or C mV measurements outside the acceptance range
CF	Slope out of Range	Calibration result for an analyte outside of the acceptance range
HW	Hardware Error	Bad A/D converter or Valve Module
LH	Linear Range High	Results are above the test range limits for a particular analyte
LL	Linear Range Low	Results are below the test range limits for a particular analyte
MN	mV Noise	mV readings for one channel differ by more than a specified amount from a mean value
MV	mV Out of Range	mVs are out of range for the specified analyte
NC	Not Calibrated	Channel result not reported because the channel is not calibrated
NF	No Flow	System could not detect either sample or calibration material
NR	Outside Limits	Test result for an analyte is outside the user defined normal or critical range
QC	QC Confidence Range	QC result for an analyte is outside the user-defined limit

Sample Transmission

H|\^&|1||0608031006|||||||LIS02-A2|20141229135714|<cr>
P|1|6363|<cr>
O|1|6363||^^^ES||||||||||Blood|<cr>
R|1|^^^pH|7.137|||NR||F||1366||20141229135700|<cr>
R|2|^^^PCO2|67.6|mmHg||NR||F||1366||20141229135700|<cr>
R|3|^^^PO2|60|mmHg||NR||F||1366||20141229135700|<cr>
R|4|^^^Hct|10|%||LL||F||1366||20141229135700|<cr>
R|5|^^^Na+|115.9|mmol/L||NR||F||1366||20141229135700|<cr>
R|6|^^^K+|2.52|mmol/L||NR||F||1366||20141229135700|<cr>
R|7|^^^Cl-|70.7|mmol/L||NR||F||1366||20141229135700|<cr>
R|8|^^^THb|---|g/dL||||F||1366||20141229135700|<cr>
R|9|^^^pH(T)|7.137|||||F||1366||20141229135700|<cr>
R|10|^^^PCO2(T)|67.6|mmHg||||F||1366||20141229135700|<cr>
R|11|^^^PO2(T)|60|mmHg||||F||1366||20141229135700|<cr>
R|12|^^^TCO2|25.0|mmol/L|||||F||1366||20141229135700|<cr>
R|13|^^^HCO3|22.9|mmol/L||||F||1366||20141229135700|<cr>
R|14|^^^BEb|---|mmol/L||||F||1366||20141229135700|<cr>
R|15|^^^BEecf|-6.4|mmol/L||||F||1366||20141229135700|<cr>
R|16|^^^SBC|---|mmol/L||||F||1366||20141229135700|<cr>
R|17|^^^%sO2c|80.9|%||||F||1366||20141229135700|<cr>
R|18|^^^ctO2|---|mL/dL||||F||1366||20141229135700|<cr>
R|19|^^^ANION-GAP|22.7|mEq/L||||F||1366||20141229135700|<cr>
R|20|^^^A-aDO2|8|mmHg||||F||1366||20141229135700|<cr>
R|21|^^^RI|0.1||||||F||1366||20141229135700|<cr>
L|1|N|<cr>

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