Designation: E 1394 – 97

An American National Standard

Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems[1]

This standard is issued under the fixed designation E 1394; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard covers the two-way digital transmission of remote requests and results between clinical instruments and computer systems. It is intended to document the common conventions required for the interchange of clinical results and patient data between clinical instruments and computer systems. This standard specifies the message content for transferring information between a clinical instrument and a computer system. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standard and interpretable form. This standard does not necessarily apply to general analytical instruments in an industrial analytical nor research and development setting.

1.2 This standard specification is intended to apply to the structure of messages exchanged between clinical instruments and computer systems by means of defined communications protocols. Low-level communications protocols and data transfer requirements are beyond the scope of this standard. A separate specification is available from ASTM detailing a standard for low-level data transfer communications (see Specification E 1381E 1381).

1.3 This standard specifies the conventions for structuring the content of the message and for representing the data elements contained within those structures. It is applicable to all text oriented clinical instrumentation. It has been specifically created to provide common conventions for interfacing computers and instruments in a clinical setting. It would also be applicable to interfacing instruments in clinical practice settings, such as physicians' offices, clinics, and satellite laboratories.

2. Referenced Documents

2.1 *ASTM Standards:*

E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems[2]

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems[2]

E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems[2]

2.2 *ANSI Standards:*[3]

X3.30 ANSI Information System Codes

X3.40 ANSI Information System Codes

X3.43 ANSI Information Systems Codes

X3.50 ANSI Information Systems Codes

2.3 *ISO Standards:*[4]

ISO 5218 Information Interchange-Representation of Human Sexes

ISO 2955-93 Information Processing—Representation of SI and Other Units in Systems with Limited Character Sets

ISO 8859-1: 1987 Information Processing—8-bit single-byte coded graphic character sets—Part 1: Latin Alphabet No. 1

2.3 *Other Standards:*

EIA/TIA-232-E

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *battery*—a group of tests ordered together, for example, an admitting battery. The term *battery* is used in the document synonomously with the term *profile* or *panel*. The test elements within a battery may be characteristic of a single physiologic system, for example, liver function tests, or many different physiologic systems. The battery is simply a convention by which a user can order multiple tests by specifying a single name.

3.1.2 *component field*—a single data element or data elements which express a finer aggregate or extension of data elements which precede it. For example, parts of a field or repeat field entry. As an example, the patient's name is recorded as last name, first name, and middle initial, each of

[1] This specification is under the jurisdiction of ASTM Committee E-31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.14 on Clinical Laboratory Instrument Interface.

Current edition approved Dec. 10, 1997. Published March 1998. Originally published as E 1394 – 91. Last previous edition E 1394 – 91.

[2] *Annual Book of ASTM Standards*, Vol 14.01.

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[4] Available from International Standards Organization, 1 Rue de Varembe, Case Postale 56, Crt1221, Geneva 20 Switzerland.

which is separated by a component delimiter. Components cannot contain repeat fields.

3.1.3 *download*—data transmitted from a computer system to a clinical instrument.

3.1.4 *field*—one specific attribute of a record which may contain aggregates of data elements further refining the basic attribute.

3.1.5 *message*—a textual body of information consisting of a header (H) record through a message terminator (L) record.

3.1.6 *record*—an aggregate of fields describing one aspect of the complete message.

3.1.7 *repeat field*—a single data element which expresses a duplication of the field definition it is repeating. Used for demographics, requests, orders and the like, where each element of a repeat field is to be treated as having equal priority or standing to associated repeat fields.

3.1.8 *test*—a determination of a single analyte or a combination of values from other determinations or observations which constitute a measure of a single system attribute.

3.1.9 *upload*—data transmitted from a clinical instrument to a computer system.

4. Significance and Use

4.1 *General Information*:

4.1.1 This specification provides for two-way transmission allowing for data-flow in either direction. It provides for sending demographic and test information to or from clinical instruments. This specification has sufficient flexibility to permit the addition of fields to existing record types or the creation of new record types to accommodate new test and reporting methodologies.

4.1.2 This specification is related to Specification E 1238E 1238. Both standards use positional convention to define the structure of messages that exchange information about clinical test requests and results. The set of conventions specifies a hierarchical set of records in which the records higher in the hierarchy contain information that is common to all records lower in the hierarchy and thus avoids redundancy in linking data together. The positional convention is simple and direct to implement, requiring only a sequence of strings each having variable length delimited fields which are positionally specified.

4.1.3 Specification E 1238E 1238, in its entirety, is not appropriate for use as a clinical instrument to computer system interface. The conventions of Specification E 1238E 1238 regarding record types and the organization of data elements within the records have been adhered to as closely as possible to ensure that common data elements defined there and used within instruments are specified as closely as possible. This facilitates the use of this specification consistent with Specification E 1238E 1238 in a number of settings. There are three compelling reasons for developing a separate standard which deviates from Specification E 1238E 1238.

4.1.3.1 The scope of Specification E 1238E 1238 is specifically targeted to accommodate information transfer between two independent computer systems requiring shared patient demographic and test result data. Specification E 1238E 1238 contains extensive requirements and limitations, much of which may be of little, if any, use by clinical instrument systems. Further, clinical instruments have test and instrument specific requirements outside the scope of Specification E 1238E 1238 and, as such, are not available within the existing Specification E 1238E 1238.

4.1.3.2 The structure of Specification E 1238E 1238 provides great flexibility in the ordering and reporting of test results and patient demographics. While this is appropriate for use by advanced computer systems of equivalent rank, Specification E 1238E 1238 clearly falls beyond the technical limitations of many clinical laboratory instruments. This specification attempts to identify, and simplify, all complex data structures and interface procedures and, where practical, restrict multiple procedural options to single procedures appropriate for the clinical instrument setting. Further, this specification has attempted to assign a master/slave hierarchy where conflicts may occur, assigning appropriate responsibility for data processing or reporting operations to the party (clinical instrument or computer system) better able to process a particular task. For example, in all cases involving the ordering or reporting of tests, the instrument manufacturer is solely responsible for assigning the test and result ID numbers (see 6.6.1). These reductions in flexibility directly result in increased structure and clarity, which is deemed more appropriate for ensuring successful interface implementation within the clinical instrument setting.

4.1.3.3 Specification E 1238E 1238 was developed independent of data protocol and transfer considerations. Specification E 1238E 1238 uses maximum field and record lengths. Combined with its record level checksum and error recovery facilities, Specification E 1238E 1238 may be implemented without a data protocol layer. By contrast, this message-content specification has been developed in cooperative effort with a correlative ASTM low-level data transfer and protocol specification. While each specification (message-content and low-level protocol) is designed to be independently implemented and maintained, the message-content specification presumes that a protocol layer exists that will handle record blocking/deblocking, error detection and recovery, and other associated data transport tasks. As such, all protocol level operations and limitations existing in Specification E 1238E 1238 are not applicable, and therefore not included in this document.

5. Information Requirements in Clinical Testing

5.1 *General Approach*:

5.1.1 Messages may contain one or more requests/results for one or more patients. Tests may be requested as groups of many individual tests. These groups are referred to as batteries. Examples of batteries are tests produced on a multichannel analyzer, such as a CHEM12, physiological groupings of tests (such as liver function tests) and Minimum Inhibitory Concentration tests (MIC's) in microbiology testing. The fact that a series of tests is contained in a battery does not imply that they are all performed on the same analytic instrument.

5.1.2 Messages consist of a hierarchy of records of various types. Records at level zero contain information pertaining to the sender identification and completion of transmission. Records at level one of the hierarchy contain information about individual patients. Records at level two contain information

about test order requests and specimens. Records at level three contain information about test results.

5.1.3 Comment records may be inserted at any level in the hierarchy. A comment record always relates to the immediately preceding patient, order, result, scientific or manufacturer information record. Therefore, if a comment record were to follow a patient record (level one), then that comment record would be treated as a level two record. A comment record may not follow the message terminator record.

5.1.4 Manufacturer information records may be inserted at any level in the hierarchy. This record type always relates to the immediately preceding patient, order, result, scientific or comment record. Therefore, if a manufacturer information record were to follow a patient record (level one), then the record would be treated as a level two record. This record may not follow the message terminator record.

5.1.5 Additional record types are the request-information record and the terminator record. The request-information record provides for the request of demographics or test results to or from the clinical instrument for specified patients, specimens, tests, and dates, and the like. The message terminator record must be the very last record of the message.

5.1.6 The smallest element of information in any record is the field, containing a single item of information, such as a date, a patient name, or a numeric test result.

5.1.7 The test order record contains information about ordering a single test, test battery, or a series of tests or batteries, as discussed in 6.5.3 and Section 9.

5.1.8 Most of the record types are related to each other in a definite hierarchy. At level zero is the message header and message terminator. At level one is the patient record, the request-information record and the scientific record. At level two is the test order record. At level three is the result record. The comment and manufacturer information records do not have an assigned level.

5.1.9 A sequence of patient records, order records, or result records at one level is terminated by the appearance of a record type of the same or higher level. Thus, a sequence of results for one battery of tests is terminated by the next test order, patient, manufacturer information, request information, or message terminator record.

5.1.10 An order record may never appear without a preceding patient record and a result record may never appear without a preceding order record.

5.1.11 When an order is transmitted, it must be preceded by a patient record. All orders that follow apply to the patient in the preceding patient record. When a result is transmitted, it must be preceded by an order record and a patient record to maintain the prescribed hierarchy.

5.1.12 Each instrument manufacturer adhering to this standard may decide which fields are applicable for their particular application with the exception of those fields necessary to identify the record type or parse individual fields. Thus the need to send the hierarchy of records need not generate large messages.

5.2 *Logical Structure of the Message Level Protocol*—See Fig. 1.

```
(Level 0)  HEADER
(Level 1)      MANUFACTURER INFORMATION 1
(Level 1)      PATIENT 1 (general information about patient)
(Level 2)          COMMENT Record (relates to previous patient record)
(Level 2)          ORDER 1 (information about the first battery requested)
(Level 3)              COMMENT 1 Record (Relates to ORDER 1)
(Level 3)              RESULT 1 (information about the first result of battery 1)
(Level 3)              RESULT 2 (information about the second result of battery 1)
(Level 4)                  COMMENT 1 Record (Relates to RESULT 2)
(Level 4)                  COMMENT 2 Record (Relates to RESULT 2)
                       .
                       .
                       .
                       RESULT n (information about the last result of battery 1)
(Level 2)          ORDER 2 (information about battery 2)
                       RESULT 1 (information about the first result of battery 2)
                       RESULT 2 (information about the second result of battery 2)
                       .
                       .
                       .
                       RESULT n (information about the last result of battery 2)
                   .
                   .
(Level 2)          ORDER n (information about the last battery for the first patient)
(Level 3)              RESULT 1 (First result of the last order)
                       .
                       .
                       .

(Level 1)      PATIENT 2 (All of the structure repeats)
                   .
                   .
(Level 1)      PATIENT n

(Level 0)  MESSAGE TERMINATOR
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FIG. 1 Logical Structure of a Message

5.2.1 *Logical Information Storage Requirements*—In order to determine buffering requirements, both transmitter and receiver must use common rules for storing transmitted data in order to ensure proper error logging and error recovery procedures (see 5.2.2). Since data content is structured in a hierarchical fashion, any decremental change in the hierarchical level shall trigger storage of all data transmitted prior to said level change. This rule may be considered as the minimal implementation. Data may be saved at more frequent intervals at the receiver's option. See Fig. 2.

5.2.2 *Logical Transmission Error Recovery Requirements*—Transmission line failure, determined at the transmission

Line #	Record Type	(Level) Increment	Action
A	Header	(Level 0)+0	
B	Patient 1	(Level 1)+1	
C	Order 1	(Level 2)+1	
D	Result 1	(Level 3)+1	
E	Order 2	(Level 2)-1	{ Save A-D }
F	Order 3	(Level 2)+0	
G	Patient 2	(Level 1)-1	{ Save E-F }
H	Order 1	(Level 2)+1	
I	Comment 1	(Level 3)+1	
J	Result 1	(Level 3)+0	
K	Comment	(Level 4)+1	
L	Result 2	(Level 3)-1	{ Save G-K }
M	Order 2	(Level 2)-1	{ Save L }
N	Patient 3	(Level 1)-1	{ Save M }
O	Order 1	(Level 2)+1	
P	Result 1	(Level 3)+1	
Q	Message Terminator	(Level 0)-3	{ Save N-P }

NOTE 1—Q is assumed as saved by virtue of the record type function
NOTE 2—Given the following example, permanent storage of data, by the receiver, should occur at points; E, G, L, M, N, Q.

FIG. 2 Logical Information Storage Requirements