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Zdravstvena informatika ï Vmesniki kliniļnih analizatorjev do laboratorijskih informacijskih sistemov ï Profili uporabe (ISO 18812:2003)

Health informatics - Clinical analyser interfaces to laboratry information systems - Use profiles (ISO 18812:2003)

Informatique de santé - Interfaces d'analyseur clinique pour systemes d'information de laboratoire - Profils d'utilisation (ISO 18812:2003)

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Informatique de santé - Interfaces d'analyseur clinique pour systèmes d'information de laboratoire - Profils d'utilisation (ISO 18812:2003)

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Foreword

This document (EN ISO 18812:2003) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

This document supersedes ENV 13728:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom.

NOTE FROM CMC The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of ISO 18812:2003 has been approved by CEN as EN ISO 18812:2003 without any modifications.

INTERNATIONAL STANDARD

ISO 18812

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Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles

Informatique de santé — Interfaces d'analyseur clinique pour systèmes d'information de laboratoire — Profils d'utilisation

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18812 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard describes messages for the transfer of data between analytical instruments (AIs) and laboratory information systems (LISs).

AIs are mainly used in hospital laboratories to analyse samples from patients. Most of these are interfaced to LISs that process the result data and produce reports for use by healthcare practitioners. In the absence of standards for the interface, each LIS supplier has to write a new interface for each new analytical instrument. The cost of writing these interfaces can amount to between 10 % and 20 % of the total cost of the LIS. One of the most effective ways of reducing this cost is to implement a standard interface between the AI and the LIS.

In the early 1990s, the E31 committee of the American Society for Testing and Materials (ASTM) published a standard entitled *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems* (ASTM E1394-91). This improved the situation by standardizing the format of the message and the syntax. It also attempted to standardize the data transferred in the messages, but suffered from implementation problems because:

— the vast choice of data items available gave implementers the choice to send the same data in many different ways;

— the relative lack of implementation guidelines meant that different implementers interpreted the same clauses of the standard in different ways;

— much of the information that is defined in the standard is intended for use in North America and does not cover international requirements.

The result of this is that each AI supplier has produced its own "standard", based loosely on ASTM E1394. Whereas this has made interfacing easier for the analytical instrument suppliers, the LIS suppliers are still faced with the need to write a different interface for most of the analytical instruments installed in a given laboratory.

In particular, the LIS interface designer has to, in theory, take into account any implementation allowed by ASTM E1394. This means that even simple AIs are normally handled by using a hugely complex interface on the LIS.

ASTM E1394-91 was reissued with minor revisions in 1997 as ASTM E1394-97.

This International Standard is intended to make interfaces between AIs and LISs simpler to implement by

— defining standard ways of conveying the same information in the same circumstances;

— defining a series of levels of complexity so that it is possible to interface a simple AI using only easy-to-implement messages;

— adapting the original standard to cover actual requirements;

— giving advice and guidance on how particular data items and functions should be implemented so as to reduce misinterpretation.

This is done by defining a series of standard messages, each of which is a subset of a comparable ASTM E1394 message. These are detailed in Clause 6. Examples of scenarios covered by this International Standard, together with models and sequence diagrams, are given in Annex B. An informative implementation guide for both ASTM E1394 and this International Standard is given in Annex C.

There is a trend for all clinical laboratories to be certified or accredited under a suitable quality management scheme. ISO/IEC 17025 require the laboratory to keep records of certain data. This means that, for the support of the users when conforming to the standard, the instruments and LIS have to be capable of handling this data (input, storage, validation, output), and also of transmitting it. This is especially important in functions that produce large amounts of data that cannot be handled effectively without automated processing. Typically, this is a task for the LIS, but certain items have to originally come from the instrument. ASTM E1394 does not explicitly handle data needed for quality management. In principle, it is capable of doing so, but the needed fields have to be defined.

This has been achieved in this International Standard by making recommendations as to which fields shall be implemented in order to satisfy the needs of quality management. These are identified in the implementation guideline included as Annex C.

This International Standard includes provisions for using existing ASTM E1394 records and fields to meet quality management requirements.

This International Standard defines records that are subsets of records defined in ASTM E1394. Therefore, all implementations conforming to this International Standard also conform to ASTM E1394. It should be noted, however, that not all implementations that conform to ASTM E1394 will conform to this International Standard.

Those not familiar with some of the concepts, e.g. profiling, described here should first refer to Annex A.

Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles

1 Scope

This International Standard specifies general messages for electronic information exchange between analytical instruments (AIs) and laboratory information systems (LISs) within a clinical laboratory. It is applicable to the specialities of clinical chemistry/biochemistry, haematology, toxicology, microbiology, virology and immunology. It is not applicable to the blood transfusion and blood bank speciality

This International Standard covers the specification of messages used by communicating parties and the syntax in which they are communicated. It does not cover the transport mechanisms used for the message interchange.

This International Standard is applicable only to character-based message information. It is not applicable to the communication of graphical or image information.

NOTE The provisions for this International Standard have been validated in the domains and for the purposes described above. However, messages conforming to this International Standard may be considered by some user communities to meet their needs for purposes outside this scope. Use of the messages in these circumstances is not precluded by the scope.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM E1394-97[1)], *Standard Specification for Transferring Information between Clinical Instruments and Computer Systems*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
analyte
component indicated in the name of a measurable quantity

3.2
analytical instrument
AI
named set of equipment that provides implementations of laboratory services

NOTE 1 In ASTM E1394, the term “Clinical Laboratory Instrument” or “Clinical Instrument” is used.

1) Available from www.astm.org.

NOTE 2 Workstations in laboratories can carry out communication between AIs and LISs. Such workstations can assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS. Therefore, a workstation connected between an AI and an LIS may, in some circumstances, be considered as an AI, or, in other circumstances, as a LIS.

3.3
battery
group of analytical instrument investigations ordered together

NOTE This supplies a convention by which the user (the LIS) can order multiple analytical instrument investigations by specifying a single name.

3.4
component
single data element or data elements that express a finer aggregation or extension of data elements that precede it

NOTE A part of a field or repeat field entry is a component. As an example, the patient's name is recorded as three components: last name, first name and middle initial, each of which is separated by a component delimiter (components cannot contain repeat fields).

3.5
download
transmission of data from an LIS to an AI

3.6
field
specific attribute of a record that may contain a single data element or aggregates of data elements

3.7
laboratory information system
LIS
information system which can provide services to one or more analytical instruments

NOTE 1 In ASTM E1394, the term “Computer System” is used.

NOTE 2 Workstations in laboratories can carry out communication between AIs and LISs. Such workstations can assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS. Therefore, a workstation connected between an AI and an LIS may, in some circumstances, be considered as an AI, or, in other circumstances, as an LIS.

3.8
loadlist
subset of one or more worklists specifically assigned to an analytical instrument

3.9
order
set of one or more analytical instrument investigation requests submitted to an analytical instrument

3.10
profile
restricted subset of a standard intended for a particular purpose

3.11
record
aggregate of fields describing one aspect of the complete message

3.12
repeat field
field containing one or more data elements, each of which is to be treated as having equal priority or standing

NOTE The repeat field is used for demographics, requests, orders, etc. For example, the repeat field “Test ID” may contain the three individual test IDs “Na”, “K” and ”Ca”.

3.13
request
request for a single laboratory service and a corresponding analytical instrument procedure to be carried out in respect of a specified subject of investigation

3.14
result
set of information including all essential or useful data relevant to the result of a single analytical instrument investigation and a corresponding analytical instrument procedure

3.15
sample
one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these

NOTE 1 In this context, “system” refers to a system under investigation, e.g. a human body, rather than a computer system.

NOTE 2 The term "specimen" is used in ASTM E1394 to denote the term “sample”.

3.16
test
determination of a single analyte or a combination of values from other determinations or observations that constitute a measure of a single system attribute

NOTE In this context, “system” refers to a system under investigation, e.g. a human body, rather than a computer system.

3.17
trigger event
action or event causing a message to be sent

3.18
upload
transmission of data from an AI to an LIS

3.19
worklist
defined set of requested analytical instrument investigations that can be assigned to an analytical instrument

4 Domains

4.1 User domain

This International Standard has been specifically created to provide common conventions for interfacing AIs and LISs in a clinical laboratory environment. It is also applicable to the interfacing of AIs to computers in other clinical practice settings, such as physicians' offices, clinics and satellite laboratories. It is not applicable to applications with a continuous flow of results from only one (or a few) implicitly identified subjects of investigation, such as is found in the monitoring of vital signs. It may not be applicable to situations where the AI is remote from the laboratory that controls it, i.e. near patient testing (NPT) or point of care (POC) AIs.

4.2 Interface domain

This applies to communication between parties where one party will assume the role of an AI and the other party will assume the role of an LIS. It is therefore also intended for communication involving independent workstations in the laboratory environment where these are capable of carrying out functions of communication between AIs and LISs. Such workstations may assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS.

5 Conformity

Messages for transmission of information between AIs and LISs covered in this International Standard shall use only the message types, records, fields and values specified in Clause 6.

Implementations conforming to this International Standard shall be in accordance with one of the profiles specified in Clause 6.

Conformity to a profile specified in Clause 6 shall entail support of the messages and records defined for that profile in 6.3, and the sequence of messages for that profile specified in 6.4.

When claiming conformity to this International Standard, implementations shall state to which of the profiles defined in Clause 6 the messages conform.

6 Profiles

6.1 General

This clause specifies the profiles to which implementations shall conform. For each profile it specifies

— the messages that shall be supported;

— the message sequence that shall be supported;

— the records allowed within each message;

— the optionality of the fields within the message;

— the values allowed within each field.

The sequence of messages that shall be supported by each profile are specified in 6.4.

6.2 Message descriptions

An overview of each message is given in Table 1.

Table 1 — Message descriptions

Message identifier	Message title	Comment
M1	Result	For sending results from AI to LIS
M2	Results by query	For sending results from AI to LIS in response to a query for results message (M6) sent from LIS to AI[a]
M3	Results by query	For sending results from LIS to AI in response to a query for results message (M6) sent from AI to LIS[a]
M4	Order	For sending orders from LIS to AI, either unsolicited or in response to a query for order message (M5)
M5	Query for order	For sending a query for an order from AI to LIS
M6	Query for results	For sending a query for results from LIS to AI, or AI to LIS

[a] ASTM E1394 requires different fields to be supported for records containing results in response to queries and different fields depending on the direction of the response message. There are no such requirements for order messages.

6.3 Profile descriptions

The messages included in each profile, the direction of message flow and the records included in each message are specified in Table 2.

Table 2 — Profile descriptions

Profile	Description	Direction[a]	Message[b]	Record[c]
P1	Simple profile for the transfer of results from AI to LIS	AI → LIS	M1: Result	H, L, P, O, R, C
P2	Simple profile for the transfer of orders from the LIS to the AI, and for the transfer of results from the AI to the LIS	LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
P3	Bidirectional query profile for the transfer of order queries from the AI to the LIS, orders from the LIS to the AI, and results from the AI to the LIS	AI → LIS	M5: Query for order	H, L, Q
		LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
P4	Bidirectional query profile for the transfer of order queries from the AI to the LIS, orders from the LIS to the AI, result queries from the LIS to the AI, orders from the LIS to the AI, and results from the AI to the LIS	AI → LIS	M5: Query for order	H, L, Q
		LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
		LIS ↔ AI	M6: Query for results	H, L, Q
		AI → LIS	M2: Results by query	H, L, P, O, R, C
		LIS → AI	M3: Results by query	H, L, P, O, R, C
P5	Implementation compliant only with either/both ASTM E1394	(no restrictions)	(no restrictions)	(no restrictions)

a The sequence of messages that shall be supported by each profile is detailed in 6.4.

b The message identifiers correspond to the entries in Table 1.

c H = message header record; L = terminator record; P = patient information record; O = test order record; R = result record; C = comment record; Q = request information record.

6.4 Sequence diagrams

6.4.1 Profile P1

Implementations of profile P1 shall support the following sequence of messages.