

**BUREAU OF INDIAN STANDARDS**

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भारतीय मानक मसौदा  
स्वास्थ्य सूचना विज्ञान - एच एल 7 इलेक्ट्रॉनिक स्वास्थ्य रिकार्ड-प्रणाली  
कार्यात्मक मॉडल, रिलीज़ 2.1 ( ईएचआर एफएम )  
[IS/ISO 10781 : 2015 का पहला पुनरीक्षण]

*Draft Indian Standard*

**Health Informatics — HL7 Electronic Health Record-System  
Functional Model, Release 2.1 (EHR FM)**

*[First Revision of IS/ISO 10781 : 2015]*

[ICS 35.240.80]

Health Informatics Sectional Committee, MHD 17

Last date for comments:  
13 April 2024

**NATIONAL FOREWORD**

*(Adoption clause will be added later)*

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 13606-1, Health informatics — Electronic health record	IS 18301 (Part 1) : 2023/ ISO 13606-1:2019, Health informatics Electronic health record	Identical

communication — Part 1: Reference model	communication : Part 1 Reference model	
ISO 13606-2, Health informatics — Electronic health record communication — Part 2: Archetype interchange specification	IS 18301 (Part 2) : 2023/ ISO 13606-2:2019, Health informatics Electronic health record communication : Part 2 Archetype interchange specification	Identical
ISO 13606-3, Health informatics — Electronic health record communication — Part 3: Reference archetypes and term lists	IS 18301 (Part 3) : 2023/ ISO 13606-3:2019, Health informatics Electronic health record communication Part 3 Reference archetypes and term lists	Identical
ISO 13606-4, Health informatics — Electronic health record communication — Part 4: Security	IS 18301 (Part 4) : 2023/ ISO 13606-4:2019, Health informatics Electronic health record communication Part 4 Security	Identical
ISO 13606-5, Health informatics — Electronic health record communication — Part 5: Interface specification	IS 18301 (Part 5) : 2023/ ISO 13606-5:2019, Health informatics Electronic health record communication Part 5 Interface specification	Identical
ISO 13940:2015, Health Informatics – System of concepts to support continuity of care	IS/ISO 13940 : 2015, Health Informatics - System of Concepts to Support Continuity of Care	Identical
ISO/TR 20514:2005, Health Informatics – Electronic health record – definition, scope and context	IS/ISO/TR 20514 : 2005, Health informatics - Electronic health record - Definition, scope and context	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

<i>International Standard/ Other Publication</i>	<i>Title</i>
ASTM E1769:1995	Standard guide for properties of electronic health records and record systems
	HL7 Fast Health Interoperable Resources (FHIR), Release 4, January 2019

HL7 FHIR Record Lifecycle Event Implementation Guide,  
part of FHIR Core Release 4, January 2019

ISO 21089:2018

Health Informatics – Trusted End-to-End Information Flows

## Scope

### 1.1 EHR-S Functional Model Scope

The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings, realms, services and specialties, enables a standardized description and common understanding of functions sought or available in a given setting (e.g., intensive care, cardiology, office practice in one country or primary care in another country).

The HL7 EHR-S Functional Model defines a standardized model of the functions that may be present in EHR Systems. From the outset, a clear distinction between the EHR as a singular entity and systems that operate on the EHR – i.e., EHR Systems is critical. This Standard makes no distinction regarding implementation - the EHR-S described in a Functional Profile may be a single system or a system of systems. Within the normative sections of the Functional Model, the term “system” is used generically to cover the continuum of implementation options. This includes “core” healthcare functionality, typically provided by healthcare-specific applications that manage electronic healthcare information. It also includes associated generic application-level capabilities that are typically provided by middleware or other infrastructure components. The latter includes interoperability and integration capabilities such as location discovery and such areas as cross application workflow. Interoperability is considered both from semantic (clear, consistent and persistent communication of meaning) and technical (format, syntax and physical connectivity) viewpoints. Further, the functions make no statement about which technology is used, or about the content of the electronic health record. The specifics of 'how' EHR systems are developed or implemented is not considered to be within the scope of this model now or in the future. This EHR-S Functional Model does not address or endorse implementations or technology, nor does it include the data content of the electronic health record.

Finally, the EHR-S Functional Model supports research needs by ensuring that the data available to researchers follow the required protocols for privacy, confidentiality, and security. The diversity of research needs precludes the specific listing of functions that are potentially useful for research.

This Functional Model is not:

- a messaging specification
- an implementation specification
- a conformance specification
- an EHR specification
- a conformance or conformance testing metric
- an exercise in creating a definition for an EHR or EHR-S

It is important to note that the EHR-S Function Model does not include a discussion of clinical processes or the interaction of the healthcare actors. However, ISO 13940 Health Informatics – System of Concepts to Support Continuity of Care, is an international standard that does

outline key principles and processes in the provision of healthcare. It is recommended that users of the EHR-S FM refer to this standard for clinical processes that EHR systems support.

This EHR-S Functional Model package includes both Reference and Normative sections. Table 1 explains the differences between Reference and Normative sections.

Table 1 — Normative Status Types

Status	Description
Reference	Content of the EHR-S Functional Model Package that contains information which clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted as part of the standard.
Normative	Content that is part of the EHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7 procedures for Balloting Normative Documents. This HL7 developed Functional Model document has been successfully balloted as a normative standard by the HL7 organization.

Each section within this document is clearly labeled "Normative" if it is normative. For example, in section 5 (Overview) section 5.3 is normative. In section 7, Conformance Clause; sections 7.1 through 7.6 are normative.

In the external Annex A, Function List, the Function ID, Function Name, Function Statement, and Conformance Criteria components are Normative in this Functional Model.

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The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO 10781:2023 or kindly contact:

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