DIN EN ISO 10781:2025-11 (E)

Health informatics - HL7 Electronic Health Records-System Functional Model, Release 2.1 (EHR FM) (ISO 10781:2023); English version EN ISO 10781:2025

Contents

Page

Foreword v

0 Introduction vii
0.1 Notes to Readers vii
0.2 Changes from Previous Release vii
0.3 Background viii
0.3.1 What are Electronic Health Record Systems? viii
0.3.2 How were the Functions Identified and Developed? viii

1 Scope 1
1.1 EHR-S Functional Model Scope 1

2 Normative References 2

3 Terms and Definitions 2

4 Overview and Definition of the Functional Model (Normative) 3
4.1 Sections of the Function List 4
4.2 Functional Profiles 5
4.3 EHR-S Function List Components 5
4.3.1 Function ID (Normative) 6
4.3.2 Function Type (Reference) 6
4.3.3 Function Name (Normative) 7
4.3.4 Function Statement (Normative) 7
4.3.5 Description (Reference) 7
4.3.6 Conformance Criteria (Normative) 7

5 Anticipated Uses (Reference) 7
5.1 Development Approach: Functional Profiles 7
5.1.1 Scenario 1 – Group Practice 8
5.1.2 Scenario 2 - Hospital 8
5.1.3 Scenario 3 - IT Vendor 8
5.2 Examples of Current Use 8
5.2.1 Functional Profile for Clinical Research based on the EHR-S FM 8
5.2.2 AHRQ adopts Health Level Seven International (HL7) Child Health Functional Profile Specification, Release 1 and incorporates key functionalities in the Children's Electronic Health Record Format 9
5.2.3 Linking clinical content descriptions to the EHR-S FM (Reference) 9

6 Conformance Clause 10
6.1 Introduction (Reference) 10
6.2 Scope and Field of Application (Normative) 10
6.3 Concepts (Normative) 10
6.3.1 Functional Profiles 10
6.3.2 Conformance Model 11
6.3.3 Profile Traceability 12
6.4 Normative Language (Normative) 12
6.5 Conformance Criteria (Normative) 13
6.5.1 Criteria in the Functional Profile 13
6.5.2 'Dependent SHALL' Criteria 13
6.5.3 Referencing Other Criteria or Functions 13
6.6 Functional Model Structure and Extensibility (Normative) 13
6.6.1 Hierarchical Structure 13
6.6.2 Naming Convention 14
6.6.3 Priorities 14

6.6.4 Extensibility 15
6.7 Functional Profile Conformance (Normative) 15
6.7.1 Rules for Functional Domain Profiles 15
6.7.2 Rules for Creating New Functions in Functional Profiles 16
6.7.3 Rules for Derived Functional Profiles 18
6.7.4 Conformance Statement 18
6.7.5 Rules for Functional Companion Profiles 18
6.8 Use Cases and Samples (Reference) 19
6.8.1 Functional Profile Use Cases 19
6.8.2 Sample Functional Domain Profile Conformance Clauses 20
6.8.3 Interpreting and Applying a Conditional 'SHALL' (Reference) 20
6.8.4 General Concepts 21
6.8.5 Rationale for 'Dependent SHALL' 21
6.8.6 How to Apply the 'Dependent SHALL' 22

7 EHR System Conformance Claim via Self-Attestation 23

8 Glossary 24
8.1 Preface (Reference) 24
8.2 Introduction (Normative) 24
8.3 Overview (Reference) 24
8.4 The Action-Verb Structure (Normative) 24
8.4.1 Secure (System) Hierarchy 24
8.4.2 Data Management Hierarchy 25
8.4.3 How Action-Verbs are defined 26
8.4.4 Deprecated Action-Verbs 31
8.5 Guidelines for Use (Reference) 34
8.5.1 General Guidance 34
8.5.2 Constructing Rigorous Conformance Criteria 35

9 Glossary Supplement: Record Lifecycle Events and Descriptions (Normative) 36

9.1 Record Lifecycle Events (See RI.1.1.1) 36

Annex A (normative) Function List 38

Annex B (informative) Glossary of Terms for the EHR-S FM 39

Annex C (informative) Background 67
C.1 What is HL7? 67
C.2 The HL7 Electronic Health Records Work Group 67

Bibliography 68