ISO/IEEE 11073-10425:2019-03 (E)

Health informatics - Personal health device communication - Part 10425: Device specialization - Continuous gl ucose monitor (CGM)

Contents

1. Overview 12
   1.1 Scope 12
   1.2 Purpose 12
   1.3 Context 12

2. Normative references 13

3. Definitions, acronyms, and abbreviations 13
   3.1 Definitions 13
   3.1 Acronyms and abbreviations 14

4. Introduction to ISO/IEEE 11073 personal health devices (PHDs) 15
   4.1 General 15
   4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs 15
   4.3 Compliance with other standards 16

5. Glucose monitoring concepts and modalities 16
   5.1 General 16
   5.2 Device types 17
   5.3 CGM agent-to-manager communication 18
   5.4 Collected data 19
   5.5 Stored data 20

6. Continuous glucose monitor (CGM) domain information model (DIM) 20
   6.1 Overview 20
   6.2 Class extensions 21
   6.3 Object instance diagram 21
   6.4 Types of configuration 22
   6.5 Profiles 23
   6.6 MDS object 23
   6.7 Numeric objects 26
   6.8 Real-time sample array objects 36
   6.9 Enumeration objects 36
   6.10 PM-store objects 40
   6.11 Scanner objects 44
   6.12 Class extension objects 44
   6.13 CGM information model extensibility rules 44

7. CGM service model 45
   7.1 General 45
   7.2 Object access services 45
   7.3 Object access event report services 47

8. CGM communication model 47
   8.1 Overview 47
   8.2 Communication characteristics 47
   8.3 Association procedure 48
   8.4 Configuring procedure 49
   8.5 Operating procedure 51
   8.6 Time synchronization 51

9. Test associations 51
9.1 Behavior with standard configuration 51
9.2 Behavior with extended configurations 52

10. Conformance 52
10.1 Applicability 52
10.2 Conformance specification 52
10.3 Levels of conformance 53
10.4 Implementation conformance statements (ICSs) 53

Annex A (informative) Bibliography 59

Annex B (normative) Any additional ASN.1 definitions 60
B.1 PHD DM status, CGM status, and measurement status bit mappings 60
B.2 Numeric extension for measurement confidence 61
B.3 Capability-mask 62
B.4 State-flag 62

Annex C (normative) Allocation of identifiers 64
C.1 General 64
C.2 Definitions of terms and codes 64
C.3 Systematic derivations of terms and codes 66

Annex D (informative) Message sequence examples 69

Annex E (informative) Protocol data unit examples 71
E.1 General 71
E.2 Association information exchange 71
E.3 Configuration information exchange 74
E.4 GET MDS attributes service 77
E.5 Data reporting 79
E.6 Disassociation 79

Annex F (informative) Revision history 80