DIN EN ISO 11073-10419:2016-10 (E)

Health informatics - Personal health device communicatio n - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2016); English version EN ISO 11073-10419:2016

Contents

1. Overview 1
   1.1 Scope 1
   1.2 Purpose 2
   1.3 Context 2

2. Normative references 2

3. Definitions, acronyms, and abbreviations 3
   3.1 Definitions 3
   3.2 Acronyms and abbreviations 4

4. Introduction to ISO/IEEE 11073 personal health devices 5
   4.1 General 5
   4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs 6
   4.3 Compliance with other standards 6

5. Insulin pump device concepts and modalities 7
   5.1 General 7
   5.2 Device types 8
   5.3 Collected data 8
   5.4 Stored data 14
   5.5 Scheduled data 15

6. Insulin pump domain information model 15
   6.1 Overview 15
   6.2 Class extensions 15
   6.3 Object instance diagram 15
   6.4 Types of configuration 17
   6.5 Profiles 18
   6.6 Medical device system object 18
   6.7 Numeric objects 21
   6.8 Real-time sample array objects 35
   6.9 Enumeration objects 36
   6.10 PM-store objects 41
   6.11 Schedule-store objects 46
   6.12 Scanner objects 55
   6.13 Class extension objects 55
   6.14 Insulin pump information model extensibility rules 56

7. Insulin pump service model 56
   7.1 General 56
   7.2 Object access services 56
   7.3 Object access event report services 58

8. Insulin pump communication model 59
8.1 Overview 59
8.2 Communications characteristics 59
8.3 Association procedure 60
8.4 Configuring procedure 61
8.5 Operating procedure 63
8.6 Time synchronization 64
9. Test associations 64
9.1 Behavior with standard configuration 64
9.2 Behavior with extended configurations 64

10. Conformance 64
10.1 Applicability 64
10.2 Conformance specification 65
10.3 Levels of conformance 65
10.4 Implementation conformance statements 66

Annex A (informative) Bibliography 71

Annex B (normative) Any additional ASN.1 definitions 72
B.1 Device status and insulin pump status bit mapping 72

Annex C (normative) Allocation of identifiers 74
C.1 General 74
C.2 Definitions of terms and codes 74
C.3 Systematic derivations of terms and codes 76

Annex D (informative) Message sequence examples 85

Annex E (normative) Schedule-store class 87
E.1 Schedule-store class 87
E.2 Schedule-segment class 91

Annex F (normative) Schedule class ASN.1 definitions 97
F.1 ACTION-method-related data types 97
F.2 Data types for new object attributes and object services 97
F.3 Data protocol definitions 100

Annex G (informative) The schedule-store concept 102
G.1 General 102
G.2 Schedule-store object hierarchy 103

Annex H (informative) Scedule communication model 107
H.1 Operating procedure 107

Annex I (informative) Protocol data unit examples 112
I.1 General 112
I.2 Association information exchange 112
I.3 Configuration information exchange 116
I.4 GET MDS attributes service 120
I.5 Data reporting 121
I.6 Disassociation 122