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2014-03-01

Corrected version  
2014-06-01

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**Health informatics — Personal health  
device communication —**

Part 10417:

**Device specialization: Glucose meter**

*Informatique de santé — Communication entre dispositifs de santé  
personnels*

iTeh **STANDARD PREVIEW**  
*Partie 10417: Spécialisation des dispositifs: Glucomètre*  
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ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

- *Part 00103: Overview*
- *Part 10101: (Point-of-care medical device communication) Nomenclature*
- *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*
- *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*
- *Part 10201: (Point-of-care medical device communication) Domain information model*

## ISO/IEEE 11073-10417:2014(E)

- Part 10404: Device specialization — Pulse oximeter
- Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)
- Part 10407: Device specialization — Blood pressure monitor
- Part 10408: Device specialization — Thermometer
- Part 10415: Device specialization — Weighing scale
- Part 10417: Device specialization — Glucose meter
- Part 10418: Device specialization — International Normalized Ratio (INR) monitor
- Part 10420: Device specialization — Body composition analyzer
- Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)
- Part 10441: Device specialization — Cardiovascular fitness and activity monitor
- Part 10471: Device specialization — Independent living activity hub
- Part 10472: Device specialization — Medication monitor
- Part 20101: (Point-of-care medical device communication) Application profiles — Base standard
- Part 20601: Application profile — Optimized exchange protocol
- Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected
- Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless
- Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet
- Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test
- Part 91064: (Standard communication protocol) Computer-assisted electrocardiography
- Part 92001: (Medical waveform format) — Encoding rules

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- On the cover page "First edition" has been replaced by "Second edition" and a sentence giving this revision information has been added in the Foreword.

Health Informatics—Personal health device communication

# Part 10417: Device specialization— Glucose meter

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**Abstract:** Within the context of the ISO/IEC 11073 family of standards for device communication, a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability are specified. A common core of communication functionality for personal telehealth glucose meters is defined in this standard.

**Keywords:** glucose meter, IEEE 11073-10417, medical device communication, personal health devices

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## Introduction

This introduction is not part of IEEE Std 11073-10417-2011, Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2010<sup>a</sup> and describes a specific, interoperable communication approach for glucose meters. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

## Revision history for IEEE Std 11073-10417

IEEE Std 11073-10417-2009	Initial release of the standard.
IEEE Std 11073-10417-2011	<p>The following changes were implemented in this revision:</p> <ul style="list-style-type: none"> <li>a) In Table 6, the Supplemental-Type attribute was changed from Conditional to Optional.</li> <li>b) In the fourth paragraph of 6.9.1, the first sentence was reworded to specify that the agent init will be disabled when a PM-store is present.</li> <li>c) In the second paragraph of 6.9.1, the use cases associated with agent-init versus manager-init transmission of measurement data were clarified.</li> <li>d) In Annex B, “Numeric class” to “Enumeration class” was corrected.</li> <li>e) A new standard configuration was added, which affects the following: <ul style="list-style-type: none"> <li>1) New paragraph in 6.4.2.</li> <li>2) Added a new Control Solution object separate from the Blood Glucose object (6.6.7).</li> <li>3) Removed MDC_CONC_GLU_CONTROL from the Blood Glucose object’s Type attribute.</li> <li>4) In 6.6.2, added +/- INFINITY as a way to indicate out-of-range sensor measurements. Also added this to the new Control Solution object in 6.6.7.</li> </ul> </li> <li>f) In Table 13, the Semantic-Modality attribute was removed and the Supplemental-Types attribute was added.</li> <li>g) MDC_CONC_GLU_UNDETERMINED_PLASMA and MDC_CONC_GLU_UNDETERMINED_WHOLEBLOOD were added for meters that report plasma or whole blood glucose concentrations taken from an unknown sample source. Also, Table 1 was modified to add the “undetermined” sample source. The new OID was added to the Blood Glucose object extended configuration and the new standard configuration (Table 7).</li> <li>h) The MDC_CTXT_GLU_MEAL_BEDTIME nomenclature code was added to the Context Meal enumeration object.</li> <li>i) The Confirm-Timeout attribute was added, which was missing in Table 22.</li> <li>j) Table 13 was corrected. The recommended Enum-Observed-Value attribute should be Basic-Bit-Str instead of Simple-Bit-Str, as explained in the text following the table.</li> <li>k) In E.5.1, the encoding of Measurement-Active-Period = 1 hour was corrected to be a FLOAT type instead of a UINT-32.</li> <li>l) In C.3, the description of Glucose   Context   Meal   BeforeMeal was corrected and lines were added for Glucose   Context   Meal   Fasting and Glucose   Context   Meal   Bedtime.</li> <li>m) In 8.3.2 and 8.3.3, the protocol-version text was modified to clarify what must be done when multiple protocol versions exist.</li> </ul>

<sup>a</sup>For information on references, see Clause 2.

	<p>n) In 8.2, the <math>N_{tx}</math> limitation requirement was modified such that there is a limit for non-PM-store configurations but not for a PM-store configuration. The <math>N_{tx}</math> value of 5120 for non-PM-store configurations is based on an event report that contains 25 measurements of each of the 11 defined objects.</p> <p>o) An additional use case description text to 5.1 was added.</p> <p>p) Title, headers and footers, copyrights, formatting, references, and so on were updated per IEEE Standards publishing guidelines.</p> <p>q) In Table 7 for the Simple-Nu-Observed-Value and Compound-Simple-Nu-Observed-Value, the qualifier to “C” was changed and the text in the Value column was expanded.</p> <p>r) In 6.6.1, the first sentence of the last paragraph was replaced with “For standard configurations the optional attributes are initially not present.”</p> <p>s) Six occurrences of “manager device” to were changed to “manager”.</p>
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## Contents

1. Overview .....	1
1.1 Scope .....	1
1.2 Purpose .....	1
1.3 Context .....	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations .....	3
3.1 Definitions .....	3
3.2 Acronyms and abbreviations .....	3
4. Introduction to ISO/IEEE 11073 personal health devices .....	4
4.1 General .....	4
4.2 Introduction to IEEE 11073-20601 modeling constructs .....	4
5. Glucose meter device concepts and modalities .....	5
5.1 General .....	5
6. Glucose meter domain information model .....	6
6.1 Overview .....	6
6.2 Class extensions.....	6
6.3 Object instance diagram .....	7
6.4 Types of configuration.....	8
6.5 Medical device system object.....	9
6.6 Numeric objects.....	12
6.7 Real-time sample array objects.....	18
6.8 Enumeration objects .....	18
6.9 PM-store objects.....	22
6.10 Scanner objects.....	26
6.11 Class extension objects.....	26
6.12 Glucose meter information model extensibility rules .....	26
7. Glucose meter service model.....	26
7.1 General .....	26
7.2 Object access services.....	26
7.3 Object access event report services .....	27
8. Glucose meter communication model .....	29
8.1 Overview .....	29
8.2 Communication characteristics.....	29
8.3 Association procedure .....	29
8.4 Configuring procedure.....	31
8.5 Operating procedure .....	33
8.6 Time synchronization .....	34

9. Test associations.....	34
9.1 Behavior with standard configuration.....	35
9.2 Behavior with extended configurations .....	35
10. Conformance .....	35
10.1 Applicability .....	35
10.2 Conformance specification .....	35
10.3 Levels of conformance .....	36
10.4 Implementation conformance statements .....	36
Annex A (informative) Bibliography .....	41
Annex B (normative) Any additional ASN.1 definitions .....	42
Annex C (normative) Allocation of identifiers.....	43
Annex D (informative) Message sequence examples.....	46
Annex E (informative) Protocol data unit examples .....	48
Annex F (informative) IEEE list of participants .....	58

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## Health informatics—Personal health device communication

# Part 10417: Device specialization— Glucose meter

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## 1. Overview

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### 1.1 Scope

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Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth glucose meters.

### 1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.