

Health informatics—Personal health device communication

# Part 10422: Device Specialization— Urine Analyzer

IEEE Engineering in Medicine and Biology Society

Sponsored by the  
IEEE 11073™ Standards Committee

Health informatics—Personal health device communication

# Part 10422: Device Specialization— Urine Analyzer

Sponsor

**IEEE 11073™ Standards Committee**  
of the  
**IEEE Engineering in Medicine and Biology Society**

Approved 30 June 2016

**IEEE-SA Standards Board**

**Abstract:** Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth urine analyzer 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 is specified. A common core of communication functionality for personal telehealth urine analyzers is defined in this standard.

**Keywords:** IEEE 11073-10422™, medical device communication, personal health devices, urine analyzer

---

The Institute of Electrical and Electronics Engineers, Inc.  
3 Park Avenue, New York, NY 10016-5997, USA

Copyright © 2016 by the Institute of Electrical and Electronics Engineers, Inc.  
All rights reserved. Published 10 November 2016. Printed in the United States of America.

IEEE is a registered trademark in the U.S. Patent & Trademark Office, owned by the Institute of Electrical and Electronics Engineers, Incorporated.

PDF: ISBN 978-1-5044-2270-3      STD21082  
Print: ISBN 978-1-5044-2271-0      STDPD21082

*IEEE prohibits discrimination, harassment, and bullying.*

For more information, visit <http://www.ieee.org/web/aboutus/whatis/policies/p9-26.html>.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

## Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page, appear in all standards and may be found under the heading “Important Notices and Disclaimers Concerning IEEE Standards Documents.” They can also be obtained on request from IEEE or viewed at <http://standards.ieee.org/IPR/disclaimers.html>.

### Notice and Disclaimer of Liability Concerning the Use of IEEE Standards Documents

IEEE Standards documents (standards, recommended practices, and guides), both full-use and trial-use, are developed within IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (“IEEE-SA”) Standards Board. IEEE (“the Institute”) develops its standards through a consensus development process, approved by the American National Standards Institute (“ANSI”), which brings together volunteers representing varied viewpoints and interests to achieve the final product. IEEE Standards documents developed through scientific, academic, and industry-based technical working groups. Volunteers in IEEE working groups are not necessarily members of the Institute and participate without compensation from IEEE. While IEEE administers the process and establishes rules to promote fairness in the consensus development process, IEEE does not independently evaluate, test, or verify the accuracy of any of the information or the soundness of any judgments contained in its standards.

IEEE Standards do not guarantee or ensure safety, security, health, or environmental protection, or ensure against interference with or from other devices or networks. Implementers and users of IEEE Standards documents are responsible for determining and complying with all appropriate safety, security, environmental, health, and interference protection practices and all applicable laws and regulations.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims all warranties (express, implied and statutory) not included in this or any other document relating to the standard, including, but not limited to, the warranties of: merchantability; fitness for a particular purpose; non-infringement; and quality, accuracy, effectiveness, currency, or completeness of material. In addition, IEEE disclaims any and all conditions relating to: results; and workmanlike effort. IEEE standards documents are supplied “AS IS” and “WITH ALL FAULTS.”

Use of an IEEE standard is wholly voluntary. The existence of an IEEE standard does not imply that there are no other ways to produce, test, measure, purchase, market, or provide other goods and services related to the scope of the IEEE standard. Furthermore, the viewpoint expressed at the time a standard is approved and issued is subject to change from time to time about through developments in the state of the art and comments received from users of the standard.

In publishing and making its standards available, IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity nor is IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing any IEEE Standards document, should rely upon his or her own independent judgment in the exercise of reasonable care in any given circumstances or, as appropriate, seek the advice of a competent professional in determining the appropriateness of a given IEEE standard.

IN NO EVENT SHALL IEEE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO: PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE PUBLICATION, USE OF, OR RELIANCE UPON ANY STANDARD, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND REGARDLESS OF WHETHER SUCH DAMAGE WAS FORESEEABLE.

## Translations

The IEEE consensus development process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English version published by IEEE should be considered the approved IEEE standard.

## Official statements

A statement, written or oral, that is not processed in accordance with the IEEE-SA Standards Board Operations Manual shall not be considered or inferred to be the official position of IEEE or any of its committees and shall not be considered to be, or be relied upon as, a formal position of IEEE. At lectures, symposia, seminars, and educational courses, an individual presenting information on IEEE standards shall make it clear that his or her views should be considered the personal views of that individual rather than the formal position of IEEE.

## Comments on standards

Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE. However, IEEE does not provide consulting information or advice pertaining to IEEE Standards documents. Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Since IEEE standards represent a consensus of concerned interests, it is important that any responses to comments and questions also receive the concurrence of a balance of interests. For this reason, IEEE and the members of its Societies and Standards Coordinating Committees are not able to provide an instant response to comments or questions except in those cases where the matter has previously been addressed. For the same reason, IEEE does not respond to interpretation requests. Any person who would like to participate in revisions to an IEEE standard is welcome to join the relevant IEEE working group.

Comments on standards should be submitted to the following address:

Secretary, IEEE-SA Standards Board

445 Hoes Lane

Piscataway, NJ 08854 USA

## Laws and regulations

Users of IEEE Standards documents should consult all applicable laws and regulations. Compliance with the provisions of any IEEE Standards document does not imply compliance to any applicable regulatory requirements. Implementers of the standard are responsible for observing or referring to the applicable regulatory requirements. IEEE does not, by the publication of its standards, intend to urge action that is not in compliance with applicable laws, and these documents may not be construed as doing so.

## Copyrights

IEEE draft and approved standards are copyrighted by IEEE under U.S. and international copyright laws. They are made available by IEEE and are adopted for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making these documents available for use and adoption by public authorities and private users, IEEE does not waive any rights in copyright to the documents.

## Photocopies

Subject to payment of the appropriate fee, IEEE will grant users a limited, non-exclusive license to photocopy portions of any individual standard for company or organizational internal use or individual, non-commercial use only. To arrange for payment of licensing fees, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

## Updating of IEEE Standards documents

Users of IEEE Standards documents should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of amendments, corrigenda, or errata. An official IEEE document at any point in time consists of the current edition of the document together with any amendments, corrigenda, or errata then in effect.

Every IEEE standard is subjected to review at least every ten years. When a document is more than ten years old and has not undergone a revision process, it is reasonable to conclude that its contents, although still of some value, do not wholly reflect the present state of the art. Users are cautioned to check to determine that they have the latest edition of any IEEE standard.

In order to determine whether a given document is the current edition and whether it has been amended through the issuance of amendments, corrigenda, or errata, visit the IEEE Explore at <http://ieeexplore.ieee.org/> or contact IEEE at the address listed previously. For more information about the IEEE-SA or IEEE's standards development process, visit the IEEE-SA Website at <http://standards.ieee.org>.

## Errata

Errata, if any, for all IEEE standards can be accessed on the IEEE-SA Website at the following URL: <http://standards.ieee.org/findstds/errata/index.html>. Users are encouraged to check this URL for errata periodically.

## Patents

Attention is called to the possibility that implementation of this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken by the IEEE with respect to the existence or validity of any patent rights in connection therewith. If a patent holder or patent applicant has filed a statement of assurance via an Accepted Letter of Assurance, then the statement is listed on the IEEE-SA Website at <http://standards.ieee.org/about/sasb/patcom/patents.html>. Letters of Assurance may indicate whether the Submitter is willing or unwilling to grant licenses under patent rights without compensation or under reasonable terms, with reasonable terms and conditions that are demonstrably free of any unfair discrimination to applicants desiring to obtain such licenses.

Essential Patent Claims may exist for which a Letter of Assurance has not been received. The IEEE is not responsible for identifying Essential Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patent Claims, or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from the IEEE Standards Association.

## Participants

At the time this standard was submitted to the IEEE-SA Standards Board for approval, the Personal Health Devices Working Group had the following membership:

**Daidi Zhong**, *Co-Chair*  
**Michael J. Kirwan**, *Co-Chair*  
**Sungkee Lee**, *Vice Chair*

Karsten Aalders	Santiago Carot-Nemesio	Christoph Fischer
Charles R. Abbruscato	Randy W. Carroll	Morten Flintrup
Nabil Abujbara	Simon Carter	Joseph W. Forler
Maher Abuzaid	Seungchul Chae	Russell Foster
James Agnew	Rahul Chauhan	Eric Freudenthal
Haidar Ahmad	James Cheng	Matthias Frohne
Manfred Aigner	Peggy Chien	Ken Fuchs
Jorge Alberola	David Chiu	Jing Gao
Murtaza Ali	Jinyong Choi	Xuemei Gao
Rolf Ambuehl	Chia-Chin Chong	Marcus Garbe
David Aparisi	Saeed A. Choudhary	John Gargiolo
Paolo Ariano	Jinhan Chung	Pink Garner
Lawrence Arne	Malcolm Clarke	Igor Gejdos
Diego B. Arquillo	John A. Cogan	Lucene Gerbovics
Serafin Arroyo	John T. Collins	Nicolae Goga
Muhammad Asim	Cory Condek	Julian Goldman
Merat Bagha	Todd H. Cooper	Raul Gonzalez Gomez
Doug Baird	David Cornejo	Chris Gough
David Baker	Douglas Coup	Channa Gowda
Anindya Bakshi	Nigel Cox	Charles M. Gropper
Ananth	Hans Crommenaker	Amit Gupta
Balasubramanian	Tomio Crosley	Jeff Guttmacher
Sunlee Bang	Allen Curtis	Rasmus Haahr
M. Jonathan Barkley	Ndifon Cyril Fru	Christian Habermann
Gilberto Barrón	Jesús Daniel Trigo	Michael Hagerty
David Bean	Paul Dassau	Jerry Hahn
John Bell	David Davenport	Robert Hall
Rudy Belliardi	Kussell Davis	Nathaniel Hamming
Kathryn M. Bennett	Sushil K. Deka	Rickey L. Hampton
Daniel Bernstein	Ciro de la Vega	Sten Hanke
George A. Bertos	Pedro de-las-Heras-	Aki Harma
Chris Biernacki	Quiros	Jordan Hartmann
Ola Björnsne	Jim DelloStritto	Kai Hassing
Thomas Blackac	Matthew d'Entremont	Marc Daniel Haunschild
Marc Blanchet	Kent Dicks	Wolfgang Heck
Thomas Buchner	Hyoungdo Do	Nathaniel Heintzman
Douglas Bogata	Alistair Donaldson	Charles Henderson
Xavier Boniface	Xiaolian Duan	Jun-Ho Her
Shannon Boucousis	Brian Dubreuil	Helen B. Hernandez
Julius Broma	Sourav Dutta	Takashi Hibino
Lynd G. Bullock Jr.	Jakob Ehrensvar	Timothy L. Hirou
Bernard Burg	Fredrik Einberg	Allen Hobbs
Chris Burns	Michihiro Enokida	Alex Holland
Anthony Butt	Javier Escayola Calvo	Arto Holopainen
Jeremy Byford-Rew	Mark Estes	Kris Holtzclaw
Satya Calloji	Leonardo Estevez	Robert Hoy
Xiaoying Cao	Roger Feeley	Frank Hsu
Carole C. Carey	Hailing Feng	Anne Huang
Craig Carlson	Bosco T. Fernandes	Sen-Der Huang

Zhiqiang Huang	Charles Lowe	Phillip Raymond
Ron Huby	Don Ludolph	Tim Reilly
David Hughes	Christian Luszick	Barry Reinhold
Robert D. Hughes	Bob MacWilliams	Brian Reinhold
Jiyoung Huh	Srikanth	Melvin I. Reynolds
Hugh Hunter	Madhurbootheswaran	John G. Rhoads
Hitoshi Ikeda	Miriam L. Makhlof	Jeffrey S. Robbins
Yutaka Ikeda	Romain Marmot	Chris Roberts
Philip O. Isaacson	Sandra Martinez	Moskowitz Robert
Atsushi Ito	Miguel Martínez de	Timothy Robertson
Michael Jaffe	Espronceda Cámara	David Rosales
Praduman Jain	Peter Mayhew	Fatemeh Saki
Wei Jin	Jim McCain	Bill Saltzstein
Danny Jochelson	László Meleg	Benedikt Salzbrunn
Phaneeth Junga	Alexander Mense	Giovanna Sannino
Akiyoshi Kabe	Jinsei Miyazaki	Jose A. Santos-Cadenas
Steve Kahle	Erik Moll	Stefan Sauermann
Tomio Kamioka	Darr Moore	John Sawyer
Kei Kariya	Carsten Mueglitz	Guillaume Scatz
Andy Kaschl	Piotr Murawski	Alois Schloeg
Junzo Kashiwara	Soundharya	Paul S. Schulte
Kohichi Kashiwagi	Nagasubramanian	Joerg Schmitt
Ralph Kent	Jae-Wook Nah	Mark G. Schnell
Laurie M. Kermes	Alex Neefus	Leonard A. Schrenker
Ikuo Keshi	Trong-Nghia Nguyen-	Antonio Scorpiniti
Junhyung Kim	Dobinsky	Kwang Seok Seo
Minho Kim	Michael E. Nidd	Riccardo Serafin
Min-Joon Kim	Tetsu Nishimura	Sid Shaw
Taekon Kim	Jim Niswander	Frank Shen
Tetsuya Kimura	Hiroaki Niwamoto	Bozhi Shi
Michael J. Kirwan	Thomas Norgall	Min Shih
Alfred Kloos	Anand Noubade	Mazen Shihabi
Jeongmee Koh	Yoshitaka Nozoe	Redmond Shouldice
Jean-Marc Koller	Abraham Ofek	Sternly K. Simon
John Koon	Brent Olive	Marjorie Skubic
Patty Krantz	Deborah Ota	Robert Smith
Raymond Krasinski	Mauro Paleari	Ivan Soh
Alexander Kraus	Charles Palmer	Motoki Sone
Ramesh Krishna	Bud Panjwani	Emily Sopensky
Geoffrey Kruse	Carl Pantiskas	Rajagopalan Srinivasan
Falko Kuester	Harry P. Pappas	Andreas Staubert
Rafael Lajara	Hanna Park	Nicholas Steblay
Pierre Landau	Jong-Tae Park	Lars Steubesand
Jaechul Lee	Myungeun Park	John (Ivo) Stivorice
JongMuk Lee	Soojun Park	Raymond A. Strickland
Kyong Hee Lee	Phillip E. Pash	Chandrasekaran
Rami Lee	TongBi Pei	Subramaniam
Sungkeun Lee	Lucian Pestritu	Hermann Suominen
Woojae Lee	Soren Petersen	Lee Surprenant
Yinghee Lee	James Petisce	Ravi Swami
Joe Lenart	Peter Piction	Ray Sweidan
Kathryn A. Lesh	Michael Pliskin	Jin Tan
Catherine Li	Varshney Prabodh	Yi Tang
Qiong Li	Jeff Price	Haruyuyki Tatsumi
Patrick Lichter	Harald Prinzhorn	John W. Thomas
Jisoon Lim	Harry Qiu	Jonas Tirén
Joon-Ho Lim	Arif Rahman	Alexandra Todiruta
John Lin	Tanzilur Rahman	Janet Traub
Wei-Jung Lo	Steve Ray	Gary Tschautscher

Masato Tsuchid  
Ken Tubman  
Yoshihiro Uchida  
Akib Uddin  
Sunil Unadkat  
Fabio Urbani  
Philipp Urbauer  
Laura Vanzago  
Alpo Värri  
Dalimar Velez  
Rudi Voon  
Barry Vornbrock  
Isobel Walker  
David Wang

Jerry P. Wang  
Yao Wang  
Yi Wang  
Steve Warren  
Fujio Watanabe  
Toru Watsuji  
Mike Weng  
Kathleen Wible  
Paul Williamson  
Jan Wittenber  
Jia-Rong Wu  
Will Wykeham  
Ariton Xhafa  
Dan Xiao

Yaxi Yan  
Qifeng Yan  
Junjie Yang  
Ricky Yang  
Melanie S. Yeung  
Qiang Yin  
Done-Sik Yoo  
Jianchao Zeng  
Jason Zhang  
Zhiqiang Zhang  
Thomas Zhao  
Daidi Zhong  
Miha Zoubek  
Szymon Zyskotier

The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Lyle Bullock  
Keith Chow  
Malcolm Clarke  
Randall Groves  
Jon Hagar  
Kai Hassing

Werner Hoelzl  
Atsushi Ito  
JongMuk Lee  
Melvin Reynolds  
Bartien Sayogo

Lars Schmitt  
Walter Stupples  
J. Wille  
Jan Wittenber  
Yuan Yuen  
Daidi Zhong

When the IEEE-SA Standards Board approved this standard on 30 June 2016, it had the following membership:

**Jean-Philippe Fauriol, Chair**  
**Ted Burse, Vice Chair**  
**John D. Kulick, Past Chair**  
**Konstantinos Karachalios, Secretary**

Chuck Adams  
Masayuki Ariyoshi  
Stephen Dukes  
Jianbin Fan  
J. Travis Griffith  
Gary Hoffman

Robert W. Hotchkiss  
Ivica Jancic  
Joseph L. Koepfinger\*  
Hung Ling  
Kevin Lu  
Annette D. Reilly  
Gary Robinson

Mehmet Ulema  
Yingli Wen  
Howard Wolfman  
Don Wright  
Yu Yuan  
Daidi Zhong

\*Member Emeritus

## Introduction

This introduction is not part of IEEE Std 11073-10422™-2016, Health informatics—Personal health device communication—Part 10422: Device Specialization—Urine Analyzer.

ISO/IEEE 11073™ standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601™-2014 and describes a specific, interoperable communication approach for urine analyzers.<sup>1</sup> 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.

---

<sup>1</sup>Information on references can be found in [Clause 2](#).

## 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
3.2 Acronyms and abbreviations .....	14
4. Introduction to ISO/IEEE 11073 personal health devices .....	15
4.1 General .....	15
4.2 Introduction to IEEE 11073-20601 modeling constructs .....	15
4.3 Compliance with other standards .....	16
5. Urine analyzer device concepts and modalities .....	16
5.1 General .....	16
5.2 Bilirubin .....	16
5.3 Blood .....	16
5.4 Glucose .....	16
5.5 Ketones .....	17
5.6 Leukocyte esterase .....	17
5.7 Nitrite .....	17
5.8 pH .....	17
5.9 Protein .....	17
5.10 Specific gravity .....	17
5.11 Urobilinogen .....	17
6. Urine analyzer domain information model .....	17
6.1 Overview .....	17
6.2 Class extensions .....	18
6.3 Object instance diagram .....	18
6.4 Types of configuration .....	18
6.5 Medical device system object .....	19
6.6 Numeric objects .....	23
6.7 Real-time sample array objects .....	33
6.8 Enumeration objects .....	33
6.9 PM-store objects .....	34
6.10 Scanner objects .....	34
6.11 Class extension objects .....	34
6.12 Urine analyzer information model extensibility rules .....	34
7. Urine analyzer service model .....	34
7.1 General .....	34
7.2 Object access services .....	34
7.3 Object access event report services .....	36
8. Urine analyzer communication model .....	36
8.1 Overview .....	36
8.2 Communication characteristics .....	36
8.3 Association procedure .....	37
8.4 Configuring procedure .....	38

8.5 Operating procedure .....	38
8.6 Time synchronization .....	39
9. Test associations .....	39
10. Conformance .....	39
10.1 Applicability .....	39
10.2 Conformance specification .....	39
10.3 Levels of conformance .....	39
10.4 Implementation conformance statements .....	40
Annex A (informative) Bibliography .....	44
Annex B (normative) Any additional ASN.1 definitions .....	45
Annex C (normative) Allocation of identifiers .....	46
Annex D (informative) Message sequence examples .....	48
Annex E (informative) Protocol data unit examples .....	50

## Health informatics—Personal health device communication

# Part 10422: Device Specialization— Urine Analyzer

## 1. Overview

### 1.1 Scope

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 urine analyzer devices and managers (e.g., cell phones, personal computers, personal health appliances, 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 urine analyzers.

### 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.

### 1.3 Context

See IEEE Std 11073-20601™-2014 for an overview of the environment within which this standard is written.<sup>2</sup>

This standard defines the device specialization for the urine analyzer, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601-2014, which in turn draws information from both ISO/IEEE 11073-10201™:2004 [B8] and ISO/IEEE 11073-20101™:2004 [B9].<sup>3</sup> The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2014.

This standard reproduces relevant portions of the nomenclature found in both ISO/IEEE 11073-10101:2004 [B7] and IEEE Std 11073-10101a™-2015 [B5], and adds new nomenclature codes for the purposes of this

<sup>2</sup>Information on references can be found in [Clause 2](#).

<sup>3</sup>The numbers in brackets correspond to those of the bibliography in [Annex A](#).