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Corrigendum 1

(11/2017)

SERIES H: AUDIOVISUAL AND MULTIMEDIA SYSTEMS

E-health multimedia services and applications – Interoperability compliance testing of personal health systems (HRN, PAN, LAN, TAN and WAN)

Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5P: Continuous glucose monitor: Alignment with CDG2016 (Iris)

Corrigendum 1

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New Corrigendum 1 to Recommendation ITU-T H.845.16

Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5P: Continuous glucose monitor: Alignment with CDG2016 (Iris)

Summary

Recommendation ITU-T H.845.16 provides a test suite structure (TSS) and the test purposes (TP) for the continuous glucose monitor in the Personal Health Device (PHD) interface, based on the requirements defined in the Recommendations of the ITU-T H.810 sub-series, of which Recommendation ITU-T H.810 (2016) is the base Recommendation. The objective of this test specification is to provide a high probability of interoperability at this interface.

Recommendation ITU-T H.845.16 is a transposition of Continua Test Tool DG2016, Test Suite Structure & Test Purposes, Personal Health Devices Interface, Part 5P: Device Specializations. Personal Health Device, Continuous Glucose Monitor (CGM), Version 1.1 (2017-03-14).

This Recommendation includes an electronic attachment with the protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

Keywords

Conformance testing, Continua Design Guidelines, continuous glucose monitor, e-health, ITU-T H.810, IEEE 11073 device specialization, Personal Health Devices interface, personal area network, personal connected health devices, touch area network.

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Electronic attachment: This Recommendation includes an electronic attachment with the protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

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Introduction

This Recommendation is the transposition of Continua Test Tool DG2016, Test Suite Structure & Test Purposes, Personal Health Devices Interface, Part 5P: Device Specializations. Personal Health Device, (Continuous Glucose Monitor -CGM-), Version 1.1 (2017-03-14) that was developed by the Personal Connected Health Alliance. The table below shows the revision history of this test specification; it may contain versions that existed before transposition.

Version	Date	Revision history
1.0	2016-09-20	Initial release for Test Tool DG2016 based on the requirements in [ITU-T H.810 (2016)]/[b-CDG 2016].
1.1	2017-03-14	This uses "TSS&TP_DG2016_PHD_PART_5P_ v1.0.doc" as a baseline and adds new features included in Continua DG 2016 + Errata and it adds some updates according to the maintenance 2016 activity.

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Recommendation ITU-T H.845.16

Conformance of ITU-T H.810 personal health system: Personal Health Devices interface Part 5P: Continuous glucose monitor

1 Scope

The scope of this Recommendation[1] is to provide a test suite structure (TSS) and the test purposes (TP) for the Personal Health Devices interface based on the requirements defined in the Continua Design Guidelines (CDG) [ITU-T H.810 (2016)]. The objective of this test specification is to provide a high probability of interoperability at this interface.

The TSS and TP for the Personal Health Devices interface has been divided into the parts specified below. This Recommendation covers Part 5, subpart 5P.

– Part 1: Optimized Exchange Protocol. Personal Health Device
– Part 2: Optimized Exchange Protocol. Personal Health Gateway
– Part 3: Continua Design Guidelines. Personal Health Device
– Part 4: Continua Design Guidelines. Personal Health Gateway
– Part 5: Device Specializations. Personal Health Devices interface. This document is divided into the following subparts:
  - Part 5A: Weighing scales
  - Part 5B: Glucose meter
  - Part 5C: Pulse oximeter
  - Part 5D: Blood pressure monitor
  - Part 5E: Thermometer
  - Part 5F: Cardiovascular fitness and activity monitor
  - Part 5G: Strength fitness equipment
  - Part 5H: Independent living activity hub
  - Part 5I: Adherence monitor
  - Part 5J: Insulin pump
  - Part 5K: Peak expiratory flow monitor
  - Part 5L: Body composition analyser
  - Part 5M: Basic electrocardiograph
  - Part 5N: International normalized ratio monitor
  - Part 5O: Sleep apnoea breathing therapy equipment (SABTE)
  - **Part 5P: Continuous glucose monitor (CGM)**
– Part 6: Device specializations. Personal Health Gateway
– Part 7: Continua Design Guidelines. BLE Personal Health Device
– Part 8: Continua Design Guidelines. BLE Personal Health Gateway– Part 9: Personal Health Devices Transcoding Whitepaper. Personal Health Devices
– Part 10: Personal Health Devices Transcoding Whitepaper. Personal Health Gateway

[1] This Recommendation includes an electronic attachment with the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.

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2 References

The following ITU-T Recommendations and other references contain provisions which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users of this Recommendation are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published. The reference to a document within this Recommendation does not give it, as a stand-alone document, the status of a Recommendation.

[ITU-T H.810 (2016)] Recommendation ITU-T H.810 (2016), *Interoperability design guidelines for personal health systems*.

[ITU-T H.811] Recommendation ITU-T H.811 (2016), *Interoperability design guidelines for personal health systems: TAN/PAN/LAN interface*.

[ITU-T H.812] Recommendation ITU-T H.812 (2016), *Interoperability design guidelines for personal health systems: WAN interface*.

[ITU-T H.812.1] Recommendation ITU-T H.812.1 (2016), *Interoperability design guidelines for personal health systems: WAN interface: Observation upload*.

[ITU-T H.812.2] Recommendation ITU-T H.812.2 (2016), *Interoperability design guidelines for personal health systems: WAN interface: Questionnaires*.

[ITU-T H.812.3] Recommendation ITU-T H.812.3 (2016), *Interoperability design guidelines for personal health systems: WAN interface: Capability exchange*.

[ITU-T H.812.4] Recommendation ITU-T H.812.4 (2016), *Interoperability design guidelines for personal health systems: WAN interface: Authenticated persistent session*.

[ITU-T H.813] Recommendation ITU-T H.813 (2016), *Interoperability design guidelines for personal health systems: HRN interface*.

[ISO/IEEE 11073-10425] ISO/IEEE 11073-10425:2016, *Health informatics – Personal health device communication – Part 10425: Device specialization – Continuous glucose monitor (CGM)*.
https://www.iso.org/standard/67821.html

[ISO/IEEE 11073-20601-2016C] ISO/IEEE 11073-20601:2016, *Health informatics – Personal health device communication – Part 20601: Application profile – Optimized exchange protocol, including ISO/IEEE 11073-20601:2016/Cor.1:2016*.
https://www.iso.org/standard/66717.html with
https://www.iso.org/standard/71886.html

3 Definitions

3.1 Terms defined elsewhere

This Recommendation uses the following terms defined elsewhere:

3.1.1 agent [ISO/IEEE 11073-20601-2016C]: A node that collects and transmits personal health data to an associated manager.

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3.1.2 manager [ISO/IEEE 11073-20601-2016C]: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

3.2 Terms defined in this Recommendation

None.

4 Abbreviations and acronyms

This Recommendation uses the following abbreviations and acronyms:

ATS	Abstract Test Suite
CDG	Continua Design Guidelines
CGM	Continuous Glucose Monitor
DUT	Device Under Test
GUI	Graphical User Interface
INR	International Normalized Ratio
IP	Insulin Pump
IUT	Implementation Under Test
MDS	Medical Device System
NFC	Near Field Communication
PAN	Personal Area Network
PCT	Protocol Conformance Testing
PCO	Point of Control and Observation
PHD	Personal Health Device
PHDC	Personal Healthcare Device Class
PHG	Personal Health Gateway
PICS	Protocol Implementation Conformance Statement
PIXIT	Protocol Implementation eXtra Information for Testing
SABTE	Sleep Apnoea Breathing Therapy Equipment
SCR	Static Conformance Review
SDP	Service Discovery Protocol
SOAP	Simple Object Access Protocol
TCWG	Test and Certification Working Group
TP	Test Purpose
TSS	Test Suite Structure
USB	Universal Serial Bus
WDM	Windows Driver Model

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5 Conventions

The key words "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "MAY", "MAY NOT" in this document are to be interpreted as in [ETSI SR 001 262]

– SHALL is equivalent to: MUST; or it is required to.

– SHALL NOT is equivalent to: MUST NOT or it is not allowed

– SHOULD is equivalent to: it is recommended to

– SHOULD NOT is equivalent to: it is not recommended to

– MAY is equivalent to: is permitted

– MAY NOT is equivalent to: it is not required that

NOTE – The above-mentioned key words are capitalized for illustrative purposes only and they do not appear capitalized within this Recommendation.

Generic reference to the ITU-T H.810 series (listed in clause 2) is made through the label [ITU-T H.810 series.

Reference is made in the ITU-T H.820-H.850-series of Recommendations to different versions of the Continua Design Guidelines (CDG) by a specific designation. The list of terms that may be used in this Recommendation is provided in Table 1.

Table 1 – List of designations associated with the various versions of the CDG

CDG release	Transposed as	Version	Description	Designation
2016 plus errata	[ITU-T H.810 (2016)]	6.1	Release 2016 plus errata noting all ratified bugs [b-CDG 2016].	–
2016	–	6.0	Release 2016 of the CDG including maintenance updates of the CDG 2015 and additional guidelines that cover new functionalities.	Iris
2015 plus errata	[b-ITU-T H.810 (2015)]	5.1	Release 2015 plus errata noting all ratified bugs [b-CDG 2015]. The 2013 edition of H.810 is split into eight parts in the H.810-series.	–
2015	–	5.0	Release 2015 of the CDG including maintenance updates of the CDG 2013 and additional guidelines that cover new functionalities.	Genome
2013 plus errata	[b-ITU-T H.810 (2013)]	4.1	Release 2013 plus errata noting all ratified bugs [b-CDG 2013].	–
2013	–	4.0	Release 2013 of the CDG including maintenance updates of the CDG 2012 and additional guidelines that cover new functionalities.	Endorphin
2012 plus errata	–	3.1	Release 2012 plus errata noting all ratified bugs [b-CDG 2012].	–
2012	–	3.0	Release 2012 of the CDG including maintenance updates of the CDG 2011 and additional guidelines that cover new functionalities.	Catalyst
2011 plus errata	–	2.1	CDG 2011 integrated with identified	–

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Table 1 – List of designations associated with the various versions of the CDG

CDG release	Transposed as	Version	Description	Designation
			errata.	
2011	–	2.0	Release 2011 of the CDG including maintenance updates of the CDG 2010 and additional guidelines that cover new functionalities [b-CDG 2011].	Adrenaline
2010 plus errata	–	1.6	CDG 2010 integrated with identified errata.	–
2010	–	1.5	Release 2010 of the CDG with maintenance updates of the CDG Version 1 and additional guidelines that cover new functionalities [b-CDG 2010].	1.5
1.0	–	1.0	First released version of the CDG [b-CDG 1.0].	–

6 Test suite structure (TSS)

The test purposes (TPs) for the Personal Health Devices interface have been divided into the main subgroups specified below. Annex A describes the TPs for subgroup 1.3.10 (shown in bold):

The Test Purposes (TP) has been divided in two main groups:

– Group 1: Personal Health Device (PHD)
  - Group 1.1: Transport (TR)
    - Subgroup 1.1.1: Design guidelines: Common (DGC)
    - Subgroup 1.1.2: USB design guidelines (UDG)
    - Subgroup 1.1.3: Bluetooth design guidelines (BDG)
    - Subgroup 1.1.4: Pulse oximeter design guidelines (PODG)
    - Subgroup 1.1.5: Cardiovascular design guidelines (CVDG)
    - Subgroup 1.1.6: Activity hub design guidelines (HUBDG)
    - Subgroup 1.1.7: ZigBee design guidelines (ZDG)
    - Subgroup 1.1.8: Glucose meter design guidelines (GLDG)
    - Subgroup 1.1.9: Bluetooth low energy design guidelines (BLEDG)
    - Subgroup 1.1.10: Basic electrocardiograph design guidelines (ECGDG)
    - Subgroup 1.1.11: NFC design guidelines (NDG)
  - Group 1.2: IEEE 20601 Optimized exchange protocol (OXP)
    - Subgroup 1.2.1: PHD domain information model (DIM)
    - Subgroup 1.2.2: PHD service model (SER)
    - Subgroup 1.2.3: PHD communication model (COM)
  - Group 1.3: Devices class specializations (CLASS)
    - Subgroup 1.3.1: Weighing scales (WEG)
    - Subgroup 1.3.2: Glucose meter (GL)
    - Subgroup 1.3.3: Pulse oximeter (PO)
    - Subgroup 1.3.4: Blood pressure monitor (BPM)

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- Subgroup 1.3.5: Thermometer (TH)
- Subgroup 1.3.6: Cardiovascular (CV)
- Subgroup 1.3.7: Strength (ST)
- Subgroup 1.3.8: Activity hub (HUB)
- Subgroup 1.3.9: Adherence monitor (AM)
- Subgroup 1.3.10: Insulin pump (IP)
- Subgroup 1.3.11: Peak flow (PF)
- Subgroup 1.3.12: Body composition analyser (BCA)
- Subgroup 1.3.13: Basic electrocardiograph (ECG)
- Subgroup 1.3.14: International normalized ratio (INR)
- Subgroup 1.3.15: Sleep apnoea breathing therapy equipment (SABTE)
- **Subgroup 1.3.16: Continuous glucose monitor (CGM)**

- Group 1.4: Personal Health Device transcoding whitepaper (PHDTW)
  - Subgroup 1.4.1: Whitepaper general requirements (GEN)
  - Subgroup 1.4.2: Whitepaper thermometer requirements (TH)
  - Subgroup 1.4.3: Whitepaper blood pressure requirements (BPM)
  - Subgroup 1.4.4: Whitepaper heart rate requirements (HR)
  - Subgroup 1.4.5: Whitepaper glucose meter requirements (GL)
  - Subgroup 1.4.6: Whitepaper weight scale requirements (WS)
  - Subgroup 1.4.7: Whitepaper pulse oximeter requirements (PLX)
  - Subgroup 1.4.8: Whitepaper continuous glucose monitoring requirements (CGM)

– Group 2: Personal Health Gateway (PHG)

- Group 2.1: Transport (TR)
  - Subgroup 2.1.1: Design guidelines: Common (DGC)
  - Subgroup 2.1.2: USB design guidelines (UDG)
  - Subgroup 2.1.3: Bluetooth design guidelines (BDG)
  - Subgroup 2.1.4: Cardiovascular design guidelines (CVDG)
  - Subgroup 2.1.5: Activity hub design guidelines (HUBDG)
  - Subgroup 2.1.6: ZigBee design guidelines (ZDG)
  - Subgroup 2.1.7: Bluetooth low energy design guidelines (BLEDG)
  - Subgroup 2.1.8: NFC design guidelines (NDG)
- Group 2.2: IEEE 20601 Optimized exchange protocol (OXP)
  - Subgroup 2.2.1: General (GEN)
  - Subgroup 2.2.2: PHD domain information model (DIM)
  - Subgroup 2.2.3: PHD service model (SER)
  - Subgroup 2.2.4: PHD communication model (COM)
- Group 2.3: Devices class specializations (CLASS)
  - Subgroup 2.3.1: Weighing scales (WEG)
  - Subgroup 2.3.2: Glucose Meter (GL)
  - Subgroup 2.3.3: Pulse oximeter (PO)
  - Subgroup 2.3.4: Blood pressure monitor (BPM)

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- Subgroup 2.3.5: Thermometer (TH)
- Subgroup 2.3.6: Cardiovascular (CV)
- Subgroup 2.3.7: Strength (ST)
- Subgroup 2.3.8: Activity hub (HUB)
- Subgroup 2.3.9: Adherence monitor (AM)
- Subgroup 2.3.10: Insulin pump (IP)
- Subgroup 2.3.11: Peak flow (PF)
- Subgroup 2.3.12: Body composition analyser (BCA)
- Subgroup 2.3.13: Basic electrocardiograph (ECG)
- Subgroup 2.3.14: International normalized ratio (INR)
- Subgroup 2.3.15: Sleep apnoea breathing therapy equipment (SABTE)
- Subgroup 2.3.16: Continuous glucose monitor (CGM)

- Group 2.4: Personal Health Device transcoding whitepaper (PHDTW)
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  - Subgroup 2.4.4: Whitepaper heart rate requirements (HR)
  - Subgroup 2.4.5: Whitepaper glucose meter requirements (GL)
  - Subgroup 2.4.6: Whitepaper weight scale requirements (WS)
  - Subgroup 2.4.7: Whitepaper pulse oximeter requirements (PLX)
  - Subgroup 2.4.8: Whitepaper continuous glucose monitoring requirements (CGM)

7 Electronic attachment

The protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A can be downloaded from http://handle.itu.int/11.1002/2000/12067.

In the electronic attachment, letters "C" and "I" in the column labelled "Mandatory" are used to distinguish between "PICS" and "PIXIT" respectively during testing. If the cell is empty, the corresponding PICS is "independent". If the field contains a "C", the corresponding PICS is dependent on other PICS, and the logical expression is detailed in the "SCR_Expression" field. The static conformance review (SCR) is used in the test tool to assert whether the PICS selection is consistent.

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Annex A

Test purposes

(This annex forms an integral part of this Recommendation.)

A.1 TP definition conventions

The test purposes (TPs) are defined according to the following rules:

– **TP Id**: This is a unique identifier (TP/<TT>/<DUT>/<GR>/<SGR>/<XX> – <NNN>). It is specified according to the naming convention defined below:

- Each test purpose identifier is introduced by the prefix "TP".
- <TT>: This is the test tool that will be used in the test case.
  - PAN: Personal area network (Bluetooth or USB)
  - LAN: Local area network (ZigBee)
  - PAN-LAN: Personal area network (Bluetooth or USB) – Local area network (ZigBee)
  - LP-PAN: Low power personal area network (Bluetooth low energy)
  - TAN: Touch area network (NFC)
  - PLT: Personal area network (Bluetooth or USB) – Local area network (ZigBee) – Touch area network (NFC)
- <DUT>: This is the device under test.
  - PHD: Personal Health Device
  - PHG: Personal Health Gateway
- <GR>: This identifies a group of test cases.
- <SGR>: This identifies a subgroup of test cases.
- <XX>: This identifies the type of testing.
  - BV: Valid behaviour test
  - BI: Invalid behaviour test
- <NNN>: This is a sequential number that identifies the test procedure.

– **TP label**: This is the TP's title.

– **Coverage**: This contains the specification reference and clause to be checked by the TP.

- Spec: This indicates the earliest version of the specification from which the testable items to be checked by the TP were included.
- Testable item: This contains testable items to be checked by the TP.

– **Test purpose**: This is a description of the requirements to be tested.

– **Applicability**: This contains the PICS items that define if a test case is applicable or not for a specific device. When a TP contains an "ALL" in this field it means that it applies to the device under test within that scope of the test (specialization, transport used, etc.).

– **Other PICS**: This contains additional PICS items (apart from the PICS specified in the Applicability row) which are used within the test case implementation and can modify the final verdict. When this row is empty, it means that only the PICS specified in the Applicability row are used within the test case implementation.

– **Initial condition**: This indicates the state to which the DUT needs to be moved at the beginning of TC execution.

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– **Test procedure**: This describes the steps to be followed in order to execute the test case.
– **Pass/Fail criteria**: This provides criteria to decide whether the DUT passes or fails the test case.

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A.2 Subgroup 1.3.16: Continuous glucose monitor (CGM)

TP Id		TP/PLT/PHD/CLASS/CGM/BV-000_A		
TP label		Get MDS Object for Continuous Glucose Monitor specialization: Mandatory, Conditional and Optional Attributes.		
Coverage	**Spec**	[ISO/IEEE 11073-10425]		
	Testable items	MDSAttrCGM 3; M	MDSAttrCGM 4; M	MDSAttrCGM 6; M
		MDSAttrCGM 7; M	MDSAttrCGM 12; R	MDSAttrCGM 15; R
		MDSAttrCGM 16; R	MDSAttrCGM 17; R	MDSAttrCGM 18; R
Test purpose		Check that: The MDS Object contains the attributes specified for a Continuous Glucose Monitor agent		
Applicability		C_AG_OXP_000 AND C_AG_OXP_157		
Other PICS		C_AG_OXP_181		
Initial condition		The simulated Personal Health Gateway (PHG) and the Personal Health Device (PHD) under test are in the Operating state.		
Test procedure		1. The simulated PHG issues “roiv-cmip-get” command with handle set to 0 (to request for MDS object) and attribute-id-list set to 0 to indicate all attributes. 2. The PHD responds with a “rors-cmip-get” service message in which the attribute-list contains a list of all implemented attributes of the MDS object: MDS Attributes: a. Attribute System-Type must not be present. b. Mandatory attribute System-Type-Spec_List ❑ attribute-id = MDC_ATTR_SYS_TYPE_SPEC_LIST ❑ attribute-type = TypeVerList ❑ attribute-value.length = 4 bytes for each configuration supported ❑ attribute-value = { MDC_DEV_SPEC_PROFILE_CGM, 1} must be found in the list c. Mandatory attribute System-model ❑ attribute-id = MDC_ATTR_ID_MODEL (0x09 0x28) ❑ attribute-type = SystemModel ❑ atribute-value.length = <Variable> ❑ attribute-value = • Manufacturer = Check against PIXIT I_AG_OXP_003 • Model = Check against PIXIT I_AG_OXP_004 d. Mandatory attribute Dev-Configuration-Id ❑ attribute-id = MDC_ATTR_DEV_CONFIG_ID ❑ attribute-type = ConfigId ❑ attribute-value.length = 2 bytes ❑ attribute-value = • IF NOT C_AG_OXP_181 then attribute-value = 0x 09C4 • ELSE attribute-value = < between 0x4000 and 0x7FFF>		

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	e. If recommended attribute Base-Offset-Time is present ❑ attribute-id = MDC_ATTR_TIME_BO (0x0A 0x81) ❑ attribute-type = BaseOffsetTime ❑ attribute-value.length = 8 bytes ❑ attribute-value = <not relevant> f. If recommended attribute Date-and-Time-Adjustment is present ❑ attribute-id = MDC_ATTR_TIME_ABS_ADJUST (0x0A 0X62) ❑ attribute-type = AbsoluteTimeAdjust ❑ attribute-value.length = 6 bytes ❑ attribute-value = <not relevant> g. If recommended attribute Power-Status is present ❑ attribute-id = MDC_ATTR_POWER_STAT ❑ attribute-type = PowerStatus (BITS-16) ❑ attribute-value.length = 2 bytes ❑ attribute-value = • ON_BATTERY(0x4000) • ON_MAINS (0x8000) h. If recommended attribute Battery-Level is present ❑ attribute-id = MDC_ATTR_VAL_BATT_CHARGE (0X09 0X9C) ❑ attribute-type = INT-U16 ❑ attribute-value.length = 2 bytes ❑ attribute-value = <not relevant> i. If recommended attribute Remain-Battery-Time is present ❑ attribute-id = MDC_ATTR_TIME_BATT_REMAIN (0X09 0X88) ❑ attribute-type = BatMeasure ❑ attribute-value.length = 6 bytes ❑ attribute-value = <not relevant>
Pass/Fail criteria	All checked values are as specified in the test procedure.
Notes	

TP Id		TP/PLT/PHD/CLASS/CGM/BV-000_B		
TP label		MDS Configuration objects events for Continuous Glucose Monitor specialization.		
Coverage	**Spec**	[ISO/IEEE 11073-10425]		
	Testable items	MDSEventsCGM 1; M		
Test purpose		Check that: A Continuous Glucose Monitor agent shall send the [MDS-Configuration-Event] using a [Confirmed] event report. The [MDS-Configuration-Event] shall include the event-info [ConfigReport]		
Applicability		C_AG_OXP_000 AND C_AG_OXP_157		
Other PICS		C_AG_OXP_010, C_AG_OXP_181		

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