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Health informatics — Personal health device communication

Part 10407: Device specialization — Blood pressure monitor (ISO/IEEE 11073-10407:2010)

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

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English Version

Health informatics - Personal health device communication - Part 10407: Device specialization - Blood pressure monitor (ISO/IEEE 11073-10407:2010)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10407: Spécialisation des dispositifs - Moniteur de pression sanguine (ISO/IEEE 11073-10407:2010)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10407: Gerätespezifikation - Blutdruckmonitor (ISO/IEEE 11073-10407:2010)

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Foreword

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ISO/IEEE 11073-10407 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-10407-2008). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. Both parties are responsible for the maintenance of this document.

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 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

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— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer*

— *Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10471: (Point-of-care medical device communication) Device Specialization — Independant living activity hub*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: (Point-of-care medical device communication) 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*

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Introduction

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[a] and describes a specific, interoperable communication approach for blood pressure monitors. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from personal health devices.

[a]Information on references can be found in Clause 2.

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INTERNATIONAL STANDARD ISO/IEEE 11073-10407:2010(E)

Health informatics — Personal health device communication —

Part 10407: Device specialization — Blood pressure monitor

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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 blood pressure monitor 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 blood pressure monitors.

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™ for an overview of the environment within which this standard is written.

This document, IEEE Std 11073-10407, defines the device specialization for the blood pressure monitor, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

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This standard is based on IEEE Std 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B5][1] and ISO/IEEE 11073-20101:2004 [B6]. The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B4] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601, all required nomenclature codes for implementation are documented.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601, where zz can be any number from 01 to 99, inclusive.[2]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-20601™-2008, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[3,4]

See Annex A for all informative material referenced by this standard.

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards Terms* [B2] should be referenced for terms not defined in this clause.

3.1.1 agent: A node that collects and transmits personal health data to an associated manager.

3.1.2 blood pressure: The cyclic pressure (i.e., amount of force applied over a given area divided by the size of this area) exerted by blood against the walls of blood vessels. Noninvasive blood pressure measurement is typically performed at the brachial artery (arm) or radial artery (wrist). There are usually two numbers reported for blood pressure, and with the home monitors, a third number is typically available. The first, and higher, number is produced by the contraction of the heart (*See:* **systolic pressure**). The second, lower number is produced by relaxation of the heart (*See:* **diastolic pressure**). The third number is the mean arterial pressure.

3.1.3 class: In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiated from the class utilize.

3.1.4 compute engine: *See:* **manager.**

3.1.5 device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

3.1.6 diastolic pressure: This is minimum pressure achieved during the cardiac cycle. It is typically the second and the lower of the readings given as the blood pressure.

[1]The numbers in brackets correspond to those of the bibliography in Annex A.
[2]Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[3]The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.
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3.1.7 handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

3.1.8 manager: 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.

3.1.9 mean arterial pressure: value of the integral of one cycle of the blood pressure curve divided by the period between successive heart beats.

3.1.10 obj-handle: *See:* **handle.**

3.1.11 object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

3.1.12 personal health device: A device used in personal health applications.

3.1.13 personal telehealth device: *See:* **personal health device.**

3.1.14 pulse: The frequency of the cardiac cycle as reported by the blood pressure monitor.

3.1.15 pulse pressure: The systolic pressure minus the diastolic pressure.

3.1.16 systolic pressure: This maximum value of the arterial blood pressure as a result of the contraction of the left ventricle. It is typically the first and the higher of the readings given as the blood pressure.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
BPM	beats per minute
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statement
MAP	mean arterial pressure
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
RT-SA	real-time sample array
PDU	protocol data unit
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

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IEEE Std 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the blood pressure monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD blood pressure monitor agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B7]. Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular the IEEE Std 11073-20601, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

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5. Blood pressure monitor device concepts and modalities

5.1 General

This clause presents the general concepts of blood pressure monitor devices. In the context of personal health devices in this family of standards, a blood pressure monitor is a device that measures blood pressure [i.e., systolic, diastolic, and mean arterial pressure (MAP)] and, optionally, pulse noninvasively. Blood pressure monitor devices considered in this standard typically inflate a cuff to occlude an artery and then to measure the reaction of the artery while the pressure is released with the results being converted into systolic, diastolic, and MAP values. Optionally, pulse rate may be determined at the same time.

Blood pressure monitor devices may use a variety of techniques for measuring blood pressure and pulse rate. One typical method is the oscillometric method where oscillations in cuff pressure are analyzed to obtain blood pressure values. Another technique is the automated auscultatory method where the device uses a microphone to detect Korotkoff sounds during cuff deflation. Auscultatory devices measure the systolic and diastolic values and estimates the MAP.

In home monitors, the oscillometric method is typically used, allowing the measurement to be done electronically. On the oscillometric method, small pressure changes (oscillations) occur in the cuff as a result of blood pressure pulses during the inflation or deflation of the cuff and are detected. These oscillations, which first increase and then decrease, are stored together with the corresponding cuff pressure values in the automated sphygmomanometer. With these stored values, the systolic, diastolic, and mean blood pressure values can be mathematically derived using an appropriate algorithm.

Blood pressure is historically most frequently measured using the units of millimeters of mercury (mmHg). Kilopascals (kPa) may also be used. This standard supports both mmHg and kPa.

5.2 Systolic and diastolic pressure

The systolic and diastolic blood pressure measurements indicate the highest and lowest blood pressures during the cardiac cycle. Normally, a single measurement is insufficient to provide the complete information regarding the state of the heart and vascular system, and so both systolic and diastolic blood pressure measurements are provided. According to this standard, both systolic and diastolic blood pressures are always reported together.

5.3 Mean arterial pressure

Mean arterial pressure is reported in the same units as systolic and diastolic blood pressure. It is reported at the same time as systolic and diastolic blood pressure. It is required for this standard.

5.4 Pulse rate

Pulse rate is measured in beats per minute (BPM). Reporting a pulse rate is supported by this standard, but it is optional in some configurations.

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6. Blood pressure monitor domain information model

6.1 Overview

This clause describes the domain information model of the blood pressure monitor.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601.

6.3 Object instance diagram

The object instance diagram of the blood pressure monitor domain information model, which is defined for the purposes of this standard, is shown in Figure 1.

The objects of the DIM, as shown in Figure 1, are described in 6.4 to 6.12. This includes the medical device system (MDS) object (see 6.5), the numeric objects (see 6.6), the real-time sample array (RT-SA) objects (see 1.1), the enumeration objects (see 1.1), the PM-store objects (see 6.9), and the scanner objects (see 6.10). See 6.11 for rules for extending the blood pressure monitor information model beyond elements as described in this standard. Each clause that describes an object of the blood pressure monitor contains the following information:

— The nomenclature code used to identify the class of the object. One example of where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.

— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using an ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601.

— The methods available on the object.

— The potential events generated by the object. Data are sent to the manager using events.

— The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers mean M — Attribute is Mandatory, C — Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601 is referenced, then it contains the conditions), R — Attribute is Recommended, NR — Attribute is Not Recommended, and O — Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented on an agent.

The attributes can be either static, meaning that they shall remain unchanged after the configuration is agreed upon, or dynamic, meaning that the attribute may change at some point after configuration.

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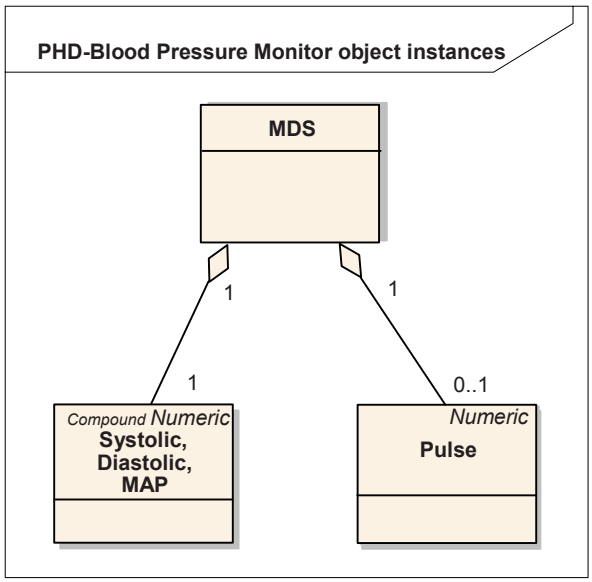

Figure 1—Blood pressure monitor—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the IEEE 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and the manager. If the manager acknowledges that it recognizes and wants to operate using the configuration, then the agent can begin sending measurements immediately. If the manager does not recognize the configuration, the agent provides the configuration prior to transmitting measurement information.

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines which objects, attributes, and values that it wants to use in a configuration and assigns a configuration identifier. When the agent associates with a manager, it negotiates an acceptable configuration. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send the configuration information as a configuration event report. If, however, the manager already understands the configuration, either because it was preloaded in some way or the agent had previously associated with the manager, then the manager responds that the configuration is known and no further configuration information needs to be sent.

6.5 Medical device system object

6.5.1 MDS object attributes

Table 1 summarizes the attributes of the blood pressure monitor MDS object. The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

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Table 1—MDS object attributes

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_BP, 1}.	M
System-Model	{"Manufacturer","Model"}.	M
System-Id	extended unique identifier (64 bits) (EUI-64).	M
Dev-Configuration-Id	Standard config: 0x02BC (700) Extended configs: 0x4000–0x7FFF.	M
Attribute-Value-Map	See IEEE Std 11073-20601.	C
Production-Specification	See IEEE Std 11073-20601.	O
Mds-Time-Info	See IEEE Std 11073-20601.	C
Date-and-Time	See IEEE Std 11073-20601.	C
Relative-Time	See IEEE Std 11073-20601.	C
HiRes-Relative-Time	See IEEE Std 11073-20601.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601.	C
Power-Status	*onBattery* or *onMains*.	R
Battery-Level	See IEEE Std 11073-20601.	R
Remaining-Battery-Time	See IEEE Std 11073-20601.	R
Reg-Cert-Data-List	See IEEE Std 11073-20601.	O
Confirm-Timeout	See IEEE Std 11073-20601.	O

NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static or dynamic.

In the response to a Get MDS Object command, only implemented attributes and their corresponding values are returned.

See IEEE Std 11073-20601 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a blood pressure monitor agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601) as shown in Table 1.

The agent sends the Dev-Configuration-Id during the Associating state (see 8.3) to identify its configuration for the duration of the association. If the manager already holds the configuration information relating to the Dev-Configuration-Id, it recognizes the Dev-Configuration-Id. Then the Configuring state (see 8.4) is skipped, and the agent and manager then enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

If an agent implements multiple IEEE 11073-104zz specializations, System-Type-Spec-List is a list of type/version pairs, each referencing the respective device specialization and version of that specialization.

6.5.2 MDS object methods

Table 2 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 2, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and response (see IEEE Std 11073-20601); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601 for ASN.1 definitions) to use in the action message for the *action-info-args* field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

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Table 2—MDS object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—

Set-Time
This method allows the manager to set a real-time clock in the agent with the absolute time. The agent indicates whether the Set-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601). Agents with an internal real-time clock (RTC) should indicate this capability by setting the mds-time-capab-real-time-clock bit in the Mds-Time-Info attribute.

If the agent supports the Absolute-Time-Stamp attribute, this method should be implemented.

6.5.3 MDS object events

Agents following only this device specialization and no others shall send event reports (see 6.5.3) using agent-initiated measurement data transmission. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style. As a result, the manager shall assume the blood pressure monitor agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601 for additional information). The data-req-init-manager-count shall be set to zero, and the data-req-init-agent-count shall be set to 1.

Agents following this device specialization as well as others shall send event reports in the appropriate fashion. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style.

Table 3 defines the events that can be sent by the blood pressure monitor MDS object.

Table 3—Blood pressure monitor MDS object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—

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