Integrating the Healthcare Enterprise

IHE Patient Care Device
Technical Framework Supplement

Medical Equipment Management
Device Management Communication
(MEMDMC)

Rev. 1.3 –Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Patient Care Device Technical Framework 7.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on November 9, 2017 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Patient Care Device Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/PCD_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at www.ihe.net.

Information about the IHE Patient Care Device domain can be found at ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Patient Care Device Technical Framework can be found at http://ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

This supplement affects Volumes 1 and 2 of the PCD Technical Framework. The supplement adds a new profile, new actors, new triggers, and a new transaction. This supplement defines a profile for the communication of detailed device component identification, hardware and software versioning information, and device, battery, and power source status in the absence of patient observations, alerts, or event notifications.

Open Issues and Questions

Identification of some observation identifications (MDC & REFID) is not currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature and so a submission will be required. In the interim an MDC value of zero and a REFID prefix of MDCX will be utilized until official values are assigned. After values are assigned they are likely to appear in the Rosetta Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once assigned official values implementations are required to use the assigned values.

Closed Issues

Communication of the same information that this profile communicates as observations in conjunction with the data, alert, and event use cases associated with existing PCD profiles can be accomplished using the observation documentation found in this profile as additional observations to existing transactions in association with existing actors without the requirement for vendor adoption of this new profile. The justification for this additional profile is the definition of a new actor type (CMMS, or more specifically a CEMS) which is distinct from existing actors as well as the trigger condition which is unrelated to any device associated patient.

Other methods for communication of equipment information exist in the operating environment (SNMP, vendor proprietary SOAP/XML, etc.) today, are expected to continue to exist, but are not expected to integrate with medical device data communication.

History of Document Changes

This section provides a brief summary of changes and additions to this document.

Date	Document Revision	Change Summary
2015-10-14	1.2	Updated for approved CPs and housekeeping corrections.
2017-11-09	1.3	Updated for approved CPs, housekeeping corrections, and explanation that MDCs and REFIDs need to be standardized and that they will appear first in RTMMS.

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of actors:

The Device Management Information Reporter (DMIR) produces observations.

The Device Management Information Consumer (DMIC) consumes observations.

Actor	Definition
Device Management Information Reporter (DMIR)	Transmits observations of device identification (unique identification, versions for software, firmware, hardware) and status (power, power source, battery, self-test, etc.).
Device Management Information Consumer (DMIC)	Receives device identification and status information.

The Device Management Information Reporter (DMIR) may also be an actor in a different profile (DEC DOR, ACM AR, IPEC DOR). The Device Management Information Consumer (DMIC) is a new and distinct destination actor and is likely to be a Computerized Maintenance Management System (CMMS), or more specifically a Clinical Equipment Management System (CEMS), but may also be an actor in a different profile (DEC DOC, ACM AM, IPEC DOC).

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

Device Management Information Observation (DMIO) [PCD-15] (from DMIR to DMIC)

Transaction	Definition
Device Management Information Observation (DMIO)	Contains observations of device identification (unique identification, versions for software, firmware, hardware) and status (power, power source, battery, self-test, etc.). This transaction might not commonly contain patient associated information and would likely be destined for a CMMS and not for an EMR for EHR storage.

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

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Acronym	Definition
CEMS	Clinical Equipment Management System, a clinical equipment specific variant of a CMMS
CMMS	Computerized Maintenance Management System
ePHI	Electronic Patient Healthcare Information

Volume 1 – Profiles

Copyright Licenses

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

NA

Domain-specific additions

None

Add Section X

X Medical Equipment Management Device Management Communication (MEMDMC) Profile

Existing profile transaction observation information does not include detailed device component identification, hardware and software versioning information, and device, self-test, battery, and power source status.

Specific triggers, transactions, and destination actors in existing profiles do not exist for the sole purpose of communication of detailed device component identification, hardware and software versioning information, and device, battery, and power source status in the absence of patient observations, alerts, or event notifications. The absence of the communication of this information outside of patient observations, alerts, or event notifications reduces the effectiveness of CMMS solutions and impacts the effectiveness of the management of medical equipment by not permitting the tracking of hardware and software versioning information across multiple patient uses for the same device or battery utilization and battery cycling in the absence of patient associations.

This is not the reporting of a patient associated medical device observational data as would be accomplished using the Device to Enterprise Communication (DEC) Profile.

This is not the reporting of a patient associated operational event as would be accomplished using an Event Communication (EC) associated profile or device specialization, such as Infusion Pump Event Communication (IPEC).

This is not the reporting of an Alert for response by a person as that would be accomplished by the Alert Communication Management (ACM) Profile.

This profile is a combination of profile types as it defines workflow through use case specification and transport through its described use of the HL7®[1] and IEEE 11073 standards for information communication.

X.1 MEMDMC Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://www.ihe.net/Technical_Frameworks.

Figure X.1-1 shows the actors directly involved in the MEMDMC Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

[1] HL7 is the registered trademark of Health Level Seven International.

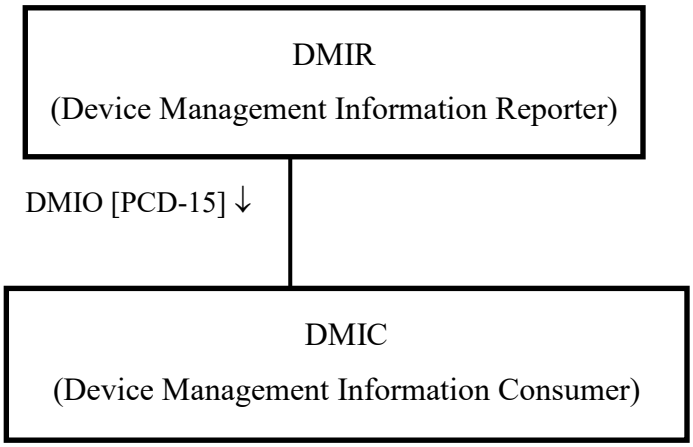


Figure X.1-1: MEMDMC Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the MEMDMC Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table X.1-1: MEMDMC Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
DMIR	DMIO [PCD-15]	R	PCD TF-2: 3.15
DMIC	DMIO [PCD-15]	R	PCD TF-2: 3.15

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 Device Management Information Reporter (DMIR)

The Device Management Information Reporter (DMIR) may also be an observation transaction sending actor in other IHE PCD profiles, such as a DEC DOR, an ACM AR, or an IPEC DOR. If that is the case then the observations defined in this document may be included in existing observation content for those profiles without adoption of this profile, unless the destination to which the observations are being sent is a CMMS and not an EMR/EHR system. If that the case then this profile should be implemented.

X.1.1.2 Device Management Information Consumer (DMIC)

It is not highly probable that the Device Management Information Consumer (DMIC) is an actor in other IHE PCD profiles. The CMMS specific role of the DMIC Actor is the justification for this unique profile as a medical device sending the observations is likely to require the destination configuration and message content for the DMIC Actor to be different from those of other IHE profile actors, such as the EMR/EHR system.

X.2 MEMDMC Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: MEMDMC - Actors and Options

Actor	Option Name	Reference
DMIR	Doesn't send ePHI	PCD TF-2: X.2
DMIC	Doesn't process ePHI	PCD TF-2: X.2

X.3 MEMDMC Required Actor Groupings

There are no required actor groupings.

X.4 MEMDMC Overview

MEMDMC is focused with sending equipment identification observations whether or not there is a patient associated with the device to equipment management systems, such as CMMS.

X.4.1 Concepts

Equipment identification, configuration, and status information needs to be recorded for effective management of the equipment, whether or not there is a patient currently associated with the equipment.

X.4.2 Use Cases

If the observations identified in this profile are added to messages of existing profiles then conformance to this profile is not required. However if the destination of the observations is not in conjunction with a device associated patient or are meant to be received by an equipment management system (CMMS) this conformance to this profile is required.

X.4.2.1 Use Case #1: Equipment Observations to CMMS

In this use case equipment observations are sent to the CMMS, whether or not the equipment is currently associated with a patient.

If the observation is of a condition for which notification of a person is required for prioritized attention then that should be an additional alert notification to an ACM AM and this profile is not appropriate, simply define a new alert and add the observation to it as an ACM PCD-04 transaction.

Depending upon information in the observation sent to the CMMS the CMMS can choose originate an ACM PCD-04 advisory alert transaction as an ACM AR Actor in order to get someone to tend to an equipment issue.

X.4.2.1.1 Equipment Observations to CMMS Use Case Description

When a piece of equipment undergoes a status or configuration change, ends a battery charging cycle, or executes a self-test, and has a status to report, it reports it as an observation. The following is a sample list of situations under which observations would be reported. This is not a complete list as new observations are expected to be able to be accommodated without updating this profile. If equipment location tracking information is available (where embedded or through coordination with a gateway) that information can be included as additional observations in this transaction without adopting the MEMLS Profile.

- Equipment power up (a last seen indication)
- Equipment network configuration is about to change (in case the change takes it offline)
- Equipment power transitions from mains to battery or back to mains (in case of battery failure)
- Self-test status is being reported and whether it failed or not (last known health)
- Battery status/level for all batteries is being reported (last known battery health)
- Battery charging success is being reported (last known battery health)
- Preventative maintenance cycle status being reported (metering)

This is not the reporting of a patient associated operational event as would be accomplished using an Event Communication (EC) associated profile or device specialization, such as Infusion Pump Event Communication (IPEC).

This is not the reporting of an Alert for response by a person as that would be accomplished by the Alert Communication Management (ACM) Profile.

X.4.2.1.2 Equipment Observations to Process Flow

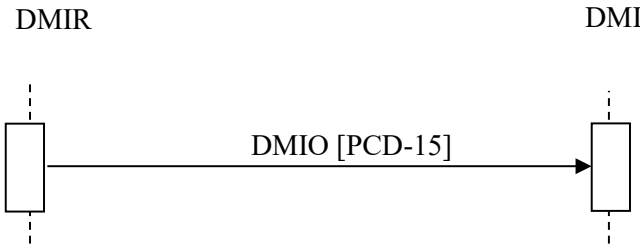


Figure X.4.2.1.2-1: Basic Process Flow in MEMDMC Profile

X.5 MEMDMC Security Considerations

During the profile development there were no unusual security or privacy concerns identified. There are no mandatory security controls but the implementer is encouraged to use the underlying security and privacy profiles from ITI that are appropriate to the transports such as the Audit Trail and Node Authentication (ATNA) Profile. The operational environment risk assessment, following ISO 80001, will determine the actual security and safety controls employed.

X.6 MEMDMC Cross Profile Considerations

A DMIR is likely to also be a DEC DOR, an ACM AR, an IPEC DOR, or a MEMLS LIOR. There is no grouping required.

Volume 2 – Transactions

Add Section 3.15

3.15 Device Management Information Observation (DMIO) [PCD-15]

3.15.1 Scope

This transaction is used to report equipment management observations whether or not the equipment is currently associated with a patient.

3.15.2 Actor Roles

The DMIR sends the DMIO to the DMIC.

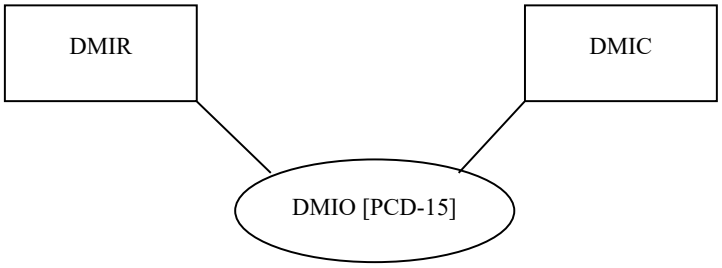


Figure 3.15.2-1: Use Case Diagram

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 3.15.2-1: Actor Roles

Role:	Producer
Actor(s):	The following actors may play the role of Producer: Device Management Information Reporter (DMIR)
Role:	Consumer
Actor(s):	The following actors may play the role of Consumer: Device Management Information Consumer (DMIC)

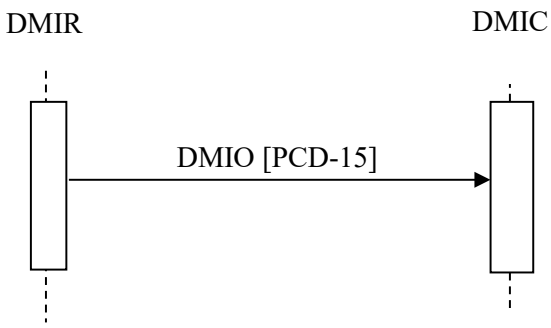
3.15.3 Referenced Standards

HL7® v2.6, Chapter 7 Observations

IEEE 11073-10101

Identification of some observation identifications (MDC & REFID) are not be currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature and so a submission will be required. After values are assigned they are likely to appear in the Rosetta Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once assigned official values implementations will be required to use the assigned values.

3.15.4 Interaction Diagram



3.15.4.1 Device Management Information Observation (DMIO) [PCD-15]

The observations are mapped to OBX segment and contained under an OBR segment.

A single transaction should report a single observation about a single piece of equipment.

More than one sending actor instance can send to the same receiving actor instance.

3.15.4.1.1 Trigger Events

The HL7® trigger event is an ORU^R01^ORU_R01.

Specific MDC codes and REFIDs for triggers are listed in the Rosetta Terminology Mapping Management System (RTMMS). This permits new triggers to be added without a version update of this document.

1. Equipment power up
2. Equipment network configuration is about to change

3. Equipment power transitions from mains to battery or back to mains
4. Self-test status is being reported (whether it failed or not)
5. Battery status/level for all batteries is being reported
6. Battery charging success is being reported

3.15.4.1.2 Message Semantics

The message is an HL7 observation. The content of the message is governed by HL7, IHE PCD Technical Framework and this profile. The objects for which the observations are being reported are governed by IEEE 11073.

The MDS, VMD, CHAN, and METRICs are to be reported per the IHE PCD Technical Framework.

Specific MDC codes and REFIDs for triggers and observations are listed in the Rosetta Terminology Mapping Management System (RTMMS). This permits new triggers and observations to be added without a version update of this document.

Identification of some observation identifications (MDC & REFID) are not be currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature and so a submission will be required. After values are assigned they are likely to appear in the Rosetta Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once assigned official values implementations will be required to use the assigned values.

Indicating Observation Result Status (OBX-11) as a value of R (Results entered – not verified) establishes an expectation that someone will manually verify the value of the observation. Review and verification of DMC Profile specific observations (primarily observations of equipment battery, power, and self-test status) is not expected as they change over time and requiring someone to review and certify them is a workload with little return for the effort. Therefore DMC observations shall indicate a value of F (Final) in Observation Result Status (OBX-11).

3.15.4.1.3 Expected Actions

In response to the receipt of the message the receiver will generate an HL7® acknowledgement to advise the sending of the status of the receipt of the message that was sent.

As a result of receiving the observation the receiver can store the information for later retrieval or the information can be used to trigger the production of transactions in other IHE profiles, such the generation of an ACM alert.

3.15.5 Security Considerations

During the profile development there were no unusual security or privacy concerns identified. There are no mandatory security controls but the implementer is encouraged to use the

underlying security and privacy profiles from ITI that are appropriate to the transports such as the Audit Trail and Node Authentication (ATNA) Profile. The operational environment risk assessment, following ISO 80001, will determine the actual security and safety controls employed.

Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

The following OIDs have been allocated to the MEMDMC Profile.

Specific IHE-PCD Transactions: 1.3.6.1.4.1.19376.1.6.15.9 / 1.3.6.1.4.1.19376.1.6.1.15.1 (PCD-15).

The 1.3.6.1.4.1.19376.1.6.1.15.1 will appear in MSH-21 to identify the PCD-15 transaction.

Specific IHE-PCD Conformance profiles: 1.3.6.1.4.1.19376.1.6.6.15.1 [PCD-15]

Appendices

Appendix A – Transaction Examples

These are the transaction examples for this profile.

A.1 Device Management Information Observation

The Device Management Information Observation (DMIO) [PCD-15] is the report of an observation of the identification, status, or configuration of a piece of equipment and the reason for the report.

Observation identifiers of MDCX with a value of zero indicate the MDC and REFID have not yet been officially assigned. Once officially assigned the MDC code will change from zero to its assigned value and the REFID will change to the officially assigned string.

Identification of some observation identifications (MDC & REFID) are not be currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature and so a submission will be required. After values are assigned they are likely to appear in the Rosetta Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once assigned official values implementations will be required to use the assigned values.

The PCD Technical Framework requires the presence of PID and PV1 segments. For communication of these segments to a CMMS they should not pass ePHI and so are required to be indicated accordingly.

> PID-31 Identity Unknown Indicator equals Y indicates the patient's/person's identity is unknown (in this case meaning not passed).
>
> PV1-2 Patient Class equals N indicates patient assigned location information is Not Applicable.

The equipment name shall be in a separate OBX segment occurrence with an observation containment identifying MDC/REFID in OBX-3 (0^MDCX_LS_ATTR_NAME^MDC is proposed until an RTMMS defined value is available) with the equipment name as the observation value in OBX-5 Observation Value.

The following example is for a PCD-15 message for an infusion pump.

MSH|^~\&|Smiths Medical^001A010000000001^EUI-64||Smiths Customer||20150119221713-0000||ORU^R01^ORU_R01|1421727433|P|2.6|||AL|NE||UNICODE UTF-8|en^English^ISO639||IHE_PCD_015^IHE PCD^1.3.6.1.4.1.19376.1.6.1.15.1^ISO

PID|1||||||||||||||||||||||||||||Y

PV1|1|N

OBR|1|2000101^Medfusion 4000^001A010000000001^EUI-64|2000101^Medfusion 4000^001A010000000001^EUI-64|0^MDCX_EVT_POWER_OFF|||20150119221713-0000

OBX|1|ST|69985^MDC_DEV_PUMP_INFUS_MDS^MDC|1.0.0.0|||||||X

OBX|2|ST|67880^MDC_ATTR_ID_MODEL^MDC|1.0.0.1|manufacturer=Smiths Medical model=Medfusion 4000||20150119221713-0000||||R

OBX|3|ST|67972^MDC_ATTR_SYS_ID^MDC|1.0.0.2|2000101^Medfusion 4000^001A010000000001^EUI-64||20150119221713-0000||||R

OBX|4|CWE|0^MDCX_DMC_ATTR_POWER_STATE^MDC|1.0.0.3|^OFF||20150119221713-0000||||F|||||||2000101^Medfusion 4000^001A010000000001^EUI-64

OBX|5|ST|0^MDCX_LS_ATTR_NAME^MDC|LOC|IV Pump 2012078||||||F|||20150127110822.229-0800

OBX|6|PL|0^MDCX_LS_ATTR_LOCATION^MDC|LOC|^^^Fraser Health^^^North Building^Main Floor^Nurse Station||||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

OBX|7|NM|0^MDCX_LS_ATTR_COORD_X^MDC|LOC|406|263441^MDC_DIM_CENTI_M^MDC|||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

OBX|8|NM|0^MDCX_LS_ATTR_COORD_Y^MDC|LOC|917|263441^MDC_DIM_CENTI_M^MDC|||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

OBX|9|NM|0^MDCX_LS_ATTR_COORD_Z^MDC|LOC|0|263441^MDC_DIM_CENTI_M^MDC|||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

Volume 3 – Content Modules

5 Namespaces and Vocabularies

Add to Section 5 Namespaces and Vocabularies

None

6 Content Modules

Not applicable. CDA®[2] is not being produced.

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

None

[2] CDA is the registered trademark of Health Level Seven International.

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

None at this time

