

Integrating the Healthcare Enterprise



5

**IHE Devices
Technical Framework Supplement**

10

**PCD Program
Medical Equipment Management
Device Management Communication
(MEMDMC)**

15

Rev. 1.5 – Trial Implementation

20 Date: September 19, 2024
Author: IHE Devices Technical Committee
Email: dev@ihe.net

25

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 Devices Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

30 This supplement is published on September 19, 2024 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 Devices Technical Framework. Comments are invited and can be submitted at https://www.ihe.net/DEV_Public_Comments.

35 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.

<i>Amend Section X.X by the following:</i>
--

40 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 [IHE.net](https://www.ihe.net).

45 Information about the IHE Devices domain can be found at [IHE Domains](#).

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at [Profiles](#) and [IHE Processes](#).

The current version of the IHE Devices Technical Framework can be found at [Devices Technical Framework](#).

50

CONTENTS

	Introduction to this Supplement.....	5
	Open Issues and Questions	5
55	Closed Issues.....	5
	History of Document Changes.....	6
	IHE Technical Frameworks General Introduction.....	7
9	Copyright Licenses.....	7
10	Trademark	7
60	IHE Technical Frameworks General Introduction Appendices.....	8
	Appendix A – Actors	8
	Appendix B – Transactions.....	9
	Glossary	9
	Volume 1 – Profiles	11
65	Copyright Licenses.....	11
	Domain-specific additions	11
	X Medical Equipment Management Device Management Communication (MEMDMC) Profile	12
	X.1 MEMDMC Actors, Transactions, and Content Modules.....	12
70	X.1.1 Actor Descriptions and Actor Profile Requirements.....	13
	X.1.1.1 Device Management Information Reporter (DMIR).....	13
	X.1.1.2 Device Management Information Consumer (DMIC)	13
	X.2 MEMDMC Actor Options	14
	X.3 MEMDMC Required Actor Groupings	14
75	X.4 MEMDMC Overview	14
	X.4.1 Concepts	14
	X.4.2 Use Cases	14
	X.4.2.1 Use Case #1: Equipment Observations to CMMS	14
	X.4.2.1.1 Equipment Observations to CMMS Use Case Description.....	15
80	X.4.2.1.2 Equipment Observations to Process Flow	15
	X.5 MEMDMC Security Considerations.....	16
	X.6 MEMDMC Cross Profile Considerations	16
	Volume 2 – Transactions	17
	3.15 Device Management Information Observation (DMIO) [PCD-15].....	17
85	3.15.1 Scope	17
	3.15.2 Actor Roles.....	17
	3.15.3 Referenced Standards	18
	3.15.4 Messages	19
	3.15.4.1 Device Management Information Observation (DMIO) [PCD-15]	19
90	3.15.4.1.2 HL7 Conformance Statement	19
	3.15.4.1.3 Device Management Information Observation [PCD-15] (ORU^R44^ORU_R44) Static Definition	20

	3.15.4.1.4 Trigger Events	21
	3.15.4.1.5 Message Semantics	21
95	3.15.4.1.6 Expected Actions	22
	3.15.5 Security Considerations.....	22
	Volume 2 Namespace Additions	22
	Appendices to Volume 1	23
	Appendix A – Transaction Examples	23
100	A.1 Device Management Information Observation	23
	Volume 3 – Content Modules.....	25
	5 Namespaces and Vocabularies.....	25
	6 Content Modules.....	25
	Volume 3 Namespace Additions	25
105	Volume 4 – National Extensions	26
	4 National Extensions	26

Introduction to this Supplement

110 This supplement affects Volumes 1 and 2 of the Devices 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

115 Identification of some observation identifications (MDC & REFID) may not be currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature. Submissions will be required as needed. In the interim, an MDC value of zero and a REFID prefix of MDCX shall be utilized until official values are assigned. After provisional values are assigned they are expected to appear in the most recent update and version of the Rosetta Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once
120 assigned official values, implementations shall use the assigned values.

A unique to this profile HL7 v2 message trigger has been granted by HL7 v2 Orders and Observations to replace current use of trigger value R01. This profile utilizes unsolicited observations and therefore MSH-9-1 Message Code shall remain ORU. The HL7 that granted trigger value is R44, is queued to first appear in a v 2.9.x release of HL7 v2, and replaces R01 in
125 the MSH-9 Message Type field in both MSH-9-2 Trigger and MSH-9-3 Message Structure components in examples and references within this document have been updated accordingly. This trigger change while impacting to existing products, test tools, and deployments will allow transactions of this profile to utilize a message structure unique to this profile which will permit discontinuance of use of the message structure associated with R01. This change will allow
130 transactions of this profile to exclude the R01 structure required HL7 message segments associated with electronic patient healthcare information (ePHI) contained in the PID Patient Identification and PV1 Patient Visit segments. Observation producer and consumer actors associated with this profile do not make use of and do not administer ePHI. Removal of ePHI message content which is not required by this profile assures patient confidentiality and avoids
135 transaction consuming actors from requiring a HIPAA (Health Insurance Portability and Accountability Act of 1996) Business Associate agreement. This migration will also allow the deprecation of the profile transaction options associated with ePHI.

140 When copying OBX instances from consumed transactions of this profile to reporter transactions of other profiles, such as DEC, IPEC, ACM, etc., the dotted notation values in OBX-4 should bear scrutiny for hierarchical conflicts with OBX-4 values of OBX instances associated with the base reporter content into which the OBX instances of this profile are being copied.

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

145 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
 150 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

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

Date	Document Revision	Change Summary												
2024-SEP	1.5	Updated for approved CPs, housekeeping corrections <table border="1" data-bbox="602 911 1469 1024"> <thead> <tr> <th data-bbox="602 911 751 980">CP #</th> <th data-bbox="751 911 992 980">CP Approval Date</th> <th data-bbox="992 911 1469 980">CP Title</th> </tr> </thead> <tbody> <tr> <td data-bbox="602 980 751 1024">DEV-003</td> <td data-bbox="751 980 992 1024">2024-06-12</td> <td data-bbox="992 980 1469 1024">MEM DMC Trigger and Template</td> </tr> </tbody> </table>	CP #	CP Approval Date	CP Title	DEV-003	2024-06-12	MEM DMC Trigger and Template						
CP #	CP Approval Date	CP Title												
DEV-003	2024-06-12	MEM DMC Trigger and Template												
2023-04-07	1.4	Updated for approved CPs, housekeeping corrections, and replacing MDCXs with allocated MDCs and REFIDs. The following CPs were integrated. <table border="1" data-bbox="591 1150 1479 1423"> <thead> <tr> <th data-bbox="591 1150 751 1220">CP #</th> <th data-bbox="751 1150 992 1220">CP Approval Date</th> <th data-bbox="992 1150 1479 1220">CP Title</th> </tr> </thead> <tbody> <tr> <td data-bbox="591 1220 751 1289">111</td> <td data-bbox="751 1220 992 1289">2015-02-27</td> <td data-bbox="992 1220 1479 1289">Move equipment name from OBX-18 to OBX-5</td> </tr> <tr> <td data-bbox="591 1289 751 1358">119</td> <td data-bbox="751 1289 992 1358">2015-03-06</td> <td data-bbox="992 1289 1479 1358">Clarification of Observation Result Status OBX-11 as F</td> </tr> <tr> <td data-bbox="591 1358 751 1423">152</td> <td data-bbox="751 1358 992 1423">2020-11-20</td> <td data-bbox="992 1358 1479 1423">MEMDMC Use of MDC_OBS_MEM in OBR-4 in [PCD-15]</td> </tr> </tbody> </table>	CP #	CP Approval Date	CP Title	111	2015-02-27	Move equipment name from OBX-18 to OBX-5	119	2015-03-06	Clarification of Observation Result Status OBX-11 as F	152	2020-11-20	MEMDMC Use of MDC_OBS_MEM in OBR-4 in [PCD-15]
CP #	CP Approval Date	CP Title												
111	2015-02-27	Move equipment name from OBX-18 to OBX-5												
119	2015-03-06	Clarification of Observation Result Status OBX-11 as F												
152	2020-11-20	MEMDMC Use of MDC_OBS_MEM in OBR-4 in [PCD-15]												
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.												
2015-10-14	1.2	Updated for approved CPs and housekeeping corrections.												

IHE Technical Frameworks General Introduction

160 The [IHE Technical Frameworks General Introduction](#) is shared by all of the IHE domain
technical frameworks. Each technical framework volume contains links to this document where
appropriate.

9 Copyright Licenses

165 IHE technical documents refer to, and make use of, a number of standards developed and
published by several standards development organizations. Please refer to the IHE Technical
Frameworks General Introduction, [Section 9 - Copyright Licenses](#) for copyright license
information for frequently referenced base standards. Information pertaining to the use of IHE
International copyrighted materials is also available there.

10 Trademark

170 IHE[®] and the IHE logo are trademarks of the Healthcare Information Management Systems
Society in the United States and trademarks of IHE Europe in the European Community. Please
refer to the IHE Technical Frameworks General Introduction, [Section 10 - Trademark](#) for
information on their use.

IHE Technical Frameworks General Introduction Appendices

175 The [IHE Technical Framework General Introduction Appendices](#) are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

180 *Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain’s Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices to the IHE Technical Frameworks General Introduction located [here](#).*

185 **NEW: REQUIRED APPROVAL OF ACTORS, TRANSACTIONS and TERMS** - To avoid duplication and ensure consistency across domains, all **new or modified** actors, transactions and glossary terms need approval by IHE’s Domain Coordination Committee (DCC) before they are published in a trial implementation supplement. Please see [this Wiki page](#) for additional guidance and links to the forms for approval submission.

[Appendix A – Actors](#)

190

*Add the following **new or modified** actors to the [IHE Technical Frameworks General Introduction Appendix A](#):*

The Device Management Information Reporter (DMIR) produces observations.
195 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.

200 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 – Transactions

205

Add the following **new or modified** transactions to the [IHE Technical Frameworks General Introduction Appendix B](#):

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

New (or modified) Transaction Name and Number	Definition
Device Management Information Observation (DMIO) [PCD-15]	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.

210

Glossary

Add the following **new or modified** glossary terms to the [IHE Technical Frameworks General Introduction Appendix D](#):

215

New (or modified) Glossary Term	Definition	Synonyms	Acronym/ Abbreviation
Clinical Equipment Management System	A clinical equipment specific variant of a CMM		CEMS
Computerized Maintenance Management System	This is the system which the hospital makes use of to maintain its inventory of medical devices, their identification, their status, their software, firmware, and hardware versioning information and history. This is a system for which reception of device location observation is well suited as a means of identifying the last known location of equipment in need of servicing, repairs, or version upgrades.		CMMS
Electronic Protected Health Information	Protected health information (PHI) that is produced, saved, transferred or received in an electronic form. In the United States, ePHI management is covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule.		ePHI

IHE Devices Technical Framework Supplement – Medical Equipment Management Device Management Communication (MEMDMC)

New (or modified) Glossary Term	Definition	Synonyms	Acronym/ Abbreviation
Health Insurance Portability and Accountability Act of 1996	The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient’s consent or knowledge. The US Department of Health and Human Services (HHS) issued the HIPAA Privacy Rule to implement the requirements of HIPAA. The HIPAA Security Rule protects a subset of information covered by the Privacy Rule. See https://www.cdc.gov/php/publications/topic/hipaa.html .		HIPAA

Volume 1 – Profiles

Copyright Licenses

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

NA

220 Domain-specific additions

None

Add Section X

225 **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.

230 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
235 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.

240 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).

245 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 v2 and IEEE 11073 standards for information communication.

X.1 MEMDMC Actors, Transactions, and Content Modules

250 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.

255 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.

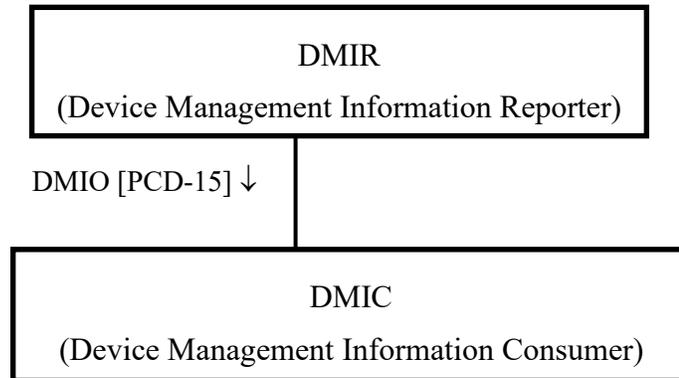


Figure X.1-1: MEMDMC Actor Diagram

260 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

265 **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)

270 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.

275 **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

280 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	No option defined	--
DMIC	No option defined	--

285

X.3 MEMDMC Required Actor Groupings

There are no required actor groupings.

X.4 MEMDMC Overview

290 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.

295 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.

300 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.

305 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 to originate an ACM [PCD-04] advisory alert transaction as an ACM AR Actor in order to get someone to tend to an equipment issue.

310 **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)
- 320 • 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)
- 325 • 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).

330 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

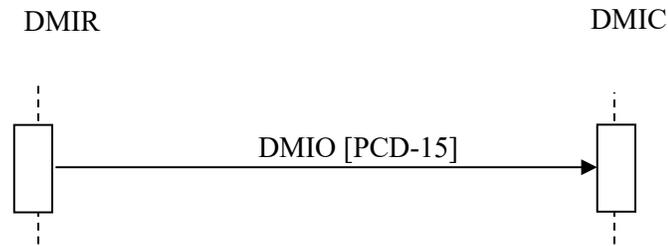


Figure X.4.2.1.2-1: Basic Process Flow in MEMDMC Profile

335 **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.

340 **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.

345

Volume 2 – Transactions

Add Section 3.15

350 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

355 The DMIR sends the DMIO to the DMIC.

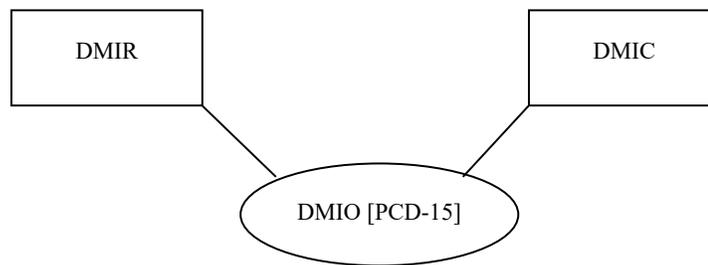


Figure 3.15.2-1: Use Case Diagram

360 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

365 HL7 v2.6, transitioning to v2.9.x once published for new trigger/template, Chapter 7
Observations

IEEE 11073-10101, minimally version B, with additional MDC/REFID values not yet in the standard (as identified by MDCX indicated value of zero and the interim REFID values).

370 Identification of some observation identifications (MDC & REFID) might not be currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature in which case a submission will be required. These are maintained external to this profile and thus have a low probability of new change proposals to this profile. 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 shall use the assigned values.

375 Below is a mapping table with an indication as to whether or not the REFID string changed from the trial to the allocated values. To reduce transcription errors, table content has been kept to a minimum. For additional details, such as value descriptions, units of measure, partition codes, and enumerations, refer to the IEEE 11073-10101 standard (normative and balloted versions) or RTMMS.

380 **Table 3.15.3-1: IEEE Nomenclature Mapping from preliminary to assigned**

Trial Values	Allocated Values	Changed
none	69135^MDC_OBS_MEM^MDC	Y
0^MDCX_DMC_ATTR_POWER_STAT^MDC or 67925^MDC_DMC_ATTR_POWER_STAT^MDC	67925^MDC_ATTR_POWER_STAT^MDC	N

385 **3.15.4 Messages**

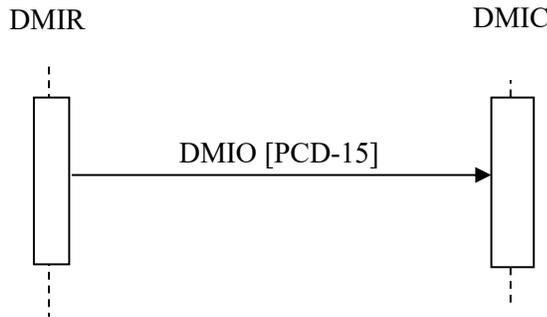


Figure 3.15.4-1: Interaction Diagram

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.

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

3.15.4.1.2 HL7 Conformance Statement

The conformance statement for this interaction described below is adapted from HL7 version 2.6 with use of the Participation Information (PRT) segment from HL7 version 2.7.

Table 3.15.4.1.2-1: Device Management Information Observation [PCD-15] Transaction Conformance

395

Publication ID:	R44
Type:	Unsolicited
Publication Name:	IHEPCD-15DeviceManagementInformationObservation
Trigger:	See Section 3.15.4.1.5 Trigger Events
Mode:	Immediate
Response:	ORU^R44^ORU_R44
Characteristics:	Sends device management information observation data
Purpose:	Report Device Management Information Observation from DMIR to DMIC
Based on Segment Pattern:	R44

3.15.4.1.3 Device Management Information Observation [PCD-15] (ORU^R44^ORU_R44) Static Definition

400 The Device Management Information Observation [PCD-15] message is used to communicate device management information observation data from a Device Management Information Observation Reporter (DMIR) to a Device Management Information Observation Consumer (DMIC).

Common HL7 segments are defined in DEV TF-2: Appendix B. Sections below discuss considerations specific to [PCD-15].

405 **Table 3.15.4.1.3-1: ORU^R44^ORU_R44 HL7 Attribute Table**

Segment	ORU Message	Usage	Card.	HL7 Ref
MSH	Message Header Segment	R	[1..1]	2.15.9
OBR	Observation Request Segment	R	[1..n]	7.4.1
OBX	Observation Result Segment	R	[1..n]	7.4.2
[PRT]	Participation Information Segment	O	[0..n] See Note	7.4.4 (V2.7)

Note: Use of PRT is required for communicating identification of referenced other equipment.

Table 3.15.4.1.3-2: ORU^R44^ORU_R44 Static Definition

ORU^R44^ORU_R44	Device Management Information Observation Message
MSH	Message Header
[{SFT}]	Software Segment
{	--- REPORT DEVICE MANAGEMENT INFORMATION OBSERVATION begin
OBR	Device Management Information Observation Identification
{	--- OBSERVATION begin
{OBX}	Device Management Information observations relative to OBR
[PRT]	Participation identifies person or equipment
}	--- OBSERVATION end
}	--- REPORT MANAGEMENT INFORMATION OBSERVATION end

410 Note: Per ORU R44 message template, PID and PV1 segments shall not be used, (X) usage. If patient identification or patient assigned location are to be communicated between DMIR and DMIC actors in a specific deployment, it shall only be through deployment documented concurrence between DMIR and DMIC actor vendor system representatives, preceded by review of justifications or requirements and HIPAA implications regarding sending and receiving of ePHI, and shall only be communicated using the PRT segment.

3.15.4.1.4 Trigger Events

The HL7 trigger event is ORU^R44^ORU_R44.

- 415 The identification of a MEMDMC packaged group of observations shall be encoded in the value of OBR-4 Universal Service Identifier (CWE data type) of the OBR segment as

69135^MDC_OBS_MEM^MDC

- 420 Specific MDC codes and REFIDs for triggers are listed in the Rosetta Terminology Mapping Management System (RTMMS). This permits new triggers to be added for use in OBX-5 Observation Value field of OBX Observation/Result instance segments to be used by this profile without a version update of this document.

1. Equipment power up
- 425 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

430 3.15.4.1.5 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.

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

When a [PCD-15] transaction is used for the purpose of communication of a packaged group of medical device observations for the purpose of equipment management primary identification of a MEMDMC group of observations shall be encoded in the value of OBR-4 Universal Service Identifier (CWE data type) of the OBR segment as

440

69135^MDC_OBS_MEM^MDC

- 445 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.

450 Identification of some observation identifications (MDC & REFID) may not be currently defined in Rosetta Terminology Mapping (RTM) or in IEEE 11073-10101 Nomenclature. Submissions will be required as needed. In the interim an MDC value of zero and a REFID prefix of MDCX shall be utilized until provisional values have been assigned. After provisional values are assigned they are expected to appear in the most recent update and version of the Rosetta Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once provisional values are assigned implementations shall use the assigned values.

455 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).

3.15.4.1.6 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.

465 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

470 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

475 *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.

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

Appendices to Volume 1

Appendix A – Transaction Examples

These are the transaction examples for this profile.

A.1 Device Management Information Observation

485 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
490 assigned value and the REFID will change to the officially assigned string and implementations shall use values published in the standard

Identification of some observation identifications (MDC & REFID) are not 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
495 Terminology Mapping Management System (RTMMS) prior to being balloted for an update to the standard. Once assigned official values implementations shall use the assigned values.

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
500 observation value in OBX-5 Observation Value.

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

```
MSH|^~\&|Device Vendor^001A010000000001^EUI-64||Device Customer||20150119221713-  
505 0000||ORU^R44^ORU_R44|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  
OBR|1|2000101^Medfusion 4000^001A010000000001^EUI-64|2000101^Medfusion  
4000^001A010000000001^EUI-64|69135^MDC_OBS_MEM^MDC |||20150119221713-0000  
OBX|1|ST|69985^MDC_DEV_PUMP_INFUS_MDS^MDC|1.0.0.0|||||F  
OBX|2|ST|67880^MDC_ATTR_ID_MODEL^MDC|1.0.0.1|manufacturer= Device Vendor  
510 model=Medfusion 4000||20150119221713-0000||||F  
OBX|3|ST|67972^MDC_ATTR_SYS_ID^MDC|1.0.0.2|2000101^Medfusion  
4000^001A010000000001^EUI-64||20150119221713-0000||||F
```

OBX|4|CWE|67925^MDC_ATTR_POWER_STAT^MDC|1.0.0.3|^OFF||20150119221713-0000||||F|||||2000101^Medfusion 4000^001A010000000001^EUI-64

515 OBX|5|ST|68512^MDC_ATTR_LS_NAME^MDC|LOC|IV Pump
2012078||||F|||20150127110822.229-0800

OBX|6|PL|68513^MDC_ATTR_LS_LOCATION^MDC|LOC|^^^Fraser Health^^^North Building^Main Floor^Nurse Station||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

520 OBX|7|NM|68525^MDC_ATTR_LS_COORD_X^MDC|LOC|406|263441^MDC_DIM_CENTI_M^MDC||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

OBX|8|NM|68526^MDC_ATTR_LS_COORD_Y^MDC|LOC|917|263441^MDC_DIM_CENTI_M^MDC||||F|||20150127110822.229-0800||||112213000174^GuardRFID^^L

525 OBX|9|NM|68527^MDC_ATTR_LS_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

530 *Add to Section 5 Namespaces and Vocabularies*

None

6 Content Modules

Not applicable. CDA is not being produced.

Volume 3 Namespace Additions

535 *Add the following terms to the IHE Namespace:*

None

Volume 4 – National Extensions

Add appropriate Country section.

4 National Extensions

540 None at this time