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INTEROPERABILITY

The Center for Medical Interoperability Specification
ASUM Solution using MEM DMC

CMI-SP-F-ASUM-MEM-DMC-D02-2019-05-31

Draft
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Document Status Sheet

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| Work in Progress | An incomplete document designed to guide discussion and generate feedback that may include several alternative requirements for consideration. |
| Draft | A document considered largely complete but lacking review by Members and vendors. Drafts are susceptible to substantial change during the review process. |
| Issued | A generally public document that has undergone Member and Technology Supplier review, cross-vendor interoperability, and is for Certification testing if applicable. Issued Specifications are subject to the Engineering Change Process. |
| Closed | A static document, reviewed, tested, validated, and closed to further engineering change requests to the specification through The Center. |

1 Scope

1.1 Introduction and Purpose

This document specifies an Automated Secure Update Mechanism (ASUM) solution for clients that support Integrating the Healthcare Enterprise (IHE) Patient Care Device (PCD).

1.2 Requirements

Throughout this document, the words that are used to define the significance of particular requirements are capitalized. These words are:

| | |
|--------------|---|
| "SHALL" | This word means that the item is an absolute requirement of this specification. |
| "SHALL NOT" | This phrase means that the item is an absolute prohibition of this specification. |
| "SHOULD" | This word means that there may exist valid reasons in particular circumstances to ignore this item, but the full implications should be understood and the case carefully weighed before choosing a different course. |
| "SHOULD NOT" | This phrase means that there may exist valid reasons in particular circumstances when the listed behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label. |
| "MAY" | This word means that this item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because it enhances the product, for example; another vendor may omit the same item. |

2 References

2.1 Normative References

In order to claim compliance with this specification, it is necessary to conform to the following standards and other works as indicated, in addition to the other requirements of this specification. Notwithstanding, intellectual property rights may be required to use or implement such normative references.

All references are subject to revision, and parties to agreement based on this specification are encouraged to investigate the possibility of applying the most recent editions of the documents listed below.

- [CMI-SP-F-ASUM]** Automated Secure Update and Management Framework
<https://medicalinteroperability.org/specifications>
- [CMI-SP-F-PF]** Provisioning Flows
<https://medicalinteroperability.org/specifications>
- [CMI-SP-CDI-IHE-PCD-IST]** Clinical Data Interoperability Based on IHE PCD – Identity & Secure Transport
<https://medicalinteroperability.org/specifications>
- [HL7-FHIR]** Fast Healthcare Interoperability Resources
<https://www.hl7.org/fhir/overview.html>
- [IEEE-10101a-2015]** Health informatics – Point-of-care medical device communication – Part 10101: Nomenclature – Amendment 1: Additional Definitions
This is a significant extension to the ISO/IEEE 11073-10101:2004 base nomenclature standard, covering terminology for over a dozen medical devices, with a strong focus on respiratory, ventilators, and anesthesia.
<http://standards.ieee.org/findstds/standard/11073-10101a-2015.html>
- [IETF-RFC2818]** HTTP over TLS
<https://tools.ietf.org/html/rfc2818>
- [IETF-RFC5246]** The Transport Layer Security (TLS) Protocol Version 1.2
<https://tools.ietf.org/html/rfc5246>

| | |
|--------------------------|---|
| [IHE-PCD-MEM-DMC] | Integrating the Healthcare Enterprise (IHE) Medical Equipment Management (MEM) Device Management Communication (DMC) https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_Suppl_PCD_MEM-DMC.pdf |
| [IHE-PCD] | Integrating the Healthcare Enterprise (IHE) Patient Care Device (PCD) https://www.ihe.net/Patient_Care_Devices/ |
| [OWASP] | Open Web Application Security Project (OWASP) https://owasp.org/ |

2.2 Informative References

This specification does not provide any informative references.

| | |
|---------------------|--|
| [CMI-DOC-TD] | Terms and Definitions https://medicalinteroperability.org/specifications |
|---------------------|--|

2.3 Reference Acquisition

- Center for Medical Interoperability, 8 City Boulevard, Suite 203 | Nashville, TN 37209; Phone +1-615-257-6410; <http://medicalinteroperability.org/>

3 Terms and Definitions

This specification uses the terms and definitions in [CMI-DOC-TD].

4 Abbreviations and Acronyms

This specification uses the following abbreviations:

| | |
|-------------|--|
| ASUM | Automated Secure Update Mechanism |
| CME | Client Management Entity |
| CMI | Center For Medical Interoperability |
| IP | Internet Protocol |
| URL | Uniform Resource Locator |

5 Overview

The foundational ASUM framework specification ([CMI-SP-F-ASUM]) illustrates the technology-independent components, requirements, and recommendations that are used to specify ASUM solutions. The rationale for separating the ASUM framework and ASUM solutions is to leverage a multitude of protocols for specific client types and the protocols they support. Accordingly, this document specifies the ASUM solution for clients that support [IHE-PCD].

Specifically, this ASUM solution leverages the device management communications provided via [IHE-PCD-MEM-DMC] to establish communications between the ASUM Management Entity and the Client. When directed by the Client Management Entity (CME), the Client sends the [IHE-PCD-MEM-DMC] PCD-15 message containing current device information (e.g. status / software version) to the ASUM Management Entity. The Management Entity returns an acknowledgement, which has been extended to notify the client of the availability of updated software and associated information. After an update attempt, the Client sends the ASUM Management Entity another PCD-15 message containing a CMI-defined status code indicating update success, failure, or other errors. As with the ASUM framework, this document allows Clients to use an ASUM framework compliant secure transport mechanism or use the one specified by the ASUM framework. Finally, the client provides the status of update via an [IHE-PCD-MEM-DMC] PCD-15 message immediately after the update succeeds or fails.

The benefits of re-using [IHE-PCD-MEM-DMC] are:

- no open port requirement on the Client which eliminates certain security concerns,
- eliminates the need for unspecified or new messages specific for ASUM.

Figure 1 summarizes the high-level logical flows associated with this ASUM solution.

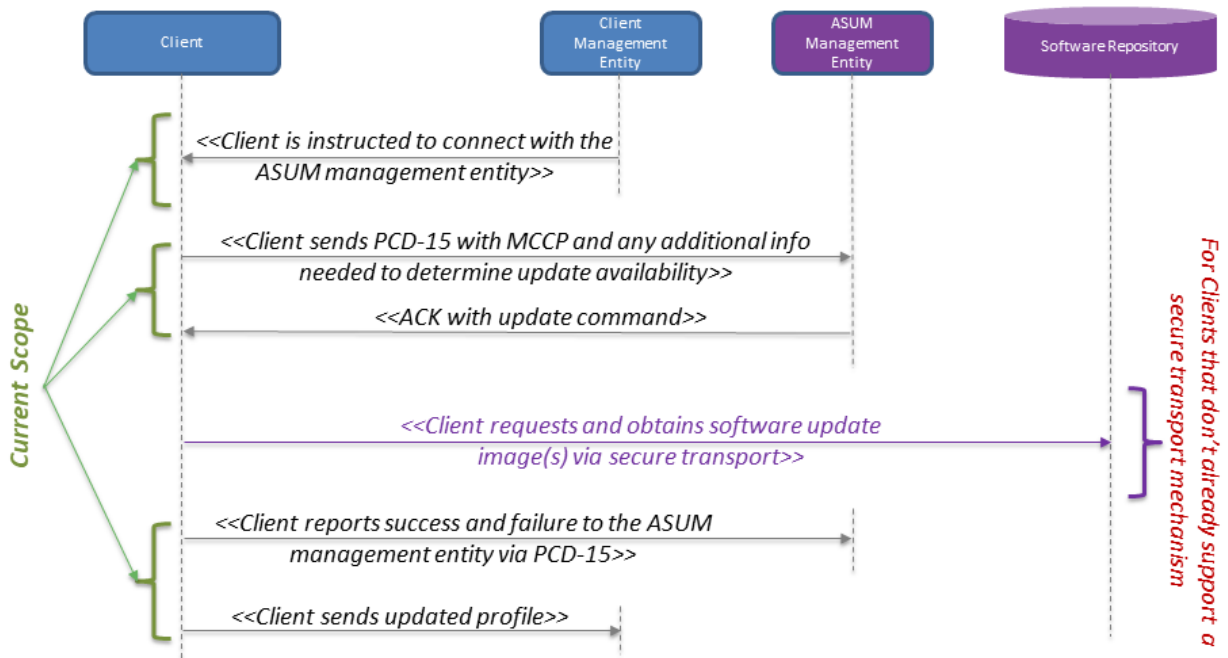


Figure 1: Architecture showing periodic MEM-DMC message

6 ASUM Solution Using MEM DMC Requirements

This document adheres to the requirements laid out in [CMI-SP-F-ASUM] and specifies the [IHE-PCD-MEM-DMC] based ASUM solution requirements within this section.

6.1 Client and ASUM Management Entity Communications

6.1.1 Client MEM DMC PCD-15 Requirement

The Client SHALL use the [IHE-PCD-MEM-DMC] PCD-15 message to communicate with the ASUM Management Entity.

6.1.2 Client IST Requirement

All communications with the ASUM Management Entity SHALL comply with [CMI-SP-CDI-IHE-PCD-IST].

6.1.3 Discovery

6.1.3.1 ASUM Management Entity Discovery

Clients SHALL communicate with the ASUM Management Entity only when directed by the CME. When ready, the CME SHALL notify the Client of the ASUM Management Entity's address.

6.1.4 Client Information

6.1.4.1 Client Information Requirement

When directed by the Client Management Entity, Clients SHALL report the Minimum Connected Component Profile (MCCP) as specified in [CMI-SP-CDI-IHE-PCD-IST] in the PCD-15 message. Clients SHALL report any additional information needed to perform the update, such as known software or hardware dependencies.

6.1.4.2 IHE PCD Infrastructure Attributes

The Reference IDs shown in Table 5, from [IEEE-10101a-2015] (Table A.11.2.1), may be used in the PCD-15 message when the Client reports additional system and version information beyond the MCCP.

Table 1 – Reference IDs for Client to Report System and Version Information

| Reference ID | Description/Definition | Part::Code | CF_CODE10 |
|--------------------------------------|--|-------------------|------------------|
| MDC_ID_MODEL_NUMBER | The model number sub-element of the MDC_ATTR_ID_MODEL attribute. | 8::7681 | 531969 |
| MDC_ID_MODEL_MANUFACTURER | The manufacturer sub-element of the MDC_ATTR_ID_MODEL attribute. | 8::7682 | 531970 |
| MDC_ID_PROD_SPEC_SERIAL | The serial-number component id group of the MDC_ATTR_ID_PROD_SPECN attribute. | 8::7684 | 531972 |
| MDC_ID_PROD_SPEC_PART | The part-number component id group of the MDC_ATTR_ID_PROD_SPECN attribute. | 8::7685 | 531973 |
| MDC_ID_PROD_SPEC_HW | The hardware-revision component id group of the MDC_ATTR_ID_PROD_SPECN attribute. | 8::7686 | 531974 |
| MDC_ID_PROD_SPEC_SW | The software-revision component id group of the MDC_ATTR_ID_PROD_SPECN attribute. | 8::7687 | 531975 |
| MDC_ID_PROD_SPEC_FW | The firmware-revision component id group of the MDC_ATTR_ID_PROD_SPECN attribute. | 8::7688 | 531976 |
| MDC_ID_PROD_SPEC_PROTOCOL_REV | The protocol-revision component id group of the MDC_ATTR_ID_PROD_SPECN attribute. | 8::7689 | 531977 |
| MDC_ATTR_SYS_ID | System ID | 1::2436 | 67972 |

Informative note: In addition to the IHE PCD infrastructure attributes noted above, the ASUM solution based on IHE PCD MEM-DMC will use elements from HL7 V2.8.2 regarding the use of the PRT segment to convey the FDA-defined 'Universal Device Identifier' (UDI).

6.1.5 Normal Flow ACK

6.1.5.1 Management Entity ACK Requirement

The ASUM Management Entity SHALL send an ACK for each PCD-15 message.

6.1.5.2 Normal Flow HL7 Ack Requirement

Normal flow SHALL consist of HL7 ACKs.

6.1.6 ACK with Command Extension

6.1.6.1 Management Entity Send Command as Extensions Requirement

The ASUM Management Entity SHALL send commands as extensions in the content of the ACK. The ASUM Management Entity SHALL use the following informational ERR segment structure for the command:

- ERR5 contains 126980^MDCC4MI_ATTR_CMI_ASUM_CMD^MDC
- ERR7 contains the command

6.1.6.2 Management Entity Multiple Command Requirement

Multiple commands MAY be sent in a single ACK by utilizing ERR segment repetition.

6.1.6.3 Management Entity Command Structure Requirement

Each ERR segment SHALL only include one command. The identifier in ERR-6 consists of a unique identifier for the command, and the ERR-7 text consists of simple key value pairs separated by spaces. The notation is described below in simplified BNF:

```

<syntax>      ::= <cmd> <parameters>
<cmd>         ::= "CMD"= "DOWNLOAD_SW" | "UPDATE_SW" |
<parameters> ::= <parameter> | <parameters>
<parameter>  ::= <key> "=" <value>
<key>        ::= text
<value>      ::= text
  
```

Restrictions beyond normal HL7 restrictions on ERR-7:

- <key> cannot contain '=' char
- <value> cannot contain '=' char unless it is escaped as %3D
- <value> cannot contain '"' char unless it is escaped as %20

Note that ERR-7 has a maximum length of 2048.

6.1.7 Command Status Report

6.1.7.1 Client Report Status Requirement

The Client SHALL report success or failure of all commands as follows:

- An OBX with the 'ST' datatype and the identifier OBX-3 = |0^MDC_NOTI_CMD_STATUS^MDC|
- Unique command identifier followed by hyphen, and string values specified in [CMI-SP-F-ASUM].

For example: OBX-5 = |123456-CMI-S-ASUM-00000|

6.2 Software Update Notification

In order to provide flexibility in health system deployments, both Client-based and Management Entity-based update scheduling can be used. In Client-based update scheduling, the update command includes information on when the Client should attempt the update, so the Client is fully responsible for monitoring the current time and performing the download/update as requested. In Management Entity-based update scheduling, the update command directs the Client to immediately begin download/update, with the expectation that the Management Entity can send this command at a scheduled time.

6.2.1 Management Entity Update Scheduling Requirement

ASUM Management Entities SHALL support both client-based and management entity-based update scheduling.

6.2.2 Client Update Scheduling Requirement

ASUM Clients SHALL support at least one update scheduling mechanism.

6.2.3 Client Update Mechanism Indication

Clients SHALL indicate which update scheduling mechanism they support using a flag in the OPT field of the MCCP as follows:

- For Clients that support Management Entity Based Scheduling, no value is required (default)
- For Clients that support Client Based Scheduling, ASUM_SCHEDULER_CBS is added to the OPT field

6.2.4 Client-based Update Scheduling

6.2.4.1 Management Entity Update Software Requirement

If a software update is ready for the Client, the ASUM Management Entity SHALL include an UPDATE_SW command in the ERR segment of the ACK with the parameters shown in the table below:

ERR Segment Parameters for Software Update Table

| Name | Description | HL7 Type | Length (characters) | Example | Required/Optional |
|-------------|---|-----------------|----------------------------|--------------------|--|
| URI | Software Download URL/URI | ST | 130 | /some/download/uri | Required; value is not further constrained |
| AUTH | Authentication Method & Related Information | ST | 20 | CVC | Required; value is not further constrained |
| DST | Start of timeframe to attempt download | TS | 17 | 201803260100-0000 | Optional; in minutes. If not specified, download may occur any time before DownloadEndTime or UpdateStartTime |
| DET | End of timeframe to attempt download | TS | 17 | 201803260159-0000 | Optional; in minutes. If not specified, download may occur any time after DownloadStartTime and before UpdateStartTime |
| UST | Start of timeframe to attempt update | TS | 17 | 201803260500-0000 | Optional; in minutes. If not specified, update may occur any time before UpdateEndTime |
| UET | End of timeframe to attempt update | TS | 17 | 201803260559-0000 | Optional; in minutes. If not specified, update may occur any time after UpdateStartTime |

6.2.4.2 Timestamp Offset Requirement

Timestamps SHALL include a valid time-zone offset. If the civil time zone offset is unknown, then UTC time SHALL be specified using a time zone offset of “-0000”.

Note: The IETF RFC 3339 “Unknown Local Offset Convention” convention is used to distinguish between the case where UTC is the preferred reference point for the specified time, denoted with +0000, and the case where the UTC time is known, but the offset to local civil time is unknown, denoted with -0000. This distinction is in some cases important to represent in device data, and in all cases, to

provide a computable date/time value traceable to UTC, including any leap seconds up to the time the ASUM command was sent.

6.2.5 Management entity-based Update Scheduling

For Management Entity-based update scheduling, the ASUM Management Entity can send a single software update command (directing the client to download then update), or separate download and update commands.

6.2.5.1 Software Download Command

6.2.5.1.1 Management Entity Download Software Requirement

In cases where the Client is directed to download a new software image but not update until requested, the ASUM Management Entity SHALL include a DOWNLOAD_SW command in the ERR segment of the ACK with the parameters shown in the table below:

ERR Segment Parameters for Software Update Table

| Name | Description | HL7 Type | Length (characters) | Example | Required/Optional |
|---------------------|---|----------|---------------------|--------------------|--|
| URI | Software Download URL/URI | ST | 130 | /some/download/uri | Required; value is not further constrained |
| AUTH | Authentication Method & Related Information | ST | 20 | CVC | Required; value is not further constrained |
| MAX_DURATION | Maximum Duration | NM | 4 | 6 | Optional; in minutes. |

6.2.5.1.2 Client Download Software Requirement

In response to the DOWNLOAD_SW command, the Client SHALL attempt to perform the download as requested. If the Client cannot perform the download as requested and within the maximum duration (if applicable), the Client SHALL report this as a failure condition as specified in section 6.2.1.

6.2.6 Software Download Command Status

6.2.6.1 Client Download Process Outcome Requirement

Clients SHALL indicate success or failure of the download process to the Management Entity in the first IHE PCD MEM DMC PCD-15 message after the download completes. The Client SHALL use the codes corresponding to the specified conditions as provided in [CMI-SP-F-ASUM].

6.2.6.2 Software Update Command

6.2.6.2.1 Management Entity UPDATE_SW Requirement

If a software update is ready for the Client, the ASUM Management Entity SHALL include an UPDATE_SW command in the ERR segment of the ACK with the parameters shown in the table below.

ERR Segment Parameters for Software Update

| Name | Description | HL7 Type | Length (characters) | Example | Required/Optional |
|---------------------|---|----------|---------------------|--------------------|--|
| URI | Software Download URL/URI | ST | 130 | /some/download/uri | Required; value is not further constrained |
| AUTH | Authentication Method & Related Information | ST | 20 | CVC | Required; value is not further constrained |
| MAX_DURATION | Maximum Duration | NM | 4 | 6 | Optional; in minutes. |

6.2.6.2.2 Client Response to UPDATE_SW Requirement

In response to the UPDATE_SW command, the Client SHALL attempt to perform the update as requested. If the software image has not already been downloaded using the command specified in section 6.2, the Client SHALL attempt to download the software image and perform the update immediately thereafter. If the Client could not perform the download (if applicable) and update as requested (e.g. performing therapy) and within the maximum duration (if applicable), the Client SHALL report this as a failure condition as specified in section 6.3.1.

6.2.7 Software Update Command Status

6.2.7.1 Client MEM DMC Initialization Requirement

Clients SHALL indicate success or failure of the download/update process to the Management Entity upon (re)initialization of the MEM DMC subsystem for both manual and automated updates in the first IHE MEM DMC PCD-15 message after the update was attempted. The Client SHALL use the codes corresponding to the specified conditions as provided in [CMI-SP-F-ASUM].

6.2.7.2 Client Maintain Operability Requirement

The Client SHALL NOT become inoperable if the update is unsuccessful. The Client SHALL retain all configuration information necessary prior to update to reconfigure and be functional after the update.

6.2.7.3 Client Manual Intervention Requirement

If a software update requires manual intervention, Clients SHALL notify the Management Entity using the codes specified in [CMI-SP-F-ASUM].

7 Security Requirements

7.1 Client Secure Transport Mechanism Requirement

The Client SHALL implement the secure software transport mechanism, including software image verification, as specified in [CMI-SP-F-ASUM].

8 Appendix A ASUM IHE MEM DMC Message Examples (INFORMATIVE)

This Appendix provides examples of ASUM IHE MEM DMC PCD-15 messages.

8.1 Sample PCD-15 Message with M CCP and Additional Info

Once the Client is directed by the CME to communicate with the ASUM Management Entity, the Client sends a PCD-15 message containing its M CCP (with scheduling modality indicated in the OPT field), plus any additional information in separate OBXs needed to determine update availability. Note that per the requirement, if this Client supported Management Entity Based Scheduling instead, it would not include ASUM_SCHEDULER_CBS in the OPT field, thus indicating the default scheduling modality to the ASUM Management Entity).

```
MSH|^~\&|CMI^001A010000000001^EUI-64||CMI HOSPITAL||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^CMI 4000^001A010000000001^EUI-64|2000101^CMI
4000^001A010000000001^EUI-
64|126979^MDCC4MI_EVT_DEVICE_INFO^MDC||20150119221713-0000
OBX|1|ST|126976^MDCC4MI_ATTR_CMI_MCCP^MDC|1.0.0.1|MCCP_VER=001
CCID=[Version]:[VendorID]:[Type]:[ComponentID] RBV=1.0.0
CCS=Operational SWV=1.0.0 MM=CMI%204000
FCCP=https://medicalinteroperability.org/make_model_xyz
CONFIG=https://medicalinteroperability.org/make_model_xyz/config
OPT=ASUM_SCHEDULER_CBS||||X
OBX|2|ST|67972^MDC_PROD_SPEC_HW^MDC|1.0.0.2|2000101^Medfusion
4000^001A010000000001^EUI-64||20150119221713-0000||||F
```

8.2 Sample ACK with Update Software Command

The MSA-1 code 'AA' is used to acknowledge acceptance by the ASUM Management Entity. An ERR segment is present and ERR-3.1 has a value of 0 and ERR-4 has a value of 'I' indicating "Informational". ERR-5.2 contains the MDC code specifying an ASUM command, ERR-6 contains the unique command identifier, and ERR-7 contains the structured command.

```
MSH|^~\&|MgmtEntityABC||VendorXYZ ^001A010000000001^EUI-
64||20150119221714-0000||ACK^015^ACK|1421727433|P|2.6||NE|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
MSA|AA|1421727433
ERR||0^Message
Accepted^HL70357|I|126980^MDCC4MI_ATTR_CMI_ASUM_CMD^MDC|123456|CMD=UPD
ATE_SW URI=/some/uri AUTH=CVC DST=201803260100-0000 DET=201803260159-
0000 UST=201803260500-0000 UET=201803260559-0000
```

8.3 Sample PCD-15 Message with Software Update Success Indication

After the Client attempts an update, it sends its newly updated MCCP, and the last OBX returns a Software Update Success Indication of |123456-CMI-S-ASUM-00000|, indicating that the software update succeeded as requested.

```
MSH|^~\&|CMI^001A010000000001^EUI-64||CMI HOSPITAL||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^CMI 4000^001A010000000001^EUI-64|2000101^CMI
4000^001A010000000001^EUI-
64|126979^MDCC4MI_EVT_CMI_DEVICE_INFO^MDC|||20150119221713-0000
OBX|1|ST|126976^MDCC4MI_ATTR_CMI_MCCP^MDC|1.0.0.1|MCCP_VER=001
CCID=[Version]:[VendorID]:[Type]:[ComponentID] RBV=1.0.0
CCS=Operational SWV=1.0.0 MM=CMI%204000
FCCP=https://medicalinteroperability.org/make_model_xyz
CONFIG=https://medicalinteroperability.org/make_model_xyz/config
OPT=ASUM_SCHEDULER_CBS|||||X
OBX|2|ST|0^MDC_NOTI_CMD_STATUS^MDC|1.0.0.6|123456-CMI-S-ASUM-
00000||20150119221713-0000||||F
```

9 Acknowledgements

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| Scott Eaton | Mindray |
| Stefan Karl | Philips |
| Steven Goeringer | CableLabs |
| Travis West | Bridge Connector |

- Sumanth Channabasappa (Chief Architect), Steve Goeringer (Chief Security Architect), Chris Riha (Working Groups Lead), Paul Schluter, Bowen Shaner, Jacob Chadwell, David Fann, Spencer Crosswy, Dr. Richard Tayrien, Trevor Pavey; and, Ed Miller (CTO) - The Center

