Introduction to the

WHO IMD-PQS Equipment Monitoring System

EMS Specification Suite

WHO Immunization Devices (WHO-IMD)
Performance, Quality and Safety (PQS) system
Vaccines & Immunization Devices Assessment Team(VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

Contents

Executive Summary 3

Background 3

Motivation 3

Applicability and Timeline 4

Device Functionality 4

Level 1: Basic local data logging with USB data access 4

Level 2: Advanced local monitoring 5

Level 3: Remote and local monitoring 5

Further information about M2M interface and data files 5

Specification Suite 6

EMS Specifications set 1: Data logger and machine-to-machine interface for Equipment Monitoring Systems 6

EMS Specifications set 2: Equipment Monitoring Devices for Equipment Monitoring Systems 7

EMS Specifications set 3: Data standards for cold chain monitoring 7

Frequently Asked Questions 8

Required data elements 8

Local access required 8

Prequalification 8

Hardware Configurations 8

Logger only 9

Logger and add-on external EMD 9

Integrated Logger and EMD 9

Executive Summary

The Equipment Monitoring System (EMS) set of specifications was created to enable standardized, interoperable collection of cold chain equipment (CCE) performance data. It aims to make those data available to service technicians, health facility workers, and optionally to remote viewers or aggregate reporting.

Key to the specifications is that each CCE appliance is a local repository of its own performance data, and that those data are accessible to a local user or service technician through a standardized interface, and optionally via visual interfaces and remote data transmission. The specifications are intended to be flexible to cover multiple device categories, and to be phased into those categories over time, starting with newly-prequalified E003 stationary refrigeration and freezing devices in 2024.

Background

Motivation

WHO PQS initiated the Equipment Monitoring System (EMS) specification development in 2017 in response to challenges and opportunities observed with existing monitoring systems. Data from existing monitoring devices were difficult to integrate into logistics management information systems (LMIS), due to a lack of standardization and inconsistent local access. Furthermore, there was limited guidance on data ownership and delivery protocols between systems.

To address these concerns, the goals of EMS are to enable standardized and interoperable data collection from cold chain equipment (CCE). The specifications require collection of performance and diagnostics parameters such as door openings, error codes, power availability, and compressor runtime to improve the value over just storage chamber temperature measurements. A history of these data must be stored in the CCE and made available for local access. A Machine to Machine (M2M) interface provides for plug-and-play upgradability of data display and remote data access.

The EMS specifications were published in January 2022 after a consultative process that included industry and immunization program stakeholders. Initially, the PQS technical advisory committee workshopped targets and high-level architectural options from 2018 through 2020. An Industry Working Group was convened and facilitated throughout 2021, with monthly technical meetings to share planned directions and solicit feedback/perspectives from Industry partners. Systematically throughout the process, country-facing program stakeholders were consulted to understand programmatic priorities and use cases for data.

The EMS specification package is intentionally forward-looking. It lays a foundation for comprehensive performance reporting and country use of data for maintenance and decision-making, although it is recognized that capacity for data use is currently a bigger limiting factor than availability of data. At the time of writing, Gavi (Global Alliance for Vaccines and Immunization) and partners are undertaking a parallel effort to increase capacity for data use by countries as well as global stakeholders.

Applicability and Timeline

EMS specifications were designed to be usable across WHO IMD-PQS categories, so that over time data from multiple parts of the cold chain can be integrated, and economies of scale can be achieved. Mandatory compliance with EMS specifications begins with E003 ice-lined refrigerator (ILR) and solar direct drive (SDD) fridges and fridge/freezer combination devices.

Starting in January 2024, any newly prequalified E003 ILR or SDD product must include prequalification to the EMS data logger specification, **WHO/PQS/E006/DL01.1**.

After January 2026, ALL prequalified E003 ILRs and SDDs must include prequalification to the data logger specification to maintain prequalified status. CCE that have Level 2 or 3 (described below) functionality in addition to data logger will also meet these requirements.

Applicability to other PQS categories is expected to follow over time and will be rolled out through the standard Target Product Profile (TPP) process and timeline, with a grandfathering period anticipated.

Device Functionality

The EMS specification set enables three levels of increasing functionality.

Level 1: Basic local data logging with USB data access[1]

Data logger functionality makes the CCE the data repository for a consistent set of performance and identification data elements. The data logger is integrated into the CCE, where it measures performance data and stores it in non-volatile memory for at least one year. The data include temperature, power availability, door openings, compressor runtime, equipment identification, and error codes. A USB port is provided to enable data access by computers, mobile phones, or other EMS-compliant devices, in both a standardized raw format and as a portable document format (PDF) human-readable report.

The motivation for providing local data access is so that a service technician can access a history of the CCE's performance, even if the unit is unpowered, to aid in diagnosing performance issues. In addition, a machine-to-machine (M2M) interface consisting of the USB port and a power output port allows equipment monitoring devices (EMDs) to access the data for display and transmission purposes. Note that Level 1 does not require a visual display.

Beginning in 2024 with new E003 category products, all CCE must include at least this minimum level of functionality to be IMD-PQS prequalified. CCE with this functionality must meet **WHO/PQS/E006/DL01.1** and be tested to **WHO/PQS/E006/DL01-VP.1**, or future revisions of those standards.

[1] Note that the labels "Level 1", "Level 2", and "Level 3" do not appear in the specifications themselves.

Level 2: Advanced local monitoring

Level 2 functionality includes the logging and data access capabilities of Level 1, and adds a local data display that allows healthcare workers or service technicians to monitor performance without needing to download data to a separate computer or smartphone. Visual and audible alarms prompt action from local users when urgently needed.

Suppliers may add advanced local display and alerting by prequalifying as a "Local EMD" within the **WHO/PQS/E006/EM01.1** specification and testing to **WHO/PQS/E006/EM01-VP.1**. It is anticipated that some CCE will have internal EMDs, and that manufacturers will also create external EMDs to be used with existing EMS-enabled CCE containing just data logging capability. These external EMDs use the M2M interface to access CCE data and obtain power. When the EMD is internal to an appliance, Level 1 Data Logger and M2M interface requirements must also be verified.

Level 3: Remote and local monitoring

Level 3 includes the capabilities of Level 2 and adds remote data transmission. This functionality allows service technicians to access data remotely and diagnose problems prior to a site visit. SMS or email alarms prompt remote users when something is amiss. The data also can be automatically routed to dashboards or future eLMIS systems to be available for aggregated visualization or reporting.

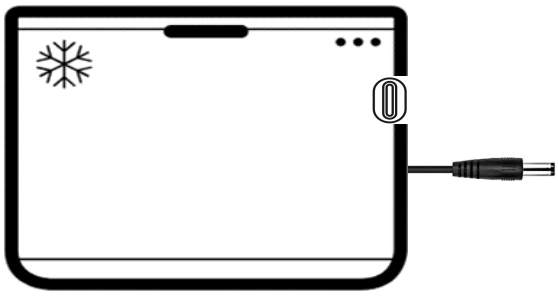
Suppliers may include remote data transmission by prequalifying as a "Remote EMD" within **WHO/PQS/E006/EM01.1** and **WHO/PQS/E006/EM01-VP.1**. Level 2 functionality must also be verified, and if integrated within the CCE, Level 1 must be verified as well.

Further information about M2M interface and data files

A key aspect of Logger functionality is the "Machine to Machine" interface. This interface enables **interoperability** and **upgradeability** as monitoring technologies evolve. CCE with higher levels of EMS functionality (display + cellular connection) must still have this M2M interface.

The M2M interface consists of two parts:

1. USB Data Interface

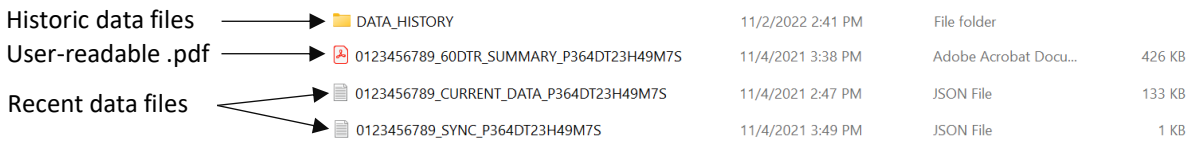


- USB-C receptacle.
- Presents as a USB mass storage device (like a USB drive).
- Read-only, but no password protection permitted.
- Data files in JSON format and a human-readable PDF report located in root directory.
- Must operate even if CCE has no external power and monitoring battery is discharged, drawing power from the USB host device (external EMD, phone, or computer).

2. Barrel plug power output to power external EMDs

- 5 V output whenever appliance is powered.
- Standard 2.1mm inside diameter / 5.5mm outside diameter size.
- 1.1 A current limit.

The files in the root directory would resemble the following:



The filenames are in the format: **xxx_<description>_PdDThHmMsS**, where:

- **xxx** is the alphanumeric unique serial number of the logger,
- **<description>** is the type of data file (CURRENT_DATA for the raw data file containing data less than 60 days old, DATA for historical raw data files, SYNC for the time synchronization file, and 60DTR_SUMMARY for a human-readable 60-day summary report file).
- The **PdDThHmMsS** string is an ISO 8601 "durations" formatted time duration string. The uppercase letters are literal, and the lowercase letters are replaced by the number of days, hours, minutes, and seconds since the logger began operation. This relative timestamp is the time that the logger was connected to the USB host.

Specification Suite

To maintain flexibility in order to accommodate different implementations, the EMS set of specifications includes three IMD-PQS specifications and associated files. These documents can be found at https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=35.

EMS Specifications set 1: Data logger and machine-to-machine interface for Equipment Monitoring Systems

Data logger functionality fulfils the requirements of **Level 1 EMS**, the minimum level of EMS that will be required. The specification describes basic CCE data logging: which parameters must be logged, the duration data must be retained, and battery power considerations. It also specifies local access to the data over USB, including the formatting and file contents. Finally, it includes details of the M2M power output port.

The current versions of the two documents as of March 2023 are:

- **WHO/PQS/E006/DL01.1,** the product specification.
- **WHO/PQS/E006/DL01-VP.1,** the verification protocol used to evaluate compliance with the specification.

EMS Specifications set 2: Equipment Monitoring Devices for Equipment Monitoring Systems

The EMD specification contains requirements for local display of cold chain data and alarming based on those data. A second portion describes data transmission, remote access, and remote alarm functions. Thus, it is applicable to both **Level 2 and Level 3** systems. There are also battery lifetime requirements and details of permissible power draw from the M2M power port.

The current versions of the two documents as of March 2023 are:

- **WHO/PQS/E006/EM01.1,** the product specification.
- **WHO/PQS/E006/EM01-VP.1,** the verification protocol used to evaluate compliance with the specification and other EMS standards.

EMS Specifications set 3: Data standards for cold chain monitoring

The data standards specification is intended to **enable interoperability between data systems** and is not a specification for a hardware device. Rather, it describes common requirements that are referenced by the data logger and EMD specifications. It covers data elements and formats for them, time management, alarming, and data ownership. The first cold chain equipment to implement EMS are refrigerators and freezers, but this specification was written to include data elements and alarm definitions that are applicable to other device categories.

The current versions of the two documents as of March 2023 are:

- **WHO/PQS/E006/DS01.1,** the product specification.
- **WHO/PQS/E006/DS01.1 Annex 1, Cold Chain Data Objects.** This document is a spreadsheet list of all defined data elements, some required and some optional. The list includes uses, data formats, example values, and other descriptions.
- **WHO/PQS/E006/DS01.1 Annex 2, JSON Schema.** This is a data structure definition for raw data files available via USB. It also includes a "validation" schema file that can be used with an online free JSON checker to verify whether data files are compliant with the standard.

Frequently Asked Questions

Required data elements

Question: There are many data elements defined in the data elements spreadsheet. Do we need all of them?

> **Answer**: While the large number of "optional" parameters were defined to provide consistency and flexibility, the mandatory data elements list for EMS compliance is quite short.

Local access required

Question: If I prequalify an EMD with remote data transmission to an internet database, do I still need to provide the local USB data access with > 1 year of data logging?

> **Answer**: Local data record available via USB is required regardless of data transmission to remote databases. This is to maintain data access for local healthcare workers and service technicians and to provide the M2M data connection for upgradability in the future.

Prequalification

Question: If I have EMS functionality applied across my entire CCE product line, do I need to laboratory test the EMS system on every model?

> **Answer**: To reduce supplier testing burden, the **DL01-VP.1** and **EM01-VP.1** verification protocols include a provision for laboratory testing a single representative model for each CCE electronics architecture (control + compressor system) in a product line.

Hardware Configurations

Question: Do the data logger and EMD need to be separate devices?

> **Answer**: A single device may contain both logger and EMD functionality. Note that such a device must still meet **WHO/PQS/E006/DL01.1** requirements, including the M2M data and power functionality. This ensures local data access for healthcare workers and service technicians.

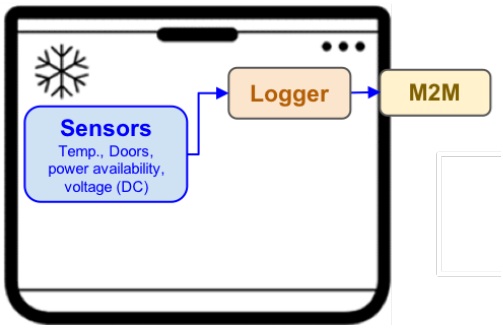
Question: What are some examples of expected EMS configurations?

> **Answer:** It is difficult to predict the most common configurations that that manufacturers will offer or purchasers will request.

Several potential configurations are illustrated on the following page:

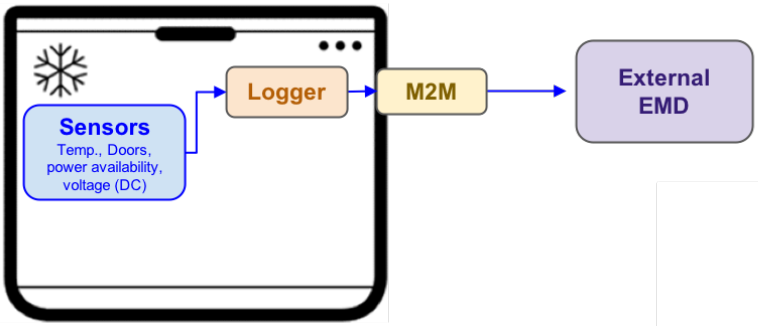
Logger only

A CCE appliance contains a logging device that records temperature, power, and other parameters described in WHO/PQS/E006/DL01. The M2M interface provides these data over its USB connector. The power output part of the M2M provides power for future EMD additions. The logger might be powered by a primary (non-rechargeable) battery supplemented with appliance power, when that is available.



Logger and add-on external EMD

A CCE appliance like the one in the previous section can be augmented with an add-on external EMD, either at the time of purchase or sometime in the future. This flexibility allows purchasers the ability to add local display and/or remote monitoring and potentially update that monitoring as needs change.



Integrated Logger and EMD

A CCE appliance is manufactured with a single integrated module that has data logging and EMD display/alarming functionality. It may also forward data to a remote data system. Note that the CCE must have the M2M interface ports. The data port allows local service technicians access to the data, even if the EMD battery is discharged. Both parts of the M2M interface allow future upgrades to the EMD functionality, potentially by adding a remote data transmission function.