EMS Frequently Asked Questions (FAQs)

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)

General questions

Q1 **Is a specific brand of compressor required to meet the Equipment Monitoring System (EMS) specification? Or can an existing compressor in the appliance be used to meet the EMS requirements?**

A A specific compressor is not required, and any compressor may be used and still meet the EMS specifications. Sensors may be added to the existing appliance to meet the datalogging requirements of the EMS specifications.

Q2 **If an integrated Level 2 or 3 appliance is provided, does a Machine-to-Machine (M2M) port still need to be included?**

A Yes, an M2M port is required for all appliances as per specification **WHO/PQS/E006/DL01**. This requirement is for manufacturer compatibility.

Q3 **How much storage memory is required for the datalogger?**

A Storage memory is to be determined by the manufacturer. However specification **WHO/PQS/E006/DL01** sets a requirement for a minimum of one year.

Q4 **Will the equipment monitoring device (EMD) dramatically increase the power consumption of the appliance?**

A No, the power consumption of the EMD is limited to 5W as per specifications **WHO/PQS/E006/DL01** and **WHO/PQS/E006/EM01**. This is very similar to the power consumption of a Remote Temperature Monitoring Device (RTMD).

Q5 **Specification WHO/PQS/E006/EM01 Clause 4.9.1 mentions sensor recalibration but only for E-EMDs (external EMDs), whereas specification WHO/PQS/E006/DL01 Clause 4.2.17 states that field recalibration must not be required. Would a replacement sensor require recalibration?**

A As field calibration of sensors is difficult, it is preferred to maintain temperature sensor accuracy through scheduled field maintenance events, especially regarding battery replacement. E-EMDs can be removed and re-calibrated in a controlled environment, therefore re-calibration of E-EMDs is allowed as per specification **WHO/PQS/E006/EM01** Clause 4.9.1.

Q6 **What could be a reason(s) to remotely mute an EMD?**

A Remotely muting an EMD could conserve battery charge or reduce the risk of creating excessive ambient noise in case a person is not immediately present to silence the alarm. Note: a visual indication of the alarm condition must nonetheless be present on the EMD.

Q7 What is the need to disable/enable alarm monitoring per specification WHO/PQS/E006/EM01 Clause 4.6.3? Should an alarm not always be enabled?

A When an appliance is no longer storing vaccines or is in service, the alarms should be disabled to conserve energy. Note: it shall be prominently displayed that the alarms are disabled so that staff know to reenable the alarms when putting the appliance back into service.

Q8 What is the reason, as per specification WHO/PQS/E006/EM01 Clause 4.6.2, to show the date/time of the last successful upload on the EMD display?

A Lack of a recent upload may indicate a communication issue that can be actionable by a technician, or the health center staff may be able to download and send the data locally.

Q9 Why is it required to show all of the Key Performance Indicators (KPIs) on the EMD display? (Given that this may cause visualization displays to become complex, and that the data is available on the dashboards.)

A Per specification **WHO/PQS/E006/EM01** Clause 4.6.9 and Annex 1, it is recommended to add a "display map" to more easily navigate the EMD display. Furthermore, the KPI information can be helpful to local staff, especially if there is a communication issue with the EMD.

Q10 Why is the IP64 rating required? 'Dust tight' is difficult to achieve if the ambient relative humidity is to be measured.

A Cold chain equipment (CCE) in primary health facilities often operate in highly dusty conditions and water may be splashed onto devices, so designs must take this into account. Digital relative humidity sensors can be negatively affected by those conditions as well. Note that external ambient relative humidity is not a required data object, though it may be helpful to understand refrigerator operation.

Required data elements

Q11 There are many data elements defined in the *data elements spreadsheet*. Are all of these elements required?

A 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

Q12 In the case of an EMD with remote data transmission to an internet database, is it still required to provide the local USB data access with > 1 year of data logging?

A 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

Q13 If EMS functionality is applied across an entire CCE product line, is it required to laboratory-test the EMS system on every model?

A To reduce supplier testing burden, the **WHO/PQS/E006/DL01-VP** and **WHO/PQS/E006/EM01-VP** 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 configuration

Q14 Do the data logger and EMD need to be separate devices?

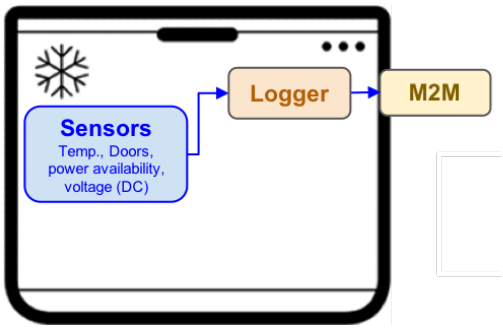
A A single device may contain both logger and EMD functionality. Note that such a device must still meet the requirements of specification **WHO/PQS/E006/DL01**, including the M2M data and power functionality. This ensures local data access for healthcare workers and service technicians.

Q15 What are some examples of expected EMS configurations?

A It is difficult to predict the most common configurations that manufacturers will offer or that purchasers will request. Several potential configurations are illustrated below.

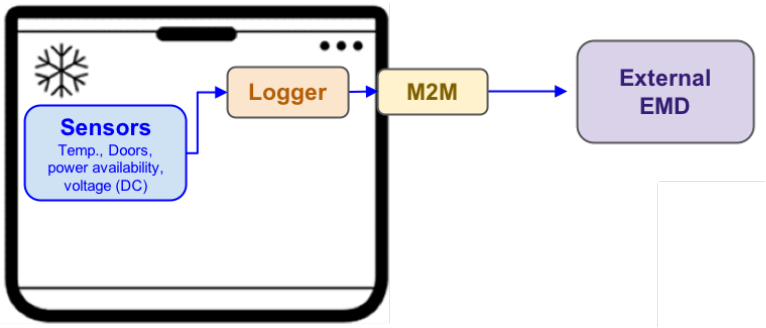
<u>Logger only (Level 1)</u>

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.



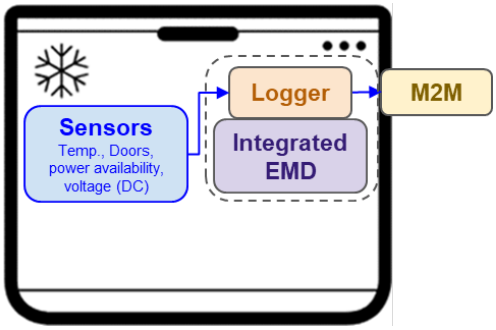
Logger and add-on external EMD

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.



Q16 Must EMD-generated data objects be made available over USB?

A In most cases, no. However, CCE must have an M2M port. In the case of an External EMD, an *additional* USB port that local technicians could use to collect data without unplugging the M2M is not required. If manufacturers choose to add one, specification **WHO/PQS/E006/EM01** Clause 4.5.8 applies, and EMD recorded data must be made available. In the case of an appliance with an Internal EMD, the M2M must provide the elements required in specification **WHO/PQS/E006/DL01**; EMD elements are not required but are encouraged.

Q17 Is it required to transmit the entire data object file ("CURRENT_DATA") every time? Doing so would duplicate data. When must the CURRENT_DATA and SYNC files be transmitted?

A It is not required to send the entire file. Specification **WHO/PQS/E006/EM01** Clause 4.5.10 states that data should be uploaded at least every 24 hours unless there is an alarm condition, in which case that should be communicated within 15 minutes.

Q18 Why does specification WHO/PQS/E006/EM01 Clause 4.6.8 require CSV when JSON is being sent from the EMD?

A The intended usage is different. JSON was chosen as the data transmission format because it is self-describing, able to handle records that have different data fields, and readable by machines. Specification **WHO/PQS/E006/EM01** Clause 4.6.8 relates to data being made available by an online dashboard to end users like health officials. These users are likely to be familiar with using spreadsheet applications to open CSV and plot data, but most would not be able to use a JSON file.

Q19 What is the data element main on/off switch (MSW) used for?

A The intention is to be able to identify if an appliance should be cooling and is therefore most relevant for vehicles or transportable devices that are likely to be switched off as part of their regular operation. That is why it is optional for stationary appliances, which in most cases are intended to operate continuously.

Q20 If a logger generates values for the ALRM data object, how should the EMD handle this?

A This issue could come up in the cases of I-EMDs (integrated EMDs) that are separate from loggers or any E-EMD. The ALRM data object is the only object that is optional for the logger but required for the EMD. It is possible that some loggers will generate an ALRM data object, in which case the EMD can either overwrite the logger-generated values with EMD-generated values or implement more complex logic to integrate the perspectives of both devices. Although both approaches are consistent with the specification, EMD manufacturers are advised to consider that the logger might have better information than the EMD insofar as the logger (at least in principle) has continuous values for the various sensors.