EMS Frequently Asked Questions (FAQs) v2.0

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 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.

Q7 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.

Q8 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.

Alarms

Q9 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.

Q10 What is the need to disable/enable alarm monitoring per specification WHO/PQS/E006/EM01 Clause 4.6.3? Should not an alarm always be enabled?

A When an appliance is no longer storing vaccines or 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.

Q11 E006/EM01 Clause 4.6.6 states that "Alarms shall have the ability to be muted remotely by each of the following: 1) sending a remote response (e.g. through SMS, email), and 2) utilizing a cancellation function in an online dashboard. The latency of this remote action and the alarm being muted on-site shall be on a best effort basis."

1) What should be the format used in remote responses through SMS and email?

A. As the alert is controlled by the manufacturer, the manufacturer can decide how to mute the alarm. Further, the manufacturer could even include instructions for how to mute in the message.

2) Remote alarm muting via the dashboard will only be possible on the EMD manufacturer's dashboard, but not on the customer's dashboard if this one is different, i.e. if the data has been forwarded to a 3rd-party server using HTTPS POST.

A. Remote muting from 3rd party systems is not currently required within the EMD performance specification. If remote muting is identified to be an important function that users of 3rd party / Country dashboards request, it could be possible to support. This would then become a requirement in a future performance specification update, which would include industry review and comment.

Battery

Q12 E006/DL01 Clause 4.2.6 requires the Level 1 EMD (Datalogger) to have a backup power of 2x the appliance autonomy for a mains-powered appliance, or 1.5x the autonomy for a solar-powered appliance or 96 hours whichever is greater.

1) Why is such a long backup required when the appliance is no longer functioning?

A The appliance autonomy or holdover time is only considered up to temperatures of +8°C. It is important to continue to monitor the temperatures in the appliance beyond +8°C, as some vaccines may tolerance warmer temperatures for some period of time.

2) Is this not a disadvantage for an appliance with a long holdover time?

A Per specification WHO/PQS/E006/DL01, Clause 4.2.7 only “essential data objects” are recorded. Therefore, the logger may implore power saving options. Furthermore, the backup power required is only that to ensure average energy consumption, not maximum energy consumption. Independent testing has shown that even a small battery can power a datalogger under these conditions for up to a year.

Q13 How accurate does the estimated remaining battery time need to be?

A From WHO/PQS/E006/DS01, Annex 1 Cold Chain Data Objects, Data Object BLOG is the “estimated number of days of battery life remaining” in the datalogger. Note that as this is an estimate only, it may be updated as the battery is discharged, or according to variations in ambient temperature, power consumption, etc.

Required data elements

Q14 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

Q15 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.

Testing

Q16 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 (power supply, controller, compressor system, etc.) in a product line.

Q17 Does the EMS need to be tested in-situ in the appliance?

A Integrated EMDs need to be tested in-situ in the appliance, as the appliance is required for sensors etc., as well thermal tests (refer to WHO/PQS/E006/D**L01-VP** Clause 5.3.5 Test 4). E-EMDs do not need to be tested with the appliance as they are separate and autonomous devices, and only interface with the appliance via the USB-C port and power cord which can be simulated for testing purposes.

Q18 Does the appliance need to be retested to E003?

A If no modifications have been made to the appliance, then no further E003 testing is required. However, if modifications have been made to the appliance to accommodate the EMS (e.g. power supply, control board, new compressor, etc.) then the appliance would need to be retested to confirm those modifications have not impacted the quality, safety, and performance of the appliance. Note: only the tests related to the

modifications would need to be performed. If there is any question regarding testing, please contact the IMD-PQS Secretariat to confirm if any retesting is required.

Q19 Can the E006 tests be performed concurrently with the E003 tests?

A Some E003 and E006 tests can be performed concurrently. Please work with the product testing laboratory to determine which tests can be performed concurrently.

Hardware configuration

Q20 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.

Q21 E006/DL01 Clause 4.5.3 states that the appliance needs to limit the current to the E-EMD to 1.05 to 1.15A. Why is there such a narrow band of acceptable currents?

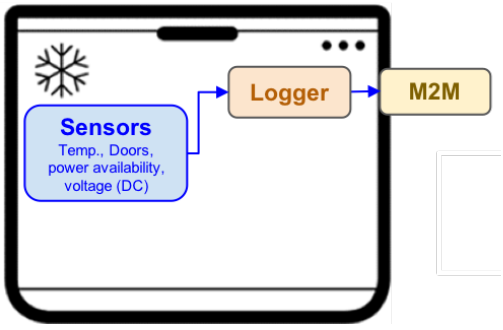
A. The output current from the appliance to the EMD is limited to 1.1A +/- 50 mA to ensure that the power supply to the EMD does not negatively affect the performance of the appliance.

Q22 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.

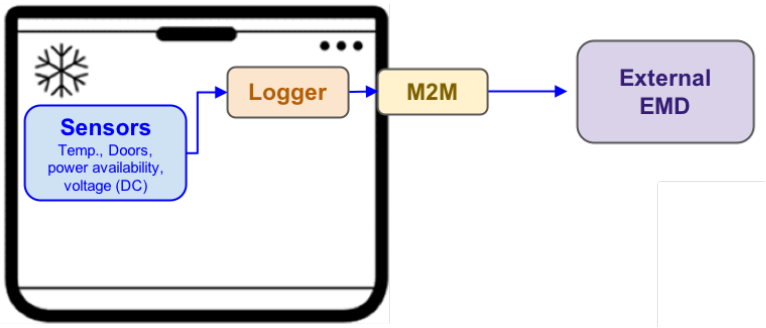
<u>Logger only (Level 1)</u>

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.



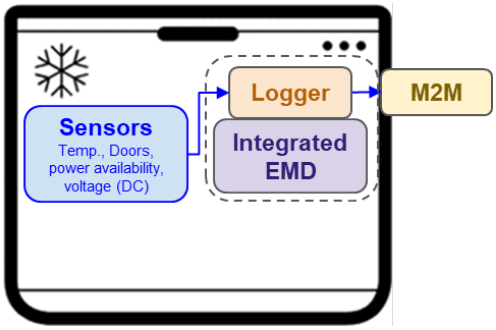
Logger and add-on external EMD

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.



Q23 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.

Q24 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.

Q25 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.

Q26 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.

Q27 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.

EMS Configurations

Q28 What is the minimum EMS requirement my appliance needs to meet?

A. Starting in 2024, all new vaccine refrigerators are now required to have EMS, and starting in 2026 ALL vaccine refrigerators are required to have EMS. Freezers are not required to have EMS at this time; however, the EMS performance specifications have been written to work with a variety of vaccine storage products, so a manufacturer could include an EMS on their vaccine freezer if they so choose.

Specifications E003/RF03 and E003/RF05 have revised Clause 4.2.9 to add the minimum requirements for EMS. At a minimum, a Level 1 EMD datalogger as per specification E006/DL01 is required. Further a Level 2 or 3 EMD E006/EM01 or 30DTR E006/TR06 is required. Refer to Table 1 below for possible monitoring configurations.

Table 1 - Possible Monitoring Configurations

Configuration	I	II	III	IV	V
Data logger plus M2M port (E006/DL01)	✓	✓	✓	✓	✓
Thermometer (E006/TH06) with display		✓		✓	✓
Integrated EMD (E006/EM01)	✓				
External EMD (E006/EM01)		✓			
Integrated EMD with remote data transmission (E006/EM01)			✓		
External EMD with remote data transmission (E006/EM01)				✓	
30 DTR (E006/TR06.3)					✓

Q29 Is it necessary to monitor the minimum data objects for a vaccine freezer?

A. No, refer to Q28 above. However, there is nothing to prevent any level of EMS being installed in a vaccine freezer, providing there is an externally-readable cabinet-mounted electronic thermometer conforming to E006/TH02.

Q30 I have a combined refrigerator-freezer. Is the high temperature alarm required for the freezer compartment?

A. No, although DS01.2 Clause 4.2 states that there needs to be a heat alarm "For freezer appliances: Exposure to a single temperature event of -15°C or above for 60 minutes", this would be for a vaccine freezer and not a water-pack freezer. Further, such an alarm on an SDD appliance would most likely cause nuisance alarms, as E003/RF05.7 Clause 4.2.7 allows for water-pack melting: "Under the water-pack freezing tests, the temperature of the water-pack freezing compartment is permitted to exceed 0°C during the 12-hour night phase and the first three hours of the 12-hour solar phase."

Q31 I have a combined vaccine refrigerator and freezer. Do I need to monitor both compartments?

A. Yes. Per specification E003/RF03 and E003/RF05 Clause 4.2.9, "If the appliance is a combined refrigerator and vaccine freezer, both compartments shall be monitored by the data logger."

Q32 Is it necessary to still use a 30DTR which, up until now, has been supplied with every appliance?

A. If a Level 2 or 3 EMD is provided, then a 30DTR is **not** necessary as the Level 2 or 3 EMD performs the same functions as a 30DTR. In all other cases it is necessary to use a 30DTR Refer to Q28.

Q33 Will RTMDs and 30DTRs be rendered obsolete?

A. No, refer to question Q32 above; these products may still be required depending on the configuration used (see also Table 1). Furthermore, they will still be required for legacy products and other applications.