PQS performance specification

TITLE: Equipment Monitoring Devices for Equipment Monitoring Systems

Specification reference:	E006/EM01.2
Protocol reference:	E006/EM01-VP.2
Issue date:	January 10, 2022
Date of last revision:	November 30, 2023

Contents

1. Scope

Equipment Monitoring Devices (EMDs) are the primary means of communicating monitored cold chain data locally and/or remotely via the Internet. EMDs source raw data directly from the appliance's integrated logger. A variety of EMD types may be prequalified based on this specification. Such types are summarized below and are differentiated based on whether there are remote communication capabilities or only local. Also, the EMD may be physically integrated within the appliance such that the EMD does not utilize the M2M connection to obtain data from the logger and power from the appliance. External EMDs are also specified such that they source data and power via the M2M connections from the appliance. It is permitted for logger functionality to be satisfied by an Integrated Equipment Monitoring Device, provided that the logger and M2M functions cannot be removed from the appliance and will continue functioning if EMD-specific functions (e.g. display, audible alarm) are inoperable, or if remote connectivity or service plans lapse.

Acceptable EMD types are defined as follows:

- Local-only communication, integrated within appliance
- Local-only communication, external to the appliance
- Local and remote communications, integrated within appliance
- Local and remote communications, external to the appliance

This specification is structured such that local-only functionalities are presented first as minimum requirements for every type of EMD, including those with remote communication capabilities. Additional requirements are specified if the EMD has remote communication capabilities. Similarly, distinct requirements are cited depending on whether the EMD is integrated within the appliance or external to it.

2. Normative references

European Union Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)
ISO 8601-1:2019 - Date and time - Representations for information interchange - Part 1: Basic rules
IEC 60529 Ed. 2.2 b: 2013 Degrees of protection provided by enclosures (IP Code)
IEC 61000-6-1:2019 Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial, and light-industrial environments

IEC 61000-6-3:2020 Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial, and light-industrial environments
IEC 61000-6-8:2020 Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for professional equipment in commercial and light-industrial environments
ISO 14001: 2015 Environmental management systems - Requirements with guidance for use
ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories
ISO/IEC 27001: 2013 Information technology—Security techniques—Information security management systems--requirements
ISO 6709: 2008 Standard representation of geographic point location by coordinates
ISO 8201: 2017 Alarm systems — Audible emergency evacuation signal — Requirements
ISO 9001: 2015:Quality Management Systems – Requirements

3. Terms and definitions

Absolute time: Coordinated Universal Time (UTC) time derived from an independent verified source (e.g. cellular tower, GPS, Internet time server), standardized according to **ISO 8601** Internet Date Time profile, using days, hours, minutes, and seconds without separators, and including the time zone specifier "Z", short for "Zulu" and indicating zero offset from UTC (YYYYMMDDThhmmssZ).
Alarm: An audio and/or visual indication of appliance or device performance that is outside safe or normal operating conditions and where the cause is driven primarily by appliance use or environmental conditions. Alarms are defined by WHO and/or immunization programmes.
Appliance: The cold chain appliance or device that is the subject of monitoring. This may be a vaccine refrigerator, freezer, cold room, refrigerated vehicle, transportable storage, or other device which is being prequalified under specification **WHO/PQS/E006/DL01.**

- AC supply appliance: A cold chain storage device that operates on an input supply of alternating current.
- DC supply appliance: A cold chain storage device that operates on an input supply of direct current.

Communication latency: The maximum allowable period between data transfers between logger and EMD.
Data object: A standardized identifier of a unique administration, performance, use or environmental metric that is used to record and analyse data.
Employer: The organization responsible for ownership and/or utilization of an appliance or device within an immunization programme, health system or initiative.
Energy Harvest Control (EHC): A control device or system to enable the use of surplus solar photovoltaic electricity for powering other electricity consuming devices in addition to an immunization appliance, when that electricity is not needed for cooling.
Equipment Monitoring System (EMS): The general term used to describe the associated components, sensors, devices, appliances, and data systems that enable cold chain equipment monitoring.
Equipment Monitoring Device (EMD): A device that functions to 1) retrieve data from the appliance logger and other onboard sensors and 2) store, analyse and communicate data,

errors, and alarms, and is the subject of specification **WHO/PQS/E006/EM01.** An EMD may be integrated within or external to the appliance as further defined below:

- External Equipment Monitoring Device (E-EMD): An EMD that is not integrated in the appliance and utilizes the M2M connection for data transmission and optional power supply.
- Integrated Equipment Monitoring Device (I-EMD): An EMD that has some or all its components built into the appliance at the point of manufacture. The I-EMD does not utilize the M2M for data transmission or power supply. The M2M affords access to the integrated logger for E-EMDs.

Error code: An alphanumeric code that is used to determine the nature of an appliance or device technical problem, and why it occurred. Errors are defined as related to equipment functionality that is not primarily user or environmentally related, but rather indicates hardware or software malfunction, defect, damage, or other issues.
Host: The party responsible for managing the Remote Data System.
Ice-lined refrigerator (ILR): A mains-powered compression-cycle appliance meant for vaccine storage or combined vaccine storage and water-pack freezing. These appliances are designed for operation in areas with intermittent electricity supply.
In writing: Communication by letter, fax, or email.
Key Performance Indicator (KPI): A metric computed using raw data object recordings, which provides a more summarized or aggregated assessment of the environment, performance, safety and/or use of cold chain equipment. KPIs are defined in the EMS Data Specification **WHO/PQS/E006/DS01.**
Legal manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.
Logger: A data recording device that is integrated within an appliance or transport device and is the subject of specification **WHO/PQS/E006/DL01**. It stores data for use and analysis and provides access to its data.
Machine-to-Machine (M2M) interface: The standardized data and power transfer interface between logger and E-EMD, enabling interoperable function of EMDs and appliances. The M2M also enables portable devices like laptop computers and mobile phones to access logger data. The M2M is physically part of the appliance.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Relative time: A timestamp with an arbitrary but constant reference point (e.g. device commissioning is t=0), standardized according to **ISO 8601** Durations profile, represented by the format PnDTnHnMnS, where the [n] is replaced by the value for each of the day and time elements that follow the [n].
Remote Data System: A networked, server-based storage system for the collection, management, and communication of EMD data. The Remote Data System is managed by the host.
Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Solar Direct Drive (SDD) refrigerator: A vaccine refrigerator or combined vaccine refrigerator and water-pack freezer powered by a solar electric system with no battery used to power the compressor or cooling circuit.

4. Requirements

4.1 General

Many of the following requirements are specified based on whether the EMD is integrated or external to the appliance. They apply to both local-only and remote communication EMDs.

4.1.1 Compatibility of external EMDs

External EMDs shall be compatible with all brands of appliances complying with the logger and M2M specification. Accordingly, appliances complying with the logger and M2M specification shall be compatible with all brands of external EMDs and common external devices like laptops and mobile phones. Reference logger and M2M specification for appliance-device connections (**WHO/PQS/E006/DL01**) and the CCE Data Standard (**WHO/PQS/E006/DS01**).

4.1.2 Field-fitted external EMDs

Legal manufacturers or resellers may prequalify an external EMD against both this specification and the RTMD specification for the purpose of providing flexible solutions that may utilize the M2M data and power connections and also field-fitted sensors for monitoring appliances without a logger and M2M. The requirements of both specifications shall be satisfied and verified through both verification protocols. Legal manufacturers or resellers interested in pursuing such an approach are encouraged to consult with PQS early on in development.

4.2 Performance

4.2.1 Absolute time keeping

Time format shall comply with the latest version of the Data Standard specification: **WHO/PQS/E006/DS01**.

- Local-only EMDs: If the EMD does not have the means or ability to sync its time via remote communication networks, absolute time keeping is not required.
- Remote EMDs: The EMD shall maintain absolute time synced via remote communication networks and server clocks. Syncing shall be automatic and frequent enough so that drift time kept on the EMD differs from global time by no more than 1 minute.

4.2.2 Absolute time drift

Drift in the absolute time on the EMD relative to the server time shall be less than 60 minutes per year at ambient temperatures ranging from +10°C to +43°C.

4.2.3 Local time

The EMD shall have the ability to be programmed based on the local time zone within which it is deployed. Any on-site display of timestamps shall show local time if such local programming has occurred.

4.2.4 Absolute timestamping at time of data download from logger

The E-EMD shall record an absolute timestamp at the time of data receipt from logger such that the logger's relative time data may be converted to UTC time within remote data systems.

At the time of initiating the USB mount of the logger, the E-EMD shall record an absolute timestamp, and shall append this timestamp to the end of the filename of all files downloaded from the logger, separated by an underscore. This permits downstream server systems and data consumers to associate the E-EMD absolute timestamp with the correct logger relative timestamp. The downloaded files with the updated filename are then transmitted unmodified to server infrastructure.

For example, a "sync" file after being downloaded from a logger will have an updated filename with the following format:
0123456789_SYNC_PnDTnHnMnS_YYYYMMDDThhmmssZ.json

It is recommended that the E-EMD also record and transmit a JSON record associated with each logger download event which contains the logger ID, logger relative timestamp, and the EMD absolute timestamp associated with the USB mount time of that download event. This could be transmitted in a standalone EMD-generated file, or directly as a JSON payload.

4.2.5 Data management

All required and optional data objects shall be recorded and formatted in compliance with the latest published version of the Data Standard specification: **WHO/PQS/E006/DS01**.

4.2.6 Data recording

For all data objects sampled on a regular, time-basis (e.g. temperature), data recording shall occur at least every 15 minutes and include a timestamp for the recording.

For all data objects that are sampled on an event-basis (e.g. door opening), the EMD shall save a record of those events in the associated time-based data object.

The EMD shall be able to access data available on any connected (via M2M interface or integrated) logger such that data and alarms may be triggered and shared locally and remotely if utilizing remote communication modalities.

4.2.7 Data transfer mode

External EMDs shall act as a "host" device and periodically mount the logger USB device and access its data. The EMD shall not mount the logger for longer than 180 seconds to avoid prolonged periods where the logger cannot record data objects.

4.2.8 Generating data objects

For EMDs, every data object is listed as either required or optional for generation. For all required data objects for generation, the EMD shall have the ability to generate data related to those data objects. For all required data objects for recording, the EMD shall have the ability to record data related to those data objects.

4.2.9 Required data objects for EMD generation

The EMD shall have the ability to generate the following data objects:

Administration:

- **Absolute time (for remote EMDs only)**: Coordinated Universal Time (UTC) time derived from an independent verified source (e.g. cellular tower, GPS, Internet time server), standardized according to ISO 8601 Internet Date Time profile, using days, hours, minutes, and seconds (YYYYMMDDThhmmssZ).
- **EMD administrative data (for remote EMDs only)**: data related to the EMD shall include manufacturer, model, software version, manufacturer serial number, date of production, WHO PQS code.

Performance:

- **EMD Battery Remaining**: estimated number of days of battery remaining to operate the EMD normally, measured in days (DDDD.D).

Error Codes:

- **Local-only EMDs**: The EMD shall generate and record error codes for any condition that may impair its normal operation (e.g. broken or disconnected M2M data or power connections, self-test failure). The EMD shall record all error codes that are available on the logger. Such error codes shall be accessible to local, on-site users via the EMD for at least 60 days.
- **Additional requirement for remote EMDs**: Error codes related to the EMD shall be communicated to Remote Data Management Systems.

4.2.10 Optional data objects for EMD generation

The EMD may have the ability to generate itself the following data objects:

Administration:

- **Location / GNSS Coordinates**: data related to the physical location of the EMD. This is optional because in some regions health facility location information can be a security concern. Any legal manufacturer or reseller

integrating geolocation features shall make this known to WHO PQS at the time of prequalification and have the ability to remove this functionality if requested by an employer.

- **Data Integrity**: File data integrity data such as cyclic redundancy check (CRC), hash, or cryptographic file signature that can be used for data validation.

Environment:

- **Ambient Relative Humidity**: relative humidity of the environment in which the appliance is deployed, measured in RH% at least once every 15 minutes.
- **Ambient temperature**: temperature of the immediate surroundings within which the EMD is operating, measured in degrees Celsius (°C) at least once every 15 minutes.

Performance:

- **Holdover, Autonomy, or Independence time remaining**: estimated number of days of holdover/autonomy/independence time remaining (DDD.D).

4.2.11 EMD data recording

The EMD shall have the ability to record all required data necessary for local visualization and remote data transmission. These data include EMD-generated data objects defined in Clauses 4.2.9 and 4.2.10, as well as downloaded logger data files/objects.

4.2.12 Continuous operation without power supply

The EMD shall continue to perform required functions in this specification, such as alarming, during periods when there is no mains or solar power supply.

This minimum period of continuous operation shall be no shorter than:

- Integrated EMDs:
  - Stationary solar-powered appliances including cold/freezer rooms: 1.5x rated autonomy time at +43 °C or 96 hours at +43 °C, whichever is greater.
  - Stationary mains-powered appliances including cold/freezer rooms: 2.0x rated holdover time at +43 °C or 96 hours at +43 °C, whichever is greater.
  - Transportable powered appliances: 1.5x rated independence time or 18 hours at +43 °C, whichever is greater.
  - Refrigerated vehicles: 1.5x rated non-idle run time of the refrigeration unit.
- External EMDs: 240 hours, such that E-EMDs can be paired with “long” holdover ILR devices that have a minimum of 120 hours of holdover.

During such periods of no power supply, EMDs may utilize methods to conserve energy, but shall maintain the following minimum functions:

- The EMD shall continue to trigger alarms within 15 minutes of the alarm event occurring.
- The visual display may be dimmed or shut off but shall be reactivated by a user in an intuitive way (e.g. touching screen or pressing a button).
- Frequency of remote communication may be limited so long as there is not a change in active alarm condition or error code. When an alarm or error code is triggered, a remote EMD shall immediately communicate this change in alarm or error status via remote communication networks. If an alarm or error condition no longer exists, this change in status shall be immediately communicated. By transmitting only changes to alarm or error status, it may not be necessary to repeatedly transmit an unchanged alarm status, thereby conserving resources.

4.2.13 Energy storage lifetime

Energy storage (e.g. electrical batteries or capacitors) is required to enable continued monitoring (specified in Clause 4.2.12) during times when supply power is lost. Various approaches to energy storage are acceptable but shall comply with the minimum requirements in this and the following sections.

Components for storing energy may be replaceable or non-replaceable and rechargeable or non-rechargeable. Minimum functional lifetimes are specified based on whether the EMD is integrated or external:

- Integrated EMD: The functional lifetime of any non-replaceable energy storage components shall be no less than the appliance within which it is integrated, i.e. 10 years for refrigerators. Replaceable energy storage components must have a functional lifetime of no less than 5 years.
- External EMD: The functional lifetime of any non-replaceable energy storage components shall be no less than 10 years. Replaceable energy storage components must have a functional lifetime of no less than 5 years.

Replacement of energy storage components: if the batteries are intended to be replaceable, such a task shall be possible by a trained technician on-site; replacement shall not require recalibration of sensors.

4.2.14 Energy storage recharging

EMD energy storage components may be rechargeable. Intelligent charging schemes should be utilized to extend the functional lifetime of the energy storage components.

For rechargeable power components: If an EMD's energy storage is fully depleted, it shall have the ability to recharge sufficiently in at most eight hours - assuming power supply - to then operate without power supply for at least 48 hours.

4.2.15 Calibration

For I-EMDs, system components for vaccine storage chamber temperature measurement are to be covered by a Certificate of Traceability and Calibration.

The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the components are traceable to an **ISO/IEC 17025** accredited testing laboratory, to NIST, or to another internationally recognized standards agency. The certificate shall be accompanied by a copy of the reference instrument calibration certificate.

4.2.16 Electromagnetic compatibility

Operation of the system and of the individual system components shall be unaffected in the normal electromagnetic compatibility environment in which the system is intended to work, considering disturbances generated by adjacent appliances which are compliant with the requirements of **IEC 61000-6-1** for immunity and **IEC 61000-6-3 or IEC 61000-6-8** for emissions. Information to ensure uninterrupted use of the device shall be stated in the user instructions.

4.2.17 Remote data systems general requirements

Remote data clauses are not applicable to local-only EMDs. Remote Data Systems are the server-based, remote software systems that manage monitored data. The legal manufacturer or reseller is required to comply with the following minimum specifications and abide by guidelines when negotiating agreements with employers.

4.2.18 Geographic location of remote data hosting

The acceptable location (country) for data hosting and associated server storage shall be negotiated between the legal manufacturer or reseller and the employer at the time of procurement. If the employer prefers to host data within their country, the legal manufacturer or reseller should make efforts to support this approach. However, the ultimate responsibility for establishing secure, functional data hosting within a programme country is the responsibility of the employer unless otherwise negotiated with the legal manufacturer or reseller.

4.2.19 Scope and period of remote hosted data access

The legal manufacturer or reseller shall make hosted data accessible for a period of time to employers and those they designate with access rights. Requirements and general guidelines of the scope of data and time period for access include:

- The legal manufacturer or reseller shall offer in their dossier submission a standard service package that includes three years of data hosting and is compliant with all Remote Data System requirements. Actual service periods shall be negotiated with the employer at the time of procurement.

- The effective time period by which the legal manufacturer or reseller of the Remote Data System shall satisfy the functional requirements within this specification shall be negotiated with the employer at the time of procurement.
- All data includes raw and summary data (e.g. alarms) related to the EMD and the appliance and logger being monitored by that EMD.
- If so desired by the legal manufacturer or reseller, older raw data may be archived after a period agreed to by the employer, but this raw data shall still be accessible upon request during the data hosting service period.
- At the end of an employer's hosting service contract period, the legal manufacturer or reseller shall provide advance notice to the employer and allow for a data transition period whereby the employer may export any or all data before it is no longer hosted or accessible via the legal manufacturer's or reseller's Remote Data System.

4.2.20 Data ownership

Ownership of all data collected and/or transmitted by the EMD is vested with the employer, and the employer has control over the use, storage, data protection requirements, transmission, internal processing and terms of access and use of the data by third parties throughout the full lifespan of the data. No data (unprocessed, processed, generated by or entered into the Remote Data System), whether anonymized or not, will be shared with any third parties by the legal manufacturer or reseller without explicit and informed consent by the customer.

4.2.21 Data delivery to external systems

When requested by the employer, the legal manufacturer or reseller providing remote communication services shall transmit cold chain data to the employer per the requirements in Clause 5 of **WHO/PQS/E006/DS01**.

4.2.22 Data security

The legal manufacturer or reseller shall demonstrate evidence of conformity with **ISO/IEC 27001:2013**.

4.3 Environmental requirements

All EMD components shall be adequately protected from the environment in which they will be deployed, including ambient temperature, ambient humidity, input voltage and dust and water ingress. Some requirements are determined by whether the device is integrated within the appliance or standalone from it.

4.3.1 Ambient temperature

All EMD components shall tolerate high and low temperatures during transportation and storage, specifically in the range of -30°C to +70°C with the system components inactivated.

All EMD components shall tolerate high and low temperatures during use, specifically in the range of +10°C to +55°C with the system components activated.

4.3.2 Ambient humidity

During transport, storage, and use, the EMD may be subject to a wide range of uncontrolled ambient relative humidity (RH) from 0 to 95% RH. The EMD shall be designed to remain undamaged and fully functional if exposed to these conditions in hot zone temperatures (+43°C).

4.3.3 Input voltage fluctuations

The functionality of the system and of the individual system components shall not be affected by voltage fluctuations due to issues including (but not limited to) problematic power grid and intense electrical storm activity.

- Integrated EMD: at a minimum, the EMD shall be protected by the appliance's voltage protection hardware such as an integrated or external voltage stabilizer.
- External EMD: the legal manufacturers or reseller of external EMD shall provide adequate voltage protection hardware as part of the procurement if utilizing M2M power supply is not feasible, and an external mains power supply is provided.

4.3.4 Dust and water ingress

Integrated EMD requirements:

- Any component directly exposed to the external environment (e.g. visual display on the external surface of the appliance) shall have no less than **IEC 60529:** IP64 protection.
- There is no minimum IP rating requirement for EMD components that are internal to the appliance and are not directly exposed to the external environment. However, the legal manufacturer(s) of the appliance and integrated EMD shall take care in the design and integration of the EMD within the appliance such that the design eliminates or minimizes the effects of dusty, humid environments with potential water splashing.
- Conformal coating of Printed Circuit Board Assembly (PCBA): any PCBA not protected by an IP-65 rated enclosure shall be protected from dust, water, and humidity through the use of a conformal coating. Manufacturers should consider coating guidelines in IPC document **IPC-HDBK-830**.

External EMD requirements:

- No less than **IEC 60529:** IP64 protection.

4.3.5 Corrosion

The legal manufacturer shall utilize non-corrodible and robust material (e.g. plastics or treated metal) for all components.

4.4 Physical characteristics

4.4.1 Overall dimensions

No requirements.

4.4.2 Weight

No requirements.

4.5 Interface requirements

4.5.1 External EMD mount

External EMDs shall provide a means of being fixed to the appliance.

4.5.2 Power supply

The following modes of power supply shall be possible:

- Integrated EMDs: I-EMDs may utilize power supplied by the appliance to allow for operation and charging of any EMD energy storage components. The power supply to the EMD shall not interfere with normal operation of the appliance.
- External EMD: E-EMDs utilize power supplied by the appliance via the M2M power connection, but shall draw no greater than 5 W (1.0 A ± 5% at 5 V).

4.5.3 M2M power connection

External EMDs shall have a female jack connection that accommodates a barrel plug connector with the following specifications:

- Type: Barrel
- Sleeve diameter: 5.5 mm
- Sleeve length: 9.5 mm
- Pin diameter: 2.1 mm
- Polarity: pin positive, sleeve negative

The legal manufacturer or reseller of external EMDs shall provide a 1.5-meter-long extension cable to connect the shorter captive cable fixed to the appliance with the external EMD. This cable shall be compatible with the male plug output from the M2M, and the input jack required on the external EMD.

4.5.4 Failsafe load design

Design of both integrated and external EMDs shall mitigate failure modes that could cause it to draw greater than 5 W from the appliance or M2M power connection.

4.5.5 External mains supply power & cable

External EMDs may also have their own dedicated power supply. If a dedicated power cable is provided to power the EMD (not from the appliance), the supply power cable shall be fitted with a plug that matches the mains electrical socket standard in the country of intended use (to be specified by the relevant procurement agent at the time of ordering). Minimum connection lead length shall be 1.5 meters.

4.5.6 External solar supply power & cable

External EMDs may also have their own dedicated solar power supply system. Solar power systems shall comply with requirements in the latest published version of the Solar Power system for low electrical requirements specification (**WHO/PQS/E006/PVdc01**).

4.5.7 M2M data connection port

The M2M data connection that an E-EMD uses to collect data from an appliance shall be compatible with the latest published version of the logger and M2M specification (**WHO/PQS/E006/DL01**). This includes support for both FAT16 and FAT32 USB Mass Storage Device filesystem formats required in that specification. Also note that some legacy 30-day temperature loggers with USB interfaces use FAT12 format: supporting FAT12 is encouraged but not required.

External EMDs shall have a USB Type-C female receptacle for the purpose of connecting a USB Type-C plug connection cable (male-male ends) with the appliance's M2M data port.

The legal manufacturer or reseller of external EMDs shall provide a compatible USB-C cable with male plugs on both sides. The cable must be at least 1.5 meters long.

4.5.8 Data access port

A data port may be incorporated as part of an External EMD for the purpose of locally accessing data that is recorded and stored within the EMD. If employed, this data port shall be a USB-C female receptacle interface such that the EMD can be mounted as a USB mass storage device. The connection shall provide access to all recorded data and if any custom software is needed to access data, that software must be freely and easily available.

4.5.9 Remote communication modalities

This section is not applicable to local-only EMDs. The ability of EMDs to communicate with Remote Data Systems via an Internet connection provides additional levels of functionality and value to immunization programmes. However, remote communication capabilities are not required of EMDs and are specified as an additional feature with flexibility on communication modality (e.g. GSM / SIM-based,

Wi-Fi®, etc.). If a legal manufacturer or reseller chooses to provide remote communication capabilities, the requirements in this clause and the next two shall be satisfied.

All data objects, alarms, error codes, etc. recorded by the logger and EMD shall be communicated to Remote Data Systems.

EMD connection to Remote Data Systems may be achieved through various modalities of transmitting information onto the Internet based on the following guidance and requirements:

- Cellular-based communication: EMDs may communicate via mobile telecommunication networks that utilize both local and global SIM cards. The employer should specify their preference at the time of procurement. The legal manufacturer or reseller shall be able to offer functionality with local, global, and M2M/IoT SIM cards as requested by the employer. After commissioning, it shall be possible to change from local to global SIM cards and vice-versa. When switching from local to global SIM cards after commissioning, it is acceptable that a configuration of Access Point Name (APN) may be required. A 3-year communications contract length shall be a standard offering with the flexibility to negotiate other terms at the time of procurement.
- Other communication capabilities: transmitting data to the Internet may also be achieved via Satellite, Wi-Fi®, and other networking solutions. The legal manufacturer or reseller should take care to ensure the remote transmission service provided is appropriate and will deliver on the functionality required under this specification for the communication environment of the employer's country.

4.5.10 Remote data transmission frequency

- Transmission frequency: Transmission frequency shall be frequent enough such that there is no greater than a 15-minute delay from when an alarm event occurs to when it is communicated and known remotely.
- Less-frequent data transmission: if no alarm conditions exist, data transmission frequency may be reduced to conserve resources so long as alarms are still triggered remotely within 15 minutes of the alarm condition occurring within the appliance. Under this condition, new data not previously communicated remotely should be uploaded at least once every 24 hours, unless otherwise agreed at time of procurement.

4.5.11 Connection and reconnection to remote data systems

When powered on, a Cellular-based EMD that has been procured with a SIM card and cellular service enabled shall automatically connect to cellular networks and transmit data to the server without any additional configuration beyond physical setup. Connection to non-cellular, Internet-connected networks (e.g. Wi-Fi®) should be simple for users or technicians to complete with sufficient knowledge of the communication modality used and local network access privileges.

In the event of any communication interruptions (e.g. loss of power supply), the EMD shall automatically reconnect to whichever Internet-enabled network is used once the interruption is resolved (e.g. power supply resumes).

4.6 Human factors

4.6.1 Visual display

Visual display requirements for both local-only and remote-enabled EMDs are specified below.

- An on-site display shall be part of the EMD. An on-site display is not required to be permanently affixed to an appliance.
- Monitored data may be displayed via secondary devices (e.g. smartphone applications), but this shall not replace the ability to visually display information via the EMD or appliance.
- One local display may display information for more than one on-site appliance.
- The display should be designed in such a way that essential performance and safety information is available, but not overwhelming to users who may have limited experience with technology.
- The display shall allow users to access required information in as few "clicks" or interactions as possible while maintaining simplicity and readability. "Home screens" should be basic and only communicate essential information such as date, time, and vaccine compartment temperature.
- **Display contents**: the visual display shall have means of displaying the following information:
    - **Local date and time**
    - **Display languages**: displays shall utilize English as a default, with translations readily available in all UN languages (Arabic, English, French, Mandarin, Russian, and Spanish). Display languages specific to certain countries are to be provided if requested by the buyer.
    - **Vaccine compartment temperature**: most recently recorded temperature of coldest point in the vaccine compartment.
    - **Alarm status**: activation of obvious visual cue that an alarm condition is occurring and specifically what type of alarm, e.g. "freezing temperature alarm"; the visual cue should serve to notify users and trigger action based on programmatic guidance for responding to specific alarms. All alarms listed in the latest published version of the Data Standard specification (**WHO/PQS/E006/DS01**) shall be visually communicated on the display when triggered. The required contents of the home screen listed here shall still be visible during an active visual alarm.
    - **Alarm history**: At least the last 30 days of heat and freeze alarm data, including alarm duration and maximum/minimum temperature.
    - **Disabled alarms**: Display alarm disabled status per Clause 4.6.7.

- **Error status**: activation of obvious visual cue that an EMS system or component error is actively occurring and specifically what type of error.
- **Historical storage chamber temperature summaries**: At least the last 30 days of daily maximum, minimum, and average storage chamber temperature data.
- **Appliance supply power**: Indication whether there is supply power available to the appliance. This visual indicator may be driven by the existence of supply power to the EMD from the appliance, or the EMD may optionally implement more sophisticated approaches to represent appliance power availability more accurately.
- **Logger connection status**: Whether the appliance logging system is operating normally, or an error has occurred.
- **Logger-generated error codes**: The EMD shall display all error codes that are available on the logger. Such error codes shall be accessible to local, on-site users via the EMD for at least 60 days.
- **Logger battery charge (if applicable)**: Level indicator OR battery replacement warning indicator; activated when the logger battery charge is below 20% of its rated capacity for non-rechargeable batteries, or for rechargeable batteries when the capacity is less than 80% of rated capacity.
- **EMD status**: Whether the EMD is operating normally, or an error has occurred.
- **EMD battery charge (if applicable)**: Level indicator OR battery replacement warning indicator; activated when the battery charge is below 20% of its rated capacity for non-rechargeable batteries, or for rechargeable batteries when the capacity is less than 80% of rated capacity.

4.6.2 Additional visual display requirements for remote EMDs

For EMD with remote communication capabilities, the following are additional display requirements:

- Cellular signal strength indicating strength of connection with remote communication network.
- Date and time of last successful data transmission.
- KPI visualization. Metrics to assess overall appliance performance shall be accessible to users and indicate the period for which the KPIs were calculated.

4.6.3 Audio-visual alarms

A combined audio-visual alarm shall be employed to notify users or employers whenever a temperature or performance event occurs outside user-programmed settings. These requirements apply to both local-only and remote-enabled EMDs.

Required alarms and their default threshold settings shall comply with the latest published version of the Data Standard specification (**WHO/PQS/E006/DS01**). It is

acceptable for E-EMDs to have up to 15-minute latency in alarm triggering due to the expected typical M2M data download interval. Local adjustment of alarm configuration is optional. If implemented in local-only EMDs, users shall have the ability to adjust these default settings using the EMD interface without the need for an Internet connection or other devices.

Functional requirements for alarms are:

- **Visual alarm**: The visual indication of an alarm shall be displayed prominently such that users cannot mistake the alarm for any other displayed information. The display of the alarm shall be generally described as "obvious" and "apparent" to any user that is within the immediate vicinity of the display.
- **Audio alarm**: 70dB(A) at one-metre distance from the sounder. The pattern of the signal is to be an intermittent pulse. The timing and/or pattern of the pulse shall be set to ensure that it cannot be confused with other emergency alarms as specified in **ISO 8201**. EMDs with an adjustable sound profile will be acceptable provided the means for adjustment is not easily accessible.
- **Alarm activation**: An audio-visual alarm shall be triggered locally automatically and immediately whenever a defined alarm condition is detected by the EMD.
- **Alarm deactivation**: An audio-visual alarm is to be automatically deactivated whenever an alarm event is no longer occurring (e.g. internal compartment has returned to a safe temperature).
- **Alarm muting**: The user shall have a means of muting the *audible* alarm on-site. The mute function shall be easily accessible to users. Muting shall not deactivate the alarm, but rather stop all audio alarming sounds for the duration of the current alarm.
- **Disable/enable alarm monitoring**: Local users shall have the ability to indefinitely disable audio-visual alarms in the event the appliance is inactive or not storing vaccines. When alarms are disabled, the disabled status must be prominently visible on the display so that users will not forget to re-enable when the appliance is placed back in use.
- **Alarm recording**: Each of the alarm actions listed here shall be recorded by the EMD.
- **Alarm data summary**: Data summarizing the alarm event shall comply with Data Standard (**WHO/PQS/E006/DS01**).

4.6.4 Remote audio-visual alarms

For EMD with remote communication capabilities, the following are additional alarm requirements.

- Alarm communication latency: within 15 minutes of an alarm state being recognized by an EMD, the EMD shall communicate the alarm to remote data systems.
- The EMD may optionally transmit alarm muting or other acknowledgement actions to remote data systems as described in the Data Standard (**WHO/PQS/E006/DS01**).

4.6.5 Remote alarm notifications

It shall be possible to send remote notifications such as SMS text and email, to users via communication networks, but the details of such a service shall be negotiated at the time of procurements with the employer.

If desired by the employer, SMS text and email are the minimum requirements for remote notifications. Such communications shall be directly actionable.

4.6.6 Remote alarm muting

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.

4.6.7 Remote disable/enable alarm monitoring

The audio-visual alarm system shall have the ability to be indefinitely suspended by remote intervention in the event the appliance is inactive or not storing vaccines. If activated, this suspension of alarms shall be visually communicated via online dashboards and on-site. Restarting alarm monitoring shall be simple to execute via the online dashboard.

4.6.8 Online dashboards

Online dashboards are Internet-based software applications that allow users and administrators to access and analyse data remotely. Numerous advanced dashboard features and functionalities may be possible, but the legal manufacturer or reseller shall offer a solution with the following minimum requirements:

- Adjust thresholds for local and remote alarms & KPIs calculated on EMDs.
- Mute active alarm(s) per Clause 4.6.6.
- Disable alarm monitoring per Clause 4.6.7.
- Grant access privileges to staff of the employer.
- Access and download all recorded data in at least CSV format.
- View an activity log of all system changes and actions taken by any party through the dashboard.

4.6.9 Additional guidelines for advanced dashboards

Feature-rich online dashboards are not required, but if offered, should allow users to easily:

- See any immediate/urgent issues/alarms.
- Generate summary views and graphs, allowing end-users to quickly see basic analysis on device performance, alarm status and some baseline data, such as high and low temperatures recorded during the day.

- View all deployed appliances/EMDs as a list and spatially (on a map).
- Select a specific EMD view information regarding that EMD and appliance at the individual sensor level.
- Create and download reports.
- Export data in CSV format and any images in JPEG and PDF formats, with export of data in JSON format optional.
- Establish an alarm escalation tree: The system should allow a minimum of three layers of alarm notification escalation. The system administrator should be able to remotely specify (through the dashboard interface) recipients at each level of this escalation tree, their preferred form of notification (e.g. SMS, voice call, email), and the allowed time period for response before the next escalation.

Manufacturers are also encouraged to use common user-interface design language for dashboards, and to create documentation to simplify learning and retention of dashboard features. A possible technique is presented in Annex 1.

4.6.10 Low-bandwidth platforms

Low-bandwidth interfaces are optional but strongly recommended to allow users access if/when utilizing slow or weak Internet connections.

4.6.11 Mobile platforms

A mobile platform/app for users to access Remote Data System information is optional.

4.6.12 Additional threshold notifications

Beyond the default alarm and KPI condition thresholds outlined in the Data Standard (**WHO/PQS/E006/DS01**), it may be possible to create additional notifications that are triggered by data object thresholds in the event "warning" notifications are desired by the employer prior to alarm thresholds being reached. The same features of activation/deactivation, muting, enable/disable and recording of notifications shall apply to these additional notifications. There is currently no WHO definition for these thresholds and thus this functionality is optional to provide an extra level of customization based on industry and programme needs over time.

4.7 Materials

4.7.1 Ozone depleting chemicals

During manufacture and assembly of the printed circuit boards and final assembly of the product, do not use any substance included in Annex A, B or C of the Montreal Protocol.

4.7.2 Other restricted materials

The product and its constituent components, including batteries, shall not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 Warranty

The EMD shall be covered by a replacement warranty in the event of any component failure arising from defective design, materials, or workmanship.
Specific requirements depending on whether the EMD is integrated or external:

- Integrated EMD requirements: the warranty of the system and all components shall meet or exceed the warranty offered with the appliance(s). Warranty provisions shall not be separate for the monitoring system and shall be included as part of the warranty provided with the appliance(s).
- External EMD requirements: all system components are to be covered by a three-year warranty in the event of any component failure.

The employer will take full ownership of the EMD, warranty and aftersales conditions at the time of delivery to the port of entry. The operation and maintenance of the system will be the responsibility of the employer for the duration of the EMD's lifetime unless otherwise agreed upon.

4.8.1 Minimum warranty for energy storage components

The minimum warranty for all energy storage components shall be no less than three years.

4.9 Maintainability

On-site maintenance of the system and the system components will be required over the lifetime of the EMD. The legal manufacturer or reseller shall declare how their EMD design mitigates long-term maintenance challenges associated with hot, humid, dusty climates with poor power quality and availability.

- Integrated EMD requirements: the integrated design of the EMD shall consider ease of maintenance. Components that may require replacement over the lifetime of the EMD or appliance shall be easily accessible and serviceable.
- External EMD requirement: the EMD shall be serviceable for common maintenance and repair needs. Key components shall be replaceable.

4.9.1 Equipment servicing provision

Integrated EMD requirements:

- The EMD shall be designed to achieve a low-maintenance life of no less than the operational lifetime of the appliance within which it is integrated (e.g. 10 years for ILR and SDD refrigerators).

- Batteries and sensors that do not require replacement throughout the lifetime of the appliance are preferable; however, they shall be serviceable or replaceable if the need arises.

External EMD requirements:

- The EMD shall be designed to achieve a low-maintenance life apart from routine cleaning, battery or sensor replacement and re-calibration. The minimum operational lifetime of the EMD shall be at least 10 years.

4.9.2 Spare parts

The legal manufacturer or reseller shall provide a complete list of the spare parts, including part numbers for all key components of the EMD.

4.10 Disposal and recycling

The manufacturer shall provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal as part of the recovery and disposal information provided for the associated cold chain equipment. For the European Union WEEE compliance in accordance with European Union Directive is mandatory.

4.11 Instructions

Each integrated or standalone EMD shall include a user manual and technician manual in Arabic, English, French, Mandarin Chinese, Russian and Spanish. An English version of all instructions and manuals are required to be supplied at time of laboratory testing and prequalification. Instructions to include easy to understand visuals whenever possible to avoid reliance on text.

The user manual shall include the following information:

- Health and safety guidance
- Basic operations description
- Advanced instructions for system administrators to configure EMD and dashboard (if applicable)
- Preventive maintenance tasks (e.g. daily, weekly, and monthly).
- Warranty and contact information for legal manufacturer or reseller.

The technician manual shall include the following information:

- Health and safety guidance
- Detailed operations description
- Correct handling to avoid EMD or appliance damage and for the safety of handling persons
- Installation procedures
- Compatible solar power system voltage (external EMD only, and only if applicable)
- Preventive maintenance tasks (e.g. daily, weekly, and monthly)

- Corrective maintenance procedures
- Diagnostic and repair procedures
- Itemised list of spare parts including part numbers
- End-of-life resource recovery and recycling procedures
- User training guidance.

Printed user-operations and maintenance instructions specifically directed at the health centre staff shall be pictorial. All key information is to be summarized on a single pictogram sheet that may be fixed onto the appliance. The sheet is to be sufficiently durable to last the life of the appliance.

All instruction manuals shall be supplied in printed format and easily available and downloadable in digital format on the Internet. Digital manual materials may also be provided with the EMD on a separate USB storage drive.

4.12 Training

If requested, the legal manufacturer or reseller shall at a minimum provide remote training in the countries where their product is deployed via suitable teleconferencing tools. Remote training shall cover the installation, on-site use, maintenance of the hardware, configuration and use of software and dashboard interface and system troubleshooting.

Training programmes shall cover the minimum requirements described in the following sections. Specific requirements related to integrated EMD and external EMD include:

- I-EMD requirements
  - Training shall be included as part of the provided training for the appliance(s).
- E-EMD requirements
  - Training shall be made available either through the installer of the appliance(s), or through other agents of the legal manufacturer or reseller of the EMD. Agreement on this arrangement shall be made among the legal manufacturer or reseller of the EMD and appliance(s), the procurement agent, and the employer.
  - The training programmes shall include physical installation and maintenance of the standalone hardware.

4.12.1 Installation and user training

Practical, hands-on installation training shall be available for the installation and use of EMDs. Some provisions may not be applicable if the EMD is integrated versus external.

Training outcomes for participants:

- Correct installation and setup of the complete EMD
- Basic system troubleshooting

- Commissioning and handover of installed equipment in the form of job completion checklists and/or reports

Minimum training requirements:

- Unpacking of the equipment and verification that the correct equipment components and accessories are available for successful installation of the EMD
- Use and interpretation of electrical circuit diagrams and installation manuals.
- Hands-on assembly and installation of different components, such as M2M cables, sensors, sensor cables, etc.
- Hands-on assembly and installation of components such as M2M data and power cables, including proper EMD positioning and cable management.
- Use of the EMD including setting alarm conditions, muting alarms, configuring monitored asset parameters, and accessing monitored information through the Internet-based web portal
- Interpretation of all displays and recorded data
- EMD system functionality test and troubleshooting
- Standard commissioning procedures, including necessary metadata collection/reporting to associate EMD with proper facility name and administrative areas.

4.12.2 Technical training

Training in correct installation of the EMD, system administration, setup, operation, troubleshooting, maintenance, interpreting of data, and training of further technicians, and system administrators shall be available to employers.

Training outcomes for participants:

- Correct installation, setup, and operation of the EMD
- Correct interpretation of displays and recorded data
- Advanced system maintenance and troubleshooting
- Commissioning and handover of installed equipment in the form of job completion checklists and/or reports
- Training of further technicians on the installation, setup, and operation of the EMD
- Training of further system administrators in the setup and operation of the EMD

Minimum training requirements:

- Demonstrate the EMD, including main components, controls, connections, and functionalities
- Demonstrate the process of installing and setting up the EMD
- Use of the EMD system, including setting alarm conditions, configuring appliance parameters, and accessing information through the Internet-based web portal.
- Interpretation of all displays and recorded data

- Daily, weekly, and monthly tasks and best practices for remote temperature monitoring, data accessing, analysis, downloading and corrective action
- Advanced troubleshooting procedures
- Standard corrective and preventative maintenance tasks
- Standard commissioning procedures
- Frequently asked questions
- Processes and best practices for training of further technicians in the installation, setup, and operation of the EMD

4.12.3 System administrator training

Training in system administration, setup, operation, troubleshooting, maintenance, interpreting of data, and training of further system administrators shall be available to employers.

Training outcomes for participants:

- Correct set up and operation of the complete EMD
- Correct interpretation of displays and recorded data
- Standard system maintenance and troubleshooting
- Training of further system administrators in the setup and operation of the EMD

Minimum training requirements:

- Demonstrate the EMD, including main components, controls, connections, and functionalities
- Use of the EMD, including setting alarm conditions, configuring appliance parameters, configuring users, SMS recipients and accessing information through the Internet
- Interpretation of all displays and recorded data
- Daily, weekly, and monthly tasks and best practices for remote temperature monitoring, data accessing, analysis, downloading and corrective action
- Standard troubleshooting procedures
- Standard corrective and preventative maintenance tasks
- Frequently asked questions
- Processes and best practices for training of technicians in the installation, setup, and operation of the EMD system
- Processes and best practices for training of further system administrators in the set up and operation of the EMD system.

4.12.4 Training materials

To support training outlined above, the following materials shall be available:

- EMD installation & commissioning:
    - Training materials on EMD installation and setup, including mounting of the base unit, positioning, and mounting of sensors, connection to

external power supply (where applicable), routing and protection of sensor and power cabling.
    - Training materials on standard commissioning procedures, including the use of commissioning and/or functionality checklists.
- EMD use and troubleshooting:
    - Training materials on device and dashboard (if applicable) operation, including setting alarm conditions, configuring monitoring parameters, configuring users, SMS recipients and accessing information through the Internet.
    - Training materials on interpretation of all displays and best practices for remote temperature monitoring, data accessing, analysis, downloading and corrective action.
    - Training materials on basic and advanced system troubleshooting and maintenance procedures.
    - Standard Operating Procedure posters for vaccine storage facilities, covering topics such as interpretation of all displays and best practices for remote temperature monitoring, data accessing, analysis, downloading and corrective action.
- Materials for training trainers:
    - Training materials on how to conduct training of further technicians.
    - Training materials on how to conduct training of further system administrators.

All training materials shall be supplied in printed format and easily available and downloadable in digital format on the Internet. Digital manual materials may also be provided with the EMD on a separate USB storage drive.

4.13 Verification

In accordance with PQS verification protocol **WHO/PQS/E006/EM01-VP.1**

5. Packaging

Integrated and external EMDs shall comply with the following packing requirements. If the EMDs is integrated within an appliance, the packaging requirements are those found in the PQS specifications for those appliances.

Materials used for packaging the finished appliance are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

The packaging is to be a sturdy export-quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. The packaging is to be not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of +70°C (tropical conditions).

To avoid destructive unpacking prior to installation, legal manufacturer or reseller is encouraged to add a resealable observation opening in their packaging to aid inspectors in finding labelling and/or placing additional markings prior to installation. Instructions on the packaging alerting inspectors to use of the opening and what information will be revealed are also advised.

The general specification of shipping containers will be subject to agreement with the individual procurement agent.

6. On-site installation

If requested and negotiated at the time of procurement, the legal manufacturer or reseller shall provide on-site installation in the countries where their product is deployed.

- Integrated EMD requirements: system components shall be installed at the point of manufacture/assembly, and the software pre-loaded prior to shipment of the appliance. Designs shall limit the amount of additional on-site setup required. Any on-site setup required shall be included as part of the provided instructions and communicated to PQS during the prequalification process.
- External EMD requirements: system components are to be installed on site, and the software loaded and commissioned by legal manufacturer or reseller.

6.1 Other commissioning services

The legal manufacturer or reseller shall provide services to support commissioning of systems both at the individual facility level and at higher levels of the cold chain system if requested by the employer.

- Facility level: equipment and system commissioning services shall be made available and provided at the time of installation. Such commissioning services include:
  - Establishing any remote server communication
  - Setting alarm thresholds
  - Adding personnel contact information for notifications and alarms, etc.
- System level: integration activities shall be available for the purpose of integrating data streams from the newly commissioned equipment with existing management information systems utilized or designated by the employer. Such services include:
  - Setting up API gateways to transfer data into designated management information system
  - Setting system-wide reporting parameters
  - Adding personnel notification and reporting features, etc.

7. Product dossier

The legal manufacturer/reseller is to provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer and any reseller(s), including name and address.

- Unique identification reference for the EMD.
- Brand name of the EMD.
- Full specifications of the EMD being offered, covering all the requirements set out in this document, including details of EMD marking and traceability.
- Certified photocopies of all type-approvals obtained for E-EMDs or appliances containing I-EMDs, such as CE marking etc.
- Certified photocopies of the legal manufacturer/reseller's **ISO 9001** quality system certification.
- Where relevant, certified photocopies of the legal manufacturer/reseller's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Evidence of conformity with **ISO/IEC 27001:2013** for remote data systems, including evidence of independent security audit completed within last two years.
- Laboratory test report(s) proving conformity with the equipment specifications.
- Indicative hardware cost of the EMD per unit, per 10 units and per 100 units, EXW (Incoterms 2010).
- Indicative costs for cellular data transmission (range is acceptable), data hosting, and portal subscription for the default three-year period.

8. On-site maintenance

The legal manufacturer or reseller shall provide ongoing system maintenance services to ensure the continued operation of the monitoring system. Such services include:

- General system administration.
- System/software upgrades.
- At request of employer, updating system parameters like personnel contact information, notifications, alarm thresholds. These updates may be completed by legal manufacturer, reseller, or employer-authorized administrator.
- Remote troubleshooting.
- Notice to employer of when service contract period is due to expire.

9. Change notification

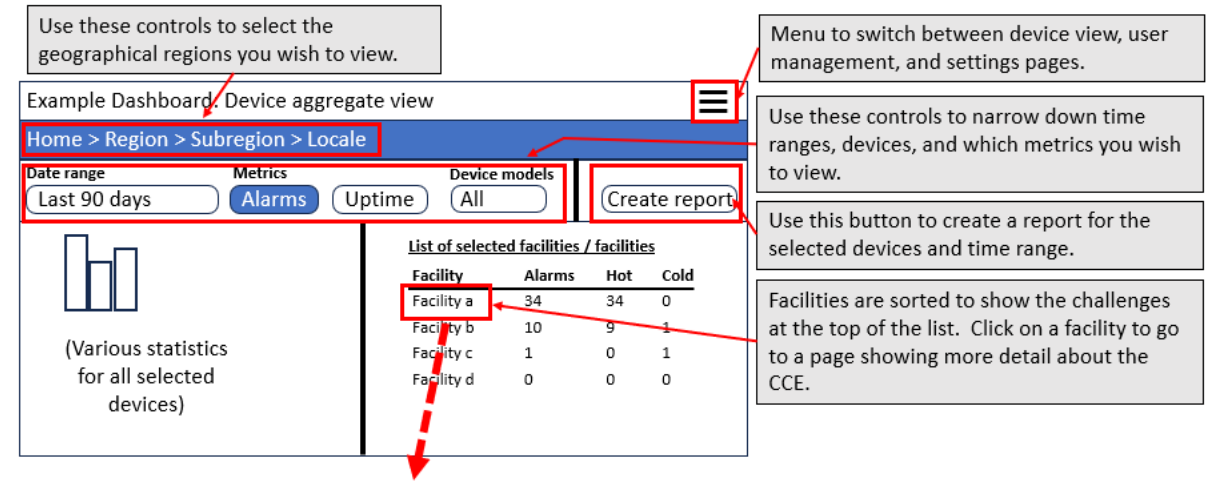
The legal manufacturer/reseller is to advise WHO in writing of any changes which affect the performance of the EMD after PQS prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **WHO/PQS/E006/EM01-VP.1** will result in a request for the EMD to be retested.

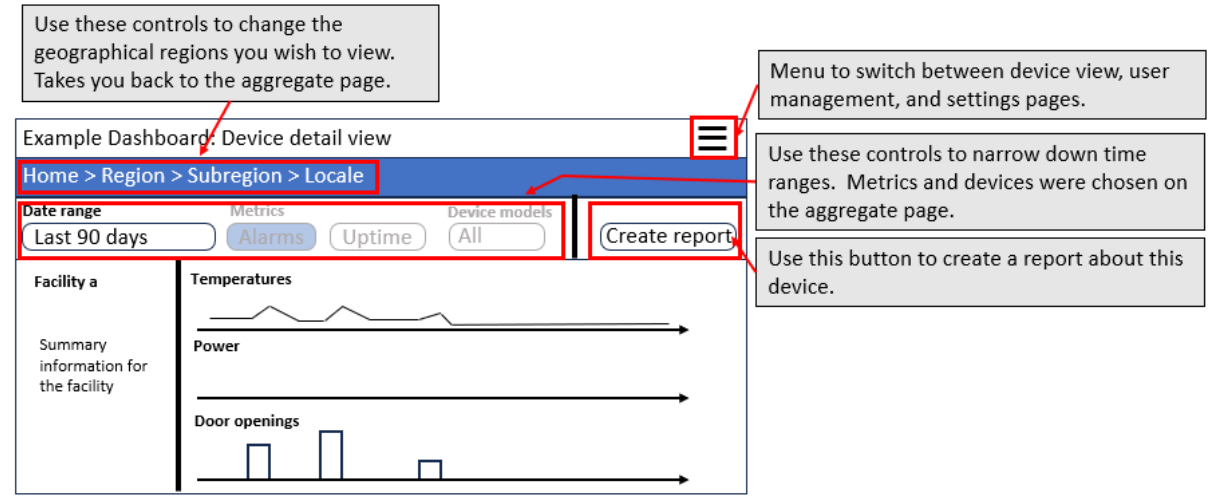
10. Defect reporting

The legal manufacturer/reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related EMD recalls, component defects and other similar events. If requested to do so by WHO/UNICEF, the manufacturer is to submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

Annex 1: Additional guidelines for advanced dashboards

This annex is an example of documentation to help users navigate a hypothetical online CCE performance dashboard. Note: the dotted arrow indicates that an action takes the user to a new page.





Annex 2: Definition of EMS levels

The Equipment Monitor System is broken down into 3 levels of functionality. Appliances are required to achieve level 1 as a minimum. Level 2 and 3 can be integrated into the appliance or can be external to it.

Level 1 is the datalogger with power and data connections for the Machine-to-Machine interface (M2M). Note: more advanced local or remote means of communication data are not required. The requirements of level 1 are specified in **WHO/PQS/E006/DL01.**

Level 2 is the Equipment Monitoring Device (EMD), and has all the same requirements of Level 1. The EMD is the primary means of communicating monitored cold chain data locally. The EMD draws raw data directly from the appliance's integrated logger. The EMD may be integrated into the appliance or external. The requirements of level 2 are specified in **WHO/PQS/E006/EM01.**

Level 3 has all of the same requirements of level 2 with the additional feature of remote communications (e.g. GSM / SIM-based, Wi-Fi®, etc.). As with level 2, the EMD may be integrated into the appliance or external. The requirements of level 3 are specified in **WHO/PQS/E006/EM01** with special attention to Section 4.5.9 - Remote communication modalities**.**

Revision History

Revision history			
Date	Change summary	Reason for change	Approved
November 2023	Addition of IEC 61000-6-8 as option instead of IEC 61000-6-3.	IEC 61000-6-3 applies to residential, commercial, and light-industrial environments and IEC 61000-6-8 applies to professional equipment in commercial and light-industrial environments.	IG
November 2023	Addition of definition of Levels as Annex 21.	This was not defined in any of the documents.	IG
November 2023	Minor edits	Clarifications	IG
November 2023	Addition of note to Section 4.6.3 to add a visual indicator that the alarms are disabled.	Users might not realize the alarms are disabled when putting the appliance back into use.	IG
November 2023	Addition of a requirement to the instruction manual for a “map” to navigate the EMD display and dashboard.	Adding this display navigation map will make it easy to user to more efficient find the information they are looking for.	IG