



TITLE: Data logger and machine-to-machine interface for Equipment Monitoring Systems

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1. Scope

This specification describes the minimum requirements of data **loggers** integrated within **appliances**, and the required **appliance** connections for data and power transfer (known as the **Machine-to-Machine interface (M2M)**) that support the functionality of external devices, including external **EMDs (E-EMD)**. The integrated **logger** and **M2M** augment the function of an **appliance** to include data recording and local access to that data. More advanced local or remote means of communicating data are not included in this specification and are instead specified in the **Equipment Monitoring Device** specification **WHO/PQS/E006/EM01**. 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 the **EMD** functions are inoperable, or if remote connectivity or service plans lapse.

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.

RTC Wakeup value (RTCW): The relative timestamp of the start of the most recent period of continuous timekeeping operation.

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

The **logger** is primarily tasked with maintaining relative time, recording **appliance data objects**, generating and recording **logger data objects**, and making that data available in a standardized way to other equipment monitoring devices and systems.

Data objects are listed as either “required” or “optional”. The **logger** shall have a means of receiving data inputs from the **appliance’s** integrated sensors and storing that data in its onboard data storage, with an associated relative timestamp. The **logger** shall apply its relative timestamp to data received from the **appliance**, as the data will not contain timestamps.

4.2 Performance

4.2.1 *Relative time keeping*

As the **logger** is not expected to have access to **absolute time**, its timestamps shall be considered relative to a constant arbitrary reference. If a **logger** has **absolute time** (e.g. logging functions are integrated with remote **EMD** functions), it may record the **absolute time** in the appropriate data element, but must still satisfy the requirement for logging **relative time** and including it in the filenames as defined in Clause 4.5.13.

Relative time requirements are specified in the **Data Standard** specification:
WHO/PQS/E006/DS01.

The **logger** shall begin keeping relative time at the point of manufacture such that relative time is a measure of the total life of the **appliance** from time of manufacture.

4.2.2 *Continuous time keeping*

The **logger** shall continue time keeping functions throughout power outages and for the life of the **appliance** within which it is integrated. There shall be no gap in time keeping during extended **appliance** supply power outages. Some recording functions of the **logger** may become deactivated after a period without supply power (see Clause 4.2.7), but **relative time** keeping shall never be disrupted by lack of power supply.

4.2.3 *Disruption to time keeping*

If for any reason there is a disruption to timekeeping (e.g. timekeeping battery failure), the **logger** shall record that a disruption occurred when normal operation is restored and continue relative timekeeping immediately after the point it left off prior to the disruption (i.e. do not reset to zero, and do not repeat timestamps). This disruption shall be recorded by updating the **RTC Wakeup value (RTCW)**, which contains the relative timestamp of the start of the most recent continuous timekeeping operation. When **logger** timekeeping is resumed after any disruption, the RTCW value shall be updated with the current relative time value. See **Annex 2** for more information about RTCW.

4.2.4 *Timestamp drift*

Maximum allowable time ‘drift’ for devices that are not able to sync to global clocks (i.e. local logging only) is 60 minutes per year at ambient temperatures ranging from +10°C to +43°C.

4.2.5 Required data objects

The **logger** shall record all of the following **data objects** unless they are not applicable to the **appliance** (e.g. DC voltage for a mains-powered **ILR**). If an **appliance** generates and communicates to the **logger data objects** not included within this list, the **logger** shall record any manufacturer-specific **data objects** based on the requirements in Clause 4.2.9.

Administration:

- **Appliance administrative information:** data related to the **appliance** shall include manufacturer, model, manufacturer serial number, date of production, and **appliance** WHO PQS code and category.
- **Compressor electronic control unit administrative information:** if available, data related to the compressor(s) or other cooling control unit(s) should include manufacturer, product code, production date, and software version.
- **Logger administrative data:** data related to the **logger** shall include manufacturer, model, software version, manufacturer serial number, date of production, and WHO PQS code.
- **Relative time:** Strictly increasing 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].
- **RTC Wakeup (RTCW):** Relative timestamp of the last time the **logger** resumed normal operation after a disruption to timekeeping (e.g. extended power failure) as described in Clause 4.2.3.

Environment:

- **Ambient temperature:** temperature of the immediate surroundings within which the **appliance** is operating, measured in degrees Celsius (°C) at least once every 15 minutes. Care shall be taken integrating ambient temperature sensors within the **appliance** to minimize the effects of sensor positioning in a location where ambient temperature sensor readings could be affected by the heat generated by the **appliance** or other environmental factors (e.g. positioning of the fridge within a facility). Appropriate positioning of sensor will be validated through performance testing.
- **AC supply voltage availability (AC supply appliances):** data indicating the number of seconds within each 15-minute period when the AC voltage is within acceptable bounds.
- **DC supply voltage to appliance (DC supply appliances):** average DC supply voltage to **appliance** within each 15-minute period. Average value of raw samples collected at intervals not longer than 10 seconds.

Performance:

- **DC current drawn by the appliance (DC supply appliances):** average DC current being drawn from supply by the operation of the [appliance](#) within each 15-minute period. Average value of raw samples collected at intervals not longer than 10 seconds, measured in Amps. This is intended to measure current for all [appliance](#) cooling, control and monitoring functions, and at supplier discretion may also include current for [Energy Harvest Control](#) outputs.
- **Compressor runtime:** Total duration compressor or other cooling system operated within each 15-minute period, measured in seconds.
- **Error codes:** any [error codes](#) related to [appliance](#) sensor or performance issues shall be generated and recorded by the [logger](#) when an error event occurs. Additionally, the [logger](#) shall generate and record [error codes](#) for any condition that may impair its normal operation (e.g. broken or disconnected sensors, self-test failure).
- **Logger battery remaining:** estimated number of hours of battery remaining to operate the [logger](#) normally, measured in days (DDDD).
- **Vaccine compartment temperature:** temperature of the location where vaccines may be stored, measured in degrees Celsius (°C) at least once every 15 minutes. For [appliances](#) storing vaccine above 0°C where freezing is a risk, the sensor shall be in the coldest location of the compartment (based on appliance testing). For [appliances](#) storing vaccines in frozen form, this sensor shall be at the warmest location of the compartment (based on appliance testing).

Use:

- **Door/lid open (cumulative):** total duration door was opened within each 15-minute period, measured in seconds; for combined refrigerator-freezer units with separate compartments and doors/lids, each compartment shall generate distinct open duration data. For appliances with inner and outer doors/lids, only the outer door/lid needs to be monitored.
- **Door/lid open (instantaneous):** continuous duration door has been open at the time of USB mount by an [EMD](#) or other USB [host](#), measured in seconds. If the door is closed at the time of USB mount, this value will be zero. For combined refrigerator-freezer units with separate compartments and doors/lids, each compartment shall generate distinct open duration data. For appliances with inner and outer doors/lids, only the outer door/lid needs to be monitored. This [data object](#) may be used by [E-EMDs](#) to inform door alarming.
- **Main ON/OFF switch:** indication of the status of the supply power switch of the [appliance](#), measured when an event occurs in terms of absolute ON/OFF status. This field is required for refrigerated vehicles and transportable powered [appliances](#) that are likely to sit unused for periods of time, but optional for all others.

4.2.6 Continuous recording without appliance supply power

The **logger** shall continue to record **data objects** noted in Clause 4.2.7 during **appliance** supply power outages. The minimum period of uninterrupted recording without **appliance** supply power assumes any power storage components are fully charged at the time power is disconnected:

- 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 at +43°C or 18 hours at +43°C, whichever is greater. It is acceptable for continuous recording to stop when the appliance is intentionally switched off, but the continuous timekeeping requirement of Clause 4.2.2 must still be satisfied.
- Refrigerated vehicles: 1.5x rated non-idle run time of the refrigeration unit. It is acceptable for continuous recording to stop when the unit is intentionally switched off, but the continuous timekeeping requirement of Clause 4.2.2 must still be satisfied.

For example, if the rated holdover time of a mains-powered **appliance** is 80 hours at +43°C, then the period of continuous recording shall be at least 160 hours.

4.2.7 Recording essential data objects during power outage

During periods when there is insufficient power to operate the **appliance**, the **logger** shall continue to record the following essential **data objects**:

- Vaccine compartment temperature
- Ambient temperature
- Door openings

4.2.8 Optional data objects

The following **data objects** are optional for **appliance** generation and **logger** recording. If any optional **data object** is generated by the **appliance**, it shall be communicated to the **logger**:

Administration:

- **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:

- **AC supply voltage to the appliance (AC supply appliances):** **Appliance** input voltage from power supply (mains/generator), measured in Volts (V) at least once every 15 minutes.

Performance:

- **AC current drawn by the appliance (AC supply appliances):** Current being drawn from supply by the operation of the [appliance](#) within each 15-minute period. Average value of raw samples collected at intervals not longer than 10 seconds. Measured in Amps (A).
- **Compartment relative humidity:** Internal vaccine compartment relative humidity, measured in RH% at least once every 15 minutes.
- **Compressor electronic unit temperature:** Unit temperature as measured by the compressor electronic unit(s) or other cooling controller(s), measured in degrees Celsius (°C) at least once every 15 minutes.
- **Compressor speed:** Maximum operating speed of the compressor, measured in revolutions per minute (rpm), within each 15-minute period.
- **Condenser temperature:** Surface temperature of the [appliance's](#) condenser coil/circuit or other heat rejection surface measured in degrees Celsius (°C) at the warmest location at least once every 15 minutes.
- **Fan speed:** Operating speed of compressor cooling fan, measured in % of max speed at least once every 15 minutes.
- **Holdover, autonomy, or independence time remaining:** Estimated number of days of holdover/autonomy/independence time remaining (DD.D).
- **Thermostat/control temperature sensor - freezer compartment:** Applicable for [appliances](#) with a freezer compartment; sensor that is responsible for controlling freezer compartment refrigeration cycle based on setpoints, measured in degrees Celsius (°C) at least once every 15 minutes.
- **Thermostat/control temperature sensor - vaccine compartment:** Sensor that is responsible for controlling vaccine compartment refrigeration cycle based on setpoints, measured in degrees Celsius (°C) at least once every 15 minutes.

Use:

- **Door openings:** Number of door openings within each 15-minute sample period.

4.2.9 *Manufacturer-specific data objects*

[Legal manufacturers](#) may define and include [data objects](#) in the JSON raw data files that are not in the [EMS data objects](#) list, provided compliance with the conditions defined in the latest version of **WHO/PQS/E006/DS01** and the following:

- Additional temperature measurements beyond those defined in the [data objects](#) list shall be communicated as manufacturer-specific [data objects](#).
- While it is recommended that custom objects are embedded along with required objects in the 15-minute data records, if custom objects are saved as separate data records, each record must contain a relative timestamp (RELT) and [RTC wakeup value \(RTCW\)](#).

4.2.10 Data standard

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.

4.2.11 Data recording interval

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 relative timestamp for the recording.

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

For example, if at minute 10 of a 15-minute sampling period the vaccine compartment door is left open for 15 minutes, the data object after opening will reflect an open duration of 5 minutes (e.g. “DORV”: 300), and the following [data object](#) will reflect an open duration of 10 minutes (e.g. “DORV”: 600).

For the special present door/lid status [data objects](#), e.g. IDRV & IDRF, the [logger](#) shall save a record of these events at the time of USB mount.

In the above example, if an E-EMD mounts the [logger](#) USB mass storage one minute after the [logger's](#) sampling period, the present door opening data object will reflect an open duration of six minutes (e.g. “IDRV”: 360). When the [E-EMD](#) mounts 15 minutes later, the door is closed, so the continuous time of door opening is zero (e.g. “IDRV”: 0).

4.2.12 Period of data recording & storage

The [logger](#) shall be able to record and store all required, optional, and manufacturer-specific parameters for a period of at least one year, and available for download via the [M2M](#) data interface. The data storage system shall be configured such that at least one year of most recent data is preserved at all times and the oldest data is overwritten on a first in, first out basis.

4.2.13 Data storage

Non-volatile, solid-state memory shall be used to avoid data loss in the event of power supply failure.

4.2.14 Data validation

[Legal manufacturers](#) or [resellers](#) are not required to employ methods for validating the integrity of data unless so requested or required by the [employer](#). If implementing any form of data validation, such methods shall not interfere with the ability of external devices to access and download data on the [logger](#).

4.2.15 Sensors

Temperature sensors:

- Operating range: upper limit: +50°C, lower limit: -30°C.
- Accuracy: $\pm 0.5^\circ\text{C}$ or better, within the range -30°C to +20°C.
- Resolution: 0.1°C in the range -30°C to +20°C.
- Response time: T90 within 20 minutes maximum.

Door/lid opening sensors:

- Operating range: upper limit: +50°C, lower limit: -30°C.
- Accuracy: binary, open/closed.
- Response time: an “open” event shall be identified whenever the door panel is not fully seated in the closed position for proper compartment sealing.

Relative humidity sensors:

- Operating range: upper limit: +50°C, lower limit: -30°C.
- Accuracy: $\pm 5\%$ or better in the range 5% at 95% RH at a temperature of +5°C.
- Resolution: 1%.
- Response time: T63 within 60 seconds maximum.

Current monitoring sensors:

- Operating range: upper limit: +50°C, lower limit: -30°C.
- Accuracy: $\pm 5\%$ in the range 0-10 A DC or $\pm 5\%$ in the range 0-30 A AC
- Resolution: 0.1 A in the range 0-10 A DC or 0.1 A in the range 0-30 A AC

Voltage monitoring sensors:

- Operating range: upper limit: +50°C, lower limit: -30°C.
- Accuracy: $\pm 2\%$ in the range 0-50 V DC (unless the [appliance](#) is designed for higher voltages, in which case the maximum input voltage applies), or $\pm 2\%$ in the range 0-600 V AC.
- Resolution: 0.1 V in the range 0-50 V DC or 0.1 V in the range 0-600 V AC.

Other sensors:

Other sensors used to monitor optional data objects are permitted. The [legal manufacturer](#) shall ensure that these sensors are robust and appropriately designed for the lifetime of the [appliance](#).

4.2.16 Sensor & cable fixings and replacement

- Fixings: all sensors and cables shall be fixed in place and integrated within the cabinet of the [appliance](#) to avoid inadvertent repositioning, damage, or monitoring disruption. On-site installation or positioning of sensors and cables shall not be required.
- Replacement: replacement of integrated sensors shall be possible by a trained technician. Designs shall allow for sensor replacement without damaging the [appliance](#) or any sensor fixings. Designs that prevent straightforward replacement are not permitted.

4.2.17 Calibration

For vaccine storage chamber temperature measurement, system components 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.

Field calibration of sensors must not be required at any time, whether due to battery replacement in designs where the operational lifetime of the battery is shorter than the required 10-year life of the [logger](#), or due to sensor replacement. As field calibration of sensors is not a reasonable expectation, the intent of this requirement is to maintain temperature sensor accuracy through expected field maintenance events.

4.2.18 Energy storage lifetime

[Logger](#) energy storage (e.g. electrical batteries or capacitors) is required to enable continuous data recording during times when [M2M](#) and [appliance](#) supply power is unavailable e.g. power outage for [ILRs](#), night-time for [SDDs](#). Various approaches to energy storage are acceptable.

The functional lifetime of any non-replaceable energy storage components of the [logger](#) (e.g. batteries) 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 five years.

In the event of a battery discharge or failure, the [logger](#) must perform logging functions when supply power is available to the [appliance](#).

4.2.19 Energy storage recharging

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

For rechargeable energy components: If a **logger'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.

Loggers may utilize long-lifetime energy storage components that do not utilize supply power for recharging.

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; shall not require recalibration of sensors.

4.2.20 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 apparatus 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.

4.3 Environmental requirements

All components shall be adequately protected from the environment in which they will be deployed, including temperature, ambient humidity, input voltage and dust and water ingress.

4.3.1 Ambient temperature

All 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 except for relative time keeping, which must begin at the point of manufacture as specified in Clause 4.2.1.

All 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, [logger](#) and [M2M](#) components may be subject to a wide range of uncontrolled ambient relative humidity (RH) from 0 up to 95% RH. The components 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

All components shall be designed to operate in unreliable and erratic power supply environments that may present risk of electrical damage to sensitive components.

For AC supply (mains) devices, the [appliance's](#) voltage protection device or system shall sufficiently protect all [logger](#) and [M2M](#) components without additional installation setup or user intervention.

4.3.4 Dust and water ingress

- [Logger](#) components: There is no minimum IP rating requirement for the [logger](#) and its components given it shall be physically integrated within the [appliance](#). However, the [legal manufacturer\(s\)](#) of the [appliance](#) and [logger](#) system shall take care in the design and integration of the [logger](#) within the [appliance](#) such that the design eliminates or minimizes the effects of dusty, humid environments with potential water splashing. This is especially relevant for sensors that may be subject to condensation.
- 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**.
- [M2M](#) power and data connections: the USB Type-C data and barrel power connections shall have a minimum rating of IP64 when left unconnected and when cables are connected to an [E-EMD](#).

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

Dimensions not critical.

4.4.2 Weight

Weight not critical.

4.5 Interface requirements

Logger interfaces consist of internal interfaces to the **appliance**, which are mostly unspecified, a **Machine-to-Machine (M2M)** interface, and a file and format specification for data available on that interface. The purpose of the **Machine-to-Machine (M2M)** interface is to provide:

- Local access to **logger** data for **E-EMDs** and other external devices utilized by local users (e.g. laptops, mobile phones).
- Supply power from the **appliance** to external devices such as **E-EMDs**.
- Supply power from external devices to the **logger** for the purpose of data access when **logger** power is depleted.

4.5.1 Power supply

The **logger** shall have reliable power supplies to enable continuous monitoring with and without supply power from the **appliance**. The following modes of power supply shall be possible:

- Dedicated energy storage: the **logger** shall have a means of continuously recording when there is no power supply available via the **appliance** as specified in Clauses 4.2.6 and 4.2.7. For specific energy storage requirements, see Clauses 4.2.18 and 4.2.19.
- **M2M** power supply: per Clause 4.5.7 *Data Access During Power Outage*, in the event the **appliance** lacks supply power and/or the **logger** power supply is depleted, it shall be possible to power the **logger** using power supplied by external devices via the **M2M** USB-C connection. This functionality is intended to ensure that **loggers** with depleted energy storage (e.g. batteries) can still be accessed by technicians or **EMDs** to extract data related to the last known performance conditions of the **appliance**.

Optionally, the **logger** may source power directly from the **appliance**:

- **Appliance** power supply: power may be supplied by the **appliance** to allow for operation and charging of any **logger** energy storage components.
- Failsafe: the power supply to the **logger** shall not interfere with normal operation or starting of the **appliance**. Additionally, design of the **logger** shall mitigate failure modes of the **logger** that could cause it to draw greater loads from the **appliance**.

4.5.2 M2M Physical interface

The M2M consists of two connections:

- Data and logger power connector: USB Type-C female receptacle shall be used for data download by external devices and power supply from external devices to the logger in the event the logger's energy storage is depleted.
- Power connector: Barrel-type male plug with captive cable connected to the appliance shall be used and have 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
 - Cable type: captive to appliance
 - Cable length: 20 cm
 - Serviceability: captive cable shall be easily replaceable by a trained technician and available a spare part from the legal manufacturer or reseller.

Under this requirement, connecting the appliance M2M data receptacle with external devices shall be achieved using male plugs on both ends of a USB-C data cable. Connecting the appliance M2M power cable with external devices shall be achieved by directly connecting the captive barrel cable and plug to the external EMD power receptacle or via a compatible extension cable that would be provided separately with the external EMD.

4.5.3 M2M Power transmission modalities and limits

Both of the following power transmission modalities shall be possible:

Appliance powering of E-EMDs: The M2M power connection shall provide power to external EMDs via the barrel connector when the appliance is supplied with power. The voltage shall be $5\text{ V} \pm 5\%$ (4.75 to 5.25 V). To ensure M2M power supply does not negatively affect the performance of the appliance within which it is integrated, the supply shall have a current limit of $1.1\text{ A} \pm 50\text{ mA}$ (1.05 to 1.15 A) for E003 appliances. For DC supply appliances, the efficiency of any voltage conversion must be greater than 80% at maximum load. E001 and E002 appliances do not have a maximum output current limit. For transportable E003 appliances, the M2M power connection is not required, but is strongly recommended for devices that are recharged by connecting to AC or DC power.

Note that for the appliance the output is nominally 5.5 W and the allowable draw from an E-EMD is 5 W. This is done to avoid conflicting logic at the current limit threshold.

External device powering appliance logger: The M2M connection shall accept power from an external device via the USB Type-C connector so that the logger data may be accessed even if the logger's energy storage is depleted. The M2M need only

support 5 V 500 mA default USB 2.0 levels required by the USB Type-C standard; the higher currents and voltages enabled by the USB Power Delivery standard are optional.

4.5.4 M2M data access

The [logger](#) shall make all recorded data accessible to on-site users and devices via USB Type-C data connection (see Clause 4.5.2). The following communications modalities are required or optional:

- **Logger-EMD access (required):** the [M2M](#) shall allow an external [E-EMD](#) to access and download data from the [logger](#).
- **External device access (required):** the [M2M](#) shall allow external devices such as laptops or mobile phones to access and download data from the [logger](#).
- **Wireless logger-device communication (optional):** the [logger/M2M](#) may, as an option, provide wireless access to recorded data in the [logger](#) via wireless communication systems such as Wi-Fi® or Bluetooth®.

All data generated and/or saved by the [logger](#) is considered to be owned by the [employer](#), and the [legal manufacturer or reseller](#) must not restrict access to data by the [employer](#) or the [employer's](#) representatives. No data (unprocessed or processed) collected from [loggers](#) will be shared with any third parties by the [legal manufacturer or reseller](#) without explicit and informed consent by the [employer](#). The following are additional requirements of the [logger](#) to enable on-site data access.

4.5.5 USB Mass Storage Device Class & uninterrupted logging

The [logger](#) shall function as a USB Mass Storage device, complying with USB Mass Storage Device Class protocol requirements as specified by the USB Implementers Forum and formatted as FAT16 or FAT32. The choice of USB Mass Storage rather than other data communication protocols is based on wide adoption and compatibility of this transfer modality across devices and operating systems. With these benefits may come some limitations in that if the [logger](#) is mounted by an external EMD, it may not be able to record new [appliance](#) data.

Therefore, the [logger](#) shall be designed such that there is never a recording gap greater than 15 minutes due to it being mounted by an external device. For example, it could be designed with temporary memory to store recorded data while the USB is mounted, or to be able to disconnect from USB to write to its filesystem. In these cases, the [logger](#) should delay connecting over USB until file writes are complete.

The [logger](#) may force a USB disconnection if an E-EMD or other USB host has mounted for longer than 180 seconds.

4.5.6 *Compatibility*

Appliances complying with this **logger** and **M2M** specification shall be compatible with all brands and models of external **EMDs** complying with **WHO/PQS/E006/EM01** and common external devices like laptops and mobile phones.

4.5.7 *Data access during power outage*

During power outages, the **logger** shall still make recorded data available via the **M2M** to the **EMD** or other connected devices e.g. laptop. **EMD** or other connected devices shall provide power to facilitate data transmission.

In the event the **logger** has no **appliance** supply power, and its energy storage is depleted, it shall be possible for external devices to power and access the **logger** using external device power via the **M2M** USB-C connection (see Clause 4.5.3).

4.5.8 *Access drivers and software*

Downloading data from the **logger** via the **M2M** to an external device (e.g. external **EMD** or laptop) shall not require drivers or software from another source such as the Internet, flash drive, or compact disc.

4.5.9 *Read and write access to logger*

Read access to the **logger's** recorded data is essential, and limited write access is acceptable for the purposes of firmware updates or configuration updates. The requirements below shall be satisfied:

- **Read access:** logger data files shall be presented to the **EMD** or local-access device (laptop, mobile phone, etc.) as a drive that does not accept write operations (USB Mass Storage Class).
- **Write access:** if firmware or configuration updates are supported, these shall be accomplished by methods that prevent inadvertent alteration of firmware or data stored on the **logger**. Some possible methods include using a separate USB communication channel as part of a USB composite device for the update, or requiring a button press by a trained technician concurrently with connecting a USB host.

See also spare parts programming requirements in Clause 4.9.1.

4.5.10 *Wireless access*

The **logger** and **M2M** may utilize wireless communication modalities (e.g. Bluetooth®, Wi-Fi®, etc.) that provide users wireless access to “read-only” data. Mobile software (e.g. mobile phone apps) may be provided to enable users to access this data wirelessly on-site.

Any hardware utilized to enable wireless data shall be built within the [appliance](#) without any components, such as antennas, exposed on the surface of the [appliance](#) that may become damaged over time.

4.5.11 Logger analysis software

If a manufacturer of the [logger](#) or third-party developer provides software or an app for analysing [logger](#) data, this software shall be available for download from the Internet via the manufacturer or provider's website or app store.

4.5.12 Folder and file structure

When mounted by a USB host, the [logger](#) shall present as a USB Mass Storage Device with each of the following available in the root directory:

- User-readable 60-day aggregated **summary report** (detailed in Clause 4.5.14), in Portable Document Format (PDF).
- **Raw data file** containing all required and optional raw data parameters, in JavaScript Object Notation format (JSON) for the most recent 0- to 60-day period. Raw data files must follow the published JSON schema referenced in the PQS data standard (**WHO/PQS/E006/DS01**) that is published on the PQS E006 “category documentation” web page.
- **Synchronization data file** containing the relative timestamp at time of mount, [RTC Wakeup value \(RTCW\)](#), present door opening data objects (IDRV and/or IDRF as appropriate), and present compartment temperature data objects (TVC and/or TFRZ as appropriate), as well as most recent full data record from the raw data file in JSON format. Synchronization file must follow the published JSON schema referenced in the PQS data standard (**WHO/PQS/E006/DS01**) that is published on the PQS E006 “category documentation” web page.
- **Folder named “DATA_HISTORY”**: This folder is where historic raw data files are located, for access to the minimum 1-year record of required and optional data parameters.

The root directory may contain other files like manuals or diagnostics information but should contain no more than 10 visible files/folders, to prevent user confusion.

4.5.13 File naming conventions

The files required in Clause 4.5.12 shall be named based on the following conventions:

60-day aggregated summary report filename convention:

The filename for the user-readable 60-day aggregated summary report shall be structured as:

0123456789_60DTR_SUMMARY_PnDTnHnMnS.pdf

Where 0123456789 is to be replaced by the alphanumeric [logger](#) unique identifier, and PnDTnHnMnS is to be replaced by the relative timestamp as of the time of USB mount in **ISO 8601** duration format.

See Clause 4.5.14 for Summary Report format and content requirements.

Active logging raw data file filename convention:

There shall be only one CURRENT_DATA file in the root directory. The filename for the most current raw data file shall be structured as:

0123456789_CURRENT_DATA_PnDTnHnMnS.json

Where 0123456789 is to be replaced by the alphanumeric [logger](#) unique identifier, and PnDTnHnMnS is to be replaced by the relative timestamp as of the time of USB mount in **ISO 8601** duration format.

Historic raw data file(s) filename convention:

The filename for historic raw data files shall be structured as:

0123456789_DATA_PnDTnHnMnS.json

Where 0123456789 is to be replaced by the alphanumeric [logger](#) unique identifier, and PnDTnHnMnS is to be replaced by the relative timestamp associated with the most recent data object stored in the file, in **ISO 8601** duration format.

Synchronization file filename convention:

There shall be only one SYNC file in the root directory. The filename for the synchronization filename shall be structured as:

0123456789_SYNC_PnDTnHnMnS.json

Where 0123456789 is to be replaced by the alphanumeric [logger](#) unique identifier, and PnDTnHnMnS is to be replaced by the relative timestamp as of the time of USB mount in **ISO 8601** duration format.

4.5.14 User-readable 60-Day aggregated summary reports

A summary report in PDF format shall be automatically generated and available for download whenever an [EMD](#) or another external device mounts the [logger](#) via the [M2M](#). The report shall include data from the last 60 days. The PDF report shall have all columns visible on the same page horizontally. If there are multiple pages, each page should at a minimum contain the [appliance](#) serial number and report creation time.

The report shall provide the following administration information:

- [Appliance](#) PQS Code
- [Appliance](#) Serial Number
- Report creation time (relative time)
- [Alarm](#) threshold information

The report shall provide data related to environment, performance and use in a tabular format organized with rows representing 24-hour periods and columns listing the following relevant data, with the most recent days at the top. It is acceptable for the first listed day to either be a partial “in progress” day or for it to represent the most recent 24-hour period. Dates and times listed in the report may be represented in absolute time, but the file naming convention must be followed as specified in Clause 4.5.13. The report must include at a minimum the following (summarized and recorded on a 24-hour basis), with additional information optionally added by suppliers:

- Average vaccine chamber storage temperature (°C)
- Status
- Low temperature
 - Minimum temperature (°C)
 - Total time below limit (hh:mm), e.g. 2°C for refrigerators.
 - Total duration the vaccine chamber is in a low-temperature alarm state (hh:mm)
- High temperature
 - Maximum temperature (°C)
 - Total time above limit (hh:mm) , e.g. 8°C for refrigerators.
 - Total duration the vaccine chamber is in a high-temperature alarm state (hh:mm)
- Number of door openings
- Cumulative total door open time in minutes per day
- AC power availability (time ON within 24-hour period, in hh:mm). For [AC supply appliances](#), this is based on the ‘AC supply voltage availability’ data object. For [DC supply appliances](#), this column is not required.
- Cumulative compressor run time (time ON within 24-hour period, in hh:mm)
- Average ambient temperature (°C)
- [Error codes](#)

A sample ‘Summary Report’ file for [ILRs](#) is included in **Annex 1**.

4.6 Human factors

4.6.1 *M2M location on appliance*

The [M2M](#) connections shall be permanently fixed to the [appliance](#) in a location that can be easily accessed by users and technicians for the purpose of connecting external [EMDs](#) and downloading data, but while also avoiding connected wires from obstructing the use or service of the [appliance](#). Guidance relevant to different [appliance](#) categories provided below:

- E001 (Walk-in Cold/Freezer Rooms): The interface shall be located where the main controls of the [appliance](#) are located. All connections shall be no less than 0.5 meters from the ground.
- E002 (Refrigerated Vehicles): The interface shall be positioned where the main controls of the cooling system are located.

- E003 (Stationary and Transportable Refrigerators & Freezers): The interface shall be located on the [appliance](#) such that the data and power connections are in the same location, are easily accessible by users without tools and any connected wires to external devices do not interfere with the general use and access of the [appliance](#) and its storage compartment(s). For stationary [appliances](#), all connections shall be no less than 0.3 meters from the ground.

4.6.2 *M2M port markings*

The [M2M](#) USB-C data connection receptacle shall be clearly labelled with “[Logger Data Access](#)” such that a user or technician understands that the port is for accessing data on the [appliance’s logger](#) and not for the charging of mobile phones or other devices.

The [M2M](#) barrel power connection plug shall be clearly labelled with “5 V Monitoring Power” such that a user or technician understands that the cable and plug is for powering monitoring devices and not for the charging of mobile phones or other devices.

All labels shall be sufficiently durable and robust such that they remain readable for the lifetime of the [appliance](#).

4.7 Materials

4.7.1 *Ozone depleting chemical*

During manufacture and assembly of the printed circuit boards and final assembly, there shall be no use of 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 [logger](#) and [M2M](#) components shall be covered by a replacement warranty in the event of any component failure arising from defective design, materials, or workmanship. The warranty of all [logger](#) and [M2M](#) components shall meet or exceed the warranty offered with the [appliance](#).

4.9 Maintainability

The [logger](#) and [M2M](#) connections shall be designed for minimal routine maintenance over the course of its designed lifetime, which shall match the designed lifetime of the [appliance](#) within which it is integrated.

The [appliance-logger-M2M](#) system shall also be designed to allow for ease of replacement and repair by a skilled technician whereby key components are easily accessible and removable with simple and relatively available tools.

4.9.1 *Spare parts*

The [legal manufacturer](#) or [reseller](#) shall make available all spare parts necessary to repair and service the [logger](#) and [M2M](#) system.

If the [legal manufacturer](#) or [reseller](#) preloads [appliance](#) administrative data about the [appliance](#) or [logger](#), replacement [logger](#) spare parts shall also be configurable to store the same information as was stored in the original integrated [logger](#). This reconfiguration of replacement [logger](#) components shall be done on-site at the time of the repair or by other means such that [appliance](#) administrative information is available on the new [logger](#) after the replacement of original [logger](#) components.

4.10 Disposal and recycling

The [legal manufacturer](#) shall provide information to the buyer on the hazardous materials contained within the components 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 [legal manufacturers](#) based in the European Union, WEEE compliance in accordance with European Union Directive **2002/96/EC** is mandatory.

4.11 Instructions

[Appliances](#) complying with this specification must include guidance on the [logger](#) and [M2M](#) interface in the [appliance's](#) 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 should 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
- 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 [logger](#), [M2M](#) or [appliance](#) damage and for the safety of handling persons
- Installation procedures
- 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 facility 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 [appliance-logger-M2M](#) system on a separate USB storage drive or within the file system of the [logger](#).

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, and download of data via the [M2M](#) data interface.

Training programs shall cover the minimum requirements described in the following sections.

4.12.1 Installation training

Practical, hands-on installation training shall be available for the installation of the [appliance-logger-M2M](#) system.

Training outcomes for participants:

- Correct installation and setup.
- 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.
- Use and interpretation of installation manuals.
- Hands-on assembly and installation of different components, such as [M2M](#) cables.
- Use of the [logger](#) and [M2M](#) including connecting external devices, accessing data, downloading data, disconnecting external devices.
- Information on types of files and folders available on [logger](#).
- Interpretation of recorded data and summary report.
- Daily, weekly, and monthly tasks and best practices for temperature monitoring, data accessing, downloading, analysis, and corrective action.
- System functionality and troubleshooting.
- Standard commissioning procedures.

4.12.2 Technical training

Training in correct installation of the [appliance-logger-M2M](#) system, 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 [appliance-logger-M2M](#) system.
- Commissioning and handover of installed equipment in the form of job completion checklists and/or reports.
- Correct interpretation of recorded data and summary reports.
- Advanced system maintenance, troubleshooting, and repair.
- Training of further technicians on the installation, setup, and operation of the [appliance-logger-M2M](#) system.

Minimum training requirements:

- Demonstrate the [appliance-logger-M2M](#) system, including main components, controls, connections, and functionalities.
- Demonstrate the process of installing and setting up the [appliance-logger-M2M](#) system.
- Use of the [appliance-logger-M2M](#) system, including connecting external devices, accessing data, downloading and exporting of data, disconnecting external devices.
- Interpretation of recorded data and summary reports.
- Daily, weekly, and monthly tasks and best practices for temperature monitoring, data accessing, downloading, analysis, and corrective action.
- Troubleshooting procedures.
- Standard corrective and preventative maintenance tasks, including sensor replacement.

- Standard commissioning procedures.
- Frequently asked questions.
- Processes and best practices for training of further technicians in the installation, setup, and operation of the [appliance-logger-M2M](#) system.

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 [appliance-logger-M2M](#) system.
- Correct interpretation of recorded data and summary reports, including any software tools that are available for aggregating data or transmitting data to logistics information management systems.
- Training of further system administrators in the setup and operation of the [appliance-logger-M2M](#) system.

Minimum training requirements:

- Demonstrate the [appliance-logger-M2M](#) system, including main components, controls, connections, and functionalities.
- Use of the [appliance-logger-M2M](#) system, including connecting external devices, accessing data, downloading and exportation of data, disconnecting external devices.
- Interpretation of recorded data and summary reports.
- Daily, weekly, and monthly tasks and best practices for temperature monitoring, data accessing, downloading, analysis, and corrective action.
- 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 [appliance-logger-M2M](#) system.
- Processes and best practices for training of further system administrators in the setup and operation of the [appliance-logger-M2M](#) system.

4.12.4 Training materials

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

- [Appliance-logger-M2M](#) system installation & commissioning:
 - Training materials on [appliance-logger-M2M](#) system installation and setup.
 - Training materials on standard commissioning procedures, including the use of commissioning and/or functionality checklists.

- [Appliance-logger-M2M](#) system use and troubleshooting:
 - Training materials on [appliance-logger-M2M](#) system operation, including connecting external devices, accessing data, downloading data, disconnecting external devices.
 - Training materials on interpretation of recorded data and summary reports.
 - Training materials on basic and advanced system troubleshooting and maintenance procedures.
- 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 digital format and easily available and downloadable on the Internet, in a format easy to print on standard A4 letter paper. Digital manual materials may also be provided with the [appliance-logger-M2M](#) system on a separate USB storage drive.

4.13 Verification

In accordance with PQS verification protocol **WHO/PQS/E006/DL01-VP.1**

5. Packaging

[Loggers](#) are intended to be integrated into [appliances](#) by the [appliance's legal manufacturer](#). [Appliance](#) packaging is covered by the relevant [appliance](#) specification. Packaging of [loggers](#) for shipment to [appliance's legal manufacturer](#) is outside the scope of this specification.

6. On-site installation

Not required, as [logger](#) is part of [appliance](#). However, the [legal manufacturer](#) or [reseller](#) shall provide remote services to support commissioning of systems and interpretation of reports and data if requested by the [employer](#).

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 [logger](#).
- Brand name of the [logger](#).
- Full specifications of the [logger](#) being offered, covering all the requirements set out in this document, including details of [logger](#) marking and traceability.
- 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.
- Laboratory test report(s) proving conformity with the equipment specifications.

8. On-site maintenance

Routine cleaning and maintenance will be carried out by the end-user and/or their agents. The product is to be designed to be otherwise maintenance-free.

9. Change notification

The [legal manufacturer/reseller](#) is to advise WHO [in writing](#) of changes that affect the performance of the [logger](#), [M2M](#), or their containing [appliance](#) after PQS prequalification has taken place. Some examples of particular concern:

- Increased peak or average power draw by the [logger](#) from [DC supply appliances](#), because these changes may affect the [appliance's](#) thermal performance.
- Similar to the case above, increased output current limit on the [M2M](#) for [SDDs](#), because this change may affect the [appliance's](#) thermal performance.
- Changes to the [logger's](#) filesystem or data formatting, because these changes may affect interoperability with other [EMS](#) components.

Any change that WHO considers would alter the test results obtained against the PQS verification protocol **WHO/PQS/E006/DL01-VP.1** will result in a request for the [logger](#) 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 [logger](#) 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: Logger summary report template (PDF file)

PDF page 1:

60 DAY PERFORMANCE REPORT

Appliance PQS Code: E003-XXX
 Appliance Serial number: XXXXXXXXX
 Report Creation Time: PnDTnHnMnS
 Upper alarm limit: Above +8.0 °C for 10h
 Lower alarm limit: Below -0.5 °C for 1h

Day	Average storage temp. (°C)	Status	Low Temperature			High Temperature			Door openings	Door open time (hh:mm)	AC Power availability (hh:mm)	Compressor runtime (hh:mm)	Average ambient temp	Faults
			Min. temp. (°C)	Total time below -0.5°C (hh:mm)	Total low alarm time (hh:mm)	Max. temp. (°C)	Total time above 8.0 °C (hh:mm)	Total high alarm time (hh:mm)						
Today	4.7	OK	3.6	0:00	0:00	5.8	0:00	0:00	0	0:00	8:48	3:13	35.6	
2	5.1	OK	4.2	0:00	0:00	6.1	0:00	0:00	0	0:00	4:36	0:53	35.4	
3	4.7	OK	3.5	0:00	0:00	5.9	0:00	0:00	0	0:00	9:09	3:29	33.6	
4	4.4	OK	3.4	0:00	0:00	5.5	0:00	0:00	0	0:00	1:15	0:03	35.6	
5	4.5	OK	3.6	0:00	0:00	5.5	0:00	0:00	0	0:00	20:03	16:45	35.6	
6	4.5	OK	3.4	0:00	0:00	5.5	0:00	0:00	0	0:00	1:42	0:07	35.6	
7	4.8	ALARM	3.6	0:00	0:00	14.5	10:05	0:05	1	0:06	6:05	1:32	24.5	3886
8	4.8	OK	3.8	0:00	0:00	6.2	0:00	0:00	0	0:00	22:40	21:24	26.7	3886, 2856
9	4.8	OK	3.6	0:00	0:00	5.9	0:00	0:00	0	0:00	15:00	9:23	25.7	3886
10	4.8	OK	3.7	0:00	0:00	5.9	0:00	0:00	0	0:00	6:22	1:41	32.5	
11	4.8	OK	3.6	0:00	0:00	5.9	0:00	0:00	0	0:00	2:35	0:16	35.6	
12	4.5	OK	3.5	0:00	0:00	5.5	0:00	0:00	1	1:19	11:23	5:24	35.6	
13	4.4	OK	3.5	0:00	0:00	5.5	0:00	0:00	0	0:00	19:41	16:09	35.6	
14	4.8	OK	3.6	0:00	0:00	6.1	0:00	0:00	0	0:00	15:25	9:54	35.6	
15	4.8	OK	3.7	0:00	0:00	5.9	0:00	0:00	0	0:00	6:37	1:50	35.6	
16	4.8	OK	3.6	0:00	0:00	6	0:00	0:00	0	0:00	23:37	23:15	35.6	
17	4.9	OK	3.7	0:00	0:00	6.1	0:00	0:00	0	0:00	19:38	16:03	35.6	
18	4.8	OK	3.7	0:00	0:00	6.1	0:00	0:00	0	0:00	19:04	15:09	35.6	
19	4.6	OK	3.6	0:00	0:00	5.8	0:00	0:00	0	0:00	19:33	15:57	35.6	
20	4.5	OK	3.5	0:00	0:00	5.6	0:00	0:00	0	0:00	11:29	5:30	35.6	
21	4.5	OK	3.6	0:00	0:00	5.6	0:00	0:00	0	0:00	22:41	21:27	35.6	
22	4.9	OK	3.8	0:00	0:00	6	0:00	0:00	0	0:00	13:15	7:19	35.6	
23	4.7	OK	3.6	0:00	0:00	5.8	0:00	0:00	0	0:00	7:01	2:03	35.6	
24	4.6	OK	3.5	0:00	0:00	5.8	0:00	0:00	0	0:00	22:53	21:49	35.6	
25	4.6	OK	3.5	0:00	0:00	5.9	0:00	0:00	0	0:00	9:47	3:59	35.6	
26	4.4	OK	3.4	0:00	0:00	5.6	0:00	0:00	0	0:00	13:17	7:21	35.6	
27	4.5	OK	3.4	0:00	0:00	5.4	0:00	0:00	0	0:00	1:29	0:05	35.6	
28	4.4	OK	3.4	0:00	0:00	25.6	0:18	0:00	4	12:00	16:11	10:55	35.6	
29	4.4	OK	3.4	0:00	0:00	5.4	0:00	0:00	0	0:00	11:48	5:48	35.6	
30	4.6	OK	3.4	0:00	0:00	5.9	0:00	0:00	0	0:00	6:30	1:46	35.6	
31	4.6	OK	3.5	0:00	0:00	6	0:00	0:00	0	0:00	4:02	0:40	35.6	
32	4.7	OK	3.7	0:00	0:00	5.9	0:00	0:00	0	0:00	5:39	1:20	35.6	
33	4.6	OK	3.6	0:00	0:00	5.9	0:00	0:00	0	0:00	0:01	0:00	35.6	
34	4.6	OK	3.7	0:00	0:00	5.6	0:00	0:00	0	0:00	16:15	11:01	35.6	
35	4.8	OK	3.8	0:00	0:00	6	0:00	0:00	0	0:00	8:47	3:13	35.6	
36	4.9	OK	3.8	0:00	0:00	5.9	0:00	0:00	0	0:00	3:58	0:39	35.6	
37	4.9	OK	3.8	0:00	0:00	6.2	0:00	0:00	0	0:00	14:21	8:34	35.6	

60 DAY PERFORMANCE REPORT

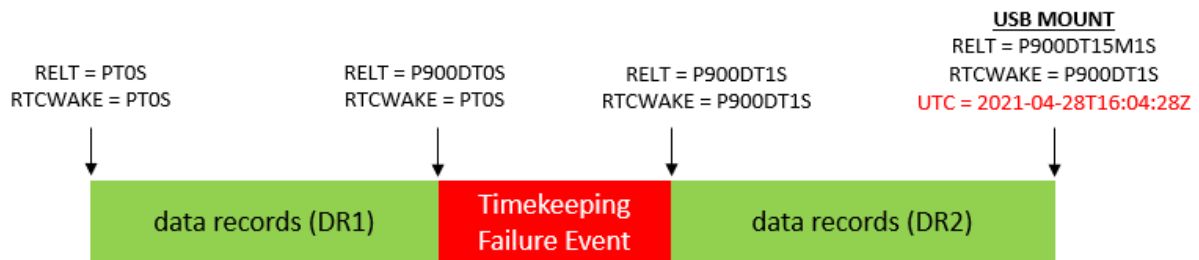
Appliance PQS Code: E003-XXX
 Appliance Serial number: XXXXXXXXX
 Report Creation Time: PnDTnHnMnS
 Upper alarm limit: Above +8.0 °C for 10h
 Lower alarm limit: Below -0.5 °C for 1h

Day	Average storage temp. (°C)	Status	Low Temperature			High Temperature			Door openings	Door open time (hh:mm)	AC Power availability (hh:mm)	Compressor runtime (hh:mm)	Average ambient temp	Faults
			Min. temp. (°C)	Total time below -0.5°C (hh:mm)	Total low alarm time (hh:mm)	Max. temp. (°C)	Total time above 8.0 C (hh:mm)	Total high alarm time (hh:mm)						
38	4.9 OK		3.8	0:00	0:00	6.1	0:00	0:00	0	0:00	19:56	16:34	35.6	
39	4.8 OK		3.6	0:00	0:00	6.1	0:00	0:00	0	0:00	19:38	16:04	35.6	
40	4.5 OK		3.5	0:00	0:00	5.7	0:00	0:00	0	0:00	15:31	10:02	35.6	
41	4.5 OK		3.4	0:00	0:00	5.5	0:00	0:00	0	0:00	2:12	0:12	35.6	
42	4.8 OK		3.6	0:00	0:00	6.1	0:00	0:00	3	9:36	3:47	0:35	35.6	
43	4.8 OK		3.7	0:00	0:00	6.2	0:00	0:00	0	0:00	10:55	4:58	35.6	
44	5 OK		3.9	0:00	0:00	6.2	0:00	0:00	0	0:00	0:42	0:01	35.6	
45	5.1 OK		3.9	0:00	0:00	6.2	0:00	0:00	0	0:00	5:32	1:16	35.6	
46	5 OK		3.9	0:00	0:00	6.1	0:00	0:00	0	0:00	18:19	13:59	35.6	
47	4.6 OK		3.6	0:00	0:00	5.7	0:00	0:00	0	0:00	4:57	1:01	35.6	
48	4.5 OK		3.6	0:00	0:00	5.6	0:00	0:00	0	0:00	15:09	9:34	35.6	
49	4.9 OK		3.7	0:00	0:00	6.1	0:00	0:00	0	0:00	17:59	13:29	35.6	
50	4.8 OK		3.6	0:00	0:00	6.1	0:00	0:00	0	0:00	17:54	13:21	35.6	
51	4.7 OK		3.6	0:00	0:00	5.9	0:00	0:00	0	0:00	19:10	15:19	35.6	
52	4.8 OK		3.8	0:00	0:00	6.1	0:00	0:00	2	4:48	15:11	9:37	35.6	
53	4.9 OK		3.7	0:00	0:00	6.2	0:00	0:00	0	0:00	3:27	0:29	35.6	
54	4.6 OK		3.5	0:00	0:00	5.7	0:00	0:00	0	0:00	16:12	10:56	35.6	
55	4.5 OK		3.6	0:00	0:00	5.6	0:00	0:00	0	0:00	18:29	14:14	35.6	
56	4.6 OK		3.7	0:00	0:00	5.6	0:00	0:00	0	0:00	1:29	0:05	35.6	
57	4.6 OK		3.7	0:00	0:00	5.6	0:00	0:00	0	0:00	12:23	6:23	35.6	
58	4.7 OK		3.8	0:00	0:00	5.9	0:00	0:00	0	0:00	10:15	4:23	35.6	
59	4.7 OK		3.7	0:00	0:00	5.8	0:00	0:00	0	0:00	14:11	8:23	35.6	
60	4.7 OK		3.8	0:00	0:00	5.9	0:00	0:00	0	0:00	9:26	3:42	35.6	

Annex 2: RTC Wakeup details

The [RTC Wakeup data object](#) is used to enable correction from relative timestamps to [absolute time](#) even if there is a stoppage of the relative time clock in the [logger](#). Per Clause 4.2.2, relative timekeeping must continue if the [appliance](#) loses power. However, if the relative time clock's battery is drained prematurely it is important that other parts of the [EMS](#) ecosystem be able to use as much of the logged data as possible.

RTCW is always the relative timestamp of the last time the [logger](#) resumed normal operation after a disruption to timekeeping. When the [logger](#) is manufactured, the relative time (RELT) is zero ("PT0S"), and so is RTCW. Every data record will contain the data object "RTCW: "PT0S". If there is a disruption to timekeeping, for example a failure of the clock's battery and an [appliance](#) power outage, upon resumption of timekeeping, RELT must start at a value after the last known timestamp. At that time, RTCW is set to this new RELT value, and remains at this value while timekeeping is continuous. An example is shown graphically below.



The graphic shows time increasing from left to right. The [logger](#) starts with RELT = PT0S and RELT = PT0S. It operates for 900 days in the region shown as "DR1", creating data records with increasing RELT and constant RTCW. At exactly 900 days it suffers a failure of timekeeping for some duration unknown to the [logger](#). Upon resumption of timekeeping, RELT must be set to a value greater than the last known RELT, in this case P900DT1S (one second after the last known RELT). Data records are logged again in the region "DR2". Fifteen minutes later in this example, a connected [EMD](#) mounts the [logger](#) and downloads the latest data and associates it with an absolute timestamp. Note that the graphic uses the extended **ISO 8601** date and time format with separators for readability, even though the simpler format is used in [EMS](#) specifications.

RTCW enables time correction back to the point of recovery from the time failure since an unchanged RTCW value indicates no disruption to relative time during the given timeframe. The absolute time of any record in the DR2 interval is just the absolute time of USB mount less the difference between relative times of USB mount and the data record:

$$T_{\text{abs,record,DR2}} = T_{\text{abs,USBmount}} - (\text{RELT}_{\text{USBmount}} - \text{RELT}_{\text{record,DR2}})$$

A change in RTCW serves as a flag that a disruption to timekeeping occurred. If there is a USB mount event with associated absolute time somewhere in a period of continuous timekeeping, all the records in that period can be corrected to absolute time.

Annex 3: Definition of EMS levels

The Equipment Monitor System is broken down into 3 levels of functions. 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	Added 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	Minor edits	Clarifications	IG
November 2023	Added definition of Levels as Annex 3.	This was not defined in any of the documents.	IG
November 2023	Added a reference to WHO/PQS/E006/DS01 for KPI definition.	KPI is better defined in WHO/PQS/E006/DS01.	IG
May 2025	Minor edits	Clarifications	IG