



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

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1. Scope

This document describes the procedure for verifying the performance of data **loggers** integrated within **appliances** and the required **appliance** connections for data and power transfer (i.e. **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 those data.

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. Applicability

Type-testing will be carried out by an independent **ISO/IEC 17025** testing laboratory, accredited by WHO.

The requirement for type-testing may be relaxed if the **appliance** undergoing prequalification meets both of the following conditions:

- The **logger** and **M2M** design incorporated into the **appliance** has been previously type-tested by **ISO/IEC 17025** testing laboratory, with no functional changes to the design since the previous type testing.
- The **appliance** which the **logger** and **M2M** is incorporated into is of a similar design (e.g. same compressor type, power electronics, and control system) as the design that the same **logger** and **M2M** were previously type-tested with.

If both conditions are satisfied, the **legal manufacturer** or **reseller** should include in the dossier the previous type-testing report, as well as a detailed summary of all differences in design between the **appliance** that was previously tested and the **appliance** which is currently being prequalified. The intent of this provision is to reduce redundant testing in cases where the **legal manufacturer** or **reseller** is implementing a **logger** / **M2M** into numerous **appliances** in a product line that are functionally similar.

5. Type-testing procedure

5.1 Evidence of conformity assessment

Appliances containing **loggers** shall carry the CE mark, UL mark and/or equivalent internationally accepted evidence of conformity assessment. **Appliances** that are not ordinarily marked (e.g. cold rooms, refrigerated vehicles) are exempt, but relevant components should have evidence of conformity assessment. Certifications from accredited tests labs are preferable. If conformity is self-declared, then a technical construction file shall be provided as part of the dossier to validate conformity.

5.2 Number of samples

The **legal manufacturer** or **reseller** must supply the testing laboratory with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification Clause 7. Two samples are to be provided as described below.

Sample 1: **Legal manufacturer** shall provide **appliance** with integrated **logger** & **M2M**. For cold rooms and refrigerated vehicles, **legal manufacturer** may provide a **logger** and **M2M** with representative sensors and instructions for simulating **appliance** power supply to the **logger** and **M2M**.

- **Sample 1's** rechargeable energy stores for data recording purposes are to be completely depleted to begin the tests; **legal manufacturer** must ensure **logger** submitted for testing is depleted to avoid extra time and costs in testing. Any energy stores dedicated to only timekeeping functions should not be depleted.
- **Sample 1** should have operated for at least 60 days before the energy stores were depleted, so that its memory contains at least one full 60-day historical data file.

Sample 2: **Legal manufacturer** to supply a second **logger** sample to be used in *Test 8: Disruption to timekeeping*. **Logger** is specially prepared so that its timekeeping functions are disrupted when there is no external power. For instance, a primary cell used to power a real-time clock may be disconnected. This device may be in an **appliance** or supplied standalone with representative sensors connected.

5.3 Test procedure

5.3.1 *General test notes*

- Use Sample 1 for all tests other than *Test 8: Disruption to timekeeping*.
- Some tests may be performed at the same time as tests in the E003 verification protocol that corresponds to the **appliance** being tested.
- *Test 2: Logger power wakeup and recharging*, (if applicable) is intended to be performed first so that energy stores do not need to be depleted during the verification process.
- *Test 7: Logger data review*, is best performed after all other tests on Sample 1 in which data is logged.
- The rest of the tests may be performed in any order.

- Data may be downloaded after every test to verify compliance or at the end of all tests. Be sure to include the raw data files as part of the report.
- A list of materials and equipment needed for the tests is in **Annex 1**.

5.3.2 Test 1: Type examination

- **Step 1:** Check sample against product dossier to verify consistency; check for any defects or damage to the [appliance](#).
- **Step 2:** Record any differences between the sample ordered and the one received.
- **Step 3:** Tabulate the following information for each model submitted for examination. Obtain any additional supporting information required [in writing](#) from the [legal manufacturer](#) or [reseller](#) and attach this information to the report:

Identification:

- Code (a unique identifier to be assigned by the testing laboratory).
- Model.
- [Legal manufacturer](#) or [reseller](#).
- Country of origin.
- Conformity assessment markings (e.g. CE, UL mark).

Performance characteristics:

- [Legal manufacturer](#) lists any manufacturer-specific [data objects](#) along with schema definition, and attests compliance with specification Clause 4.2.9.
- [Legal manufacturer](#) attests that [logger](#) and [M2M](#) are compatible with external devices, including external [EMDs](#) from other manufacturers, as in specification Clause 4.5.6 and that the Mass Storage Device format is FAT16 or FAT32 as in specification Clause 4.5.5.
- [Legal manufacturer](#) declares whether wireless access is available and provides details on type and means of operation for users, as in specification Clause 4.5.10.
- [Legal manufacturer](#) declares whether [logger](#) data analysis software is available, and if so, provides download location and instructions for use, as in specification Clause 4.5.11.
- [Legal manufacturer](#) attests that non-volatile solid-state memory is used as in specification Clause 4.2.13.
- [Legal manufacturer](#) attests to energy storage lifetime through specifications and calculations of energy storage design as in specification Clause 4.2.18.
- [Legal manufacturer](#) has provided evidence of electromagnetic compatibility as in specification Clause 4.2.20.

Materials and construction:

- [Legal manufacturer](#) attests to compliance with corrosion requirements as in specification Clause 4.3.5.
- [Legal manufacturer](#) attests to compliance with ozone-depleting chemical requirements as in specification Clause 4.7.1.

- [Legal manufacturer](#) attests to compliance with other restricted materials requirements as in specification Clause 4.7.2.

Environmental requirements:

- [Legal manufacturer](#) attests that ambient temperature operation conforms to specification Clause 4.3.1.
- [Legal manufacturer](#) attests that ambient humidity operation conforms to specification Clause 4.3.2.
- [Legal manufacturer](#) has provided evidence of conformity to dust and water ingress requirements of specification Clause 4.3.4.

Physical characteristics:

- No requirements.

Interface requirements:

- [M2M](#) physical interface conforms/does not conform to specification Clause 4.5.2.

Human factors:

- [M2M](#) location on [appliance](#) conforms/does not conform to specification Clause 4.6.1.
- [M2M](#) port markings conform/do not conform to specification Clause 4.6.2.

Warranty:

- Warranty conforms/does not conform to specification Clause 4.8.

Servicing provision:

- [Legal manufacturer](#) provides evidence of conformity of maintenance provisions to specification Clause 4.9.

Spare parts:

- [Legal manufacturer](#) attests to compliance with spare parts provisions in specification Clause 4.9.1.

Disposal and recycling:

- [Legal manufacturer](#) provides evidence of conformity with disposal and recycling requirements of specification Clause 4.10.

Instructions:

- Instructions conform/do not conform to specification Clause 4.11.
- [Legal manufacturer](#) provides evidence of conformity of training to specification Clause 4.12.
- [Legal manufacturer](#) provides evidence of instructions detailing sensor replacement process per specification Clause 4.12.2.
- [Legal manufacturer](#) provides evidence of conformity of commissioning services to specification Clause 6.

Packaging:

- No requirements.

- **Step 4:** Take digital photographs of all sides of the sample. Take any other photographs needed to illustrate features of the device for the report. These images should be provided for attachment to the PQS report.

Acceptance criteria: Inspection indicates full conformity with all specification requirements.

Rejection criterion: Failure to meet one or more of the acceptance criteria.

5.3.3 Test 2: Logger power wakeup and recharging

Test 2 is to be performed only on loggers with rechargeable batteries. Further, the rechargeable batteries are to be in a fully-depleted state, and a 5W load is to be placed on the M2M power plug. This is to stress test the appliance and place the maximum possible load on the available power to the logger from the appliance.

- **Applicability:** [Loggers](#) with rechargeable energy storage for recording functions; [loggers](#) utilizing non-rechargeable batteries shall not complete this test.
- **Test Conditions:** Ambient temperature +20°C to +25°C, [appliance](#) begins the test disconnected from input power.
- **Logger energy storage for recording status at start:** Fully depleted; not currently recording monitored data; must still be keeping relative time.
- **Step 1:** Connect a simulated load of 5W (5V, 1A) to the M2M power plug on the [appliance](#). See **Annex 1** for a description of recommended loads.
- **Step 2:** Steps 2-4 shall be completed in less than 10 minutes to prevent significant charging of the [logger](#) via the connected lab computer. The limited power available from an unpowered USB Type-A hub also helps limit charging. Connect Type-A end of the USB cable to an unpowered hub as described in **Annex 1** connected to the lab computer. Connect the other end of the cable to the appliance [M2M](#) USB-C data connection.
- **Step 3:** Use lab computer's folder explorer to open the [logger](#) as a mounted USB device and download all available data files per Annex 3.
- **Step 4:** Disconnect USB-C cable from [appliance](#).
- **Step 5:** Connect [appliance](#) to supply power for a period of eight hours.
- **Step 6:** Remove [appliance](#) supply power after eight hours and leave disconnected for 48 hours.
- **Step 7:** After 48 hours have passed, repeat Steps 2-4 to download all data files.
- **Step 8:** Inspect raw data file from Step 3 to verify that logging recording function was stopped (i.e. [logger](#) power depleted) prior to connection.
- **Step 9:** Inspect raw data file from Step 7 to verify that logging function continued for 48 hours following disconnection from supply power.

Acceptance criteria:

- Fully depleted **logger** without supply power was “awoken” by the connection of external computer and made its contents accessible.
- **logger** successfully recorded 48 hours of continuous data following eight hours of charging.

Rejection criteria:

- Failure of fully depleted **logger** to be “awoken” by the connection of external computer power supply and data connection; no access to **logger** files or folders.
- **Logger** fails to record data for 48 hours following eight hours of charging.

5.3.4 Test 3: Logger data access

- **Applicability:** all **loggers** & **M2M** connections.
- **Test Conditions:** Ambient temperature +20°C to +25°C.
- **Step 1:** Connect a simulated load of 5W (5V, 1A) to the **M2M** power plug on the **appliance**.
- **Step 2:** Connect **M2M** USB Type-C data port to a lab computer with an appropriate cable.
- **Step 3:** Use computer folder explorer to open the **logger** as a mounted USB device; check properties to verify that:
 - Type is listed as USB Drive.
 - File system is listed as FAT16 or FAT32. Note that some versions of Microsoft Windows do not show “FAT16”, but rather just “FAT”.
- **Step 4:** Explore **logger** folder and file structure. Note file and folder names.
- **Step 5:** Attempt to download all data to laboratory computer per Annex 3.
- **Step 6:** Attempt to perform write-access functions, including deleting, renaming, adding files and folders.
- **Step 7:** Disconnect data connection and reconnect to ensure no write-access functions affected the files and folders. Note that synchronization (“SYNC”), “CURRENT_DATA” and 60DTR “SUMMARY” files may have slightly different filenames because the filenames contain the timestamp when USB mount occurs.

Acceptance criteria:

- **Logger** mounts as a FAT16 or FAT32 USB Drive.
- User able to access and download all files on **logger** without need for drivers or software.
- The computer is unable to permanently rename or delete files and folders on the logger.

Rejection criteria:

- **Logger** does not mount as USB Mass Storage FAT16 or FAT32 Drive.
- User able to delete, rename, or add files or folders.

5.3.5 Test 4: Endurance of timekeeping and recording functions, including timestamp drift

The logger must continue record data during a power outage longer than the holdover time of the appliance, to ensure monitoring of temperature excursions that could affect vaccine potency.

- **Applicability:** all [appliances](#), [loggers](#) & [M2M](#) connections.
- **Relevant appliance tests:** for [ILRs](#), this test may be performed in conjunction with the holdover time test in the relevant [ILR](#) verification protocol. For [SDDs](#), this test must be performed separate from and after the autonomy time test in the relevant verification protocol because the duration of this test depends on the rated autonomy. Also, this test requires a complete power interruption, while the autonomy test is performed with minimal but non-zero simulated solar power. For transportable powered [appliances](#), this test may be performed in conjunction with the primary performance test. Note: it is possible to return at any moment once the [appliance](#) holdover test has been completed to begin the freeze-protection classification test. That is, it is possible to delay the beginning of the [appliance](#) freeze-protection test to complete this endurance test.
- **Step 1:** Stabilize [appliance](#) for 48 hours at rated upper ambient temperature limit (e.g. +43 °C for “hot” zone appliances) based on Holdover or Autonomy test.
- **Step 2:** Remove [appliance](#) supply power at the end of the next power cycle.
- **Step 3:** After removing power supply to the [appliance](#), download data files from the [logger](#) per Annex 3. Referencing an accurate Internet-provided clock, note the time to the nearest second at the moment of connecting the USB plug to the [logger](#).
- **Step 4:** Leave [appliance](#) disconnected from power. For [ILRs](#), evaluate holdover time.
- **Step 5:** Once the following duration has elapsed since power disconnection, download data files from the [logger](#) per Annex 3:
 - Stationary solar-powered [appliances](#) including cold/freezer rooms: 1.5x rated autonomy time or 96 hours (at maximum rated ambient temperature), whichever is greater.
 - Stationary mains-powered [appliances](#) including cold/freezer rooms: 2.0x rated holdover time or 96 hours (at maximum rated ambient temperature), whichever is greater.
 - Transportable powered [appliances](#): 1.5x rated independence time or 18 hours, whichever is greater.
 - Refrigerated vehicles: 1.5x rated non-idle run time of the refrigeration unit.
- **Step 6:** Open the “CURRENT_DATA” raw data file as well as the 60DTR “SUMMARY” file downloaded in Step 5, and by comparing the timestamps of data records with the files downloaded in Step 3, confirm that the [logger](#) has continued to save essential data objects as defined in specification Clause 4.2.7 every 15 minutes through the period of the power disconnection.
- **Step 7:** If total time elapsed since the data download event in Step 3 is less than 120 hours, reconnect supply power to the [appliance](#) while leaving the ambient temperature at the upper rated ambient temperature limit, and download [logger](#) files again when the total time elapsed since Step 3 is greater than 120 hours.

Referencing an accurate Internet-provided clock, note the time to the nearest second at the moment of connecting the USB plug to the [logger](#) for the data download event.

- **Step 8:** Calculate and report the [logger](#) elapsed time between the data downloads in Step 3 and Step 7 by calculating the difference between the relative timestamps in the *filenames* (not the contained data) of the “CURRENT_DATA” raw data files downloaded in each step. Alternately, the instantaneous timestamp in the “SYNC” file may be used, because it is recorded at the time of USB connection. Also calculate and report the difference between noted download times based on the Internet-provided clock. Calculate and report timestamp drift in parts per million (ppm) using the following formula.

$$\text{Timestamp drift (ppm)} = \frac{(\text{logger elapsed time in seconds} - \text{internet clock elapsed time in seconds}) \times 1,000,000}{\text{internet clock elapsed time in seconds}}$$

Acceptance criteria:

- Ability to access [logger](#) and download data without [appliance](#) supply power.
- Verification that [logger](#) has continued to save required data objects through the period of power disconnection.
- Absolute value of timestamp drift calculated in step 8 is less than 114 parts per million (ppm), translating to less than 60 minutes of timestamp drift per year.

Rejection criteria:

- Inability to access [logger](#) and download data without [appliance](#) supply power.
- Any gaps in logging of essential [data objects](#) during power disconnection.
- Absolute value of timestamp drift calculated in step 8 is greater than 114 parts per million (ppm), translating to greater than 60 minutes of timestamp drift per year.

5.3.6 Test 5: Door opening

- **Applicability:** all [appliances](#), [loggers](#) & [M2M](#) connections.
- **Relevant appliance tests:** This test may be performed in conjunction with the door opening test in the relevant [appliance](#) verification protocol, e.g. Test 11 in **WHO/PQS/E003/RF03-VP.4** and Test 9 in **WHO/PQS/E003/RF05-VP.5**. The doors are opened in the [appliance](#) tests to verify thermal performance; here they are used to verify that door opening data is generated.
- **Step 1:** Ensure that all compartment lids or doors have been closed for at least 15 minutes before beginning this test. This step ensures that data records written during the test will only include data related to the test.
- **Step 2:** Open all compartment lids/doors and record the time that they were opened.
- **Step 3:** Wait one to two minutes and then download the “SYNC” file per Annex 3, recording the time of download.
- **Step 4:** Verify that the IDRV and/or IDRF instantaneous door opening [data objects](#) in the “SYNC” file are correct (values represent the number of seconds that the doors had been open at time of download).

- **Step 5:** When the doors have been open for 10 continuous minutes, close the lids/doors, recording the time they were closed.
- **Step 6:** After waiting at least 15 minutes from the time that the door(s) was (were) closed, download data files from the [logger](#) per Annex 3.
- **Step 7:** Verify that the door opening duration values (the DORV and DORF data objects) in the data are correct. Note: the total door-open duration may be spread across two different sample records in the “CURRENT_DATA” file, and that therefore it is required to add both DORV values as part of the acceptance criterion. (E.g., a one-minute open time in the first sample and a nine-minutes open time in the second sample for a total of 10 minutes).
- **Step 8:** If the optional door opening count (DRCV and/or DRCF) data objects are in the data files, verify that the values in the data match the number of door-opening events (one count for this test).
- **Step 9:** Verify that the IDRV and/or IDRF data objects in the “SYNC” file downloaded in Step 6 contain the value “zero seconds”, as the door(s) were closed during that download.

Acceptance criteria:

- Instantaneous door opening durations IDRV (and/or IDRF for a freezer compartment) match the length the door was open at the time of USB mount in Step 3 and zero at the time of Step 6.
- Logged door opening durations DORV (and/or DORF for a freezer compartment) match the total length the door was open.
- Logged door opening counts DRCV (and/or DRCF for a freezer compartment) match the total number of times the door was opened.

Rejection criterion:

- Failure to correctly record door openings

5.3.7 Test 6: M2M load safety

- **Applicability:** all E003 category [appliances](#), [loggers](#) & [M2M](#) connections. E001 (cold rooms) and E002 (refrigerated vehicles) [appliances](#) need not perform this test.
- **Relevant appliance tests:** This test can be performed during or after the [appliance's](#) cool-down or stable running tests when the [appliance](#) is connected to power.
- **Step 1:** Connect [appliance](#) to supply power.
- **Step 2:** Connect a simulated load to the [M2M](#) power plug on the [appliance](#).
- **Step 3:** Starting at 0.5 A, increase simulated load in increments of 0.05 A, measuring the [M2M](#) output voltage at each step.
- **Step 4:** Record what load level (in Amps) the [appliance](#) no longer outputs supply power to the load (the current limit).
- **Step 5:** Halt the test when the load has reached 1.50 A, or sooner if the [appliance](#) no longer outputs supply power to the load.

Acceptance criteria:

- **M2M** output voltage is in the range 4.75 V to 5.25 V while the load is < 1.05 A.
- **M2M** output current limit is in the range 1.05 A to 1.15 A.

Rejection criterion:

- Failure to meet both acceptance criteria.

5.3.8 Test 7: Logger data review

- **Applicability:** all **appliances**, **loggers** & **M2M** connections.
- **Step 1:** After all **appliance** performance testing is complete, connect lab computer to **logger** and download all available files and folders from the root directory of the mass storage device presented by the **logger** over the **M2M**.
- **Step 2:** Verify that the files and folders satisfy the naming conventions included in specification **WHO/PQS/E006/DL01** Clause 4.5.13:
 - Verify that in the root directory of the **logger's** mass storage device there is exactly one JSON raw data file following the naming convention of 0123456789_CURRENT_DATA_PnDTnHnMnS.json.
 - Verify that in the root directory of the **logger's** mass storage device there is exactly one JSON synchronization data file following the naming convention of 0123456789_SYNC_PnDTnHnMnS.json.
 - Verify that the timestamp portions of the CURRENT_DATA and SYNC filenames are the same.
 - Verify that in the root directory of the **logger's** mass storage device there is a 60-Day aggregated summary report following the naming convention of 0123456789_60DTR_SUMMARY_PnDTnHnMnS.pdf.
 - Verify that in the root directory of the **logger's** mass storage device there is a folder named "DATA_HISTORY".
 - Verify that in the DATA_HISTORY folder there is at least one JSON raw data file following the naming convention of 0123456789_DATA_PnDTnHnMnS.json.
- **Step 3:** Using an online JSON schema validator (for example, <https://www.jsonschemavalidator.net/>) or one of the JSON schema validator tools as downloaded from <https://json-schema.org/implementations.html#validators> with the published PQS JSON schema included in specification **WHO/PQS/E006/DS01** validate that the contents of the "CURRENT_DATA " raw data and synchronization ("SYNC") files located in the root directory and the historic raw data files located in the "DATA_HISTORY" folder comply with the published JSON schema.
- **Step 4:** Review the 60-Day aggregated summary report (PDF file) and verify that the report contains the following data as described in more detail in specification Clause 4.5.14:
 - **Administrative information:** **Appliance** PQS Code, Serial Number, Report creation time (relative time), and **alarm** threshold information.

- **Environment, performance and use data:** Data from the previous 60 days aggregated in 24-hour periods, with the most recent days at the top. Verify that the minimum set of information listed in specification Clause 4.5.14 is included.
- **Step 5:** Note the file size of data created over the test period (starting at Test 2 [Test 3 for loggers with non-rechargeable batteries] until the download as part of Test 7); record the size of the data storage of the logger, verify whether all recorded data may be stored for at least a period of one year based on the average data generated and recorded during the test period. For example, if test period was one month and generated 5 MB of data, the total **logger** memory size shall be at least 60 MB (5 MB per month * 12 months). Note: if the logger memory contains additional files (e.g. manuals, analysis tools, etc.), these may be subtracted from the stated memory capacity.

Acceptance criteria:

- Data file naming conventions comply with specifications.
- Recorded data complies with specifications in terms of completeness of required **data objects**, formatting and recording period.
- Summary report complies with specifications.
- **Logger** has sufficient storage to record at least one year of administrative, environmental, performance, and use data.

Rejection criterion: Failure to comply with any of the above acceptance criteria.

5.3.9 Test 8: Disruption to timekeeping

- **Applicability:** All **loggers**. Use **logger** Sample 2.
- **Appliance or Logger power status at start of test:** disconnected.
- **Logger energy storage for recording status at start of test:** Fully depleted; not currently recording monitored data; not keeping relative time. Alternately, if the logger has a removable battery, the battery may be removed for the test.
- **Step 1:** Connect Type-A end of the USB cable to an unpowered hub connected to the lab computer. Connect the other end of the cable to **appliance M2M** USB-C data connection. Optional: record the power being consumed by the logger.
- **Step 2:** Use computer file explorer to download the “CURRENT_DATA” raw data JSON file from the **logger’s** root directory, if it exists.
- **Step 3:** Disconnect the USB-C cable from the **M2M** interface.
- **Step 4:** Inspect the “CURRENT_DATA” file and note if data with timestamps had been recorded before the sample was submitted for testing.
- **Step 5:** Apply power to the **appliance** or **logger** and allow it to operate at least 30 minutes before removing power.
- **Step 6:** If no data had been recorded in Step 4, wait 30 minutes, then apply power again for at least 30 minutes and remove power again. By this point, regardless of initial conditions, the **logger** should have experienced at least two periods of power and no power/no timekeeping in the intervals between those periods.
- **Step 7:** Download the “CURRENT_DATA” file as in Steps 1-3.

- **Step 8:** Inspect the “CURRENT_DATA” file from Step 7 and verify that data was recorded during the powered period of Step 5 and also Step 6 if power was applied a second time. Verify that the RELT timestamps are strictly increasing throughout the data file. Also verify that the RTCW field’s value changes when there is a disruption to timekeeping as power is removed and that it corresponds to the RELT timestamp of the first data recorded after timekeeping resumes. See **Annex 2** for examples of passing and failing timestamps.

Acceptance criteria: All of the below must be satisfied.

- Fully depleted **logger** without supply power was “awoken” by the connection of external computer and made its contents accessible.
- **Logger** records data when supplied with power.
- RELT timestamps in data file are strictly increasing.
- RTCW values are constant during periods of continuous timekeeping and change when timekeeping is disrupted. The value recorded after a disruption to timekeeping corresponds to the RELT timestamp when operation resumed (the value is after the last RELT timestamp before operation resumed).

Rejection criteria: Any of the below are true.

- Failure of fully depleted **logger** to be “awoken” by the connection of external computer power supply and data connection; no access to **logger** files or folders.
- **Logger** does not record data when powered.
- RELT timestamps in data file decrease or reset to zero when timekeeping is disrupted.
- RTCW values do not change when timekeeping is disrupted.

5.4 Test criteria for qualification

A final report shall be issued after all testing is complete. The report of the tests shall contain the following data and analyses:

- **Summary:** Conclusions and recommendations.
- **Test 1:** Comments on samples received, tabulated data, compliance with required specifications (plus supporting documentation) and photographs of samples.
- **Test 2:** Results of **logger** power wakeup and recharging test.
- **Test 3:** Results of **logger** data access test.
- **Test 4:** Results of endurance of timekeeping and recording functions test.
- **Test 5:** Results of door opening test.
- **Test 6:** Results of **M2M** load safety test, including a table or graph of voltage and current measurements.
- **Test 7:** Results of **logger** data review.
- **Test 8:** Results of disruption to timekeeping test.
- **Data:** Report all data downloaded from tests.
- **Annexes:** A pre-approved test protocol verifying that the procedures set out in this document have been followed. Description of the test apparatus. Test chamber temperature and humidity records. Copies of reference thermometer and humidity

measurement calibration certificate(s). Additional supporting documentation requested and received from the [legal manufacturer](#) or [reseller](#) during the course of the type-testing.

6. Quality control checklist

6.1 Quality control standards

All testing and reporting must be carried out in accordance with the requirements of **ISO 17025:2017** or later edition.

6.2 Quality control checklist

An on-site inspection of the manufacturing plant is not required.

6.3 Quality control evaluation

Not required.

7. Prequalification evaluation

An [appliance](#) will qualify for inclusion on the register of PQS prequalified CCE that include data [logger](#) and [M2M](#) functionality in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **WHO/PQS/E006/DL01**.

8. Modified products

The [legal manufacturer](#) or [reseller](#) shall notify WHO **in writing** of changes that affect the performance of the [logger](#), [M2M](#), or their containing [Appliance](#) related to the requirements in specification **WHO/PQS/E006/DL01**. For example:

- 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.

WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the [logger](#), [M2M](#), or [appliance](#), WHO may request full or partial re-verification based on the test procedures described in this document.

Annex 1 – Materials and equipment

The following materials and equipment are useful or required to complete this verification protocol:

- An environmental chamber capable of holding the [logger](#) if it is being tested by itself, or a complete [appliance](#) if the [logger](#) is being tested in conjunction with an [appliance](#) that contains it. Must be able to reach +43 °C.

- Standard USB Type-C “legacy” cable with USB Type-C plug on one end and USB Type-A plug on the other end.
- USB Type A unpowered hub, that is a USB hub that derives all its power from the host computer without a separate power input. This hub will be used to connect to the [logger](#) device under test (DUT) in *Test 2* and ensure that the [logger](#) is powered by no more than 500 mA. The intention of this arrangement is to minimize the amount of battery charging that can happen during that part of the test.
- Computer or mobile device to download data from the DUT.
- A simulated load for the [M2M](#) 5 V power output. It should be adjustable in 0.05 A or smaller steps up to the maximum expected output of 1.15 A. This could be a set of switchable resistors or a programmable DC load.
- Cable with a 2.1 mm ID / 5.5 mm OD jack on one end to connect the [M2M](#) power output plug to the simulated load.
- Access to an accurate time service, such as a website that displays the present time in seconds synchronized to network time sources.
- Tools to validate [logger](#) JSON data files to a JSON schema, either custom software, one of a number of software tools available for download at <https://json-schema.org/>, or one of a number of online JSON schema validators, such as <https://www.jsonschemavalidator.net/>.
- Helpful, but not required: a software tool for loading and examining [logger](#) JSON data files. An example is a spreadsheet like Microsoft Excel.

Annex 2 – Examples of Data Timestamps

For simplicity, this annex only shows the “records” portion of “CURRENT_DATA” raw data files, and only shows three data objects: the timestamp, RELT; the timestamp when clock started its most recent continuous operation, RTCW; and vaccine compartment temperature, TVC Deleted data are shown by ellipses (“...”).

A2.1 Example data file obtained in Test 8, Step 2

Assume that the [legal manufacturer](#) had operated the [logger](#) with continuous logging since manufacture for three days and two hours with its sensors in room ambient temperature before preparing it for test. Assume also that timekeeping was disrupted at three days, two hours, and 10 seconds. The last data records might look like below, where the value of RTCW indicates continuous logging since time zero.

```
{
...
  "records": [
...
    { "RELT": "P3DT1H45M", "RTCW": "PT0S", "TVC": 25.6, ... },
    { "RELT": "P3DT2H", "RTCW": "PT0S", "TVC": 25.6, ... }
  ]
}
```

A2.2 Example of a compliant data file obtained in Test 8, Step 7

```
{
...
  "records": [
...
    { "RELT": "P3DT1H45M", "RTCW": "PT0S", "TVC": 25.6, ... },
    { "RELT": "P3DT2H", "RTCW": "PT0S", "TVC": 25.6, ... },
    { "RELT": "P3DT2H15M", "RTCW": "P3DT2H1S", "TVC": 21.7, ... },
    { "RELT": "P3DT2H30M", "RTCW": "P3DT2H1S", "TVC": 21.6, ... }
  ]
}
```

There are two additional records, corresponding to the half-hour of power applied in Step 5. RELT is continuously increasing. In this case, it resumes with a value that is 15 minutes after the last value recorded at the [legal manufacturer](#).

RTCW enables time correction for all records in DR2, since an unchanged RTCW changes and takes on the value of the RELT clock when timekeeping resumes. In this case RELT starts at the last known recorded RELT value, plus one second. It could also start at P3D2H10S if the [logger](#) had kept track of the 10 extra seconds between the last recorded data and the time the device was unpowered.

A2.3 Example of a non-compliant data file: timestamps are not strictly increasing

```
{
...
  "records": [
...
    {"RELT": "P3DT1H45M", "RTCW": "PT0S", "TVC": 25.6, ...},
    {"RELT": "P3DT2H", "RTCW": "PT0S", "TVC": 25.6, ...},
    {"RELT": "PT15M", "RTCW": "PT0S", "TVC": 21.7, ...},
    {"RELT": "PT30M", "RTCW": "PT0S", "TVC": 21.6, ...}
  ]
}
```

Here the timestamp resets to zero when power resumes.

A2.4 Example of a non-compliant data file: disruption not recorded

```
{
...
  "records": [
...
    {"RELT": "P3DT1H45M", "RTCW": "PT0S", "TVC": 25.6, ...},
    {"RELT": "P3DT2H", "RTCW": "PT0S", "TVC": 25.6, ...},
    {"RELT": "P3DT2H15M", "RTCW": "PT0S", "TVC": 21.7, ...},
    {"RELT": "P3DT2H30M", "RTCW": "PT0S", "TVC": 21.6, ...}
  ]
}
```

In this case, RTCW does not change so it is impossible to determine when timekeeping was disrupted.

Annex 3 – Logger data download procedure

- **Step 1:** Create a new folder on the lab computer. Give the folder an appropriate name that can be traced back to the time noted in the next step. Using the time directly in the folder name is a good practice.
- **Step 2:** Reference an accurate Internet-provided clock. Connect M2M USB Type-C data port to a lab computer with an appropriate cable. Note the time to the nearest second* at the moment of connecting the USB plug to the logger.
- **Step 3:** Copy all data from the root of data logger storage device into the new folder.
- **Step 4:** Disconnect the USB cable after the data download has been completed.

The data download should in all cases take less than three minutes. Data that is not needed for the particular test may not have to be downloaded if a full data download takes too long.

*For test 4 it is important to note the time to the nearest second.

For the other tests the time may be recorded to the nearest minute, referencing an accurate clock.

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
May 2025	Minor updates to clarify test procedures.	Clarifications	IG