

Record of Compliance

For EasyLog data loggers, to the applicable requirements of BS EN 12830:2018 Temperature recorders for the transport, storage and distribution of temperature sensitive goods.

Products covered, all models prefixed:

- EL-21CFR
- EL-IOT
- EL-MOTE
- EL-WIFI

Clause	Requirement	Compliance
5.1 General	<p>The means of temperature measurement used by the recorder shall be independent of any temperature measurement which is used to control the refrigerating system.</p> <p>The system shall have the possibilities to prevent and/or detect manipulation and to prove the validity of the data;</p> <p>The system shall have the possibility to log changes in the parameters that influence the relevant data for example:</p> <ul style="list-style-type: none"> a) measurement value; b) time stamp; c) correlation between measurement value and time stamp; d) settings: <ul style="list-style-type: none"> 1) measurement interval; 2) measurement limits; 3) measurement mode (e.g. start/stop); 4) location. <p>Manipulation of the log has to be prevented and/or at least detected; the logs have to be kept at least as long as the data itself.</p>	<p>All products are designed as stand-alone data loggers that operate independently of any refrigeration system.</p> <p>PC and Cloud-based software provide controls to safeguard data from manipulation.</p> <p>Changes to configuration parameters are logged; such logs cannot be altered and are retained for as long as required.</p>
5.2 Measuring range	The temperature recorder shall be able to measure in the measuring range that it is defined by the manufacturer.	The performance of all products in line with published specifications is confirmed before they are shipped to users.

5.3 Protection of the data from manipulation		
5.3.1 General	The software shall prevent and/or at least detect both intended and not intended manipulation of the relevant data. This is true for all relevant data as long as they are managed by the measurement system, including during storage and transmission.	Logged data cannot be manipulated.
5.3.2 Audit trail	The software of the measurement can have an audit trail.	Full audit trails are provided.
5.3.3 Clearly readable data copies	The software shall be able to present the relevant data in a way that is directly readable by persons or authorities in an easy way.	Data is available both in tabulated format and graphically.
5.3.4 Safekeeping of accessibility of the data	The software shall have a possibility to make sure the user can access the relevant data any time, provided he/she has the rights to do so.	Both PC and Cloud-based software can be accessed by verified users at any time.
5.3.5 Safekeeping of readability of the data	The software shall have a possibility to ensure that the relevant data are directly readable by persons.	All data can be directly read by authorised users.
5.3.6 Safekeeping of correctness of the data	The software shall have a possibility to ensure that the data are inviolate.	Once data has been logged by a product it cannot be altered in any way.
5.3.7 Access restrictions	The software shall make sure that critical parts of the software can't be accessed without user verification. This means it has to have a user management system with user names and passwords to identify the users, and options to declare user rights to define various user roles (e.g. administrator vs. regular user).	Both PC and Cloud-based software have a full user management system with various access levels and individual user passwords.
5.3.8 Detailed documentation of the software	The documentation of the software shall be compiled in a way that the software mechanics are comprehensible for qualified personnel, e.g. computer scientists.	Full software documentation and technical support are available.
5.4 Locking of settings	<p>The date and time of the beginning of recording shall be readable from the recorded data or it shall be possible to make them readable.</p> <p>The possibility for adjusting settings which configure the recording shall either be</p> <ul style="list-style-type: none"> • protected against accidental or unauthorised modifications; • or record each adjustment of any settings that remain accessible. 	The date and time of all recordings are fully readable, and protected from adjustment.

5.5 Recording		
5.5.1 General	<p>At least the temperature and the time shall be recorded. The record shall also indicate the date and the time zone e.g. GMT or UTC. Other information as the place of measurement (e.g. return air, back door) could be also recorded, however it shall not impact the temperature data.</p>	<p>All products record temperature and time, the Time Zone can be set on the Cloud</p>
5.5.2 Traceability	<p>It shall be possible to identify and retrieve the recorded data. It shall be possible to read those data, intended for archiving for a period of at least a year.</p> <p>The recorder shall allow the user to keep the data for at least one year.</p> <p>The manufacturer of the device shall define instructions in its documentation for operation and maintenance taking in account, i.e. life time of batteries, storage periods and operational limitations of the device.</p>	<p>All data can be kept and read for as long as required, on the product, in the PC software or indefinitely on the Cloud.</p> <p>Operational and maintenance limitations for all products are provided in the published documentation.</p>
5.6 Autonomous power supply	<p>For devices with an autonomous power supply, this shall be indicated on the recorder or on the power supply or in the technical documentation, with the corresponding usage temperature.</p> <p>The manufacturer is recommended to install an indicating device (warning light or message) warning the user that the power source needs replacing.</p> <p>The battery lifetime shall be indicated by the manufacturer for relevant operation temperatures taking into account typical operation of e.g. display, transmission of data, LEDs, number and kind of sensors.</p> <p>The manufacturer shall indicate if the battery is fixed or replaceable and/or rechargeable.</p>	<p>All products are capable of operating from batteries, with details of the types to be used given in the published documentation.</p> <p>All products warn users if the battery needs replacing.</p> <p>Expected battery life is in the documentation, and can be provided for custom applications on request.</p>
5.7 Degree of protection provided by the enclosure	<p>The minimum degree of protection provided by the enclosure shall be:</p> <ul style="list-style-type: none"> • IP 20 for recorders used in heated/air conditioned closed premises or in the cabin of transport vehicles; • IP 55 for recorders used inside cold enclosures (storage or transport vehicles) and for external sensor; • IP 65 for recorders used outside buildings or transport vehicles, with sensor inside the cold enclosure. 	<p>All products meet the required standard for the recommended use cases.</p>

5.9 Operating characteristics linked to external electrical influences		
5.9.2 Autonomous supply	<p>The manufacturer shall specify the operating time without external power at a reference temperature.</p> <p>The device shall give an indication if the battery status is low.</p>	Expected battery life is in the documentation, and can be provided for custom applications on request.
5.9.4 Power cut-offs	The recorded data shall not be lost during a power cut-off. The manufacturer shall state the duration for which the data are protected when the recorder is disconnected from the primary source of power.	All recorded data is retained indefinitely within the logger if power is cut off.
5.9.5 Electrical power disturbances and susceptibility to radiated electromagnetic field	The recorder shall conform with the requirements of EN 61000-6-2 and EN 61000-6-3, or any other specific standard, if applicable.	All products pass these requirements. Refer to individual Declarations of Conformity for more details.
5.10 Metrological characteristics and usage profiles		
5.10.2.1 Maximum permissible errors and resolution	The recorder, under rated operating conditions, shall conform to at least one of the classes indicated in Table 2.	All products conform to either Class 0.2, 0.5, 1 or 2. Refer to individual product data sheets for details.
5.10.2.2 Operational requirements	<p>Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick frozen food and ice-cream should have the minimum accuracy class 0.5 within the temperature range of -25°C to $+7^{\circ}\text{C}$.</p> <p>For traceability a minimum storage time for frozen food application of 1 year is required. This does not refer to the storage capacity of the measurement instrument.</p>	<p>Refer to individual data sheets for products that conform to Class 0.5.</p> <p>All such products can store data for more than 1 year.</p>
5.10.2.3 Recording interval and storage capacity	<p>The manufacturer shall define the recording intervals, periods and storage capacity with its minimum and maximum limits. The maximum time window for calculated temperatures shall be measured with 5% of the recording interval and a maximum period of 15 min.</p> <p>If there is any possibility of overwriting the recorded values it shall be indicated by the manufacturer.</p>	<p>The required information is defined on individual product data sheets.</p> <p>All products allow users to select recording intervals as required.</p> <p>Recorded values cannot be over-written.</p>
5.10.2.4 Maximum relative timing error	<p>The maximum relative timing error shall be:</p> <ul style="list-style-type: none"> • 0.1% of the recording duration when the date is reset up to 31 d; • 0.02% of the recording duration including the error of the date and time when the date is reset after 31 d. 	All products have timing errors smaller than these requirements.

5.10.2.5 Response time	<p>The response time shall be:</p> <ul style="list-style-type: none"> • for recorders with external air sensors maximum 5 min; • for recorders with internal sensors maximum 20 min. <p>The response time is the time needed for the recorded value to reach 90% of the actual change of applied temperature.</p>	All products meet these requirements, refer to individual data sheets for details.
5.10.3.1 Climatic environment	<p>The manufacturer shall give a clear statement for the climatic environmental limits for:</p> <ul style="list-style-type: none"> • the complete temperature recorder or each individual subunit of the temperature recorder; • specified temperature ranges for batteries including their expected operation lifetime at certain temperatures (including minimum and maximum of operating temperature) and at specific recording intervals (see 5.10.2.3). 	These details are provided in individual product data sheets. Additional information for custom applications can be provided on request.
5.10.3.4 Different versions and combinations of components	<p>The manufacturer shall give a clear description of possible combinations and versions of devices, interfaces and sensors including e.g. connectors, length of wires and distances (maximum equipment).</p>	All products are fully specified on the individual product data sheets, including any available accessories.
5.11 Data security	<p>The data shall be protected against alteration.</p>	No recorded data can be altered.