

SupaTrak – Cold Chain Monitoring EU Legislation Compliance

The Standard – EN 12830: 1999

EN 12830: 1999 is a pan European standard. Its full title is:

“Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream – Tests, performance and suitability”

This is the definitive standard for cold chain monitoring devices and applies to all European countries. In Great Britain it is a British Standard BS EN 12830: 1999.

This document summarises all the relevant requirements of the standard and explains how the CMS system complies.

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Introduction

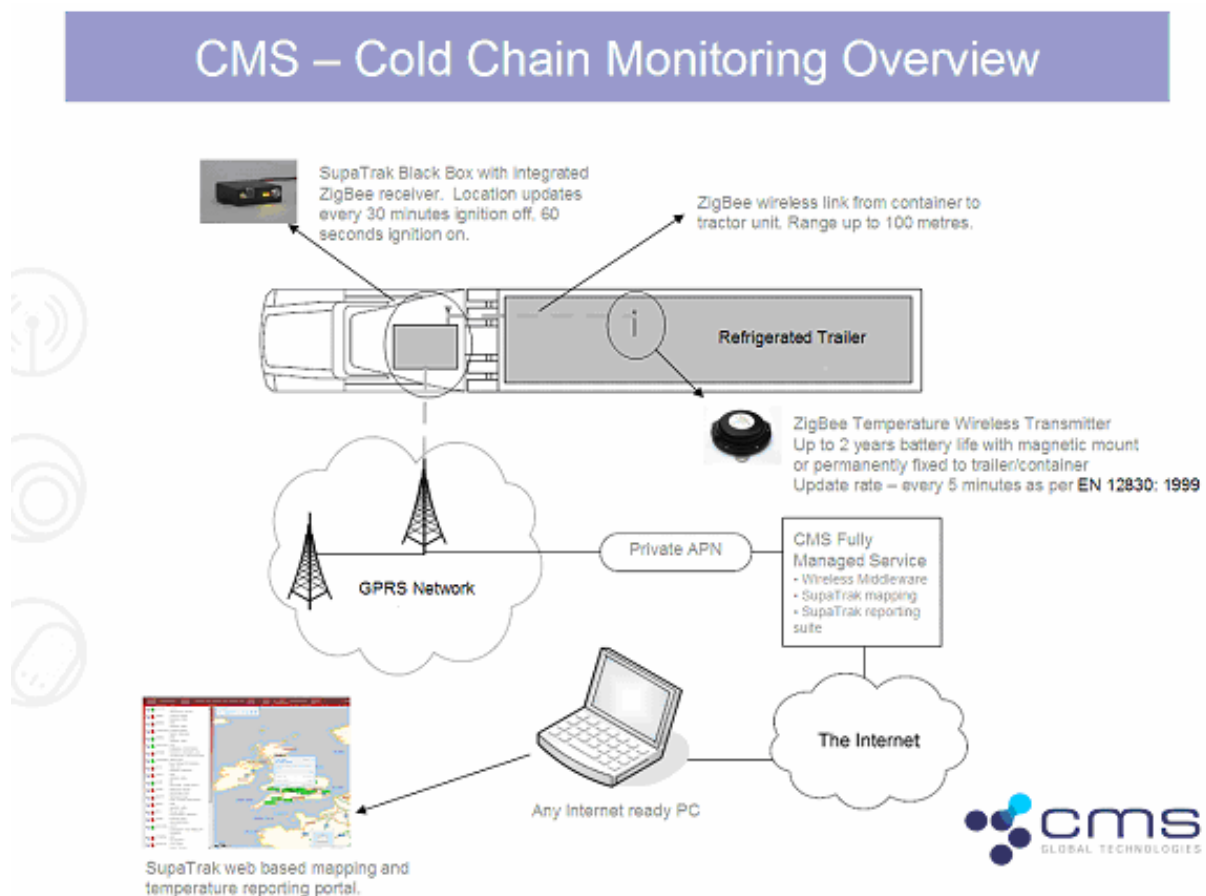
1.2. Scope of the Standard

The committee reviewing the draft standard, prior to its approval, envisaged that it would apply to traditional stand alone data loggers and chart recorders with either integral sensors or probes connected by wires. The CMS Integrated Cold Chain Management system is a distributed system. It uses wireless sensors connected via radio and GPRS to a recording facility on a centralized data server.

The CMS system uses a technology not envisaged by the review committee. Nevertheless, on careful reading, the standard applies to “temperature recorders”, and explicitly includes the sensor and the recording system. It also explicitly allows for sensors to be remote from the recorder (Section 1). It is therefore applicable in full to the CMS Integrated Cold Chain management system which implements the main recording functionality on a web server with remote sensors located in the refrigerated areas.

The diagram below illustrates the CMS Cold Chain Management system and highlights the components which implement the recording system as referred to in the standard.

Figure 1: Temperature Recording System



2. Requirements of the Standard

The subsections below summarise the requirements of the standard as applicable to recorders for use in refrigerated transport application. Sections of the standard that are not referred to below are not applicable to transport applications.

2.1. General (EN 12830:1999 4.1)

REQUIREMENT: The means of temperature measurement must be independent of any temperature measurement which is used to control the refrigerating system. This requirement is met by having independently powered radio sensors inside the refrigerated space.

2.2. Measuring Range (EN 12830:1999 4.2)

REQUIREMENT: The measurement range of the sensors must be $\leq -25^{\circ}\text{C}$ to $\geq 15^{\circ}\text{C}$ with a span of $>50\text{K}$. The sensors measure from -50°C to $+110^{\circ}\text{C}$.

2.3. Locking of Settings (EN 12830:1999 4.3)

REQUIREMENT: The time and date of the beginning of a recording shall be readable and any settings which configure the recording shall be protected against unauthorized or accidental modification.

Every sensor reading is time stamped with the absolute time (UTC) maintained in a real time clock which is set from a GPS receiver. There are no mechanisms for altering these times. The measurement interval is set by a command which is accessible only by authorized personnel.

2.4. Recording, General (EN12830:1999 4.4.1)

REQUIREMENT: At least the time and temperature shall be recorded. The place of measurement and the date has to be indicated.

Time stamped temperature readings are recorded centrally on a web server in a read only database. Each sensor is mapped to a specific location or refrigerated trailer. This information is made available to the users over a read-only interface as web pages.

2.5. Traceability (EN12830:1999 4.4.2)

REQUIREMENT: It shall be possible to identify and consult the charts and the recorded data. Records shall be available for at least one year.

The database which is maintained on the web server is a permanent record and will be available for viewing on line for at least one year. Archives of older data will be retained indefinitely.

2.6. Autonomous power supply (EN12830:1999 4.5)

REQUIREMENT: Devices with an autonomous power supply shall be marked as such along with an indication of operating temperature range. (It is recommended, but not required, that an indication of battery life is given)

The database server will indicate the battery condition of each sensor and when the battery is nearing the end of its life. Sensors will be marked with the type of battery they require.

2.7. Degree of protection provided by the enclosure (EN12830:1999 4.6)

REQUIREMENT: The degree of protection shall be at least IP20, IP55 or IP65 for different environments.

The wireless sensors are protected in enclosures offering protection to IP67.

2.8. Electrical Safety (EN12830:1999 4.6)

REQUIREMENT: The recorder shall conform to the requirements of EN61010-1.

The sensors comply with EN61010-1, EN50081-1 and 50082-1.

2.9. Maximum permissible errors and resolution (EN12830:1999 4.9.2.1)

REQUIREMENT: Under rated operating conditions the recorder shall conform to one of the two classes indicated as follows:

Class 1 2

Maximum permissible errors $\pm 1^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Resolution K 0.5 $^{\circ}\text{C}$ K 1 $^{\circ}\text{C}$

Table 1: Classes of Recorder Accuracy

The sensors exceed the requirement of Class 1 with a resolution of K 0.1 $^{\circ}\text{C}$ and accuracy better than $\pm 0.5^{\circ}\text{C}$.

2.10. Recording Interval (EN12830:1999 4.9.2.2)

REQUIREMENT: The maximum recording interval for transport shall be 5m for recording durations shorter than 24 hours, 15m for 1-7 days, and 60m for durations longer than 7 days. For storage monitoring the recording interval shall be 30m.

The sensors default to recording temperature every minute, exceeding all of the above requirements. The interval is programmable in integer number of minutes up to 18 hours.

2.11. Recording duration (EN12830:1999 4.9.2.3)

REQUIREMENT: The manufacturer shall specify the recording capacity as either the duration at a given interval or as a number of readings.

The system has an indefinite recording capacity, limited only by hard disk storage space on the server.

Sensors may, at times, operate offline when no tractor unit is nearby or, for example, when power is lost to the tractor unit or the vehicle is outside GSM coverage. Under these circumstances the sensors will buffer readings. Data in the buffer is compressed and the compression rate depends on the variability of the temperature. The absolute minimum period that is buffered is 2.5 days, but with a normal temperature characteristic, the sensor will buffer 2-5 weeks' data. These periods apply to a 1minute recording interval.

2.12. Maximum relative timing error (EN12830:1999 4.9.2.4)

REQUIREMENT: 0.2% up to 31 days, 0.1% over 31 days.

The sensors are constantly updated with time from a GPS receiver whenever it is available.

The timing is therefore extremely accurate.

When operating offline, the sensors buffer data using a self-maintained clock. This is accurate to better than 1 minute per week (0.01%).

2.13. Response time (EN12830:1999 4.9.2.5)

REQUIREMENT: The response time shall be, for recorders with external sensors, maximum of 10 minutes for transport. This is the time for the recorder to reach 90% of the applied temperature (using a step change of >20K in a moving air stream at 1ms⁻¹)
The sensors have a response time of less than 5 minutes, measured this way.

2.14. Climatic environment (EN12830:1999 4.9.3.1)

REQUIREMENT: Table 3B in the standard requires operating range -30°C to +65°C, limiting conditions of -30°C to +70°C and storage conditions of -40°C to +85°C.
The sensors operate from -40°C to +70°C and can be stored from -40°C to +85°C.

2.15. Mechanical vibrations (EN12830:1999 4.9.3.1)

REQUIREMENT: The equipment shall withstand vibration from 5Hz to 8.6Hz 10mm amplitude and from 8.6Hz to 150Hz, acceleration of 3g.
The sensors are designed to withstand these conditions.

2.16. Data Security (EN12830:1999 4.10)

REQUIREMENT: The data shall be protected against alteration.
Data is stored in a read only database viewable via web pages. Data cannot be modified.

3. Conclusion

EN 12830:1999 is the only applicable European Standard that is relevant to this system.
The requirements of the system are met or exceeded in every area.