DIN EN 12830:2018-10 (E)

Temperature recorders for the transport, storage and distribution of temperature sensitive goods - Tests, pe rformance, suitability

Contents

Page

European foreword 5

1 Scope 6

2 Normative references 6

3 Terms and definitions 7

4 Concepts 11
4.1 General 11
4.2 Temperature recorder elements 12
4.3 Temperature recorder architecture (or configuration) 12
4.3.1 General 12
4.3.2 Monolithic instrument 13
4.3.3 Monolithic instrument with external relevant data 13
4.3.4 Temperature recorder with digital probes 14
4.3.5 Temperature recorder on the cloud 15

5 Requirements 16
5.1 General 16
5.2 Measuring range 17
5.3 Protection of the data from manipulation 17
5.3.1 General 17
5.3.2 Audit trail 17
5.3.3 Clearly readable data copies 17
5.3.4 Safekeeping of accessibility of the data 17
5.3.5 Safekeeping of readability of the data 18
5.3.6 Safekeeping of correctness of the data 18
5.3.7 Access restrictions 18
5.3.8 Detailed documentation of the software 18
5.4 Locking of settings 18
5.5 Recording 18
5.5.1 General 18
5.5.2 Traceability 18
5.5.3 Chart only for mechanical recorder 19
5.6 Autonomous power supply 19
5.7 Degree of protection provided by the enclosure 19
5.8 Electrical safety (if applicable) 19
5.9 Operating characteristics linked to external electrical influences 20
5.9.1 External supply voltage (if applicable) 20
5.9.2 Autonomous supply (if applicable) 20
5.9.3 Frequency (AC) (if applicable) 20
5.9.4 Power cut-offs 20
5.9.5 Electrical power disturbances and susceptibility to radiated electromagnetic field 20
5.10 Metrological characteristics and usage profiles 20
5.10.1 General 20
5.10.2 Metrological characteristics 20
5.10.3 Usage profiles 22
5.11 Data security 22
5.12 Software verification levels 22

6 Test methods 23
6.1 Test list 23
6.2 General conditions for tests 24
6.2.1 Pre-tests adjustments 24
6.2.2 Normal atmospheric conditions 24
6.2.3 Reference conditions 24
6.3 Determination of temperature measurement error 25
6.3.1 Test method 25
6.3.2 Reading the recording 25
6.3.3 Expression of results 25
6.4 Determination of response time 26
6.5 Determination of time recording error 26
6.6 Action of influence quantities 27
6.6.1 General 27
6.6.2 Variation in voltage supply (if applicable) 27
6.6.3 Influence of ambient temperature 27
6.6.4 Temperature testing under storage and transport conditions for the recorder 28
6.6.5 Shock resistance test (if applicable) 28
6.6.6 Mechanical vibrations (if applicable) 28
6.6.7 Degrees of protection provided by enclosures (IP Code) 29
6.6.8 Electrical safety (if applicable) 29
6.6.9 Dielectric strength (if applicable) 29
6.7 Software test 29
6.7.1 Test objective 29
6.7.2 Test procedure 29

7 Conditions of acceptance 33
7.1 Requirements 33
7.2 Operating error limits 33

8 Marking 34

9 Initial and periodic verification 34

Annex A (normative) Software testing 35

A.1 Software test general part - Test objective 35
A.2 Test procedure 35
A.2.1 General 35
A.2.2 Determine the temperature recorder subunits 35
A.2.3 Determine the relevant software of each unit or subunit 35
A.2.4 Define the applicable test blocks of each unit or subunit 35
A.2.5 Determine the type of each unit or subunit 36
A.3 Software test for type P1 and type P2 37
A.3.1 General 37
A.3.2 Block G: Basic requirements 37
A.3.3 Block L: Specific software requirements for long-term storage 48
A.3.4 Block T: Transmission of measurement data via Communication Networks 55
A.3.5 Block S: Software separation 61
A.3.6 Block D: Download of relevant software 64
A.4 Software test for type P3 69

Annex B (informative) Manufacturer software test form 70

B.1 Identification 70
B.1.1 Manufacturer identification 70
B.1.2 Test object 70
B.1.3 Documents list 70
B.1.4 Define the applicable test blocks of each unit or subunit (L, T, S and D) 71
B.1.5 Selection of the type of each unit or subunit 71
B.2 Test requirement for type P1 and P2 73
B.2.1 General 73

B.2.2 Basic requirements 73
B.2.3 Extension L: Specific software requirements for long term storage 80
B.2.4 Extension T: Specific software requirements for data transmission 84
B.2.5 Extension S: Specific software requirements for software separation 87
B.2.6 Extension D: Specific software requirements 89
B.3 Test requirement for type P3 93

Annex C (informative) Example of data form describing suitability for use of equipment of a specific series (to be filled in by the manufacturer) 94

Annex D (informative) Expected operation time and storage capacity 95

D.1 Storage capacity dependent on the measurement interval 95
D.2 Battery lifetime dependent on usage 95

Annex E (informative) Required access to recorded data or functions is given in Table E.1 96