INTERNATIONAL RECOMMENDATION

OIML R 146-2

Edition 2016 (E)

Protein measuring instruments for cereal grain and oilseeds

Part 2: Metrological controls and performance tests

Instruments de mesure de protéine pour grains de céréales et graines oléagineuses

Partie 2: Contrôles métrologiques et essais de performance

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword

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- **International Recommendations (OIML R),** which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;
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Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

This publication – reference OIML R 146-2, Edition 2016 (E) – was developed by Project Group 1 in Technical Subcommittee TC 17/SC 8 *Instruments for quality analysis of agricultural products*. It was approved for final publication by the International Committee of Legal Metrology in 2016 and was submitted to the International Conference on Legal Metrology in 2016 for formal sanction.

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Part 2: Metrological controls and performance tests

The OIML recognizes that the ideal legal metrological control strategy for one country or region is not necessarily the ideal for all others. OIML D 16:2011 *Principles of assurance of metrological control* [8] discusses the factors to consider in order to design and implement more effective control systems. R 146-2 is based on a system with several elements comprising type evaluation and approval, initial verification and metrological supervision.

1 Type evaluation and approval

Each type of a protein measuring instrument used for trade shall be submitted for type approval. Without authorization from the national responsible body, no modification may be made to an approved type.

1.1 Application

General application requirements are available from the national responsible body. The application for type approval shall be accompanied by

(a) at least two sample instruments representative of the submitted type for testing according to the full program in Annex A, and

(b) descriptive documents and drawings.

1.1.1 Sample instruments

1.1.1.1 Manufacturers shall provide the national responsible body with at least two instruments and an operating manual. The sample instruments shall be in full working order and shall include all functions and calibrations to be examined for type approval.

1.1.1.2 It is recommended that a third (additional) unit is provided in order to expedite the climatic performance tests. This additional unit will be maintained at reference conditions and used to monitor the P_{MB} stability of grain samples after they are cycled through various temperature and humidity settings during the climatic tests.

Note: In the absence of a third unit, another approved type of protein measuring instrument can be used to monitor the sample stability.

1.1.1.3 If the protein measuring instrument is a module (i.e. part of a system that includes non-metrological functions), manufacturers are permitted to submit only parts associated with P_{MB} measurements for evaluation. This is particularly relevant where testing the instrument as a whole is difficult or impossible, or where modules are manufactured and/or placed on the market as separate units to be incorporated in a complete instrument.

1.1.2 Documentation file

In addition to the documents listed in Table 1, the applicant may submit other evidence to support the assumption that the design and characteristics of the type comply with the requirements of this Recommendation.

Table 1: Contents of a documentation file submitted for type evaluation

Required documentation	Application notes and/or examples
General description of the instrument	Functional description; measurement principle.
General characteristics of the instrument	Manufacturer; manufacturer specifications for the rated operating ranges, e.g. ambient temperature, voltage; manufacturer specifications for the sample temperature and maximum differential between instrument and sample; single or multi-calibration.
Drawings of general arrangement and details of metrological interest	Safeguards, restrictions, securing components, adjustment devices, controls, protected access to adjustment operations; calibration selection and display; place for application of control marks, descriptive markings and conformity and/or approval marks.
Description of calibrations submitted for approval	Calibration principle; calibration names and version number; limitations of use e.g. applicable types of grain, P_{MB} measuring ranges, min/max moisture content of samples; regression data (e.g. number of points, data sources, reference method, validation results); calibration equation, values for fixed and adjustable parameters.
Descriptions and characteristic data for all devices and sub-assemblies of the instrument	Examples of devices: printing device; memory storage device, levelling device and indicator; sample receptacle (input and output); other functions (if not limited to P_{MB} measurements).
Technical description, drawings and plans of devices, sub-assemblies	Devices involved in the measurement principle (e.g. for NIR – spectroscope, transducers, receptors and data integrators); electrical connection elements including length of signal lines; indicator (e.g. block and schematic diagrams, internal processing and data exchange via interface).
Declarations of the manufacturer	e.g. for interfaces, for protected access to instrument and calibration adjustment parameters, for other software based operations.
Samples of all intended printouts	
Information concerning special cases	Subdivision of instrument into legally relevant modules (if the processes are not limited to P_{MB} measurements); operating conditions (if different to requirements in R 146-1, 4.4.1); suppression of results outside rated ranges; reaction of the instrument to significant faults; functioning of the display after switch-on.
Additional documents according to R 146-1, 6.5	For software-controlled instruments.
Results of tests performed by the manufacturer using protocols from R 146-2 and R 146-3	Or tests from other laboratories using protocols from R 146-2 and R 146-3. Include scope of third-party accreditation/ proof of competence.
Certificates of other type approvals or separate tests	Relating to other modules of the submitted instrument, together with testing protocols.

Drawing or photo of the instrument	The principle of application and the location of verification and securing marks shall be shown.
Manufacturer's manual according to R 146-1, 5.1	A draft is permitted.

1.2 Examinations

1.2.1 Administrative examination

The national responsible body shall review the documentation submitted against the requirements in 1.1.2 to determine if it is adequate and correct. The operating manual, which may be a draft, shall be assessed for its completeness and clarity of operating instructions.

1.2.2 Examination against metrological and technical requirements

The national responsible body shall visually inspect the instrument to ensure compliance with the documentation (e.g. specifications by the manufacturer).

The documentation, in conjunction with at least one sample instrument, shall be examined to confirm compliance with metrological or technical requirements in this Recommendation that cannot be evaluated during the performance tests (e.g. markings and sealing mechanisms). Suitable checks shall be performed on the instrument to establish confidence that all the functions are in accordance with the documentation. Reactions to significant faults need not be triggered.

1.2.3 Software examination

The national responsible body may opt to complete validation (software examination) after the performance tests. Compliance with the requirements of R 146-1, 6 is confirmed by the validation methods described in Annex B. If a particular requirement does not apply to the submitted type, it shall be marked as "not applicable" in R 146-3 *Examination checklist – requirements for software controlled devices and security*.

1.3 Performance tests

Whole-grain measurement standards used in the performance tests shall fulfil the requirements in R 146-1, Annex B.

At least two sample units shall be tested according to the conditions and procedures in Annex A. The type of instrument is presumed to comply with the metrological requirements in R 146-1, 4.7, 4.8 and 4.9 if it passes the performance tests in Table 2.

Table 2: Tests to demonstrate compliance with selected metrological requirements

Metrological requirements	Test(s) for compliance
Requirements for calibration [R 146-1, 4.7]	Assessment of calibrations in the submitted type [A.7] Accuracy and precision at reference conditions [A.7.1] Sample temperature sensitivity (STS) [A.7.2]
Variation of selected influence factor(s) within the rated operating ranges [R 146-1, 4.8.1]	Tests for influence variations within the rated operating conditions [A.5] Instrument levelling [A.5.1] Cold [A.5.2] Dry heat [A.5.3] Damp heat [A.5.4] AC mains voltage variation [A.5.5] Variation in voltage supplied by external 12 V and 24 V road vehicle batteries [A.5.6]
Effect of disturbances on instrument [R 146-1, 4.8.2] *Notes:* (1) Instruments that do not contain any active electronic circuits (e.g. transistors, ICs, radio tubes), are presumed to comply without being subject to the electrical disturbance tests. (2) Only applicable to portable instruments that are designed not to require reverification after transportation between different sites.	Tests for disturbances [A.6] AC mains voltage dips, short interruptions and voltage variations [A.6.1] Bursts (transients) on AC mains [A.6.2] Radiated radiofrequency, electromagnetic [A.6.3] Conducted radio-frequency electromagnetic fields [A.6.4] Electrostatic discharges [A.6.5] Storage temperature (extreme shipping conditions) [A.6.6] Random vibration(2) [A.6.7]
Error due to changes in instrument over time. [R 146-1, 4.9]	Tests for time related effects [A.4] Instrument warm-up time [A.4.1] Instrument drift and instability [A.4.2]

1.4 Test report

The report on the tests carried out for type approval shall contain, as a minimum, the items of information prompted by the test report format provided in R 146-3. The manufacturer shall be provided specific comments about any test failures.

2 Initial verification

A new instrument shall undergo initial verification only after type approval. Further to the provisions below, general guidance for the development of verification protocols is included in OIML D 20:1988 *Initial and subsequent verification of instruments and processes* [9].

2.1 Legal status of the instrument submitted for verification

Initial verification includes a procedure to ensure that individual measuring instruments conform to the approved type and the metrological requirements in R 146-1, 4.6 under typical in-service conditions. But, notwithstanding this initial verification carried out by the appropriate legal authority or under its responsibility, the manufacturer has the full responsibility to ensure that the instrument complies with the requirements in this Recommendation (i.e. production of measuring instruments shall be in conformance with the approved type).

2.2 Examination

Before starting the tests, the examinations to be performed include:

(a) assessment of the instrument and surroundings;

(b) visual inspection to determine conformance with the approved type and to obtain a general appraisal of its design and construction;

(c) completeness and the correctness of the inscriptions; and

(d) the presence, completeness, and the language of the documentation intended for the user.

2.3 Test procedure

The national responsible body shall specify the test procedure to determine if the performance of a protein measuring instrument meets the accuracy requirements, or whether the instrument requires servicing and/or adjustment. Whole-grain reference material with certified P_{MB} values, i.e. CRMs as described in R 146-1, Annex B, shall be used.

2.4 Verification marks, seals and document

After successful initial verification, the verification marks and/or the sealing shall be attached and/or an accompanying document shall be made up according to national requirements.

3 Metrological supervision

Further to the provisions below, relevant to protein measuring instruments, general guidance can be found in OIML D 9:2004 *Principles of metrological supervision* [10].

3.1 Reverification (subsequent verification)

3.1.1 Frequency

Reverification is mandatory after any repair, adjustment or change that affects the metrological performance of an instrument that has been initially verified.

The obligation of reverification in absence of any metrologically significant changes and the mandatory time interval is subject to national requirements. Due to the seasonal variability of crops mentioned in R 146-1, 3.5.1, this Recommendation proposes annual reverification of instruments, with the interval not to exceed 18 months.

3.1.2 Examination and tests

Reverification shall only be performed provided that

(a) earlier verification has been successfully performed and the appropriate verification marks are undamaged,

(b) the period elapsed since the previous verification does not exceed the mandatory reverification period (if one is prescribed), and

(c) seals are not broken.

Deviation from any of the listed conditions suggests a breach of metrological controls, and may necessitate implementation of corrective actions (e.g. removal of the instrument from service, investigation, initial verification) in accordance with national requirements.

As with initial verification, reverification shall be carried out according to the procedure specified by the national responsible body.

While consideration of instrument conformity, installation and suitability are afforded at initial verification, reverification shall focus on the following:

(a) instrument and calibration accuracy;

(b) software integrity;

(c) appropriateness of use; and

(d) adequacy of maintenance.

3.2 In-service surveillance

For countries without a system of mandatory reverification, metrological supervision may consist of random or scheduled checks (in-service surveillance) of the following:

- the presence of the correct, valid and undamaged verification marks and seals;
- accuracy of P_{MB} measurements performed using whole-grain CRMs;
- evidence of regular maintenance according to the manufacturer's instructions.

3.3 Routine performance monitoring

The national responsible body may require the user of a protein measuring instrument to carry out a routine performance check before and/or after a series of protein content measurements. The purpose is to ensure adequate measurement reproducibility across 'linked instruments' and to monitor instrument drift so that corrective adjustments are carried out before the measurement error exceeds the MPE.

Note: A 'linked instrument' is defined as being linked, either electronically or manually under a quality system, to an instrument aligned with a whole-grain CRM. This allows the performance to be monitored on a daily basis or according to a schedule set by the quality system administrator.

For regular performance checks, a sub-set of the verification procedure may be adopted using secondary standards. Routine monitoring is not intended to be as thorough as the tests for accuracy during verification, however the frequency of performance checks is expected to surpass that of verification.

3.4 Maintenance and reconfiguration of the approved software

Only versions of the legally relevant software that conform to the approved type are approved for use.

The assessment and approval of software versions other than those submitted at type evaluation of the instrument is at the discretion of the national responsible body. Full examination as described in Annex B, or a sub-set of the validation procedure (in accordance with the changes declared by the manufacturer and the risk determined by the examiner), is recommended.

Updating the legally relevant software of a verified protein measuring instrument should be considered as

- a modification of the instrument, when exchanging the software with another approved version, or
- a repair of the instrument, when re-installing the same version.

In general, this necessitates verification in accordance with the guidelines for *Verified update* in OIML D 31:2008 [5], 5.2.6.2. In the place of a verified update, the national responsible body may allow for a *Traced update* as described in OIML D 31:2008, 5.2.6.2. A prerequisite for this provision is approval by the national responsible body that implementation of the software in the instrument fulfils the requirements for traced updates.

3.5 In-field updates to grain calibrations

3.5.1 Seasonal variability of crops and inevitability calibration updates

Grain protein measuring instruments measure P_{MB} indirectly via multivariate calibrations, e.g. in NIR instruments the spectral data from which P_{MB} is inferred is affected to some extent by other constituents and physical properties of the grain.

A calibration based on the discrete properties of a particular grain crop may not be valid for subsequent grain crops due to seasonal variability in chemical and physical properties.

The national responsible body may therefore authorize updates on the grain P_{MB} calibrations based on grain data collected during the current and/or recent years to accommodate for the seasonal and crop year variations. The national responsible body may also require retention of the data that is used to adjust the grain calibrations.

3.5.2 Calibration version

Only approved P_{MB} calibrations shall be used for the applicable grain types and P_{MB} ranges specified by the national responsible body (see R 146-1, 4.1). To facilitate audits on the calibrations, a protein measuring instrument must be capable of displaying the calibration constants that are adjustable, and a unique name or a unique version number for every calibration available for use.

3.5.3 Security of calibrations and reverification

There shall be provision to allow only authorized persons to change calibrations, for example, bias adjustments. In addition, changes to the grain calibrations of the instrument shall be impossible or recorded in an audit trail. Refer to R 146-1, Annex E for guidance on methods of sealing.

Changes to grain calibration data may be downloaded to a verified instrument using available communication interfaces. The national responsible body may not consider these as software changes that require a change to the software identification on the type approval certificate, however reverification of each modified instrument is required.

If calibration constants are digitally stored in an electronically alterable form, the instrument shall be designed to make automatic checks to detect corruption. An error message must be displayed if calibration constants have been electronically corrupted and no further measurement shall be possible.

The national responsible body may authorize a calibration update process which is not a verified update, provided that the instrument fulfils the requirements for traced updates at type evaluation as first mentioned in 3.4. The procedure for reverification of an instrument following a calibration update is determined by the national responsible body and may vary from the reverification processes described in 2 and 3.1.2.

Annex A
Type evaluation test procedures
(Mandatory)

A.1 General

A.1.1 This mandatory Annex defines the program of performance tests intended to ensure that the submitted type of protein measuring instrument performs and functions as intended under a specified range of conditions as required in R 146-1, 4.4. The procedures from A.5.2 to A.6.5 are in accordance with OIML D 11:2013 General requirements for electronic measuring instruments [4].

A.1.2 With the exception of the storage temperature test, the disturbance tests are described for a single instrument, i.e. one sample unit is the equipment under test (EUT). The remaining procedures illustrate two units undergoing a test simultaneously, i.e. the EUT is two sample units. The national responsible body may modify these procedures to accommodate for the number of units received.

A.2 Instrument preconditioning, conditioning and recovery

A.2.1 Prior to commencing the climatic tests and the STS test, the facility for suppressing measurements or results outside specified temperature ranges shall be disabled to ensure that error shift values can be calculated during the tests.

A.2.2 The guidelines for preconditioning, conditioning and recovery listed in the relevant test standard shall be observed. Where there are no preconditioning guidelines, the instrument shall be stabilized according to the manufacturer's specifications.

A.2.3 Prior to assessing the calibrations under reference conditions in accordance with A.7.1, the EUT may be adjusted so that the intrinsic error is as close to zero as possible.

A.2.4 Particularly during disturbance tests, the EUT shall not be adjusted at any time during the test except to reset it if a significant fault has been indicated.

A.3 Type evaluation test conditions

A.3.1 Reference conditions

Unless otherwise specified by the test procedure, the influence ranges below define the reference conditions under which the mean P_{MB} reference value or the intrinsic error is determined for each influence factor test.

*Ambient temperature (t_{ref}):	20 °C to 27 °C
Relative humidity (RH_{ref}):	30 % to 70 %
Atmospheric pressure:	86 kPa to 106 kPa (see note below)
Power voltage:	nominal mains or test voltage, V_{nom} or U_{nom}
Power frequency:	nominal frequency, F_{nom}
Instrument tilt:	level at 0º ± 0.1º

Note: It is not deemed necessary to monitor these values beyond measures specified in the test standard/ procedure.

Any reference condition applicable to grain samples has been marked by an asterisk (*).

During each test, the t_{ref} and RH_{ref} shall not vary by more than ±2 °C and ±10 % respectively within the allowable ranges.

A.3.2 Influence quantities

Influence quantity values representing the rated operating conditions and potential disturbances on electronic instruments are indicated in R 146-1, 4.4. When the effect of one influence quantity or

disturbance is being evaluated, all other influence quantities and disturbances are to be held relatively constant, at values close to reference conditions.

A.3.3 Sample temperature

The grain sample temperature shall be t_{ref} during each test, except for the sample temperature sensitivity (STS) tests and the climatic tests. The sample temperature range and Δt_{max} according to R 146-1, 4.3 shall be observed during all tests.

After the climatic tests, the effect of thermal cycling on the P_{MB} measurements of grain samples shall be monitored using a spare instrument of the same type maintained under reference conditions.

A.3.4 Summary of the tests concerned with measurement reproducibility

To define the reproducibility conditions, Table 3 specifies the conditions changed and unchanged.

Table 3: Conditions changed and unchanged in the measurement reproducibility tests

Measurement reproducibility test	Conditions of measurement	
	Changed	Unchanged
Tests for time related effects [A.4] The magnitude of an error shift indicates the level of reproducibility in measurements taken at different times on the same instrument	Measurement time or session	Instrument (same unit) Measurement procedure Operating conditions Location Operator Sample
Tests for influence variations within the rated operating conditions [A.5] The magnitude of an error shift indicates the level of measurement reproducibility while select influence factors are varied within the rated operating conditions	Influence(s) in the title of the test, e.g. ambient temperature and humidity; supply voltage Sample temperature (change inevitable during climatic tests)	All other influence factors Instrument Measurement procedure Measurement session (still the same session if within 48 hours) Location Operator Sample (except sample temperature during climatic tests)
Tests for disturbances [A.6] The magnitude of a fault indicates the level of measurement reproducibility while disturbances are applied (or after exposure)	Disturbance in the title of the test, e.g. voltage interruptions, electromagnetic fields, mechanical shock	All other influence factors Instrument Measurement procedure Measurement session Location Operator Sample
Assessment of calibrations in the submitted type [A.7] SDD_I indicates the level of reproducibility in measurements from two units of the same type	Instrument unit	Type of instrument Measurement procedure Operating conditions Measurement session Location Operator Sample

A.4 Tests for time related effects

A.4.1 Instrument warm-up time

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	Five P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at reference conditions, immediately after power is switched on or after warm-up; ii) EUT at reference conditions, well after the instrument has warmed-up and stabilized.
Suggested steps	1) The EUT is powered off and equilibrated at reference conditions with the grain sample. 2) The EUT is powered on and after waiting for the manufacturer's specified* warm-up time, a series of P_{MB} measurements is taken – alternating between the units after each single measurement – until five P_{MB} measurements are recorded for each instrument. 3) After waiting for one hour or twice the manufacturer's recommended warm-up time (whichever is greater), another series of P_{MB} measurements is taken using the EUT as described in step 2. *Where the manufacturer has not specified a warm-up time, it is assumed that turning the power on will immediately provide accurate results. The sample shall be tested immediately upon the EUT being powered on and then again after 1 hour.
Test result	The error shift on the grain sample is calculated for each unit. Error shift = Mean P_{MB} (step 3, condition ii) – Mean P_{MB} (step 2, condition i).
Acceptance requirements	All error shift values shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.4.2 Instrument drift and instability

EUT	Two or more sample instruments of the submitted type
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	This test is commenced prior to other type evaluation tests (except of the warm-up time test). Five P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at reference conditions, prior to any influence factor and disturbance tests; ii) EUT at reference conditions, after at least four weeks but less than six weeks have elapsed, prior to any disturbance tests or changes to the EUT.
Suggested steps	1) The EUT and grain samples are stabilized under reference conditions. 2) A series of P_{MB} measurements is taken on the first grain sample – alternating between the units after each single measurement – until five P_{MB} measurements are recorded for each instrument. The second and third samples in the set are analyzed in the sample manner. 3) After at least four weeks* and prior to any disturbance tests, further P_{MB} measurements are taken using the EUT on the same three samples, as described in step 2. *The minimum time period for assessing instrument stability shall be four weeks without any modifications, repairs, or adjustments performed on the EUT. However, the EUT may be cycled through various influence factor variations (within the rated operating ranges) followed by recovery at reference conditions. In the event of a modification to the EUT within the four-week period, the instrument drift and instability test shall be recommenced.
Test result	The error shift on every grain sample is calculated for each unit. Error shift = Mean P_{MB} (step 3, condition ii) – Mean P_{MB} (step 2, condition i).
Acceptance requirements	All error shift values shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.5 Tests for influence variations within the rated operating conditions

A.5.1 Instrument levelling

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	Five P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at reference alignment; ii) EUT tilted in at least two orientations*; iii) EUT after recovery at reference alignment.
Test severity	Instruments without level indicators: 5 % (approximately 3°). Instruments with level indicators: maximum allowable tilt on the indicator.
Suggested steps	1) The EUT, mounted on a level surface, is powered on and equilibrated at reference conditions with the grain samples. 2) A series of P_{MB} measurements is taken – alternating between the units after a single measurement – until five measurements are recorded for each instrument. 3) The EUT is tilted and another series of P_{MB} measurements is taken using the EUT as described in step 2. 4) Further P_{MB} measurements are taken using the EUT as described in step 2 at the other orientations* of tilt. 5) The EUT is returned to the reference alignment and step 2 is repeated. *A minimum of 2 orientations of tilt shall be applied e.g. front to back and left to right (select the direction with the greatest effect).
Test result	The error shift on the grain sample is calculated at every tilt orientation for each unit. Error shift (tilt 1) = Mean P_{MB} (step 3, tilt orientation 1) – Mean P_{MB} (step 2, condition i). Error shift (tilt 2) = Mean P_{MB} (step 4, tilt orientation 2) – Mean P_{MB} (step 2, condition i). Error shift (recovery) = Mean P_{MB} (step 5, condition iii) – Mean P_{MB} (step 2, condition i).
Acceptance requirements	All values for the error shift shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.5.2 Cold

EUT	Two sample instruments of the submitted type, setup according to A.2.1.
Spare unit	A sample instrument of the submitted type, setup according to A.2.1 and maintained at reference conditions for the duration of the test.
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type. Except during an analysis, each sample is kept in its enclosure during the test. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-1 [14], IEC 60068-3-1 [15]
Test method and procedure (in brief)	Test A: Cold. The test consists of exposure of the EUT to the specified minimum temperature under "free air" conditions for the specified time. The change of temperature shall not exceed 1 °C/min during heating up and cooling down. IEC specifies that the power to the EUT shall be switched off before the temperature is raised. Five P_{MB} measurements on every sample are taken using each unit, at every test condition: i) EUT and grain samples at reference temperature; ii) EUT after exposure to cold, grain samples at minimum temperature; iii) EUT and grain samples after recovery at reference temperature.
Sample monitoring	To ensure that cooling and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored throughout the test by a spare unit.
Test severity	Exposure duration (after EUT stabilization): 2 h; Minimum temperature: t_C or 10 ºC. t_C is the minimum temperature in the operating range specified by the national responsible body.
Suggested steps	1) The EUT is powered on and stabilized at the reference temperature. 2) In a separate chamber, the spare unit is powered on and equilibrated at reference temperature with the grain samples. 3) Sample 1 is analyzed once on instrument 1, then once on instrument 2, then once on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until five P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT and grain samples are subjected to the minimum temperature and stabilized. 6) All the cold grain samples are analyzed in turn on both units of the EUT, alternating between the two instruments, until three P_{MB} measurements per grain sample are recorded for each instrument. 7) The samples are retained at the location of the EUT for as long as necessary to equilibrate at the minimum temperature. Each sample is analyzed twice on both units of the EUT again. 8) After ensuring that five P_{MB} measurements on each cold sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 9) Steps 3 – 4 are repeated.
Test result	Values for the error shift on every grain sample are calculated at each test condition for each unit (of the EUT). Error shift (cold) = (Mean P_{MB} condition ii – Mean P_{MB} condition i). Error shift (recovery) = (Mean P_{MB} condition iii – Mean P_{MB} condition i) – Correction*. *Application of a correction is required if a significant change in the sample P_{MB} during cooling and/or recovery is indicated by the sample stability test.
Grain sample stability test and correction	The P_{MB} variation on a grain sample *calculated from measurements on the spare unit* shall be within the limit in R 146-1, 4.5.4, Table 4, column 9 for no correction to apply. Sample P_{MB} variation (recovery) = Mean P_{MB} (condition iii) – Mean P_{MB} (condition i). Any sample P_{MB} variation that exceeds the limit, shall be applied as a correction, e.g.: Sample P_{MB} variation (recovery) = Correction for error shift (recovery).
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.5.3 Dry heat

EUT	Two sample instruments of the submitted type, setup according to A.2.1.
Spare unit	A sample instrument of the submitted type, setup according to A.2.1 and maintained at reference conditions for the duration of the test.
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type. Except during analysis, each sample is kept in its enclosure during the test. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-2 [16], IEC 60068-3-1 [15]
Test method and procedure (in brief)	Test B: Dry heat. The test consists of exposure of the EUT to the specified maximum temperature under "free air" conditions for the specified time. The change of temperature shall not exceed 1 °C/min during heating up and cooling down. The absolute humidity of the test atmosphere shall not exceed 20 g/m^3. When testing is performed at temperatures lower than 35 °C, the relative humidity shall not exceed 50 %. Five P_{MB} measurements on every sample are taken using each unit, at every test condition: i) EUT and grain samples at reference temperature; ii) EUT and grain samples after dry heat exposure; iii) EUT and grain samples after recovery at reference temperature.
Sample monitoring	To ensure that heating and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored throughout the test by a spare unit.
Test severity	Exposure duration (after EUT stabilization): 2 h; Maximum temperature: t_H or 30 ºC. t_H is the maximum temperature in the operating range specified by the national responsible body.
Suggested steps	1) The EUT is powered on and stabilized at reference temperature. 2) In a separate chamber, the spare unit is powered on and equilibrated at reference temperature with the grain samples. 3) Sample 1 is analyzed once on instrument 1, then once on instrument 2, then once on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until five P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT and grain samples are subjected to the maximum temperature and stabilized. 6) All the hot grain samples are analyzed in turn on both units of the EUT, alternating between the two instruments, until five P_{MB} measurements per grain sample are recorded for each instrument. 7) After ensuring that five P_{MB} measurements on each hot sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 8) Steps 3 – 4 are repeated.
Test result	Values for the error shift on every grain sample are calculated at each test condition for each unit (of the EUT). Error shift (dry heat) = (Mean P_{MB} condition ii – Mean P_{MB} condition i). Error shift (recovery) = (Mean P_{MB} condition iii – Mean P_{MB} condition i) – Correction*. *Application of a correction is required if a significant change in the sample P_{MB} during heating and/or recovery is indicated by the sample stability test.
Grain sample stability test and correction	The P_{MB} variation on a grain sample *calculated from measurements on the spare unit*, shall be within the limit in R 146-1,4.5.4, Table 4 column 9 for no correction to apply. Sample P_{MB} variation (recovery) = Mean P_{MB} (condition iii) – Mean P_{MB} (condition i). Any sample P_{MB} variation that exceeds the limit, shall be applied as a correction, e.g.: Sample P_{MB} variation (recovery) = Correction for error shift (recovery).
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in R 146-1,4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.5.4 Damp heat

EUT	Two sample instruments of the submitted type, setup according to A.2.1.
Spare unit	A sample instrument of the submitted type, setup according to A.2.1 and maintained at reference conditions for the duration of the test.
Grain samples	One set from a single grain type comprised of three samples that represent the legally relevant P_{MB} range (i.e. one sample for each low, mid and high P_{MB}). Allowable grains are specified by the national responsible body. Wheat is the preferred grain type. Except during analysis, each sample is kept in its enclosure during the test. The enclosed samples are only introduced to the damp heat 2 hours prior to testing. Samples used in a climatic test shall not be reused in other tests.
Standards	IEC 60068-2-78 [17], IEC 60068-3-4 [18]
Test method and procedure (in brief)	Test Cab: Damp heat, steady state. The test consists of exposure of the EUT to the specified maximum temperature and the specified constant relative humidity for the specified time. The change of temperature shall not exceed 1 °C/min during heating up and cooling down. The absolute humidity of the test atmosphere shall not exceed 20 g/m^3. When testing is performed at temperatures lower than 35 °C, the relative humidity shall not exceed 50 %. Ten P_{MB} measurements on every sample are taken using each unit, at every test condition: i) EUT and grain samples at reference temperature. ii) EUT after damp heat exposure, grain samples at maximum temperature and RH. iii) EUT and grain samples after recovery at reference conditions.
Sample monitoring	To ensure that heating, exposure to moisture and recovery do not change the P_{MB} of grain samples significantly, the grain samples are monitored by a spare unit.
Test severity	Exposure duration (after EUT stabilization): two days; Maximum RH: 85 % Maximum temperature: t_H or 30 ºC. t_H is the maximum temperature in the operating range specified by the national responsible body.
Suggested steps	1) The EUT is powered on and stabilized at reference temperature. 2) In a separate chamber, the spare unit is powered on and equilibrated at reference temperature with the grain samples. 3) Sample 1 is analyzed twice on instrument 1, then twice on instrument 2, then twice on the spare unit. Further P_{MB} measurements are taken across the three units in the same manner, until ten P_{MB} measurements are recorded for each instrument. 4) Step 3 is repeated for the other two grain samples. 5) The EUT is subjected to the maximum temperature and humidity and stabilized. The exposure duration is observed. Two hours prior to the end of the exposure duration, the enclosed grain samples are introduced to damp heat conditions. 6) All the hot grain samples are analyzed in turn on both units of the EUT, alternating between the two instruments, until five P_{MB} measurements per grain sample are recorded for each instrument. 7) The samples are retained at the location of the EUT for as long as necessary to equilibrate at the maximum temperature. Each sample is analyzed five times on both units of the EUT again. 8) After ensuring that ten P_{MB} measurements on each hot sample are recorded for each instrument, the EUT and grain samples are recovered to reference temperature. 9) Steps 3 – 4 are repeated.
Test result	Values for the error shift on every grain sample are calculated at each test condition for each unit (of the EUT). Error shift (damp heat) = (Mean P_{MB} condition ii – Mean P_{MB} condition i). Error shift (recovery) = (Mean P_{MB} condition iii – Mean P_{MB} condition i) – Correction*. *Application of a correction is required if a significant change in the sample P_{MB} during heating and/or recovery is indicated by the sample stability test.
Grain sample stability test and correction	The P_{MB} variation on a grain sample *calculated from measurements on the spare unit*, shall be within the limit in R 146-1, 4.5.4, Table 4, column 9 for no correction to apply. Sample P_{MB} variation (recovery) = Mean P_{MB} (condition iii) – Mean P_{MB} (condition i). Any sample P_{MB} variation that exceeds the limit, shall be applied as a correction, e.g.: Sample P_{MB} variation (recovery) = Correction for error shift (recovery).
Acceptance requirements	All values for the error shift (i.e. with any necessary correction) shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.5.5 AC mains voltage variation

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC/TR 61000-2-1 [19], IEC 61000-4-1 [20]
Test method and procedure (in brief)	Variation in AC mains power voltage. The test consists of exposure of the EUT to the specified power condition for a period sufficient for achieving temperature stability and for performing the required measurements. Ten P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at nominal test voltage (U_{nom}); ii) EUT at the upper voltage limit; iii) EUT at the lower voltage limit; iv) EUT after recovery at nominal test voltage (U_{nom}). *Note*: In case of three phase mains power, the voltage variation shall apply for each phase successively.
Test severity	Stabilizing period after voltage change: 30 min Test voltage upper limit: U_{nom} +10 %; Test voltage lower limit: U_{nom} –15 % The values of U_{nom} are those marked on the measuring instrument. In case a range is specified, the "-" relates to the lowest value and the "+" to the highest value of the testing range.
Suggested steps	The units are tested in sequence at each test condition, i.e. all ten P_{MB} measurements are taken in succession on one unit before the next unit. The order in which the instruments are tested at each condition shall be randomized.
Test result	The error shift on the grain sample is calculated at every voltage setting for each unit. Error shift (high voltage) = Mean P_{MB} (test condition ii) – Mean P_{MB} (test condition i). Error shift (low voltage) = Mean P_{MB} (test condition iii) – Mean P_{MB} (test condition i). Error shift (recovery) = Mean P_{MB} (test condition iv) – Mean P_{MB} (test condition i).
Acceptance requirements	All values for the error shift shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed. The standard deviation of repeat P_{MB} measurements at any voltage level shall not exceed 0.10 %.

A.5.6 Variation in voltage supplied by external 12 V and 24 V road vehicle batteries

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	ISO 16750-2 [21]
Test method and procedure (in brief)	Variation in supply voltage. The test consists of exposure of the EUT to the specified maximum and minimum power supply voltage conditions for a period sufficient for achieving temperature stability and performing the required measurements at these conditions. Ten P_{MB} measurements on the sample are taken using each unit, at every test condition: i) EUT at nominal test voltage (U_{nom}); ii) EUT at the lower voltage limit; iii) EUT at the upper voltage limit; iv) EUT after recovery at nominal test voltage (U_{nom}). The power is switched off after each test condition and switched on at the next test voltage.
Test severity	Stabilizing period after voltage change: 30 min 12 V battery – test voltage lower limit: 9 V, test voltage upper limit: 16 V. 24 V battery – test voltage lower limit: 16 V, test voltage upper limit: 32 V. The values of U_{nom} are those marked on the measuring instrument.
Suggested steps	The units are tested in sequence at each test condition, i.e. all ten P_{MB} measurements are taken in succession on one unit before the next unit. The order in which the instruments are tested at each condition shall be randomized.
Test result	The error shift on the grain sample is calculated at every voltage setting for each unit. Error shift (low voltage) = Mean P_{MB} (test condition ii) – Mean P_{MB} (test condition i). Error shift (high voltage) = Mean P_{MB} (test condition iii) – Mean P_{MB} (test condition i). Error shift (recovery) = Mean P_{MB} (test condition iv) – Mean P_{MB} (test condition i).
Acceptance requirements	All values for the error shift shall be within the limit in R 146-1, 4.5.4, Table 4, column 9. All operational functions shall operate as designed.

A.6 Tests for disturbances

A.6.1 AC mains voltage dips, short interruptions and voltage variations

EUT	One sample instrument of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-11 [22], IEC 61000-6-1 [23], IEC 61000-6-2 [24]
Test method	Short-time reductions in mains voltage
Test procedure (in brief)	Over four tests, the EUT is subjected to voltage reductions and interruptions of varying intensity and duration. A test generator suitable to reduce the amplitude of the AC mains voltage for a defined period of time is used. The performance of the test generator shall be verified before connecting to the EUT. The mains voltage interruptions and reductions shall be repeated with a time interval less than the time required for a single measurement so that at least one voltage interruption occurs per measurement. At least 10 cycles are necessary for each test to enable the required number of measurements. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while ten P_{MB} measurements are taken at every test condition.
Test severity	Test condition a) U_{nom} to zero for a duration equal to half a cycle of frequency. Test condition b) U_{nom} to zero for a duration equal to one cycle of frequency. Test condition c) U_{nom} to 70 % of U_{nom} for a duration equal to 25/30* cycles of frequency. Test condition d) U_{nom} to zero for a duration equal to 250/300* cycles of frequency. *Values are for 50 Hz and 60 Hz respectively.
Test result	The fault on each P_{MB} measurement is calculated with the mean of five P_{MB} measurements at reference conditions as the reference P_{MB} value. For example: Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16 is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.6.2 Bursts (transients) on AC mains

EUT	One sample instrument of the submitted type
Grain sample	One sample with mid-range P_{MB} stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-1 [20], IEC 61000-4-4 [25]
Test method	Electrical bursts
Test procedure (in brief)	The test consists of subjecting the EUT to bursts of double exponential waveform transient voltages. All bursts shall be applied during the same measurement in symmetrical mode and asymmetrical mode. The characteristics of the burst generator shall be verified before connecting the EUT. The duration of the test shall not be less than 1 min for each amplitude and polarity. The injection network on the mains shall contain blocking filters to prevent the burst energy being dissipated in the mains. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while at least ten P_{MB} measurements on the sample are taken with the bursts applied.
Test severity	Amplitude (peak value): 1 kV; Repetition rate: 5 kHz Number of test cycles: At least 10 positive and 10 negative randomly phased bursts shall be applied at 1000 V. The bursts are applied during all the time necessary to perform a measurement.
Test result	The fault on each P_{MB} measurement is calculated with the mean of five P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16 is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.6.3 Radiated radiofrequency, electromagnetic fields

EUT	One sample instrument of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-3 [26]
Test method	Radiated, radio-frequency, electromagnetic field immunity test
Test procedure (in brief)	The test consists of exposure of the EUT to electromagnetic field strength as specified by the severity level and field uniformity as defined by the referred standards. The specified field strength shall be established prior to the actual testing (i.e. without the EUT in the field). a) the strip line is used at low frequencies (below 30 MHz or in some cases 150 MHz) for small EUT; b) the long wire is used at low frequencies (below 30 MHz) for larger EUT; c) dipole antennas or antennas with circular polarization placed at least 1 m from the EUT are used at high frequencies. The field shall be generated in two orthogonal polarizations and the frequency range shall be scanned slowly. If antennas with circular polarization (i.e. log-spiral or helical antennas) are used to generate the electromagnetic field, a change in the position of the antennas is not required. When the test is carried out in a shielded enclosure to comply with international laws prohibiting interference on radio communications, care needs to be taken to handle reflections from the walls. The frequency ranges to be considered are swept with the modulated signal, pausing to adjust the RF signal level or to switch oscillators and antennas as necessary. Where the frequency range is swept incrementally, the step size shall not exceed 1 % of the preceding frequency value. The dwell time of the amplitude modulated carrier at each frequency shall not be less than the time necessary for the EUT to be exercised and to respond, but shall in no case be less than 0.5 s. The sensitive frequencies (e.g. clock frequencies) shall be analyzed separately. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages). As many P_{MB} measurements as possible are taken over the sweep across the frequency range.
Test severity	EM frequency range: 26* MHz to 2 GHz; Field strength: Radiated 10 V/m Modulation: 80 % AM, 1 kHz sine wave *For the frequency range 26 MHz to 80 MHz, the testing laboratory may carry out the test according to A.6.4.
Test result	The fault on each P_{MB} measurement is calculated with the mean of five P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16, is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.6.4 Conducted radio-frequency electromagnetic fields

EUT	One sample instrument of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-6 [27]
Test method	Immunity to conducted disturbances, induced by radio-frequency fields
Test procedure (in brief)	The test procedure involves the use of radio frequency EM current, simulating the influence of EM fields coupled or injected into the power ports and I/O ports of the EUT using coupling/decoupling devices as defined in the referred standard. The performance of the test equipment consisting of an RF generator, de-coupling devices, attenuators, etc. shall be verified. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while at least ten P_{MB} measurements on the sample are taken with the conducted radio-frequency fields applied.
Test severity	EM frequency range: 0.15 MHz to 80* MHz; RF amplitude (50 Ω): 10 V (e.m.f) Modulation: 80 % AM, 1 kHz sine wave *For the frequency range 26 MHz to 80 MHz, the testing laboratory may carry out the test according to A.6.3. However, in case of dispute, the result from the test according to A.6.4 shall prevail.
Test result	The fault on each P_{MB} measurement is calculated with the mean of five P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16 is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.6.5 Electrostatic discharges

EUT	One sample instrument of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 61000-4-2 [28]
Test method	Section 2: Electrostatic discharge (ESD) immunity test
Test procedure (in brief)	A capacitor of 150 pF is charged by a suitable DC voltage source. The capacitor is then discharged through the EUT by connecting one terminal to ground (chassis) and the other via 330 Ω to surfaces which are normally accessible to the operator. The test includes the paint penetration method, if appropriate. For direct discharges, the air discharge shall be used where the contact discharge method cannot be applied. Before starting the tests, the performance of the ESD generator shall be verified. For EUT not equipped with a ground terminal, the EUT shall be fully discharged between discharges. Direct application: In the contact discharge mode to be carried out on conductive surfaces, the electrode shall be in contact with the EUT. In the air discharge mode on insulated surfaces, the electrode is approached to the EUT and the discharge occurs by spark. Indirect application: The discharges are applied in the contact mode to coupling planes mounted in the vicinity of the EUT. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages) while at least ten P_{MB} measurements on the sample are taken with the discharges applied.
Test severity	Air discharge voltage: 2, 4, 6 and 8 kV; Contact discharge voltage: 2, 4, and 6 kV. Number of test cycles: At least one direct discharge and one indirect discharge shall be applied during the one measurement. The time interval between successive discharges shall be at least 10 seconds.
Test result	The fault on each P_{MB} measurement is calculated with the mean of five P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (during disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16 is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.6.6 Storage temperature (extreme shipping conditions)

EUT	Two or more sample instruments of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Test procedure (in brief)	1) The EUT is placed in the environmental chamber. 2) After the specified warm-up period, a series of P_{MB} measurements is taken – alternating between the units after each single measurement – until ten P_{MB} measurements are recorded for each instrument. Power off the EUT. 3) The chamber temperature is then increased to maximum temperature over a 1 hour period and maintained at that temperature for 3 hours. 4) The chamber temperature is then decreased to minimum temperature over a 1 hour period and maintained at that temperature for 3 hours. 5) The temperature cycle is repeated. 6) The EUT is equilibrated under reference conditions for at least 12 hours unpowered. 7) After the specified warm-up period, a series of P_{MB} measurements is taken again – alternating between the units after each single measurement – until ten P_{MB} measurements are recorded for each instrument. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages).
Test severity	Minimum temperature: –20 ºC; Maximum temperature: 55 ºC or a lower temperature specified by the national responsible body.
Test result	The fault on each P_{MB} measurement is calculated with the mean of ten P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (after disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16 is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.6.7 Random vibration

EUT	One sample instrument of the submitted type
Grain sample	One sample with mid-range P_{MB} and stable moisture content. Allowable grains are specified by the national responsible body. Wheat is the preferred grain type.
Standards	IEC 60068-2-47 [29], IEC 60068-2-64 [30], IEC 60068-3-8 [31]
Test method	Exposure to random vibration
Test procedure (in brief)	The EUT shall be mounted on a rigid fixture by its normal mounting means so that the gravitational force acts in the same direction as it would in normal use. After having been switched off, vibrations shall be applied in three mutually perpendicular axes for at least two minutes per axis. After the vibrations, the EUT is switched on and the warm-up period is observed. A series of P_{MB} measurements is taken until ten P_{MB} measurements are recorded. The functional performance of the EUT is observed (e.g. displayed indications and/or error messages).
Test severity	Vibration duration per axis: 1 h; Total frequency range: 10 Hz to 150 Hz; Total RMS level: 7 ms^{-2}; ASD level 10 Hz to 20 Hz: 1 m^2s^{-3}; ASD level 20 Hz to 150 Hz: – 3 dB/octave.
Test result	The fault on each P_{MB} measurement is calculated with the mean of five P_{MB} measurements at reference conditions as the reference P_{MB} value. Fault = P_{MB} measured value (after disturbance) – Mean P_{MB} prior test. Exemption from the definition of a significant fault in R 146-1, 2.2.16 is considered for any values of fault exceeding the limit in R 146-1, 4.5.4, Table 4, column 10.
Acceptance requirements	One of the following shall be fulfilled: 1) The effect of the disturbance shall not exceed a significant fault and all operational functions shall operate as designed. 2) The instrument shall detect and react to a significant fault by either an error message or blanking the display (see R 146-1, 5.1.1).

A.7 Assessment of calibrations in the submitted type

A.7.1 Accuracy and precision at reference conditions

Grain sample sets	To evaluate each submitted P_{MB} calibration, a set of test samples comprised of at least 30 different whole-grain CRMs is required. The samples in each set shall represent the grain in the scope of the calibration under test. The P_{MB} values shall evenly cover the full measurement range specified for the type of grain (see R 146-1, 4.1), i.e. there shall be a near equal number of samples in each of the following intervals: low P_{MB}, medium P_{MB}, and high P_{MB}. Whole-grain reference materials (RMs) with indicative P_{MB} values that are later assigned a P_{MB} value using the reference method (i.e. certified) are also permitted. Each RM sample shall be large enough to divide into two portions – one portion sufficient for the instrument and another portion sufficient for reference method analysis. Assessment and control of spatial inhomogeneity in the larger sample is paramount in this approach. One grain sample set is adequate for testing a calibration on at least two sample units of the submitted type.
Test procedure – suggested steps	As two sample units of the submitted type are tested simultaneously, references to the EUT mean both instruments. Prior to assessing the calibrations, the EUT may be adjusted so that the intrinsic error is as close to zero as possible. Each set of test samples representing one grain type (GT) submitted for approval will be tested entirely in succession. 1) The EUT is powered on and allowed to equilibrate under reference conditions with the grain samples. 2) The first sample in the set for grain type 1 (GT1) is opened and if it is not a CRM, a portion of the RM is put aside for reference method analysis. 3) The remainder of first test sample of GT1 is analyzed with the EUT, alternating between the units after each single measurement, until three measurements are recorded for each instrument. 4) Steps 2 – 3 are repeated on the remaining test samples in the set (i.e. other GT1 samples). 5) If applicable, steps 2 – 4 are repeated on the remaining sets, (i.e. GT2, GT3, etc.). 6) If RMs are used in place of CRMs, reference P_{MB} values are obtained for RM portions segregated in step 2.
Result: Accuracy test – average bias of mean and *SEP*	The extent of inaccuracy is indicated by the error of P_{MB} values averaged over all the samples in the set, $\bar{y}$, together with the standard error of prediction, *SEP*, which is the standard deviation of the measurement error on each sample. An improved estimation of $\bar{y}$ (also known as the 'calibration bias') is possible by using the mean P_{MB} in the calculation of y for each sample. For the *SEP*, only a single P_{MB} value (the first, j=1) from each sample is considered in the error calculation to emulate conventional measurements. $\bar{y} = \frac{1}{n}\sum_{i=1}^{n} y_i$ **Equation 1** $SEP = \sqrt{\frac{\sum_{i=1}^{n}\left(y_{i,j=1} - \bar{y}_{i,j=1}\right)^2}{n-1}}$ **Equation 2** where: $y_i = \bar{x}_i - r_i$ $\bar{x}_i = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}$ (i.e. the mean of 3 measurements on sample i, under repeatability conditions) $y_{i,j=1} = x_{i,j=1} - r_i$ (i.e. the error on first P_{MB} measurement on sample i) $\bar{y}_{i,j=1} = \frac{1}{n}\sum_{i=1}^{n} y_{i,j=1}$ r_i = certified P_{MB} value for sample i $x_{i,j=1}$ = first P_{MB} measurement on the sample i n = number of samples in the set (30 CRMs minimum)
Result: Instrument repeatability test – Averaged SD of replicates	The repeatability of a measurement is indicated by the standard deviation, *SD*, of the 'three replicates' (three measurements performed under repeatability conditions). The repeatability of an instrument with a particular calibration is assessed by averaging the *SD* across all the samples in the set (refer to Equation 3).

	$\overline{SD} = \sqrt{\frac{\sum_{i=1}^{n}\sum_{j=1}^{3}\left(x_{i,j} - \bar{x}_i\right)^2}{2n}}$ **Equation 3** where: $x_{i,j}$ = measured P_{MB} value for sample i and replicate j, $\bar{x}_i = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}$ (i.e. the mean of 3 measurements on sample i, performed under repeatability conditions) n = number of samples in the set (30 CRMs minimum)
Result: Instrument reproducibility test – *SD* of differences between two instruments	Reproducibility between two instruments with the same calibration is assessed by calculating the standard deviation of differences, SDD_I (refer to Equation 4). Variations in the performance of both units are minimized under reference conditions, therefore the calculated value of SDD_I is expected to be the lowest possible for the type of instrument. $SDD_I = \sqrt{\frac{\sum_{i=1}^{n}\left(d_i - \bar{d}\right)^2}{n-1}}$ **Equation 4** where: $\bar{d} = \frac{1}{n}\sum_{i=1}^{n} d_i$ $d_i = \bar{x}_i^{(1)} - \bar{x}_i^{(2)}$ $\bar{x}_i^{(1)} = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}^{(1)}$ (i.e. the mean of 3 measurements on sample i, on instrument 1) $\bar{x}_i^{(2)} = \frac{1}{3}\sum_{j=1}^{3} x_{i,j}^{(2)}$ (i.e. the mean of 3 measurements on sample i, on instrument 2) n = number of samples in the set (30 CRMs minimum)
Acceptance requirements	Values for the following shall not exceed the following limits in R 146-1, 4.5.4, Table 4. $\bar{y}$ (Equation 1) and *SEP* (Equation 2) – the limits in columns 4 and 5 respectively. Averaged *SD* (Equation 3) – the limit in column 6. SDD_I (Equation 4) – the limit in column 7.

A.7.2 Sample temperature sensitivity (STS)

EUT	Two sample instruments of the submitted type setup according to A.2.1.
Grain samples	One set for each P_{MB} calibration (grain type) submitted for approval. A set is comprised of six samples that represent the legally relevant P_{MB} range at two moisture levels (i.e. a low and high moisture sample in each low, mid and high P_{MB} ranges). Except during analysis, each sample is kept in its enclosure during the test. Samples used to test STS shall not be reused in other tests. *Note*: A duplicate sample set is recommended in case of retesting at a later date (following recalibration or modification due to a failed STS).
Test procedure (in brief)	Three P_{MB} measurements on every sample are taken using each unit, at every test condition: i) Grain samples at the reference temperature, $t_{ref}^{(1)}$ ii) Grain samples cooled to $t_{ref} - \Delta t_{C,max}$ iii) Grain samples recovered to the reference temperature, $t_{ref}^{(2)}$ iv) Grain samples heated to $t_{ref} + \Delta t_{H,max}$ v) Grain samples recovered to the reference temperature, $t_{ref}^{(3)}$ *Note*: The EUT is maintained at t_{ref} for the duration of the test.
Test severity (sample and instrument temperatures)	Sample temperature: $t_{ref} \pm \Delta t_{max}$ where: Δt: magnitude of the temperature difference between a sample and an instrument at t_{ref} Δt_{max}: maximum Δt specified by the national responsible body for type testing $\Delta t_{C,\,max}$: maximum permitted Δt_{max} below t_{ref} (if unequal to $\Delta t_{H,\,max}$) $\Delta t_{H,\,max}$: maximum permitted Δt_{max} above t_{ref} (if unequal to $\Delta t_{C,\,max}$)

	$t_{ref} + \Delta t_H < 45$ °C, however, the Δt_H and Δt_C need not be equal.
Suggested steps	1) The EUT is powered on and equilibrated at reference conditions with the grain samples. 2) Sample 1 of grain type 1 (GT1) is analyzed, alternating between the units after each single measurement, until three P_{MB} measurements are recorded for each instrument. 3) Step 2 is repeated for the remainder of the sample set (i.e. other GT1 samples, followed by all GT2 samples, ending with GT4). 4) All the grain samples are placed in the environmental cabinet set at $t_{ref} - \Delta t_{C,max}$ and allowed equilibrate for at least four hours. 5) A cold GT1 sample 1 is removed from the cabinet and temperature is checked using a thermometer. The grain sample must be within ± 2 °C of the target temperature before analyzing once on instrument 1. 6) GT1 sample 1 is returned to the cabinet. GT1 sample 2 is analyzed once on instrument 2. *Note*: Each instrument is given 10 min to equilibrate to ambient conditions before the next sample is analyzed. 7) In order to efficiently analyze all the samples, all the odd numbered samples are analyzed on instrument 1 and all the even numbered samples on instrument 2 starting with GT1, followed by GT2, ending with GT4 (cycle 1). GT1 samples should be reconditioned to the target temperature by the time GT4 samples analyzes are completed. *Note*: If there are less than four grain types, samples may require additional time to equilibrate in the cabinet to before further testing. Sample temperatures are checked before analysis. All the odd numbered samples are then analyzed on instrument 2 and the even numbered samples on instrument 1 (cycle 2) to complete one measurement of the all the cold samples on both instruments. Cycle 1 and cycle 2 are repeated (twice) until three P_{MB} measurements on every cold sample are recorded for each instrument. 8) After all the cold analyses are performed, the grain samples are equilibrated (recovered) at reference conditions for at least four hours. 9) Steps 2 – 3 are repeated. 10) All the grain samples are placed in the environmental cabinet set at $t_{ref} + \Delta t_{H,max}$ and allowed to equilibrate for at least four hours. 11) All the hot grain samples are analyzed using the same test sequence applied for the cold samples in step 7. 12) After three P_{MB} measurements on every hot sample are recorded for each instrument, the grain samples are equilibrated (recovered) at reference conditions for at least 4 hours. 13) Steps 2 – 3 are repeated.
Test result	For each instrument, values for the average error shift are calculated at the high and low moisture levels for every grain type by averaging the measured values from 3 samples. Two values of the average error shift are calculated at each level of moisture based on the following differences: $\Delta t_{C,max}$ average error shift = Mean P_{MB} 3 cold samples – Mean P_{MB} 3 samples at $t_{ref}^{(1)}$ & $t_{ref}^{(2)}$ $\Delta t_{H,max}$ average error shift = Mean P_{MB} 3 hot samples – Mean P_{MB} 3 samples at $t_{ref}^{(2)}$ & $t_{ref}^{(3)}$ Four values of averaged error shift are calculated for each grain type.
Acceptance requirements	All values for the average error shift shall be within the limit in R 146-1, 4.5.4, Table 4, column 8. All operational functions shall operate as designed.
Grain sample stability check	To ensure that thermal processing and recovery are not changing the P_{MB} of grain samples significantly, the P_{MB} variation in the grain samples, shall be within the limit in Table 4, column 9. Sample variation (1st recovery) = Mean P_{MB} sample at $t_{ref}^{(2)}$ – Mean P_{MB} sample at $t_{ref}^{(1)}$ Sample variation (2nd recovery) = Mean P_{MB} sample at $t_{ref}^{(3)}$ – Mean P_{MB} sample at $t_{ref}^{(2)}$

Annex B
Software examination
(Mandatory)

Further details are included in OIML R 146-3 *Test report format*.

Refer to OIML D 31:2008, 6.3.2 for the specific items of interest associated with the following validation methods recommended for a grain protein measuring instrument:

AD – Analysis of documentation and specification and validation of the design [OIML D 31:2008, 6.3.2.1]

VFTM – Validation by functional testing of the metrological functions [OIML D 31, 6.3.2.2]

VFTSw – Validation by functional testing of the software functions [OIML D 31, 6.3.2.3]

Refer to Welmec Guide 7.2 [32] for a systematic method of checking the submitted software documentation.

Software and security checks in R 146	OIML D 31:2008 reference	Validation method(s)
6.1 Specification of the software requirements		
6.1.1 – Description of how software is implemented	--	AD
6.1.2 – Software identification	5.1.1	AD + VFTSw
6.1.3 – Correctness of algorithms and functions	5.1.2	AD + VFTM
6.1.4 – Conformity of manufactured devices to the approved type (validation during type evaluation is optional)	5.2.5	AD + VFTSw
6.1.5 – Support of fault detection	5.1.4.1	AD + VFTSw
6.1.6 – Separation of software parts	5.1.2.1	AD
6.1.7 – Compatibility of operating systems and hardware	5.2.4	AD + VFTSw
6.1.8 – Specification of national requirements for recording of the measurement data.	--	--
6.1.9 – Specification of national requirements for measurement data used at another place or time via an insecure environment.	--	--
6.2 Data storage		
6.2.1 – Automatic storing	5.2.3.4.a	AD + VFTSw
6.2.2 – Storage of necessary measurement information	5.2.3.1	AD + VFTSw
6.3 Data transmission		
6.3.1 – Protection to ensure authenticity, integrity and correctness 6.3.2 – Cryptographic means of data protection may be required*.	5.2.3.2	AD + VFTSw (+ SMT)
6.3.3 – Transmission delay	5.2.3.5	AD + VFTSw
6.3.4 – Transmission interruption	5.2.3.6	AD + VFTSw

6.4 Provision for software and calibration security		
6.4.1 – Sealing	5.1.3.2.d	AD + VFTSw
6.4.2 – Fraud protection	5.1.3.2.a - c	AD + VFTSw
6.5 Software documentation	6.1.1	--
9.4 Maintenance and reconfiguration of the approved software		
Requirements for traced updates (if permitted)	5.2.6.2	AD + VFTSw
9.5 In-field updates to grain calibrations		
9.5.3 – Security of calibrations and reverification	5.2.6.1 and/or 5.2.6.2	AD + VFTSw

*More intensive examination such as software module testing (SMT) may be required by the national responsible body if it mandates cryptographic means of data protection in instruments that are allowed to be used in open networks.