INTERNATIONAL STANDARD

ISO 19614

First edition
2017-05

Traditional Chinese medicine — Pulse graph force transducer

Médecine traditionnelle chinoise — Transducteur d'intensité du pouls

Reference number
ISO 19614:2017(E)

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Foreword

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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Traditional Chinese medicine — Pulse graph force transducer

1 Scope

This document specifies the technical requirements, classification and test method for a pulse graph force transducer, hereafter referred to as transducer.

It only applies to pulse graph acquisition over the patient's radial artery based on TCM pulse condition requirements.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

IEC 60068-2-6, *Environmental testing — Part 2-6: Test Fc: Vibration (sinusoidal)*

IEC 60068-2-14, *Environmental testing — Part 2-14: Tests — Test N: Change of temperature*

IEC 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
pulse graph force transducer
transducer that can detect pulsation of the radial artery and its peripheral tissues as a mechanical quantity and convert it into an electrical signal output according to a certain pattern for the purpose of TCM pulse condition acquisition

Note 1 to entry: Transducers involved in this document only refer to pressure or force transducers.

3.2
calibration
process of recording input/output data through applied standard mechanical quantities to determine the performance of transducers

Note 1 to entry: The calibration unit of transducers may be the unit of either pressure or force.

3.3
radial artery pulse graph
pulse graph
electrical signal waveform converted from peripheral vascular pulsation at the radial artery, expressed in time-amplitude coordinates, hereafter referred to as pulse graph

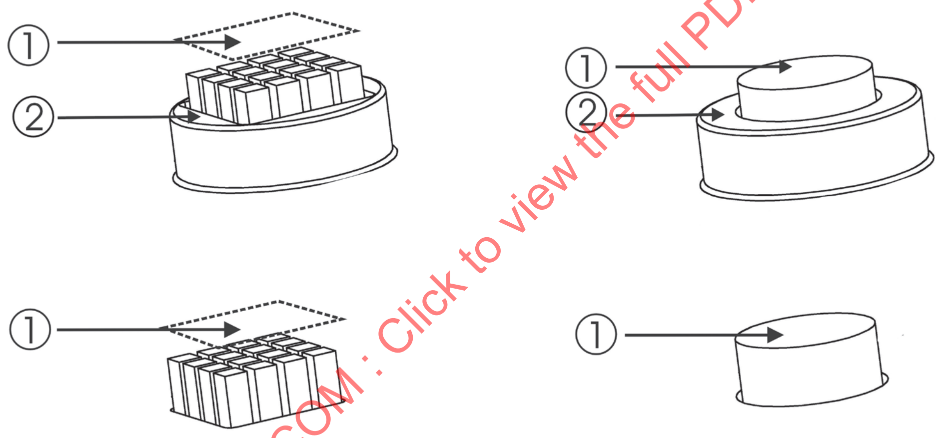
3.4
effective plane
plane of transducers with the sensitivity during radial artery pulsation acquisition

Note 1 to entry: See Figure 1.

3.5
auxiliary plane
plane with no sensitivity and lower than the *effective plane* (3.4) of transducers

Note 1 to entry: See Figure 1.

3.6
applied plane
contact plane of transducers with patients during pulse graph acquisition, including the *effective plane* (3.4) and *auxiliary plane* (3.5)



a) Array transducer **b) Single transducer**

Key

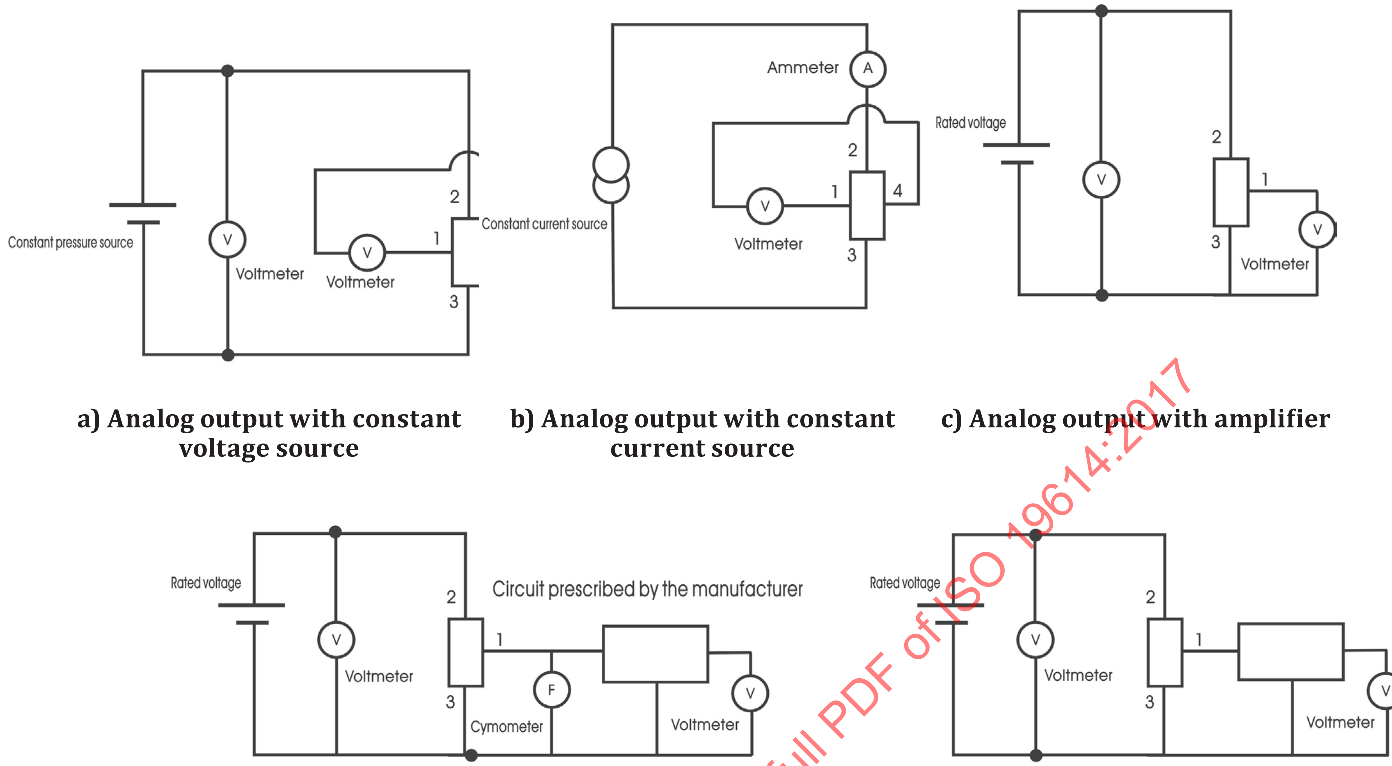
1 effective plane

2 auxiliary plane

Figure 1 — Effective plane, auxiliary plane of transducers

3.7
output quantity
electrical signal quantity produced by a transducer, which is a function of a measurand

Note 1 to entry: See Figure 2.



a) Analog output with constant voltage source **b) Analog output with constant current source** **c) Analog output with amplifier**

d) Frequency output **e) Digital or other forms of output**

Key

1 output+
2 input+
3 input-
4 output-

NOTE 1 The output format includes analog output (e.g. a continuous function of a measurand such as changes in voltage amplitude, voltage ratio, and capacitance) which can be classified into amplified and unamplified.

NOTE 2 Frequency output (i.e. the number of cycles or pulses per second as a function of a measurand) and frequency-modulated output (i.e. frequency deviation from a centre frequency) are also forms of analog output.

NOTE 3 Another output format is digital output which represents a measurand in the form of discrete quantities coded in a system of notation (e.g. binary code).

Figure 2 — Different transducers

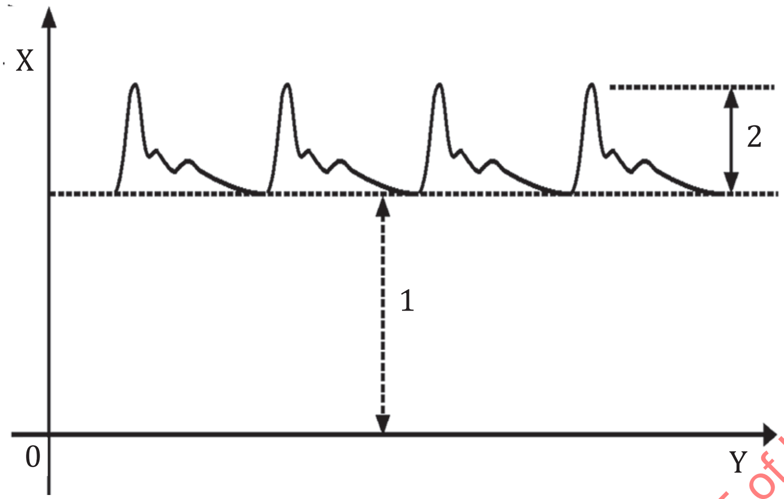
3.8
resistive bridge transducer
transducer receiving *excitation* (3.11) from alternating or direct electrical energy, the output of which is directly proportional to the product of the applied mechanical quantities and excitation

3.9
static signal
electrical signal transferred from the applied force

Note 1 to entry: See Figure 3.

3.10
dynamic signal
electrical signal transferred from pulsation at the radial artery and its peripheral tissues detected

Note 1 to entry: See Figure 3.



Key
X amplitude
Y time
1 static signal
2 dynamic signal

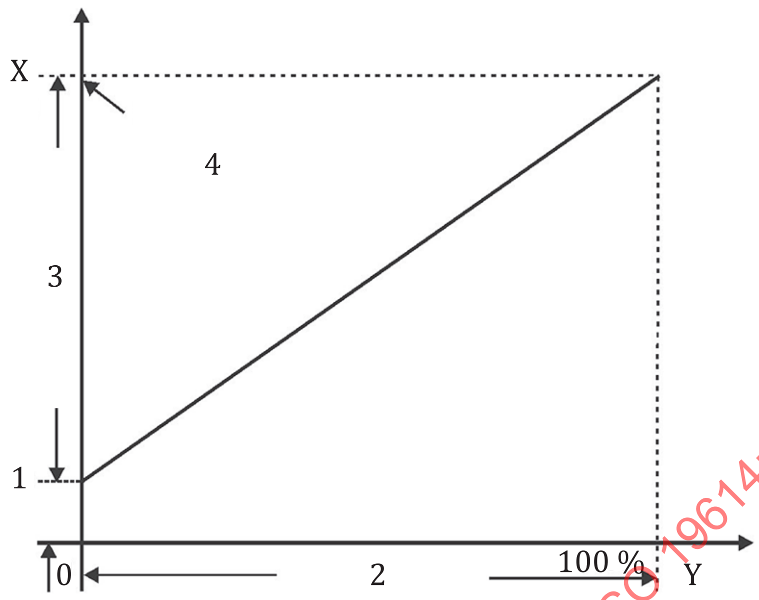
Figure 3 — Static signal and dynamic signal

3.11
excitation
external energy (voltage or current) applied to a transducer for its proper operation

3.12
measuring range
set of values for a measurand for which the error of the transducer is intended to lie within specified limits

Note 1 to entry: See Figure 4.

[SOURCE: IEC 60747-14-1:2010, 3.2.11]



Key

X output (e.g. voltage)
Y measurand (e.g. force)
1 offset
2 measuring range
3 full scale span (FSS)
4 full scale output (FSO); FSO = FSS + offset

Figure 4 — Output-measurand relationship of a linear-output sensor with an offset

3.13
full scale span
FSS
algebraic difference between the end-points of the transducer output

Note 1 to entry: The upper limit of the transducer output over the *measuring range* (3.12) is called the full scale output (FSO). This signal is the sum of the offset signal plus the full scale span.

[SOURCE: IEC 60747-14-1:2010, 3.2.4]

3.14
linearity
closeness between the *calibration* (3.2) curve and a specified straight line of the transducer

Note 1 to entry: This document adopts the end-point or terminal linearity. There are two methods for calculating linearity: end-point straight line fit or a least squares best line fit. While a least squares fit gives the “best case” linearity error, the calculations required are burdensome. Conversely, an end-point fit will give the “worst case” error and the calculations are more straightforward for the user. The result is called the end-point or terminal linearity.

[SOURCE: IEC 60747-14-1:2010, 3.2.7]

3.15
rated load
load value assigned to the transducer by the manufacturer

3.16
stability
ability of a transducer to maintain its performance characteristics for a certain period of time

Note 1 to entry: Stability is the ability of a transducer to reproduce output readings, obtained during the original calibration, and under constant room conditions, for a specified period of time. It is typically expressed as a percentage of FSO.

[SOURCE: IEC 60747-14-1:2010, 3.2.24]

3.17
hysteresis
maximum difference in output, at any measurand value, within the *measuring range* (3.12) when the value is approached first with an increasing and then a decreasing measurand

Note 1 to entry: Hysteresis is expressed in percent of FSO during one calibration cycle.

[SOURCE: IEC 60747-14-1:2010, 3.2.5]

3.18
drift
undesired change in transducer output, which is irrelevant to the measurand, caused by temperature change at a certain time interval

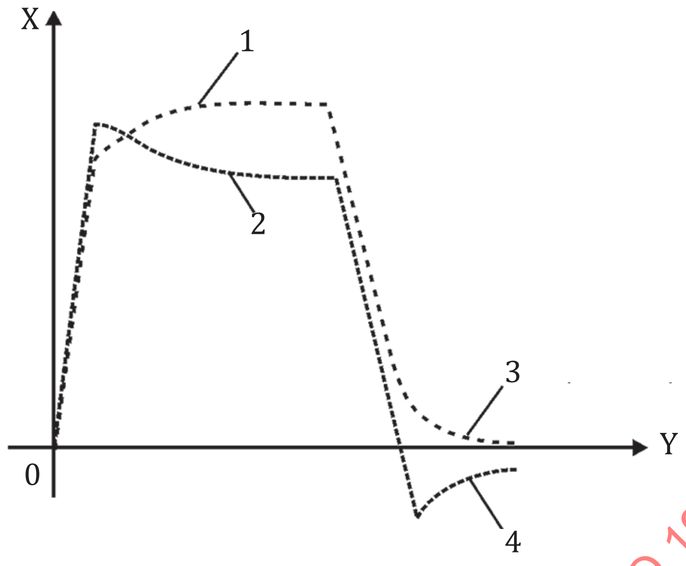
3.19
repeatability
ability of a transducer to reproduce output readings at room temperature, when the same measurand is applied to it consecutively, under the same conditions and in the same direction

[SOURCE: IEC 60747-14-1:2010, 3.2.17]

3.20
eccentricity
consistency among measurement values of different points applied with identical mechanical quantity on the same *effective plane* (3.4) of the tested transducer under the same measuring conditions

3.21
creep
change in *output quantity* (3.7) within a specified time when applying a measurand to the transducer quickly and then keeping all other external conditions constant

Note 1 to entry: See Figure 5.



Key

X output
Y time
1 positive creep
2 negative creep
3 positive creep recovery
4 negative creep recovery

Figure 5 — Creep and creep recovery

3.22
input resistance
resistance measured across the *excitation* (3.11) terminal of the transducer

Note 1 to entry: It is sometimes called “excitation resistance”.

3.23
output resistance
effective resistance across the output terminals of the transducer presented to the associated external circuit

Note 1 to entry: It is sometimes called “signal resistance”.

3.24
testing mechanical quantity generator
apparatus which may generate force or pressure to test radial artery mechanical transducer

4 Symbols

Table 1 — Symbols

No.	Letter symbol	Description	Unit
1	R_i	Input resistance	Ω
2	R_o	Output resistance	Ω
3	F_n	Rated load	N , kPa
4	FSO	Full scale output	μV, mV , V , Hz , PF
5	FSS	Full scale span	μV, mV , V , Hz , PF
6	FS	Full scale span error	% FSS
7	C	Effective plane	mm^2
8	V_{off}	Offset	μV, mV , V , Hz , C
9	L	Terminal linearity error	% FSS
10	H	Hysteresis	% FSS
11	R	Repeatability	% FSS
12	Cp	Creep	% FSS
13	Sz	Eccentricity	% FSS
14	Ov	Overload capacity	% F_n
15	Zs	Offset stability	% FSS
16	Zt	Offset temperature drift	%/ FSS °C
17	St	Sensitivity temperature drift	%/ FSS °C
18	Y	Output independence	%

NOTE The symbols for the actual detection value during the test are formed by adding a lowercase *m* before the symbols specified in this table. For example, the symbol of the actual detected offset is expressed as mV_{off}.

5 Classification

Transducer shall be classified into two types based on the structures (see Annex A):

a) Type A transducer: single transducer;

b) Type B transducer: array transducer.

6 Test conditions and preparation

6.1 Test conditions

6.1.1 Environmental conditions

Tests are carried out within the range of environmental conditions specified in 6.1.1, unless otherwise specified by the manufacturer. Where ambient temperatures cannot be maintained and the test conditions are to be consequently modified, the results are adjusted accordingly:

a) an ambient temperature range of 25 °C ± 3 °C;

b) a relative humidity range of 30 % to 80 %, (non-condensation);

c) an atmospheric pressure range of 86 kPa to 106 kPa.

6.1.2 Loading condition

The transducer shall be installed using fixing device to make the intersection angle between the load direction and the main axis of the transducer not greater than 0,3°.

6.1.3 Preconditioning

The transducer shall be stored at least 4 h under the environmental conditions specified in 6.1.1.

6.1.4 Warm-up

Before the test, the transducer under test shall be warmed up.

6.2 Preparation

According to the different transducer types, the test equipment and the tested transducer are linked as per Figure 3, and the output mechanical quantities are imposed on the effective surface of the transducer by testing the mechanical quantity generator.

a) The rated load F_n is imposed on the transducer three times and zero load is returned to after each loading. The rated load is maintained for a period of 10 s each time.

b) Forward stroke: The load on the transducer is imposed in uniform steps from zero load to the rated load (i.e. 0 %, 20 %, 40 %, 60 %, 80 % and 100 % of the rated load). The output voltage value is read after the loading at every point is stabilized.

c) After the rated load is reached, the load is increased to 105 % rated load and maintained for 10 s before being reduced back to the rated load. After the load is stabilized, the output value is read as the output value of the rated load on the backward stroke.

d) Backward stroke: Following the reduction back to rated load, a tapered load is imposed with the same decrement as specified in 6.2 b). The output value is then read after the loading at every point is stabilized.

e) Zero load is returned to and the offset value is read after an interval of 5 s;

f) The procedures in b) to e) are repeated at an interval of not less than 1 min and this is repeated three times.

g) The working straight line is calculated according to the test result. This document specifies that the terminal point linearity of the measured value acts as the working straight line.

h) $\overline{mV_{\text{off}}}$ and $\overline{mFSO}$ are mean values calculated from six corresponding measured values obtained from three testing cycles.

i) According to the obtained result, the corresponding values of Type A and Type B transducers are calculated using the following formula described in Clause 7.

7 Requirements

7.1 Labelling

7.1.1 Product marking

Products shall be conspicuously and permanently marked with (including but not limited to):

a) a model or type reference;

b) a serial number or lot or batch identifier;

c) marking of connections or terminal (e.g. positive pole and negative pole of excitation voltage, and output terminal).

Compliance is checked by inspection.

7.1.2 Technical description

Each transducer shall be provided with technical description or, where multiple items are ordered, the descriptions may be provided as required. The technical description shall at least include the following information:

a) function information of connecting conductor or terminal at the output terminal;

b) the rated load of transducer;

c) the geometric dimension of the effective plane and the auxiliary plane (if applicable) with the group (children or adults) applicable to such geometric dimensions;

d) environmental conditions for operation and storage;

e) parameters of transducer: overall dimension, installation dimension, outgoing line length, weight, temperature characteristic and performance parameters listed in Clause 4;

f) fatigue life of transducer;

g) name and specification/model of the materials to which the patient may be exposed to;

h) a warning statement to the effect: “WARNING: To avoid acute impact on the effective surface while the transducer is in use.”;

i) details and precautions about cleaning and disinfection methods that may be used;

j) digital protocol for output in terms of digital quantity;

k) name and address of manufacture and acceptable customer service organization.

Compliance is checked by inspection of the technical description.

7.2 Rated load (F_n)

Disclosure shall be made of the rated load of transducer in technical description which:

a) for rated load of units of Type A transducer, F_n shall be at least 93 kPa;

b) for rated load of units of Type B transducer F_n shall be at least 93 kPa.

Compliance is checked by inspection of the technical description.

7.3 Temperature characteristics

The temperature characterizing range of the transducer shall be at least from 15 °C to 40 °C.

Compliance is checked by inspection.

7.4 Geometric dimension of transducer applied plane

a) For a transducer without auxiliary plane, the geometric dimension of the applied plane shall be that of the effective plane.

When the transducer is used for pulse collection, the length of the effective plane parallel to the radial artery (a) (see Figure 6) shall be no less than 3 mm and no larger than 15 mm and the length vertical to the radial artery (b) (see Figure 6) shall be no less than 3 mm and no larger than 10 mm.

Figure 6 — Geometric dimension of transducer applied plane

b) If the transducer has an auxiliary plane, the geometric dimension of the applied plane shall be that of the auxiliary plane.

The auxiliary plane shall be below the effective plane. The height difference between the two planes shall be no less than 1 mm and no larger than 2 mm.

Compliance is checked by measuring the geometric dimension of the transducer applied plane (see Figure 1).

7.5 Input resistance (R_i)

Disclosure shall be made of the input resistance (R_i) of transducer in technical description which:

a) for a Type A transducer, the measured input resistance shall not vary from R_i by more than ±10 %;

b) for a Type B transducer with independent input terminals of the units, the measured input resistance shall not vary from R_i by more than ±10 %.

NOTE This clause only applies to resistive bridge transducer with unamplified analog output.

Compliance is checked by measurement at the input terminal using a digital ohmmeter when the output terminal is in open circuit.

7.6 Output resistance (R_o)

Disclosure shall be made of the output resistance (R_o) of transducer in technical description which:

a) for a Type A transducer, the measured output resistance shall not vary from R_o by more than ±10 %;

b) for a Type B transducer with independent input terminals of the units, the measured output resistance shall not vary from R_o by more than ±10 %.

NOTE This clause only applies to resistive bridge transducer with unamplified analog output.

Compliance is checked by measurement at the output terminal using a digital ohmmeter when the output terminal is in short circuit.

7.7 Transducer output independence

The output of array units of Type B transducer shall be mutually independent and the interference between units shall not be greater than 10 %.

Test: Load the array units of Type B transducer separately with testing mechanical quantity generator and superpose a static signal with 80 % rated load. Measure U_y, the output of an array transducer unit under a rated load (not including V_{off}) and U_n, the output of an array transducer unit without rated load (not including V_{off}). Then Y shall be calculated by applying Formula (1):

$$Y=\left|\frac{U_n}{U_y}\right|\times 100\ \% \tag{1}$$

Compliance is checked if Y exceed 90 %.

7.8 Full scale span error (Fs)

Full scale span error of Type A and Type B transducers (Fs) shall not exceed ±2 %.

Compliance is checked by the following test.

$\overline{mV_{off}}$ and $\overline{mFSO}$ are mean values calculated from six corresponding measured values obtained from three testing cycles.

Fs shall be calculated by applying Formula (2):

$$Fs=\frac{\overline{mFSS}\text{ - }FSS}{\overline{mFSS}}\times 100\ \% \tag{2}$$

$$\overline{mFSS}=\overline{mFSO}-\overline{mV\text{off}} \tag{3}$$

7.9 Terminal linearity error (L)

Linearity error of Type A transducer and array units of Type B transducer (L) shall not exceed ±1 % FSS.

Compliance is checked by the following test.

$\Delta U1_{max}$ is the maximum absolute value of the difference between the arithmetic mean value of the voltage outputs measured at every testing point of three forward strokes and three backward strokes (six times in all) and the corresponding points on the working straight line.

L shall be calculated by applying Formula (4):

$$L=\frac{\Delta U1_{\max}}{mFSS}\times 100\ \% \tag{4}$$

7.10 Hysteresis (*H*)

Hysteresis of Type A transducer and array units of Type B transducer (H) shall not exceed ±1 % *FSS*.

Compliance is checked by the following test.

Calculate respectively the arithmetic mean value of the voltage outputs in three forward strokes and three backward strokes measured at every testing point, as well as the absolute value of the difference of the arithmetic mean value between the forward and backward strokes at each testing point, and take the maximum absolute value as $\Delta Uh_{\max}$.

H shall be calculated by applying Formula (5):

$$H=\frac{\Delta Uh_{\max}}{mFSS}\times 100\ \% \tag{5}$$

7.11 Repeatability (*R*)

Repeatability of Type A transducer and array units of Type B transducer (R) shall not exceed ±1 % *FSS*

Compliance is checked by the following test.

$\Delta Uui_{\max}$ is the maximum of the difference values obtained by comparing three output voltages measured at the same testing point on a forward stroke with each other.

$\Delta Udi_{\max}$ is the maximum of the difference values obtained by comparing three output voltages measured at the same testing point on a backward stroke with each other.

R shall be calculated by applying Formula (6):

$$R=\frac{\Delta U_{\max}}{mFSS}\times 100\ \% \tag{6}$$

$$\Delta U_{\max}=\max(\Delta Uui,\Delta Udi) \tag{7}$$

7.12 Creep (*Cp*)

The creep (Cp) for Type A transducer shall not exceed 0,03 % *FSS*.

Compliance is checked by the following test.

Apply the rated excitation voltage or current, warm up for 30 min and apply the rated load in a quick and impact-free way. After 5 s of loading, read the output signal value Ua and after 30 min of loading, read the output signal value Ub.

Cp shall be calculated by applying Formula (8):

$$Cp=\frac{\left|U_a-U_b\right|}{mFSS}\times 100\ \% \tag{8}$$

7.13 Offset stability (*Zs*)

The offset stability (*Zs*) for Type A transducer and array units of Type B transducer shall not exceed ±0,5 % *FSS*.

Compliance is checked by the following test.

Under a no load condition, apply the rated excitation voltage or current and warm up for 30 min. Read the initial offset value and then the following offset voltage values at an interval of 15 min consecutively for 2 h (nine readings). ΔUo_{max} is the absolute value of the maximum difference of offsets during offset stability testing.

Zs shall be calculated by applying Formula (9):

$$Zs = \frac{\Delta Uo_{max}}{mFSS} \times 100\ \% \tag{9}$$

7.14 Offset temperature drift (*Zt*)

The offset temperature (*Zt*) for Type A transducer and array units of Type B transducer shall not exceed ±0,05 % *FSS*.

Compliance is checked by the following test.

Under a no load condition, apply rated excitation voltage or current, place in a temperature test chamber, and after keeping at the test environment temperature, lower limit working temperature and upper limit working temperature for at least 1 h, read the offset values respectively at the temperatures above.

Zt shall be calculated by applying the formula and take the larger value between Zt_1 and Zt_2 as *Zt*:

$$Zt_1 = \frac{Uo_{t_1} - Uo_t}{mFSS(t_1 - t)} \times 100\ \% \tag{10}$$

$$Zt_2 = \frac{Uo_{t_2} - Uo_t}{mFSS(t_2 - t)} \times 100\ \% \tag{11}$$

where

t is the test environment temperature;

t_1 is the lower limit working temperature;

t_2 is the upper limit working temperature;

Uo_t is the offset value of the transducer at room temperature;

Uo_{t1} is the offset value of the transducer at the lower limit working temperature;

Uo_{t2} is the offset value of the transducer at the upper limit working temperature.

7.15 Sensitivity temperature drift (*St*)

The sensitivity temperature drift (*St*) for Type A transducer and array units of Type B transducer shall not exceed ±0,05 % *FSS*.

Compliance is checked by the following test.

Under a no load condition, apply the rated excitation voltage or current, place the transducer in a temperature test chamber, and after keeping at the test environment temperature, lower limit working temperature and upper limit working temperature for at least 1 h. Under rated load, read the full scale span values respectively at the temperatures above.

St shall be calculated by applying the formula and take the larger value between St_1 and St_2 as *St*:

$$St_1 = \frac{UmFSS_{t_1} - UmFSS_t}{mFSS(t_1 - t)} \times 100\ \% \tag{12}$$

$$St_2 = \frac{UmFss_{t_2} - UmFss_t}{mFss(t_2 - t)} \times 100\ \% \tag{13}$$

where

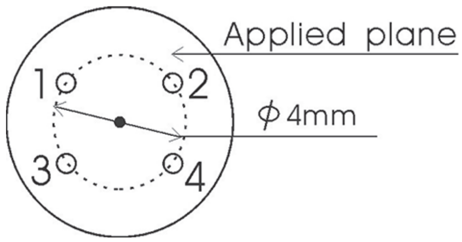
t	is the test environment temperature;
t_1	is the lower limit working temperature;
t_2	is the upper limit working temperature;
$UmFSSt$	is the full scale span value of the transducer at room temperature;
$UmFSSt_1$	is the full scale span value of the transducer at the lower limit working temperature;
$UmFSSt_2$	is the full scale span value of the transducer at the upper limit working temperature.

7.16 Eccentricity (*Sz*)

The eccentricity error of Type A transducer (*Sz*) shall not exceed 5 % *FSS*.

Compliance is checked by the following test.

1) Using the centre of the transducer effective plane as the origin, take four points at 90°intervals from the circle 4 mm in diameter (as shown in Figure 7).



Key

1 testing point 1
2 testing point 2
3 testing point 3
4 testing point 4

Figure 7 — Four testing points

2) Then apply rated load three times at each point. Maintain at the rated load for 30 s and then read the output value then. After 30 s, return to zero load and then apply the second and third loads in the same way. After loading, work out the mathematical mean of the three values (not including V_{off}) for each point, i.e. Ue_1, Ue_2, Ue_3 and Ue_4.

3) Work out the values from $\left|U_{e_1} - \overline{mFSS}\right|$ to $\left|U_{e_4} - \overline{mFSS}\right|$ and take the maximum therein as *Ue*.

4) *Sz* shall be calculated by applying Formula (14):

$$Sz = \frac{Ue}{\overline{\overline{mFSS}}} \times 100\ \% \tag{14}$$

The diameter of the contact plane for applying force at each point shall be less than or equal to 1 mm.

NOTE This clause applies to the transducers with an effective area larger than a circle 4 mm in diameter.

7.17 Overload (*Ov*)

The transducer shall be designed and constructed to withstand overload.

Test: Under overload, continuously apply load to the transducer for 3 min and then reduce to zero load. For Type A and Type B transducers, the overload, *Ov*, shall be at least 200 % F_n. The transducer shall be overload according to this method three times.

Compliance is checked if after 10 min recovery; the transducer meets the requirements from 7.9 to 7.14 (inclusive).

7.18 Vibration, impact and temperature influence

The transducer shall be designed and constructed to withstand vibration, impact and temperature change which may occur during transit, storage and normal condition of use.

Test:

a) Vibration: According to the conditions and parameters specified in IEC 60068-2-6, set the transducer in an off-work state on a scanning frequency vibration table. The vibration frequency is 20 Hz to 100 Hz and the vibrating acceleration is 100 m/s^2. Five vibrations are cycled on the sensitive direction and the two vertical directions, respectively. The transducer is then taken down and left to stand for 30 mins.

b) Impact: According to the conditions and parameters specified in IEC 60068-2-27, set the transducer in an off-work state on the bounce table using a special fixture. The impact acceleration is 300 m/s^2 and the pulse duration is 11 ms. 100 times of impacts are applied to the sensitive direction of the transducer and the two vertical directions, respectively. The transducer is then taken down and left to stand for 30 min.

c) Temperature influence: Carry out this test according to the conditions and parameters specified in IEC 60068-2-14. The low temperature value T_a is −20 °C, high temperature value T_b is 70 °C, the exposure time t_1 under the high and low temperature is 1 h, conversion time t_2 should be less than 5 min and three cycles are carried out.

Compliance is checked if after completing the test procedure the transducer meets the requirements from 7.9 to 7.14 (inclusive).

7.19 Fatigue life

The transducer shall be designed and constructed so that any gradual, long-term change that might occur within the lifetime shall not result in an unacceptable risk.

Test: Install the transducer on a fatigue failure tester and impose the rated load with the condition that no excitation is added. The load change frequency is 1 Hz to 3 Hz and the cycle times are 200,000 cycles.

Compliance shall be checked if after completing the test procedure the transducer meets the requirements from 7.9 to 7.14 (inclusive).

