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

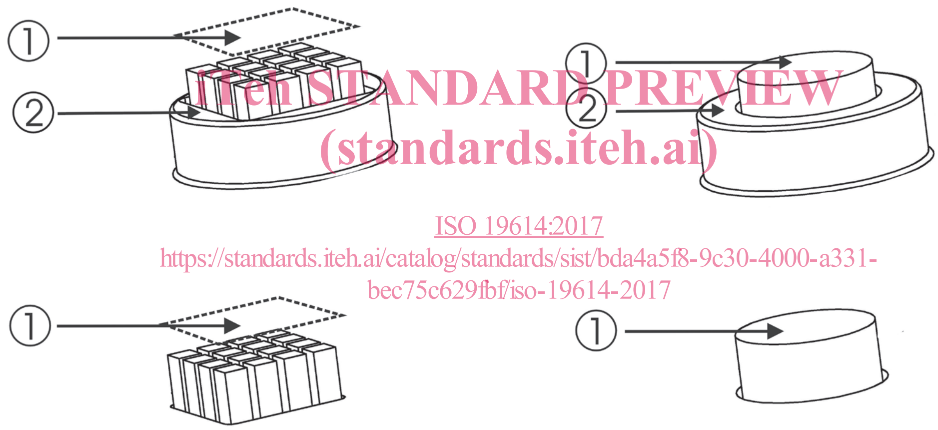
**3.4**
**effective plane**
plane of transducers with the sensitivity during radial artery pulsation acquisition

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

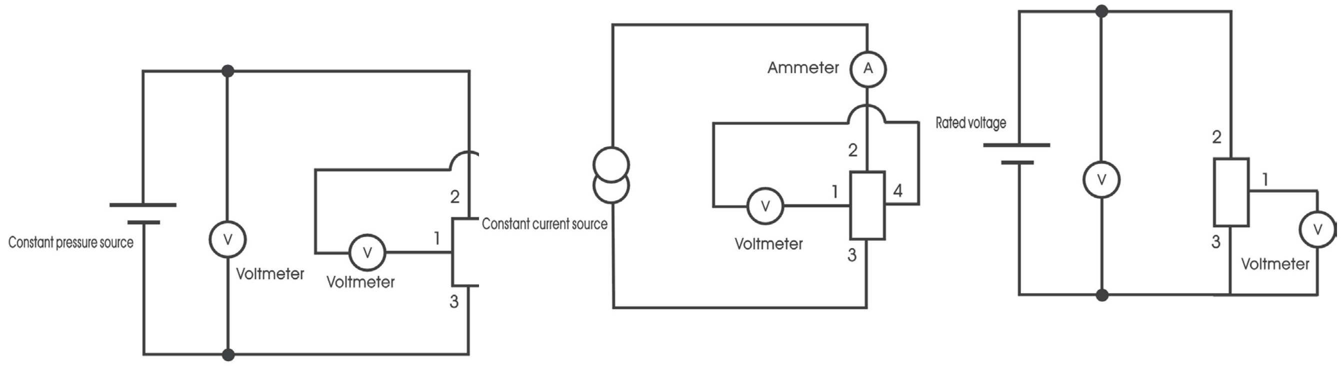
2 auxiliary plane

**Figure 1 — Effective plane, auxiliary plane of transducers**

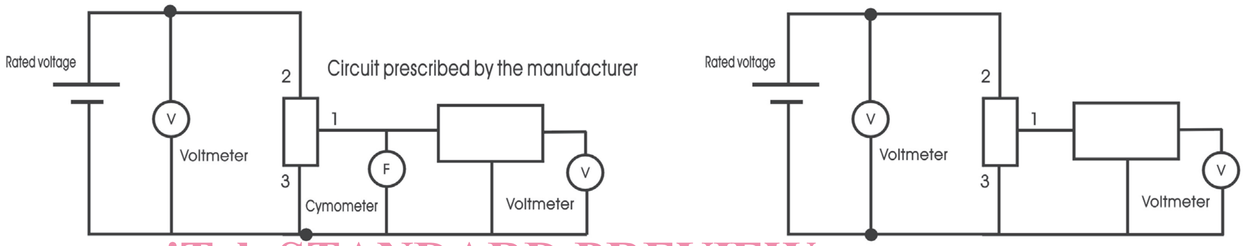
**3.7**
**output quantity**
electrical signal quantity produced by a transducer, which is a function of a measurand

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

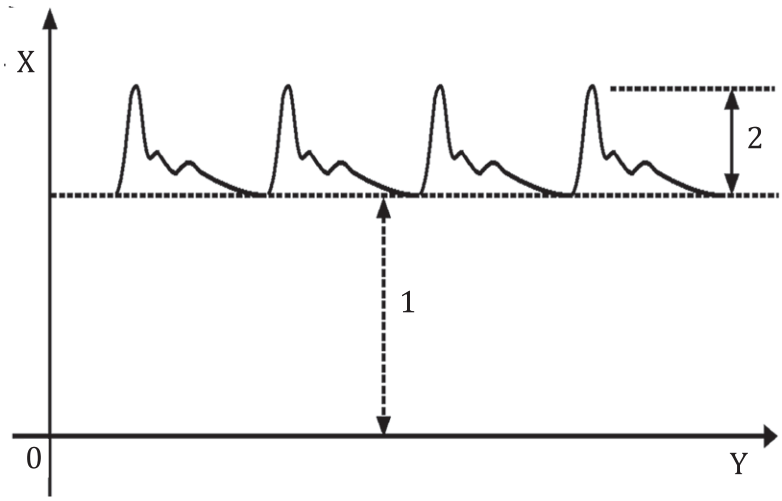
**3.9**
**static signal**
electrical signal transferred from the applied force

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



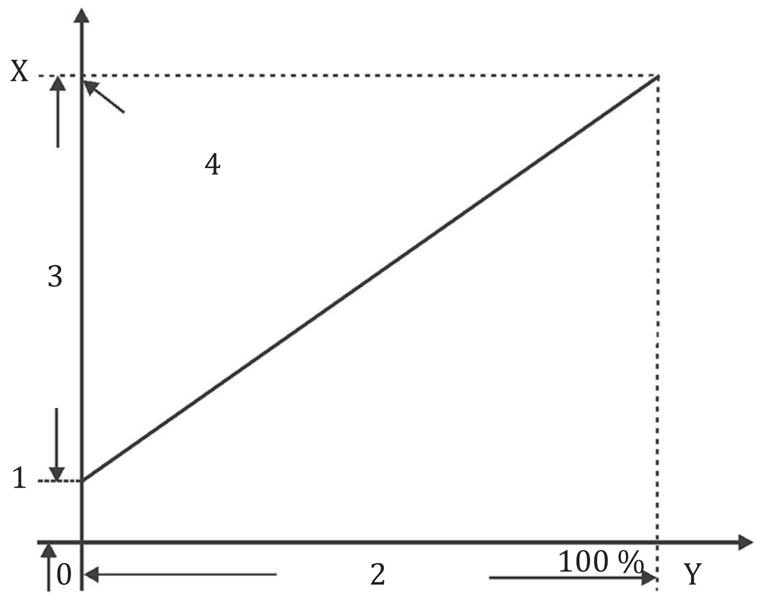
**Figure 3 — Static signal and dynamic signal**

**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



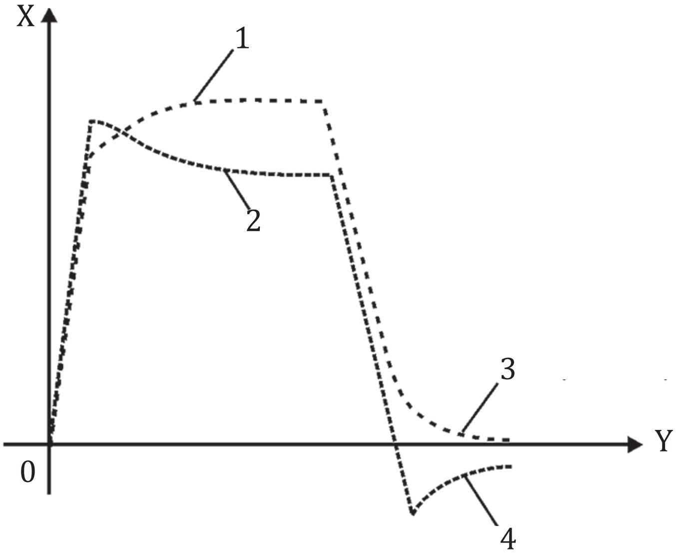
[SOURCE: IEC 60747-14-1:2010, 3.2.17]



**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