

First edition
2019-03

Corrected version
2019-05

**Traditional Chinese medicine —
Computerized tongue image analysis
system —**

**Part 1:
General requirements**

*Médecine traditionnelle chinoise — Système d'analyse d'images
numérisées de la langue —*

Partie 1: Exigences générales

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Reference number
ISO 20498-1:2019(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

A list of all parts in the ISO 20498 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 20498-1:2019 incorporates the following corrections:

- edition date in the running header changed to 2019;
- copyright date in the footer changed to 2019.

Introduction

The tongue's colour, form, motion, substance and coating are the main factors to be considered when analysing tongue features. Measuring the geometric shape involves observing the changes in the thickness and size of a tongue and the cracks and teeth marks on its surface. The important features of the tongue coating which cover the surface of the tongue are colour, degree of wetness, thickness, form and distribution.

Although tongue diagnosis is convenient and non-invasive, it is difficult to achieve an objective and standardized examination. Differences in inspection circumstances, such as light source or a client's posture, affect the result significantly. Moreover, as the diagnosis relies on the observer's experience and knowledge, it is hard to obtain a standardized result. Recently, many research projects have attempted to solve these problems, and various types of computerized tongue image analysis system (CTIS) have been developed.

Various cameras, such as a commercial digital camera, bayer charge-coupled device (CCD) camera, high-performance 3CCD camera and a hyperspectral camera, were used for the CTIS. Recently, a multi-view CTIS has been developed designed for 3D tongue modelling and sublingual vein acquirement, comprising 3D CTIS.

Different CTIS technologies have unique advantages and specificities according to the application and diagnostic environment, but this variation may cause inconsistent diagnoses in practical clinical application. To improve CTIS performance and clinical approach, it has become necessary to develop an International Standard for the functions and elements of a CTIS.

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Traditional Chinese medicine — Computerized tongue image analysis system —

Part 1: General requirements

1 Scope

This document specifies general requirements for a computerized tongue image analysis system (CTIS).

This document is limited to the safety aspects and technical requirements for a CTIS, excluding the diagnosis or interpretation of tongue images.

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 for 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*

ISO 20498-2, *Traditional Chinese medicine — Computerized tongue image analysis system — Part 2: Light environment*

IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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 <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 computerized tongue image analysis system CTIS

device or system used to acquire tongue images to be analysed by computer

3.2 charge-coupled device CCD

device for the movement of electrical charge, usually from within the device to an area where the charge can be manipulated

3.3 tongue positioning

guiding and maintaining the posture of the protruding tongue

**3.4
lighting part**

structure for illuminating the tongue surface with various light sources and optical techniques

**3.5
image acquisition part**

image sensor and optical lenses used to produce the tongue image data

**3.6
data processing part**

computer and image correction algorithms for computing and displaying the tongue properties

4 Components of CTIS

The CTIS consists of a lighting part, an image acquisition part, a data processing part, a display and, if provided, a tongue positioning part.

5 Technical requirements

5.1 General

The technical requirements for the components of a CTIS are specified in this document to improve the accuracy and reproducibility of the acquisition, correction, and feature extraction of the tongue image.

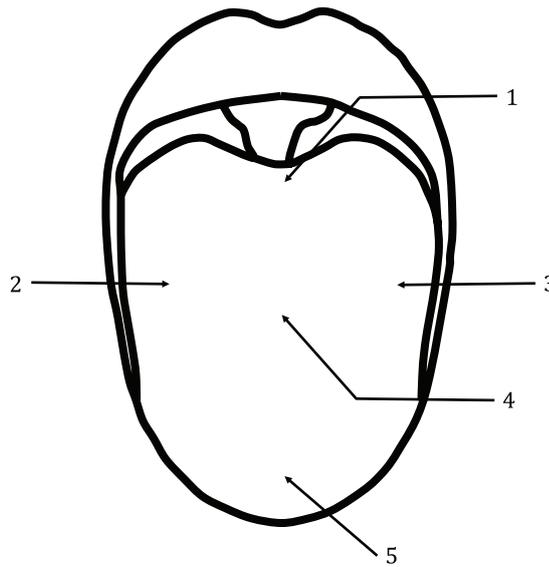
5.2 Tongue positioning

CTIS shall be applied to the tongue positioning to obtain an undistorted tongue image. Tongue positioning is not necessary for CTIS with non-tongue positioning and mobile CTIS.

Differences in the location and incident angle of the image acquisition part can diminish the reproducibility of the information in tongue images. The whole area of the exposed tongue shall be included in the image for analysis. See [Annex A](#) for additional information.

5.3 Lighting part

For the colour image acquisition, the luminance, colour temperature, colour rendering index and illumination distribution shall be considered. The light shall illuminate five areas of the tongue (see [Figure 1](#)). The detailed requirements for the lighting part described in ISO 20498-2 shall be used. See [Clause 6](#) for information on electrical safety and the biocompatibility of the lighting part.

**Key**

- 1 root of the tongue
- 2 right margins of the tongue
- 3 left margins of the tongue
- 4 centre of the tongue
- 5 tip of the tongue

Figure 1 — Five areas of the tongue

5.4 Image acquisition part

5.4.1 General

The CTIS can acquire the image from the root to the tip of the tongue. See [Annex B](#) for testing methods for the accuracy of colour measurements and the repeatability of image acquisition.

5.4.2 Spatial resolution

For accurate image acquisition, an image sensor with a resolution of at least 1,0 megapixels shall be used.

5.4.3 Colour components

At least one colour model or at least three colour components of the tongue shall be obtained. The types of colour components which can be used are as follows:

- a) red-green-blue (RGB);
- b) Commission Internationale de l'Eclairage lightness, green-red, blue-yellow (CIE Lab);
- c) cyan-magenta-yellow-key or black (CMYK);
- d) other colour components.

5.4.4 Colour components acquirement

The colour components of the tongue shall be obtained. As a method for acquiring colour components, any of the following techniques can be used:

- a) Bayer filter;
- b) separate measurement of the red, green or blue light using three CCDs;
- c) hyperspectral imaging.

5.5 Data processing part

The data processing part is necessary to obtain a clear tongue image and an accurate result. Among various data processing issues, indispensable components of the data processing part are included in this subclause. Various algorithms can be applied. See [Annex C](#) for additional information.

5.6 Display

CTIS shall require the use of a peripheral visual instrument (e.g. monitor) for displaying the tongue images. The original resolution of the tongue image shall be shown by the display devices of the CTIS. The image data, such as an original image, a corrected image or a segmented tongue image, shall be encoded into editable and storable image formats.

6 Safety

6.1 Safety of material

The biocompatibility of the tongue positioning shall be assessed and documented according to the guidance and principles given in ISO 10993-1. In certain situations, a sponsor may propose to use a material that has known toxicities, but where the material could be acceptable for the end use. In this case, risk assessment should include consideration of the intended persons who will use or be treated with the device, and a discussion of the potential benefits of using the chosen material as well as potential risk mitigation, such as supplying protective masks for clinicians.

Conformity is demonstrated by:

- a) analogy with published data;
- b) selection of materials shown to be biocompatible by proven clinical use in a similar application;
- c) experience with similar devices already on the market together with evidence of traceability to the materials used in the CTIS;
- d) conformity with published procedures for biological evaluation.

6.2 Prevention from infection

Closed CTIS is related to protection against foreign substances, including infections. This includes:

- a) prevention of mould growth by appropriate cleaning routines;
- b) avoidance of inclusion of allergens, sensitizing substances and chemicals known to cause hypersensitivities in products, foodstuffs and environments.

6.3 General requirements for testing of ME equipment

IEC 60601-1:2005/AMD1:2012, Clause 5, shall apply.

6.4 Electrical hazards

IEC 60601-1:2005/AMD1:2012, Clause 8, shall apply.

6.5 Mechanical hazards

IEC 60601-1:2005/AMD1:2012, Clause 9, shall apply.

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Annex A (informative)

Tongue positioning

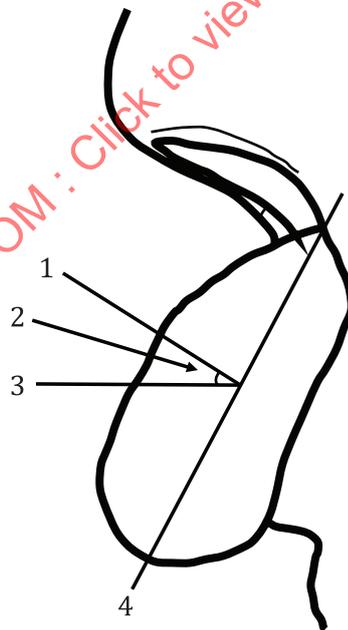
A.1 Tongue positioning techniques

The whole area of the exposed tongue shall be included in the image for analysis. The tongue can be positioned using the following tongue position techniques:

- contact with a part of the face;
- feedback guideline on the display;
- location adjustment of the image acquisition part;
- other techniques identified in standard operating procedures (SOP) for acquisition of a tongue image.

A tongue position part may be used to correctly position the tongue. If a tongue position part is provided, it shall meet the material safety requirements in [6.1](#).

The incident angle between the exposed tongue surface and the image acquisition part should be between 0° and 30° . [Figure A.1](#) illustrates the valid range of the incident angle between the exposed tongue surface and the image acquisition part.



Key

- surface normal factor
- valid range of the incident angle (0° to 30°)
- image acquisition part
- exposed tongue surface

Figure A.1 — Valid range of incident angle between the exposed tongue surface and the image acquisition part

Annex B (informative)

Test methods for CTIS

B.1 Test method of accuracy of colour measurement

The accuracy of colour measurement can be assessed by calculating measurement errors between gold standards and measurement values of colour samples. The colour samples shall be measured as follows:

- a) there shall be at least 24 colour samples;
- b) the test shall be performed under general lighting conditions;
- c) colour samples shall be located in the range of the tongue positioning.

The measurement error can be calculated using Formula (B.1):

$$\text{Mean squared error} = \frac{1}{n} \sum_{i=1}^n (\hat{Y}_1 - Y_i)^2 \quad (\text{B.1})$$

where

\hat{Y}_1 is a vector of n measurements for the colour samples;

Y_i is the vector of the true colour values of each sample (gold standard).

A low value of the mean squared error indicates the high accuracy of the colour measurement

B.2 Test method of repeatability of image acquisition

The repeatability of image acquisition can be assessed by calculating intra-class correlation from experiments for repeated image acquisition of the tongues. The experiment shall be performed under the following conditions:

- a) the number of subjects participating in the experiment shall be over five;
- b) the number of image acquisitions for each subject shall be over three;
- c) intervals between repeated image acquisitions shall be over 1 min;
- d) general lighting conditions.

See [Figure B.1](#) for the experimental procedure.

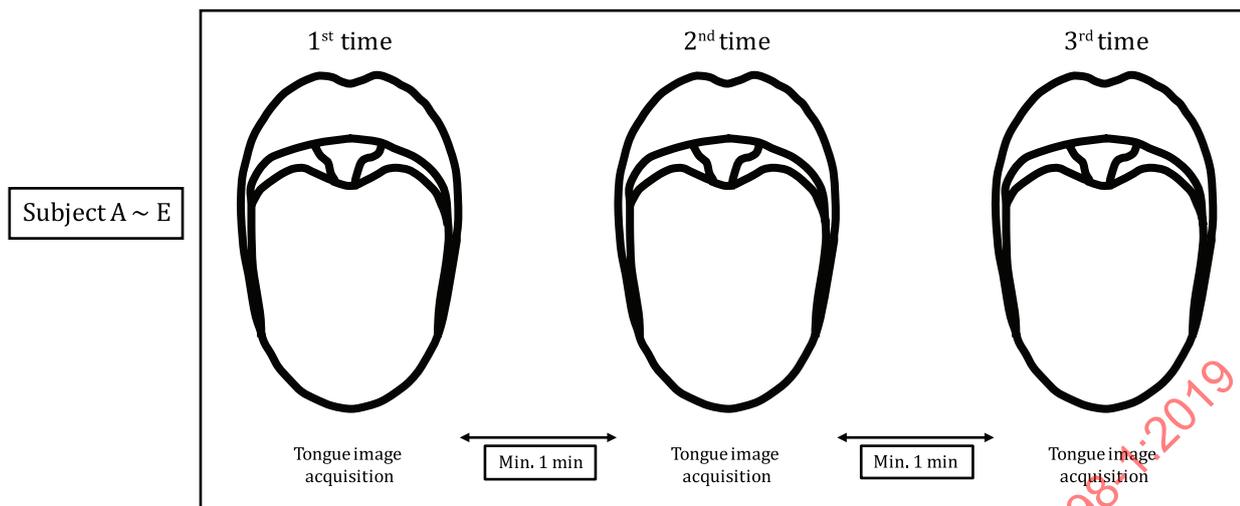


Figure B.1 — Experimental procedure

For repeated image acquisition corresponding to rates, the intra-class correlation is calculated from the colour information variables in the whole tongue area of the subjects. An intra-class correlation coefficient of 1 indicates a perfect performance of the repeatability, and a low value of around 0 represents low performance of the repeatability.

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