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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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Foreword

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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).

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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.

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.

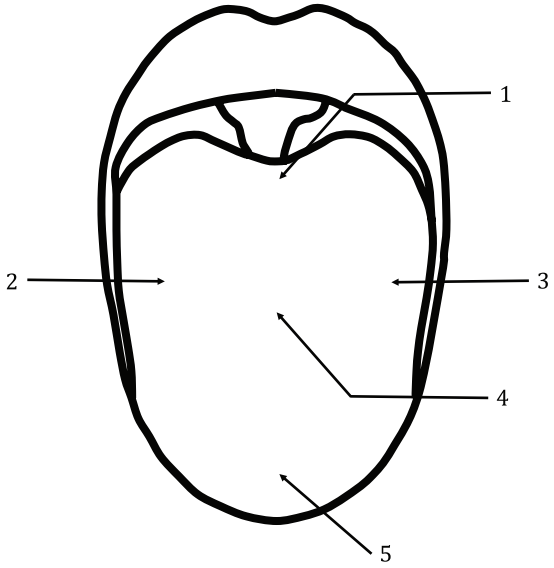
5.2 Tongue positioning

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.