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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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).

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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.

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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

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