Traditional Chinese Medicine.
As a consequence TC 249 instructs its secretariat to request the text of the ISO/DTS 18790-1 from TC 215 no later than 9 June 2014. Accept in principle with further editorial clarification of resolution needed.

[*TC 215 resolution 35 [JWG1-R01] ISO/AWI/DTS 18790-1 for DTS ballot
For ISO/AWI/DTS 18790-1,*Health informatics--Profiling Framework and Classification for Traditional Medicine informatics standards development--part1:Traditional Chinese Medicine*, ISO/TC215approves the recommendation of JWG 1 to issue a DTS ballot; instructs the project lead to provide the text of ISO/DTS 18790 to the TC215 Secretary no later than 9 June 2014; instructs the TC215 Secretary to launch a two month DTS ballot no later than 12 June 2014(to be available for the Berlin meeting Oct 5 -10, 2014) and request that TC249 launch a parallel ad-hoc 2-month DTS ballot.]

Resolution 132 (Kyoto 2014:50)[JWG1-R2: ISO/AWI TS 16843-1 Categorical structure for representation of acupuncture—Part 1: Acupuncture points and ISO/AWI TS 16843-2 Categorical structures for representation of acupuncture - Part 2: Needling]
ISO/TC 249 resolves to accept the recommendation of JWG1 that ISO/AWI TS 16843-1 *Categorical structure for representation of acupuncture—Part 1: Acupuncture points* and ISO/AWI TS 16843-2 *Categorical structures for representation of acupuncture -Part 2: Needling* will not be put into JWG1 since these two projects are reinstatement projects from TC215 and as these projects are well advanced, they remain in TC215. Noting that comments from TC249 are still very welcome.

Resolution 133 (Kyoto 2014: 51)
ISO/TC 249 resolves that the secretariat with Work Coordination Group (CAG2) will prepare a paper for the 6th plenary meeting proposing a Technical Report on levels of evidence.

Resolution 134 (Kyoto 2014: 52)
ISO/TC 249 resolves that the introduction of relevant standards will include a statement that "the standard is applicable to TM systems derived from ancient Chinese medicine".

Resolution 135 (Kyoto 2014: 53)
ISO/TC 249 resolves to express its deep appreciation to Japan for hosting the 5th plenary meeting in Kyoto.

Resolution 136 (Kyoto 2014:54)
China has offered to host the next plenary in a city to be decided in first week of June 2015.

NEW WORK ITEM PROPOSAL	
Closing date for voting	Reference number (to be given by the Secretariat)
Date of circulation	ISO/TC / SC N
Secretariat	☐ **Proposal for new PC**

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, or organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are contained **in Annex C of the ISO/IEC Directives, Part 1.**

☐ The proposer has considered the guidance given in the Annex C during the preparation of the NWIP.

Proposal (to be completed by the proposer)

Title of the proposed deliverable.
(in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title Abdominal Physiological Parameter Detectors

French title
(if available)

Scope of the proposed deliverable.

This International Standard specifies the general requirements for basic safety and quality of the abdominal physiological parameter detectors. This standard is limited to the safety and performance control of the devices during abdominal physiological parameters detection and does not prescribe the clinical abdominal diagnosis associated with the findings obtained from the devices.

New work item proposal

Purpose and justification of the proposal*

This proposal aims to establish an international standard for abdominal physiological parameter detectors. Abdominal palpation is a key technique in traditional medicine, of which the basic ideas can be found in 'Nan Jing', 'Shang Han Lun' and 'Jingui Yaolue', and was developed in Kampo medicine to gather abdominal distress information, and is popularly applied to clinical diagnosis all over the world. The abdominal physiological parameter detectors are used in gathering and processing the abdominal findings and offer strong technological support for further development of the abdominal palpation technique. The devices also provide a foundation for academic exchange, education and international cooperation. Despite their extensive use in clinical practice, international standards addressing abdominal physiological parameter detectors is lacking. To guarantee performance and safety of abdominal physiological parameter detectors, it is necessary to develop an international standard for this device.

**The reason for requiring justification statements with approval or disapproval votes is primarily to collect input on market or stakeholder needs, and on market relevance of the proposal, to benefit the development of the proposed ISO standard(s). Any NSB vote in relation to a proposal for new work may result in significant commitments of resources by all parties (NSBs, committee leaders and delegates/experts) or may have significant implications for ISO's relevance in the global community. It is especially important that NSBs consider and express why they vote the way they do. In addition, it is felt that it would be useful for ISO and its committees to have documentation as to why the NSBs feel a proposal has market need and market relevance. Therefore, please ensure that your justifying statements with your approval or disapproval vote convey the reason(s) why your national consensus does or does not support the market need and/or global relevance of the proposal.*

If a draft is attached to this proposal,:

Please select from one of the following options (note that if no option is selected, the default will be the first option):

☒ Draft document will be registered as new project in the committee's work programme (stage 20.00)
☐ Draft document can be registered as a Working Draft (WD – stage 20.20)
☐ Draft document can be registered as a Committee Draft (CD – stage 30.00)
☐ Draft document can be registered as a Draft International Standard (DIS – stage 40.00)

Is this a Management Systems Standard (MSS)?

☐ Yes ☒ No

NOTE: if Yes, the NWIP along with the Justification study (see Annex SL of the Consolidated ISO Supplement) must be sent to the MSS Task Force secretariat (tmb@iso.org) for approval before the NWIP ballot can be launched.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal.

☒ International Standard ☐ Technical Specification ☐ Publicly Available Specification ☐ Technical Report

Proposed development track ☐ 1 (24 months) ☒ 2 (36 months - default) ☐ 3 (48 months)

Known patented items (see ISO/IEC Directives, Part 1 for important guidance)

☐ **Yes** ☒ **No** **If "Yes", provide full information as annex**

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized.

There are no similar works or ISO and IEC deliverables proposed or existing thus far.

A listing of relevant existing documents at the international, regional and national levels.

New work item proposal

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s)

The following are the stakeholders of this international standard:
1. Manufactures engaged in developing relevant devices and systems supporting abdominal palpation diagnosis.
This international standard will specify the general technological requirements for abdominal physiological parameter detectors and will provide basic technological guidelines.
2. Researchers, physicians, teachers, and students engaged in studies, education, and academic activities in the field of abdominal palpation diagnosis.
This international standard will provide a foundation of academic exchange, education, and international cooperation in the field of abdominal palpation diagnosis. This international standard will also offer a strong technological support for further development and studies in abdominal palpation diagnosis techniques.
3. Physicians and patients who use traditional medicine.
This international standard will promote the objectification and visualization of the traditional medicine and will help to collect quantified evidence of abdominal palpation diagnosis, which will promote traditional medicine toward evidence-based medicine. In addition, the communications between physicians and patients will be greatly improved.

Liaisons:

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s).

Joint/parallel work:

Possible joint/parallel work with:

☐ IEC (please specify committee ID)
☐ CEN (please specify committee ID)
☐ Other (please specify)

A listing of relevant countries which are not already P-members of the committee.

N.A.

Preparatory work (at a minimum an outline should be included with the proposal)

☐ A draft is attached ☒ An outline is attached ☐ An existing document to serve as initial basis

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

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Supplementary information relating to the proposal

☒ This proposal relates to a new ISO document;
☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;
☐ This proposal relates to the re-establishment of a cancelled project as an active project.

Other:

Annex(es) are included with this proposal (give details)

☒ Annex A: Purpose and Justification of Abdominal Physiological Parameter Detectors
Annex B: Outline of Abdominal Physiological Parameter Detectors

Annex A

Purpose and Justification of General Requirements of

Abdominal Palpation Diagnosis Devices

1. Purpose and necessity

1.1 Background

The movement to re-evaluate the importance of Oriental medicine has experience recent growth in many developed and developing countries. In the fields of medicine and therapeutics, Oriental medicine has filled the gaps and limitations of Western medicine. The progressing principles of Western science have produced a generational trend manifested by the search for solutions in Oriental culture. In addition, the treatment objectives of modern medicine have changed to include maintenance and improvement in the quality of life. It is believed that this tendency to emphasize the quality of life will become even stronger, and that Oriental medicine will be in demand as a means of ameliorating subjective symptoms without serious adverse events, and for treating disease in a non-invasive manner, thereby expanding its range of application.

During recent decades, World Health Organization (WHO) has also emphasized the importance of revitalizing traditional medicine as part of the suggested therapeutics, particularly in developing countries, which has encouraged a positive reappraisal and restructuring of traditional medicine on the global scale. Moreover, various types of symposiums and conferences have been often held in many countries to promote awareness of Oriental medicine.

Traditional Chinese medicine (TCM) is a widely practiced type of Oriental medicine used worldwide. Kampo, or traditional Japanese medicine, is also representative of Oriental medicine that has an independent unique system created from the development and refinement of ancient Chinese medicine over centuries in Japan. Particularly influenced by Chinese clinical textbooks such as "Nan Jing," "Shang Han Lun," and "Jingui Yaolue," Kampo medicine is a part of traditional Japanese culture, and its therapeutic technique was developed by the accumulation, organization and systemization of the massive amount of experience in its long clinical history.

This unique conceptual system is used to interpret causes and conditions of such states as yin/yang, deficient/excessive, superficial/interior and cold/heat, or theoretical etiology such as qi, blood and water). These elements are essential for the "Sho" concept, which expresses the evaluated status and treatment direction taken by the homeostatic imbalance. The Sho concept is a holistic pattern of symptoms diagnosed using the four diagnostic procedures of observation, listening, questioning and palpation. Therefore, the Sho concept includes both Kampo diagnosis manifesting in the patient's status and the treatment directive. For the evaluation of Sho, abdominal palpation is an essential and extensively developed diagnostic method that is typically used in Japan [1]. In addition, this technique has been introduced in many other countries [2].

Fig.1 Illustrations of abdominal palpation cited

from Kampo medicine textbook "Fukusyoukiran".

Abdominal palpation techniques were well summarized in representative Kampo medicine textbooks "Fukusyoukiran" and "Fukusyoukiranyoku" written by Bunrei Inaba and Yoshitora Wakuda respectively in 1800 and 1802. Figure1 illustrates examples of abdominal palpation quoted from "Fukusyoukiran". The dynamic or static changes in particular regions of the abdomen reflect systemic irregularities rather than focused problems affected by disease. Physicians practicing Kampo medicine gently palpate the patients' body surface where they believe the essence of patients' disorders is reflected and adopt the findings as an important basis in the choice of treatment. Therefore, the treatment based on abdominal palpation clearly leads to the maintenance of systemic homeostasis and thus restoration of the entire body balance. Because abdominal palpation leads to more detailed and beneficial treatment information, physicians practicing Kampo medicine highly regard abdominal palpation compared over TCM.

1.2 Purpose

This proposal aims to establish an international standard for abdominal palpation diagnosis devices. Abdominal palpation is a key technique in traditional medicine of which the basic idea can be found in "Nan Jing," "Shang Han Lun," and "Jingui Yaolue", and was developed in Kampo medicine to gather abdominal distress information and is popularly applied to clinical diagnosis worldwide. The abdominal palpation diagnosis devices are used for gathering and processing the abdominal examination findings and offer strong technological support for further development of abdominal palpation techniques. These devices also provide a foundation for academic exchange, education, and international cooperation.

1.3 Necessity of an international standard for abdominal palpation diagnosis devices

As previously stated, abdominal palpation is a key technique developed in Kampo medicine to gather information of abdominal distress and is popularly applied to clinical diagnosis. However the diagnosis of abdominal palpation relies on the tactile sense and recognition capability of each practitioner, therefore, the results can differ among practitioners. Moreover, information on abdominal palpation has inadequately been explained or scientifically examined until recently [3]. Many aspects of Kampo medicine still need to be explored, such as the development of a scientific explanation for the unique Kampo diagnosis, and the efficacy and safety of Kampo should be evaluated to ensure medical progress.

To achieve these objectives, the development of new medical devices is one solution. Figure 2 illustrates the progression of the diagnosis process toward objectification. In recent years, measures have been enacted to objectify the diagnosis of abdominal palpation by using diagnostic devices. Essentially, the diagnosis of abdominal palpation consists of two components including the area to be palpated and the findings of examination. The latter is again divided into components of physical quality and physical quantity. For example, if a hard glomus is present in the stomach in a particular patient, the resistance may be expressed as displacement by pressure (physical quality) of 1 kg per 1 m^2 or, 1 cm (physical quantity).

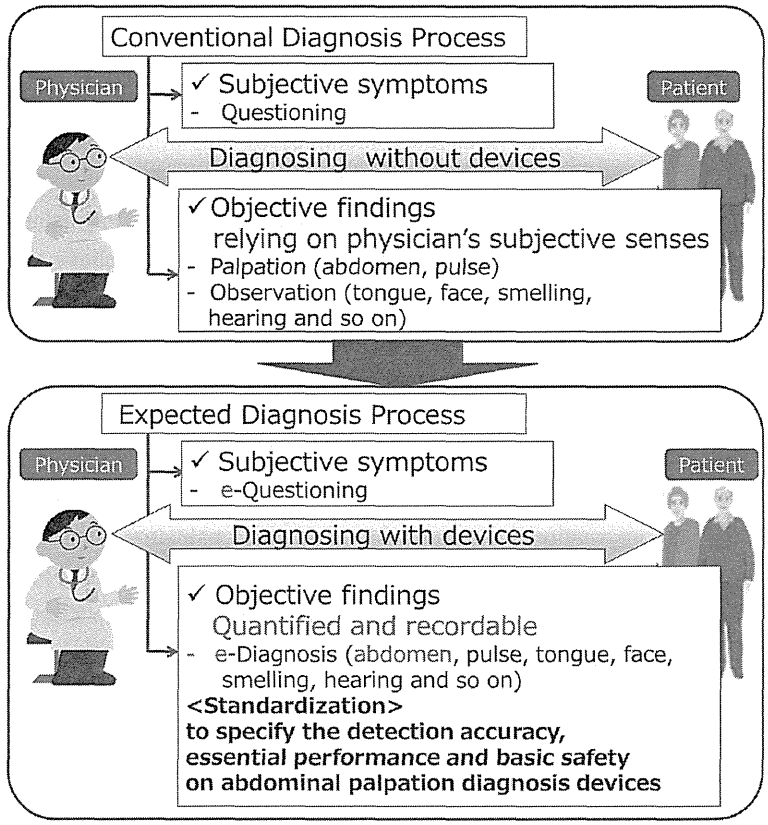

Fig.2: Illustration of the progression of the diagnosis process toward objectification of Kampo medicine.

The objectification of abdominal palpation with diagnostic devices would lead to the accumulation of shared basic and clinical data results so that various Kampo practitioners and researchers can discuss the findings with greater accuracy and ease. Thus, research on Kampo medicine will increase in popularity, and increasing numbers of medical clinicians and patients will become aware of the benefits of Kampo medicine. However, these devices are considered to be useful only when their safety is secured and their reliability is high. The objective of this proposal is to standardize abdominal palpation diagnosis devices with the ability to detect the components of abdominal palpation with essential accuracy and safety. Currently, implementation of abdominal palpation has become widespread in many countries other than Japan, as described in [1][2][3]. It is our hope that the standardization of abdominal palpation diagnosis devices will help more practitioners to conduct abdominal palpation worldwide.

2 Expected impacts of abdominal palpation diagnosis devices

The followings are the stakeholders of this international standard:

1. Manufactures engaged in developing relevant devices and systems supporting abdominal palpation diagnosis.

This international standard will specify the general technological requirements for abdominal palpation diagnosis devices and will provide basic technological guidelines.

2. Researchers, physicians, teachers, and students engaged in studies, education, and academic activities in the field of abdominal palpation diagnosis.

This international standard will provide a foundation of academic exchange, education, and

international cooperation in the field of abdominal palpation diagnosis. This international standard will also offer a strong technological support for further development and studies in abdominal palpation diagnosis techniques.

3. Physicians and patients who use tradition medicine

This international standard will promote the objectification and visualization of the traditional medicine and will help to collect quantified evidences of abdominal palpation diagnosis, which will promote traditional medicine toward evidence-based-medicine. In addition, the communications between the physicians and patients will be greatly improved.

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Annex B
Outline of General Requirements of
Abdominal Palpation Diagnosis Devices
Scope
This International Standard specifies the general requirements for basic safety, essential performance, and quality of the abdominal palpation diagnosis devices. This standard is limited to the accuracy and safety of the devices and does not prescribe the interpretation of the abdominal findings obtained by the devices.

Normative References
The following referenced documents are indispensable for the application 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.

IEC 60601-1: Edition 3.1 2012-08, Medical electrical equipment–Part 1: General requirements for basic safety and essential performance
IEC 60601-1-1: 2007, Medical electrical equipment–Part 1-1: General requirements for safety–Collateral standard: Safety Requirements for medical electrical system
IEC 60601-1-2: Edition 3.0 2007-03, Medical electrical equipment–Part 1-2: General requirements for basic safety and essential performance–Collateral standard: Electromagnetic compatibility – Requirements and tests
ISO 14971: Corrected version 2007-10-01, Medical electrical equipment–Part 1-2: Medical devices–Application of risk management to medical devices
ISO 10993-1: Fourth edition 2009-10-15, Biological evaluation of medical devices–Part 1: Evaluation and testing within a risk management process
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ISO 15223-1:2012, Medical devices–Symbols to be used with medical devices labels, labelling and information to be supplied Part 1: General requirements
IEC 62366: 2007, Medical devices–Application of usability engineering to medical devices
ISO10993-10:2010 Biological evaluation of medical devices–Part 10: Tests for irritation and skin sensitization
ISO 13485: 2003 Medical devices–Quality management systems–Requirements for regulatory purposes
OIML R60: 2000 Metrological regulation for load cells

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

3.1 Abdominal palpation
Evaluation of the physical status reflected on the abdomen.

3.2 Abdominal palpation area
Palatable area between the level of xiphoid process and the inguinal ligament (area inside of the dashed line shown in Fig.1).

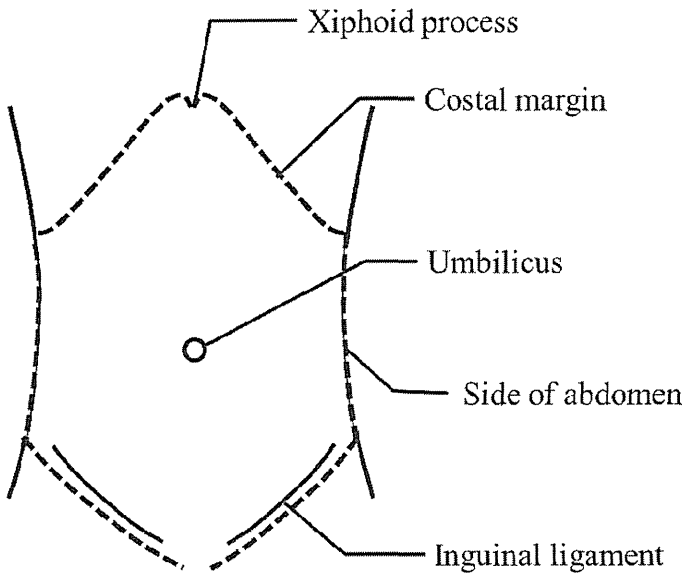

Fig.1: Abdominal palpation area.

3.3 Regions of abdominal palpation area

Division of areas used for explanation of abdominal findings (sample areas shown in Fig.2).

・Sub-sternal region

The area under xiphoid process in the epigastric region.

・Subcostal region

The area beneath the bilateral costal margin.

・Periumbilical region

The area circumscribing the umbilicus.

・Lower abdomen

The area between the levels of the umbilicus and superior margin of the bilateral inguinal ligament.

・Palpation region for abdominal pulsation

Paramidline area along the course of aorta.

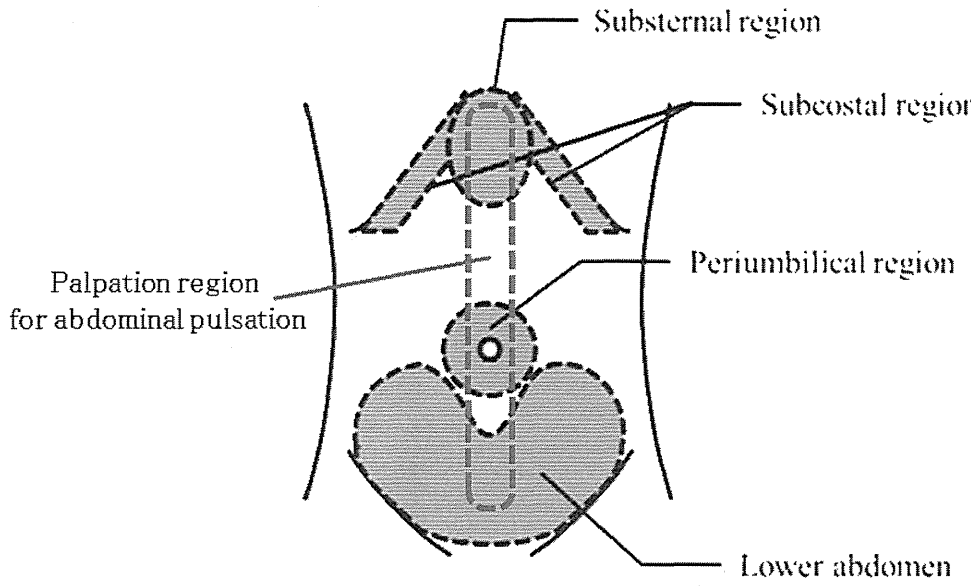

Fig. 2: Regions of abdominal palpation area.

3.4 Abdominal findings
Diagnosis of abdominal palpation.

3.5 Abdominal strength
General tonicity in the abdominal palpation area.
3.6 Abdominal firmness
Hypertonicity detected in the sub-sternal region, subcostal region, periumbilical region or lower abdomen.

3.7 Abdominal pulsation
Pulsation of the abdominal aorta detected in the substernal region or above/beside/below the periumbilical region.

3.8 Abdominal sound
Specific sounds such as tympanic or splashing detected in the abdominal palpation area.

General Requirements

4.1 Physical values to detect and record
Abdominal palpation is a diagnostic method adopted by a physician to touch, press, stroke, or tap certain regions of a patient's abdomen by using his fingers or palms, so that the physician can identify abdominal strength, tonicity, firmness, or other abnormal changes, by which he can infer the disease site, nature and symptoms. Figure 3 shows an example of a physician performing abdominal palpation to identify abdominal strength. The following basic physical value should be detected and recorded, when an abdominal palpation diagnosis device is used to conduct or support the abdominal palpation.

- Palpation position (x, y, z)
- Static and dynamic pressure
- Pulsation
- Sound

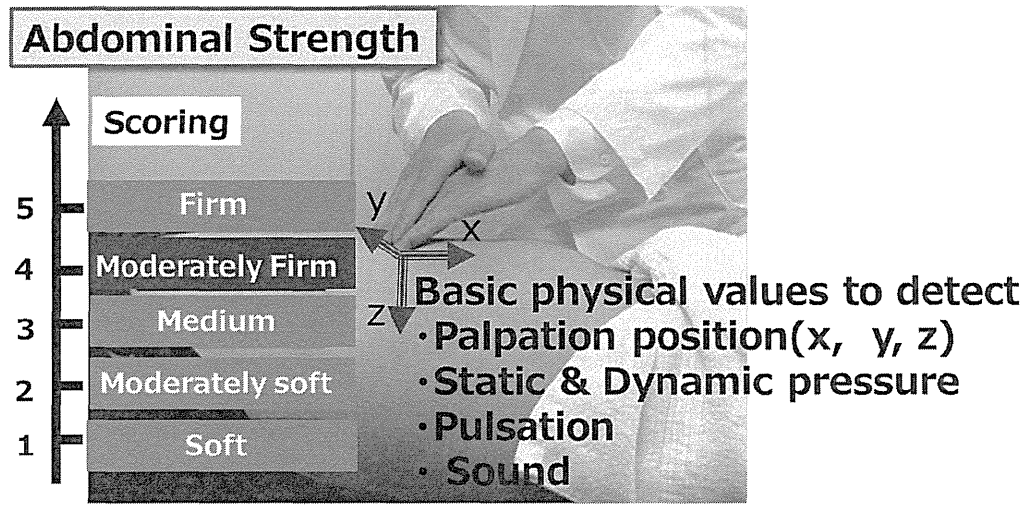

Fig. 3: An example of abdominal palpation used to determine the abdominal strength.

The basic function configuration of an abdominal palpation diagnosis device is shown in Fig. 4. To detect the above-stated physical values, the abdominal palpation diagnosis device basically consists of a 3D position detection unit, a pressure detection unit, and a sound detection unit. The 3D position detection unit will measure and record the palpation position (x, y, z) in real time. The pressure detection unit will measure and record the local static and dynamic stress when the palpation is performed. The abdominal pulsation can be detected by the pressure detection unit. The sound detection unit will sense and identify sounds from the abdominal palpation area, such as tympanic or splashing. The three units work together under a synchronized control, so that the detected physical values can be corresponded on a time axis. The collected abdominal palpation data can be memorized with correspondences to sampling time (t) and position (x, y, z).

Abdominal diagnosis devices must secure the basic safety aspects including electrical safety, mechanical safety, electromagnetic field safety and biocompatibility of human contact material. The system should avoid excess loads applied to the patient body and should consider the secure measurements. From perspective of safety, noncontact measurement technologies are suggested.

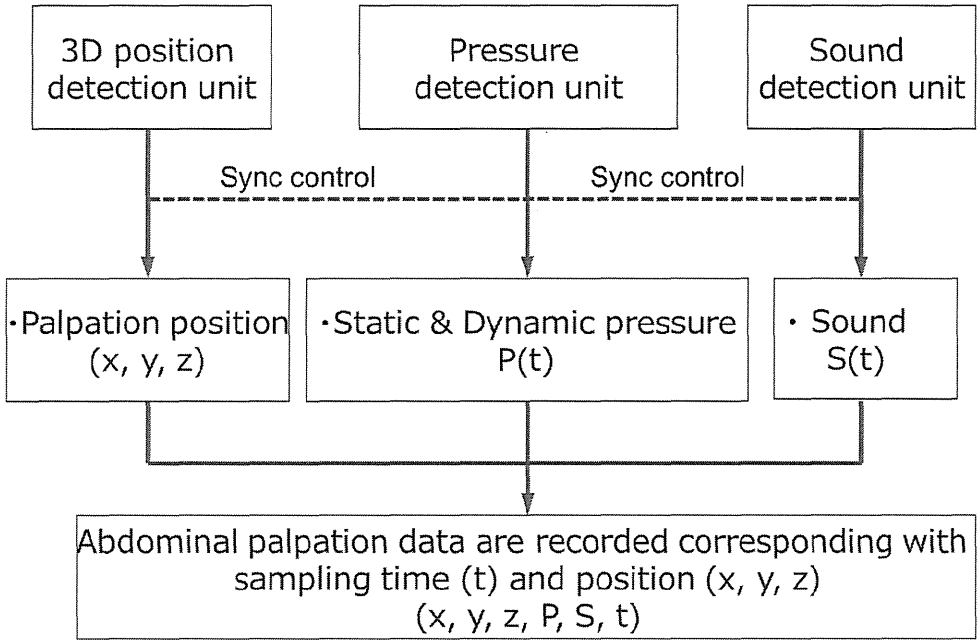

Fig. 4: Basic function configuration of an abdominal palpation diagnosis device.

4.2 Essential performance

Table 1 is a list of the potential essential performance to be considered by the manufacturer in the risk management process.

Requirement Sub-clause

Table 1: List of essential performance

Requirement	Sub-clause
Accuracy of position detection unit	12.1.1
Accuracy of pressure detection	12.1.2.1, 12.1.2.2
Accuracy of sound detection	12.1.3

General requirements for testing ME Equipment

Classification of ME Equipment or ME system

ME Equipment identification, marking, and documents

Protection against electrical hazards from ME Equipment

Protection against mechanical hazards of ME Equipment or ME Equipment parts

Protection against unwanted and excessive radiation hazard

Protection against excessive temperatures and other hazards

Accuracy of controls and instruments and protection against hazardous outputs

12.1 Accuracy of controls and instruments

12.1.1 Accuracy of position detection unit

Accuracy of palpate position detection shall be a maximum of 1mm, and the maximum resolution shall be 0.2mm within measurement range, which is larger than abdominal palpation area. The data sampling rate shall be at least 50 samples per second. Position detection shall be noncontact so as not to disturb palpation. To enhance the accuracy, a marker is allowed to be attached to the back of the doctor's hand so as not to disturb palpation.

Compliance is checked by testing.

12.1.2 Accuracy of pressure detection

12.1.2.1 Accuracy of pressure detection of fingertip sensor

The palpation pressure measurement range of the fingertip sensor shall be 10mm Hg to 2000 mm Hg, and resolution shall be better than 10mm Hg. The combined effects of sensitivity, repeatability, non-linearity, and hysteresis shall be within ±10% of the reading or ±10 mm Hg, whichever is greater. The data sampling rate shall be at least 1000 samples per second. The range of frequency shall be at 0.1 Hz to 5 Hz. In the case of a pressure sensor attached to the fingertip, it shall be flexible so as not to degrade the fingertip haptic sense of the physician.

Compliance is checked by testing.

12.1.2.2 Accuracy of pressure detection of palm sensor

The palpation pressure measurement range of the palm sensor shall be at 10mm Hg to 1000 mm Hg, and maximum resolution shall be 1mm Hg. The combined effects of sensitivity, repeatability, non-linearity, and hysteresis shall be within ±10% of the reading or ±10 mm Hg, whichever is greater. The data sampling rate shall be at least 1000 samples per second. The range of frequency shall be 0.1 Hz to 5 Hz. In the case of a pressure sensor attached to the palm, it shall be flexible so as not to degrade the palm haptic sense of physician.

Compliance is checked by testing.

12.1.3 Accuracy of sound detection

The sound detection dynamic range shall be 0 dB to 50 dB, and maximum accuracy shall be 3dB. The detection range of frequency shall be 20 Hz to 10K Hz. The data sampling rate shall be at least 30,000 samples per second. The microphone shall be placed close to the patient so as not to be disturbed by ambient noise.

Hazardous situations and fault conditions for ME Equipment

Programmable Electrical Medical Systems (PEMS)

Construction of ME Equipment and system

ME System

Electromagnetic compatibility of ME equipment and systems

Annex A (informative)

Bibliography

平成26年度厚生労働科学研究委託事業（地域医療基盤開発推進研究事業）H26-統合-一般-002

「ISO/TC249における国際規格策定に資する科学的研究と調査および統合医療の一翼としての漢方・鍼灸の基盤研究」

業務項目⑥「舌診機器の規格と安全性に関する研究と調査」報告

舌診機器の規格と安全性に関する研究

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要旨：TC249/WG4では舌診機器に関して、舌面に照射する照明の規格案が提出され、今年の全体会議で審議される。本分担課題では全体会議での議論を踏まえ、国外における舌診機器開発状況について現地調査を行う。本年度は、台湾での舌開発現状調査と現地の研究者との意見交換を行った。同時に第7回国際東洋医学会での漢方の特徴と魅力と題して紹介し、研究者や関係者と意見交換を図った。また平成24/25年度の厚生労働科学研究費の成果を踏まえ、舌診機器の安定的撮影法に関する研究（基礎・臨床）を実施した。

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（50音順）

A．研究目的

日本伝統医学である漢方は、他の東アジア伝統医学とは異なる独自の優れた医療技術や学問体系を備え、臨床においても、日本は西洋医の資格を得た医師がさらに研鑽を重ねて伝統医学を実践するシステムを持つ世界で唯一の国であり、すでに西洋医学との協調によって世界に類のない日本型の統合医療を展開している。しかし、近年ISO/TC249において、中医学の国際標準化を提訴した中国に対し、日本には国の標準として提起できる伝統医学の資料が少ない。このような状況を踏まえ、早急に日本伝統医学の国際的立場を確立し、国民の医療福祉向上のために国際規格策定に資する科学的研究と調査をする必要がある。我々はその基盤となる日本伝統医学の学問的整備と標準化をすすめていたが、その次の段階として、いまだ標準化が立ち遅れている漢方での診断技術の標準化を推し進める。本分担班では、舌診と腹診を中心に科学的に解明しつつある漢方の診断技術の成果を国際問題の対応（TC249）にも役立てることを目的とする。TC249/WG4では舌診機器に関し

て、舌面に照射する照明の規格案が提出され、今年の全体会議で審議される。本分担課題では全体会議での議論を踏まえ、国外における舌診機器開発状況についても現地調査を行う。

B．研究方法および結果

B．1　基礎研究：舌撮影装置の改良および漢方診断支援ソフトの開発（担当：千葉大学医療支援システム）：既に開発した舌撮影解析システム（Tongue Image Analyzing System：TIAS）により、一定の条件下で安定して撮影できるようになっていたが、キャリブレーションの問題の改良を行った。また、TIASにおいて、色と湿度が測定できるような開発を行った。これについては中口らにより、BioMed Research International, Articleに発表した。すなわち先行研究では舌の色彩や舌の形状を客観的に計測・評価する方法が報告されているが、舌表面の光沢に関して検討した例は少ないそこで本研究では舌診での舌湿潤度を定量するために光沢成分に着目した。舌湿潤度は撮影画像の光沢として現れると仮定し、光沢の安定的な計測手法を検討した。被験者13名に対し撮影画像から光沢量を定義し舌表面の水分量を実測し、光沢量と舌表面の水分量の関係を解析した。その結果、両者は高い相関を示し、画像的に計測できる光沢量から舌湿潤度が推定できることが示された。計測によって舌が乾燥し舌湿潤度が変化するため、繰り返し撮影時に設けるべき撮影間の待機時間は少なくとも3分間であった。以上を利用して舌表面の色彩と光沢を同時に安定して記録できるTIASを構築した。

B．2　臨床研究：舌の診断法の科学的検証（担当：千葉大学・北里大学・金沢大学・九州大学・鶴見大学・富山大学・広島国際大学・大阪大学・麻生飯塚病院・明治国際医療大学）すでに臨床応用を開始した舌撮影解析システム（TIAS）を用いて、漢方での舌診の科学的な検証を行う。すでにこのシステム活用を行う全国的な組織として舌診研究会（代表世話人：並木隆雄）を2011年に立ち上げ、成果を2013/2014年からの厚労科研補助金事業の成果発表会の一環で行った。各施設ではそれぞれの専門に関連したデーターの集積が行われた。例えば、消化器関連の検討を九州大学では行っており、TIASを用いて健診での胃内視鏡所見と舌診の色所見や形態との関連を検討した今後、この全国組織を中心に舌診の日本での標準化研究を行う。血液生化学データーと舌の色や形態などの指標など基礎的データーの収集。また漢方的診断（気・血・水）との関連も研究。それらのデーターを用いた統計学的な関連を検討する。また、千葉大学の王子らは舌診診断における観察側の問題点を明らかにする研究を行った。今後も舌診の客観的診断をするための要因をさらに明らかにする必要がある。

B．3　国際東洋医学会参加とシンポジウム開催

第7回国際東洋医学会（ICOM：International Congress of Oriental Medicine）が台湾の台北で開催された。舌診関連としてその中でも「Modernization and Clinical Application of TCM Diagnosis」を発表された羅綸謙先生（彰化基督教醫院　彰基體系中醫部主任、副教授；Director Lun-Chien Lo, Department of Chinese Medicine, Changhua Christian Hospital, Taiwan）の発表は、台湾における「中醫藥傳統醫學の證診斷法」の研究であった。中醫藥の診断（望診・聞診・問診・切診）における客観的に測定器機の紹介があった。舌診では舌の撮影・診断システムにおける過去から現在までの簡単な紹介があった。最近に開発された舌診システムの特徴はアタッシュケースに入れて携帯できる自動化舌診システム（Automatic Tongue Diagnosis System）を紹介していた。舌写真の分析は舌質分析、舌苔の厚さの分析、裂紋分析、瘀斑分析などを事例に説明した。また舌写真の特徴的な画

像を合成、分析結果を表示できるなども紹介していた（この舌診システムは後日、見学に行く國立中山大學工学部の蒋先生が開発した)。その他、爪甲による微小循環所見、音声分析、身体問診票（Body constitution questionnaire)、脈診測定装置（脈診儀）などを紹介し、望聞問切の四診による客観的測定により、病証を判断することを解説された。なお台湾では四診の診察は保険点数があり、このこともあって診断器機の開発は積極的に進められている。

その中の日本のセッションで日本漢方の紹介をするシンポジウム（オーガナイザー・司会：並木隆雄、矢久保修嗣 11 月 3 日 9：20～11：00 Traditional Medicine and Culture（Ⅲ）(JAPANESE Session, 傳統醫學與文化(Ⅲ)）で日本の伝統医学、漢方医学の特徴について、その独自性や魅力を紹介した。その中で舌診の現状についても紹介した（別紙の和辻　直明治国際医療大学准教授の報告書参照)。

B．4　台湾国内の舌診撮影装置の現状調査

台湾国内には大きく分けて 3 つの研究ループがあるという。そのうち 2 つのグループの撮影装置の見学の機会を得た。

台北市立連合病院　中西醫診療センター視察

現在中國醫薬大学の張　恒鴻教授は一つのグループのリーダーである。中國醫薬大学に転身する前は、台北周辺の病院で舌診の機械の研究をされていた。今回は以前所属していた台北市内の病院での見学を紹介していただいた。中醫醫學部主治醫師の黃伯瑜先生の勤務先である台北市立連合病院　中西醫診療センター（臺北市立聯合醫院 林森院區 中西醫診療中心；臺北市鄭州路 145 號）を視察。さらに、基礎研究部門を担当する徐　明景教授（Jim Shyu）と面談。徐教授は千葉大学で博士号を取った色彩に関する専門家である。台北市の北にある高台にある中国文化大学での研究状況を視察した。

国立中山大学工学部の視察

もう一つのグループの見学として舌撮影システム装置の開発担当を担っている蒋　依吾教授（Prof. Jim Y Chiang）の高雄の国立中山大学工学部に伺った。ICOM でもお会いすることのできた羅綸謙先生（彰化基督教醫院　彰基體系中醫部主任、副教授）らが臨床疾患との関連を積極的に発表しているグループである。蒋教授が開発した舌の撮影装置は撮影時の照明の処理は注意が必要であるが、ポータブルでアタッシュケース 1 つに収まるサイズである。病棟などへも容易に持参できる点が大変評価される点である。また、その解析ソフトはかなり完成度が高く、日本のソフトの改良の参考になった。機会があれば、臨床での活用の現場である病院での状況を視察したいと考えている。

C．考察

C．1　基礎研究

ISO/TC249 の提案として、一番大事な点は色の再現性の確保である。

その点を述べてからカラーパッチ・カメラ・ディスプレイなど各要素の精度・感度を規定する。

項目としては、①sRGB や adobeRGB など、舌診評価に用いる色空間に関する規②撮影環境も踏まえた舌診専用カラーパッチに関する規定②市販のデジカメも用いられるような、確保されるべき色域に関する規定③目視用ディスプレイに要求される性能に関する規定（4K 程度の可能性も）④視環境として満たされるべき最低限の条件の規定などに関してなどがある。今後、上記の条件設定の基礎資料としての色調・および形態からの解析の推進と日本の危機としての漢方的診断をパソコンで行う診断支援システム構築を ISO 協力企業とともに完成させる方針である。

C．2　臨床研究

各施設ではそれぞれの専門に関連したデーターの集積が行われており、消化器関連の検討を九州大学では健診で行った胃内視鏡所見と舌診の色所見や形態との関連で検討を学会報告した。今後、論文化し公開する予定である。さらにほかのグループも臨床での舌診診断における問題点の検討を複数の施設で行う必要がある。

C．3　ISO 関係各国での舌診撮影装置の視察と開発者関係者との交流

本年度は台湾での視察を行ったが、各国独自の工夫もあり、参考となり、刺激になる点も多々あることが再認識された。今回の視察結果を関係者に紹介したところ、舌診の解析システムが進む原動力になった印象もある。また、各国の開発者との交流は、国際会議での討論での活性化や連帯を生むことがあり、ぜひ必要なことであることも確認できた。次年度も、まだ未見学国の視察をする。さらに、欧米諸国への舌診機械の啓蒙活動を同時並行で行う。このことは、一種ロビー活動にもなり賛同する国を増やす可能性もある。

D．結論

2015 年 1 月現在、①一般要求（韓国）、②光源（中国・日本）が既に新規案件として投票段階にあり、来年、③カラーパッチ、④再現性の環境要求　に関する提案を、日本を中心に共同で行う。ISO/TC249 加盟国のうち、最低 5 か国からエキスパート参加協力を得る必要性がある。この点も踏まえて、研究と並行して、視察や関係者との交流が不可欠である。

E．健康危険情報

なし。

F．研究発表

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