

# Digital Infrared Thermal Imaging System



"New Concept of Pain & Breast Screening"

# **ThermaCheck**

FDA cleared Medical Thermography Imaging System

## **Medical Thermography**

#### **NEW CONCEPT OF PAIN & BREAST SCREENING SYSTEM**

#### ▶ ThermaCheck

ThermaCheck screening is obtained by US-FDA/CE approved Medical Infrared thermography system and it displays the thermal images of sensitive changes on the pain area by detecting the extra minimum infrared rays emitting from the body.

It is very useful test to diagnose the Neuropathy, Breast cancer, Physiological Problems, Inflammation and Circulatory disorder which are difficult to be found by CT or MRI without any radiation.

#### ▶ Why Should You Use ThermaCheck?

#### 



- International Medical Certificates [US-FDA, CE, CFDA]
- Built the Standard Reference of Body Temperature for Normal People
- Researches for over 20 years internationally

#### **Solution** Benefits



- The procedure is totally non-invasive & no-pain [Available for pregnant women]
- As it does not involve ionizing radiation, there is no patient risk
- Provides information for the physiological problems which other imaging systems could not detect
- It is easy to compare the results of before and after treatment by thermal imaging.

#### Usefulness



- Quantitatively analyze and visualize the Physiological States of Pain
- Judge and screen the blood circulation and the underlying disease related to ANS dysfunction
- □ The unique tool to visually indicate the Musculoskeletal Disorder

#### Clinical Applications

#### Cancerous Diseases

Breast Cancer Screening, Thyroid & Parathyroid Disease

#### Neural Diseases

Disc & Spinal Nerve Injury, Spinal Stenosis, Neuralgia, Chronic & Acute Back Pain, Carpal Tunnel Syndrome, Peripheral Nerve Injury, Causalgia, Autonomic Nerve Injury, CRPS, Hyperhidrosis, CVA, Facial Palsy, Migraine, Sensory Nerve Abnormality

#### Musculoskeletal Diseases

Myofascial Pain Syndrome, Arthritis, Brachial Plexus Injury, Rheumatoid Arthritis, Sprain & Strain, Myofascitis

#### Vascular Diseases

Deep Vein Disease, Varicose Vein, Thrombosis, Peripheral Vascular Disease, Buerger's Disease, Raynaud's Syndrome, Vascular Inflammatory Disease

## **Optimized in Medical Use**

### **DESIGNED FOR MEDICAL THERMOGRAPHY**

#### ▶ Features

- World-Class IR Imaging Resolution
- Digital Zooming & Auto Focusing Technology
- Motorized Stand & Rotatable Camera Head by Remote Control
- Actual Temperature Realization
- Auto Temperature Compensation Function according to Room Condition
- Automatic Diagnosis Function
- Provide Standard Temperature Data of Normal People
- Region of Interest [ROI]
  - Automatic ROI & Thermal Pattern Identification
- Automatic Win Level Adjustment
- Positioning & Clinical Guide Program
  - Positioning guide for 22 poses and clinical guide for 53 diseases are provided
- Pain Drawing Chart
  - Draw the actual pain area and compare it with thermal image

#### Auto ROI & Thermal Pattern Identification



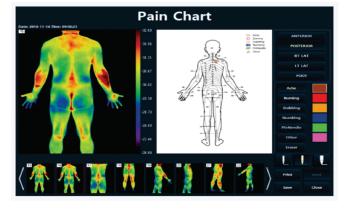
#### **Automatic Diagnosis**



#### **Clinical Guide Program**

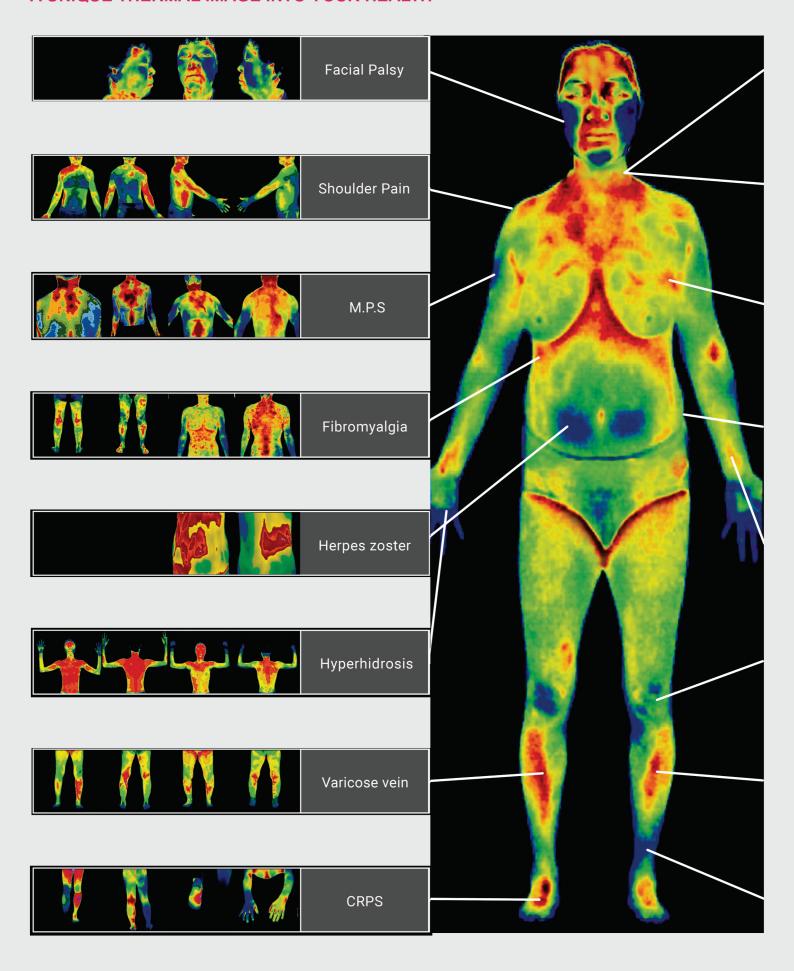


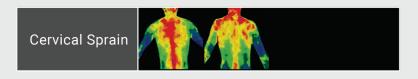
#### **Pain Drawing Chart**

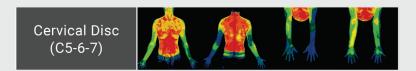


## **Clinical Cases**

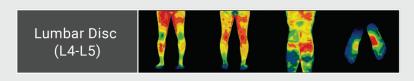
### A UNIQUE THERMAL IMAGE INTO YOUR HEALTH



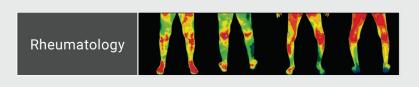


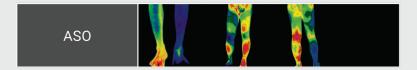


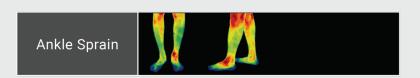
# Breast Cancer











#### **▶** Breast Thermography

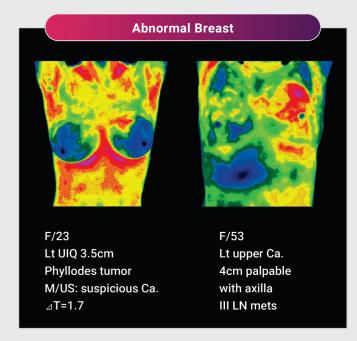
It is a valuable procedure for alerting doctor for changes that can indicate early stage breast disease.

We offer the opportunity of earlier detection of breast cancer that has been possible only by mammography alone.

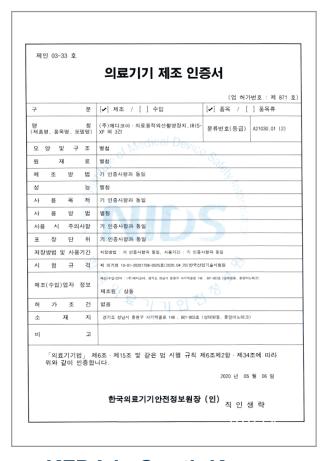
#### ► Painless & Non-Invasive

Unlike mammography, the procedure fo thermography is painless, non-invasive, and radiation free.

- No radiation
- Closer monitoring available without being exposed to radiation
- No painful compression
- Detects early warning signs before a lump formation
- Effective for women with dense breast tissue
- Effective for women with fibrocystic breast
- Effective for women with breast implants
- Effective for younger women/ teens
- Comfortable
- Convenient



## **Medical Certificates**



## KFDA in South Korea





Medicore Co., Ltd. % DoGyun Lim Senior Researcher GMS Consulting 4th Floor, Digital Cube, 34, Sangamsan-ro Seoul, Mapo-gu 03909 REPUBLIC OF KOREA

Re: K212412

K212412
Trade/Device Name: IRIS-XP
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulation Valame: Telethermographic System
Regulatory Class: Class I, reserved
Product Code: LHQ
Dated: July 26, 2021
Received: August 3, 2021

Dear Dogyun Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessati.dda.gov/scipics/dc/hc/fcloss/fcl/hc/fcloss/fcl/my/mym.fm. (indurifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

September 13, 2021

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

### **FDA in USA**

#### 中华人民共和国医疗器械注册证

•	
注册证编号:	国械注进20142215258
注册人名称	Medicore Co., Ltd
注册人住所	delice b/d, 164, Sagimakgol-ro, Sangdaewon-dong, Jungwon-gu, Seongnam-si, Gyeonggi-do
生产地址	delice b/d, 164, Sagimakgol-ro, Sangdaewon-dong, Jungwon-gu, Seongnam-si, Gyeonggi-do
代理人名称	北京高思明创科技有限公司
代理人住所	北京市朝阳区望京园601号楼20层2310
产品名称	医用红外热像仪 Infrared Imaging System
型号、规格	IRIS-XP
结构及组成	该产品由红外摄像头,显示器(包含图像处理及显示单元),打印机,台车,红外摄像头支架,脚踏开关和电源模块组成。
适用范围	本产品为医用红外线热成像装置,是感知从体表释放 出来的红外线,并采集,将体表温度分布用图像来表示 的设备
附件	注册产品标准
其他内容	
备注	10000000000000000000000000000000000000
审批部门: 国家食	品药品监督管理总局

## **Clinical Papers**

## We have published more than 200 Clinical Papers including SCI Level.

Clinical Trial/Experimental Study





#### Effectiveness and safety of moxibustion for alleviating symptoms of overactive bladder

A prospective, randomized controlled, crossover-design,

Hye-Yoon Lee, KMD, PhDa, Young-Ju Yun, MD, KMD, PhDa, Jun-Yong Choi, KMD, PhDa, Jin-Woo Hong, KMD, PhDa, in Lee, KMD, PhDa, Seong-Ha Park, KMD, PhDa, Jung-Nam Kwon, KMD, PhDa,  $^{\rm ab, *}$ 

Abstract
Background: This study aimed to evaluate trial feasibility and explore the potential efficacy and safety of moxibustion in the treatment of overactive bladder (OAB).

treatment of overactive bladder (CAB).

Method: A randomized, controlled, cross-over, assessor blinded design was used. This study was conducted in an outpatient department of a university hospital in Republic of Korea. The overall study period was 8 weeks. Participants were randomly allotted to either Group A or Group B. Group A participants underwent 8 to 12 sessions of moxibustion with behavioral training during the fifth weeks, while the Group B participants received behavioral training only. Over the next 4 weeks, the treatment offered to the 2 groups was reversed (Group A participants received behavioral training only, while Group B participants underwent the moxibustion session with behavioral training). The OAB-validated 8-question awareness tool (OAB-V8), OAB symptom scores (OABSS), visual analog scale (VAS) for lower urinary tract symptoms, and frequency voiding chart were used to assess outcomes. For analysis, we used effect size, measured as Hedge's g, to present descriptive results indicating the actual difference between the groups.

Results: Compared to that in Group B, the Hedge's g of OAB-V8 for the former 4 weeks in Group A was –0.248, that of OABSS was –1.531, and that of VAS was –0.713. During the latter 4 weeks, Group B showed similar effect with g=0.465, 1.207, and 0.427 for OAB-V8, OABSS, and VAS, respectively, compared to Group A. The portion of nocturnal voiding volume decreased (g=0.696), the mean voiding volume increased (g=0.696), and the voiding frequency decreased (g=0.698) with mobilished with minimal modification in outcome measures and comparator population.

Other information: This clinical trial has been registered on clinicaltrials.gov (NCT02271607).

Abbreviations: ADLs = activities of daily living, AEs = adverse events; ANS = autonomic nervous system, BT = body temperature, CONSORT = consolidated standards of reporting trials, DBP = diastolic blood pressure, DITI = digital infrared themsinging, NC = frequency-volume chart, ICI = inter-contraction interval, IPSS = international prostate symptoms score, IRB = institutional Review Board, ITT = intention-to-treat, KHO = King's health questionnaire score, KMD = doctor of Korean medicine. UTS = lower uninary tract symptoms, MI = multiple imputation, NGF = neural growth factor, OAB = overactive bladder, OABSS = OAB symptom scores, OAB-VB = OAB-Validated 8-question awareness tool, PPS = per-protocol-set, PPR = pulserate, OoL = quality of life, SPB = systolic blood pressure, as el sandard deviation, STRICTA = standards for reporting interventions in clinical trials of acupuncture, UA = urine analysis, UTI = urinary tract infection, VAS = visual analog scale.

Keywords: CV4, lower urinary tract symptoms, LR3, moxibustion, overactive bladder, SP6

Declarations: Ethics approved and consent to participate: This study was approved by the institutional review board (RB) of Pusan National University Korean Medicine Hospital (RB No. 2014005).

Consent for publication: Not applicable

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request The authors have no funding and no conflicts of interest to disclose.

The authors have no funding and no conflicts of Interest to disclose.

Supplemental Digit Content is available for this article.

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#### Infrared Thermographic Imaging in the Assessment of Successful Block on Lumbar Sympathetic Ganglion

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Department of Anesthesiology and Pain Medicine, Yonsei University College of Medicine, Seoul, Korea.

This study examined the net changes in temperature at various regions of the lower extremities in an attempt to iden-tify the regions demonstrating the most significant tempera-ture changes following a lumbar sympathetic ganglion block (LSGB).

ture changes following a lumbar symputhetic ganglion block (LSGB). Thermography was performed before and after the LSGB in 26 symputhetic nerve system disorder cases. The inspection points were the anterior and posterior surfaces of the thigh, the sace and leg, and the doesal and plantar surfaces of the feet. The net increases in skin temperature following the LSGB (4) at the plantar and dorsal surfaces of the feet, were  $6.2 \pm 2.68$ °C (mean  $\pm$  SD) and  $39 \pm 1.89$ °C, respectively, which were higher than those observed in the other regions of the lower extremites (p-0.05). The areas, in order of decreasing  $J^{10}$ —are as follows: the plantar surface of the foot, the dorsal surface of the foot, the shin, the anterior surface of the lower temperature of the lower temperature of the liquid the posterior surface of the high. There was one case of orthostate bypotension during the thermography procedure. In conclusion, thermographic imaging is a useful method for demonstrating the accesses of a LSGB in various diseases. An evaluation of the  $J^{10}$ " on the plantar surface of the feet using thermographic imaging in the most effective, simple, and safe method for seasesing a successful LSGB.

Key Words: Lumbar sympathetic ganglion block, thermo-

#### INTRODUCTION

A great deal of experimental and clinical evi-

ceived October 30, 2002 cepted December 23, 200

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dence has indicated that a lumbar sympathetic ganglion block (ISGB), with the local anesthetics or neurolytic agents, is a useful diagnostic, prognostic or therapeutic procedure for various diseases, including complex regional pain syndrome (ICRPs), hyperhidrosis and peripheral vascular diseases. When a neurolytic ISGB is being contemplated, a diagnostic or prognostic ISGB with local anesthetics is first recommended in order to predict the patient's response to the neurolytic block. The efficacy of the procedure and the minimization of side effects must be demonstrated before a neurolytic ISGB is performed. \*\*
Evaluating the effect of a ISGB, or its comprehensiveness, requires that specific tests of the sympathetic function be undertaken. The methods include skin conductance response, sweat tests, skin plethysmography and the ice response test. \*\*
Measuring the changes in blood flow following a ISGB is a local prographic and the creating the standard of the changes in skin plethysmography and the creating the changes in skin and the standard of the victions cycle of sympathetically maintained pain. Blood flow in the skin can be measured by the changes in skin can be measured by the changes in skin can be measured by the changes in skin emperature, washout techniques, laser Doppler flowmetry, uter healing process, or the tissue PaOs. \*\*

The temperature at the extremities is largely dependent on blood flow. Therefore, its measure-

The temperature at the extremities is largely The temperature at the extremities is largely dependent on blood flow. Therefore, its measurement by means of infrared thermographic maging has been found to be useful. In addition, thermography has the advantages of being non-invasive, safe (without X-ray irradiation), simple, can be monitored remotely, and is capable of

## Digital Thermography of the Fingers and Toes in Raynaud's

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ບ imatology, Department of Internal Medicini Hospital, 27 Inhang-ro, Jung-gu, Incheon 711, Korea 82.32-890-3483, Fax: +82.32-882-6578 \*\* nodownn@inha.ac.kr

The aim of this study was to determine whether skin temperature measurement by digital thermography on hands and feet is useful for diagnosis of Raynaud's phenomenon (RP). Fifty-seven patients with RP (primary RP, n = 33; secondary RP, n = 24) and 146 healthy volunteers were recruited. After acclimation to room temperature for 30 min, thermal imaging of palmar aspect of hands and dosoal aspect of feet were taken. Temperature differences between pain (center) and the coolest finger and temperature differences between poin (center) and first toe significantly differed between patients and controls. The area under curve analysis showed that the temperature difference of the coolest finger (cutoff value: 2.2°C) differentiated RP patients from controls (sensitivity/specificity: dosout 88/69%, respectively). A combination of thermographic assessment of the coolest finger and first toe was highly assessment of first toe was solely sufficient for women (sensitivity/specificity: about 88/69%, respectively) while thermographic assessment of first toe was solely sufficient for women (sensitivity/specificity: about 88/69%, respectively) while thermographic assessment of first toe was solely sufficient for women (sensitivity/specificity: about 88/69%, respectively). Thermographic assessment of first toe was found first toe is 74/68%, respectively). Thermographic assessment of the coolest finger and first toe is useful for diagnosing RP. In women, thermography of first toe is highly recommended.

Keywords: Raynaud Disease; Thermography; Digital Thermography; Temperature

#### INTRODUCTION

Raynaud's phenomenon (RP) is characterized by a three-phase color change of blanching, cyanosis, and rubor in distal extrem-ities after exposure to cold and subsequent rewarming (1). RP is not easily diagnosed in the clinic. It is difficult to observe the triphasic color change even in winter because most patients wait phasic color change even in winter because most patients wait in a warm waiting room long enough for any color change to disappear. Thermography on hands has been used to assess RP for a long time. Typically, an infrared camera was used to deter-mine skin temperature distributions by measuring thermal ra-diation (2). Whether RP is primary or secondary, the symptoms and signs of RP are manifested via vasospasms of the small muscular arteries and arterioles of the digits (3). Blood carries heat to the skin of the fingers, but vasospasms reduce blood flow, resulting in low temperature of the fingers. However, concerns about the reproducibility of thermography have limited its use (4). As RP affects both hands and feet (5, 6) we used inis use (4). As for an extra both frames and feet (3), by we used in frared thermography to measure skin temperature differences between the palm of the hand and the fingers and between the dorsum of the feet and the toes in patients with RP and normal healthy controls.

#### MATERIALS AND METHODS

We recruited 57 patients with RP (primary RP, n=33; secondary RP, n=24). All patients with primary RP (21 women, 12 men) satisfied the diagnostic criteria of LeRoy and Medsger (7) and had no clinical or immunological evidence of connective tissue disease, including normal nailfold capillary finding. Patients disease, including normal natiolic capillary linding. Patients with secondary RP (20 women, 4 men) had the following underlying diseases: systemic sclerosis (n = 10), mixed connective tissue disease (n = 2), rheumatoid arthritis (n = 3), Siogens's syndrome (n = 6), systemic lupus erythematosus (n = 1), Buerger's disease (n = 1), or atherosclerosis (n = 1). In addition, 146 thesates (ii = 1), or authors serious (ii = 1). In audinoit, ii to healthy people (86 women, 60 men) who has no underlying dis-ease such as diabetes mellitus or hypertension volunteered for the study. Infrared digital thermography was performed at a sin-gle rheumatism center in Incheon (Korea).

Thermography images were acquired using an infrared ther-mography camera (IRIS-XP\*, Medicore, Seoul). A technician who has acquired official qualification of infrared thermography and has experience of 5 yr in Inha University Hospital per-

Original Article

#### Effects of different sitting positions on skin temperature of the lower extremity

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- <sup>1)</sup> Department of Physical Therapy, Kangwon National University: 3 Hwangjo-ri, Dogye-eup, Samcheok-si, Gangwon-do 245-907, Republic of Korea
  <sup>2)</sup> Department of Skin & Health Care, Susung College, Republic of Korea

Abstract. [Purpose] The purpose of this study was to identify the effect of different sitting positions on the skin temperature of the lower extremity, [Subjects] The subjects of this study were 23 healthy university students (8 males, 15 feamles), [Methods] Normal sitting (8N), purper leg cross (LIC), and nalice on knee (AOK) positions were conducted to measure the changes in skin temperature using digital infrared thermographic imaging (DITI), [Results] ULC upper sahle, SV upper shin, ULC upper shin showed significant declines in temperature with time [Conclusion] These finding suggest that the ULC and NS sitting positions cause define of blood flow whomat to the lower extremity resulting in decrease of temperature of the lower extremity. Especially, sitting with the legs crossed interferes with the circulation of blood flowing volume much more than just sitting in a chair. Key words: Sitting position, Skin temperature, Blood flow

(This article was submitted Apr. 21, 2015, and was accepted May 18, 2015)

With recent rapid economic growth, an affluent diet, lack of exercise, professional jobs, and a sedentary life-style in which people are usually standing or sitting for long hours, is on the rise. Also, as people spend more and more time using computers at home and in the workplace, thanks to the popularization of the PC and universal usage of computers at work, hours of sedentary work are increasing.<sup>20</sup>

popularization of the PC and universal usage of computers at work, hours of sectionary own far in encreasing. Crossing the logs can cause hip adduction, provide stability to the sacroliae joint? and increase the torque on the lambar region by rotating the pelvis of a Person with a limited joint range of motion in the cosy.? It has been reported that when working in a standing position, an asymmetrical weight supporting stand-up position causes asymmetric activation of the left and right truth muscles and the muscles surrounding of the hip joint, imposition causes asymmetric activation of the left and right truth muscles and the muscles surrounding of the hip joint, imposition causes asymmetric activation of the left and right truth muscles and the muscles surrounding of the hip joint and sacroliae joint?. Also, the base in the position of the latter of the surrounding of the tissue surrounding the hip joint and sacroliae joint?. Also, the habit of stiffing with crossed lege can cause kyphosis, with the additional possibility of causing scoliosis. Minimal stimulus following a postural change eliosis at 8-min strange in the peripheral circulation. Stiffing with the legs crossed has the same impact on the nuclei and perspect and proposed pressures, temporarily causing partial numbness with a stinging tingly

\*Corresponding author. Sungloong Kim (E-mail: lymphkim@Kangwon ac.kr) C2015 The Society of Physical Therapy Science. Poblished by IPEC Inc. This is an open-scoss article distributed under the terms of the Cre-ative Commons Attribution Non-Commercial No Derivatives (byse-ni Liowac-that/Caretivecommons off/cineasely-in-end/3.05).

feeling, as if pricked by pins and neclets, due to neural pressure or blockage of blood supply.

If the peripheral circulation does not function smoothly, the tissue or cells are not provided with sufficient oxygen, causing organic change?

The skin temperature is associated with the change of blood flow rate, and the skin's absolute temperature of blood flow rate, and the skin's absolute temperature are incomment, time, and the measured part. The controlling actor of skin temperature is blood flow rate, and a lot of blood vessels and nerves are concentrated in the skin of the body, playing a privotal rule in controlling the body temperature of the external extraording the body temperature of the external temperature and the simple position with the gradient of the external temperature in the string position with the legs crossed.

change in skin temperature in the sitting position with the legs crossed.

Accordingly, this study was conducted to test they have a six that if the sitting position with crossed legs were to be continued, it would lead to neurothipsis and blockage of the blood supply to the lower extremities, causing leg numbness and poor blood circulation. Infra-red computer thermogra-phy was used to measure the change in blood flow rate and the variation of skin temperature in the lower extremities over the course of time:

# **Specification**

Туре	Premium Type • Camera • Motorized Stand • Work Station  Standard Type • Camera • Motorized Stand • Software  • Software  Economy Type • Camera • Tripod Stand • Software
IR Camera	- IR Resolution : 384x288 pixels or 640x480 pixels - Pixel Size : 17um - Thermal Sensitivity (NETD) : ≤50mk - Focal Length : 8.1mm - FOV : 49° x 36° - Spatial Resolution(IFOV) : 1.1mRad - Spectral range : 8~14 Microns - Detector Type : Uncooled Micro-bolometer - Frame Rate : 9 or 30 Hz
H/W	<ul> <li>Focusing Type: Auto Focusing [Premium], Manual Focusing [Economy / Standard]</li> <li>Stand Type: Motorized Stand [Premium / Standard], Tripod Stand [Economy]</li> <li>Rotating Camera Head by Remote Control [Premium]</li> <li>Electric Power: AC 100~220V, 50/60Hz, 250W</li> </ul>
S/W	<ul> <li>Color mode: 19 different color modes</li> <li>Auto Temperature Compensation Function</li> <li>Image process functions: Zoom, Crop, Isotherm, Flip, Reset, Magnify, Pan, Fit etc.</li> <li>Software functions: Auto Win Level, ROI, Auto ROI &amp; Thermal Pattern Identification, Automatic Diagnosis by AI, Real time IR image recording</li> <li>Image network system: PACS System</li> </ul>
Certificates	US-FDA CE CFDA (SO)



