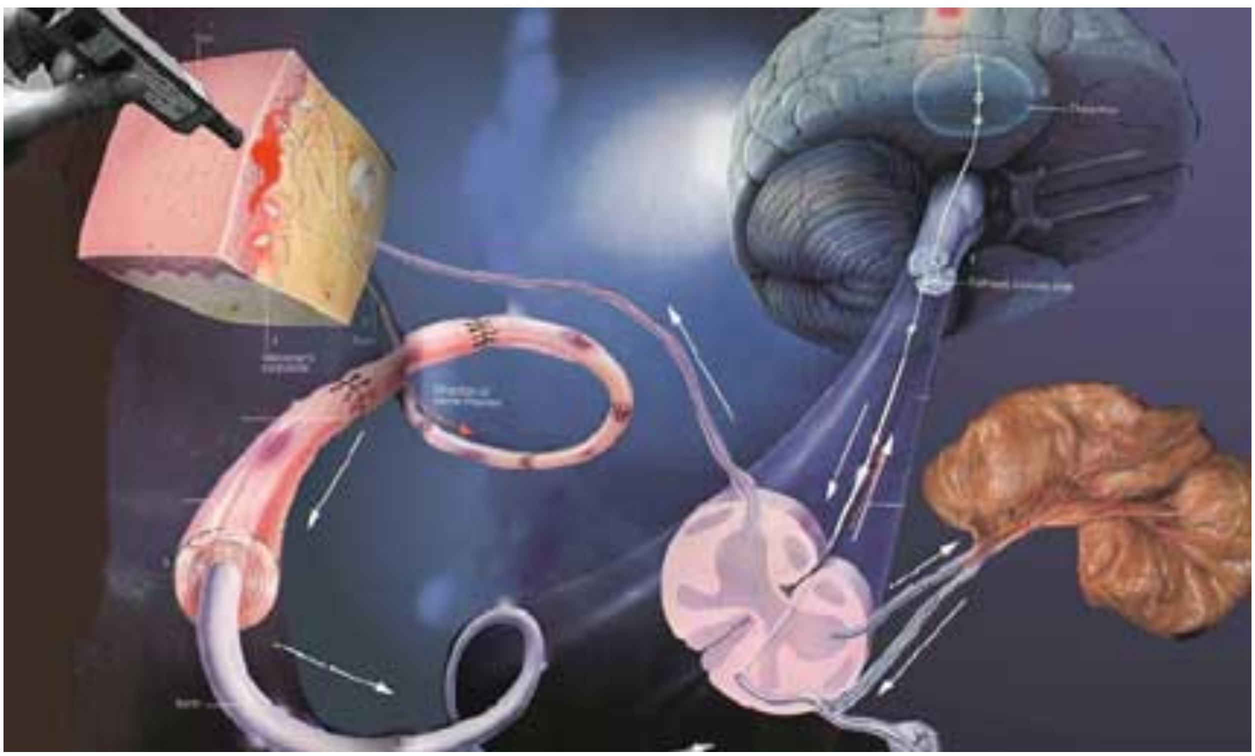
Bioregulatory Medicine Institute

INTRODUCTION TO CONTACT REGULATION THERMOGRAPHY



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Thermoregulation is the control of body temperature. Body temperature is kept constant in a very small range despite large differences in temperature of one's environment and level of physical activity. Strict regulation of body temperature is necessary for optimal biochemical process of hundreds of enzymatic reactions.

Contact Regulation Thermography (CRT) is a thermodynamic diagnostic method that utilizes the physiologic behavior of the body's skin temperature when exposed to a cold stimulus in order to determine the functionality and health status of certain organs, glands and tissues. Additionally, numerous investigators from different geographical regions that include Denmark, France, Germany, Italy, Japan, United Kingdom and the United States have investigated the efficacy of contact thermography, and more recently liquid crystal, contact thermography in detecting diseases such as cancer. Studies investigating breast abnormalities have shown that contact thermography was effective as a diagnostic tool with high sensitivity for detecting breast abnormalities. Breast abnormalities in breast cancer patients were associated with increases in local regional hyperthermia as related to the tumor as well as a useful adjuvant tool for diagnosing suspected breast neoplasms. The current CRT 2000® Thermographic system has the following indications for use as an adjunctive diagnostic device under its US FDA 510(k):

- Abnormalities of the female breast
- Peripheral vascular disease
- Musculoskeletal disorders
- Extracranial cerebral and facial vascular disease
- Abnormalities of the thyroid gland
- Various neoplastic and inflammatory conditions

In an Italian study of contact thermography and breast development it was reported that CRT was useful in evaluating pubertal breast development and in differentiating between premature thelarche and true precocious puberty. (*Frejaville E, Pagni G, Cacciari E)* Also in Italy in a study sample consisting of 12,000 patients it was shown that CRT proved reliable in those patients aged under 30 in detecting benign pathologies or palpable nodules of the breast. *(Sforza M, Ballerini A, Russo R, Carzaniga PL, Vertemati G.)*

Geshelin and colleagues have reported that CRT is extremely useful as a supplementary diagnostic modality that can significantly distinguish between cancer of the breast and benign tumors. *(Geshelin SA,* *Noskin AL, Kravchenko VA.)* Gautherie and Gros, who have evaluated a cohort sample of 58,000 women in the USA over 12 years, have reported that contact thermography had made a significant contribution to the evaluation of patients suspected of having breast cancer.*(Gautherie M, Gros CM.)*

In a study from Japan with various cancer patients it was observed and reported that patients with abnormal contact thermography profiles had cancer recurrences at more than one site. *(Ikeda T, Abe O, Enomoto K, Kikuchi K, Fujiwara K.)*

Contact thermography has also been extensively used in numerous other patient types and conditions that include deep vein thrombosis *(Kohler A, Hoffmann R, Platz A, Bino M),* surgical patients that have examined wound healing *(Horzic M, Bunoza D, Maric K),* skin damage due to chemical irritants *(Agner T, Serup J.),* diabetics with foot ulcers *(Benbow SJ, Chan AW, Bowsher DR, Williams G, Macfarlane IA.),* orthopaedic patients and those with temporomandibular dysfunction *(Specchiulli F, Mastrosimone N, Laforgia R, Solarino GB),* pregnant women with respiratory infections *(Fisher Iula, Oborotistova AN, Brio GB),* children with migraine *(Wolstein JR, Reed MH, Seshia SS, Kubrakovich P, Linsey B, Samuel A),* facial pain and fifth cranial nerve neuralgia *(Hardy PA, Bowsher DR.),* as well as lung cancer patients *(Loviagin EV, Mus VF, Litvinov PD, Iakovleva LA.).*

History

The association between temperature and disease is almost as old as medicine itself. The first recorded use of thermobiological diagnostics can be found in the writings of Hippocrates around 480 B.C: a mud slurry spread over the patient was observed for areas that would dry first and was thought to indicate underlying organ pathology. After Galileo introduced the thermoscope, thermometry evolved slowly and became established in medicine in part by the work of Carl Wunderlich in the 19th Century. Wunderlich published temperature recordings from over 1 million readings in over 25,000 patients made with a foot-long thermometer used in the axilla. He established a range of normal temperature from 36.3 to 37.5 °C. Temperatures outside this range suggested disease. Since that time, continued research and clinical observations proved that certain temperatures related to the human body were indeed indicative of normal and abnormal physiologic processes. In the 1940s and 50's, military research into infrared monitoring systems for nighttime troop movements ushered in a new era in thermal diagnostics. The first use of diagnostic imaging thermography came in 1957 when R. Lawson discovered that the skin temperature over a cancer in the breast was higher than that of normal tissue. While infrared image thermography was developing in the 50s, other scientists in Germany were interested in contact thermography as well as the physiological thermal regulation patterns that develop during illness. Beginning in 1953, Dr. Ernst Schwamm developed thermal functional diagnosis, a contact thermography, which he later called thermal regulation diagnosis. In 1954, Dr. Schwamm founded the German Society of Thermography and Regulation. At that time, Dr. Arno Rost, a German physician and researcher, was elected President of this society. Dr. Rost devoted his life to research in regulation thermography and in collaboration with his wife, Dr. Jutta Rost, MD, published several texts on contact regulation thermography. In 1975, Dr. Rost partnered with Werner Eidam (Werner Eidam Medizintechnologie GmbH) to further develop contact regulation thermography measurement equipment. In 1980, Werner Eidam and Dr. Rost developed the Eidatherm, a predecessor to the current CRT 2000 Thermographic System. Dr. Rost died in March 2005 at the age of 86. The Board of the German Society of Regulation Thermography then elected Prof. Dr. Reinhold Berz as its president. In 2003, Werner Eidam's company compiled 22 years of research data, including thermographic data, case files, and patient pathologies. This data was used in the development of the CRT 2000 machine. In 2005, Eidam Diagnostics Corporation was founded and purchased the intellectual property rights from Werner Eidam's company. In 2006, Eidam Diagnostics re-engineered the Contact Regulation Thermographic-2000 system into its present-day model.

Aside from CRT, modern infrared imaging systems offer high-resolution images of human body temperature, measuring the infrared heat of tissue metabolism. An infrared scanning camera translates infrared radiation emitted from the skin surface and records them on a color monitor. This visual image graphically maps the body temperature and is referred to as a thermogram. The spectrum of colors indicates an increase or decrease in the amount of infrared radiation being emitted from the body surface. In healthy people, there is a symmetrical skin pattern which is consistent and reproducible for any individual.

Contact regulation thermography and infrared thermal imaging are vastly different diagnostic approaches, though each is based on thermodynamics. It is important to differentiate that CRT is a functional diagnostic involving a cold challenge and as such measures the regulatory capacity of organs, gland and tissues. Whereas thermal imaging is a static image and does not assess the regulatory capacity of the body, CRT assesses the regulatory capacity of more than 20 organs, glands and tissues given a cold challenge. Infrared imaging is not as organ specific as CRT, and as a static thermal image, it does not provide regulatory or functional information.

It is unfortunate, but many physicians still hesitate to consider thermography (contact regulation or infrared imaging) as useful tools in clinical practice in spite of the considerable research database, continued improvements in both contact thermographic technology and image analysis, and continued efforts on the part of the thermographic societies. This attitude may be due to the fact that the physical and biological bases of thermography are not familiar to most physicians. Regulation physiology and functional diagnostics is still in its infancy in comparison to structural diagnostic measurements and imaging (x-ray, MRI). The other methods of investigations refer directly to topics of medical teaching. For instance, radiography and ultrasonography refer to anatomy.

Thermography, however, is based on thermodynamics and thermokinetics, which is of central interest to the world of physics but unfamiliar to most physicians. In many areas conventional medicine has not caught up with quantum physics. Hence, in the United States, CRT as a functional diagnostic method is still not generally well known or understood among clinicians even though it is an FDA-registered diagnostic.

The Contact Regulation Thermography Procedure

The CRT process is based on a double measurement of the skin temperature at 119 locations (specific points) on the surface of the body. The patient first sits fully clothed in a slightly cool room (20°C to 23° C) for 10 to 15 minutes while the body temperature acclimates. The technician begins the measurements by gently touching a temperature probe on specific points on the face and neck. The patient is then asked to remove their clothes from the waist up, so that the remainder of the measurements on the arms, chest, upper and lower abdomen, back and breast can be taken. After that, the patient is asked to disrobe from the waist down and sit unclothed in their underwear, with arms by the side, exposed to the cool room air for 10 minutes. The exposure provides a challenge to the body's temperature regulation processes. While still undressed, the same points are measured again to conclude the test. The computer software then analyzes the data and provides a graphic and interpretation based on the combined data. The CRT-2000 device produces an immediate printout and computerized interpretation.

Principles of Regulation Thermography

The interpretation principles involve both the absolute temperature values and the differences between the measurements before and after the cold stimulus. The ongoing collaboration of The International Medical Academy for Thermography scientific board with clinical experts together with EIDAM Diagnostics Corporation, has resulted in the recognition of many different patterns in the CRT-2000 printout.

The observed temperature patterns are classified according to their regulation types (normal, hyporegulation, hyperregulation, rigid regulation and paradoxical regulation) and used to assess functional pathology and gain diagnostic information. A set of interpretation principles has been established over several decades that incorporates a detailed computer analysis of the contact regulation thermograph.

CRT is based on the physiological condition that diseases of the human body (or their prephases) entail changes in the body's ability to adapt to the current ambient temperature. A comparison of the body's actual thermoregulation capacity with an expected or ideal healthy regulation pattern provides information relevant for the diagnosis of certain diseases.

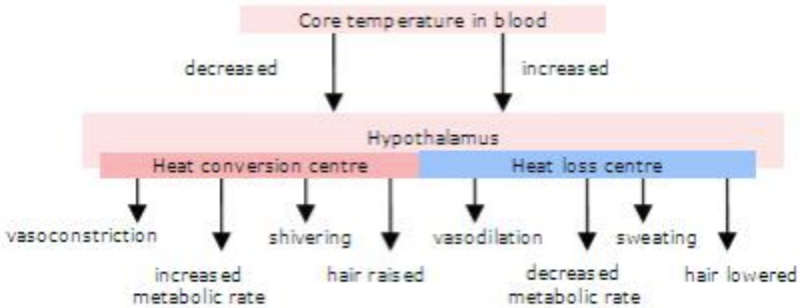
The healthy body continuously regulates the heat production and loss with the aim to maintain a specific temperature pattern. This pattern is determined by organ, gland and tissue function, anatomy and body thermodynamics. The liver produces a lot of heat, which is transported around the body by the blood. Normal body temperature in humans is 37°C. Stability and circadian variation in core body temperature are homeostatic responses that have been well documented for many decades. The temperature of the body's core, as well as that of the head, must be kept constant as to ensure the unrestricted functioning of the inner organs and the brain. Arms and legs exhibit a variation of temperature. The axial symmetry of temperature distribution has simple anatomic reasons, while the radial decrease of temperature values represents the flow of energy from their source through the body's surface into the ambient space.

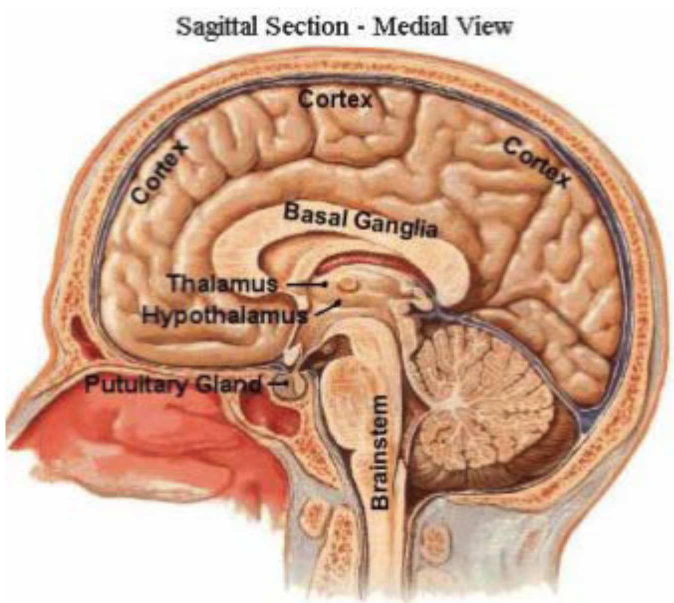
Previously, average oral temperature for healthy adults had been considered 37.0 °C (98.6 °F), while normal ranges are 36.1 °C (97.0 °F) to 37.8 °C (100.0 °F). In Poland and Russia, the temperature had been measured axillary. 36.6 °C was considered "ideal" temperature in these countries, while normal ranges are 36 °C to 36.9 °C.

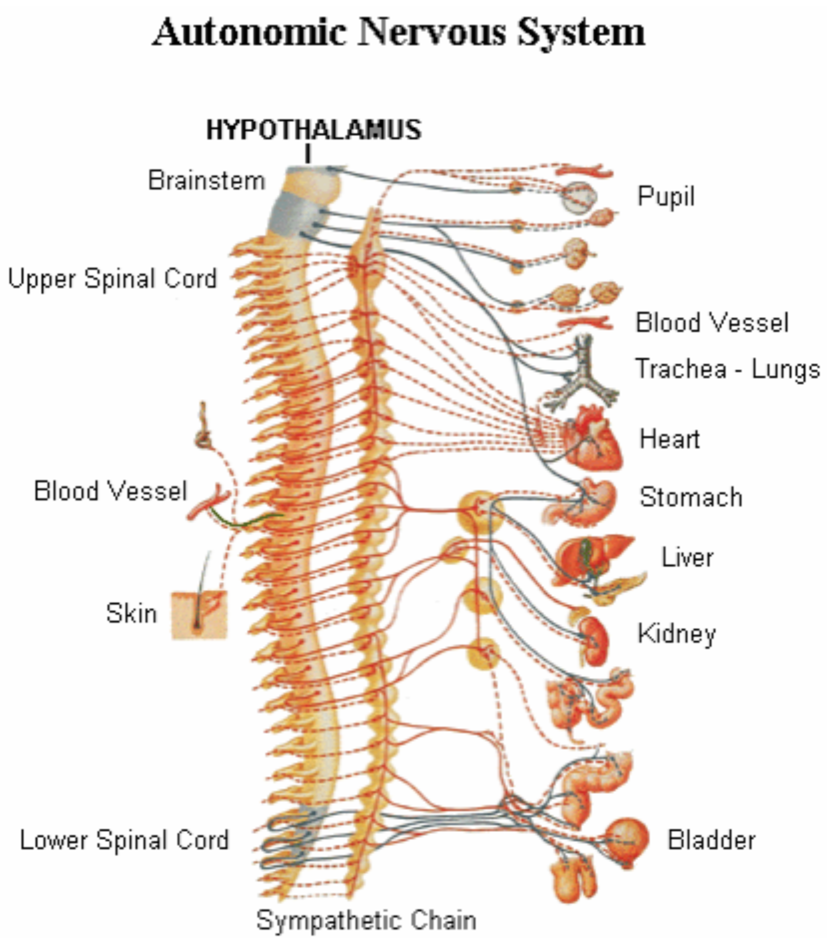
Recent studies suggest that the average temperature for healthy adults is 98.2 °F or 36.8 °C (same result in three different studies). Variations (one standard deviation) from three other studies are:

- 36.4 - 37.1 °C (97.5 - 98.8 °F)
- 36.3 - 37.1 °C (97.3 - 98.8 °F) for males, 36.5 - 37.3 °C (97.7 - 99.1 °F) for females
- 36.6 - 37.3 °C (97.9 - 99.1 °F)

The regulation of the heat distribution inside the body is performed by a multitude of organ, glandular and neurological components in response to the environment. Most body heat is generated in the deep organs, especially the liver, brain, and heart, and in contraction of skeletal muscles. Humans have been able to adapt to a great diversity of climates, including hot humid and hot arid. High temperatures pose serious stresses for the human body, placing it in great danger of injury or even death. For humans, adaptation to varying climatic conditions includes both physiological mechanisms as a byproduct of evolution, and the conscious development of cultural adaptations. The center of this control system is constituted by the hypothalamus, located below the thalamus, just above the brain stem. The hypothalamus receives input from two sets of thermoreceptors. The first is located in the hypothalamus itself as it monitors the temperature of the blood passing through the brain (the core temperature). The second are the receptors in the skin (especially on the trunk) which monitor the external temperature. Both sets of information are needed so that the body can make appropriate adjustments. The hypothalamus then sends impulses to the autonomic nervous system to adjust body temperature. Depending on environmental and physiological conditions the hypothalamus can activate or deactivate the metabolic activity. Some of these mechanisms are to a certain extent self-sufficient, some others can directly interact with each other (see following diagrams).

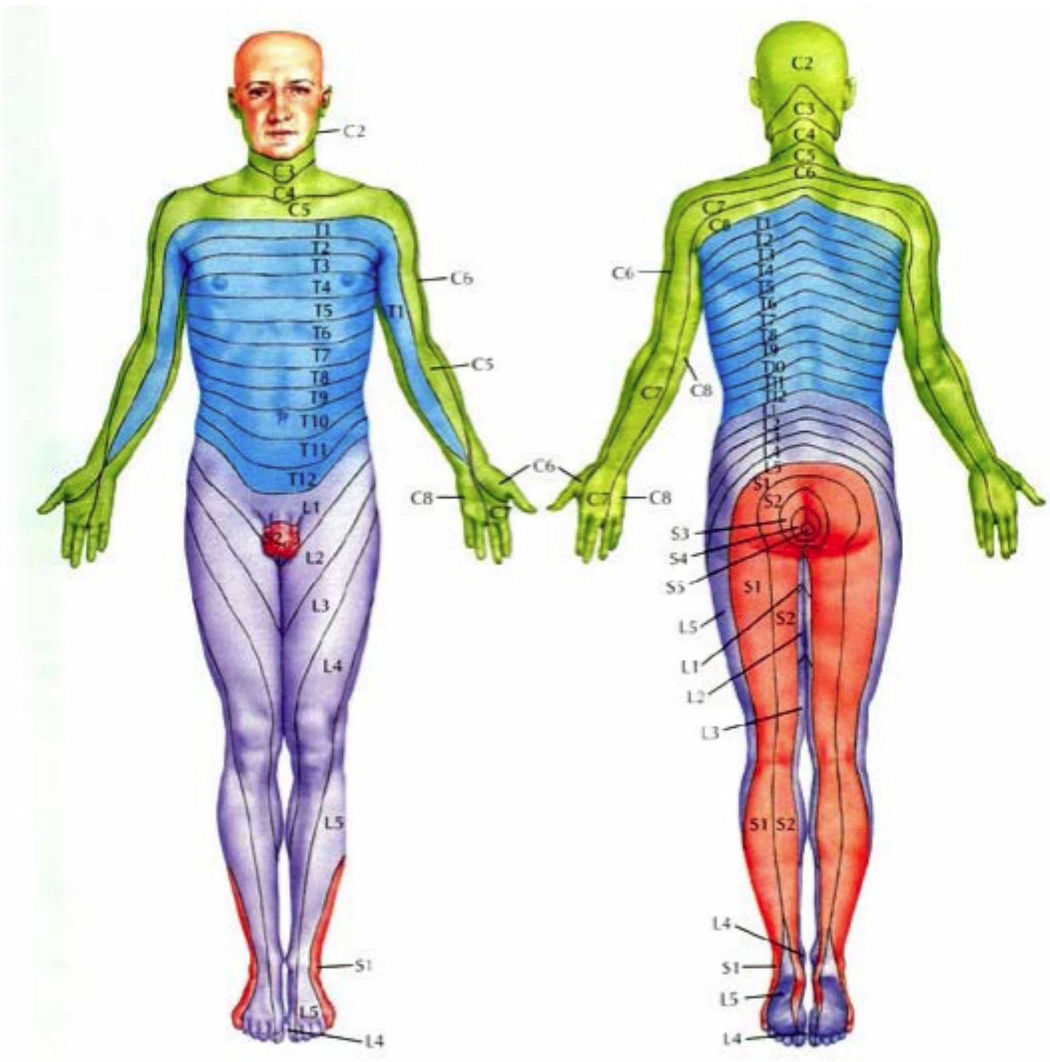

Core temperature in blood
decreased
increased
Hypothalamus
Heat conversion centre
Heat loss centre
vasoconstriction
increased metabolic rate
shivering
hair raised
vasodilation
decreased metabolic rate
sweating
hair lowered


Sagittal Section - Medial View
Cortex
Cortex
Cortex
Basal Ganglia
Thalamus
Hypothalamus
Putuitary Gland
Brainstem



The physiology and anatomy of the vascular supply to the skin produces a certain temperature pattern that may be within certain limits that are considered normal. Yet humans show strong deviations from this ideal pattern. Such deviations may have underlying chronic illness correlations. For example, in neonatal medicine middle ear infections in neonates often present as a unilateral complaint. That is one side of the head and face produces a pattern of local area temperature increases such as reddening of that side of the face whilst the other side remains normal.

In order to better understand the way pathophysiological processes can influence the bodies' thermoregulation ability, it is necessary to examine the autonomic neurological innervations involved. Basically, it is circuitous and may be simply described as follows: information flows from skin to afferent (sensory) nerves to the spinal cord then becomes organ input and then (depending on the heath status of the organ) organ information is relayed back to the spinal cord and then to efferent nerves connecting to the skin. Due to reasons lying in the embryonic evolution of humans, all nerves leaving the spine between two specific intervertebral disks innervate a horizontal slice of the body. Moreover some innervated areas are arranged in a vertical direction (see following diagram).



Levels of principal dermatomes

C5	Clavicles	**T10**	Level of umbilicus
C5, 6, 7	Lateral parts of upper limbs	**T12**	Inguinal or groin regions
C8, T1	Medial sides of upper limbs	**L1, 2, 3, 4**	Anterior and inner surfaces of lower limbs
C6	Thumb	**L4, 5, S1**	Foot
C6, 7, 8	Hand	**L4**	Medial side of great toe
C8	Ring and little fingers	**S1, 2, L5**	Posterior and outer surfaces of lower limbs
T4	Level of nipples	**S1**	Lateral margin of foot and little toe
		S2, 3, 4	Perineum

The main consequence of this segmentation is that different nerves running to or coming from areas in one and the same segment can interact in the spinal cord. An impulse sent by an inner organ can induce an impulse connected to a specific part of the skin. This phenomenon is termed the visceral-cutaneous reflex system or reflex arc.

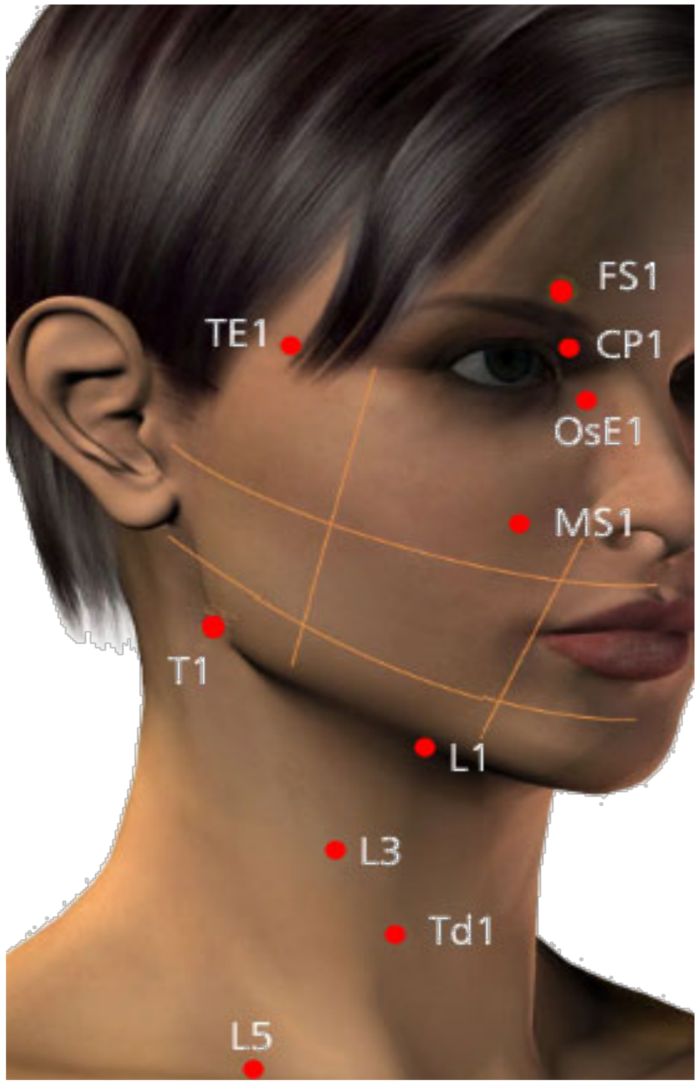
Impulses coming from organs, glands and tissues alter various properties of the skin, like the temperature, perspiration, the mechanical tonus and sensitivity. Consequently, pathological changes of an inner organ can locally influence the metabolism, temperature and other properties of the skin via this reflex arc. These phenomena are the basis of CRT.

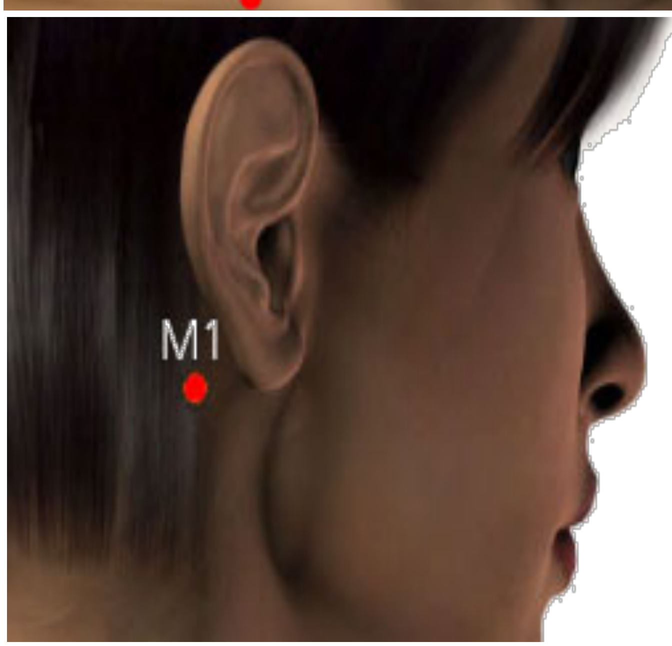
The Areas and Corresponding Organs, Gland and Tissues Measured:

To achieve comparability in CRT ,a standard set of points was defined by Dr. Arno Rost in 1975. These points were grouped into three subsets: the 6 standard areas, the dental/jaw areas, and the mamma, both right and left. Additionally, the areas at the cubital fossa of the elbows are measured twice, at the beginning and at the end of each of the first and the second measurement. This is primarily done to evaluate general regulatory capacity as well as temperature laterality.

The 6 standard areas of the body included:

Area 1 - Head Points:
GL – glabella - reference point
RN - radix nasi – circulation
FS 1 - frontal sinus R
FS 2 - frontal sinus L
T 1 - temple R – pituitary; brain; external carotid
T 2 - temple L – pituitary; brain; external carotid
CP 1 - commissura palpebrarum medialis R – internal carotid; brain; sinus
CP 2 - commissura palpebrarum medialis L – internal carotid; brain; sinus
M 1 - Mastoid 1 R - atlas/axis, R/L asymmetry = subluxation; inner ear; brain
M 2 - Mastoid 2 L - atlas/axis, R/L asymmetry = subluxation; inner ear; brain
OsE 1 - os ethmoidale R – immunity, R/L asymmetry suggest chronic virus
OsE 2 - os ethmoidale L – immunity, R/L asymmetry suggest chronic virus
MS 1 - maxillary sinus R
Ms 1 - maxillary sinus L


FS1
TE1
CP1
OsE1
MS1
T1
L1
L3
Td1
L5


M1

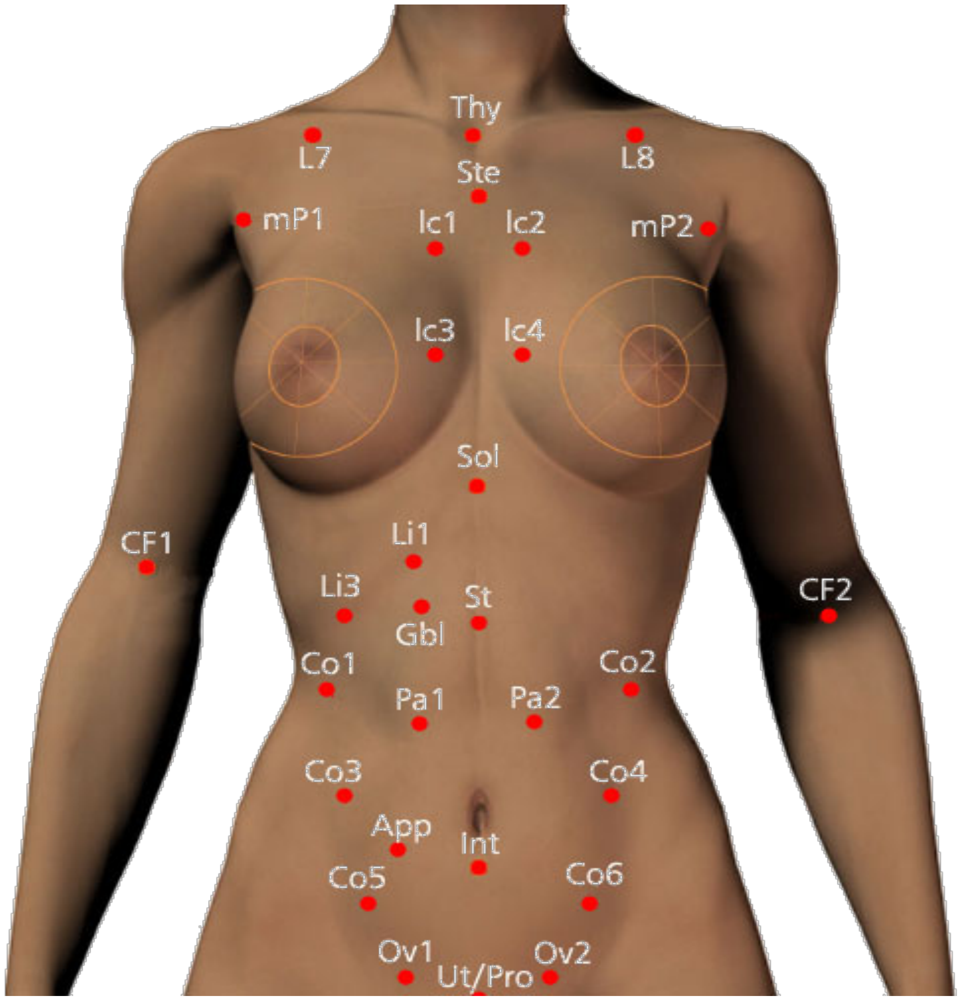
Area 2 - Neck Points
T 1 – tonsil R
T 2 – tonsil L
L 1 – inframandibular gland R
L 2 – inframandibular gland L
L 3 – ventral edge of m. sternocleidomastoideus R
L 4 – ventral edge of m. sternocleidomastoideus L
L 5 – supraclavicular fossa R
L 6 – supraclavicular fossa L
L 7 – infraclavicular fossa R
L 8 – infraclavicular fossa L
Td 1 – thyroid lobe R
Td 2 – thyroid lobe L
Thy - thymus

Area 3 - Chest Points
Sternum
mP 1 - Pectoris right lateral edge
mP 2 - Pectoris left lateral edge
Ic 1 - Intercostal right (reference)
Ic 2 - Intercostal left (atrium)
Ic 3 - Intercostal right (reference)
Ic 4 - Intercostal left – (myocardial)

Area 4 - Upper Abdominal Points
Solar Plexus
Stomach
Liver 1
Liver 3
Gall Bladder
Pancreas 1 (head)
Pancreas 2 (tail)

Area 5 - Lower Abdominal Points
Small Intestine
Colon 1-hepatic flexure)
Colon 2-splenic flexure)
Colon 3 (ascending)
Colon 4 (descending)
Colon 5 (cecum)
Colon 6 (descending sigmoid area)
Appendix
Uterus/Prostate
Ovary/Lymph right
Ovary/Lymph left

Area 6 - Back Points:
Kidney 1 right
Kidney 2 left
Sacroiliac 1 right
Sacroiliac 2 left


Thy
L7
L8
Ste
mP1
Ic1
Ic2
mP2
Ic3
Ic4
Sol
CF1
Li1
CF2
Li3
St
Gbl
Co1
Co2
Pa1
Pa2
Co3
Co4
App
Int
Co5
Co6
Ov1
Ov2
Ut/Pro


Kid2
Kid1
Sac2
Sac1

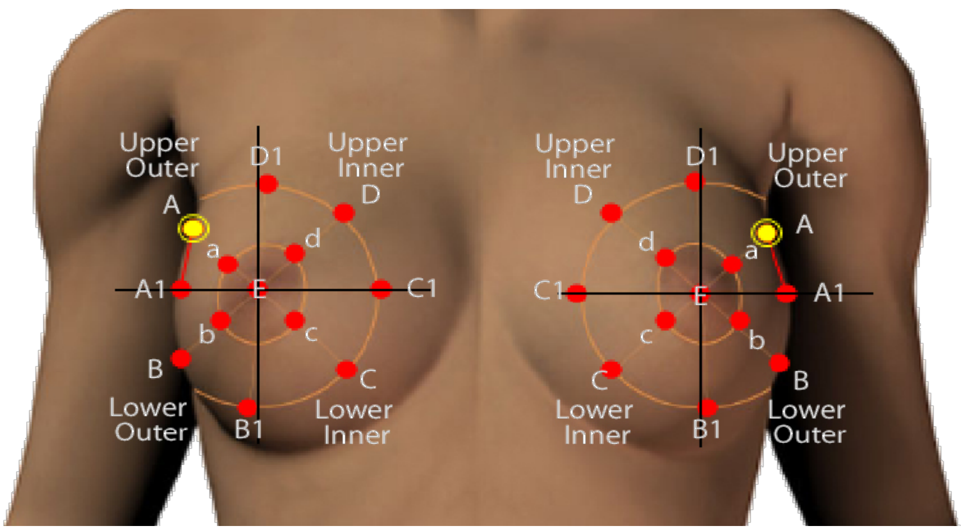
The Dental/Jaw areas:

Points are located over all 32 teeth areas. These are arranged in quadrants of 8 points per quadrant; hence, upper right jaw, upper left jaw, lower right jaw, and lower left jaw. The posterior teeth regulate cooler than the anterior ones, and this pattern forms a sine wave in the thermographic result.

The Breast areas:

The breast areas are mainly measured for female persons in particular in the context of breast disease diagnosis, but can also be an aid in cardiovascular regulatory evaluation in both females and males.

The breast areas include 11 points on each breast and are arranged as follows:



The primary abnormal contact regulation patterns in the mamma include:

- Hot spots in mamma
- Rigid regulation points in mamma
- Temperature asymmetry from right mamma to left mamma that exceeds greater than 0.7 C.
- Temperature asymmetry in the chest (area 3) from right to left that exceeds greater than 0.5 C.
- Hot spot in pectoris points of area 3 and/or asymmetry of pectoris points from right to left more than 0.5 C.
- Area 3 sternum point rigid regulation
- Rising chaos index in the mamma
- Rising chaos index in the chest

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About Eidam

Eidam Diagnostics Corporation is a privately held Canadian company headquartered in Richmond, British Columbia. The company's primary product, the CRT 2000 Thermographic System, is intended for use in preventive healthcare. The CRT 2000® has obtained both the CE Mark and has been for sale in the United States based upon the device's premarket notification (510(k)).

Note: The CRT 2000® is not intended to serve as a sole diagnostic screening procedure.

CRT 2000 Thermographic System

Supply voltage: AC 110 - 240 V
Power Input: 180 Watt
Frequency: Hz 50/60
Storage Temperature Range: 0°C - 50°C
Graphic LCD Display

Sensor
Contact measurement
Response Time: <1 seconds
Temperature Resolution: <0.1°C
CE: This device complies with EU directives 93/42/EU*
FDA 510K # K 973177 (USA)

Requires Internet Connection

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