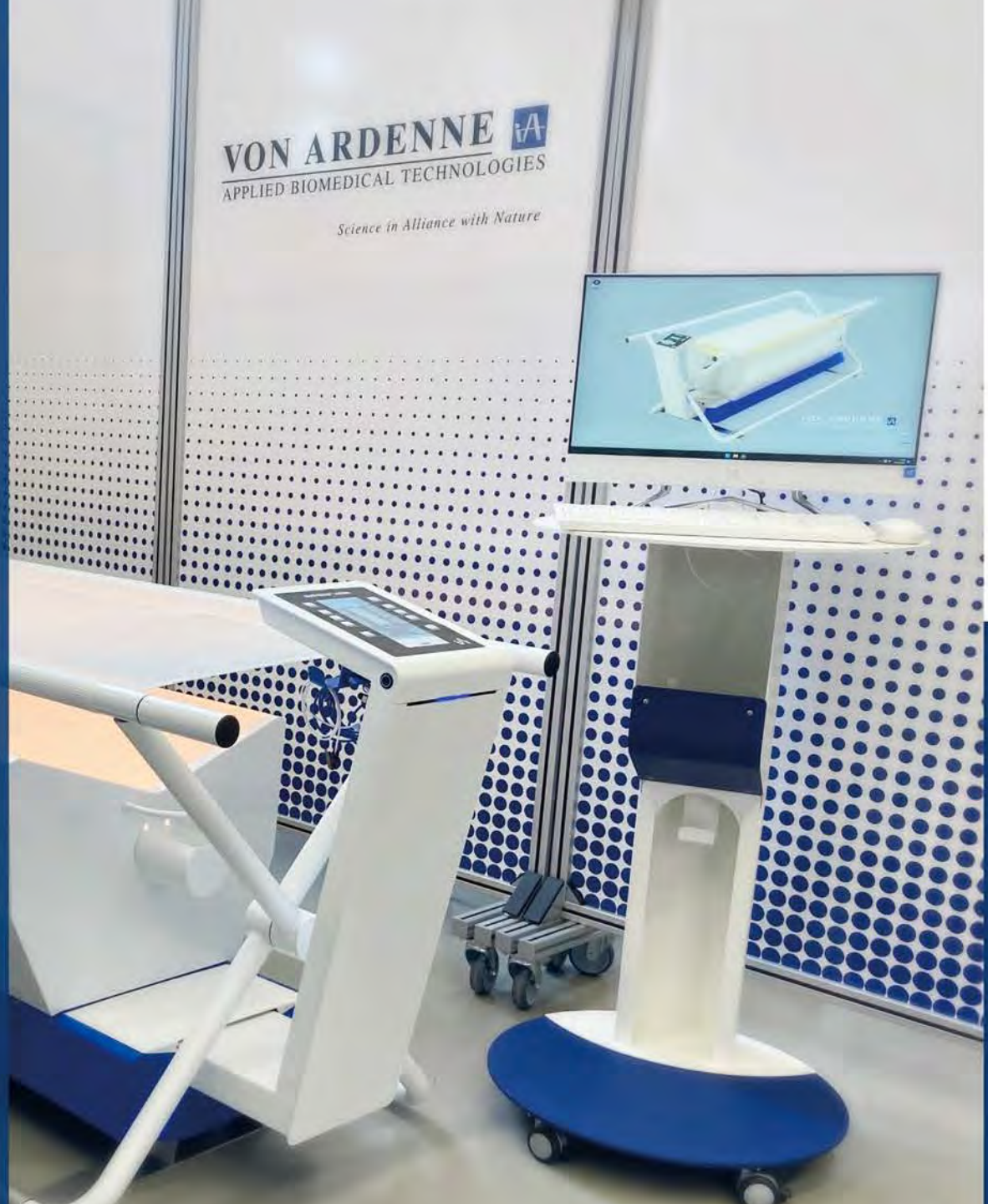
AASPL Anti-Aging Sciences Propulsion Labs Co., Ltd.

VON ARDENNE
APPLIED BIOMEDICAL TECHNOLOGIES

IRATHERM Whole-Body Hyperthermia

IRATHERM ® 1000M



VON ARDENNE

APPLIED BIOMEDICAL TECHNOLOGIES

Science in Alliance with Nature

Founder

VON ARDENNE
APPLIED BIOMEDICAL TECHNOLOGIES

Manfred von Ardenne, a German applied physicist, medical doctor (honoris causa), and inventor, held around 600 patents in diverse fields including electron microscopy, medical technology, nuclear energy, plasma physics, and radio transmission.
During World War II, he led a laboratory for electron physics research, and after the war, he was invited to contribute to the Soviet atomic bomb project, for which he received the Stalin Prize. His invention of the Duoplasmatron was applied in particle accelerators and space rocket propulsion systems.

In the Medical Field |

- Awarded an Honorary Doctorate in Medicine by the Dresden Medical Academy
- Recipient of the Ernst–Krokowski Award from the Biological Cancer Defense Society
- Developer of a systemic multi–step cancer therapy, focused on high–temperature and hyperglycemia–based treatment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Company Overview

1928 - 1945

- Laboratory for Electron Physics (Berlin, Germany)

1955

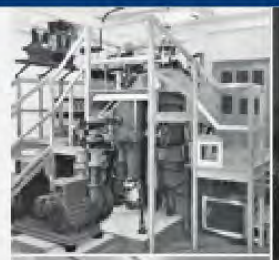
- Manfred von Ardenne Research Institute (Dresden, Germany)
- Electron beam technology
- Plasma physics technology
- Vacuum coating technology

1963

- Biomedical Engineering
- Biomedical Research

1945 - 1955

- Institute for Isotope Separation in Industry (Sukhumi, Soviet Union)



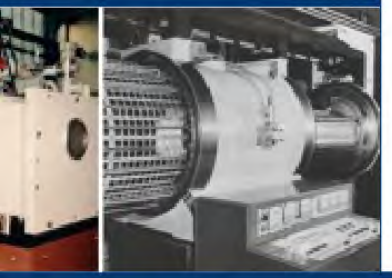
1928–1945 Led research in electron physics during this period.

1991

- Main Spin-off Company: VON ARDENNE GmbH
- Provider of industrial vacuum coating systems and technology (67 employees)
- Capable of depositing multi-layer functional thin films on various substrates
- Thin films possess excellent optical, electrical, thermal, and mechanical properties
- Electron beam guns with output power up to 1200 kW
- Applicable for thermal evaporation of highly reactive or high-melting-point metals
- Technology plays an increasingly important role on a global scale

1994

- Launch of IRATHERM®1000
- Establishment of Von Ardenne Institute of Applied Medical Research GmbH
- Medical device technologies developed: Whole-body hyperthermia, Multistep oxygen therapy and Systemic multistep cancer therapy



2014

- Launch of IRATHERM®1000
- Establishment of Von Ardenne Institute of Applied Medical Research GmbH
- Medical device technologies developed: Whole-body hyperthermia, Multistep oxygen therapy and Systemic multistep cancer therapy

2019

- Formation of the VON ARDENNE Group
- A corporate network consisting of the German headquarters and overseas subsidiaries
- Global presence: China, USA, Malaysia, Taiwan, Vietnam, Japan (Approx. 1,000 employees)

2020 - 2021

- IvA established regional offices in: Taiwan, Singapore, Malaysia, and Spain

Company History

1960

- Launched the first medical research initiative and began collaborative research with Nobel Laureate Otto Heinrich Warburg.

1962

- Developed the first multistep cancer therapy concept.

1963

- Established the first biomedical research team.
- Developed the dual-chamber hyperthermia probe and head cooling device (1965).

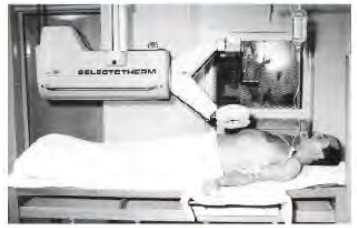
1970

- Systemic Cancer Multistep Therapy (sCMT)

1972

- Oxygen Multistep Therapy (O_2MT)

1976



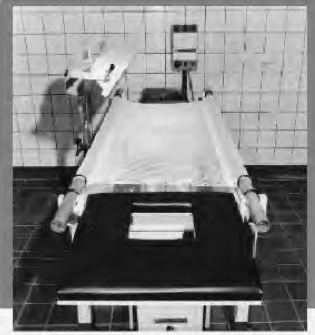
SELECTOTHERM

- Introduced local and whole-body hyperthermia therapy using a 27 MHz high-frequency scanning system (SCMT: Systemic Cancer Multistep Therapy)

1987

IRA II

- Device combining IRATHERM® technology and water-filtered infrared-A (wIRA)

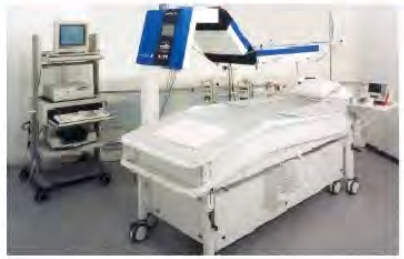


1990 - 1991

Establishment of IvA

- Separated from the Von Ardenne Research Institute
- In the same year, established the VON ARDENNE Clinical Center
- Focused on advancing Systemic Cancer Multistep Therapy

1992



- IRATHERM® 2000
- Used for extreme whole-body hyperthermia (maximum temperature 42.5°C)

1994

- IRATHERM®1000
- Designed for non-cancer therapies, provides mild to moderate whole-body hyperthermia (WBH)

IRA II

- Used for moderate whole-body hyperthermia (WBH) with IRATHERM® AST

1999

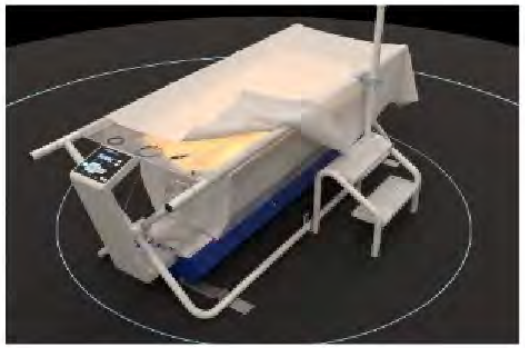
- IRATHERM®800
- Used for mild whole-body hyperthermia (WBH)

2003

- IRATHERM®1000
- + IRAcom®

2020

- IRATHERM®1000M
- Equipped with IRAcom® communication system and IRAsoft 5.0 control software
- Successfully re-certified under Annex V of the EU Medical Devices Directive (MDD)



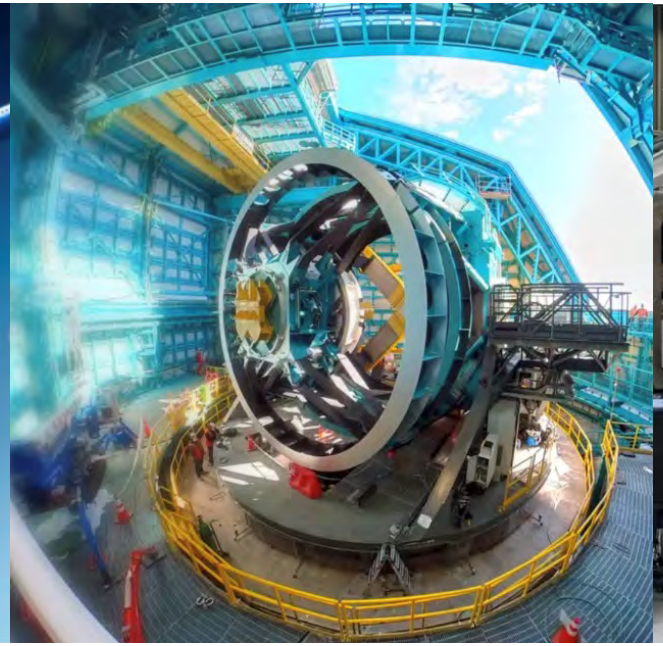
IRATHERM Whole-Body Hyperthermia

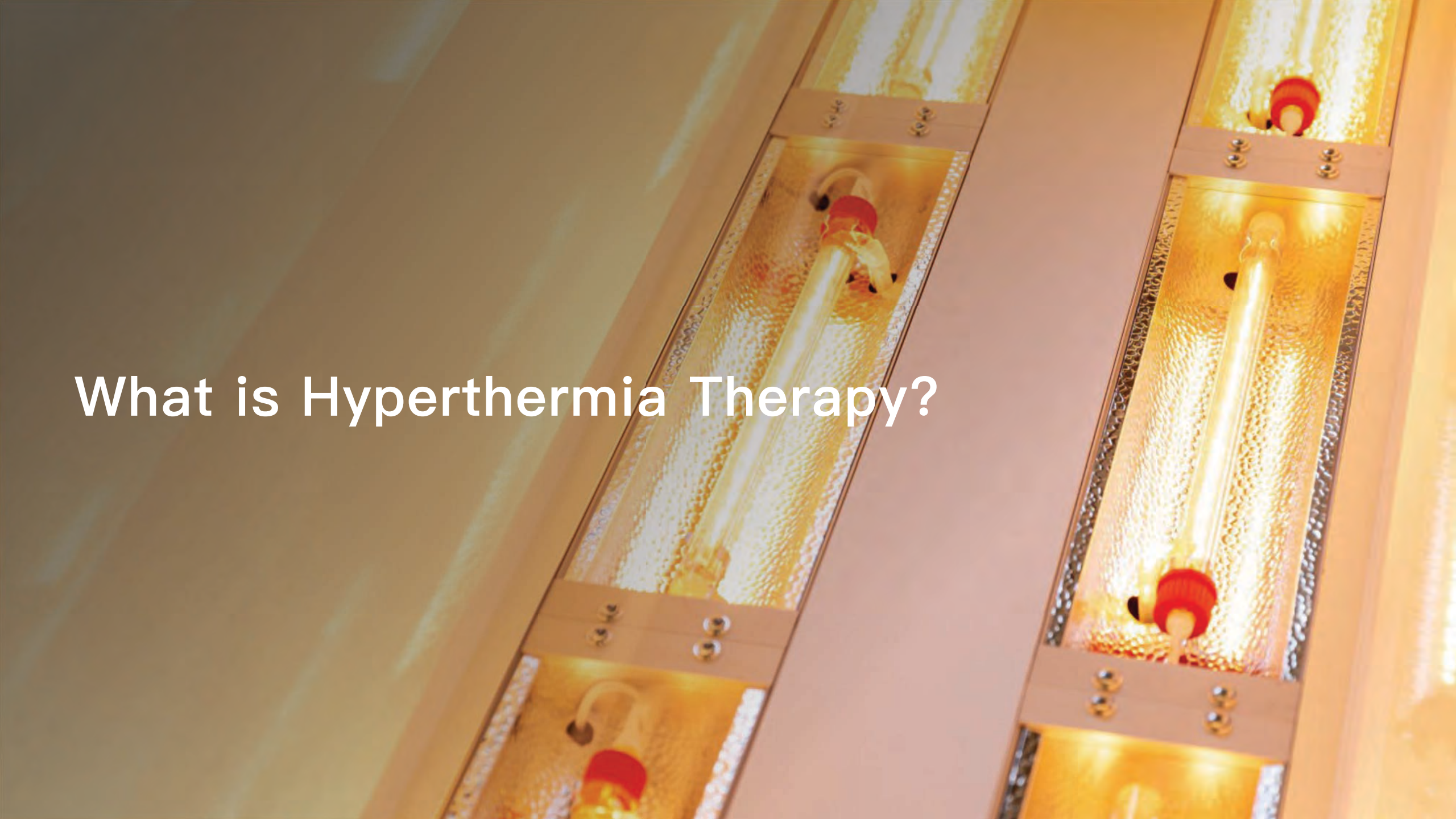
Institute of Applied Medical Research

A Global Leader in Vacuum Coating and Thin Film Technology

With the world's largest-scale Electron Beam Evaporation Systems and Magnetron Sputtering technology, VON ARDENNE enables atomic-level precision coating.

The company holds a global market-leading position in energy-saving architectural glass coatings (e.g., Low-E glass) and solar cell coatings (such as CIGS, CdTe, etc.).





What is Hyperthermia Therapy?

Hyperthermia Therapy

Fever is a powerful self–repair mechanism. By raising the body temperature to 38.5—40°C, hyperthermia mimics the body's natural fever response and activates the body's innate self–healing capabilities.

Mechanism	Physiological Action	Medical Applications
Vasodilation	Improved circulation + Tissue repair	Skin, fatigue, dermatology
Immune Cell Activation	Enhanced phagocytic activity	Infections, tumor immunity
HSP70 Induction	Cellular protection + Anti–stress	Neurology, immunity, anti–aging
Autophagy	Repair + Clearance of damaged cells	Metabolism, aging, functional medicine
Inflammation Suppression	↓ IL–6 / ↓ TNF–α	Mental health, internal medicine, chronic diseases

Applications of Whole–Body and Local Hyperthermia Therapy

Local Hyperthermia Therapy | A tactical heat approach that enhances therapeutic effects on targeted areas.
Whole–Body Hyperthermia Therapy | A systemic method that regulates immunity and metabolism throughout the body. It is suitable for treating chronic diseases and functional medicine applications.

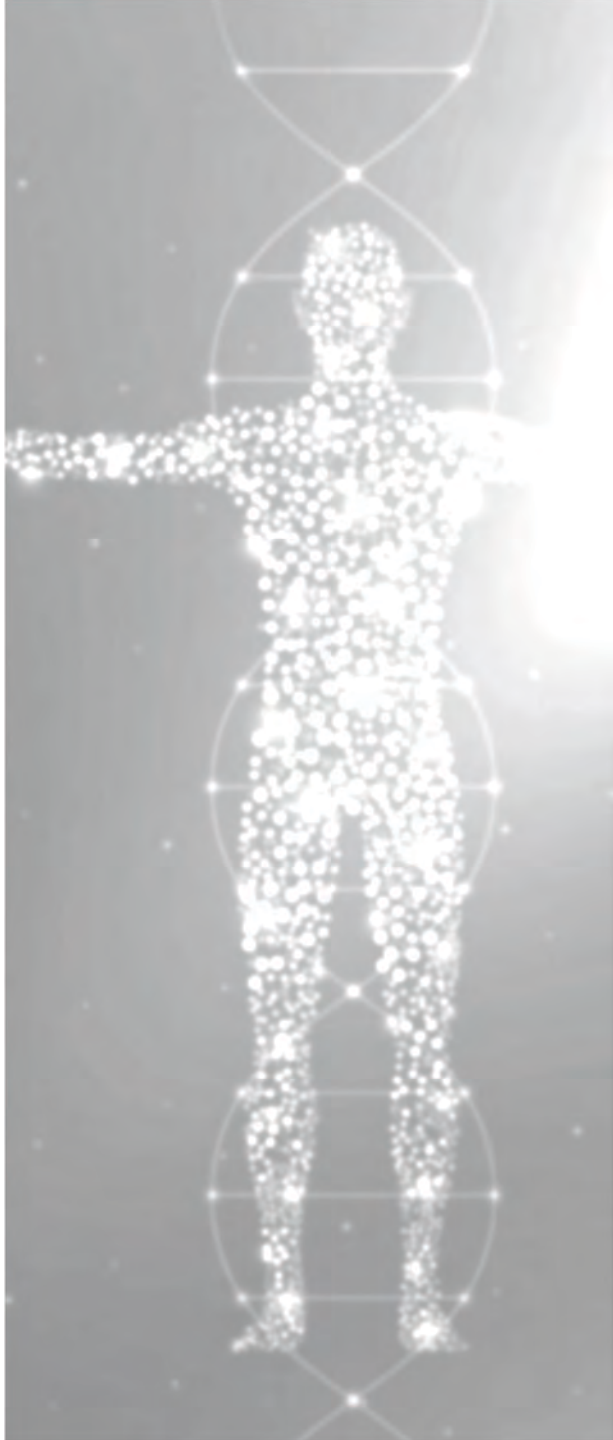
Item	Local Hyperthermia	Whole–Body Hyperthermia (WBH)
Target	Localized tumors or pain lesions	Entire body systems (immune, metabolic, autonomic, etc.)
Application Method	Direct heating of the affected area	Horizontal positioning, full–body irradiation via water–filtered infrared A (wIRA)
Heating Technique	Focused energy such as microwave (MW), radiofrequency (RF), or high–intensity focused ultrasound (HIFU)	wIRA (Water–Filtered Infrared–A) whole–body exposure
Temperature Range	41—43˚C local temperature	38.5—39.5˚C core temperature
Treatment Duration	30—60 minutes	30—120 minutes
Clinical Areas	Liver, pancreas, and gynecological tumors; adjuvant to chemo/radiotherapy	Anti–inflammatory, immune regulation, anti–aging, fatigue, stress, metabolism & detoxification
Common Risks	Local skin burns, swelling, redness, energy leakage, electrical hazards	Low risk; potential for dry mouth, dizziness, fatigue, rare hypotension
Safety Control	Requires constant supervision by trained professionals	Fully automated system, continuous temperature regulation, low operational risk

Grades of Whole-Body Hyperthermia

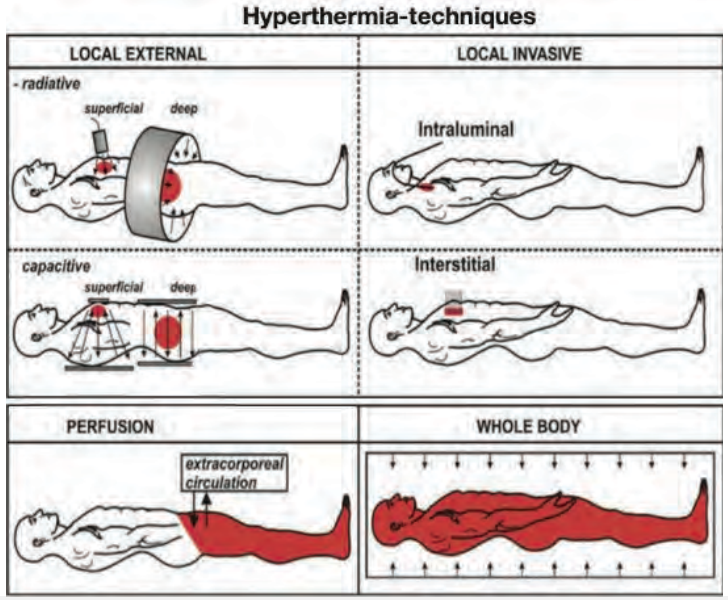
Whole-Body Hyperthermia (WBH)

Whole-Body Hyperthermia (WBH), also known as systemic hyperthermia therapy, is a medical technique that raises the body's core temperature in a controlled manner to achieve therapeutic effects.
Based on the mechanism of natural fever, this therapy utilizes physiological responses triggered at different temperature ranges. It is classified according to the intensity of heating and is applied across various clinical indications, offering high medical value.

Treatment Level	Core Temperature Range	Application Features	Technology / Clinical Use
Mild WBH	Approx. 38.5˚C	Safest; suitable for regular use; promotes metabolism and immune balance	Safe therapeutic programs; anti-aging and wellness therapies
Moderate WBH	Approx. 38.5 – 40.5˚C	Modulates immune function; activates self-healing and cellular repair	Mid-range protocols; for chronic diseases and cancer support
Extreme WBH	40.5 – 42˚C (High Risk)	Enters high-risk zone; reserved for cancer therapy with specialized systems	Intensive thermal oncology therapy (requires anesthesia monitoring)

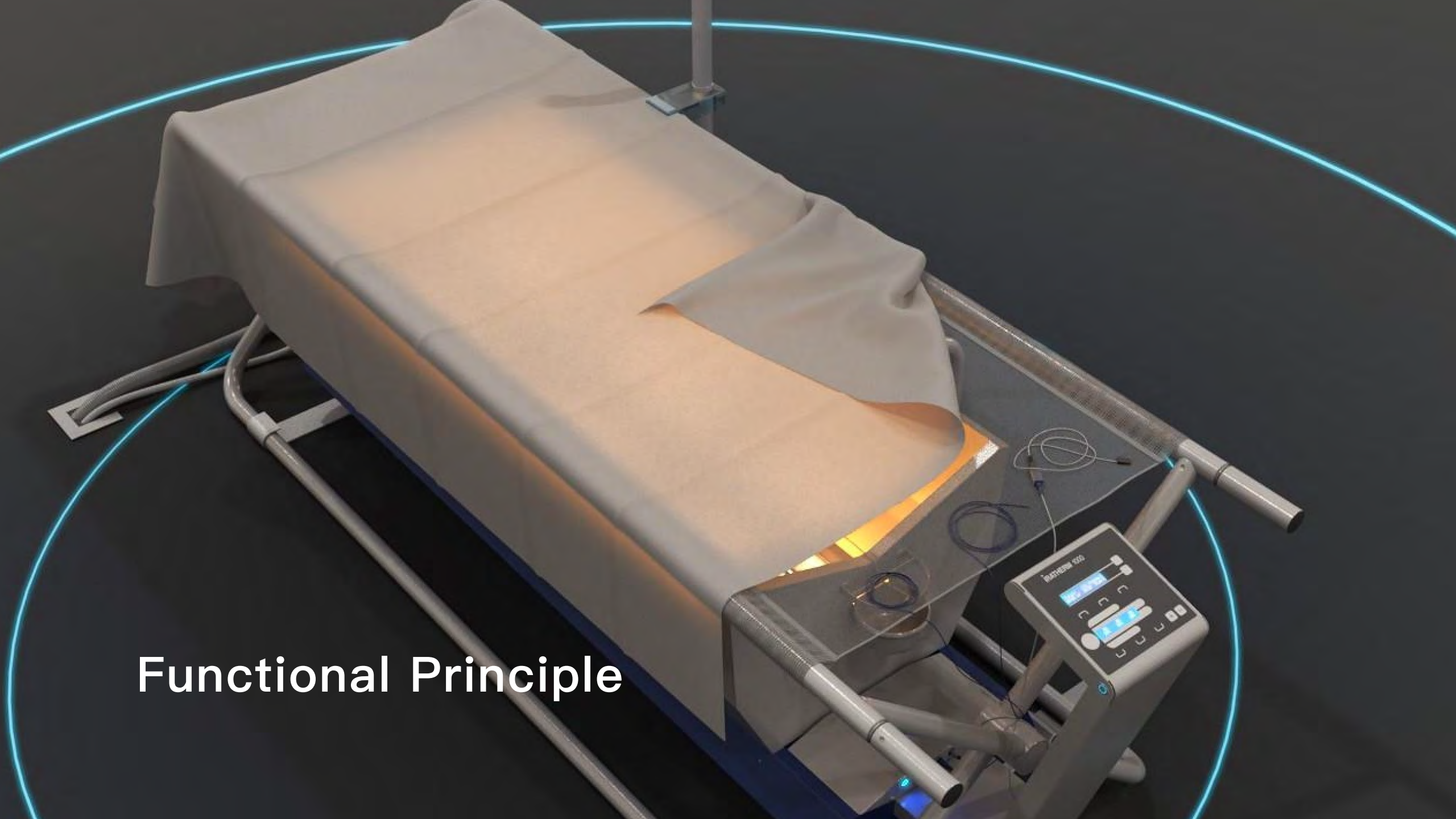


Types of Hyperthermia Therapy



Category	Core Concept	Common Indications
Local Hyperthermia	Targets specific areas (e.g., tumor sites) to increase localized blood flow and immune response; supports tumor reduction and local healing	Local tumors (e.g., breast, head and neck, cervical cancer), arthritis, localized muscle pain, non–healing wounds
Whole–Body Hyperthermia (WBH)	Elevates core body temperature (⩾38.5°C) to simulate inflammatory responses; enhances immunity, self–healing, and metabolic regulation	Chronic inflammation, immune dysregulation, depression, fibromyalgia, fatigue syndrome, anti–aging, metabolic syndrome

Indications	Enhancing Effects				Relieving Effects				Eliminating / Inhibiting	
	Metabolism	Immune System	Detoxification	Life Situation	Anti–inflammatory	Pain Processes	Stress Potential	Toxification	Cancer Cells	Growth of Tumors
Local Hyperthermia	+	+ +	+	+	+	+	+	+	+ + +	+ +
Whole–Body Hyperthermia	+ +	+ +	+ +	+	+ +	+ +	+ +	+ +	+ +	+ +



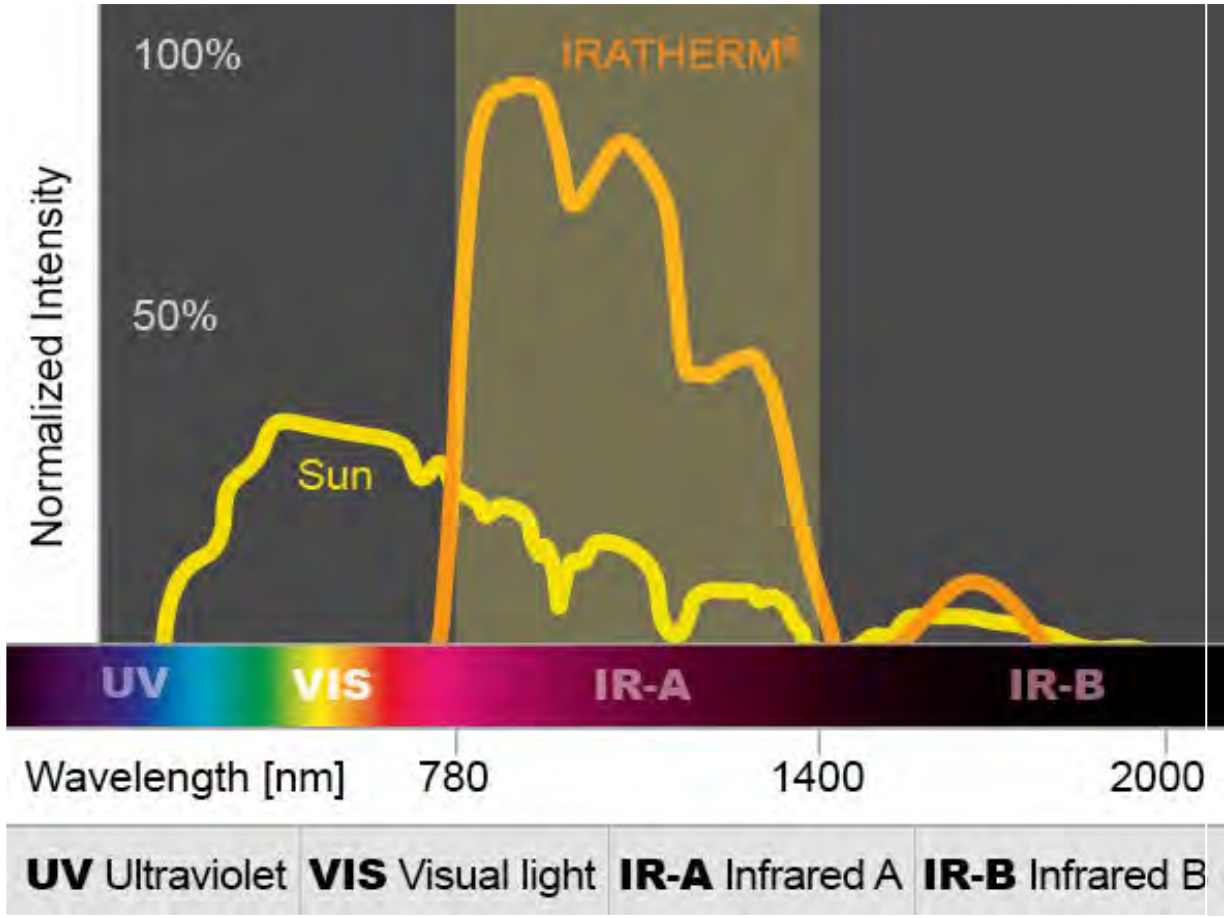
Functional Principle

Integrating Aerospace and Medical Science for Deep Thermal Penetration

Derived from **VON ARDENNE's radiation control technology** (Infrared A – IR–A), this system utilizes precision coating and thermal distribution techniques to deliver heat **evenly, safely, and deeply** into human tissues, achieving the **deep thermal penetration and therapeutic effects** required in clinical practice.

The **vacuum thermal technology** adopted by **NASA**, **Bosch**, and the **European solar industry** has been applied to whole–body hyperthermia systems, marking a **revolution in precise human body heating**.

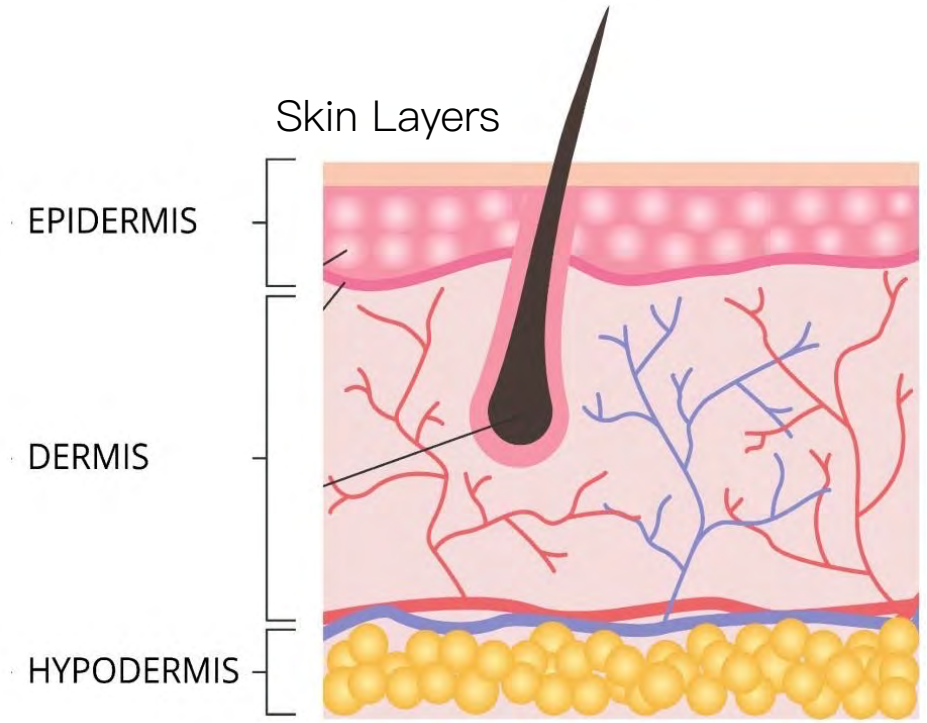
Functional Principle of Water–Filtered Infrared–A Radiation (wIRA)

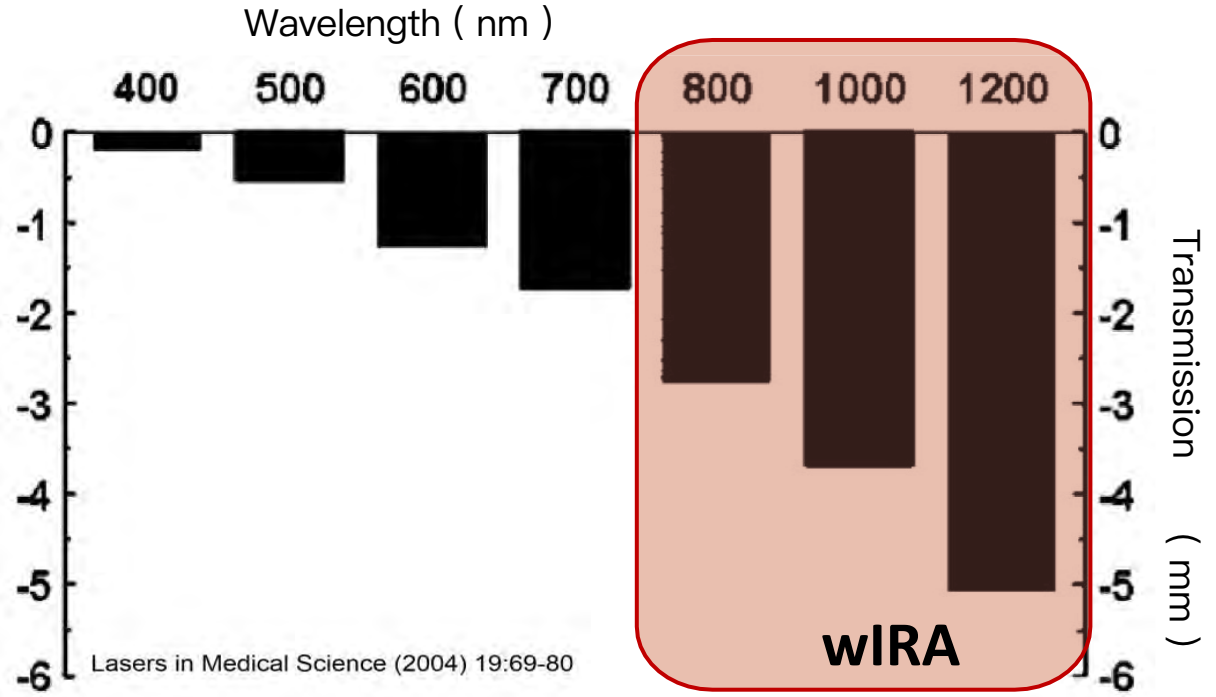


Harmful wavelengths to the skin (IR–B/C and part of IR–A) are filtered out, selectively allowing the transmission of IR–A waves (approximately 780—1400 nm), which **penetrate deeply** and are **gentle on the skin**.

Functional Principle of Water–Filtered Infrared–A Radiation (wIRA)

Thermal energy reaches directly into the subcutaneous tissue and vascular bed, effectively promoting blood flow and metabolism.
It does **not** cause burns or overheating of the epidermis.

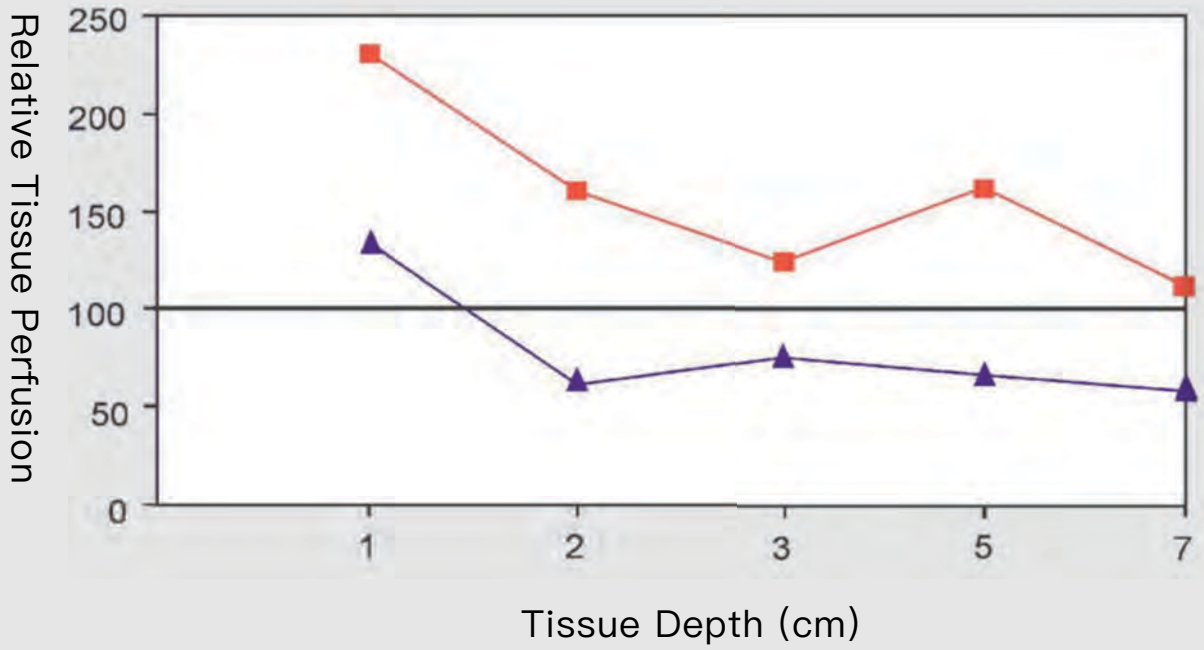




Water-Filtered Infrared-A Radiation (wIRA)

Thermal radiation penetrates deep into tissues, increasing perfusion volume by 100% to 230%.

Spreads from the skin surface to deeper layers (changes in blood flow)



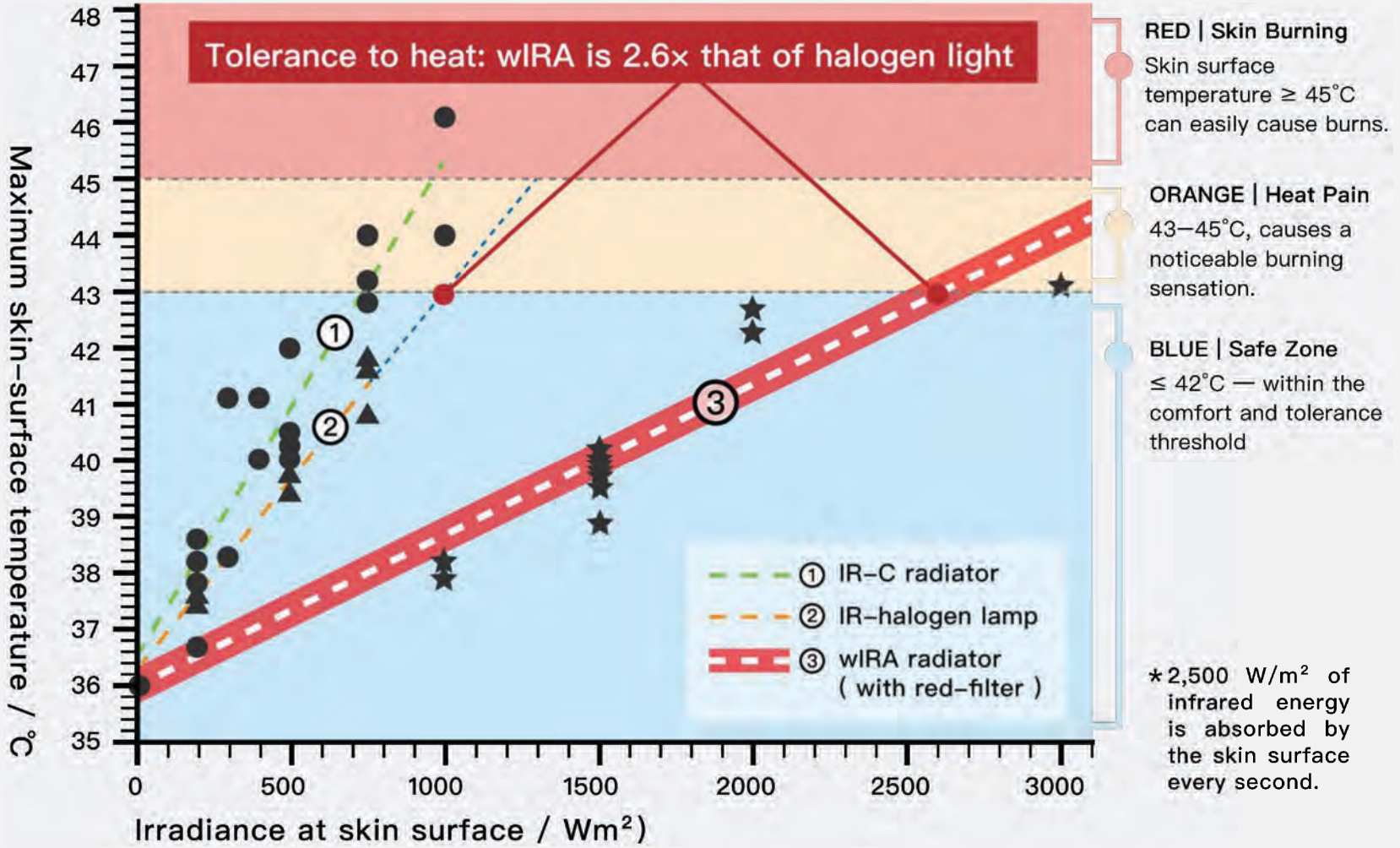
- From the surface down to a depth of 7 cm, the overall perfusion rate remains higher than without the use of wIRA.
- Within the 1—2 cm range, perfusion increases up to 200% of the baseline, clearly demonstrating the penetration capability and significant blood flow enhancement of wIRA.

* Water-Filtered Infrared-A Radiation (wIRA)

With wIRA Without wIRA

Deep Tissue Penetration and Superior Thermal Tolerance of wIRA

- **Deep penetration, low surface burden |**
  Heat focuses deep, mild on surface, avoids burns.
- **High tolerance at 2500 W/m² |**
  Skin stays safe (~42°C), better than IR-halogen and IR-C.
- **Efficient temperature control |**
  Stable heating, quick cooling, comfortable and safe.



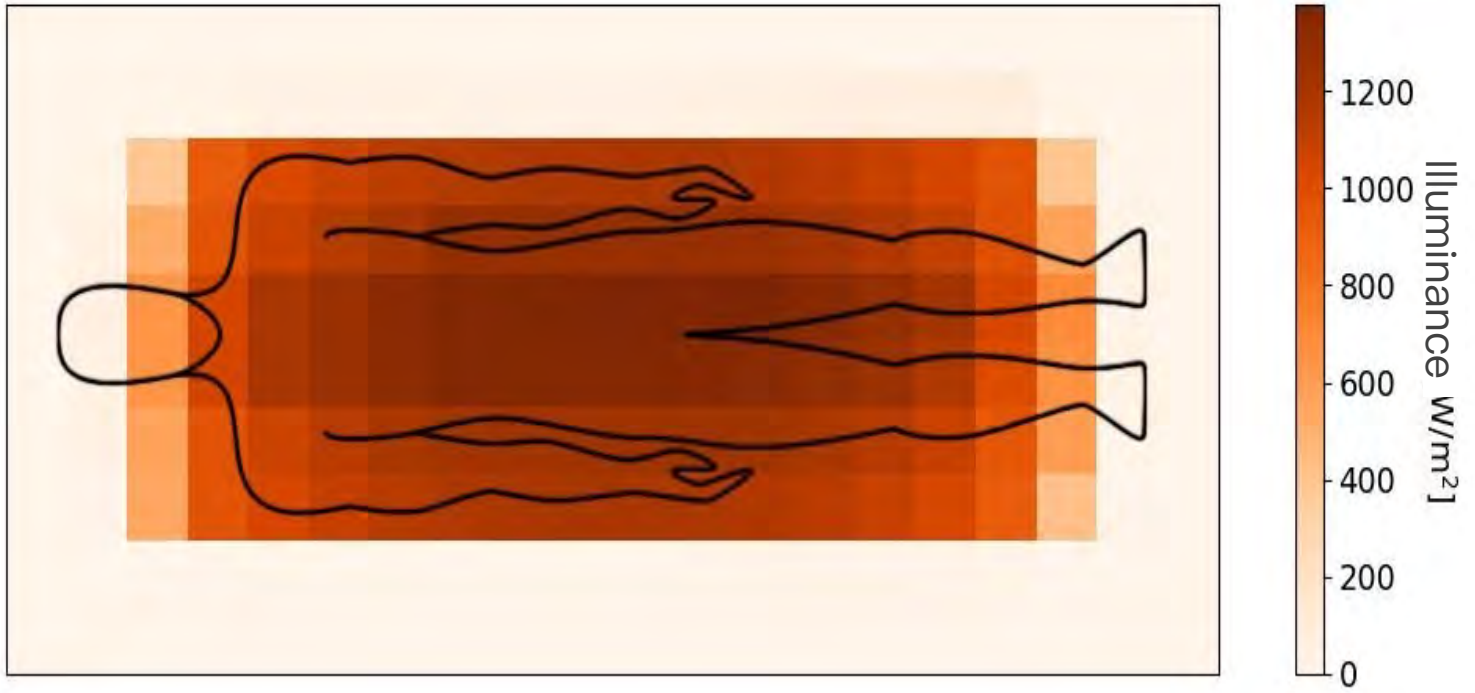
Functional Principle of Water–Filtered Infrared–A Radiation (wIRA)

Emits high–intensity and uniformly distributed thermal energy across the entire body.

- Irradiance measurements taken while the patient lies in a horizontal position demonstrate that the radiation intensity delivered is extremely high, effectively penetrating the skin and subcutaneous tissue to achieve deep therapeutic effects.

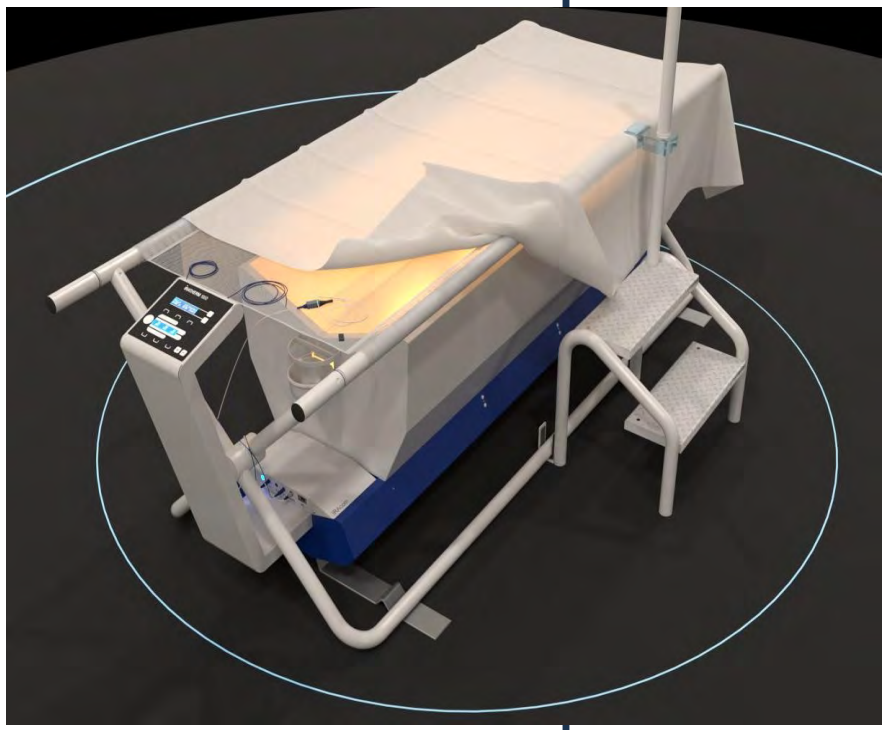
- The measurement results also show that the central torso and upper thigh regions are the most intensively irradiated areas.
  The distribution of thermal energy is uniform and concentrated in the center, contributing to the optimization of therapeutic efficacy.

The irradiation is precisely controlled, heating deep tissues without causing local overheating.



Advanced Technological Challenges of IRATHERM ® 1000M

Achieving medical efficacy requires cross-disciplinary integration of optics, fluid dynamics, cooling and thermal control systems, and medical electronics — a culmination of 100 years of German scientific and precision engineering excellence.



- Compliant with European MDR medical-grade standards
- Equipped with Water-Filtered Infrared-A (wIRA) technology
- Advanced temperature control system: delivers stable output within ±0.1°C, no risk of burns
- Passed durability tests for high-output light source
- Medical-grade nano vacuum tube cooling radiator removes IR-B/C
- Nano-precision spectral thermal control module
- Backed by over 40 clinical studies and medical publications
- High safety profile: enables up to 360 minutes of continuous treatment without side effects or hot spots

Medical Indications

IRATHERM Whole-Body Hyperthermia /

IRATHERM ® 1000M

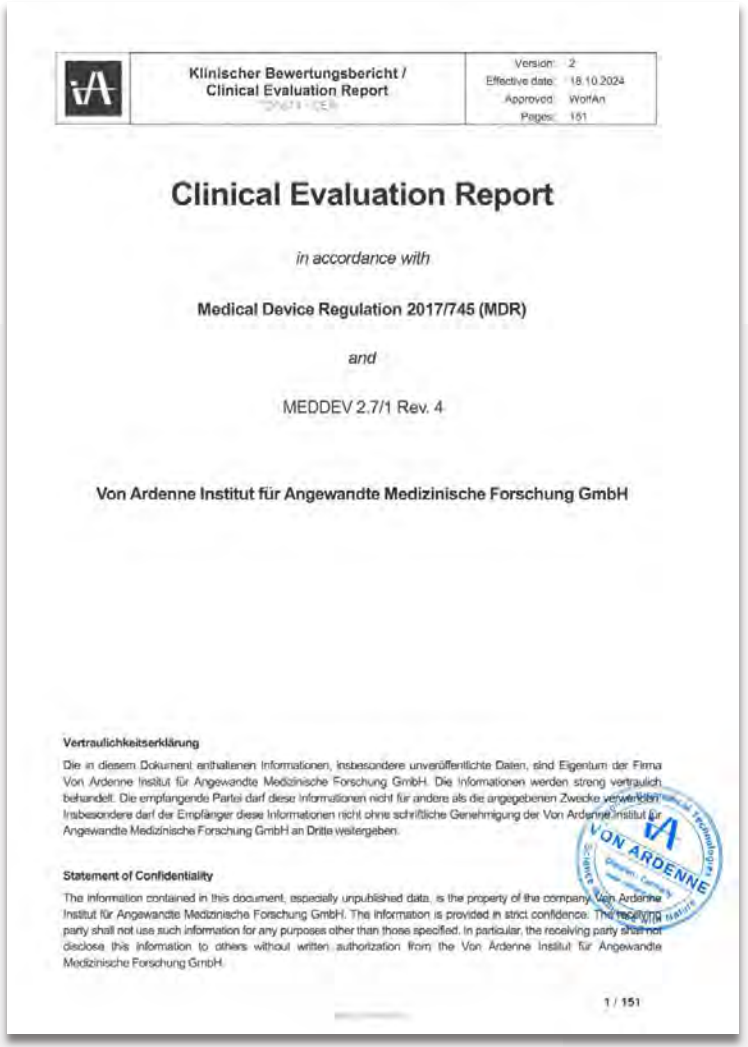
Indications

IRATHERM ® 1000M can be used for the following conditions

- Hypertension
- Back pain
- Fibromyalgia
- Ankylosing spondylitis
- Systemic sclerosis
- Depression
- Cancer adjunct therapy

Notable post-treatment effects

- **Fibromyalgia**: VAS pain scores decreased by more than 30% in 60% of patients
- **Hypertension**: Reduced blood pressure and improved circulation
- **Chronic pain**: Significant reduction in pain index
- **Immune function**: NK cell activity increased by over 25%
- **Inflammatory markers**: Decreased levels of IL-6, IL-10, and interferon-γ
- **Cancer adjunct therapy**: 15% increase in overall treatment effectiveness when combined with chemotherapy
- **Quality of Life (QOL)**: Over 20% improvement in patients with chronic diseases


Klinischer Bewertungsbericht / Clinical Evaluation Report

Version: 2
Effective date: 18.10.2024
Approved: WolfAn
Pages: 151

Clinical Evaluation Report

in accordance with

Medical Device Regulation 2017/745 (MDR)

and

MEDDEV 2.7/1 Rev. 4

Von Ardenne Institut für Angewandte Medizinische Forschung GmbH

Vertraulichkeitserklärung

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Medical Device Clinical Evaluation Report
(Compliant with MDR 20171745)

Arterial Hypertension (AH)

Arterial hypertension is a condition characterized by a prolonged elevation of blood pressure in the arterial system.

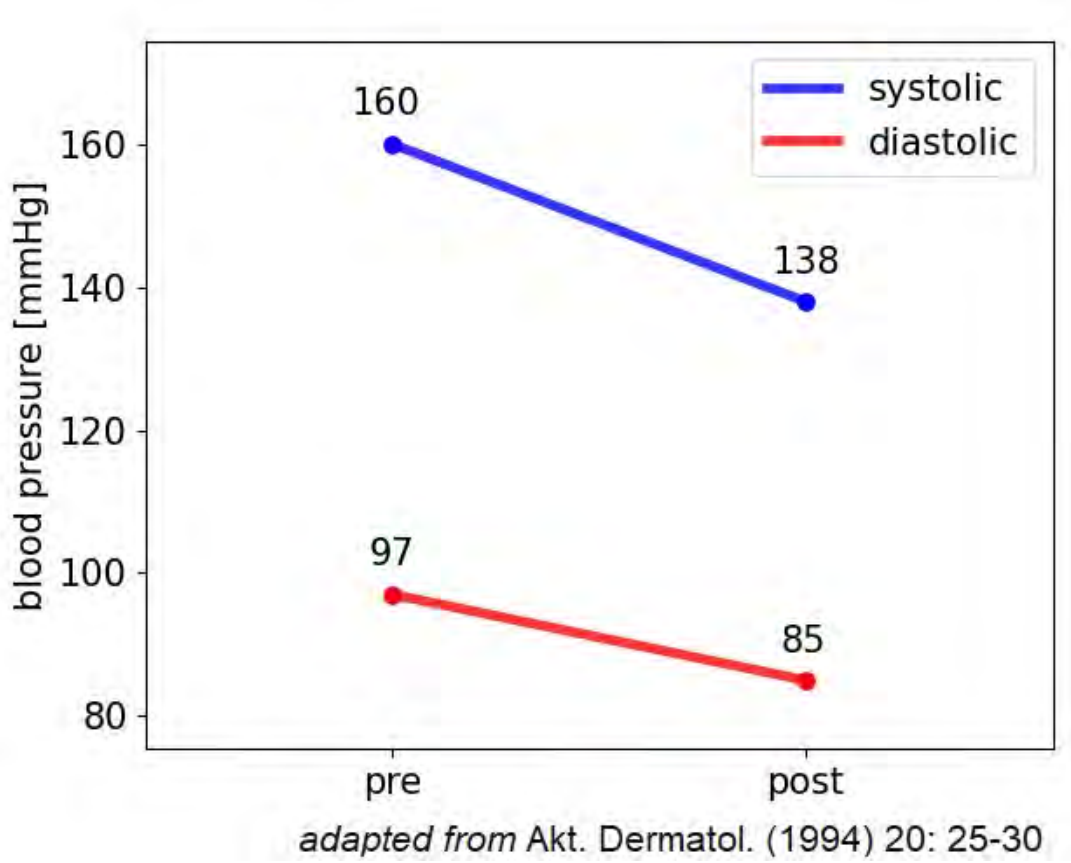
Clinical Study :

40 patients (average duration of illness: 3.9 years)

Parameter	
Temperature (Rectal)	38.3 °C
Heating Phase	30 minutes
Resting Phase	30 minutes
Number of Sessions	8 (within 4 weeks)

Results

- Systolic blood pressure decreased by 22 mmHg; diastolic blood pressure decreased by 12 mmHg
- No treatment response observed in 10% of participants



adapted from Akt. Dermatol. (1994) 20: 25-30

Fibromyalgia

Fibromyalgia is a chronic widespread pain syndrome characterized by non-restorative sleep, fatigue, stiffness, and emotional disturbances.

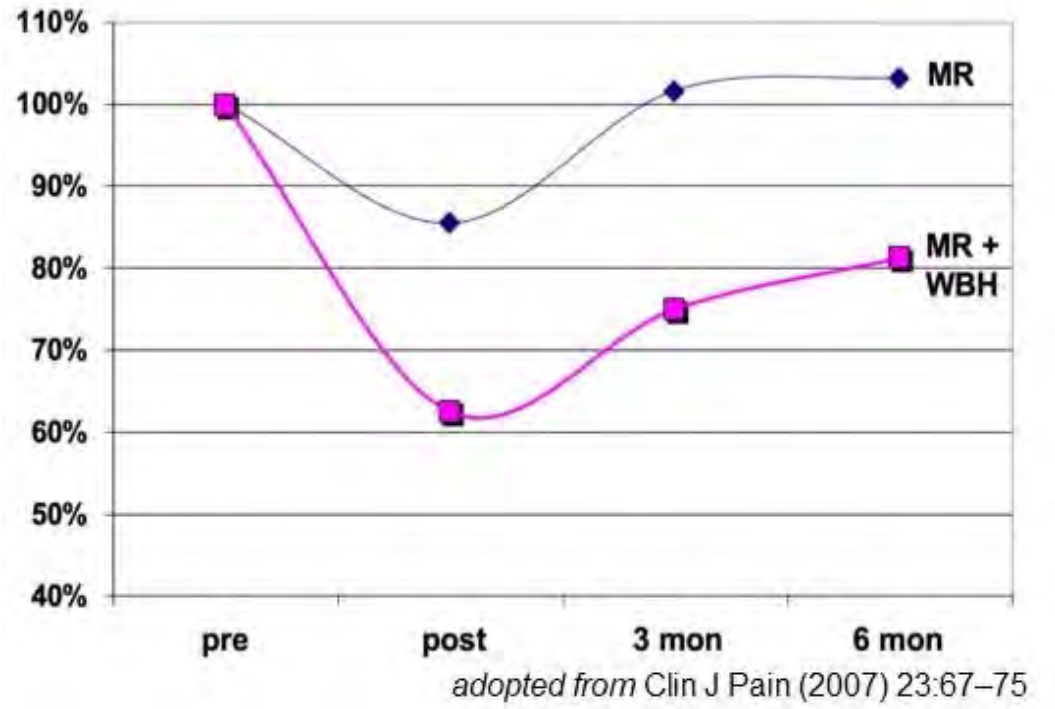
Randomized Controlled Trial :

Conducted with 139 patients divided into two groups

Parameter	
Temperature (Rectal)	38.1˚C
Heating Phase	55 minutes
Resting Phase	30 minutes
Number of Sessions	6 (within 3 weeks)

Results

- Significant pain reduction observed in approximately 20% of patients
- Whole-body hyperthermia is strongly recommended as an important adjunct in multimodal rehabilitation



adopted from Clin J Pain (2007) 23:67–75

Ankylosing Spondylitis (AS)

Ankylosing spondylitis is a chronic inflammatory rheumatic disease characterized by pain and joint stiffness.

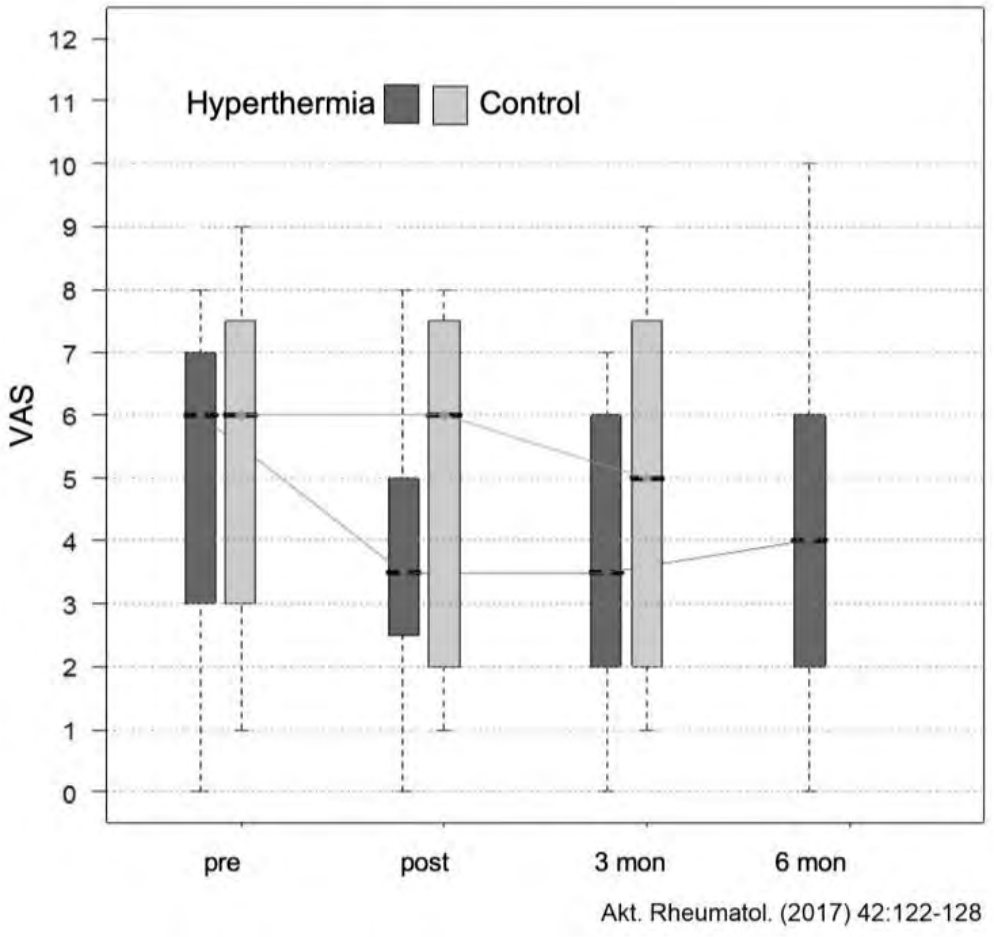
Randomized Controlled Trial :

Conducted with 35 patients divided into two groups

Parameter	
Temperature (Rectal)	38.5 ˚C
Heating Phase	60 minutes
Resting Phase	30 minutes
Number of Sessions	6 (within 8 days)

Results

- Whole-body hyperthermia induced **anti-inflammatory effects**, as evidenced by changes in cytokine levels
- Pain was reduced, and the overall effectiveness of AS treatment was improved



Immune System Activation

Effects of Whole-Body Hyperthermia on Immune Function

- Enhances phagocytic activity of **leukocytes** and **macrophages**
- Activates **B cells**
- Improves activity of **dendritic cells**
- Increases the production of cytokines

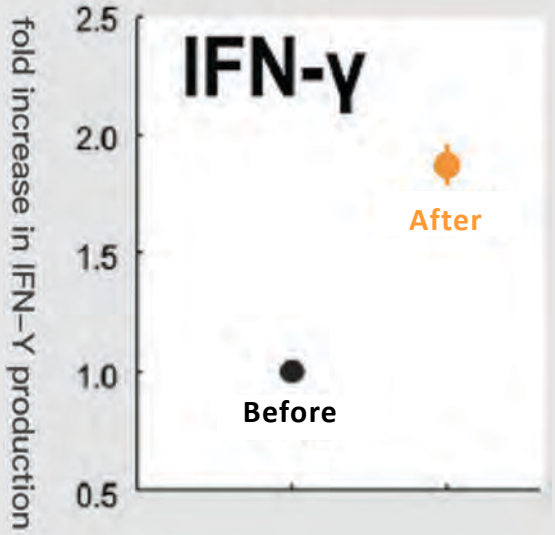
* Increases IL-2, TNF-α, and interferons (e.g., IFN-γ), thereby enhancing immune attack functions and anti-tumor capabilities.

Parameter	
Temperature (Rectal)	38.5 ℃
Heating Phase	60 minutes
Resting Phase	–
Number of Sessions	1

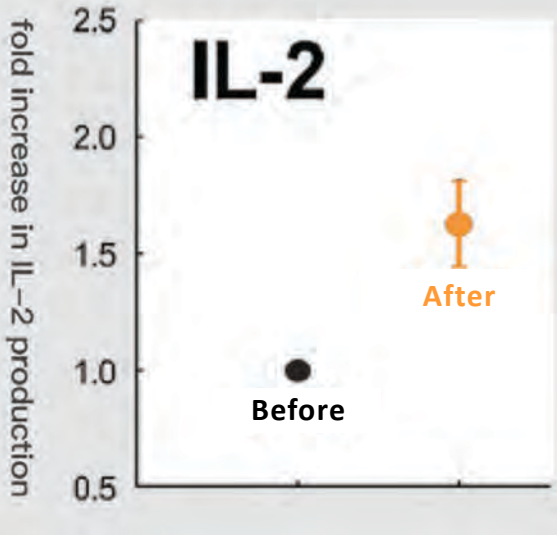
Enhanced Activity of Immune Cell Factors

- **Over 2× increase** → Marked enhancement in cytotoxicity and antiviral activity
- **Approx. 1.6 – 1.8× increase** → Enhanced T cell proliferation and immune response

Doubling of IFN-γ production



Doubling of IL-2 productio



* Immunology Letters (2014) 162:256-261

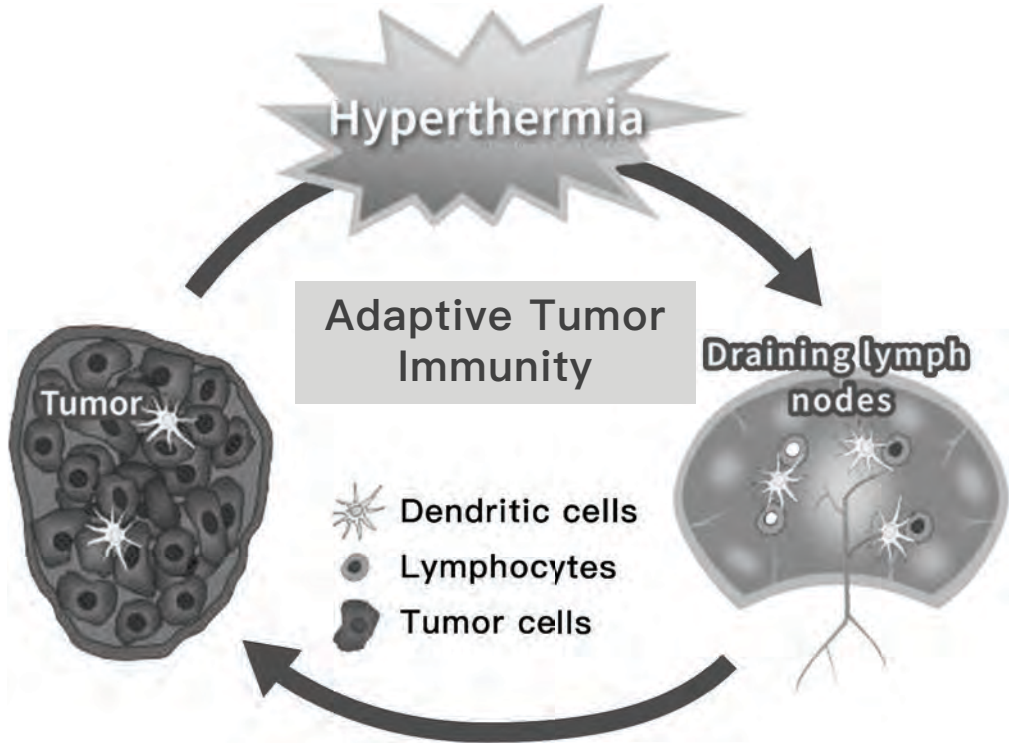
PMCID : PMC2828267 NIHMSID : NIHMS178333 PMID : 19513944

Adjunctive Tumor Therapy

Whole-body hyperthermia is used as an adjunctive approach in cancer immunotherapy:

- Enhancement of anti-tumor immune responses
- Improved immune reactivity through :
    1. Induction of heat shock protein (HSP) release
    2. Activation of antigen-presenting cells
    3. Promotion of lymphocyte trafficking

Using hyperthermia as an adjuvant to current immunotherapy allows for a non-toxic, easy-to-apply method that can reinvigorate otherwise weak cancer treatment protocols.



- Induces release of heat shock proteins
- Activates antigen-presenting cells
- Promotes migration and activation of dendritic cells
- Stimulates release of leukocyte chemoattractants
- Induces activation and migration of leukocytes
- Improves tumor control

Curr Opin Investing Drugs. (2009) 10:550-558

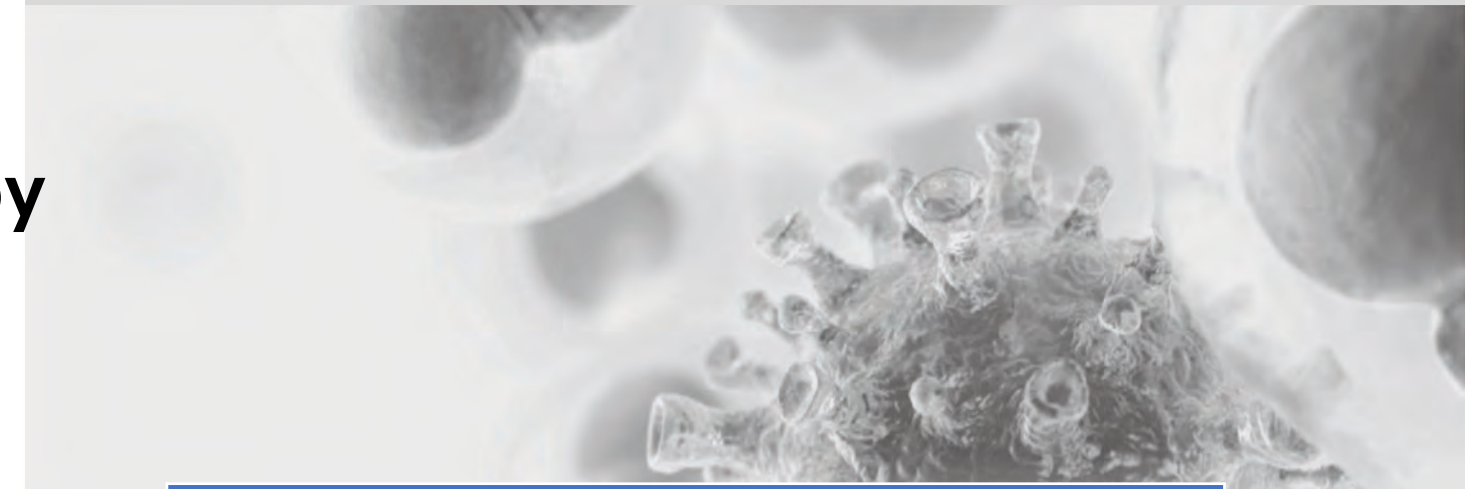
PMCID: PMC2828267 NIHMSID: NIHMS178333 PMID: 19513944

Adjunctive Tumor Therapy

Phase I / II Clinical Trial

Combination of whole-body hyperthermia and various pharmacological agents:

- 37 patients with treatment-resistant, metastatic, or advanced solid malignant tumors.
- Each treatment cycle included daily low-dose IFN-α for one month, 4-hour intravenous infusion of cisplatin, two doses of gemcitabine, and one session of hyperthermia therapy
- This cycle was repeated up to 7 times



Parameter	
Therapy Temperature	40 °C
Heating Duration (Rectal)	360 minutes
Resting Phase	—
Number of Sessions	Variable (1–8)

Results

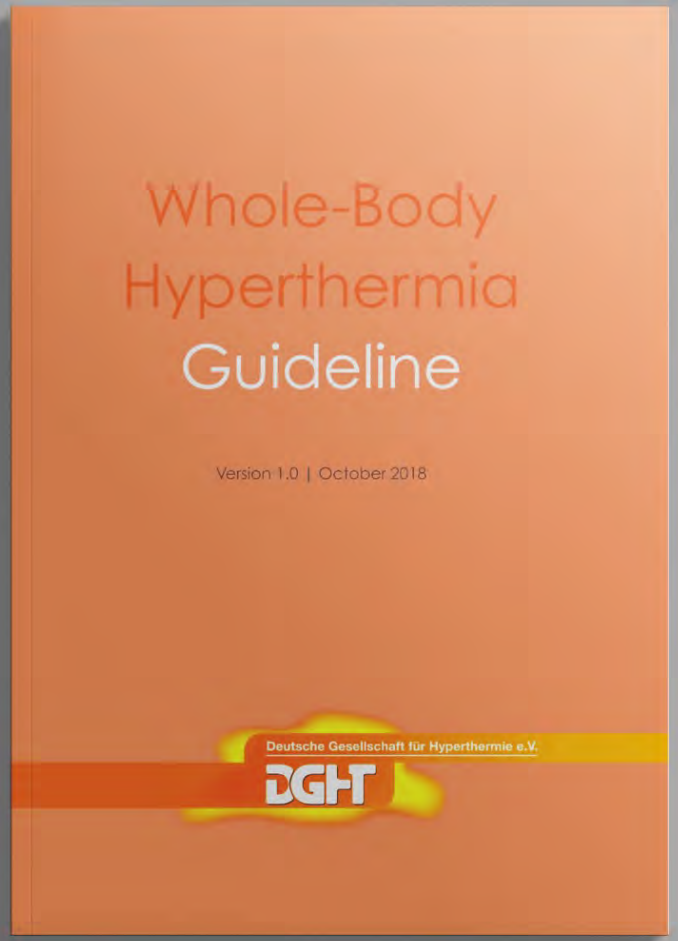
- Improvement in quality of life (pain, body weight, fatigue)
- 16 out of 37 patients (43%) responded to cisplatin

IRATHERM Hyperthermia Therapy – Operating Parameters

Indication	Total Sessions / Duration	Target Temperature	Therapy Time	Heating Phase	Core Temp Maintenance	Cooling Phase	Clinical Findings Summary
Arterial Hypertension (AH)	8 times / 4 weeks	38.3 °C	30 min	30 min	0 min	30 min	Systolic BP ↓22 mmHg, Diastolic ↓12 mmHg in 10%, no adverse effects
Fibromyalgia	6 times / 3 weeks	38.1 °C	45 min	30 min	15 min	30 min	
Ankylosing Spondylitis (AS)	12 times / 6 weeks	38.5 °C	60 min	45 min	15 min	30 min	
Muscle Regeneration	6 times / 3 weeks	38.3 °C	30 min	30 min	0 min	15 min	Pain improved in 20%, considered a complementary therapy
Immune System Activation	6 times / 8 days	38.5 °C	75 min	45 min	30 min	30 min	Reduce inflammatory cytokines, alleviate pain and improve mobility
Depression	Once (single session)	38.5 °C	105 min	45 min	60 min	15 min	IL–2 and IFN–γ increased, immune resilience improved
Cancer Immunotherapy Support	1–8 times (parallel to chemotherapy)	39.0 °C	120 min	60 min	60 min	60 min	43% improved therapeutic response and quality of life (cancer, fatigue, etc.)

Clinical Evaluation Report of Medical Devices_Medical Device Regulation 20171745 (MDR)

IRATHERM Hyperthermia Therapy Operation Manual



IRATHERM® Hyperthermia Therapy Parameters

Indication	Target Core Temp (Rectal)	Heating Phase	Plateau Phase	Cool-Down Phase	Treatment Frequency	Monitoring	Clinical Notes	References
Hypertension	38.3 °C	30 mins	0 mins	30 mins	8 sessions (2×/week or every other day)	Ear / Axilla	Systolic BP ↓22 mmHg,Diastolic ↓12 mmHg,10% non-responders	[22, 23]
Chronic Pain	38.5 °C	45 mins	15 mins	30 mins	7 sessions (1×/week)	Ear / Axilla	After 6 months: ↑Pain threshold ↑10%	[15, 16]
Fibromyalgia	38.1 °C	40 mins	15 mins	30 mins	6 sessions (2×/week or 6-day intensive)	Ear / Axilla	After 6 months: Pain score ↓ 20%Improved FIQ index	[11, 12], [13, 14]
Psoriatic Arthritis	38.5 °C	45 mins	15 mins	30 mins	6 sessions (within 8× or 6-day intensive)	Ear / Axilla	After 6 months: ↓Disease activity (DAS28)	[21]
Osteoarthritis	38 °C	30 mins	15 mins	≥120 mins	6 sessions (2×/week)	Ear / Axilla	After 3 months: Pain reduction observed	[20]
Ankylosing Spondylitis	38.5 °C	45 mins	15 mins	30 mins	6 sessions (within 8× or 6-day intensive)	Ear / Axilla	After 3 months: Pain relief, improved joint mobility over 3 months; BASDAI ↑, ESR ↑, IL-10 ↑, TLR-4 ↑	[17, 18, 19]
Scleroderma	38.5 °C	30 mins	0 mins	30 mins	15 sessions (2×/week or every other day)	Ear / Axilla	In specific cases:Improved skin hardening and itchiness	[23, 35, 36]
Severe Depression	38.5 °C	110 mins	60 mins	0 mins	1 session	Ear / Axilla	Rectal temp ~38.5–39°C during gWBH; axillary temp maintained at low level	[24, 25, 26]

IRATHERM Hyperthermia Therapy Operation Manual

IRATHERM® Hyperthermia Therapy Parameters

Indication	Target Core Temp (Rectal)	Heating Phase	Plateau Phase	Cool-Down Phase	Treatment Frequency	Monitoring	Clinical Notes	References
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Commitment to Quality and Certifications

- The manufacturing process strictly adheres to the highest quality management standards of **DIN EN ISO 13485**, and fully complies with the conformity requirements for **Class IIa medical devices** under **Annex V of the EU Medical Devices Directive (Directive 93/42/EEC – MDD)**. This ensures both the **safety and consistency** of the product.

- IvA products are approved for sale and distribution by several international medical device regulatory authorities, in accordance with **GDPMD standards**, including:

1. Health Sciences Authority (HSA), Singapore
2. National Medical Products Administration (NMPA), China
3. Ministry of Health (MOH), Malaysia


SLG Prüf- und Zertifizierungs GmbH

Certificate

The present document is a translation. In case of dispute the German version shall prevail.

Company: Von Ardenne Institut für Angewandte Medizinische Forschung GmbH
Zeppelinstraße 7
01324 Dresden, Germany

Certificate number: 10992M8
Audit report: 5062-18-PP-19-QB001
Valid from: 2019-08-29
Valid until: 2022-08-28

SLG Prüf- und Zertifizierungs GmbH certifies that the above mentioned company has implemented and uses a quality management system covering the scope of

Manufacture, production, maintenance and sales of whole-body hyperthermia systems as well as maintenance, sales and provision of oxygen concentrators and accessories, also for oxygen multistep therapy

In accordance with the requirements of

DIN EN ISO 13485:2016-08
(ISO 13485:2016)

DAkkS

Hartmannsdorf, 2019-08-29
SLG file no.: 5062-18-PP

M. Herrig
Certification Body

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DIN EN ISO 13485
2019–2022


SLG Prüf- und Zertifizierungs GmbH

EG-Zertifikat
EC Certificate

Qualitätssicherung Produktion
Production Quality Assurance

Richtlinie 93/42/EWG für Medizinprodukte, Anhang V (Klasse IIa-Produkte)
Directive 93/42/EEC on Medical devices, Annex V (Class IIa Devices)

Produkt / Kategorie(n):
Product / Category(ies):
Qualitätssicherungssystem Production
Quality Assurance System Production

Im Zertifikat enthaltene Produkte:
Products covered by certificate:
Produkt
Product
Hyperthermieanlage IRATHERM 1000M
Klassifizierung
Classification
IIa

Kategorie
Category
Hyper- und Hypothermiegeräte MD1403
Devices for hyperthermia / hypothermia
UMDNS:
17-570

Hersteller
Manufacturer:
Von Ardenne Institut für Angewandte Medizinische Forschung GmbH
Zeppelinstraße 7
01324 Dresden, Deutschland / Germany

Zertifikats-Nr.
Certificate no.:
10996JN5

Gültig ab
Valid from:
2020-04-30

Gültig bis
Valid until:
2024-05-26

Die Benannte Stelle 0494 SLG Prüf- und Zertifizierungs GmbH bescheinigt der zuvor genannten Firma die Anwendung eines Qualitätssicherungssystems für die Herstellung der entsprechenden Produkte / Produktkategorien nach Medizinprodukte-Richtlinie, Anhang V.

The Notified Body 0494 SLG Prüf- und Zertifizierungs GmbH declares that the aforementioned company has implemented a quality assurance system for manufacture of the respective devices / device categories in accordance with the Medical Device Directive, Annex V.

Die Einhaltung der anwendbaren Anforderungen des Anhang V wurde bewertet in:
Compliance with the applicable requirements of Annex V was reviewed in:

Auditmethodenbericht:
Final Audit Summary Report:
SLG - 5062-18-PP-20-QB002

Das zuvor beschriebene Qualitätssicherungssystem entspricht der Herstellung gemäß Anhang V Abschnitt 4
The quality assurance system described above is subject to periodic surveillance in accordance with Annex V section 4.

Hartmannsdorf, 2020-04-30
SLG file no.: 5062-19-PP

M. Herrig
Zertifizierungsstelle
Certification Body

www.slg.de.com

MDD 93 / 42 / EEC–V
2020–2024


中华人民共和国医疗器械注册证

注册人名称	德国冯阿登纳医学研究有限公司 Von Ardenne Institute of Applied Medical Research GmbH
注册人住所	Zeppelinstraße 7, 01324 Dresden, Deutschland/Germany
生产地址	Zeppelinstraße 7, 01324 Dresden, Deutschland/Germany
代理人名称	北京天道恒永科技有限公司
代理人住所	北京市朝阳区望京利泽中园106号楼2层205室
产品名称	热疗系统 Equipment for Hyperthermia Therapy
型号、规格	IRATHERM 1000
结构及组成	本产品由主机、阿托防护床及红外线可遥控护塑料膜组成。主机由发射器单元、水过滤系统、控制面板及电源线组成。
适用范围	在医疗机构中使用，临床用于缓解神经系统肉的疼痛。
附件	产品技术要求
其他内容	/
备注	注册证编号、国食药监械（进）字2014[illegible]有效期至[illegible]。

CN: 2014–2023


Medical Device Authority

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: SB/MD/221-05575
Registration No.:
Tarikh Sah Berkuatkuasa: 30/01/2021 - 29/01/2026
Registration Validity Date:

QUALTIK CONSULTING SDN. BHD.

N-19-01, FIRST SUBANG, JALAN SS15/4G,
47500 SUBANG JAYA, SELANGOR.,
47500
SUBANG JAYA SELANGOR DARUL EHSAN

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

MY: 2021–2026

Medical Specialty Applications

IRATHERM ® 1000M /

IRATHERM Hyperthermia Therapy

Medical Specialty Applications of Whole-Body Hyperthermia

Medical Specialty	Primary Applications	Common Indications
Oncology	Enhances anti-tumor response, supports chemotherapy, promotes drug elimination	Breast cancer, prostate cancer, melanoma
Immunology / Functional Medicine	Activates the immune system, suppresses autoimmune conditions, relieves allergies & inflammation	Autoimmune disorders, lupus, chronic fatigue syndrome
Psychiatry / Neurology	Improves mood and sleep, reduces stress and headaches	Depression, insomnia, neurocognitive issues
Dermatology	Promotes skin metabolism and regeneration, reduces inflammation and fibrosis	Chronic wounds, scars, inflammatory skin conditions
Rheumatology and Immunology	Relieves inflammatory diseases, improves circulation and oxygenation	Rheumatoid arthritis, ankylosing spondylitis
Environmental / Detox Medicine	Supports detoxification and metabolism, assists in elimination of toxins and heavy metals	Chemical exposure, metabolic syndrome, drug residues
Anti-aging Medicine	Stimulates cell repair, slows aging	Aging population, wellness and longevity programs
Physical Wellness / Preventive Care	Enhances metabolism, improves organ function, relieves chronic stress	Suboptimal health, long COVID, autonomic dysfunction
Sports Medicine	Promotes recovery, prevents injuries, reduces exercise-induced fatigue	Athletes, fitness enthusiasts, active individuals
Rehabilitation Medicine	Supports recovery after surgery, improves joint flexibility and mobility	Postoperative care, stiffness, chronic physical decline

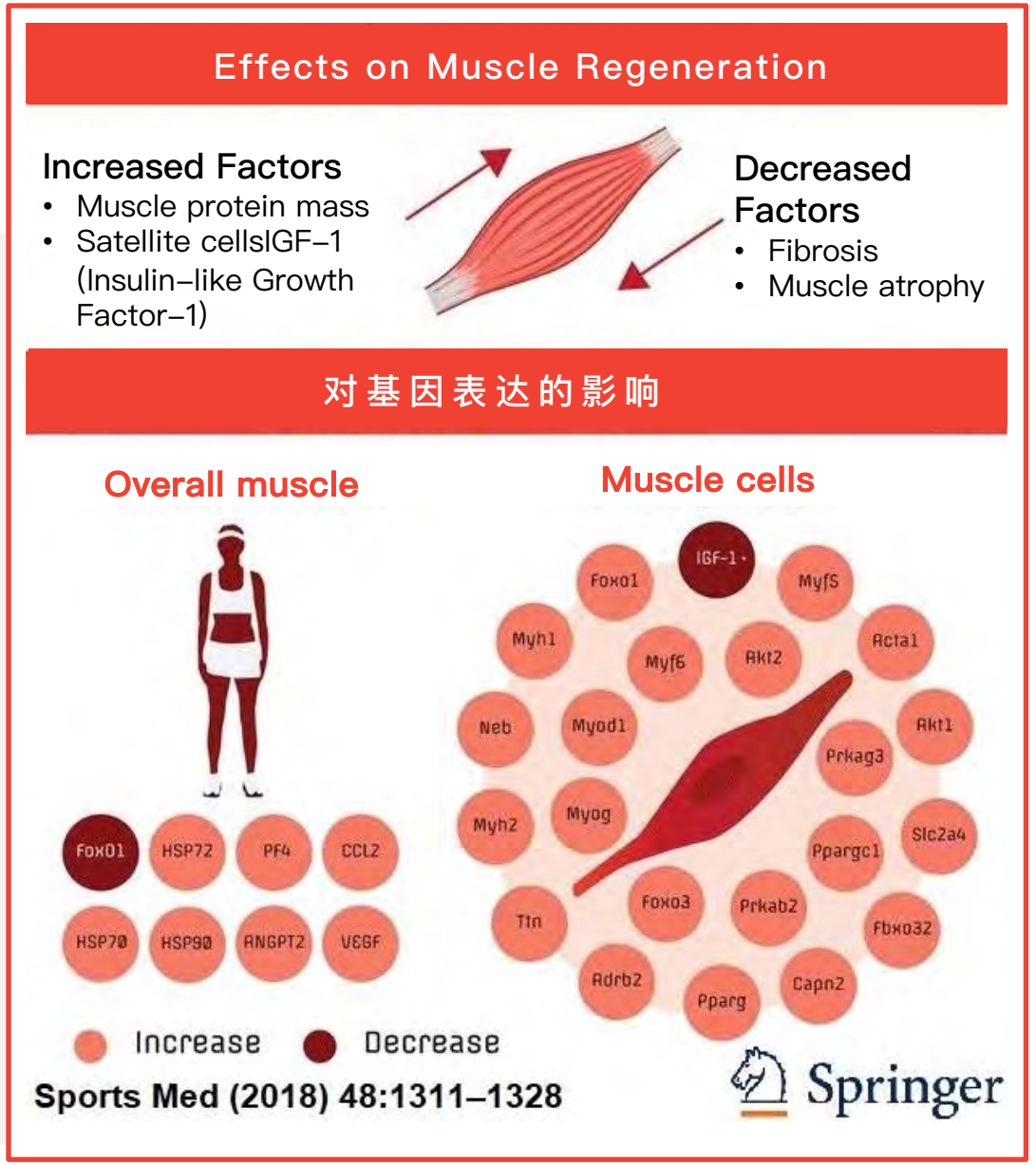
Promotion of Muscle Growth & Suppression of Atrophy

Thermal energy promotes muscle regeneration

1. **Stimulation of cellular and protein synthesis**
   Heat activates satellite cells and protein synthesis mechanisms, promoting muscle repair and growth.

2. **Suppression of muscle atrophy and fibrosis**
   Hyperthermia helps prevent muscle atrophy and connective tissue fibrosis caused by injury or aging, maintaining muscle flexibility and function.

3. **Regulation of gene expression**
   Upregulates genes related to muscle hypertrophy (IGF–1, MyoD), while downregulating genes associated with atrophy (FoxO3, Fbxo32), supporting the regeneration process.



Long-COVID / Post-COVID Syndrome

Whole-body hyperthermia (WBH) is being applied to support recovery from Long-COVID (Post-COVID Syndrome) by providing a non-invasive method that promotes tissue perfusion, enhances metabolism, and stimulates immune responses.

Treatment Frequency and Duration

- Number of sessions: 3 to 6 treatments are recommended
- Treatment interval: 1—2 times per week, depending on the patient's condition
- Total duration: 75 minutes
  | First phase: 45-minute heating phase (gradual rise in core body temperature)
  | Second phase: 30-minute maintenance phase (core body temperature is held stable within the therapeutic range)

Target Core Body Temperature

- Maintained at 38.5—39.0°C
- This temperature range activates the immune system while preventing overheating

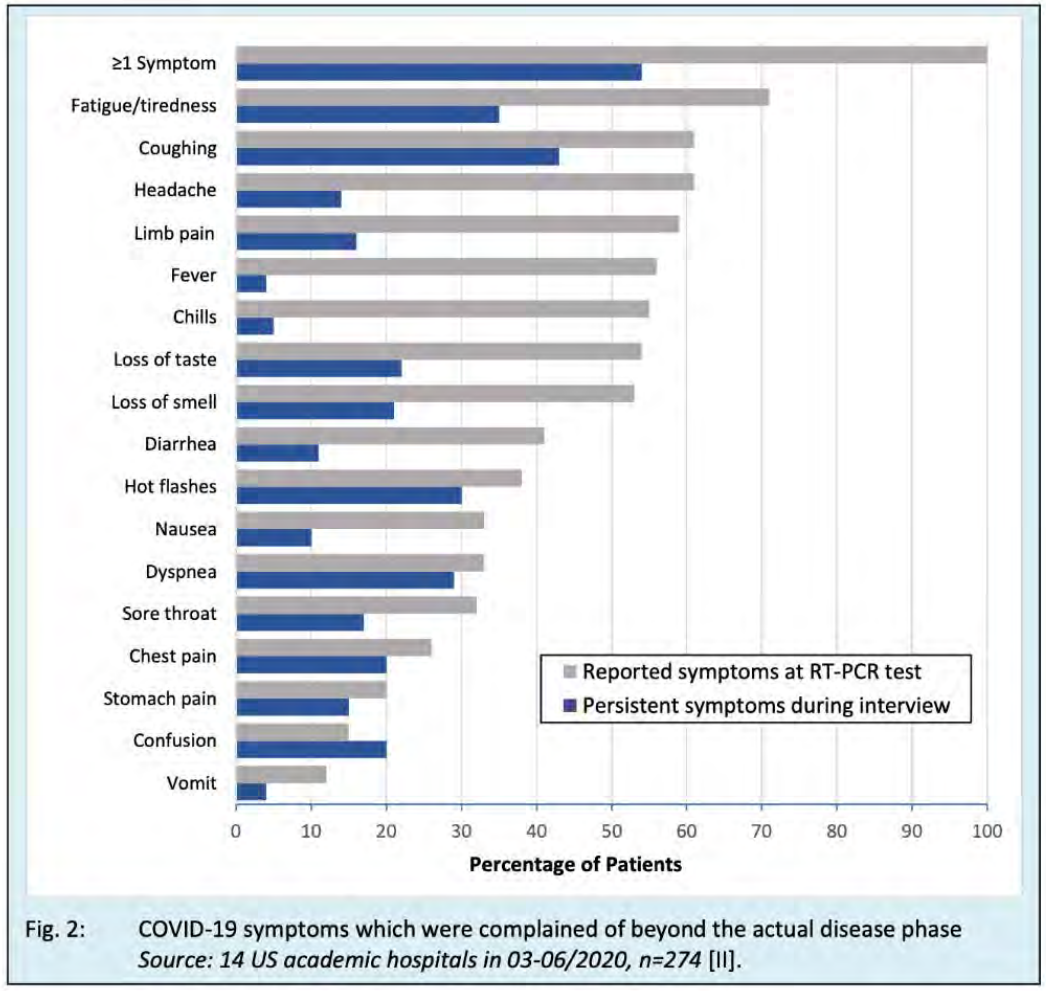


Fig. 2: COVID-19 symptoms which were complained of beyond the actual disease phase
Source: 14 US academic hospitals in 03-06/2020, n=274 [II].

Medical Aesthetic Dermatology

This therapy goes beyond temporary surface tightening, bringing

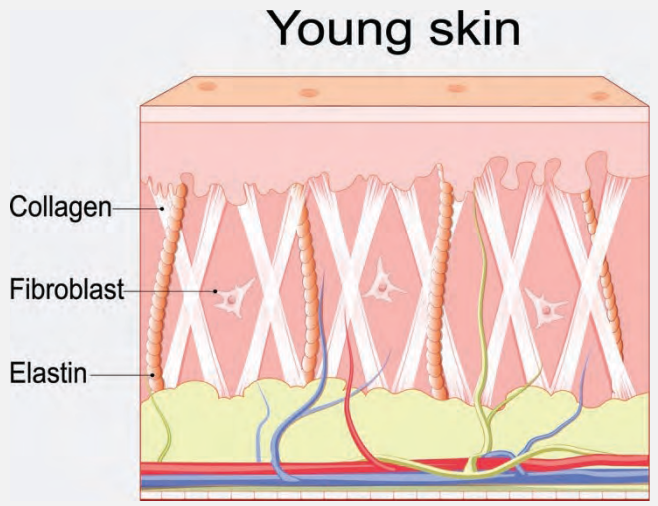
progressive improvements from the cellular level →

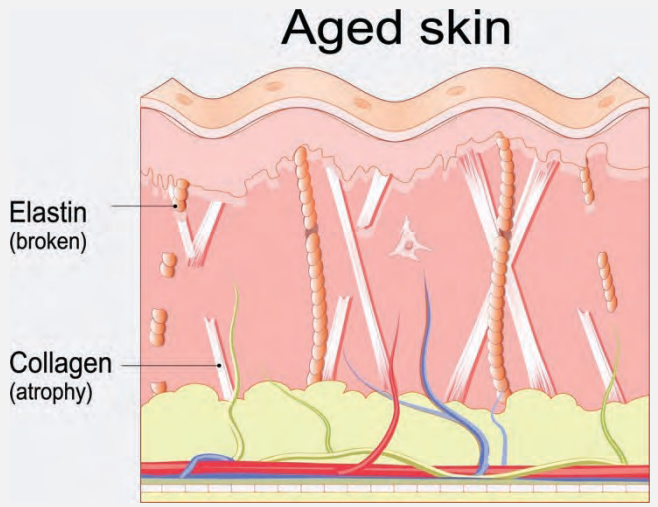
to the tissue level → **to the appearance of the skin.**

The skin is guided toward a truly healthy state — **aging is slowed**, **regeneration is enhanced**, and **inflammation is reduced**.

Thermal Skincare (A deep, inside-out anti-aging and skin-rejuvenation treatment)

Thermal Effect Mechanism	Medical Interpretation	Aesthetic Applications
+39% Blood Flow, Increased Oxygen Supply	Enhances circulation and nutrient delivery	Reduces puffiness, promotes collagen synthesis, brightens skin tone
Promotes Repair of Epidermal Barrier, Speeds Up Metabolism	Activates fibroblasts and rejuvenates skin	Improves fine lines, rough texture, enlarged pores, and dryness
Boosts Type I & III Collagen Production	Restructures dermal matrix and enhances elasticity	Reduces wrinkles, firms skin, improves uneven pigmentation
Decreases Inflammatory Markers (IL-6 / TNF-α)	Suppresses immune overreaction and inflammatory responses	Improves redness, rosacea, and chronic inflammatory skin conditions





Anti–Aging Medicine

When the human body is exposed to short–term and controllable stressors (e.g., thermal exposure, fasting, exercise), physiological mechanisms involved in cellular repair and aging suppression are activated. Hyperthermia therapy is a clinical application of this principle, promoting self–regulation and repair functions through temperature–controlled heat stimulation.

Hyperthermia & Anti–Aging

Immune Activation

- Elevation of core body temperature (38.5 —39.5˚C)
- Induction of HSP70 / HSP90 expression
- Enhanced NK cell activity
- Promotion of cellular repair

Autophagy Activation

- Removal of damaged cells and mitochondria
- Activation of TFEB function
- Promotion of cellular repair

Redox Optimization — Mitochondrial Support

- Enhanced ROS signaling
- Activation of the NRF2 pathway
- Increased ATP production
- Improved cellular function

Supported by Published Literature:

- Zschaeck et al., 2021 (Head and Neck Cancer)
- Foerster et al., 2005 (NK Cell Activation)
- Gomez et al., 2021
- Boothbay, 2022 (Autophagy Repair Mechanism)
- McCormick 2021《The Biology of Aging》

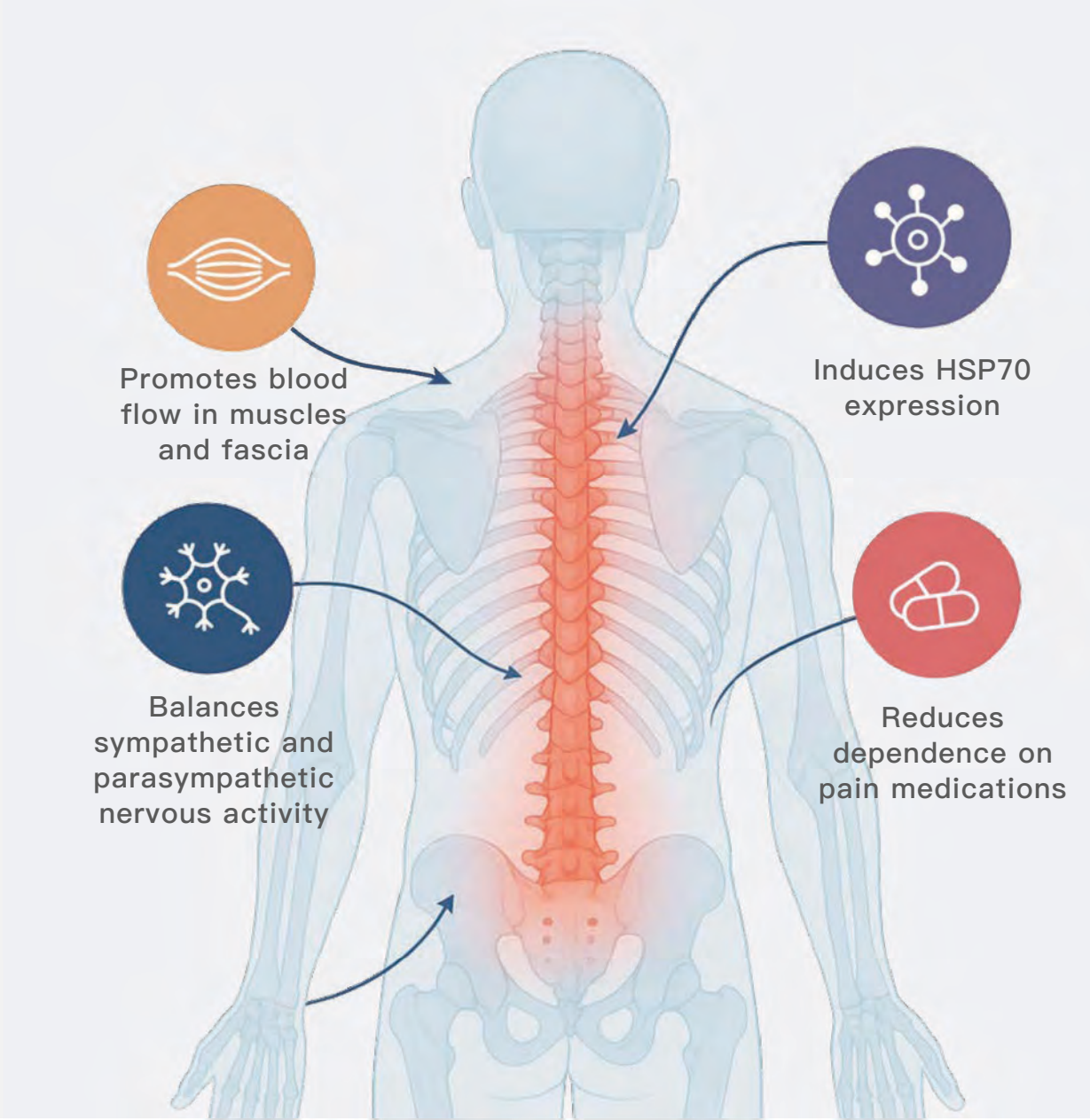
Rehabilitation Medicine

Core Indications: Chronic pain, musculoskeletal disorders, postoperative neuroregulation.

Hyperthermia provides **multiple therapeutic benefits** for chronic myofascial pain and spinal inflammation through a **triple mechanism** : induction of **heat shock proteins (HSPs)**, **improved blood circulation**, and **autonomic nervous system modulation.**

Particularly suitable for

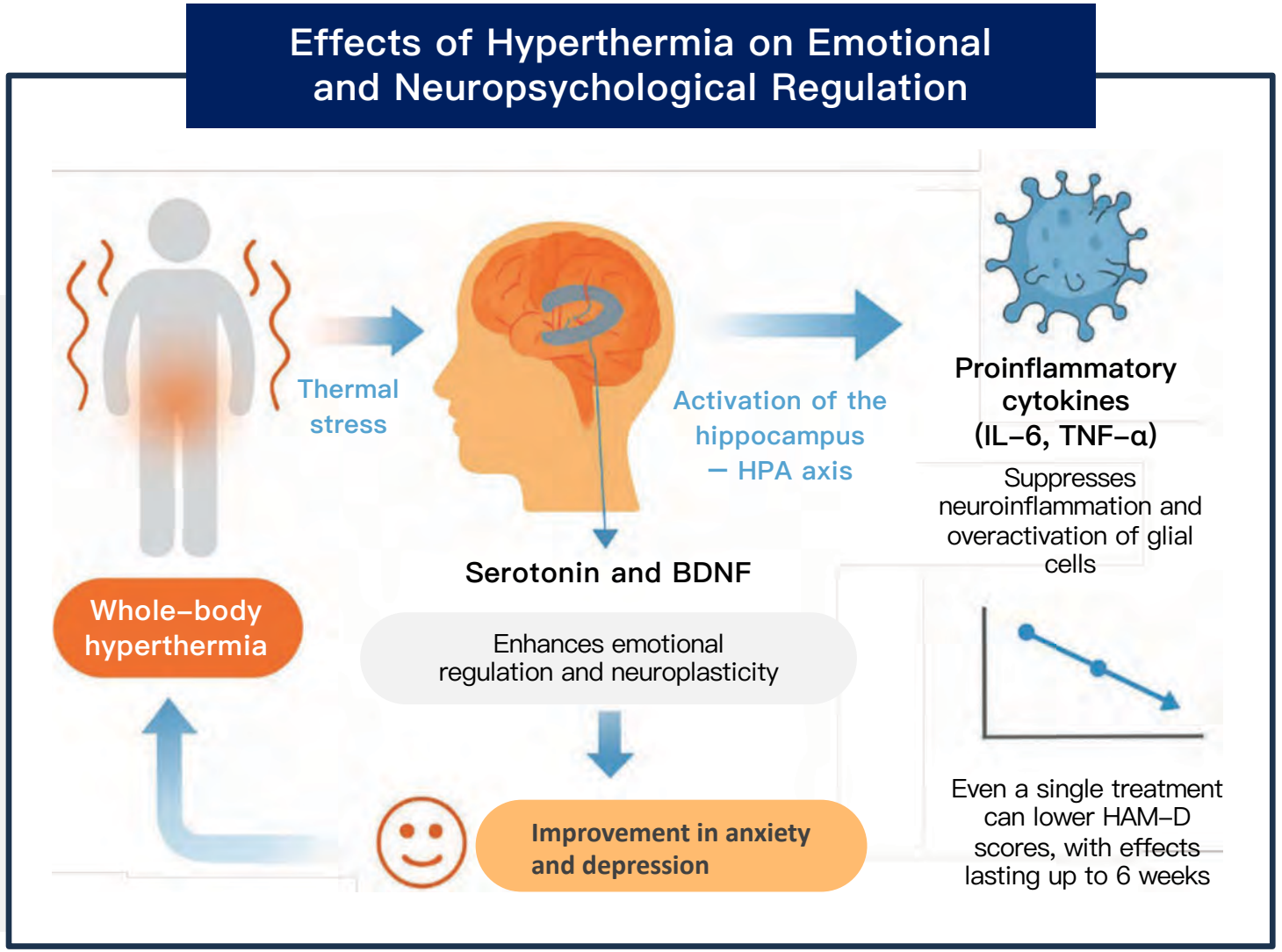
- Fibromyalgia
- Ankylosing spondylitis
- Low back pain
- Postoperative neuropathic pain
- Autonomic nervous system disorders



Psychiatry

Core Indications : Emotional and psychological symptoms such as anxiety, depression, and autonomic nervous system dysregulation

- Emotional and neuropsychological disturbances are **not always caused by structural abnormalities in the brain**; some are linked to **systemic inflammation** and **imbalances in the neuroendocrine axis**.
- Hyperthermia therapy acts as a **systemic regulatory intervention**, supporting psychological and psychophysiological recovery through **autonomic nervous system modulation**, **chronic inflammation suppression**, and **endocrine optimization**.



Physiological Mechanisms and Potential Applications of Hyperthermia in Anti–Aging Medicine

From Cancer to Longevity : Whole–body hyperthermia holds potential as a therapy for **life extension**.

Immune System

Hyperthermia enhances innate immunity by activating **natural killer (NK) cells**, **cytotoxic T cells**, and **macrophages**, promoting the recognition and elimination of pathogens and damaged cells.

Muscular System

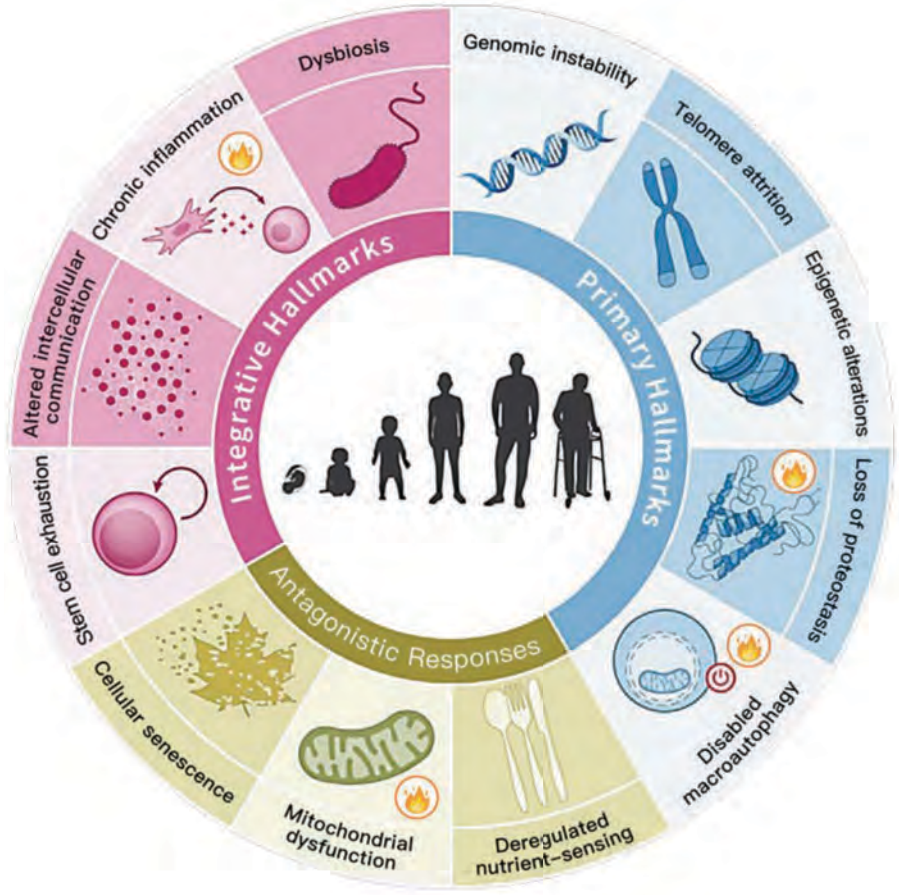
Supports muscle regeneration by upregulating **muscle–related gene expression**, activating **mTOR kinase**, and suppressing **intramuscular IL–6**.

Tissue Perfusion

Increases blood flow and oxygen delivery, improving nutrient supply and waste removal in tissues, while also potentially reducing the risk of metastasis.

Metabolism

A **1°C increase in body temperature** raises the **basal metabolic rate by approximately 10%**, contributing to improved **insulin sensitivity**.



Icons in the diagram indicate areas where the scientific literature has demonstrated the efficacy of hyperthermia.

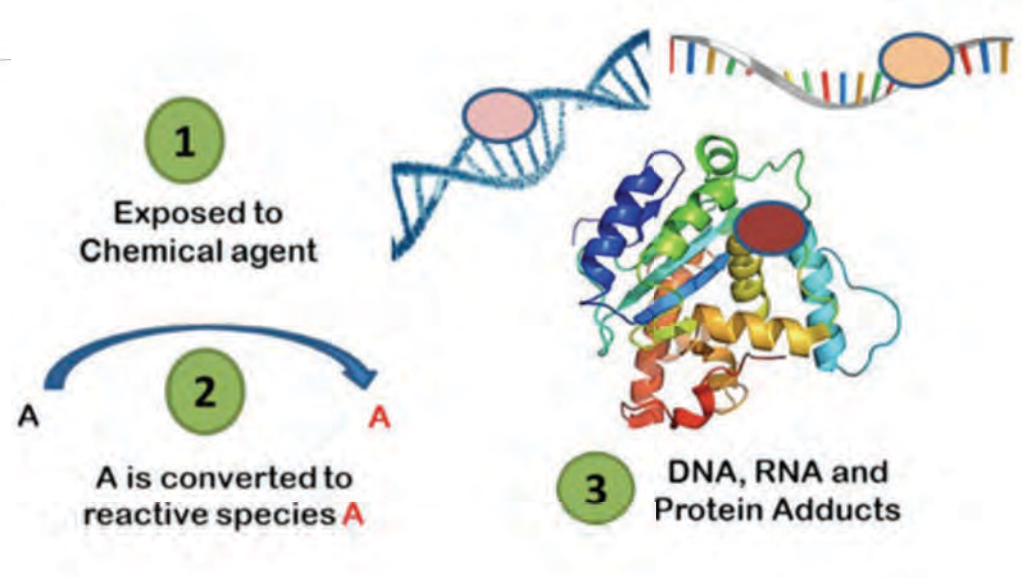
Fig. : Physiological effects of WBH on the human body.

Integrated Applications in Detoxification and Anti-Aging Medicine

Stimulating Detox and Cellular Recovery

Molecular Damage Process Caused by Toxic Chemicals:

- **Exposure to Chemical Agents**
  DNA, RNA, and proteins are exposed to toxic substances in the environment.
- **Generation of Reactive Species**
  The toxic compound A is metabolized into highly reactive free radicals or toxic derivatives (A^+).
- **Formation of Adducts**
  Reactive A^+ binds with DNA, RNA, or proteins, forming molecular adducts that can lead to gene mutations, functional impairment, and the development of chronic diseases.



effects

- Cancer
- Birth defects
- Diabetes
- Auto-immune diseases
- Cardio-vascular diseases

Integrated Applications in Detoxification and Anti–Aging Medicine

Stimulating Detox and Cellular Recovery

These molecular damages may lead to:

- birth defects
- Diabetes
- autoimmune diseases
- cardiovascular diseases
- cancer

Treatment parameters	
Rectal temperature	38.0 – 38.5 ˚C
Heating phase	45–60 min
Resting phase	–
Number of treatment sessions	1–3

- Combining the following supportive nutrients/IV infusions can enhance detoxification and antioxidant functions:

Vitamin B complex (especially B12) — Support nerve and cellular metabolism.

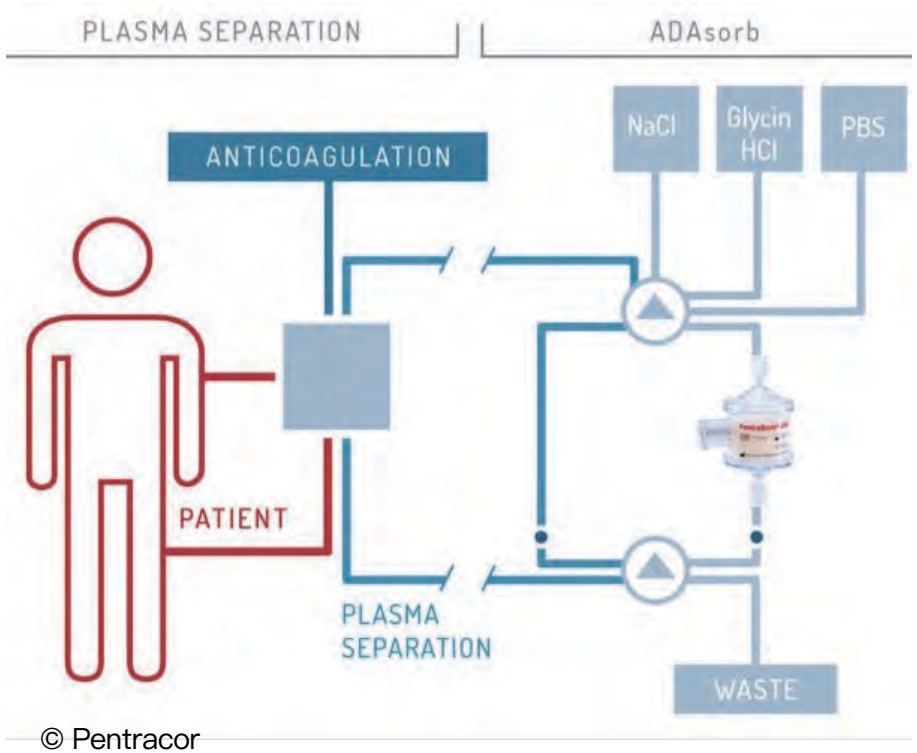
Vitamin C — Antioxidant, supports collagen and immune function.

Alpha–lipoic acid — Supports liver detoxification and mitochondrial metabolism.

Glutathione — A powerful antioxidant that directly participates in cellular detoxification and repair.

The mechanism of action of thermal therapy in detoxification and anti-inflammation

Enhance plasma clearance capacity to improve detoxification and anti-inflammatory effects.



- **Microvascular Dilation and Circulation Promotion**
  Thermotherapy dilates microvessels and accelerates blood circulation, enhancing the mobility of toxins and inflammatory substances in the bloodstream, thereby creating favorable conditions for their clearance.
- **Synergistic Inflammation Reduction for Dual Anti-Inflammatory and Detoxification**
  Thermotherapy lowers inflammatory cytokines such as IL-6 and TNF-α. When combined with plasmapheresis (Apheresis), it produces a dual anti-inflammatory and detoxifying effect.
- **HSP Induction for Immune Regulation Optimization**
  Thermotherapy induces HSP expression, improving the body's treatment tolerance and prolonging the maintenance of therapeutic effects.

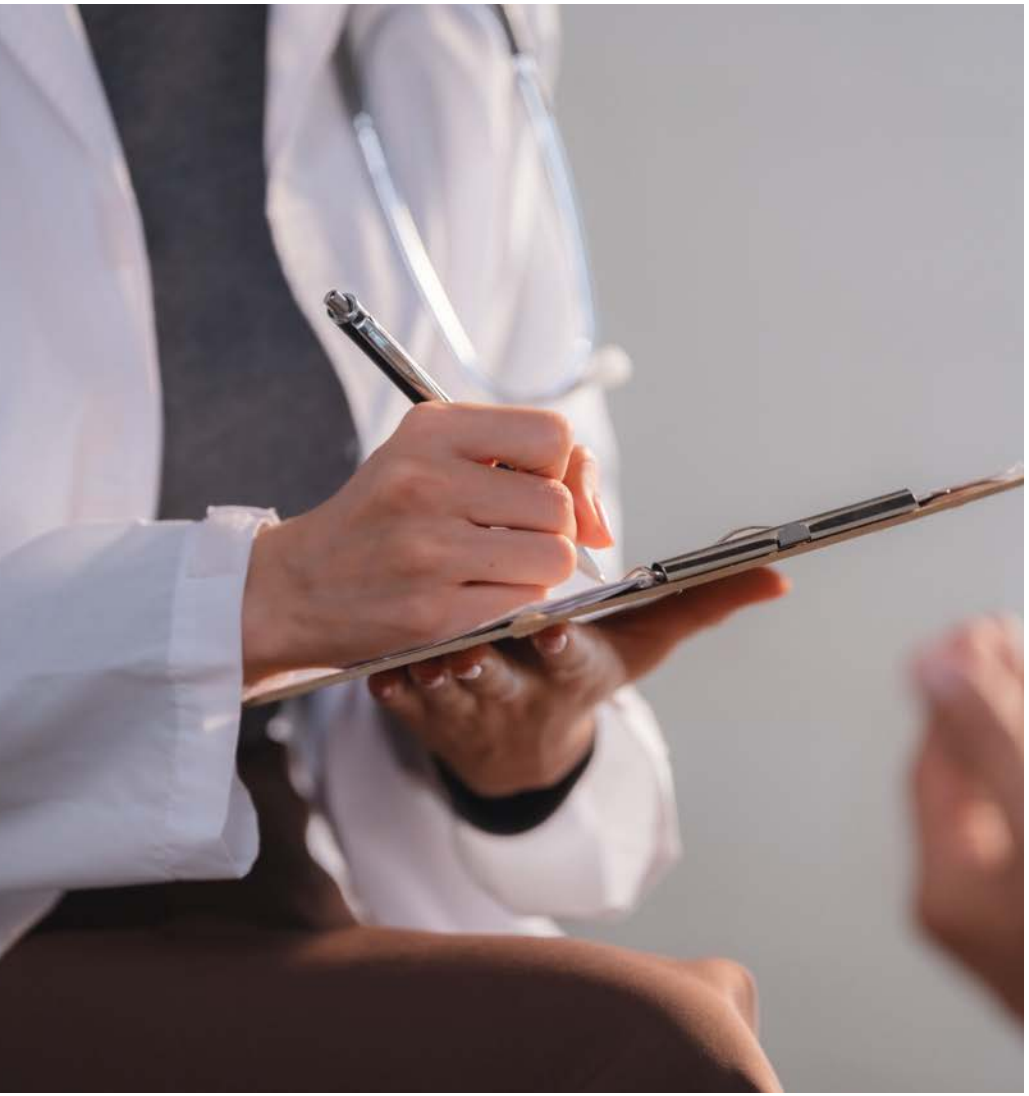
Treatment parameters	
Rectal temperature	38.5 °C
Heating phase	60 min
Resting phase	30 min
Number of treatment sessions	Single collection procedure per session

Thermotherapy Promotes Inflammatory Clearance and Immune Regulation

The INUSpheresis® system description has officially listed 'thermotherapy recommended in combination' as part of the standard procedure.

- Multiple studies demonstrate that the clearance efficiency of inflammatory mediators, such as IL-6, depends on their free plasma concentration and circulation mobilization rate. Thermotherapy enhances their bioavailability to support this process.
- IRATHERM® mild whole-body hyperthermia (38.5°C) safely promotes blood flow and immune activation without interfering with apheresis procedure safety.

Apheresis Treatment	IRATHERM® Whole-Body Hyperthermia (WBH)	Synergistic Effect
Separation and removal of pathological substances in plasma (such as cytokines, endotoxins, antibodies, etc.)	Dilate microvessels and increase blood perfusion	Facilitate mobilization of more pathological substances into the plasma, enhancing clearance efficiency
Does not possess inherent active immune regulatory function	Induce HSP70 expression and activate leukocyte function	Dual anti-inflammatory mechanisms to prolong therapeutic effects
Clears inflammatory mediators	Suppress inflammatory cytokines such as TNF-α and IL-6	Dual anti-inflammatory mechanisms to prolong therapeutic effects
Some patients may experience fatigue or stronger reactions after treatment	Regulate autonomic nervous system and enhance mitochondrial energy production	Alleviate post-treatment fatigue and adverse reactions, improving patient compliance

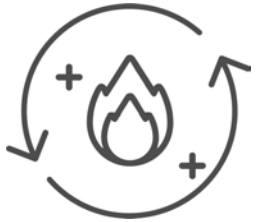


Conclusions

Maintaining an internal environment that resists cancer is more important than merely treating disease.

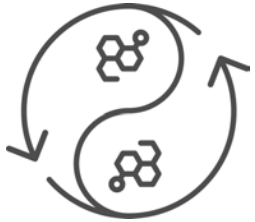
A body in its optimal state helps reduce the risk of cancer.

Homeostasis



Balanced Metabolism

Activated Immunity



Healthy Circulation

Conclusions

Thermotherapy Intervention Opportunities in Cancer Risk Management

Chronic Inflammation (a fertile ground for cancer)	Immunosuppression (immune surveillance failure)	Toxin Accumulation (mutagenic burden)	Autonomic Nervous System Imbalance (immune suppression)	Poor Blood Circulation (local hypoxia)
Thermal intervention induces heat shock proteins (HSP), regulates immune cell activity, and attenuates inflammation.	Enhances natural killer (NK) cell activity, activates the interferon system, and mimics fever responses.	Deep sweating facilitates the metabolism and excretion of heavy metals and environmental toxins.	Supports autonomic nervous system balance (sympathetic and parasympathetic), facilitating restorative sleep and physiological recovery.	Enhances microvascular flow and limits tumor hypoxia and necrosis.


IRATHERM
Heat is therefore life

IRATHERM®1000M

AASPL
Anti-Aging Sciences
Propulsion Labs Co., Ltd.