Whole-Body Hyperthermia with the Iratherm® 1000 (wIRA) in Fibromyalgia

Peer-reviewed evidence & regulatory status — a chairside reference for explaining the therapy to patients.
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What the device is. The Iratherm® 1000 (Von Ardenne Institut für Angewandte Medizinische Forschung, Dresden) is a whole-body hyperthermia (WBH) system that uses **water-filtered infrared-A (wIRA)** radiation to raise core body temperature into a controlled, fever-like range. For fibromyalgia it is used in the **mild** band — a target core temperature of roughly 38.5–38.7°C held for a short plateau — to produce analgesia, not the higher oncological dose.

A naming note for accuracy. Von Ardenne's clinical range is the Iratherm 800 and Iratherm 1000 / 1000M. There is **no "Iratherm 2000"**; a device sometimes called "WBH 2000" is a different product from another manufacturer (Oncotherm). All fibromyalgia evidence below concerns the Iratherm **1000** (or the generic wIRA-WBH method).

How to read the evidence tiers

TIER A	Randomised, sham/placebo-controlled — strongest causal evidence.
TIER B	Randomised or controlled, no sham — supportive.
TIER C	Uncontrolled / pilot / secondary / non-randomised — hypothesis-generating.

Peer-reviewed studies — protocol, results & conclusion

TIER A — **Langhorst J, Koch AK, Kehm C, Öznur Ö, Engler H, Häuser W. *J Clin Med* 2023;12(8):2945. (NCT05135936)**

Design	Prospective, single-centre, single-blind, **randomised sham-controlled** trial — the only sham-controlled RCT of wIRA-WBH in fibromyalgia.
Device	Iratherm 1000 (sham = insulating foil reflecting most radiation, identical setting/ritual).
Protocol	n = 41 (WBH 21 / sham 20), ACR-2016 confirmed, age 18–70, baseline pain ≥ 4. Six outpatient sessions over 3 weeks (≥1 rest day between), 60 min each; target core 38.5°C, mean maximum 38.7°C held ~15 min. Primary outcome: Brief Pain Inventory pain at week 4.
Results	Pain was significantly lower with WBH at week 4 (**p = 0.015**) and the benefit persisted to week 30 (**p = 0.002**). Immune-cell counts rose more in the WBH group; higher lymphocytes and IL-6 tracked with lower pain. Well tolerated — no withdrawals due to side-effects.
Take-home	*First controlled proof that mild wIRA-WBH reduces fibromyalgia pain, with an effect lasting ~7 months.*

TIER B — **Brockow T, Wagner A, Franke A, Offenbächer M, Resch KL. *Clin J Pain* 2007;23(1):67–75. (NCT00324441; German version *Phys Med Rehab Kuror* 2008;18:171–180)**

Design	**Randomised controlled trial** (open, adjunct design; no sham). The foundational RCT that powered later studies.
Device	Iratherm 1000.
Protocol	139 inpatients (ACR-1990) randomised to near-infrared WBH (heated to 38.1°C core + 15-min retention) added to a standard multimodal rehabilitation programme, vs rehabilitation alone; 2×/week over 3 weeks.
Results	Adding WBH produced an additional reduction in pain over rehabilitation alone, with a **moderate effect size (Cohen's d ≈ 0.60)** judged clinically relevant.
Take-home	*Established mild WBH as a worthwhile add-on to multimodal rehabilitation for fibromyalgia pain.*

TIER B	**Walz J, Hinzmann J, Haase I, Witte T. *Schmerz* 2013;27(1):38–45.**
Design	**Controlled clinical trial**, three arms (a dose/frequency comparison).
Device	wIRA-WBH (Von Ardenne method; specific model not stated in the sources reviewed).
Protocol	67 inpatients in 3 groups — wIRA-WBH **once** weekly, **twice** weekly, or rehabilitation only — over 3 weeks; pain measured at baseline, discharge and 6 months.
Results	**Once-weekly** WBH was significantly better than twice-weekly and than control for pain reduction and the affective component of pain, with trends toward better fibromyalgia-related quality of life and mood.
Take-home	*Benefit can persist to 6 months; more frequent treatment is not necessarily better — a lower-frequency schedule may be optimal.*

TIER C	**Langhorst J, et al. *Biomedicines* 2023;11(11):2949. (Secondary & mixed-methods analysis of the NCT05135936 RCT)**
Design	Secondary **predictor analysis + qualitative interviews** nested in the sham-controlled RCT above.
Device	Iratherm 1000.
Protocol	Same 6-session / 3-week protocol (target 38.5°C; irradiance stepped 80% → 40% to hold the plateau). Pain at baseline and week 12; structured patient interviews at week 12.
Results	Baseline pain and the **duration of the temperature plateau** significantly predicted week-12 pain. Every interviewed patient reported improved pain and well-being, though the onset and duration of relief varied between individuals.
Take-home	*Time held at target temperature may predict more durable relief — useful for protocol optimisation and for setting realistic patient expectations.*

TIER C	**Schleenbecker HG, Schmidt KL. *Phys Rehab Kur Med* 1998;8:113–117. (DOI 10.1055/s-2008-1061834)**
Design	**Uncontrolled pilot study** — the earliest published signal.
Device	Iratherm 1000.
Protocol	WBH 30 min per session, mean core temperature 38 ± 0.32°C, 3×/week over 3 weeks, alongside a standardised drug and physical-therapy programme.
Results	Pain fell significantly immediately after a single session; after 3 weeks of treatment pain remained below the pre-treatment level.
Take-home	*First indication of an analgesic effect — strongest with repeated application; hypothesis-generating only (no control group).*

Supporting / adjacent evidence (multimodal context)

Two non-randomised controlled studies by **Romeyke & Stummer** embedded systemic WBH within multidisciplinary inpatient care and reported improvements in pain intensity and mental state, including in severe, treatment-resistant fibromyalgia (*J Musculoskelet Pain* 2014;22(4):341–355; *Clin Interv Aging* 2015;10:69–79). These reinforce the direction of effect but are **Tier C**: not randomised, WBH was one component of a complex programme, and the device was not identified as an Iratherm in the sources reviewed — so they should not be cited as Iratherm-specific.

What the evidence shows, in one paragraph

Across roughly three decades and several German centres, mild wIRA whole-body hyperthermia has **consistently reduced fibromyalgia pain**, and in the best-designed study the effect lasted about seven months. The therapy is **generally well tolerated**, with adverse effects largely limited to short-lived physiological responses to heating. The caveats matter: the studies are **small** (the only sham-controlled RCT had 41 patients), they are concentrated in a few groups, and the strongest data come from WBH used **as an adjunct** to multimodal care rather than as a stand-alone cure. The honest summary for a patient is: *promising, repeatedly positive, well tolerated — but built on limited controlled evidence, and best used alongside guideline care.*

Regulatory status

The Iratherm 1000M is registered as a medical device in the EU, Singapore and Malaysia. The entries below reflect the manufacturer's CE documentation and the **official Singapore (SMDR) and Malaysian (MDA) registration records on**

file. Note that all three frameworks register the device for whole-body hyperthermia / relief of muscle fatigue, stiffness and pain — **not as a fibromyalgia-specific indication**.

Jurisdiction	Status	Key registration details
European Union CE / MDR	**CE-marked, Class IIa** (type 1000M).	Per manufacturer conformity documentation: CE under the Medical Devices Directive 93/42/EEC (plus RoHS 2011/65/EU), ISO 13485 quality system; intended purpose = mild and moderate whole-body hyperthermia using infrared-A. MDR certification stated to be *in progress*, with EU market access secured under transitional provisions to **end of 2028**. (EU Class IIa corresponds to the GHTF/ASEAN **Class B** used by HSA and MDA below.)
Singapore HSA (SMDR)	**REGISTERED** Class B Reg. no. DE0506482	Listed on the Singapore Medical Device Register as "Von Ardenne Institute of Applied Medical Research IRATHERM®1000M", medical specialty **Physical Medicine**. Registered **15 Dec 2021** (change notification approved 23 Sep 2022). Registrant: **Qualtech Consulting Corporation Pte Ltd** (Singapore); product owner: Von Ardenne (Dresden). Listing covers the 1000M system, IRAcom, IRAsoft 5.0 and the temperature / pulse-oximeter sensors. **Registered intended use:** raises core temperature to about 40.5°C within mild/moderate WBH, to relieve muscle fatigue, muscle stiffness and muscle pain — *not a fibromyalgia indication*.
Malaysia MDA (MOH / KKM)	**REGISTERED** Class B, Group: System Reg. no. GB6786221-55575	Registered under the Medical Device Act 2012 (Act 737), s.5(1). Manufacturer: Von Ardenne (Dresden); registrant / Authorised Representative: **Qualtek Consulting Sdn Bhd** (Subang Jaya). Covers IRATHERM 1000M / 1000 (firmware 4.1), IRAcom and IRAsoft 5.0. **Certificate validity 30 Jan 2021 – 29 Jan 2026** (5-year term) — on its face this window has now elapsed; **confirm renewal before continued import or marketing**. Conditions of note: advertising must state the intended purpose, must not imply MDA endorsement, must not reference the 20 prohibited diseases under the Medicines (Advertisement & Sale) Act 1956, and professional-use devices must not be marketed to the public.

Safety & screening

- Generally well tolerated; adverse effects mostly short-lived responses to heating; no side-effect withdrawals in the sham-controlled RCT.
- Typical study exclusions: febrile illness / core temp >37.5°C, significant cardiovascular disease (e.g. heart failure), severe somatic or psychiatric comorbidity, pregnancy.
- Caution with drugs affecting thermoregulation or fluid balance.
- Monitor core temperature, pulse and SpO_2 throughout; ensure hydration.

References

1. Langhorst J, Koch AK, Kehm C, Öznur Ö, Engler H, Häuser W. Mild Water-Filtered Infrared-A Whole-Body Hyperthermia Reduces Pain in Patients with Fibromyalgia Syndrome — A Randomized Sham-Controlled Trial. *J Clin Med* 2023;12(8):2945. DOI 10.3390/jcm12082945. (NCT05135936)
2. Brockow T, Wagner A, Franke A, Offenbächer M, Resch KL. A Randomized Controlled Trial on the Effectiveness of Mild Water-filtered Near Infrared Whole-body Hyperthermia as an Adjunct to a Standard Multimodal Rehabilitation in the Treatment of Fibromyalgia. *Clin J Pain* 2007;23(1):67–75. DOI 10.1097/AJP.0b013e31802b4f80. (NCT00324441)
3. Walz J, Hinzmann J, Haase I, Witte T. Ganzkörperhyperthermie in der Schmerztherapie — eine kontrollierte Studie an Patienten mit Fibromyalgiesyndrom. *Schmerz* 2013;27(1):38–45. DOI 10.1007/s00482-012-1288-4.
4. Langhorst J, et al. Investigating the Influential Factors of Mild Water-Filtered Infrared-A Whole-Body Hyperthermia for Pain Relief in Fibromyalgia: A Mixed-Methods Approach. *Biomedicines* 2023;11(11):2949. DOI 10.3390/biomedicines11112949.
5. Schleenbecker HG, Schmidt KL. Zur Wirkung einer iterativen milden Ganzkörperhyperthermie auf den Fibromyalgieschmerz — Pilotstudie. *Phys Rehab Kur Med* 1998;8:113–117. DOI 10.1055/s-2008-1061834.
6. Romeyke T, Stummer H. Multi-Modal Pain Therapy of Fibromyalgia Syndrome with Integration of Systemic Whole-Body Hyperthermia. *J Musculoskelet Pain* 2014;22(4):341–355. DOI 10.3109/10582452.2014.949336.
7. Romeyke T, Scheuer HC, Stummer H. Fibromyalgia with severe forms of progression in a multidisciplinary therapy setting with emphasis on hyperthermia therapy — a prospective controlled study. *Clin Interv Aging* 2015;10:69–79. DOI 10.2147/CIA.S74949.
8. Von Ardenne Institut für Angewandte Medizinische Forschung GmbH — Iratherm 1000M conformity documentation & product information (manufacturer). CE / ISO 13485 / MDR transition statements.