

ZAMAR - Clinical & Technical Sales Guide

Version EN 1.0 - 12/25

Summary

1. Introduction	2
2. Fundamentals of the ZAMAR System	2
3. Who really does the thermal work	2
4. No Ice - No Water	2
5. Cooling power and thermal control	3
6. Closed Clean System	3
7. Plug & Play and operational workflow	3
8. Controlled Pneumatic Compression	3
9. CE and FDA 510(k) Compliance	3
10. HMI Interface	4
11. ZAMAR Range	4
12. Management of major objections	4
13. Distributor toolkit	6
14. Quick check for identification of the appropriate model	7
15. Qualifying questions	7
16. Technical-clinical insights	10
17. Final pitches and closings	11
18. Technical appendices	12

1. Introduction

This guide is designed to support ZAMAR distributors in the presentation, positioning, and proper technical argumentation of ZAMAR thermal control systems to physical therapists, physicians, hospital departments, sports facilities, and technical buyers.

ZAMAR is not a "cold machine," but a CE and FDA 510(k) compliant medical system designed for active, precise and stable tissue temperature control, integrated with controlled pneumatic compression.

2. Basics of the ZAMAR System

ZAMAR is a medical system to control the temperature of the desired body part. It is designed to extract or release heat to the body district in a stable, controlled and repeatable manner. Unlike ice- or water-based systems, ZAMAR uses a professional refrigeration circuit, with real heat output expressed in watts, to maintain the set temperature for the duration of the treatment.

3. Who really does the heat work

The fundamental difference between ZAMAR and traditional systems is in the direction of the heat work: who really does the work, the patient or the machine?

- In ice systems (ice boxes, cool bags, recirculating systems) the patient does the work: body heat melts the ice, heats the water, and progressively collapses the cooling power. The direction of the work is Patient → System.
- In Peltier systems the cooling power is very low: that is why they are limited to small areas and a single band, with rapid loss of effectiveness in prolonged sessions.
- With ZAMAR the opposite happens: the thermal work is done by the system on the treated part. The direction is System → Patient. The machine delivers enough cooling (or thermal) power to maintain the set temperature, even over large areas and with multiple active wraps.

4. No Ice - No Water

ZAMAR does not use ice or water. This completely eliminates all operations related to the management of ice (production, transport, disposal) and water (filling, replacement, emptying, tank cleaning).

The circuit is sealed: the working fluid never comes into contact with the outside. There is physiological micro-evaporation due to the flexibility of the wraps and normal pressurization cycles; refilling is simple, non-invasive, and does not interfere with daily use of the device.

5. Cooling capacity and thermal control

Cooling capacity expresses the system's ability to extract heat from the treated district without losing effectiveness over time. In ice systems, the power depends on the amount of residual ice and tends to zero as the ice melts; in Peltier systems it is limited by the technology itself and allows only small surfaces.

ZAMAR uses a professional refrigeration circuit with sufficient power to keep the set temperature stable even in prolonged sessions, treating from one to 4 wraps depending on the model. Stable ΔT (delta temperature) is an essential requirement for standardizable and repeatable rehabilitation protocols.

6. Closed Clean System

ZAMAR's circuit is a closed clean system: the working fluid is never drained, is not filled with mains water, and does not come into contact with the environment. This significantly reduces the risks of contamination, eliminates stagnant water formation, and resets internal circuit flushing procedures to zero.

7. Plug & Play and operational workflow

ZAMAR wraps are pre-loaded and ready to use. There is no need to fill tanks, manage ice, or perform water changes. The operator plugs in the band, sets temperature and compression, starts treatment, and focuses on the patient.

This approach reduces downtime, simplifies the workflow and allows more patients to be treated for the same number of resources.

8. Controlled pneumatic compression

ZAMAR integrates controlled pneumatic compression with three pressure levels (40-60-80 mmHg) and five operating modes, from intermittent to constant. The compression contributes to edema management and enhances the effectiveness of heat treatment.

9. CE and FDA 510(k) compliance.

ZAMAR is a medical device that complies with CE requirements for medical devices and is FDA 510(k) compliant. This regulatory framing ensures that the system is designed, manufactured and tested to high standards of safety, performance and quality, and is a key element in evaluation processes for hospitals and orthopedic departments.

10. HMI Interface

The user interface is touchscreen-based (5", 7" or 11" depending on the model) and allows rapid setting of temperature, treatment duration and compression, displaying real-time system status and active parameters. The ability to store protocols reduces errors, accelerates staff training and helps standardize treatment.

11. ZAMAR Range

11.1. ZAMAR Range Table

Model	Type	T° Range	Simultaneous ranges	Mobility	Typical Application
Z-ONE	Portable	5-15°C	1-2 wraps	High	Sports, simple postoperative, single treatment in the ward
ZC4	Portable	0-40°C	2 wraps via T-Hose	High	Physiotherapy, sports medicine, field activities with thermotherapy
ZH4	Wheeled	0-40°C	2 wraps always operational	Stationary	High-volume physical therapy centers, hospitals, intensive rehabilitation
ZTClinic MED	Wheeled	0-45°C	Up to 4 simultaneous patients	Stationary	Orthopedics, surgical departments, clinics with high flow, large sports teams

12. Handling major objections

This section provides technical, clear and professional answers to address the most common objections that have arisen in clinical, physical therapy and sports settings.

12.1. "The cost is higher than other solutions."

ZAMAR is a CE and FDA 510(k) compliant medical device designed to provide stable thermal power, precise temperature control and repeatable treatments. Ice- or Peltier-based solutions cannot offer continuity or clinical standardization.

Recommended response: Price follows technology: ZAMAR uses an active thermal system with real power and controlled parameters. Passive or low-power systems are not in the same technology category.

12.2. "The device is heavier."

The weight comes from the presence of a professional refrigeration circuit, equipped with highly reliable components. Other systems are lighter because they lack a true internal thermal system.

Recommended response: The weight comes from the presence of the components necessary for a true refrigeration system: it is these elements that make it possible to guarantee stable thermal power and continuity of treatment

12.3. "The connectors result in stiffness."

Initial stiffness is typical of hermetically sealed systems. NO LEAK connectors ensure safety, no leakage and stability of the working fluid.

Recommended response: Stiffness is functional for hermetic sealing and circuit safety. With regular use, connectors become more manageable while still maintaining the same tightness

12.4. "Is the liquid consumed?"

The device does not consume coolant. There is physiological micro-evaporation related to the flexibility of the wraps. Refilling, when necessary, is simple and does not interfere with daily use.

Recommended response: There is no consumption of the liquid: micro-evaporation is minimal and topping up does not affect operation.

12.5. "Is compression really necessary?"

Controlled pneumatic compression aids edema management and enhances the overall effectiveness of heat treatment.

Recommended answer: Controlled compression complements heat therapy and is a relevant part of the protocol.

12.6. "Why not use ice?"

Ice cannot provide thermal stability or repeatability of treatment. The temperature depends on the patient and degrades rapidly during the session.

Recommended answer: The variability of ice prevents real temperature control and does not allow for standardized protocols.

12.7. "Peltier systems are more practical."

Peltier modules have very low cooling output, limit therapeutic surface area, and do not allow simultaneous treatments or prolonged sessions. The output progressively degrades as the treatment progresses.

Recommended response: *Practicality is no substitute for the thermal power and therapeutic efficacy required for stable treatments on adequate surfaces.*

12.8. "Cold is enough; we don't need heat."

Quality cryotherapy is essential in the acute phase, but comprehensive rehabilitation also requires controlled thermotherapy, especially in the sub-acute and functional phases. Thermotherapy helps improve perfusion, joint mobility, tissue elasticity, and preparation for functional loading.

Having a system that integrates heat and cold allows practitioners to structure more comprehensive rehabilitation programs, cover the entire therapeutic pathway (acute → sub-acute → functional), and offer more extensive and remunerative rehabilitation packages.

13. Distributor Toolkit

This section provides operational and communication tools to present ZAMAR in a way that is technically correct and consistent with its positioning as a medical device compliant with CE and FDA 510(k) requirements.

13.1. Key messages for technical presentation:

- ZAMAR is a CE and FDA 510(k) compliant medical system designed for precise tissue temperature control.
- Thermal output is stable over time and ensures continuity even in prolonged sessions.
- The refrigeration circuit is completely closed: no contact with the outside and no routine internal maintenance.
- Treatment is standardizable and repeatable, reducing clinical variability.
- Controlled pneumatic compression complements and optimizes heat treatment, contributing to edema management.

13.2. Recommended technical demonstration (1-2 minutes):

1. Apply a preloaded bandage, highlighting the absence of water and ice.
2. Set the temperature (T1) and show the rapidity of stabilization.
3. Activate compression, illustrating levels and modes.
4. Highlight the device's operational continuity even in prolonged sessions.

13.3. Technical aspects to **avoid** in communication:

- Do not equate ZAMAR with ice- or water-based systems.
- Do not use generic terms such as "cold machine" or "cold pack."

- Do not describe ZAMAR as a passive cooling system.
- Avoid improper comparisons with non-pneumatic elastic compressions.

14. Quick check for identifying the appropriate model.

The first discriminator is the type of user: physical therapy center, hospital/orthopedic ward, sports team or individual athlete.

14.1. Table - Model Selection Based on Type of User.

Type of facility	Recommended Model	Operational Notes
Physical therapy and rehabilitation centers	ZC4, ZH4	ZC4 for portability + thermotherapy; ZH4 for intensive use with two wraps always ready.
Hospitals, orthopedics, post-surgery	ZH4, ZTClinic MED, Z-ONE (single patient)	ZTClinic MED for high volume; ZH4 for post-surgery; Z-ONE for simple bedside protocols.
Sports teams, athletes, performance	Z-ONE, ZC4, ZTClinic MED	Z-ONE for portable cryotherapy; ZC4 for hot+cold in the field; ZTClinic MED to treat many athletes sequentially or simultaneously.

Then evaluate need for thermotherapy, number of patients treated in parallel, level of mobility required, and intensity of use.

15. Qualifying questions

Qualifying questions help the distributor understand the clinical and operational context to propose the most appropriate model:

15.1. In what area do you primarily operate?

(physical therapy, orthopedics/post-operative, sports medicine, hospital ward)

Why it matters:

The context immediately determines the technological orientation.

- **Hospital/orthopedics** → Stability, continuity, protocols → ZH4 / ZTClinic MED / Z-ONE

- **Physiotherapy** → Hot+cold, variable protocols → ZC4 / ZH4
- **Sports** → Speed, portability → Z-ONE / ZC4

How to interpret:

Context is the first discriminator for not getting the model wrong.

15.2. How many patients do you treat on average per day?

Why it matters:

Daily flow defines whether you need to:

- simple portability
- continuity of treatment over 2 wraps
- capacity for up to 4 simultaneous patients

15.3. Which body districts do you treat most frequently?

Why it matters:

Shoulder, knee, ankle, hip, back → require different treatments in terms of thermotherapy and surface area.

Interpretation:

Recommend the most appropriate kit for the client's needs.

15.4. Do you need cold, hot or both?

Why it matters:

This is the question that often leads the client to *realize* the need for heat.

Interpretation:

- Cold only → Z-ONE (but it is rare that hot is not needed in full pathways)
- Hot + cold → 90% of real cases → ZC4 / ZH4 / ZTClinic MED

Useful note:

The "cold only" response often comes from technological limitations of other devices, not from real clinical need.

15.5. Do you need to treat multiple districts or multiple patients simultaneously?

Why it matters:

Determines the capacity of the system: 1, 2 or 4 wraps.

Interpretation:

- One/two small/medium sized wraps → Z-ONE
- Two wraps wraps with no size limitation → ZC4/ZH4
- Up to four Wraps/Patients → ZTClinic MED

15.6. How important is the portability of the system?

Why it is important:

Mobility = Z-ONE or ZC4

Fixed location = ZH4 or ZTClinic MED

Interpretation:

- Study or need for transportation → portable
- Hospital ward → wheeled
- Sports field → absolutely portable

15.7. Do you manage structured postoperative protocols?

Why it's important:

Post-surgical protocols require:

- thermal stability
- repeatability
- controlled compression
- continuity

Interpretation:

Z-ONE for acute phase cold-only protocols; ZC4/ZH4/ ZTClinic MED for larger volumes.

15.8. Do you have a need to reduce treatment preparation time?

Why it matters:

ZAMAR eliminates:

- ice
- water
- emptying
- spares
- preliminary preparations

Interpretation:

If the answer is "Yes," ZAMAR becomes immediately superior to passive systems.

15.9. Are you interested in comprehensive rehabilitation pathways (acute → sub-acute → functional)?

Why it is important:

This is the key question for introducing thermotherapy.

Interpretation:

If they work with comprehensive protocols → they should use a hot+cold system (ZC4, ZH4, ZTClinic MED).

16. Technical-clinical insights.

16.1. Clinical-technical rationale on thermal control

Active temperature control enables ΔT stability, prevention of vascular rebound, controlled physiologic modulation, integration with pneumatic compression, and therapeutic repeatability. Clinical efficacy derives from the system's ability to deliver cold or heat consistently and predictably.

16.2. Main clinical indications by district

- Knee: edema, pain, post-arthroscopy, ligament reconstruction, prosthesis.
- Ankle: sprains, tendinopathies, post-fractures.
- Shoulder: post-cuff, post-arthroscopy, post-immobilization stiffness.
- Hip: prosthesis, sub-acute stages of recovery.
- Lumbar and soft tissue area: controlled thermotherapy for tension reduction, improved mobility and load preparation.

16.3. Technical-engineering rationale

ZAMAR uses a professional refrigeration circuit with real thermal power, high-efficiency exchangers, and a compressor sized to ensure stability even in prolonged sessions. The closed circuit avoids contamination and stagnant water, reducing risks and maintenance activities.

16.4. Risk Management - Key Concepts.

No free water and ice, sealed circuit, NO LEAK connectors, and controlled parameters help reduce operational, hygienic, and treatment variability risks.

16.5. Economic and operational advantages

Compared with ice- or water-based systems, ZAMAR eliminates ice purchase, water management, reduces the number of devices needed (cold, heat, compression), and allows more treatments per unit of time due to reduced preparation time.

16.6. Anatomical Thermal Wraps

Highly compliant anatomical wraps ensure even cold/hot distribution, no structural stiffness, better heat transfer and greater patient comfort.

16.7. Clinical workflow

Always-ready wraps, storable protocols, rapid patient alternation, and no emptying or flushing of the circuit allow for a linear, efficient, and easily organized workflow.

16.8. Evidence-based rationale (general concepts)

Controlled cryotherapy is used to reduce pain and edema; controlled thermotherapy to improve perfusion and mobility; and pneumatic compression to support edema management. The combination of these three elements, delivered in a stable and repeatable manner, maximizes therapeutic efficacy.

17. Final pitches and closures

17.1. Elevator pitch (15 seconds):

"ZAMAR is a CE and FDA 510(k) medical system for active temperature control and pneumatic compression. It provides stable thermal power, repeatable treatments, closed circuit without ice or water, and extremely low operational management compared to ice and Peltier."

17.2. Synthetic technical pitch (30-45 seconds):

"ZAMAR uses a professional refrigeration circuit to precisely control cold and heat by integrating pneumatic compression. The system ensures thermal stability, protocol repeatability and operational continuity even with prolonged or multiple treatments. The closed circuit, free of water and ice, minimizes internal management requirements and simplifies daily work."

17.3. Full pitch (90 seconds):

"ZAMAR is a CE and FDA 510(k) compliant medical device designed to provide active, precise and stable tissue temperature control by integrating controlled pneumatic compression. Unlike ice- or Peltier-based systems, ZAMAR uses a professional refrigeration circuit that can maintain thermal output throughout the session, ensuring repeatable treatments and standardizable protocols.

The system is fully enclosed, requiring no emptying or internal flushing, and involves minimal operational management (such as periodic fluid refilling when necessary). Anatomical wraps ensure high compliance and uniform heat transfer. ZAMAR enables operation in cold, hot or contrasted mode, expanding therapeutic possibilities in acute, sub-acute and functional phases.

It is a scalable platform, available in portable or wheeled configuration, capable of handling from a single patient up to four simultaneous patients, each treated with a dedicated bandage. For physical therapists, orthopedists, hospital departments and sports staff, ZAMAR offers operational efficiency, continuity and superior therapeutic quality compared to traditional systems."

Final positioning sentence:

"ZAMAR is an active thermal control medical system designed to ensure stable, repeatable and clinically effective treatments. No ice, no water, minimal operational management: maximum continuity and therapeutic precision."

18. Technical appendices

18.1. Glossary

- ΔT (Delta Temperature): difference between set temperature and actual temperature on the district.
- Thermal power (Watts): ability to extract or release heat over time.
- Closed circuit: sealed system with no fluid contact with the outside.
- Controlled pneumatic compression: pressure applied by the band, regulated by the system.
- Thermal protocol: T1/T2 programmed sequence, duration and compression.
- Micro-evaporation: small physiological loss of fluid in the wraps, compensated by periodic top-ups.

18.2. Summary technical attributes.

Overall operating temperature range: $0 \rightarrow 45$ °C, depending on model.

Compression levels: 40 / 60 / 80 mmHg.

Compression modes: intermittent, progressive, modulated, constant.

Highly compliant anatomical wraps, compatible with cold, hot and contrasted cycles.

Date 12/25

Written by: Gianmarco Zanotti