ZAMAR®

Designed and Delveloped by HTFenix® GmbH - Austria

Installation, use and maintenance

CE 1370

Original Instruction - 0MAN455BC00E US Rev.05 - 2021.05

Z-ONE

English

Designed and Delveloped by HTFenix® GmbH - Austria

We would like to thank you for having chosen our products.

This manual has been designed in order to give you all the explanations thus enabling you to use your unit at its best. Therefore you are kindly invited to read it carefully before operating the unit.

DEALER STAMP

Date .....

Signature .....

English

CONTENTS

English

1 GENERAL INFORMATION

1.1 Declaration of conformity (example)

ZAMAR MEDICAL d.o.o. Sv. Martin, 6 52450 Vrsar Istria,Croatia	CE	**1370**

CERTIFICATO CE DI CONFORMITA' – EC CERTIFICATE OF CONFORMITY

Nome e indirizzo della ditta Name and address of the firm	**ZAMAR MEDICAL d.o.o.** Sv. Martin, 6 52450 Vrsar - Istria,Croatia

Dichiariamo sotto la Nostra Responsabilità che
We declare under our sole responsibility that

Il dispositivo medico The medical device	**APPARECCHIATURA A SCAMBIO TERMICO PER CRIOTERAPIA E TERMOTERAPIA** **MEDICAL DEVICE BASED ON HEAT EXCHANGE FOR CRYOTHERAPY AND THERMOTHERAPY**
Nome Name	**Z-ONE**
Anno costruzione Year of manufacture **2018**	Tipo -Modello Type – Model **MG455AA00E**
Matricola Matrikelnummer Numero de serie **XXXXXXX** Serial number Numero de serie	Direttiva Directive **93/42/EEC as amended** **(in accordance with Annex II – excluding par .4)**
Della Classe Of Class **IIa**	Regola 9 Secondo l'allegato IX della direttiva 93/42/CE-2007/47/CE Rule 9 According to annex IX of directive 93/42/EEC-2007/47/EEC

Soddisfa i requisiti essenziali dell'allegato I, II e VII della direttiva 93/42/CE-2007/47/CE(dispositivi medici),
IEC 60601-1 (Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali), IEC 60601-1-2 (compatibilità elettromagnetica)
Soddisfa i requisiti della direttiva 2014/30 /UE(compatibilità elettromagnetica), **e della direttiva 2006/42UE (direttiva macchine)**
Satisfying the essential requirements of annex I, II and VII directive 93/42/EEC -2007/47/EEC (medical device),
IEC 60601-1 (General requirements for basic safety and essential performance), **IEC 60601-1-2 (electromagnetic compatibility)**
Satisfy the requirements of directive 2014/30/EU (electromagnetic compatibility), **and directive 2006/42/UE (machinery directive)**

Certificato n° Certificate N°	**IT256270**
Organismo notificato Notified body	**Bureau Veritas Italia, Viale Monza 347 – 20126 Milano (IT)** **CE 1370**
Il Fascicolo Tecnico è redatto e custodito dal Resp.di Progetto	**Gianmarco Zanotti / Responsabile Tecnico di Progetto**
Nome e funzione Name and Function	**Raffaele Zanotti / Amministratore Unico**
Luogo, data - Place, date	Vrsar, ……..
Il fascicolo tecnico ha validità per tutta la durata del prodotto.	

1.2 Symbology

The pictogrames in the next chapter convey quick and precise information for the correct and safe use of the unit.

Service

- It marks situations where you have to contact the internal company SERVICE: CUSTOMER SERVICE.

General warnings

- It marks the procedure described may result in personal injuries, when not carried out according to security regulations.

Index

- This symbol means that the paragraph contains very important information, specifically concerning safety.

Failure to follow these procedures may result in:

- safety risk for operators;
- cancellation of the contractual warranty;
- manufacturer's disclaimer.

Prohibition

- It marks things you must not do.

Dangerous voltage

- It marks that the described procedure, when not carried out according to the safety regulations, may result in electric shock.

Intense heat danger

- It marks that the described procedure, when not carried out according to safety regulations, may result in contact burns caused by high temperature components.

Wast disposal

The symbol on the item or the package indicates that the item should not be treated as normal household waste, but must be taken to an appropriate collection point for the recycling of electrical and electronic equipment.

Correct disposal of this item will help prevent possible negative consequences for the environment and health.
For further information about recycling this product, please contact the local authority or waste disposal service, or the shop where you purchased the product.

This arrangement is valid in the EU States only.

1.3 General safety warnings

You should always use the optional accessories on-demand only. The unit should always be operated by a single operator. Working and control position is opposite the control panel.

1.4 Permitted use

- Z-ONE unit has been designed for rehabilitation through dynamic management of temperature, designed and built for the complex needs of clinics and hospitals to treat more patients using the same program simultaneously.
- The unit is designed for medical use in normal environmental conditions.
- The unit should be operated by trained personnel specifically instructed on the unit's characteristics and informed on this manual's content.
- The unit usually works in automatic mode, the operator is responsible for the operator panel and the therapeutic wraps.

1.5 Not permitted use

It is forbidden to use the unit, even partially:

- without protective clothing and/or with disabled, damaged or missing security devices;
- if it hasn't been correctly set up;
- in hazardous conditions or in case of malfunctioning;
- for improper use or by unqualified personnel;
- for any use contrary to the relevant legislation;
- if a supply defect occurs;
- in case of serious maintenance deficiencies;
- without the DPI gloves required for the specific procedure;
- without having adequately educated and trained the operator as required by D.Lgs. 81/2008 (and its further supplements and modifications) regarding safety in workplaces;
- after unauthorized modifications;
- with materials and/or tools different from the ones specified for the normal operation of the unit;
- with operating temperatures over 95°F;
- with partial or total inobservance of instructions.

The unit should not be used if one or more of these conditions occur:

- environments with a temperature below 50°F and over 86°F;
- relative humidity less than 10% and more than 50%;
- altitudes exceeding 6500 ft above sea level;
- in explosive atmospheres or where there is a fire hazard.

DEVIATIONS FROM THESE STANDARDS SHOULD REQUIRE A SPECIFIC WRITTEN DECLARATION BY ZAMAR S.R.L.

YOU WILL BE COMPLETELY RESPONSIBLE FOR ANY CHANGE, UNAUTHORIZED BY THE MANUFACTURER, WHICH MODIFIES THE FEATURES, THUS ALTERING AND/OR CAUSING ADDITIONAL RISKS.

THOSE MODIFICATIONS, IF CARRIED OUT WITHOUT THE AUTHORIZATION OF THE MANUFACTURER, WILL RESULT IN THE CANCELLATION OF THE OF THE MANUFACTURER'S WARRANTIES AND IN THE INVALIDATION OF THE DECLARATION OF CONFORMITY REQUIRED BY THE MACHINERY DIRECTIVE 2006/42/ CE.

ZAMAR disclaims any responsibility for any damages to persons, properties or animals arising from an improper use of the machinery.

1.6 Manufacturer and unit identification data

ZAMAR MEDICAL d.o.o.
Head Office:
Sv. Martin, 6
52450 Vrsar - Croatia (HR)

Tel. +385 (0) 52 496 111
+385 (0) 52 496 444
Fax: +385 (0) 52 496 112
info@zamar.care

1.7 Technical support information

Please contact the Supplier where you bought your unit for any service and maintenance not mentioned in these instructions.

1.8 How to place stickers and label

On the machine are affixed identification stickers.

It is mandatory to acknowledge them before any use.
Any different use from that specified shall be considered not proper and may cause damage to the unit and the Operators.

On the front side of the device in addition to the label with the company logo, close to fittings,
a label identifies the application parts to be connected to the device which are "BF" type.

On the back of the device there are some technical and informative labels.
- "TECHNICAL" label, made by a material such that in case of removal can not be used, which shows the technical data of the device, model - serial number - year of manufacture - Electrical Technical Data
- "LIQUID" label warning that the tank of the device can be refilled liquid ONLY with liquid recommended by Zamar Medical d.o.o.
- "Transport" Label that provides information on the conditions of TRANSPORT, STORAGE AND CONDITIONS OF USE
- "WARNING" Label that informs the operator in case of maintenance or service to disconnect the electrical power before servicing.

English

1.9 Symbol legend

SYMBOL LEGEND

Consult Instruction for Use

Attention - Read Manual before use

In accordance with 2012/19/EEC RAEE protocol

BF Applied Part

CE Mark with registration Number

1370

Manufacturer

Model

Serial Number

Date of Manufacturing

Keep Dry

Protection class 1 - devices with connection with protective conductor

2 BEFORE YOU START

2.1 Overview

Portable unit with a comfortable handle for moving with several shelves for pipes and wraps. The ideal solution for Rehabilitation Centres and Leisure Centres.
The touch screen uses a TFT panel which makes it easy to read even in critical light conditions and can be used by the operator even when wearing gloves.
The operator is able to access the different preset programs that allow the application of therapies. It is possible for your doctor to create and store countless cycles of work in absolute freedom, adapting them to the patient's needs and the physical shape.
The intuitive touch-screen interface, with simple icons and graphics, allows the operator to use the system in all its power and practicality continuously monitoring the patient.
The Zamar wraps allow an ideal transferring of the heat on the part to be treated thanks to the anatomical shape which increases the contact surface.
The disposable wraps are also available for hospital use or provided with a sheet of "tissue no tissue" TNT sterile for use on more then one patient. The technical material used keeps the wraps flexible and soft even with treatments at temperatures below zero in the acute stages, helping to prevent cold burns.
Through the Zamar wraps it is possible to apply an air compression pulsed suitably programmed by touch screen, which plays an important role as lymphatic drainage. The wraps are available for all parts of the body: shoulder, elbow, hand-wrist, thigh, knee, ankles, face and breasts.

SYMPTOMATOLOGIES TREATED

Zamar Therapy applies to:

- Muscles
  - Contusions
  - Contractures
  - First and second grade lesions
- Tendineous apparatus
  - Tendinitis
  - Tenosynovitis
  - Tendinopathy
- Osteocartilagineous apparatus
  - Contusions
  - Fractures
- Capsular Ligament structures
  - Strains
  - Ligaments contusions
- Post-surgical
  - Ligaments
  - Meniscus
- Cosmetic surgery
  - Rhynoplasty operation, mastoplasty
  - Liposuction and mesotherapy operations

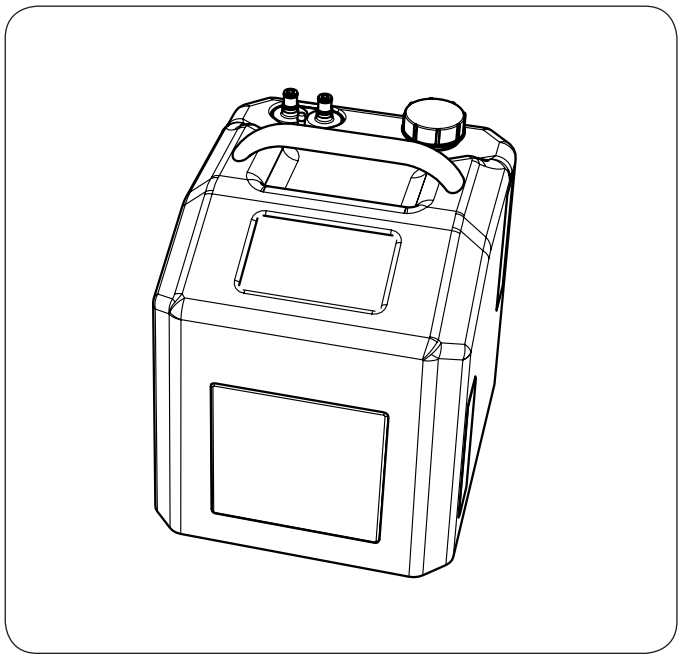
2.2 Features

- Achievable temperature min. 41°F max. 59°F
- Managing up to 2 wraps simultaneously
- Touch screen control panel 5"
- Selection of duration, temperature and pressure of the treatment
- Transportable with the ergonomic handle
- Specific NON-TOX coolant
- Treatment temperature and duration alarms.

English

2.3 Specifications

- Dimension: 11 x 10 x 12 in hight
- Power supply: 115V 60Hz.
- Weight fully loaded: 26 lb.
- Coolant: R134A
- Temperature range: 41°F ÷ 59°F
- Screen: Touch Screen 5”TFT.



2.4 Accessories

A. Power cable.
B. Liquid for circuits, tank of 1 l (cod. 3LIQ010).
C. Use and maintenance instruction manual.

3 TRANSPORT AND HANDLING

3.1 General cautions

All the personnel involved in the unit transport and installation should be informed about these instructions.

3.2 How to package

The unit should be packaged for transport in a carton box where you can find the instructions "TOP" and "FRAGILE". The unit, packaged as said, can be carried by hand by an operator with a hand-truck.

3.3 How to store

Please store the packaged unit in an indoor enclosed environment, soil isolated through wood sleepers or similar. Temperature between 50°F and 104°F; humidity between 30%RH and 60%RH.

Don't turn the packaging upside down. Check the arrow "TOP" printed on the box.

Don't stack up the units.

The unit without packaging must stand stable and covered with a cloth.

3.4 Delivery

The packaging is made of proper material and carried out by trained personnel, therefore the units leave our company complete and in perfect conditions. The goods are at buyer's risk and peril when travelling, even if delivered home for free. However, in order to check transport service's quality and in case of insurance, please proceed as follows:

- as the unit is delivered, before proceeding with unpacking, immediately verify whether the packaging is damaged: if it is, make the goods conditional accepted, taking pictures as evidence of possible apparent damages;
- unpack, checking the correspondence between lists and contents;
- verify that the unit's components haven't been damaged during transport and notify, within

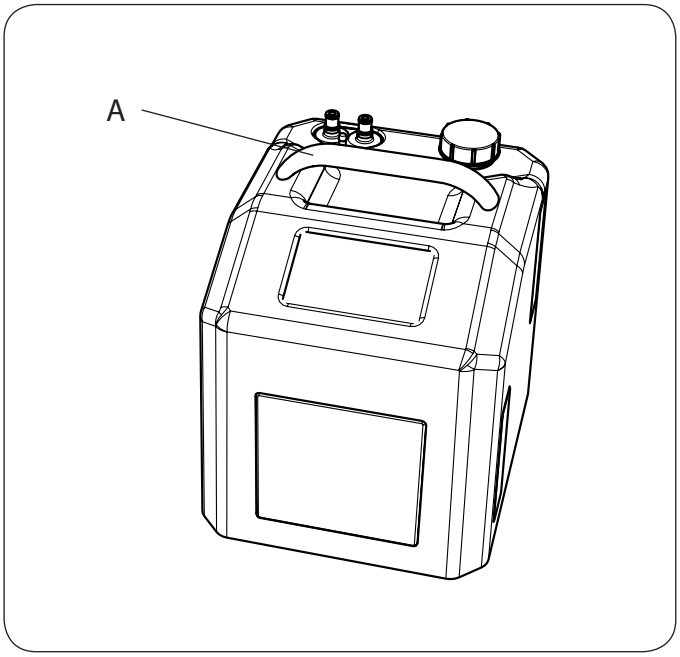
3 days from delivery, possible damages to the courier with a registered mail, return receipt requested, contextually showing documented photographic evidence. Send the same information to ZAMAR.

Information regarding damages during transport will not be considered after 3 days from delivery. After 10 days from delivery complaints will not be accepted. With respect to any dispute which may arise you consent to the jurisdiction of the court of Porec .

3.5 How to handle the unpacked unit

The machine, once unpacked, is always carried by handle (rif. A).

Pay attention: uncoordinated movements may result in imbalance and possible fall of the unit with damage to persons and properties.



3.6 Package dimensions

The packaging is made of double corrugated cardboard with double flaps on the bottom.
Dimensions of the box:
16 Inch x 12 Inch x 18 Inch height.

3.7 Packaging labels

On two sides of the package there are some very important identification labels to guarantee the integrity of the product and some indications useful for maintaining the best conditions of the device over time.

in the lower part of the package a label defines some indication of the conditions of TRANSPORT, STORAGE and USE


KEEP AWAY FROM SUNLIGHT


KEEP AWAY FROM WATER


FRAGILE


DO NOT ROW


THIS SIDE UP

4 INSTALLATION

4.1 General cautions

Place the unit in a stable and levelled ground. Always make sure that the unit's wheels are blocked before any use.

4.2 Initial cleaning

You should clean the unit before starting.

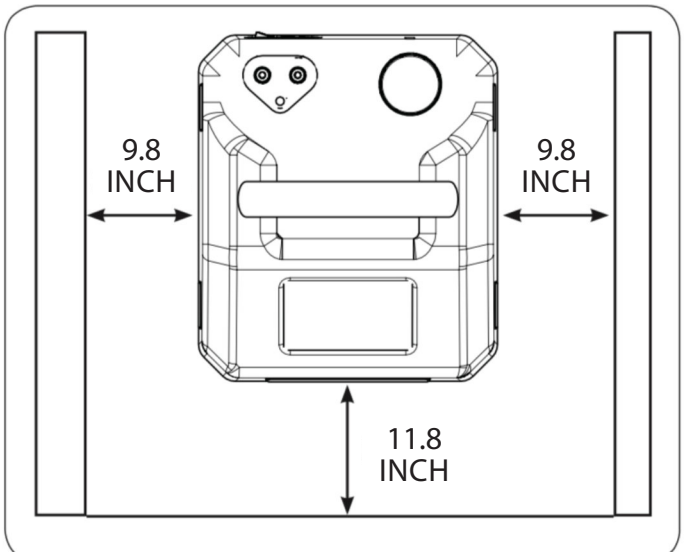
Clean the unit when the power cable is disconnected from mains only.

Clean the outer surfaces with a soft cloth moistened with lukewarm water containing neutral detergent only.

The screen panel should be cleaned with a soft and dry microfiber cloth.

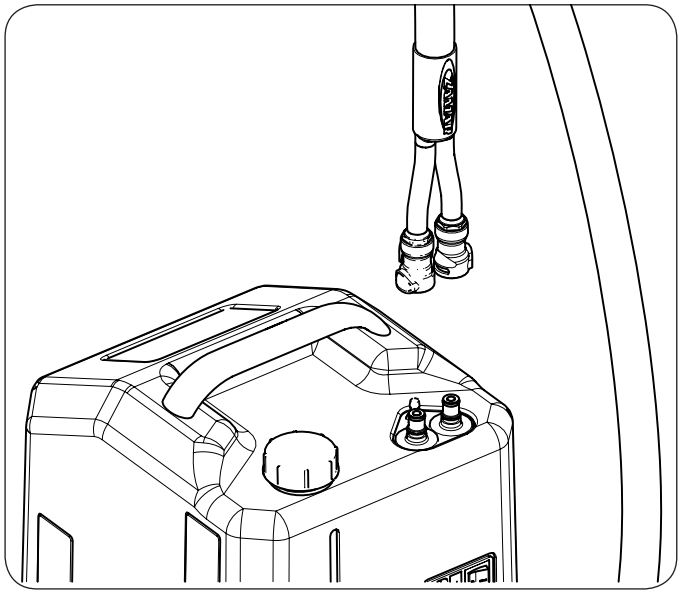
4.3 Space required to use the unit

Place the unit as to facilitate movements of the personnel of the unit itself; pay attention to the hoses connecting to the thermal wraps, you should not push them to let the coolant flow properly. The control and programming panel should be easily reachable and correctly visible.



4.4 How to connect hoses

Insert the hoses in the quick release connection in the unit's topside.



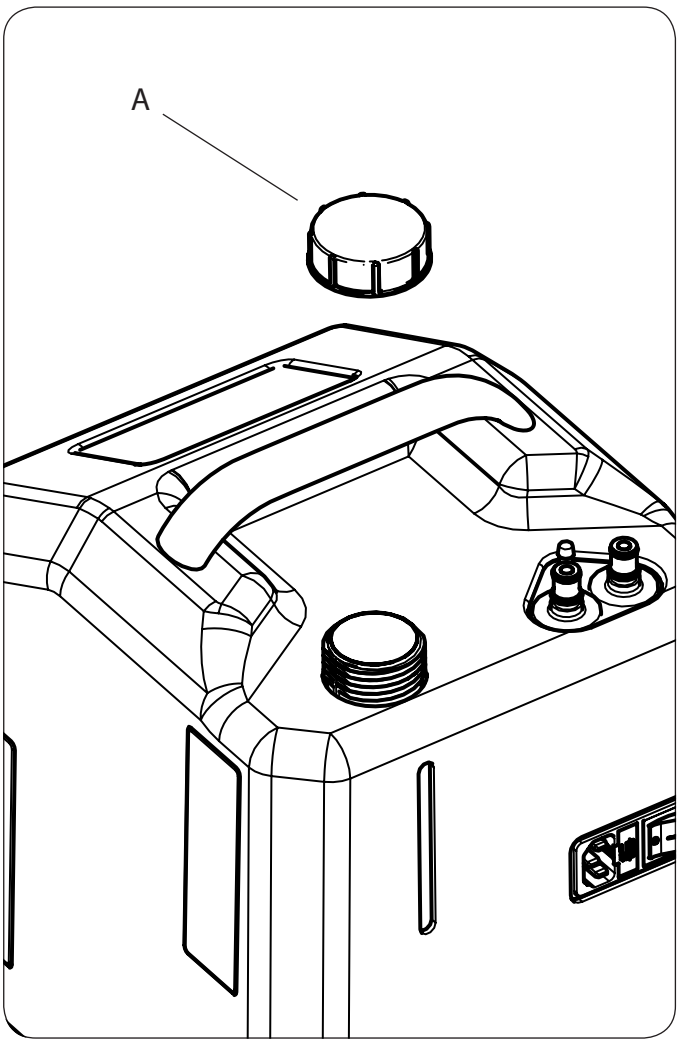
4.5 How to place hoses during transport

You can envelop the carrying handle with the hoses, after having removed them from the quick release connections.

Before moving the unit, unplug the hoses from the front quick release connections and the power plug from the wall socket.

4.6 How to supply coolant

The unit is endowed with a tank containing the coolant. You must open the cap (A) and add the extra coolant supplied with the unit (on-demand when finished) every time you see the alarm lack coolant.

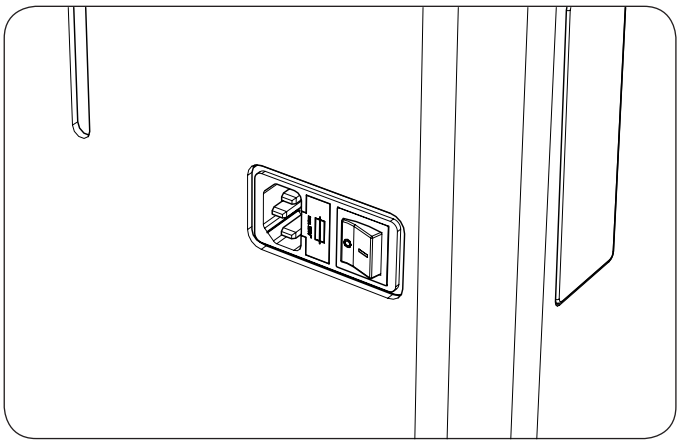


4.7 How to connect the unit to the mains

The unit is endowed with a plug that can be connected to the earthed power outlet (A).

Make sure the earthing system in the mains where the unit is installed is adequate.

Before connecting the device to the mains power supply it is necessary to verify that the main supply has the voltage and frequency which correspond to what is indicated on the rating plate of the device; then you can connect the harness to the switch on the rear of the device, then to the plug to the main power supply.



5 PREPARATION OF THE MACHINE

CONTRAINDICATIONS

The cold-hot treatment by Z-ONE device should not be applied on patients who:

• who are in the acute stages of inflammatory phlebitis in the concerned area

• who have previously suffered or are actually suffering for clinical signs which suggest deep vein thrombosis or pulmonary embolism in the concerned area.

• with significant arteriosclerosis or another ischemic vascular disease in the concerned area

• presenting a patolagia (eg carcinoma) for which it is not appropriate an increase of venous return or lymph in the affected part

• who have hypertonia in decompensated phase in the affected area

• with a significant vascular compromise in the concerned area(eg because of previous freezing, diabetes, arteriosclerosis, or arterial ischemia)

• with blood dyscrasias which influence the on-set of thrombosis (including, paroxysmal hemoglobinuria, cryoglobulinemia, sickle cell anemia, cold agglutinins in the serum).

WARNINGS

- incorrect positioning or prolonged use of the Zamar Medical system can cause tissue injury
- in the course of therapy, patients should be monitoring the skin around the treated area of the treated limb or fingers to detect possibly burning, itching, increased swelling, or pain. If these symptoms are present or if any alterations of superficial skin (such as blistering, redness, discoloration or other signs of change) patients are advised to discontinue use and consult a doctor
- the thermal wraps are available in various con figurations but are not intended for all possible orthopedic uses

For example, the Ankle Wrap is not intended to be used on the fingers and the Lumbar Wrap is not intended to be used the in abdominal region

- Thermic therapy should be used only under the control of an authorized physician operator:
  1) has a wound in the concerned area (the wound should be medicated before treatment with the device)
  2) presenting an acute fracture, unstable in the concerned area
  3) that are less than 18 years or who suffer from cognitive disabilities or barriers to communication, both temporary (due to drugs) and permanent
  4) who suffer from heart failure or congestive heart failure
  5) which have a localized skin condition (eg dermatitis, vein ligation, gangrene) in the concerned area
  6) suffering from erysipelas or other active infection in the affected region
  7) suffering from Raynaud's phenomenon or hypersensitivity to cold
  8) who suffer from hypertension or extreme hypotension
  9) who suffer from diabetes
  10) who suffer from impaired local circulation, or neurological impairment

  in the concerned area
  11) who suffer from rheumatoid arthritis in the concerned area.

PRECAUTIONS

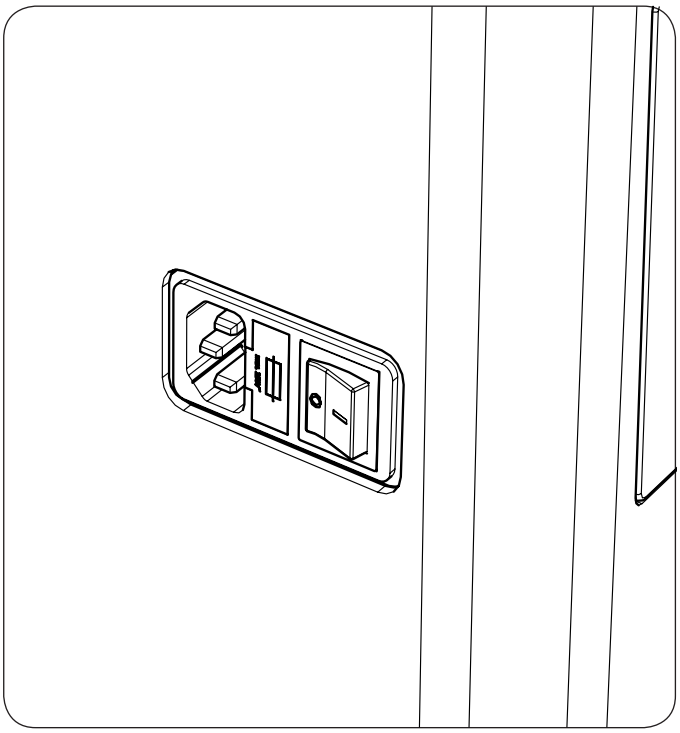
- to avoid the risk of electric shock do not remove any panel from the control unit. For any maintenance or repair, contact the Technical Assistance Zamar Medical d.o.o.
- to prevent electric shock, malfunction or product damage, never operate the device with cables and pipes and accessories mechanically damaged whose condition can jeopardize the correct operation of the machine
- fill the tank always and exclusively with Zamar Medical d.o.o. recommended product

English

- to avoid potential damages to the product, do not use thermal wraps of other brands with Zamar Medical System
- to avoid injury, be careful not to trip over power harness
- the Zamar Medical Device is Medical Technical device; to avoid damaging the product, treat it with care, do not drop, hit it or treat it with neglect.

5.1 General warnings

Place the unit on a stable and levelled ground. Always make sure you have blocked the unit's wheels before any use. Connect the hoses to the unit in the quick release connections on the unit's front; connect the power outlet (see par. 4.7) and supply power to the unit switching on position "I" (A).



5.1.1 Application thermal wraps

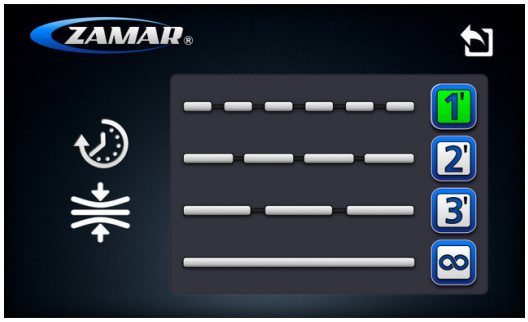
For application and connection of various thermal wraps it is necessary to check the use and maintenace of accessories reference code "0IST100".

5.2 How to programme

When the machine is turned on, the HOME PAGE screen appears. First on the left is the button used to select different settings AIR Compression function. On the right side is the selection of 2 programmable buttons, and in the middle 1 quick start functions.

5.2.1 Compression settings

By pressing this button  on the home page you can select AIR compression or parameters during the treatment. The buttons on the right indicate the compression time applied to the treated part from a minimum of 1'up to continuous compression.



5.2.2 Programming Buttons

1. The 2 programmable buttons contain the following parameters:
   A) Temperature
   B) Duration (hours)
   C) Duration (minutes)

2. The execution of each treatment occurs by pressing one of the 2 button

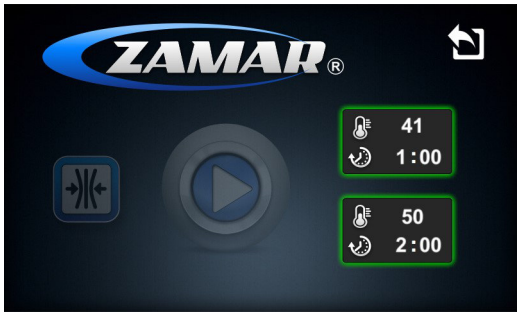
3. The default values inside the keys are all 0 (zero)

4. The programming of each button is done by pressing the edit key. 

5. After pressing the EDIT button, the system is in the programming mode of all the buttons.

From the HOME PAGE by clicking on the EDIT icon you can access the programming mode for all the buttons 

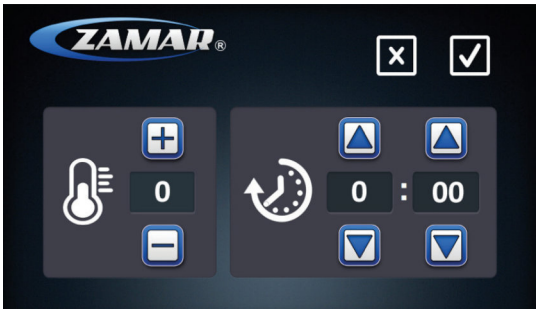
When the system flashes and now you can customize the therapies in each individual button.



By pressing any button, you will enter in the screen for programming the treatment parameters like temperature and duration of treatment.

To exit from the EDIT mode (button programming) and return to HOME PAGE you press the BACK icon 

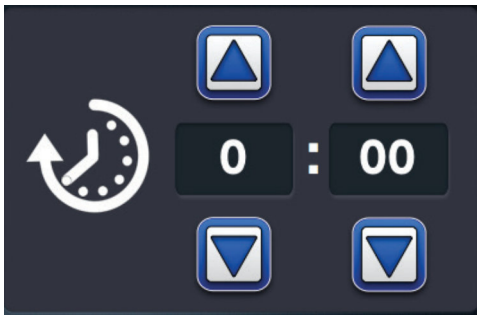
5.2.3 Parameters setting



Inside the parameters setting screen you can set the temperature by increasing or decresing with the ''+'' and ''-'' keys. The temperature setting can be set within a range of +41°F to +59°F.

English

The duration of treatment is defined by two parameters:
HOURS - duration time can be set with in a range from 0 to 9 hours.
MINUTES - duration time can be set within a range from 0 to 50 minutes.
The duration settings are performed by setting the "up" and"down"buttons above each treatment duration setting field.



The settings are then confirmed or cancelled using the buttons:

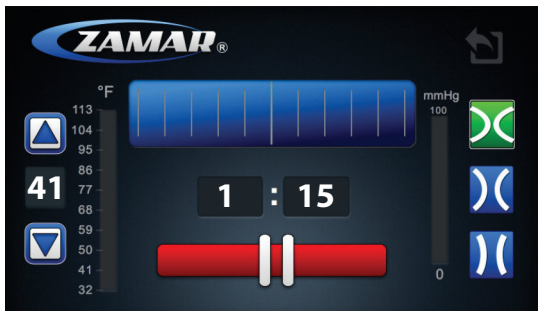
5.2.4 Start treatment

After the settings you can start the treatment by selecting the button or choose the Quick Button.

The button of the quick function is preset for start a COLD treatment.
When you select the quick function button, the temperature range is limited. Before starting the treatment, it is possible to change the temperature and the treatment duration.

The temperature value of the quick functions is the last used value. All the changes made after selecting the programmable buttons are temporary and will not be saved.

It is possible to change the temperature setting even after starting the treatment. Pressing the PLAY key will start the therapy.



When treatment is executed, the duration parameters starts to count down. The side graduated bar indicates the current temperature of the machine. The horizontal bar above the countdown timer indicates the progress of the treatment.

The treatment can be paused and resumed from the same point of progress.
There is a possibility to turn on the air compression function and choose 3 different levels of compression: MIN, MED, and HIGH.

Forced treatment exit is performed by selecting the BACK icon 

5.3 Alarms

5.3.1 Liquid level alarm

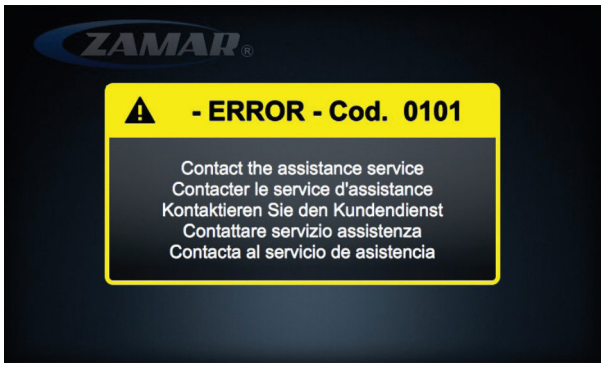
Liquid level alarm signals the lack of liquid inside the system.
The system remains locked until the user replenishes the tank with the "Zamar" liquid. Once the system is filled, it automatically resumes from where it left off.
The alarm can appear on any screen and within the execution of the treatment.

5.3.2 End of treatment alarm

The end of treatment alarm signals that the treatment performed has reached 0:00 on the countdown timer and the progress bar has reached the set time.
The alarm remains displayed until you press the BACK icon and then return to the HOME PAGE.

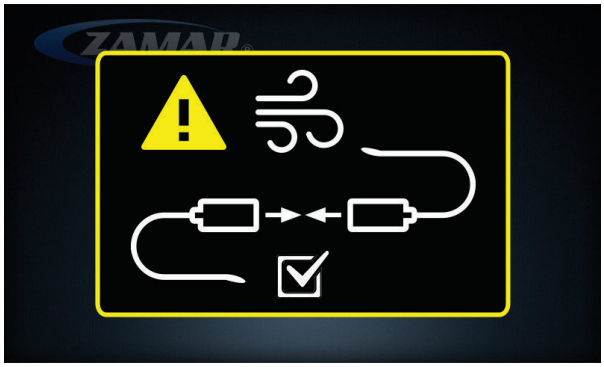
5.3.3 Fault alarm

Generic alarm caused by a system malfunction. The alarm signals that the user must contact technical assistance.



5.3.4 AIR connection alarm

This alarm appears when the AIR Tube is not connected. You have to check the connection to the machine and to the wrap. The device restarts the treatment only by touching the "V button" on this screen"



English

6 ACCESSORIES ON DEMAND

1. Linear pipe 1ACS423A
2. "V" shape pipe 1ACS424A
3. Thermal wraps (Check dedicate catalogue 0IST100 last rev.)

For mounting, ordinary maintenance and cleaning of Applied Parts an instruction dedicated reference code 0IST100 Rev.00 is supplied with all of Accessories on request .

N.B. all of our connections are equipped with a safety valve to prevent leakage of liquid.

7 MAINTENANCE

7.1 Routine maintenance

- Once a week check the integrity of the power harness and the connecting pipes to accessories, if you notice exposed parts or particularly damaged parts, replace the damaged harness / pipe with another provided and recommended by the manufacturer.
- Check every 15 days the liquid level of the circuit; Always top up with the original liquid ZAMAR NON-TOX (1 liter).
- Monthly clean with compressed air the left side grille air inlet; absolutely not wash with water or other cleaning liquids.
- Annually check the leakage current at a qualified laboratory or contact the manufacturer.

7.2 Special maintenance

- On an annual basis from the first operation you should contact your local dealer or distributor to arrange a complete maintenance service, necessary to maintain the efficiency of the device, during which in addition to the normal functioning checks from a mechanical point of view and simulations alarms, it is also important the check if necessary the calibration of the temperature probe with certified instrument to ensure the proper operation of the device.

8 TROUBLESHOOTING

ALARMS	FAULTS	SOLUTIONS
The unit does not power on	Lack of electric power	- Check the power supply connection - Check the fuse's conditions in the mains - Check the fuse's conditions in the switch at the unit's edge
Level alarm	Low glycol level in the tank	- Check the glycol level in the tank - If necessary, add liquid up to ¾ of the tank

8.1 Useful life

When properly used and maintained, the construction materials and components confer heat exchange equipment Z-ONE model MG455B has a significantly elevated useful life; by convention, it is assigned a theoretical deterioration of materials due to wear and established an average useful life of 5 years.

To applied parts (thermal wraps) it is given an average useful life of 1 year or 200 uses.
Sterile wraps are considered disposable.

8.2 Accident or Serious Anomaly of Device

Users must inform their competent authority about every accident or serious anomaly during device use.
For more information, check the last revision of MEDDEV 2.12-1

9 ELECTROMAGNETIC COMPATIBILITY

The medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the technical datasheet.

The portable and mobile communications equipment can affect the operation of the EUT.

The use of accessories, transducers and cables different than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in an increase in emissions and a decrease in immunity.

The equipment or system should not be used near or placed on top of other equipment and, if you must use it near or on other devices, the equipment or system should be checked to control the normal operation in the configuration in which it is used it.

This tool has been tested and found in compliance with the emission limits and immunity of the devices according to the standard electro-IEC60601-1-2: last re.. These limits are designed to ensure an adequate protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment, interacting with another device, cause or receive interference detected, the user is encouraged to limit the interference by one or more of the following measures:

- Reorient or relocate the receiving device (concerned);
- Increase the separation between the equipment;
- Connect the equipment into an outlet on a circuit different from device or devices that cause interference;
- Contact the manufacturer or local technical assistance for assistance.

9.1 Electromagnetic emission

<table>
<tr><th colspan="3">Manufacturer Guidelines and Declaration - Electromagnetic emission</th></tr>
<tr><td colspan="3">Z-ONE is rated to operate in electromagnetic environment under specified. The operator should guarantee that it is employed in this environment</td></tr>
<tr><td>Emission Test</td><td>Conformity</td><td>Electromagnetic Environment</td></tr>
<tr><td>RF CISPR 11 emission</td><td>Group 1</td><td rowspan="4">Z-ONE uses RF energy only for its internal operations. Consequently there are very low RF emission

Z-ONE is proper for using in all environment connected to a public net low tension which supplies domestic buildings.</td></tr>
<tr><td>CISPR 11 emission</td><td>Class B</td></tr>
<tr><td>Harmonic Emission IEC 610003-2</td><td>Class A</td></tr>
<tr><td>Floating of tension/tickeremission IEC 61000-3-3</td><td>Satisfying</td></tr>
</table>

9.2 Electromagnetic immunity

Manufacturer Guidelines and Declaration - Electromagnetic Immunity			
Z-ONE is rated to operate in electromagnetic environment under specified. The operator should guarantee that it is employed in this environment			
Immunity Test	Test Level IEC60601	Conformity Level	Electromagnetic Environment
Electrostatic Discharge	in contact +-6kV	in contact +-6kV	Floors should be in wood, concrete or in ceramic tiles. If floors are coated with synthetic material humidity should be at least equal to 30%
	in air +- 8kV	in air +- 8kV	
Electrical fast transient sequence IEC 61000-4-4	+-2kV for supply lines	+-2kV for supply lines	Line voltage quality should be similar of a typical commercial/ hospital environment
	+-1kV in/out lines	+-1kV in/out lines	
Overvoltage IEC 61000-4-4	+-1kV between phases	+-1kV between phases	Line voltage quality should be similar of a typical commercial/ hospital environment
	+-2kV between phases And earth	+-2kV between phases and earth	
Tension Leaks, short interruptions and voltage variations in the input supply line IEC 61000-4-11	<5% 230V (95% leak in 230V) 0,5 cycles	<5% 230V (z95% leak in 230V) 0,5 cycles	Line voltage quality should be similar of a typical commercial/ hospital environment. If operator must use device during voltage interruption It's recommended to support Z-ONE with group of continuity or batteries
	40% 230V (60% leak in 230V) 5 cycles	40% 230v (60% leak in 230v) 5 cycles	
	70% 230V (30%) leak in 230V) 25 cycles	70% 230V (30%) leak in	
	<5% 230V (95% leak in 230V)5 s	<5% 230V (95% leak in 230V) 5 s	
Magnetic field in high frequency (50/60Hz) IEC 61000-4-8	3A/m	3A/m	Magnetic field of net frequency should similar of a typical commercial/hospital environment

Electromagnetic Immunity

Manufacturer Guidelines and Declaration - Electromagnetic Immunity

Z-ONE is rated to operate in electromagnetic environment under specified. The operator should guarantee that it is employed in this environment

Immunity Test	Test Level IEC60601	Conformity Level	Electromagnetic Environment
			RF Comunication devices portable or not shouldn't be used near any part of Z-ONE, includes cable, under the recommended separation distance calculate as per equation applicable on transmitter frequency
Conducted RF IEC 61000-4-3	3Veff from 150 kHz to 80 MHz	3Veff	$d= 1.2\sqrt{P}$
Irradiate RF IEC 61000-4-3	3 V/m from 80 MHz to 2,5 GHz	3V/m	$d= 1.2\sqrt{P}$ from 80MHz to 800MHz $d= 2.3\sqrt{P}$ from 800 MHz to 2,5 GHz

P is max power transmitter output (watt W) according to manufacturer declaration and "d" is the recommended distance (meter m). The transmitter field strength with RF fixed determined by an evaluation in place(1) should be less than conformity level for each frequency range(2). Interference may occur near devices with this symbol:

NOTE 1: At 80MHz and 800MHz is applied separation distance for high frequency range

NOTE 2: These guide lines should be not applicable in all the situations. Electromagnetic propagation is influenced by absorption and reflection of structure, objects and people.

1. Field strength of fix transmitter, as base station for radiophones (mobile phones, cordless) and terrestrial radio base station, radio transmitter AM and FM, TV transmitter cannot be previous foreseen with precision. Evaluate an electronic magnetic environment caused by RF fix transmitter should be consider an electromagnetic investigation of site. If strength of field measured in place exceed from level of conformity declares above It should be put under observation the device functioning. If It notice abnormal performance change device's position could be necessary.
2. Field strength frequency range from 150kHz to 80 MHz should be less than 3 V/m

9.3 Recommended separation distances between the communications equipment portable and mobile and Z-ONE

Recommwnded separation distances between the communications equipment portable and mobile and Z-ONE

Z-ONE is rated to operate in electromagnetic environment under specified. The operator should guarantee that it is employed in this environment. Operators can prevent electromagnetic interference assuring a minimum distance from RF communication mobile/portable devices and Z-ONE in connection with output max power of radio communication devices.

Transmitter nominal output power (W)	Separation distance in relation with transmitter frequency (m)		
	from 150kHz to 80MHz d=1,2√P	**from 80MHz to 800MHz d=1,2√P**	**from 800MHz to 2,5GHz d=2,3√P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

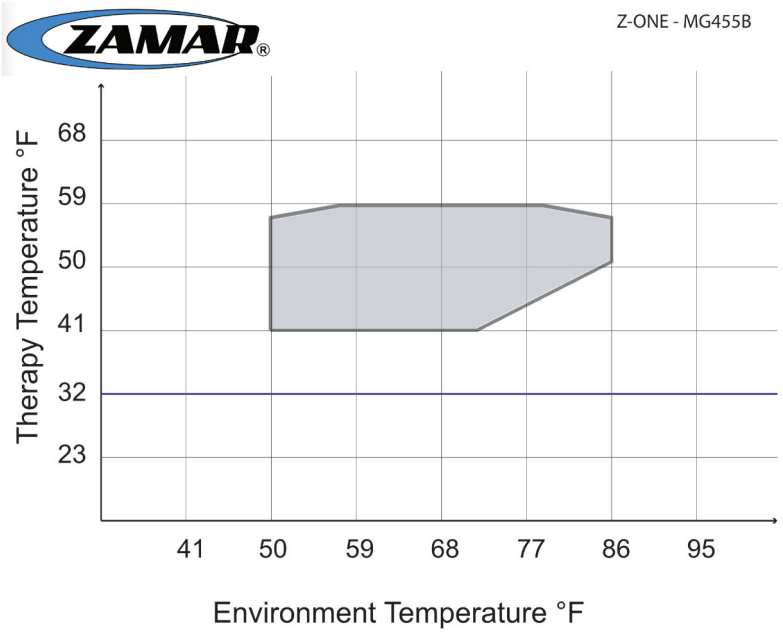
If max output power transmitter is not specified above the recommended distance d in meter (m) can be calculated using equation applicable on transmitter frequency, where P is transmitter max nominal output power in watt (W) according to transmitter manufacturer declaration.

NOTE 1: At 80MHz and 800MHz is applied separation distance for high frequency range

NOTE 2: These guide lines should be not applicable in all the situations. Electromagnetic propagation is influenced by absorption and reflection of structure, objects and people.

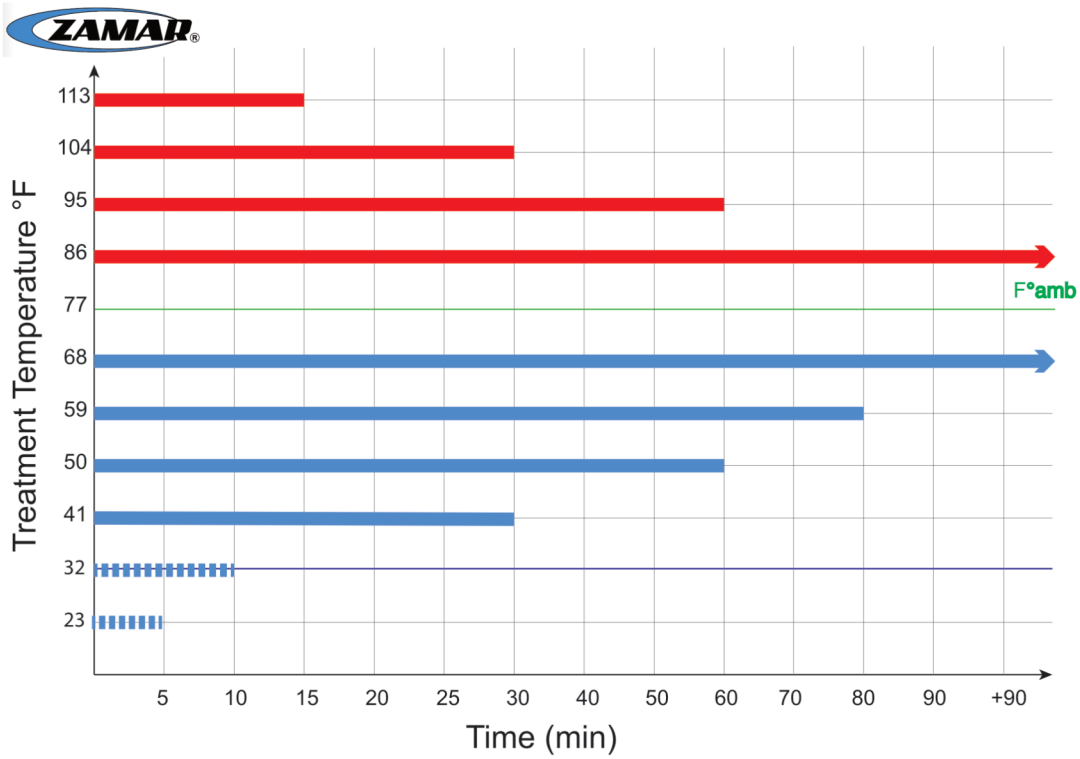
10 CONDITION OF USE

10.1 Condition of use/ Temp° Target example graph



The ambient temperature affects the performance of the device. ZAMAR suggests to remain in a range between 64°F and 75°F in order to make the most of the device.
The conditions may vary according to the applications and type of wraps used.

10.2 Temp° Target / Time Phase example graph



This graph is for indicative purposesonly. It wants to underline that alower temperature should correspond to a shorter time in phase. Theduration of the temperature phase dependson the part of the body to be treated, the physical stateof the patient and the type of treatment for which the ZAMAR unit is being used.