

1. Purpose

This document defines the operational procedures for performing **routine maintenance of ZAMAR devices**.

The objective is to ensure:

- correct device operation
- maintenance of thermal and compression performance
- safety for both patient and operator

All activities described are intended to be performed by qualified technical personnel without any internal intervention on the device.

Maintenance activities are to be carried out **based on device usage and operating conditions**, as defined in this document.

2. Scope

This manual applies to:

- all ZAMAR devices installed at end-user facilities
- maintenance activities performed by:
 - authorized distributors
 - trained technical personnel

This document does not cover corrective maintenance or internal repairs.

3. Maintenance Frequency

Routine maintenance is recommended based on device usage and operating conditions.

The frequency of maintenance should be determined by the distributor or technical personnel, taking into account:

- intensity and frequency of use
- number of patients treated
- operating environment
- usage of accessories (pads)

As a general reference, periodic maintenance is typically performed on a yearly basis, but more frequent checks may be appropriate in high-usage conditions.

Maintenance should also be carried out whenever a reduction in performance or abnormal behavior is observed.

4. Maintenance Activities

4.1 General Visual Inspection

The first step consists of a complete visual inspection of the device.

Check:

- integrity of the external structure

- absence of mechanical damage
- condition of the display and controls
- integrity of all connections (air and fluid)

This step allows early identification of visible issues that may affect performance or safety.

4.2 Device Cleaning

Cleaning must be performed on the external surfaces of the device.

Operations:

- use a soft, slightly damp cloth
- remove dust and residues
- clean ventilation grilles, including by vacuum if necessary

Avoid the use of aggressive chemicals or solvents.

Proper cleaning supports correct thermal dissipation and overall performance.

4.3 Fluid Circuit Check

The fluid circuit is essential for thermal performance.

Verify:

- correct fluid level
- absence of leaks
- proper fluid circulation during operation

Ensure that flow is continuous and stable.

Any irregularity (leakage or poor circulation) must be addressed before returning the device to service.

4.4 Thermal Performance Verification

The thermal performance test must be carried out under standard operating conditions.

Test setup

- connect **one pad only**
- start the device in cooling mode and then in heating mode

Parameters to verify

- **Cooling mode:** the device must reach approximately **the MIN Temp°** according to the device specs
- **Heating mode:** the device must reach approximately **the MAX Temp°** according to the device specs

Operational checks

- **Temperature reaching time**

The target temperature must be reached within **10 minutes**

- **Temperature stability**

Once the target temperature is reached, it must remain stable for at least **20 minutes**, without significant fluctuations.

This test confirms the system's ability to deliver consistent thermal energy.

4.5 Compression System Verification

The compression system must be tested using a properly connected pad.

Test setup

- connect one pad
- wrap the pad around a support, such as:
 - a bottle
 - a cylinder
 - a simulated limb

⚠ Never test the pad empty, as this may cause deformation or damage.

Functional test

Check the following pressure levels:

- 40 mmHg
- 60 mmHg
- 80 mmHg

During the test, verify that the pad:

- inflates correctly
- maintains pressure
- deflates properly

4.6 Accessories Check (Pads)

Pads are critical components and must be carefully inspected.

Check:

- material integrity
- absence of leaks
- condition of connectors

Service life

Pads are recommended to be replaced:

- after approximately 12 months of use, or
- after around 200 applications, whichever occurs first

Replacement intervals may vary depending on frequency of use, handling, and storage conditions.

Regular inspection of the pads is advised. If signs of wear, reduced performance, or damage are observed, replacement should be carried out accordingly.

Using worn pads may compromise performance and safety.

4.7 General Functional Verification

This step ensures correct overall device operation.

Check:

- **Power on/off:** the device starts without issues
- **User interface:**
 - buttons respond correctly
 - parameters can be adjusted
 - no freezes or malfunctions
- **Program management:**
 - correct parameter setting
 - correct saving of programs
 - correct recall of saved programs

4.8 Safety Alarm Verification

Alarm functionality must be tested with the device running.

Preparation

- ensure all connections are properly installed
- start a treatment

Test 1 – Air alarm (compression)

1. Disconnect the **air connector**
2. Activate compression

Expected result: alarm is triggered

Test 2 – Fluid Circuit Alarm

(available on devices manufactured from 2026 onwards)

1. With the treatment running, disconnect the fluid connectors
2. Wait approximately 30 seconds
3. Verify that the system detects the interruption and triggers the alarm

Expected result: alarm is triggered

Note – Fluid circuit alarm behavior

If a pad has not been used for an extended period, it may be partially or completely empty due to normal micro-evaporation within the closed circuit.

In this condition, the fluid circuit alarm may be triggered not because of incorrect connection, but due to the absence of fluid return from the pad.

In case of alarm:

- Always verify that the pad is properly filled
- Position the pad on a flat surface (e.g. table)
- Allow the system to refill the pad

If the pad is empty or partially filled, press the alarm pop-up to allow the system to continue operation until complete filling is achieved.

Once the pad is fully filled and normal fluid circulation is restored, the alarm should no longer occur.

Reset

After testing:

- reconnect all connectors
- verify that the device returns to normal operation

This procedure confirms correct operation of safety systems.

5. Maintenance Activity Table

Activity	Description	Result	Notes
Visual inspection	General integrity	☐	
Cleaning	Surfaces and ventilation	☐	
Fluid circuit	Level, leaks, circulation	☐	
Thermal performance	0°C / 45°C, timing and stability	☐	
Compression	40–60–80 mmHg test	☐	
Pads	Integrity and service life	☐	
General functions	Interface and programs	☐	
Alarms	Air and fluid alarms	☐	

6. Maintenance Record

- Date:
- Model: ZTCLINIC MED
- Serial Number:
- Technician:
- Signature:

7. Warnings

- Do not open the device
- Do not perform internal repairs
- Use only original ZAMAR accessories and fluids