lipo

Instructions for use

Z Lipo Med

zimmer

EN

Figure

Front of the device

Fig. 1

1 Display
2 Applicators

Figure

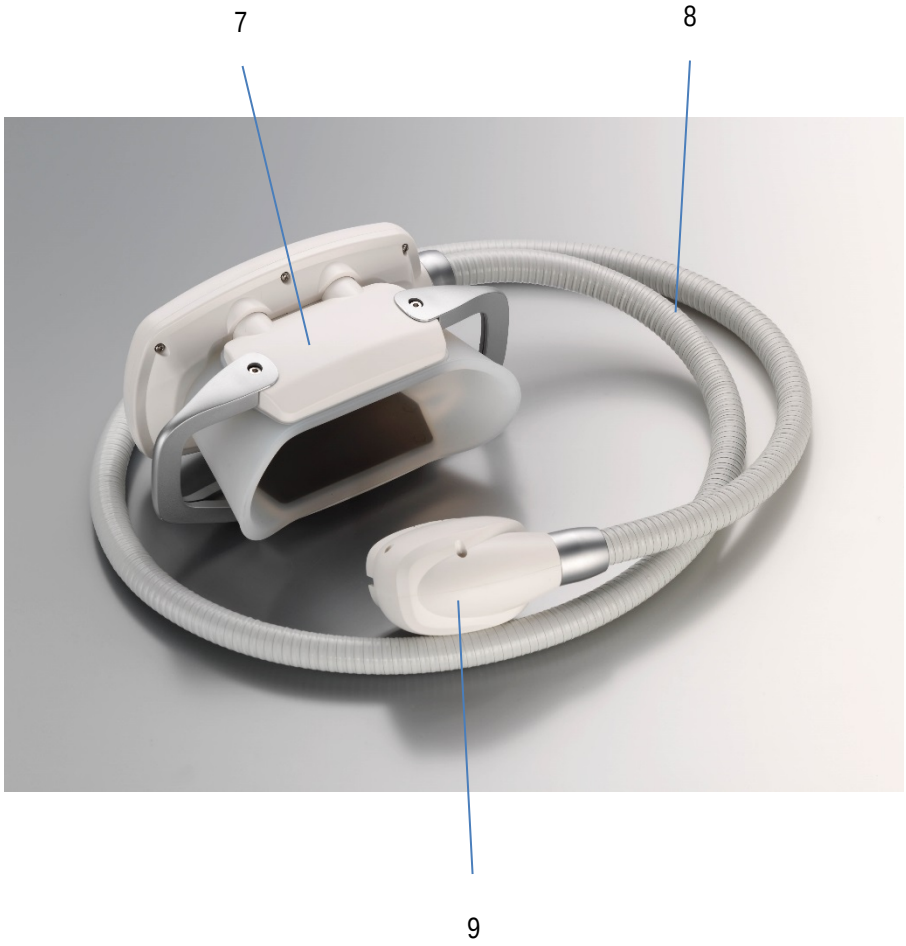
Rear of the device

3 Applicator connections
4 Door lock release
5 Fuses and test connection (earthing cable UL1015 16awg yellow green)
6 Power switch and socket for power cable

Figure

Rear of the device

Fig. 3



7 Applicator head
8 Applicator tube
9 Applicator connection

Fig. 4 Applicators available in 4 sizes

Explanation of symbols

In the instructions for use this symbol indicates “Danger”.

Caution!

In the instructions for use this symbol indicates “Caution” with regard to possible damage of the device.

Applied part type BF

Follow instructions for use.

Products marked with the adjacent symbol must not be disposed of with household waste.

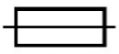
Serial number

Item number

Manufacturer

Date of manufacture

This symbol points out hazardous areas on the device.



Fuse specification

Content

Content

Applicable to the Z*Lipo*^{Med} device.

These instructions for use are an integral part of the device. They must be stored with the device and kept accessible at all times for anyone authorised to operate this device.

Last updated: September 2018

Indication / areas of application / contraindications

1

Indication	Male pseudogynaecomastia
Contraindications	Make sure that your patient visits his doctor before treatment. Treatment is not recommended in the following cases • Pregnant/breastfeeding women • Blood clotting disorders • Immune conditions • Cardiovascular conditions/heart failure • Liver conditions/liver failure • Kidney conditions/kidney failure • Patients with pacemakers • Severe cardiac dysrhythmias • Mental disorders • Unstable motivations • Large fat deposits • Obesity • Malignant tumours • Diabetes • Infection/eczema or acute inflammation in the treatment area • Hypertrophic scars in the treatment area • Regular consumption of anti-inflammatories or blood-thinning medication • Skin conditions in the treatment area • Erythema • Allergies to components of the cooling fleece • Area in which cryolipolysis treatment took place within the past 8 weeks

Side effects

The following side effects may occasionally occur:

- erythema
- swelling
- bruising
- local sensation of numbness
- tenseness
- hypercooling with skin burns
- allergy to cold
- vasoconstriction
- hypothermia

In very rare cases, paradoxical adipocyte hyperplasia has occurred after cryolipolysis treatment.

Application information

3

General instructions for use

Z*Lipo*^{Med} has been designed to comply with international safety standards.
Prior to using Z*Lipo*^{Med} on a patient, the user/technician should become familiar with the instructions for use and individual treatment methods to be used as well as the indications, areas of application / contraindications, warnings and application information. Additional sources of information about the treatment should also be followed.

The device may only be used by doctors with appropriate specialist knowledge of fat reduction. Make sure that all users are familiar with the use of the device and know how to switch off the device immediately in an emergency.

Caution! During use, the device is to be located in a position allowing direct access to the device´s central mains supply so that it can be disconnected from the mains at any time.

Access to the treatment room must be restricted to staff who have been instructed in the safety procedures.

Caution! Do not use the device if it has been dropped or exposed to other massive forces. Try to minimise shocks and vibrations.

Caution! Make sure that the handpieces do not come into contact with hard materials that could damage them.

Caution! Before use, ensure that the device is powered via a properly grounded mains socket (e.g. electrical installation according to DIN VDE 0100 Part 710). The device must only be operated with the supplied power cable. The power cable must be protected against mechanical stress.

Caution! Z*Lipo*^{Med} is not suitable for use in areas with an explosive, flammable or combustive atmosphere. Corrosive materials can damage the device. Dust and hairs should be minimised.

Caution! To avoid the risk of electric shock, the plug must be disconnected from the power supply before performing any cleaning or maintenance activities. Do not touch the plug with wet hands.

Caution! Only accessories provided by Zimmer MedizinSysteme GmbH may be used.

Caution! In order to ensure adequate ventilation, the device must be kept at least 0.5 metres away from other devices or walls.

Treatment with *ZLipo*^{Med}

Inspect the device before use. If there is any damage, it must not be used. Make sure that the inner and outer surfaces of the handpieces are clean, paying particular attention to the Peltier elements and the vacuum opening.

Clean and disinfect the handpieces before each treatment session.

The user can adapt the program settings to the patient's fat and skin condition. Auto mode is preset with proven parameters. However, the user can adjust the settings to the patient's condition.

Treatment results may vary.

The cooling fleece is essential and must be used at every treatment.
Always use a cooling fleece supplied by Zimmer MedizinSysteme GmbH, not only to improve efficacy but also to protect the treated area.

Caution!

Do not alter the temperature during treatment.

Warnings

4

ZLipo^{Med} is a cryolipolysis device for medical and aesthetic treatments. The device emits high levels of cooling energy than can damage the skin if used excessively.

All cooling devices can cause skin damage if incorrectly used. Be aware of the potential danger at all times and comply with the safety guidelines described in these instructions for use.

These instructions for use should always be kept with the device and users must know where they are.

Steps must be taken to ensure that the staff administering treatment are familiar with the operation of the device and are capable of switching it off in an emergency.

Changing the settings or using the device other than as described here can cause danger to the user and/or the patient.

The device must be switched off before inserting and removing the applicators. Do not touch the handpiece connections during operation.

The patient must not be left unattended during treatment.

Never leave the device switched on, open or unattended.

Use in wet areas is not permitted and may in case of non-compliance lead to considerable damage and endanger both the patient and the user. No components may be immersed directly in liquid.

The electromagnetic field may affect other devices and computers during treatment. For this reason, place the device at least 2 metres away from computers or other electrical devices.

The requirements set out in chapter 9 must be complied with in order to ensure proper care of the device during storage and transport as well as during use.

The device may only be transported while empty of water. This is to prevent the water freezing, which could damage the device.

A brief introduction to Z*Lipo*^{Med}

What is Z*Lipo*^{Med}?

A safe cryolipolysis device to reduce fat cells in the male torso.

As triglycerides in fat become solid at low temperatures, Z*Lipo*^{Med} uses advanced cryotechnology to selectively treat pockets of fat and so start to eliminate fat cells without damaging surrounding tissue.

Was does Z*Lipo*^{Med} do?

A non-invasive applicator is placed on the selected treatment area, draws energy from the underlying fat tissue while protecting the skin, nerves, muscles and other tissue. This process triggers apoptosis (controlled cell death) in the cooled fat cells, and the cells are gradually broken down within about 90 days by means of normal metabolisation.

What are the benefits of Z*Lipo*^{Med}?

Simultaneous use of two applicators cuts treatment times.
The use of applicators of different sizes allows efficient and effective treatment of parts of the body.
The modern colour display showing all treatment-related parameters and the modern touch operation ensure convenience during treatment.
Clear, simple menus offer the user maximum convenience.

Intended use

Z*Lipo*^{Med} is a medical device used to treat male pseudogynaecomastia.

Note:

The user should read these instructions for use carefully before using the device and become familiar with the safety and operating instructions it contains. Changes to the device or operation other than described here can cause risks to the user and/or patient.

Device set-up

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6.1 Site preparation

Note: *Do not expose the device to direct sunlight. Operate the device at room temperatures of between 10 and 26°C and air humidity of between 30 and 75%. Do not set the device up close to fan heaters or air conditioners.*

Note: *Make sure that the power switch of the device is set to "0".*

Site preparation

When setting up the device, the operator should take account of the spatial and electrical requirements and transport and storage conditions. The following requirements must be met before unpacking.

The premises must be supplied with adequate ventilation and a free flow of air. In order to ensure optimum ventilation, the housing sides should be at least 0.5 metres away from the wall or other elements that could block the flow of air.

The device can affect computers or other electrical or medical devices. A distance of at least 2 metres from such devices should be kept.

The device must be connected to a power outlet with a protective contact. The power supply data on the identification plate must be respected. The device should not share its power supply with high-draw devices such as air conditioners. Ideally it should be connected to a separate power supply with a separate protective switch.

The device must be operated in a corrosion-free atmosphere. Corrosive materials such as acids can damage the electrical wiring, electrical components and the surface of the treatment components.
Minimise dust and hair particles.

Do not place the device close to heaters or other devices that affect the temperature.

Safe operation depends on good condition.

Connect power cable

Connect the power cable to the provided port (6) on the device and connect the cable to the mains.

Note: *The device may only be connected to power outlets with a protective contact*

Note: *All cables must be protected from pinching or other mechanical damage.*

Connect applicators

Place the applicator in its mounting. Then connect it with the device by inserting the plug into the correct socket until you hear two clicks.

To remove the applicator, press the buttons on either side of the plug simultaneously.

Switch off the device and disconnect the power cable from the mains before changing handpieces.

Caution! Failure to connect the applicators with the device correctly can lead to water spillage.

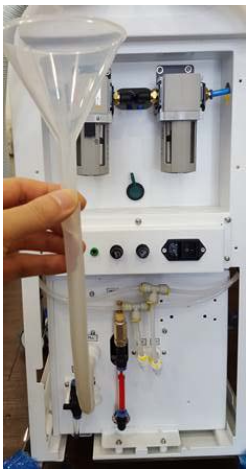
Fill with distilled water

Press the black slider to the right to open the doors on the rear of the device.
Open the filler neck by turning the white “Fill” cap a quarter-turn to the left and removing it.
Connect the filler tube to the filler neck and slowly pour in distilled water until the red marker is reached.

Caution! Only use distilled or deionised water, not tap water.

Caution! The water should be replaced every 3 months.

6.2 Starting up the device



Distilled water must run through the whole system when installing the device for the first time. Do this by starting up the device for 30 seconds (without selecting a treatment) and then fill up again to the red mark.

Caution! This procedure must be repeated for each handpiece when it is connected for the first time.

Switch device on

Switch on the device using the power switch (6).
Carry out a function test (see chapter 12).

Note:

You should always perform the following checks before using the device:

- *Are the housings and handpieces clean and disinfected?*
- *Are the device's castors securely placed on the floor?*
- *Is the power cable connected to an earthed socket?*

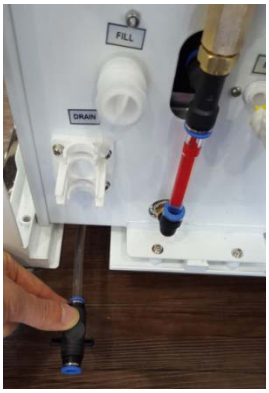
Note:

When starting up the device, the handpieces should be connected and in their mountings.

Switch device off

The device is switched off using the power switch (6).
To fully (all poles) disconnect the device from the mains, the power cable must be disconnected.

Caution! We recommend removing water from the device via the drain tap if the device is not being used for a prolonged period or is exposed to lower temperatures (e.g. in transit).

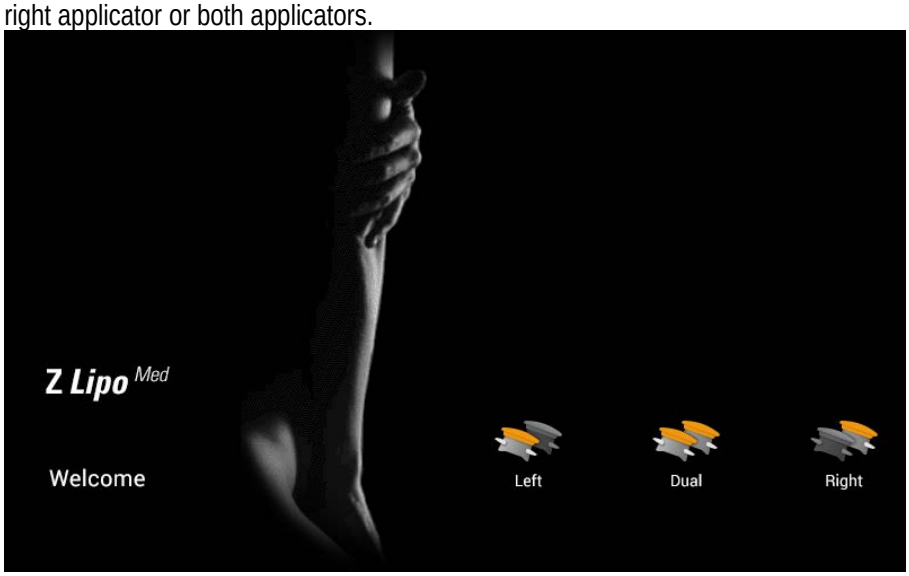


Start-up screen
Self-test

Z*Lipo*^{Med} carries out a self-test after it has been switched on. The current status of pre-cooling can be read off during the test.

Applicator selection

Once precooling has been completed, the user can select the left applicator, the right applicator or both applicators.

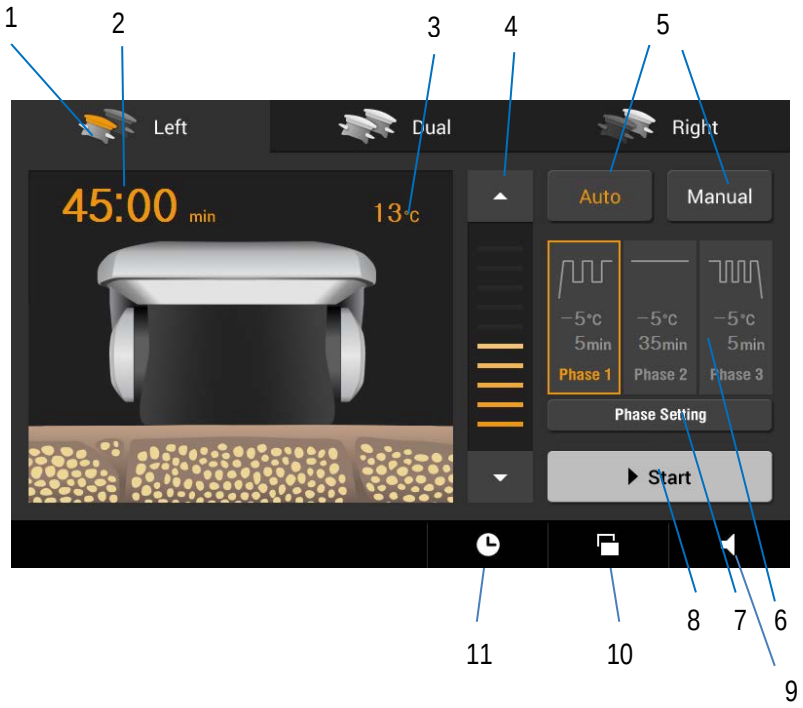


Note: *Depending on the area to be treated, treatment can be carried out with just one applicator (left or right) or with both applicators at the same time.*

Note: *The program settings and changing the settings are the same for each of the 3 possible selections. Consequently, the section below describes the individual steps only for treatment with the left applicator.*

The selected applicator (left, right or both) is shown in orange.

Program screen (in auto mode)

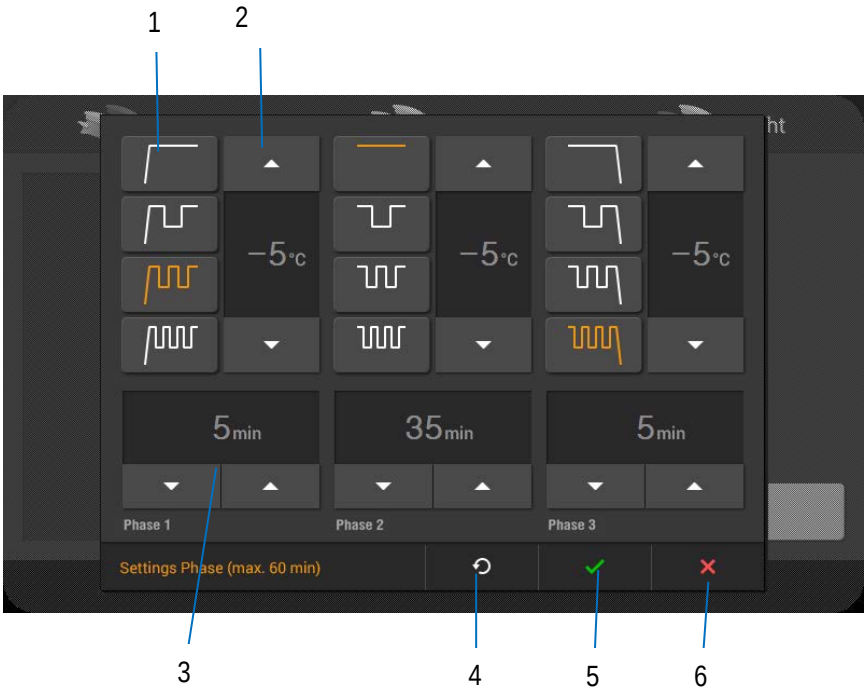


(1) Selected applicator	The selected applicator (left, right or both) is shown in orange. Press the corresponding button to switch applicator.
(2) Treatment time	The remaining treatment time is displayed.
(3) Temperature	The temperature in the applicator is displayed.
(4) Vacuum intensity	The vacuum intensity is displayed. Press the arrows to increase or decrease the vacuum. Vacuum intensity: 1 – 10. The intensity is preset at 5.
(5) Operating mode	Press the corresponding button to select the operating mode (auto or manual), which is then displayed in orange.
(6) Program	Program sequences are displayed.
(7) Phase setting	Menu selection to change program sequences.
(8) Start of treatment	Press the start button to start treatment.
(9) Sounds	Switches signal sounds on and off by pressing a button.
(10) Background colour	Changes the display background colour from dark to light and vice versa. The device is automatically switched off and back on when this is done.
(11) Reset treatment time	Pressing the reset button sets the treatment time back to the beginning.

Phase setting (in auto mode)

Pressing the phase setting button opens the selection window in which phases can be defined.
The settings defined during the previous session are displayed.

The process of constructing and setting the first phase is explained below.
The other two phases are constructed in a similar way.



(1) Pulse mode

The vacuum can be selected as unpulsed or at 3 different pulse rates.
The pulse rate selected is shown in orange.

(2) Temperature

The temperature emitted by the applicator can be set to between -10°C and 5°C.
Press the arrows to increase or decrease the temperature.

(3) Treatment time

Press the arrows to set the treatment time.

Note:

The maximum treatment time is 60 minutes. This takes account of the treatment times of the individual phases.

(4) Reset

Press the button to reject the parameters selected. The preset values are then displayed.

(5) Save

The parameters selected are accepted for the treatment.

Note:

The parameters selected that have been saved are retained after the current treatment session. The parameters used in the previous session are automatically loaded when the device is switched on again.

(6) Cancel

The menu is exited without saving.

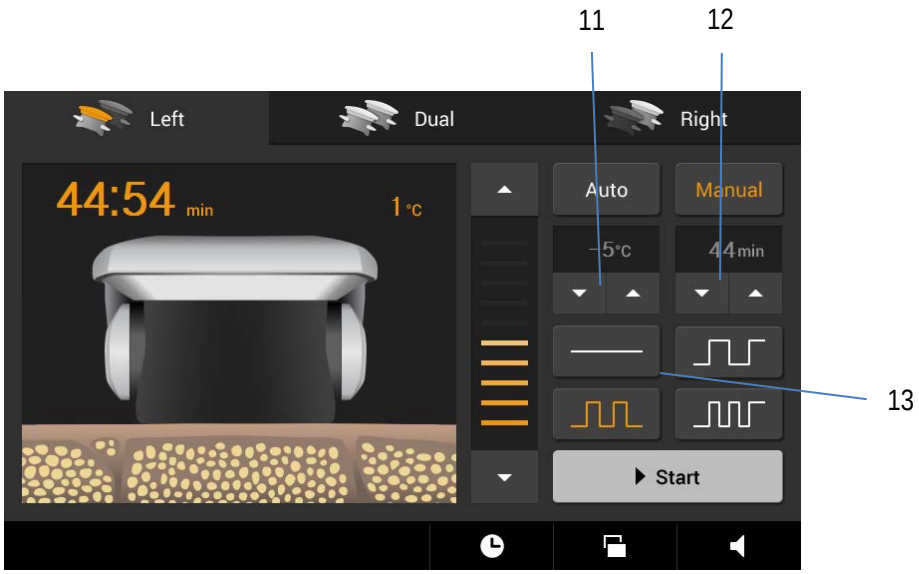
Program screen

1 2 3 4 5

(in manual mode)

(1) Selected applicator	The selected applicator (left, right or both) is shown in orange. Press the corresponding button to switch applicator.
(2) Treatment time	The remaining treatment time is displayed
(3) Temperature	The temperature in the applicator is displayed
(4) Vacuum intensity	The vacuum intensity is displayed. Press the arrows to increase or decrease the vacuum. Vacuum intensity: 1 – 10. The intensity is preset at 5.
(5) Operating mode	Press the corresponding button to select the operating mode (auto or manual), which is then displayed in orange.
(6) Parameters	The parameters are displayed
(7) Start of treatment	Press the start button to start treatment.
(8) Sounds	Switches signal sounds on and off by pressing a button
(9) Background colour	Changes the display background colour from dark to light and vice versa
(10) Reset therapy time	Pressing the reset button sets the treatment time back to the beginning.

Setting parameters (in manual mode)



(11) Temperature — The temperature emitted by the applicator can be set to between -10°C and 5°C. Press the arrows to increase or decrease the temperature.

(12) Treatment time — Press the arrows to set the treatment time.

Note: — *The maximum treatment time is 60 minutes.*

(13) Pulse mode — The vacuum can be selected as unpulsed or at 3 different pulse rates. The pulse rate selected is shown in orange.

Note: *The following recommendations are only guidelines and must of course be adapted to the patient's individual situation.*

Note: *Restrict access to the treatment room to staff who have been instructed.*

Note: *Always use the cooling fleece during treatment to protect the area being treated and to increase efficacy.*

Note: *Always clean and disinfect the handpieces before each treatment session.*

Treatment

The tissue in the area to be treated should be softened before treatment. This can be done by massage or a warm cloth.
Put the cooling fleece on the area to be treated and place the applicator on top.
Make sure that there are no air pockets between the skin and the cooling fleece.
Use all the gel in the cooling fleece pack.
Once you are certain that the applicator is correctly positioned and the patient is lying in a comfortable position, start the application (via the start button on the screen or the start button on the actual applicator).

The patient must not be left unattended during operation. He should be asked how he is feeling at regular intervals (at least every 15 minutes).
Please monitor the temperature on the screen for 2-3 minutes until the ideal temperature has been reached.
If the ideal temperature does not remain steady, please stop the treatment and call the service technician.

If the tissue is too firm to be sucked in sufficiently, you may need to increase the vacuum.

Please do not alter the temperature during treatment.

Note: *The cooling fleece is a disposable item and must not be used more than once.*
If the applicator needs to be repositioned during application, a new cooling fleece must be used.
The cooling fleece "mini" has to be used only with the mini applicator.

Operation with two applicators at the same time

If two applicators are being used at the same time, select the medium or small applicator size.

Basic device power supply	220 - 240 Vac, 50 Hz
Fuse	2xT10AH, 250 V and 16 A automatic fuse in power switch
Power consumption	1200 VA
Protection class	I
IP class	IPX0 (device, applicator)
Vacuum	max. 693 hPa (520 mmHg)
Intensity levels	Intensities 1-10, 4 different pulse modes
Maximum cooling temperature on applied component	-10 °C ± 5 °C
Dimensions	W 665 mm / D 629 mm / H 1082 mm
Weight	approx. 84 kg (with handpieces)
Operation	10 to 26 °C, 30 % to 75 % relative humidity, without condensation at 700 to 1060 hPa
Storage / transport (without filled water)	-10 to 50 °C, 10 % to 90 % relative humidity, without condensation at 500 to 1060 hPa
Applicators Dimensions	Medium-sized handpiece W 108 mm / D 188 mm / H 138 mm Large handpiece (optional) W 118 mm / D 220 mm / H 142 mm Small handpiece (optional) W 108 mm / D 172 mm / H 120 mm Mini handpiece (optional) W 64 mm / D 113 mm / H 99 mm
Applied part	BF type, applicator with cooling fleece
Filling medium	Distilled water max. 1.8 litres

Note:

Storage and transport only in original packaging. Store the device in an environment free from corrosive substances such as salts or acids. Protect the device from dust when in store.
Minimise shocks and vibrations. Do not drop the device.
Always use suitable equipment when lifting.

Subject to technical changes!

Cleaning Disinfection

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Note: *Always keep the device and handpieces clean in order to achieve optimum results.*

Before starting any maintenance and cleaning measures the device must always be switched off at the main switch and the mains cable must be disconnected.
Cleaning the device while it is in operation can be dangerous for the user and/or the device.

Neither the device nor the handpieces may be immersed in liquid.

Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.
If during cleaning or disinfecting liquid penetrates the device, please put the device out of service, protect it from being used again and contact your service representative.

Make sure that when cleaning and disinfecting the labelling of the device (such as warnings, labels of control devices, identification plate) is not damaged.

Note: *If 70% isopropyl alcohol is used for cleaning, the device must be completely dry before being used.*

The device and its applied part are considered as uncritical in relation to hygiene when used on non-injured and healthy skin.

Applicators

Use a soft cloth for cleaning and disinfection.
The inner surfaces of the applicator must be cleaned with a damp cloth after each use.

Housing/cables

In the event of visible contamination, the housing and all cables can be cleaned using commercially available alcohol-free plastic cleaners. Wipe the surface until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

Housing and all cables can be disinfected using disinfectant wipes. Use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the instructions for use of the respective manufacturer. Wipe all surfaces using a soft cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloths pre-impregnated with disinfectant (wipes).

Also observe requirements for drying or post-cleaning, where applicable.

LCD touch screen

The LCD screen should be cleaned with a cleaning solution for LCD screens and a microfibre cloth. If the screen is dirty, do not apply force to try to clean it.

Note: *Use the device only in a hygienic environment.*

CE mark and manufacturer

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The Z*Lipo*^{Med} device bears the CE mark

CE 0123

in accordance with the EC directive on medical devices 93/42/EEC.

Manufacturer

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Tel. +49 731 / 9761-0
Fax +49 731 / 9761-118
info@zimmer.de
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Scope of delivery and accessories

Scope of delivery

Item no.		
5192	1	Z*Lipo*^{Med} incl. filler tube
58000410	2	applicators, medium size
58000500	20	cooling fleeces
117	1	power cable
10102665	1	instructions for use

Accessories

Item no.		
58000400	1	applicator, small size
58000410	1	applicator, medium size
58000420	1	applicator, large size
58000559	1	applicator, mini size
58000510	1	pack of 25 cooling fleeces
58000560	1	pack of 50 cooling fleeces “mini”

Device combinations

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The manufacturer has not specified any combination devices for the Z*Lipo*^{Med} device.

Anyone who combines devices against these guidelines and thus creates a medical system does so under his/her own responsibility.

This chapter describes general safety rules for the use of Z*Lipo*^{Med}, focusing in particular on low-temperature and electrical safety. Suitably qualified users can operate the device safely if it is correctly used and maintained. All staff who work with or maintain the device must be familiar with the safety rules set out in the instructions for use.
The safety of the person receiving treatment, the user and other staff have top priority. The safety of the person receiving treatment is guaranteed primarily by well-trained staff and a properly equipped treatment room. It is important that information be provided to the person receiving treatment, and this must also include the nature of the treatment.

Z*Lipo*^{Med} generates high voltages. Some components can discharge energy when the device is switched off. For this reason, no parts of the housing may be removed. Removing the housing can be dangerous.
Make sure that you always switch off the device before connecting or disconnecting a handpiece.
Never use the device in the presence of flammable or combustible materials.
Water and electricity are a hazardous combination. Do not use Z*Lipo*^{Med} in a wet environment. Do not immerse any components directly in liquid.
The use of third-party cables and accessories can lead to increased emissions or a reduction in safety. Third-party accessories must not be connected to the device.
Do not use damaged cables.

As the manufacturer, Zimmer MedizinSysteme GmbH can only consider itself to be responsible for the safety and reliability of the device if

- the device is operated using a proper power outlet with earth contact and the electrical installation complies with DIN VDE 0100 part 710,
- the equipment is operated in accordance with the instructions for use,
- extensions, readjustments or modifications are carried out only by persons authorised by Zimmer MedizinSysteme,
- the user has confirmed the functional safety and the proper operating condition of the device before use,
- the device is operated only by properly trained personnel
- the device is not operated in hazardous areas and / or a combustive atmosphere,
- the device is immediately disconnected from the mains when penetrated by liquid.

The device does not contain any parts that can be repaired by the operator.

Air filters

Both air filters should be checked once a month and cleaned if dirty.

Press the black slider on the door to the right to open the doors on the rear of the device.

To release the air filter, push down the black slider on the filter and turn the air filter to the left in the direction of the opened lock. Then pull the air filter down and away. Use a mild soap solution to clean the air filter, and dry it afterwards.
Then replace the air filter and turn it to the right in the direction of the closed lock.

Functional test

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A function test should be carried out if you have any doubts about whether the device is functional.

Note: *Check whether the applicators are correctly connected to the device before carrying out the function test.*
Check whether the power cable is correctly connected to the device and live.

Functional test

Switch device on.

Select an applicator that is connected to the device.
Press the start button on the screen.
The LEDs on the applicator turn blue and cooling starts.
The animation on the screen starts, and the time starts to count down.

Note: *Switch off ZLipo^{Med} after the functional test has been completed.*

If the device is to be used immediately afterwards, adjust the desired treatment parameters and proceed as described in chapter 7.

Error message Water level low

first warning

If this symbol appears on the left-hand side of the bottom screen bar, the water level in the device is getting low. Please top up with distilled or deionised water as described in chapter 5.

second warning

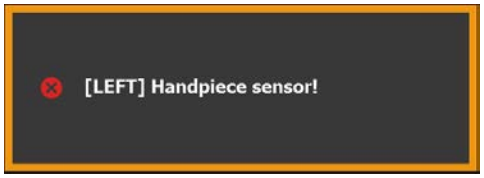
This symbol appears after 24 operating hours if the device has not been topped up with water after the first warning. Please top up with distilled or deionised water as described in chapter 5.

The device can no longer be used safely if it contains less than 900 ml of water, and the error message displayed appears. Please top up with distilled or deionised water as described in chapter 5.

Error message Handpiece not connected

Handpiece not (or not correctly) connected.
Check whether the handpiece is correctly connected. The plug must be fully inserted (this is indicated audibly by two clicks).

Error message Handpiece sensor



The temperature sensor of the handpiece is no longer working properly. Please replace the handpiece.

If two handpieces are being used to administer treatment, the user can continue to administer treatment using the intact handpiece.

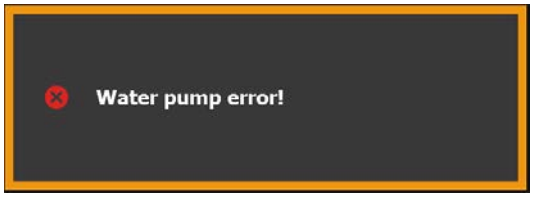
Error message Handpiece temperature

The temperature in the handpiece is not properly regulated. Please replace the handpiece.

If two handpieces are being used to administer treatment, the user can continue to administer treatment using the intact handpiece.

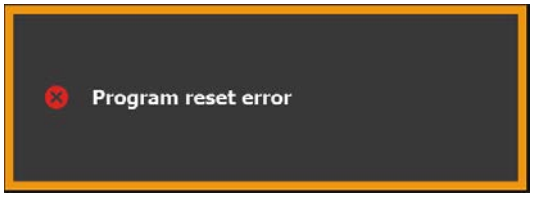
Error code (left/right):
0: normal
1: Error

Error message Water pump



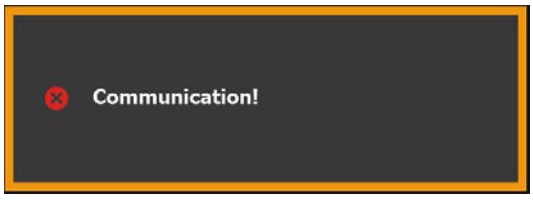
The water pump is not working properly.
Please contact customer service.

Error message Program Reset



The device is not working properly and must be switched off. If the error message appears again after the device has been switched back on, please contact customer service.

Error message Communication



There is a communication error between the CPU and the LCD.
Please contact customer service.

Customer service

It is essential that you notify technical support / customer service of any problems that occur frequently or cannot be resolved.
You may get in touch with them via your sales representative or via the main office in Neu-Ulm.

Main office

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm
Tel. +49 731 / 9761-0
Fax +49 731 / 9761-118
info@zimmer.de
www.zimmer.de

Disposal

The device may only be returned to the factory in its original packaging. It must be disposed of by the factory in Neu-Ulm.
In foreign (European) countries please refer to national regulations for disposal. Contact your distributor if necessary.

Legal notice

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The Z*LipoMed* device is not listed in annex 1 of the MPBetreibV (German Medical Devices Operation Ordinance).

The device is not listed in annex 2 of the MPBetreibV (German Medical Devices Operation Ordinance).

In Germany, the German Social Accident Insurance (DGUV) (Regulation 3 – Electrical systems and equipment), as amended, must also be observed.

Note: *This information applies to the operation of the unit in Germany. Please consider divergent national regulations in your country, if applicable.*

Medical electrical devices, such as Z*Lipo*^{Med}, are subject to special precautionary measures with regard to EMC (electromagnetic compatibility) and must be installed and put into operation according to the EMC information in the instructions for use or accompanying documentation.

Portable and mobile HF communication devices (such as mobile phones, cell phones) can affect medical electrical devices.

Z*Lipo*^{Med} may only be operated with the original power cable indicated in the list of the scope of delivery and accessories.
Operation of the device with a different power cable can lead to increased emissions or reduced interference immunity of the device!

<table>
<tr><td colspan="3">Guidelines and manufacturer's declaration – Electromagnetic emissions</td></tr>
<tr><td colspan="3">The ZLipo^{Med} device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the ZLipo^{Med} should ensure that it is operated in such an environment.</td></tr>
<tr><td>Interference emission measurements</td><td>Compliance</td><td>Electromagnetic environment - Guideline</td></tr>
<tr><td>HF emissions according to CISPR 11</td><td>Group 1</td><td>The ZLipo^{Med} device uses HF energy only for its internal functioning. This means that its HF emissions are very low, and it is very unlikely that adjacent electronic devices would suffer interference.</td></tr>
<tr><td>HF emissions according to CISPR 11</td><td>Class A</td><td rowspan="3">The ZLipo^{Med} device is suitable for use in facilities other than those in a residential area, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes, subject to compliance with the following warning.
Warning:
This device is intended to be used exclusively by medical professionals. This is a class A device according to CISPR 11. This device can cause malfunctions in residential premises, and consequently in that case it may be necessary to adopt suitable remedies such as reinstallation, rearrangement or protection of the device or filtering the connection to the site.</td></tr>
<tr><td>Harmonic emissions according to IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flickers according to IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Z*Lipo*^{Med} device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the Z*Lipo*^{Med} device should ensure that it is used in such an environment.			
Immunity tests	IEC 60601- test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must be at least 30%.
Rapid transient electrical disturbances/bursts according to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	± 2 kV for power cables	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11.	<5% U_T (>95% dip in the U_T for ½ cycle) 40 % U_T (60 % dip in the U_T for 5 cycles) 70 % U_T (30 % dip in the U_T for 25 cycles) <5% U_T (>95 % dip in the U_T for 5 seconds)	<5% U_T (>95% dip in the U_T for ½ cycle) 40 % U_T (60 % dip in the U_T for 5 cycles) 70 % U_T (30 % dip in the U_T for 25 cycles) <5% U_T (>95 % dip in the U_T for 5 seconds)	The quality of the supply should correspond to that of a typical business or hospital environment. If the user of the *ZLipo*^{Med} requires continued function even if interruptions in the power supply occur, it is recommended to power *ZLipo*^{Med} from an uninterruptible power supply or a battery.
Magnetic field at power supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in a business or hospital environment.
Note: U_T is the a.c. supply voltage prior to application of the test level.			

Key performance features of the Z*Lipo*^{Med} are: smooth operation of all functions. Uninterruptible operation is not necessary to the intended use.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Z*Lipo*^{Med} device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the Z*Lipo*^{Med} device should ensure that it is used in such an environment.			
Immunity tests	IEC 60601- test level	Compliance level	Electromagnetic environment - Guidelines
Conducted HF disturbances according to IEC 61000-4-6 Radiated HF disturbances according to IEC 61000-4-3	3 $V_{Effective\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 $V_{Effective\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile radio equipment should not be used at a distance away from the Z*Lipo*^{Med}, including the cables, that is less than the recommended safety distance which is calculated according to the equation applicable to the transmission frequency. Recommended safety distance: d= 1.2 √P d= 0.35 √P for 80 MHz to 800 MHz d= 0.7 √P for 800 MHz to 2.5 GHz with P as the rated output of the transmitter in watts (w) according to the information of the manufacturer of the transmitter and d as the recommended safety distance in meters (m). At all frequencies, the field strength of stationary radio transmitter should be less than the compliance level[b] according to on-site testing[a]. In the environment of devices which bear the following symbols, interferences are possible: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.			

[a] The field strength of stationary transmitters, such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with regard to the stationary transmitters, an electromagnetic site survey is to be recommended. If the measured field strength in the location in which the Z*LipoMed* device is used exceeds the above compliance level, the *ZLipoMed* device must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *ZLipoMed* device.

[b] Above a frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended safety distances between portable and mobile HF telecommunication devices and the Z*LipoMed* device.

The *ZLipoMed* device is intended to be operated in an electromagnetic environment in which the HF disturbances are controlled. The customer or user of the *ZLipoMed* device can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication devices (transmitters) and the *ZLipoMed* device – depending on the output power of the communication device as indicated below.

Rated output of the transmitter W	Safety distance depending on the transmission frequency m		
	150 kHz to 80 MHz d= (3.5/V1) √P	80 MHz to 800 MHz d= (0.35/E1) √P	800 MHz to 2.5 GHz d= (7/E1)√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters whose maximum rated output is not listed in the table above, the recommended safety distance d in metres (m) can be determined using the equation applicable to the respective column, where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.

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Instructions for use

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