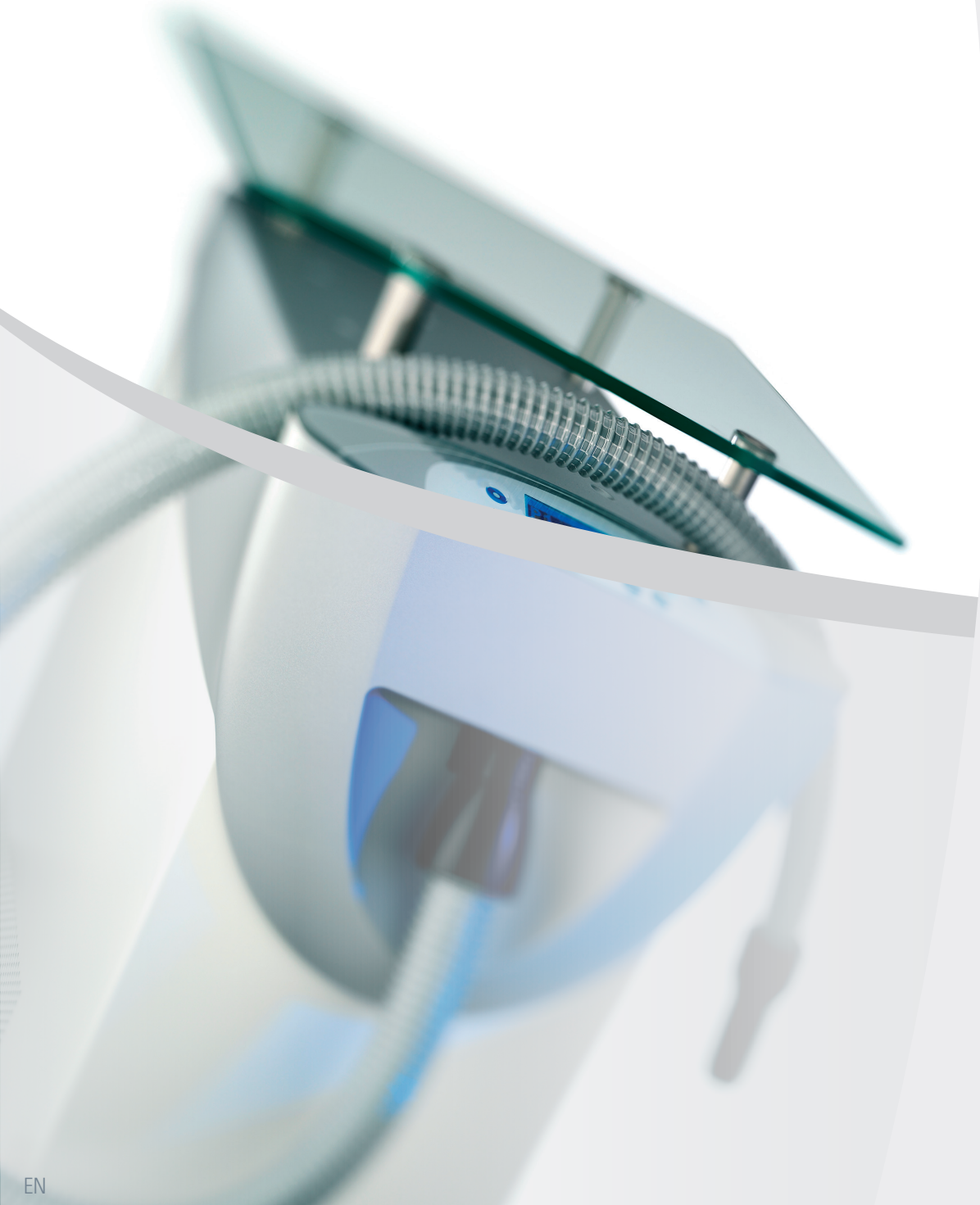
Zimmer
MedizinSysteme

Instructions for Use

Cryo 6

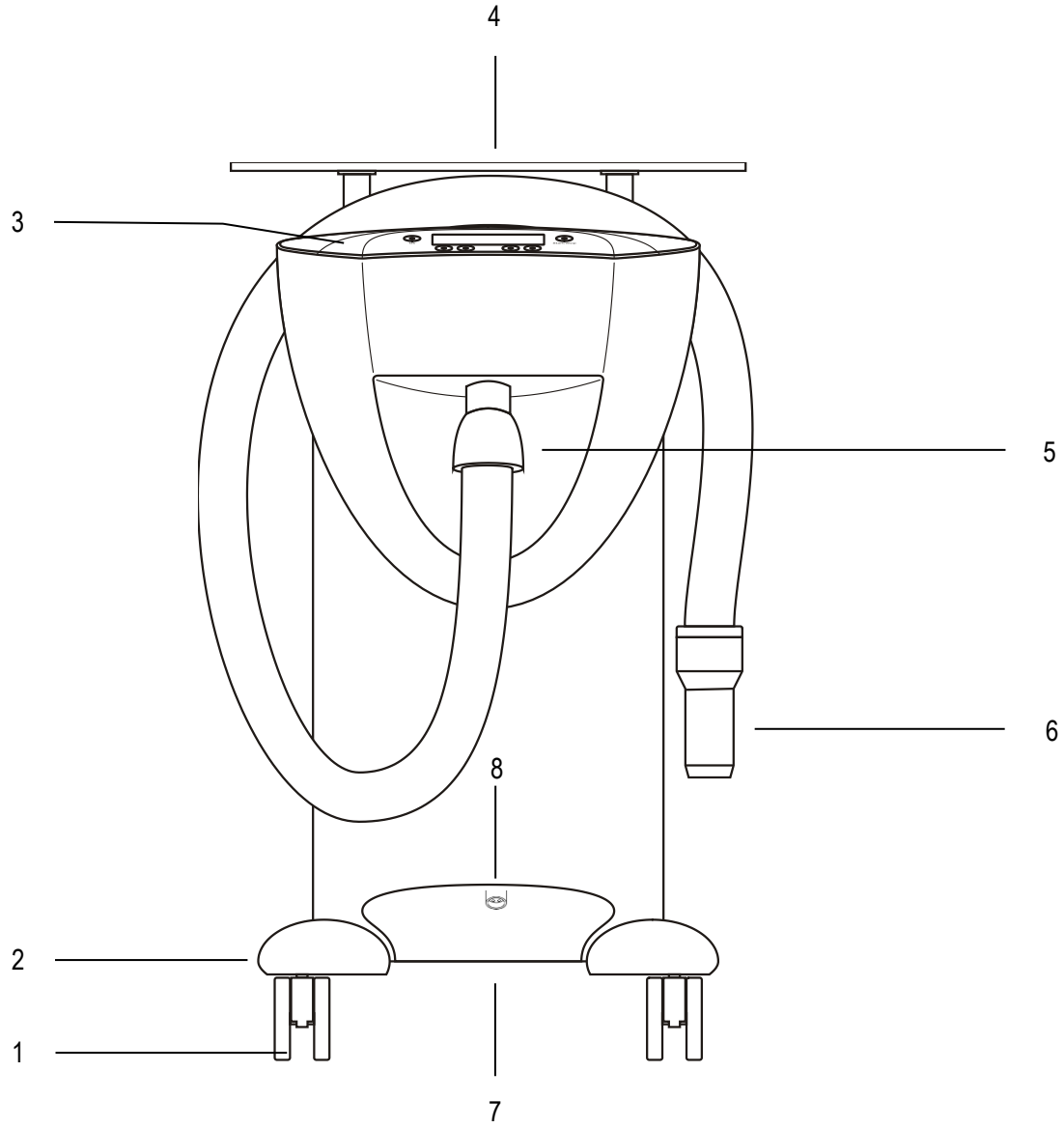


EN

Illustrations

Front of the device

Fig. 1



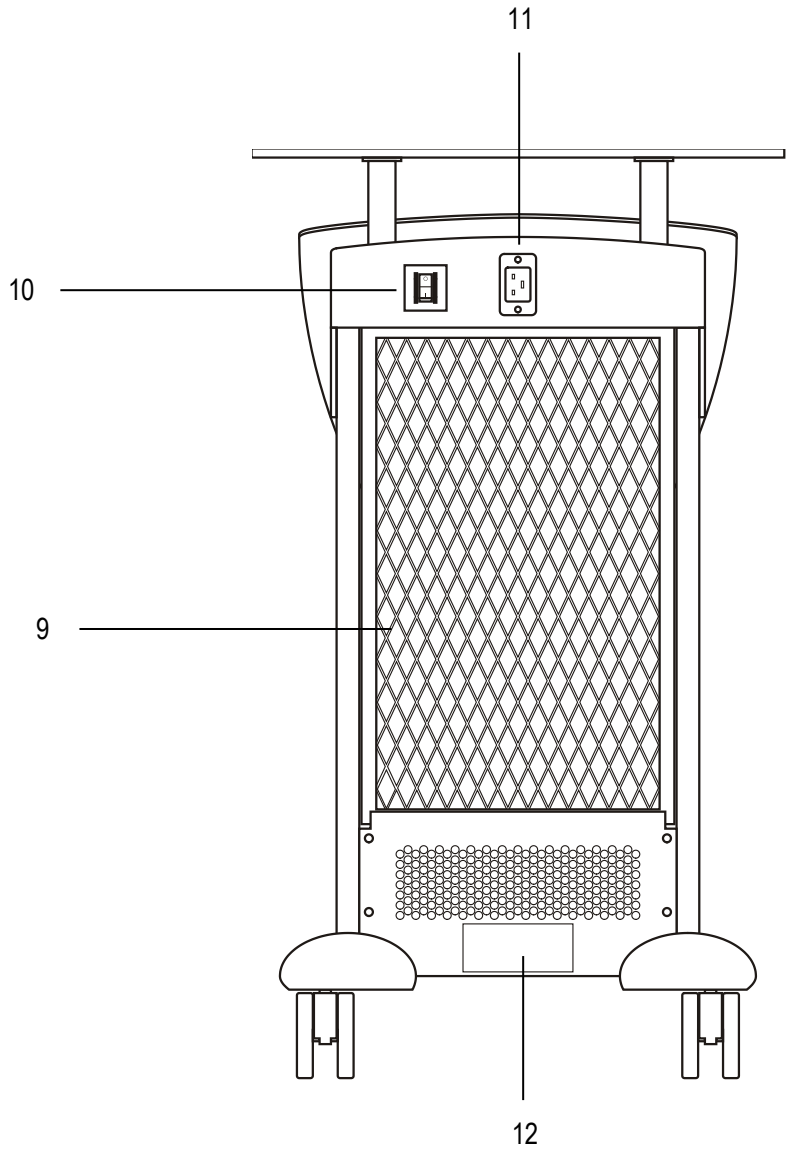
Device and operating elements

1 Castors
2 Castor guards
3 Control panel
4 Shelf plate
5 Treatment tube connection
6 Treatment tube
7 Defrost water container
8 Defrost opening

Illustrations

Rear of the device

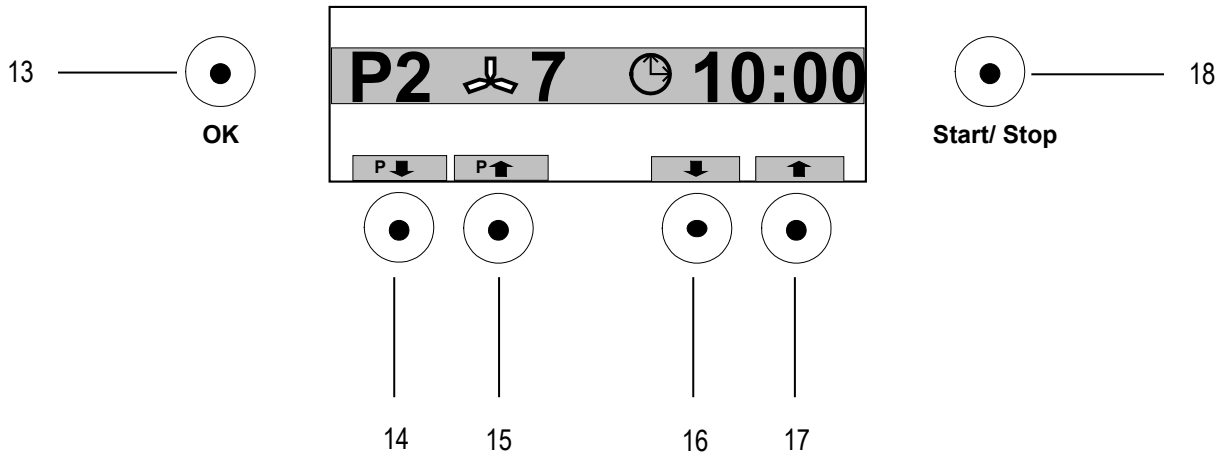
Fig. 2



Device and operating elements

9 Air filter
10 Mains switch
11 Mains connection
12 Identification plate

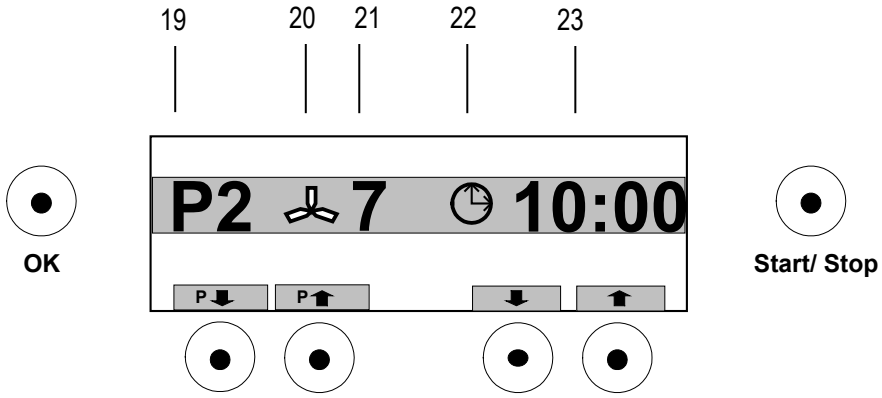
Fig. 3



Operating elements display

13 OK key
14 Arrow for navigation / changing parameters
15 Arrow for navigation / changing parameters
16 Arrow for navigation / changing parameters
17 Arrow for navigation / changing parameters
18 Start/stop key

Fig. 4



Display views

19 Program view
20 Airflow level display (graphical)
21 Airflow level display (numerical)
22 Treatment time display (graphical)
23 Treatment time display (numerical)

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 B

do not push sideways

max. permitted load on glass plate 35 kg

Follow instructions for use.

Instructions for use

Serial number

Item number

Manufacturer

Date of manufacture

Disposal of electrical and electronic equipment as well as used batteries and accumulators. Products marked with the adjacent symbol must not be disposed of with household waste.

Content

Content

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.

The instructions for use are valid as of July 2018.

Indications / Contraindications

1

1.1 Indications / Contraindications for Cryo 6 Physio

Indications

Cryo 6 Physio is designed for the following uses:

- Reduction of pain and stiffness and to support treatment of acute and chronic painful conditions of the musculoskeletal system
  - Arthritis
  - Bursitis
  - Tendinitis
  - Tenosynovitis
  - Myositis
  - Fibrositis
  - Muscle tenseness
  - Cervical syndrome
  - Post-whiplash disorders
  - Lumbar syndrome
  - Muscle or joint injuries
- Pain reduction, improved mobility and reduction of joint stiffness in rheumatic conditions
  - Rheumatoid arthritis (progressive chronic arthritis)
  - Post-synovectomy condition
- Reduction of spasticity in neurological disorders
  - Multiple sclerosis
  - Post-apoplectic hemiplegia

other possible uses:

- to support movement therapy by prior cooling
- in combination with compresses in acute injuries
- to prevent oedema and haematoma
- in sports, as preventive early-stage treatment before the development of pain immediately after major exertion, such as after a competitive event
- to treat muscular trigger points in combination with stretching

Other indications must be discussed with the patient's doctor or derived from relevant specialist literature.

Absolute contraindications

- Cryoglobulinaemia
- Cold agglutinin disease and cold haemolysis
- Cold urticaria
- Parts of the body with impaired circulation
- Raynaud's disease
- Parts of the body with impaired sensitivity
- Trophic disorders
- Hypersensitivity to cold

Relative contraindications

- When treating children, parts of the body that are not being treated must be covered and kept warm.
- When treating the face, the eyes must be covered.
- Do not treat the face or trunk if the patient has severe arterial hypertension and severe cardiac insufficiency.
- The patient should not become excessively cold during treatment.

Indications

Cryo 6 Derma is designed for the following uses:
Reduction of pain and inflammation by cooling with cold air during and after dermatological and cosmetic treatments

- Laser therapy
- Injections
- Photodynamic therapy

Advantages

The analgesia associated with cold air makes the treatment much more pleasant for the patient.

Reduction in the side effects that are often related to laser treatment:

- less erythema
- fewer swellings and encrustations
- reduction of pain and thermal skin damage

Absolute contraindications

- Cryoglobulinaemia
- Cold agglutinin disease and cold haemolysis
- Cold urticaria
- Parts of the body with impaired circulation
- Raynaud's disease
- Parts of the body with impaired sensitivity
- Trophic disorders
- Hypersensitivity to cold

Relative contraindications

- When treating children, parts of the body that are not being treated must be covered and kept warm.
- When treating the face, the eyes must be covered.
- Do not treat the face or trunk if the patient has severe arterial hypertension and severe cardiac insufficiency.
- The patient should not become excessively cold during treatment.

Note:

When using Cryo 6 with ablative lasers, make sure that the wound produced is given appropriate antiseptic care after the treatment.

Side effects

2

Side effects

Cold-related skin damage such as skin reddening and even mild frostbite and chilblains can occur, especially in sensitive patients.

Application information

3

3.1 General

Prior to using the device on a patient, the user should become familiar with the instructions for use and individual treatment methods to be used as well as the indications / contraindications, warnings and application information. Additional sources of information about the treatment should be followed.

These instructions for use must always be stored with the device and kept accessible at all times for anyone authorised to operate this device.

Caution! After the device has been in transit on its side, place it upright and keep it in an upright position for at least 30 minutes before switching it on. Otherwise the compressor will be damaged.

Caution! Before use, ensure that the device is powered via a properly grounded mains socket (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! Magnetic and electrical fields can affect the function of the device. For this reason, do not operate Cryo 6 in the vicinity of devices which generate strong electromagnetic fields (X-ray or diathermy equipment, MRI machines). Please keep a safe distance of several meters.

Caution! Cryo 6 is not suitable for use in areas with an explosive, flammable or combustive atmosphere.

Caution! Do not place the device adjacent to heat sources (heating, hot mud products, sauna etc.), and leave a gap of at least 50 cm between the device and a wall (to allow for the supply of treatment products and cold air).
When used in combination with a laser device, the laser ventilation system must not impede Cryo 6 cooling.

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.

Caution! To avoid the risk of electric shock, the plug must be disconnected from the power supply before performing any cleaning or maintenance activities.

Caution! Inspect the device before use. If there is any damage, it must not be used.

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

3.2 Cryotherapy

Patients should be given an explanation of the aims and effects of cold air therapy with Cryo 6 prior to treatment.

Tell patients that if they experience any discomfort, such as a sensation of extreme cold during treatment, they must tell the therapist immediately.
During treatment, the therapist should ask patients if they are feeling all right.
The treatment parameters (airflow level and distance from area being treated) should be adjusted if necessary.

Use the most appropriate nozzle for the various applications, from treatments administered to large areas of the body through to trigger point treatment. Simply unscrew a nozzle and screw in a different one when you want to switch.

Short distances between the skin and the nozzle are suitable for brief cooling:

- 1 cm distance for treatment times of up to 10 seconds,
- 5 cm distance for treatment times of up to 30 seconds.

Medium distances between the skin and the nozzle are suitable for dynamic cooling of larger areas of skin and static cooling of smaller areas:

- 10-15 cm distance for treatment times of approximately 15-30 minutes.

Long distances between the skin and the nozzle are suitable for dynamic cooling of large areas of skin:

- 15-20 cm distance for treatment times of over 30 minutes.

Longer treatment times are needed for joints and muscles, as otherwise only the surface and upper layers of the skin are cooled. In patients with joint inflammation, brief cooling causes reactive hyperaemia.

In patients with diseases of the musculoskeletal and support systems, best results are obtained with a distance of 5-20 cm between the outlet nozzle and the surface of the skin.

When used in conjunction with laser devices, a distance of 5 cm for a treatment area of 10 cm² is recommended. The distance should be increased when treating larger areas. A longer treatment period is needed to obtain adequate cooling.

Please note that the temperature of the air stream can increase during prolonged treatment.

Cold air output can be reduced if the environmental conditions are unfavourable (room temperature over 30°C and high air humidity).

Warnings

The patient must not be left unattended during therapy.

Any treatment instructions regarding treatment location, duration and intensity require medical knowledge and should be given by authorised physicians, therapists and health paraprofessionals. These instructions must be followed.

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.

Dispose of the packaging material properly. Make sure that it is not accessible to children.

The cold air stream must not be applied to open wounds.

When using Cryo 6 to cool skin, do not increase the output of the laser device beyond the level recommended by the manufacturer.

When applying cold to the face it is essential to protect the eyes.

The air stream should be directed evenly over the area to be treated. Avoid static or excessively intensive cooling as this can lead to cold burns and hypothermia.

The use of the device out of the settings or applications specified in the instructions for use may lead to hazard by the uncontrolled effects of cold.

Children can become too cold. Parts of the body that are not being treated should be covered and kept warm. This is also recommended for adults undergoing prolonged cooling.

Frostbite can occur if the skin temperature falls to 0°C or below This can occur if the nozzle is less than 10 cm away from the skin. If it is not possible to respect this distance on therapeutic grounds, it is recommended that the nozzle be directed dynamically over the area being treated.

Do not push the sides of the device that are marked with the warning symbol.

Do not lean on the device.

Cryo 6 - in brief

What is Cryo 6?

A compact cold-air device used to treat diseases of the support and musculoskeletal systems.
Cryo 6 can also be used to cool the skin of patients undergoing dermatological laser treatment to relieve pain and thermal skin damage.

What does Cryo 6 do?

It blows very cold air onto the parts of the body to be treated at various speed settings.

What are the benefits of Cryo 6?

It is very easy to use thanks to the pre-set program parameters and also very powerful in prolonged use, matching the performance of much larger devices.

What are the other benefits of Cryo 6?

Its clear LCD display and ergonomic keyboard reflect the state of the art.
Therapy can be customised through six user-focused, pre-set programs as well as three programs with free choice of settings and an individual start-up program.

How is the necessary concentration of cold achieved?

Air volume can be set to one of nine levels depending on the size of the area to be treated and how accessible it is.
Three nozzle sizes are supplied as standard for individual therapy (diameters of 5, 10 and 15 mm).

A special nozzle is also available for cooling the skin of patients undergoing dermatological laser treatment.

Note:

Use of the device is reserved for medical professionals (such as physicians, therapists, medical paraprofessionals).

Intended use

6

The Cryo 6 cold air device is used to cool skin

- when treating injuries or diseases affecting the musculoskeletal system
- in order to reduce local pain
- in patients undergoing dermatological laser treatment to prevent thermal skin damage

Device types

1. Cryo 6 Physio to treat diseases of the support and musculoskeletal systems.
2. Cryo 6 Derma to cool the skin of patients undergoing dermatological laser treatment to relieve pain and thermal skin damage.

The device types are preconfigured in the factory and differ in respect of the pre-set fan settings and treatment periods as well as the start-up program.

Device set-up

7.1 Fitting

7

Caution!

Cryo 6 must be placed upright and kept in an upright position for at least 30 minutes before being switched on if the device has been transported on its side or had fitting work done on it.
Otherwise the compressor could be damaged.

Connect power cable

Connect the power cable to the provided port (11) on the device and connect the cable to the mains.

Note:

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

Switching device on

The device is switched on using the toggle switch (10).

Switching device off

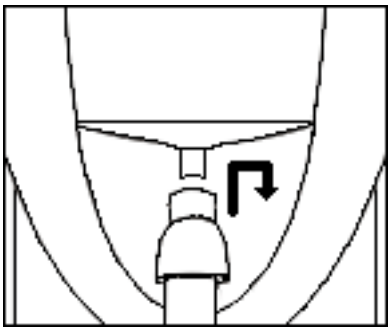
The device is switched off using the toggle switch (10).
To fully (all poles) disconnect the device from the mains, the power cable must be disconnected.

Caution!

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

Fitting the treatment tube

Insert the treatment tube into the connector (5) on the front of the device and lock it into place.



The treatment tube can be stored in the curved groove above the control panel (3) when not in use.

Fitting the castor guards

Attach the castor guards (2) to the wheel holders.

Fitting the glass plate

Four spacing bolts are already fitted to the top of the device to allow the glass plate to be attached.

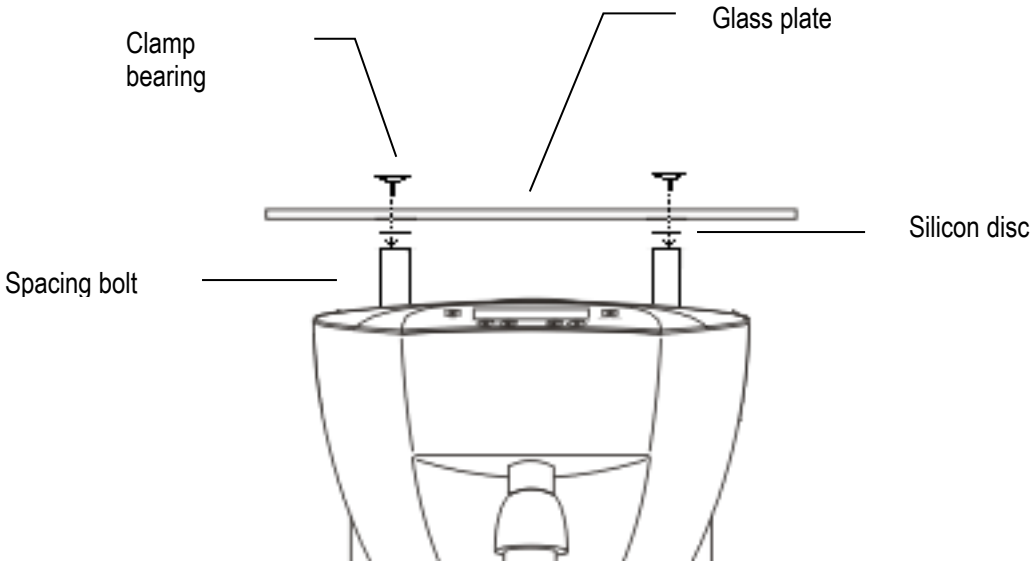
Place a silicon intermediate disc onto each of the four spacing bolts.

Then put the glass plate on the spacing bolts.

Now secure the glass plate by screwing one of the clamp bearings provided into each of the four spacing bolts.

You do not need to use a tool for this, in order to prevent damage to the glass plate.

Use your fingers to tighten the clamp bearings.



Carry out the steps described above in reverse order to dismantle the glass plate.

Never lift the device by the glass plate.

Note: *The treatment nozzle and the nozzle attachments can be kept in the storage box.*

7.2 Fitting the supporting arm

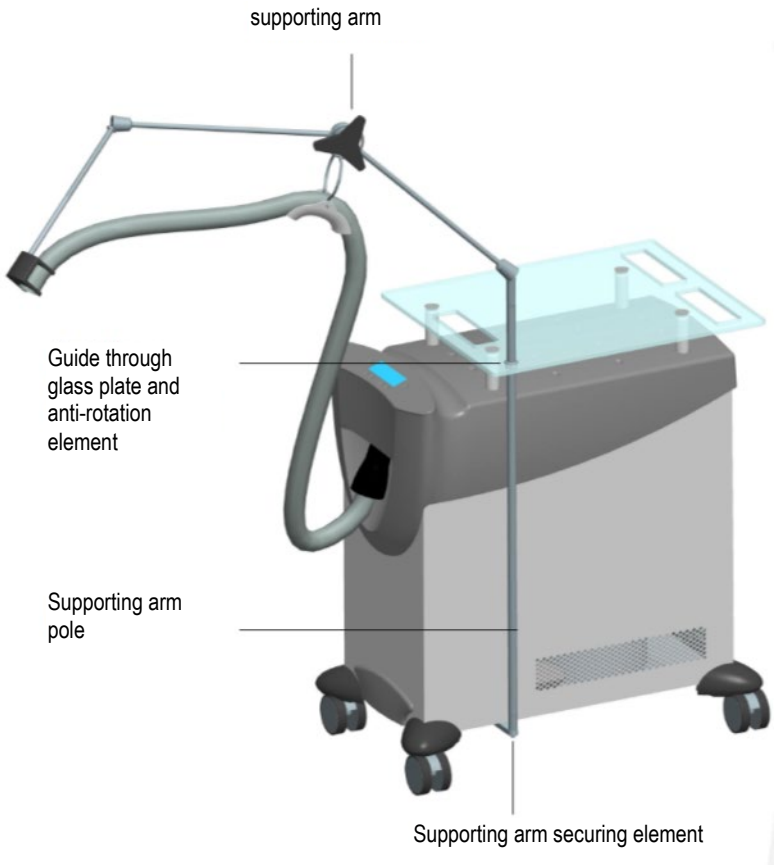
Supporting arm

The Cryo 6 device can be fitted with a supporting arm as an extra option. This arm allows a particular part of the body to be cooled without the therapist having to hold the tube.

The supporting arm accessory kit consists of:
1 supporting arm mounting bracket
2 M6x16 screws and allen key for mounting
1 anti-rotation element
1 supporting arm pole
1 rotating supporting arm
1 tube clip
1 tube holder

Also required:
Glass plate
Guide sleeve

Picture of the supporting arm after fitting



7.2 Fitting the supporting arm

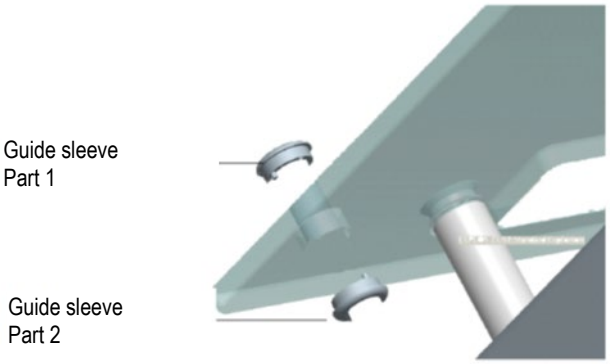
Fitting instructions

The glass plate must be attached to the device so that a supporting arm can be fitted (see 7.1 Fitting) The glass plate contains an opening through which the supporting arm passes.

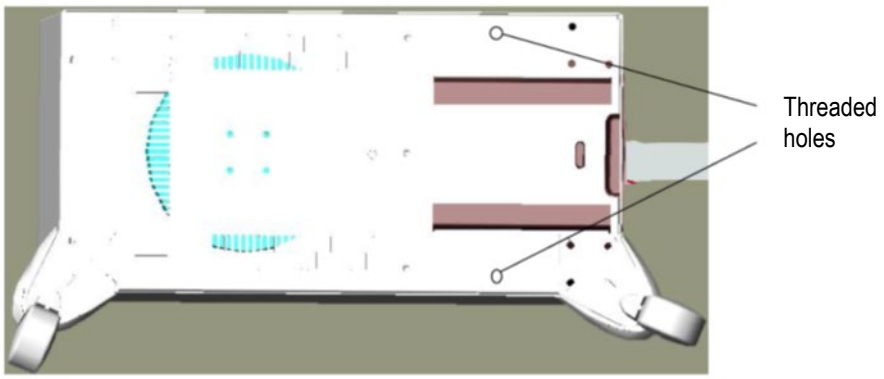
Note:

The glass plate can be fitted so that it is symmetrical with the device. If a supporting arm is also fitted, the glass plate is laid on the spacing bolts in such a way that the hole for positioning the supporting arm is on the correct side of the device.

Step 1 - fitting the guide sleeve
Assemble the guide sleeve (supplied with the glass plate) in the hole made for this purpose.



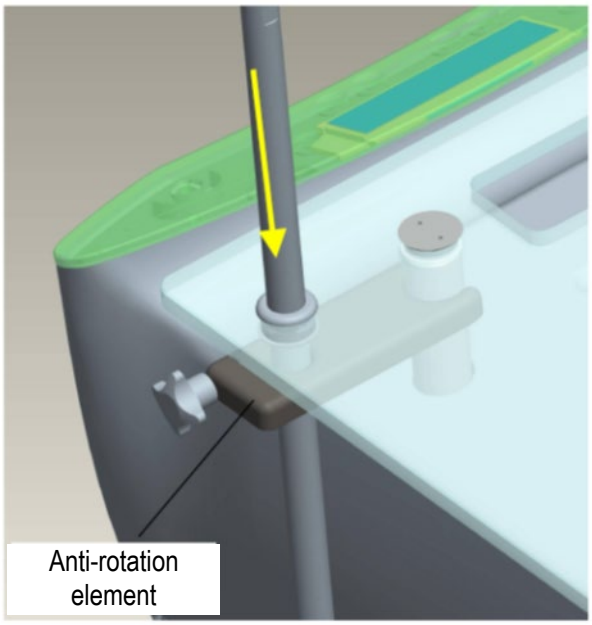
Step 2 - fitting the supporting arm securing element
Use the Allen key and the M6x16 screws to screw the mounting bracket to the base of the device.
Threaded holes are already in place on the base of the device for this purpose.



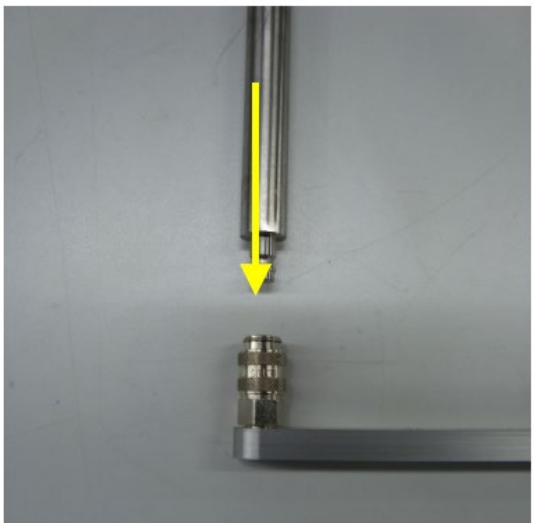
Caution!

The view from below is only presented for clarification, please DO NOT put the device down for fitting!

Step 3 - attaching the anti-rotation element and pole
Place the anti-rotation element on the glass plate spacer as shown in the picture.

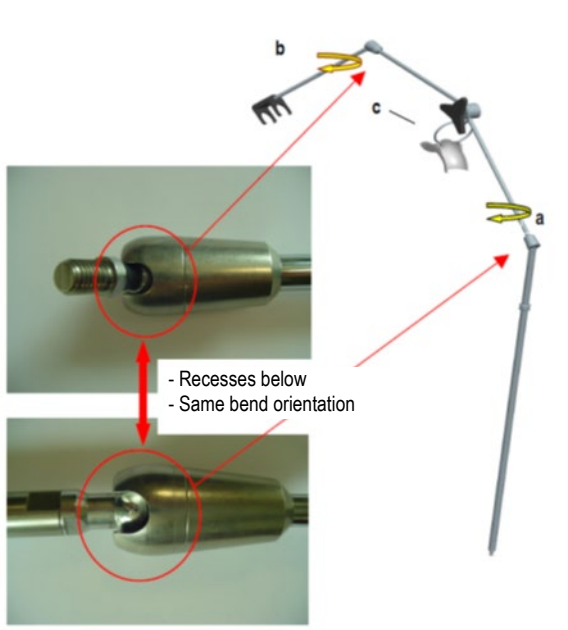


Then pass the supporting arm pole through the guide sleeve and the anti-rotation element from above, and lock it into place in the supporting arm securing element.



7.2 Fitting the supporting arm

Step 4 - attaching the supporting arm
Screw the supporting arm (a) onto the fitted pole. The recesses must be aligned in order to ensure that the supporting arm can move freely up and down. They must lie along an axis and allow the pole to bend.



Step 5 - attaching the tube clip / tube holder
Screw the tube clip (b) onto the rotating supporting arm, and hang the tube holder (c) onto the fixing screw of the supporting arm.

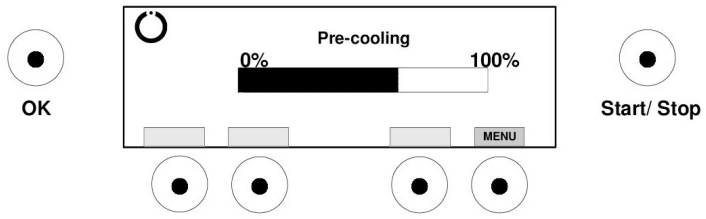
The treatment tube can now be passed through the tube securing element and the handpiece can be engaged in the tube clip.

Settings

8.1 Device menu

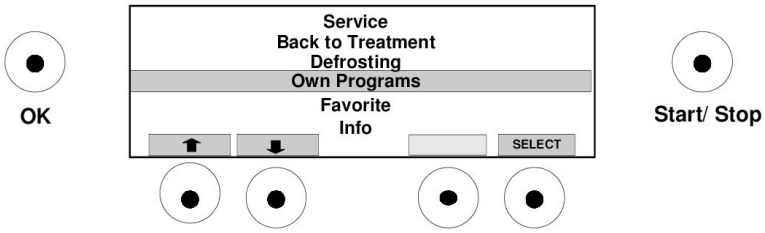
8

The Cryo 6 performs a self-test once it has been switched on.
You can switch to the configuration menu during the self-test and subsequent pre-cooling of the device.



Selecting the menu

Press the “Menu” key to select the menu.



You can use the menu to call up technical information, change factory settings, select a favourite program or define your own programs.

You can choose from eleven menu items:
- Service
- Back to treatment
- Defrost
- Own programs
- Favourite
- Info
- Automatic maintenance program S01
- Automatic maintenance program S02
- Cryo device type
- Device configuration
- Basic settings

Use the arrows (14 and 15) to navigate among the individual menu items.

Selecting menu items

Press the “Select” key (17) to select a menu item.

End menu

Select the “Back to treatment” menu item to end the menu and return to the treatment screen.

8.2 Device type and device configuration

Device type

Cryo 6 can be used as “Cryo 6 Physio” or “Cryo 6 Derma”.

Use the arrows (14 and 15) to navigate to the pre-set configuration that you want to use. Then press the “Save” key to select it.

See chapter 9.3 for more information about device types and specific parameters.

Device configuration

This menu item offers various settings, such as languages or aspects of the start-up process.
Use the arrows (14 and 15) to navigate through the sub-menu.
Press the “Select” key (17) to select an item.

Languages
The following languages are available:
German, English, French, Italian and Polish.

Note:

The “External control input”, “External control output” and “External start input” sub-menus are inactive.

Start-up process
Cryo 6 offers two different options here:

1. Direct start
2. Programs

Press the “Select” key to select the menu.
Press the “Change” key to switch between direct start and programs.
Press the “Save” key to save the start-up process you want to run and the “Yes” key to confirm and apply your choice.

8.3 Default settings and service

Default settings

You can restore factory settings under this menu item.

Press the “YES” key to reset all the parameters that have been changed back to the factory settings.

Own programs and the favourite program that you have saved will not be lost.

Press the “NO” key to retain changed parameters.

Service

This area is password-protected and is only accessible to people who have been trained by Zimmer MedizinSysteme GmbH.

Press the “OK” key to quit the menu.

8.4 Defrosting

Defrost

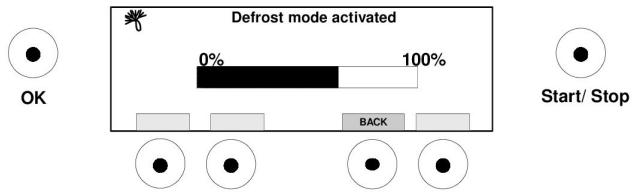
The “Defrost” menu item triggers defrosting of the heat exchanger.

Note:

Perform defrosting when the outgoing air stream is less strong than usual. This is often caused by the Cryo 6 being placed in a humid environment such as a bathing area or sauna. We also recommend defrosting the Cryo 6 and emptying the defrost water container if it has not been used for a prolonged period, for instance during holidays.

Performing defrosting

Press the “Select” key to immediately begin the defrosting process. The defrosting process is carried out in standby mode.



The treatment fan starts up and runs until the cooling unit’s defrosting temperature has been reached. The blower then switches off.

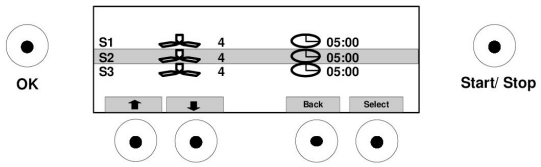
The message “Defrost complete” appears on the display once the defrosting process has been completed.

Press the “Back” key if you want to interrupt the defrosting process before it has finished.

Note: *The “Internal programs”, “Programming of 1 and 2-phase programs” and “Favourite program” can only be activated if “Programs” is activated as the start-up process (see point. 8.2).*

Own programs

Cryo 6 offers storage options for three own programs in addition to the six factory pre-set programs which cannot be permanently changed.
Fan level and time can be allocated individually to a storage location.
The programs can be programmed either for one phase or for two consecutive phases.



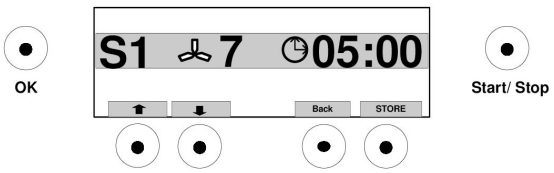
Programming a 1-phase program

Use the arrows (14 and 15) to navigate among the three storage locations.
Press the “Select” key (17) to select the stored program that you want to use.

You can then use the arrows (15 and 16) to select the desired fan level. The fan symbol (20) flashes.
Press the “Save” key to save the fan level.
The fan symbol now stays lit and the time symbol (22) flashes.

Use the arrows (14 and 15) to select the desired time.
Press the “Save” key to save the time.

Activate the “Back” key to stop programming the 1-phase program. Press the “Back” key to quit the menu.



Programming a 2-phase program

Here you can arrange for two programs with different fan levels and times to run consecutively in a single treatment session.
Start in the same way as when programming a 1-phase program. Now, instead of pressing the “Back” key to quit the program, press the “Save” key again. The parameters for phase 1 now appear in small font at the top of the display.

Favourite

Here you can select a personal favourite program that is automatically loaded whenever the device is started up. You can choose one of the six factory pre-set programs P1-P6 or one of the own special programs S1-S3. Use the arrows (14 and 15) to navigate among the program locations. Choose the program you want to define as the favourite and press the “Select” key to confirm.

Info Technical information about various device components is displayed under this menu item.

Note: *No settings can be applied.*

Maintenance programs The S01 and S02 maintenance programs simulate long-term operation and logs the correct condition of the device.
Any faults are diagnosed and recorded.

SO1 This program simulates two 15-minute treatment sessions and one defrosting process. The program records key parameters such as temperature and duration.

The current temperatures of the compressor and evaporator can be checked during the test.

SO2 The device cools down to - 40°C / - 38°C and starts a 15-minute treatment session at fan level 9.

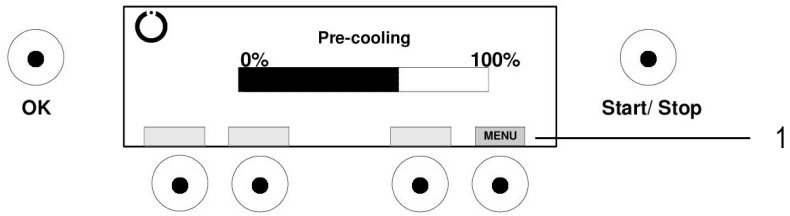
This program is repeated until the start/stop key is pressed.

Operation instructions

9.1 Device description

Pre-cooling

As soon as Cryo 6 is switched on, the device starts to pre-cool to the minimum temperature to be reached. The compressor and condenser fan work together during this phase. At the same time the device performs a self-test. No data can be entered via the display during the self-test or pre-cooling. The only active key is the “Menu” key (1), which users can press to reach the configuration menu. When sufficient pre-cooling has been carried out, the display automatically switches to the start screen. Cryo 6 is now ready for use.



Operation

During treatment, the treatment fan blows cold air through the treatment tube. At the same time, the compressor / condenser starts up automatically during treatment in order to ensure constant cooling.

Standby mode

Cryo 6 is in standby mode when no treatment is being carried out. The compressor automatically starts up as soon as a certain temperature is exceeded, in order to ensure that sufficient cold air is available at all times. Treatment can be started immediately from standby mode.

Recommendation for optimum treatment

We recommend that about 10 minutes should be left between the end of pre-cooling and the start of treatment. This ensures that the device has reached peak cold air output.

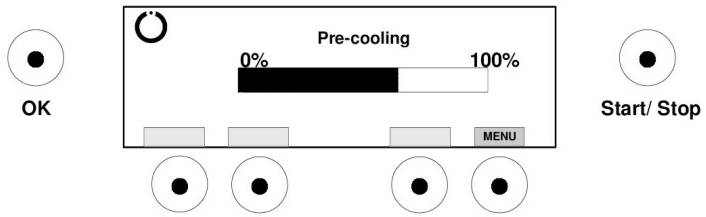
We also recommend that Cryo 6 is only switched off when there are prolonged breaks in treatment or at the end of the day.

Switching device on

Switch on the device at the mains switch (10), display lights up.

Initialisation

The current status (self-test, pre-cooling) can be read off at the display during initialisation.

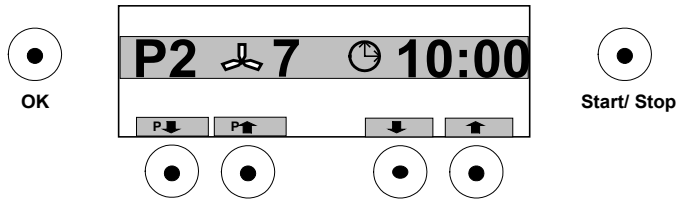


Note:

The factory settings mean that the start-up screen and start-up process are different depending on whether you are using the device with the Cryo 6 Physio or Cryo 6 Derma pre-set parameters.
See the next page for illustrations of both start-up screens.

Selection Program and treatment time

The device is ready to use as soon as the treatment screen (in this case “Physio”) appears.



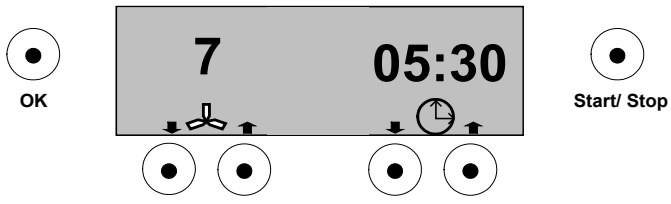
Use the program selection keys (14 and 15) to set the desired treatment program and the timer keys (16 and 17) to set the desired treatment time.

Note:

The fan level cannot be altered before the start of treatment.

Start of treatment

Press the start/stop (18) key to start the program running.
The fan level (14 and 15) and treatment time (16 and 17) can be altered by pressing the corresponding keys during treatment.



Note:

If parameters are altered during treatment, the factory settings are restored after the end of treatment (or the favourite program settings if a favourite program has been stored).

End of treatment

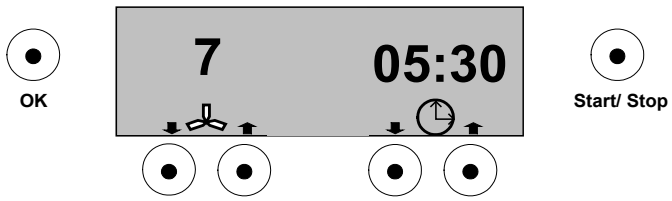
An acoustic signal indicates the end of treatment, and the fan is automatically switched off. This also applies to premature interruption of treatment via the start/stop key (18).

9.3 Start-up screens

Start-up screens

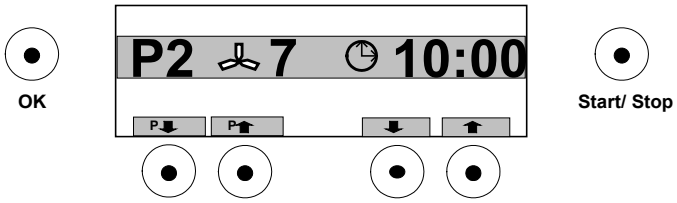
The factory settings mean that the start-up screens and start-up process of the Physio and Derma versions are different.

Derma start-up screen / direct start



Direct start: Fan level and time can be selected directly.

Physio start-up screen / programs



Programs: direct selection option among various pre-set programs and the use of interval programs.

Note: *The device configuration menu item offers a free choice of the desired start-up process. See chapter 8 for instructions.*

Cryo 6 Physio - pre-set parameters

	Phase 1		Phase 2	
Program	**Fan level**	**Time**	**Fan level**	**Time**
1	9	3 min	-	-
2	6	5 min	-	-
3	4	5 min	-	-
4	3	10 min	-	-
5	9	30 sec	6	2:30 min
6	7	1 min	5	4 min

Cryo 6 Derma - pre-set parameters

Program	**Fan level**	**Time**
1	7	45 min
2	5	45 min
3	3	45 min
4	8	15 min
5	6	15 min
6	4	15 min

Note: *Cryo 6 Derma is factory-set for direct start operation. Use the "Device configuration" menu to switch to program operation.*

Changing the pre-set values

Cryo 6 offers options to adjust the fan level and treatment time to individual requirements and to save these changes (see chapter 8.5).

The treatment fan can be set to nine levels using the keys (14 and 15).

Treatment time can be set to any duration between 00:00 and 99:59 minutes.

If an excessively high treatment time has been selected by mistake, press the start/stop key (18) twice to return to the factory pre-set time.

Technical information

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Mains power	100-120 V / 50 Hz / 60 Hz (9-12 A) 220-240 V / 50 Hz (7 A) 240 V / 60 Hz (7 A)
Mains fuse	16 A circuit breaker in mains switch
Protection class	I
Applied part	Type B
Dimensions	H 645 mm x W 390 mm x D 680 mm
Weight	60 kg
Operation	+10°C to +35°C, 20% to 80% relative humidity, without condensation at 700 hPa to 1060 hPa
Transport	-10°C to +50°C, 10% to 90% relative humidity, without condensation at 600 hPa to 1060 hPa
Storage	0°C to +40°C, 10% to 90% relative humidity, without condensation at 600 hPa to 1060 hPa
Note:	*Storage and transport only in original packaging.*

Evaporator temperature generated

	115 V device	**230 V device**
minimum (standby)	- 38°C	- 40°C
maximum (standby)	- 25°C	- 25°C

Air output temperature (room temperature up to 25°C)

average:	- 25°C
at the start of treatment:	- 31°C
maximum:	- 18°C (after 15 minutes of treatment)

Figures accurate to +/- 10%

Max. treatment time that can be set 99:59 min

Maximum load on glass plate The maximum weight and size of devices (such as laser devices) that can be placed on the glass plate is 35 kg and 50 x 50 x 35cm (W x D x H).

Subject to technical changes.

Cleaning
Disinfection

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- 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.
- Make sure that when cleaning and disinfecting the labelling of the device (such as warnings, labels of control devices, identification plate) is not damaged.
- 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.
- The device and its applied part are considered as uncritical in relation to hygiene due to the use on non-injured and healthy skin.

Housing / accessories

Cleaning: In the event of visible contamination, the housing, cables and accessories 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.

Disinfection: We recommend that disinfection is to be carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection. Housing, cables and accessories 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 application instructions of the 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.

Defrost water container

Cleaning: The defrost water container (7) should be cleaned whenever it has been emptied. Follow the procedure described under "Housing / Accessories".

Disinfection: Follow the procedure described under "Housing / Accessories".

Caution!

The device may only be operated with the defrost water container in place.

Air filter

The air filter (9) should be cleaned regularly, and in any event after no more than 200 operating hours (maintenance notice appears on the display).
This is done by vacuuming the air filter from the outside using a commercially available domestic vacuum cleaner.

Note:

Use the device only in a hygienic environment.

CE mark / manufacturer

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The device has a CE mark

CE 0123

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

Manufacturer

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89231 Neu-Ulm
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Scope of delivery / accessories

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Scope of delivery Item no.	Version Cryo 6 Physio
95850912	1 treatment tube Physio
65370216	1 adapter for nozzles
65370225	1 nozzle ∅ 5mm
65370224	1 nozzle ∅ 10mm
65370223	1 nozzle ∅ 15mm
66850122	1 glass plate with handles
94851511	1 screw Set for glass shelf
80400756	4 plastic castors ∅ 75 mm
65851610	1 defrosted water container
67300124*	1 mains cable 230 V
65853112	1 accessory storage tray
10101665	1 instructions for use

Scope of delivery Item no.	Version Cryo 6 Derma
95853411	1 treatment tube Light Neo
66850122	1 glass plate with handles
94851511	1 screw Set for glass shelf
80400756	4 plastic castors ∅ 75 mm
65851610	1 defrosted water container
67300124*	1 mains cable 230 V
65853112	1 accessory storage tray
10101665	1 instructions for use

	Optional device castors
80400756	Plastic castors ∅ 75 mm
80401004	Plastic castors ∅ 100 mm

Subject to technical changes.

* Individual mains cable available. Please contact your distributor.

Scope of delivery / accessories

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Accessories **For both device versions**

Item no.	
65851610	1 defrosted water container
87413230	Blank plug for defrosted water container
65853112	Accessory storage tray
80400756	Plastic castors ∅ 75 mm
80401004	Plastic castors ∅ 100 mm

Version Cryo 6 Physio

Item no.	
95850912	Treatment tube Physio
65370216	Adapter for nozzles
65370225	Nozzle ∅ 5mm
65370224	Nozzle ∅ 10mm
65370223	Nozzle ∅ 15mm
66850122	Glass plate with handles
93852620	Supporting arm for Physio tube

Version Cryo 6 Derma

Item no.	
95853411	Treatment tube Light Neo
65373510	Nozzle for Derma tube
66850112	Glass plate without handles
94851511	Screw Set for glass shelf
93852630	Supporting arm for Derma tube
95855610	Bracket for laser tube

For safety reasons only use original accessories, as proper functioning cannot otherwise be guaranteed.

Subject to technical changes.

Device combinations

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Cryo 6 can be used in combination with various laser devices. Please comply with the laser manufacturer's instructions for use when doing so.

The party combining the devices and thus operating a medical system is independently responsible for combining the devices correctly.

When using devices in combination, please comply with the safety regulations of DIN EN 60601-1.

Safety and maintenance

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15.1 Safety

Cryo 6 is manufactured according to the DIN EN 60601-1 safety regulations.

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 for him-/herself before use,
- the device is operated only by properly trained personnel,
- the device is not operated in areas at risk of explosion and / or a combustive atmosphere, and
- 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.

Cleaning the air filter

There is a filter element on the rear of the device (9) to ensure that the treatment air and the cold air needed for the cooling machine are free from coarse dust particles. It is normally sufficient to clean this regularly by vacuuming the whole of the outside with a commercially available domestic vacuum cleaner, no later than when the software issues a reminder after 200 operating hours. We recommend cleaning the filter element more frequently in carpeted rooms or in areas where dust formation is likely to be higher for other reasons.

Note:

The software message must be confirmed by pressing the "OK" key after the air filter has been cleaned.

Emptying the defrost water container

When Cryo 6 is switched off after use, or when the defrosting program is started, the cooling system heats up and so produces defrost water.
The tank, which has a capacity of approximately 1 litre, can be removed by pulling it out of the device and can then be emptied.
It should then be replaced in the device.
Please also follow the instructions for cleaning and disinfection (chapter 11).

Functional test

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Functional test

After being switched on, Cryo 6 automatically performs a self-test and checks the function of the technical components.

If necessary, the user can check the function of the cooling technology as described below:

1. Switch on the device.
2. Wait until the device is ready for use.
   This is the case when the device displays the program selection menu / direct start menu.
3. Press the start/stop key (18) to start up Cryo 6.
4. Select the various airflow levels one after the other and check the strength of the air stream and the cold air output.

Safety checks
Metrological control

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In Germany, no safety checks according to section 6 of the MPBetreibV (Medical Device Operator Ordinance) are required for the device Cryo 6. The device is not listed in attachment 1 of the ordinance.

A metrological control (MTK) according to section 11 of the MPBetreibV (Medical device operator ordinance) is also not required for the device Cryo 6. The device is not listed in attachment 2 of the ordinance.

Note: *These requirements apply to the operation of the device in Germany. Please consider divergent national regulations in your country.*

Mains fuse is activated

Cryo 6 is fitted with a bipolar overload protection element integrated into the main switch (10) to protect the device in the event of supply problems. If the fuse trips, the device automatically switches off via the toggle switch (10). The device can only be made ready for use again by switching it on via the toggle switch (10).

Please notify the customer service department if this fault occurs frequently.

Reduced cold air output / reduction in cold air output

Dirt in and around the defrost opening (8) may be the cause of a significant reduction in cold air output and a weak air stream. Dust particles are deposited in the heat exchanger by the treatment air. This can eventually lead to blockage of the defrost opening and a build-up of defrost water.

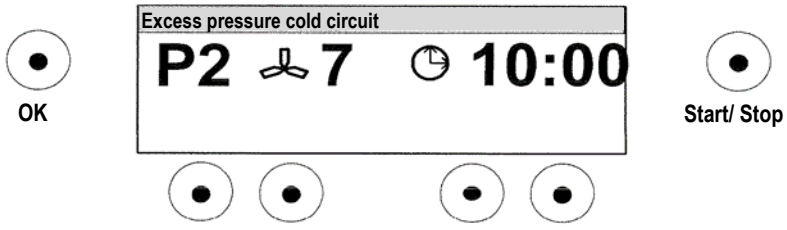
The defrost opening is located above the defrost water container. The device must be defrosted before cleaning the defrost opening (see page 18, “Performing defrosting”). After defrosting, switch off the device and remove the plug from the socket.

Remove the defrost water container and place a flat container underneath the device to capture the defrost water. Slowly pull out the defrost opening, using a twisting motion.
Clean the defrost opening under running water and screw it back into place.

Error messages

Device components that are important to the running of programs are tested when the device is switched on and sometimes also when it is in use. If an error is detected during these tests, treatment is terminated, and an error message is displayed in the top line of the display and an acoustic signal is produced.

Error messages are shown in plain text in the top line of the display. Treatment cannot be continued, the device can only be switched off.



Errors that do not affect continued work with the device can be resolved by switching the device off, waiting for five seconds and then switching it back on.

If the error message relates to excessively high temperature or pressure, you should wait for 30 minutes before switching the device back on as the device needs time to cool down. These error messages may be caused by high external temperatures and room temperatures which impair cold air output.

Please notify the customer service department if this fault occurs frequently. You may get in touch with them via your sales representative or via the main office in Neu-Ulm.

For other functional problems, contact your service representative.

Main office

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Junkersstraße 9
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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.

Manufacturer´s EMC declaration

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Medical electrical devices, such as Cryo 6, 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.

Cryo 6 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><th colspan="3">Guidelines and manufacturer's declaration – Electromagnetic emissions</th></tr>
<tr><td colspan="3">The Cryo 6 device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the Cryo 6 should ensure that it is operated in such an environment.</td></tr>
<tr><th>Interference emission measurements</th><th>Compliance</th><th>Electromagnetic environment - Guideline</th></tr>
<tr><td>HF emissions according to CISPR 11</td><td>Group 1</td><td>The Cryo 6 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 B</td><td rowspan="3">The Cryo 6 device is suitable for use in all facilities, including those in a residential area, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes.</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>not applicable</td></tr>
</table>

The device should not be used in the direct vicinity of or stacked with other devices. If operation near or stacked with other devices is necessary, the device should be observed to check its proper operation in the arrangement used.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Cryo 6 device is intended to be operated in the electromagnetic environment as indicated below. The customer or user of the Cryo 6 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 ± 1 kV for input and output 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 Cryo 6 requires continued function even if interruptions in the power supply occur, it is recommended to power Cryo 6 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 Cryo 6 are: smooth output of cold air, smooth operation of all functions.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Cryo 6 device is intended to be operated in the electromagnetic environment as indicated below. The customer or user of the Cryo 6 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 Cryo 6, 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= 1.17 √P d= 1.17 √P for 80 MHz to 800 MHz d= 2.33 √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 Hz 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 Cryo 6 device is used exceeds the above compliance level, the Cryo 6 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 Cryo 6*.*

[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 Cryo 6 device

The Cryo 6 device is intended to be operated in an electromagnetic environment in which the HF disturbances are controlled. The customer or user of the Cryo 6 device can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication devices (transmitters) and the Cryo 6 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= 1.17 √P	**80 MHz to 800 MHz** d= 1.17 √P	**800 MHz to 2.5 GHz** d= 2.33 √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	3.70	3.70	7.37
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.

Cryo 6

Instructions for Use

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