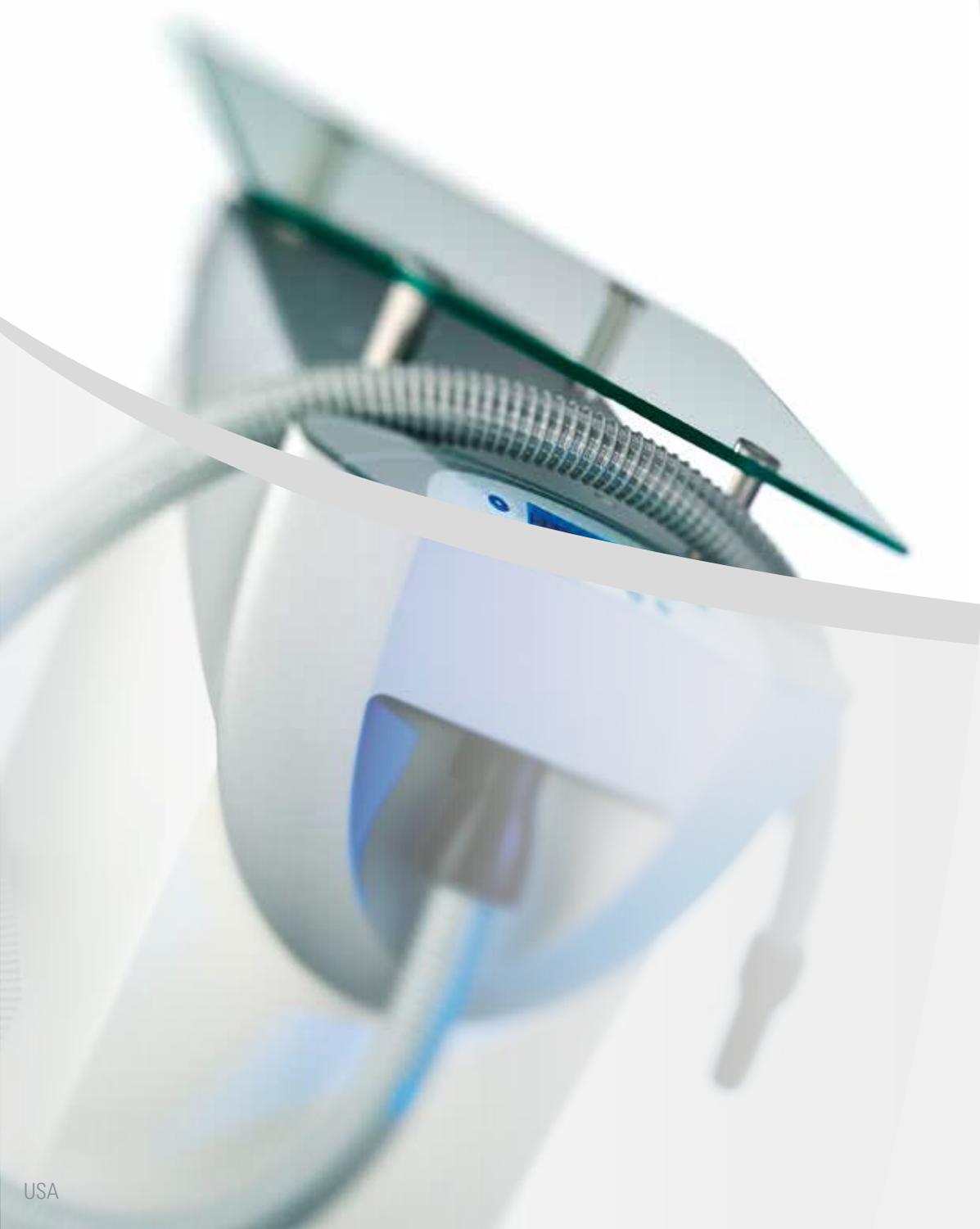


# Instructions for Use

## Cryo 6

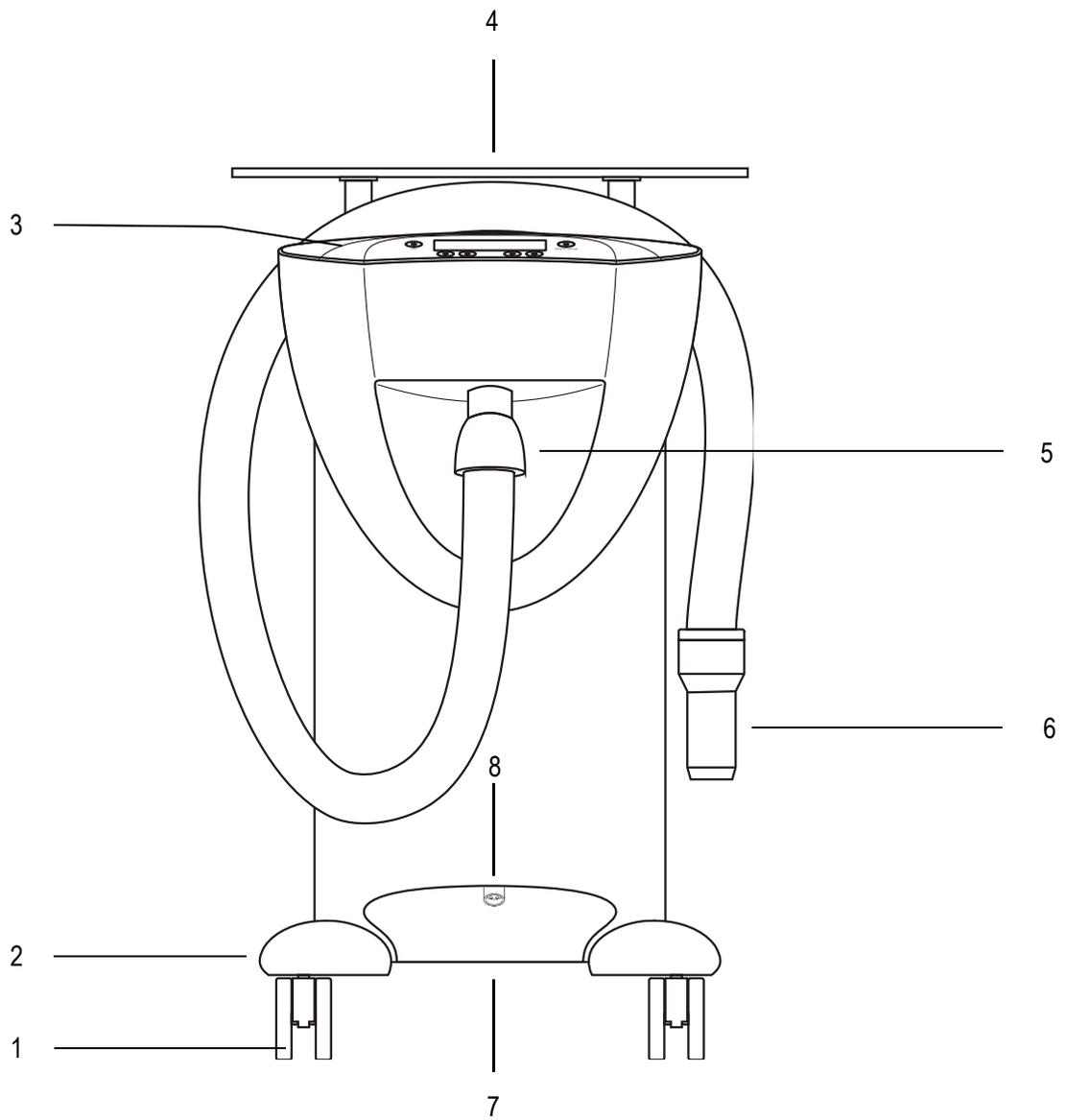


Zimmer

# Illustrations

## Front of the Device

Fig. 1



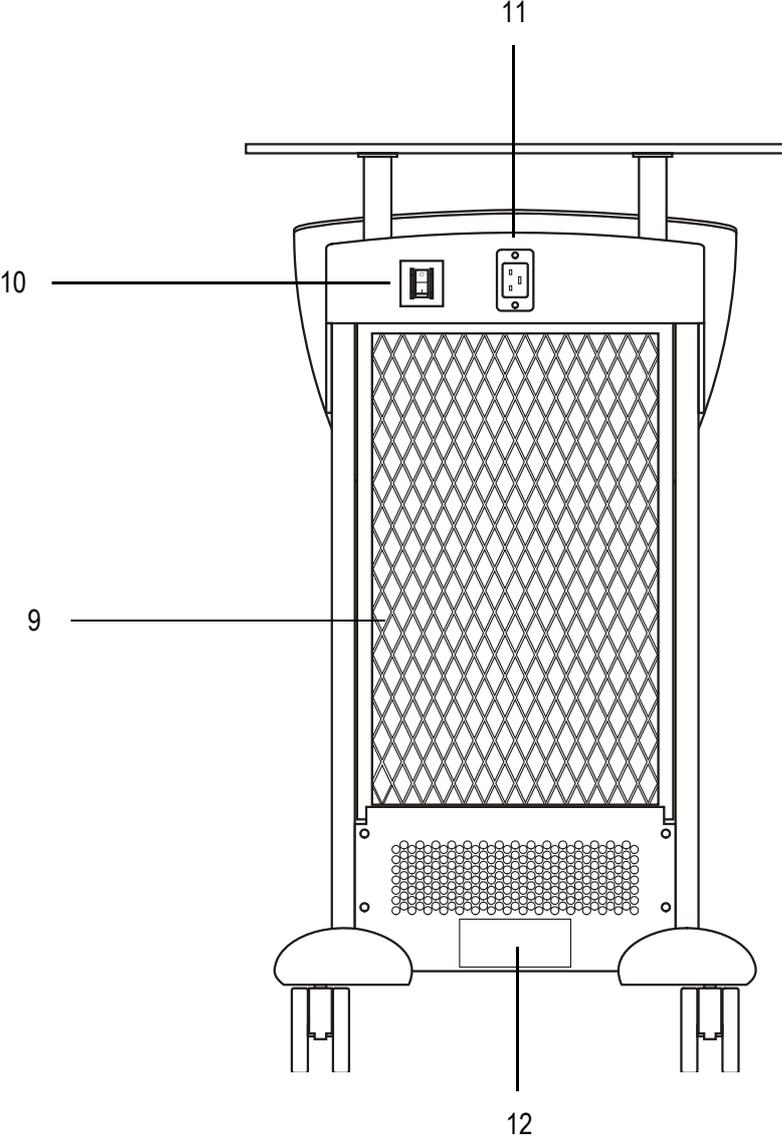
### Devices and operating elements

- 1 Castor
- 2 Castor guards
- 3 Control panel
- 4 Tray
- 5 Treatment tube connector
- 6 Treatment tube
- 7 Container for defrosted water
- 8 Defrost drain

# Illustrations

## Rear of the Device

Fig. 2



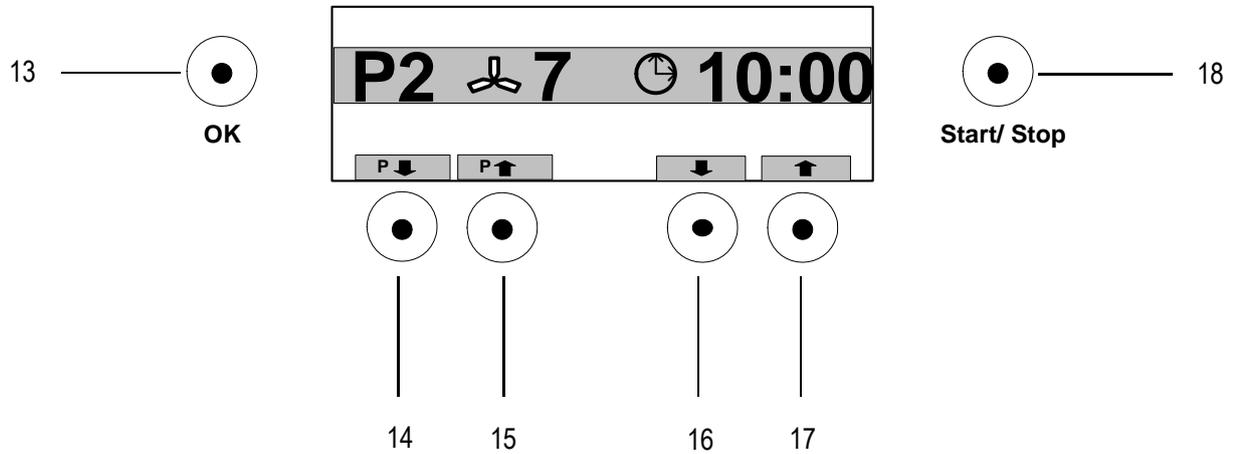
Devices and  
operating  
elements

- 9 Air filter
- 10 Mains switch
- 11 Power inlet
- 12 Identification plate

# Illustrations

## Screens and Displays

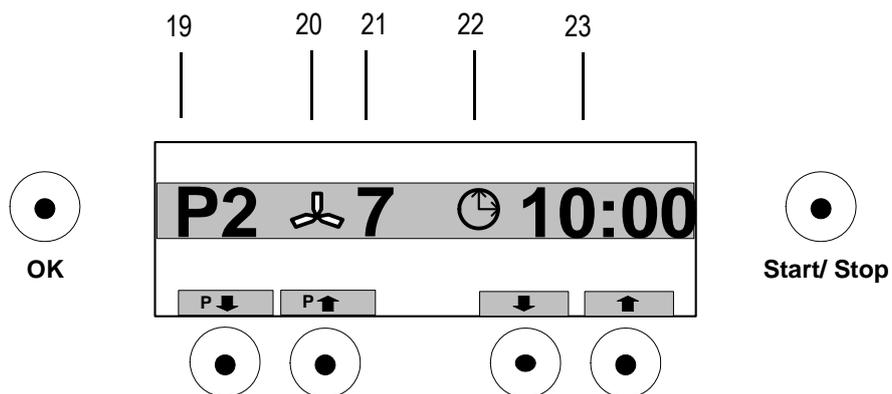
Fig. 3



Operating  
element display

- 13 OK key
- 14 Arrow key for navigation / changing parameters
- 15 Arrow key for navigation / changing parameters
- 16 Arrow key for navigation / changing parameters
- 17 Arrow key for navigation / changing parameters
- 18 Start/Stop button

Fig. 4



Displays

- 19 Program display
- 20 Graphic air power level display
- 21 Numeric air power level display
- 22 Graphic therapy time display
- 23 Numeric therapy time display

## 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



Maximum permissible load on the glass plate 35kg

Max 35kg/  
77.16lb



Follow instructions for use



Operation instructions



Serial number



Article number



Manufacturer



Date of manufacture

# Contents

## Illustrations

Front of the Device  
Rear of the Device  
Screens / Displays

## Explanation of Symbols

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Valid for Cryo6 devices.

This instructions for use is an integral part of the device. It must be stored with the device and kept accessible at all times for anyone authorized to operate this device.

Full observation of these instructions is a requirement for the correct application an operation of the equipment and for the consequent safety of both patient and operator.

The instructions for use is valid as of February 2015.

## Indications

Cryo 6 cold air device is intended to minimize pain and thermal injury during laser and dermatological treatments and for the temporary topical anesthetic relief for injections.

## Contraindications

- hypersensitivity to cold
- areas of impaired sensation
- areas of impaired circulation
- open wounds
- ablative laser treatment
- frostbites
- Raynaud disease
- cryo-globulinemia
- cold agglutinin disease

## 2.1 General

Before the device is used on a patient, the user should become acquainted with the operating instructions and individual treatment methods as well as the indications / contraindications, warnings and application information. Additional sources of information about types of therapy should be consulted.

Prior to treatment, patients should be informed of the goals and effects of cold air therapy with Cryo 6.

Clearly advise the patient that the therapist must be immediately informed if discomfort, such as an extreme sense of heat or cold, occurs during the treatment. The operator should continue to inquire into the patient's comfort during the treatment. If necessary, the treatment parameters (air power level and distance to the treatment area) should be adjusted.

The airflow level and the distance between the treatment tube's handpiece and the treated area should be selected to maximize patient's comfort. During the treatment the patient has to be asked about his sensations. If necessary the treatment parameters (airflow and therapy distance) should be modified.

For temporary topical anesthetic relief for injections, the treated area should be cooled to a comfortable level for the patient. Prior to the injection, the treated area must be disinfected to avoid contamination.

When using the device in conjunction with a laser device, a distance of 5 cm for a treatment surface of 10 cm<sup>2</sup> is recommended. When treating larger areas, the distance should be increased accordingly. Longer treatments are required to achieve sufficient cooling.

Please be aware that the temperature of the air current can increase after longer treatments.

### 2.2 Cryotherapy



To treat larger areas, the distance from the nozzle to the skin should be increased, resulting in longer treatment times for adequate cooling.

At a distance of 5cm, the cooling spot covers app. 10cm<sup>2</sup>.

Hygienic gloves should be worn during the treatment.

Before treatment, the purpose and effect of cryotherapy using Cryo 6 should be explained to the patient.

Advise the patient to report any adverse reactions during treatment (e.g. extreme cold sensations) immediately to the practitioner.

Throughout the treatment, the practitioner should check the wellbeing of the patient by asking appropriate questions.

If necessary, adjust the treatment parameters (air flow rate, distance from treatment area).

For use in conjunction with laser equipment, a distance of 2 inches (5cm) is recommended for a treatment area of 4 square inches (10cm<sup>2</sup>). Larger areas should be treated using a correspondingly larger distance. In such cases, a longer treatment time is necessary to achieve the required cooling

- Caution!** The device may only be used by trained medical personal
- Caution!** After horizontal transport, let the device stand upright for at least 30 minutes prior to switching it on. The cooling aggregate might become damaged otherwise!
- Caution!** Do not install the device in the immediate vicinity of heat sources (heaters, hot mud heaters, saunas, etc.) and make sure it is at least 50 cm from the wall.  
When simultaneously using a laser device, the laser exhaust system must not negatively impact the Cryo 6 cooling system.
- Caution!** Unfavorable ambient conditions (e.g. ambient temperature above 86 F / 30°C and high humidity) may lead to a reduction in performance (reduced cooling capacity).
- Caution!** Before use, ensure that the device is powered via a properly earthed plug with a grounded outlet (electrical installation according to DIN VDE 0100 Part 710). The device must only be operated with the supplied power cord. The power cord must be protected against mechanical stress.
- Caution!** When in operation, the device must be positioned in such way that direct access to the power supply of the device is possible, so that it can be disconnected from the mains at any time.
- Caution!** Inspect the device prior to use. In case of damage, it must not be used.
- Caution!** Only accessories provided by Zimmer MedizinSysteme GmbH are to be used.
-  Magnetic and electric fields may affect the operation of the unit. Do not use Cryo 6 close to equipment that generates strong electromagnetic fields (e.g. X-ray or diathermy equipment or nuclear magnetic resonance tomography devices)
-  Dispose of the packaging material properly. Make sure that it is not accessible to children.
-  Cryo 6 is not suitable for use in areas with an explosive, flammable or combusive environment.
-  User of the device must be trained in how to use the device properly and have the appropriate skills
-  To avoid contamination with non-filtered air on open wounds, the Cryo 6 must not be used during or after injection.
-  To avoid freezer burns and over-cooling, the air stream should be directed evenly over the entire area to be treated. Static cooling, or overly intensive cooling, should be avoided.



Do not increase laser output power or energy when using Cryo6 for skin cooling.



Skin cooling may reduce effectiveness of some laser treatment on identical power output of the laser.



To avoid the risk of electric shock; the device must be disconnected from the mains by unplugging the power cord before performing any maintenance or cleaning activities.



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 authorized physicians, therapists and health paraprofessionals. It is imperative that these instructions are followed.



The use in wet areas is not permitted and may in case of non-compliance lead to considerable damage to the device and endanger both the patient and the user.



Eyes must be protected during cooling applications on the face.



Operating the device with settings/for uses other than those in the operating instructions can lead to risks due to uncontrolled effects of cold.



Children are at risk of extreme cooling. The body parts not undergoing treatment must be covered and kept warm. This is also recommended for adults undergoing long-term cooling.



If the temperature of the skin drops to 0° C or below, frostbite may occur. This can be happen if the distance from the nozzle to the skin is under 10 cm. If this distance cannot be maintained for therapeutic reasons, dynamically guiding the nozzle across the treatment area is recommended.



Do not push the device on the sides marked with warning symbols.



Do not lean against the device.

- What is the Cryo 6?** Cryo 6 is used for skin cooling in conjunction with dermatological laser treatments for alleviating pain and thermal damage to skin tissue.
- What does the Cryo 6 do?** Cryogenic air is blown onto the area of the body to be treated using an adjustable flow speed.
- What are the advantages of Cryo 6?** Its user-friendliness due to preset program parameters in conjunction with a capacity in continuous mode that is usually only achievable with significantly larger devices.
- What are other advantages of Cryo 6?** The clearly structured LCD display and the ergonomic keyboard stand for state-of-the-art technology.  
In addition to 6 user-oriented preset programs, 3 free programs and an internal start program enable customized treatment.
- How is the necessary cooling concentration achieved?** Depending on the surface and accessibility of the treatment area, the amount of air can be adjusted to nine levels.

*Notice:*

*The device is intended to be used exclusively by medical professionals (e.g. physicians, therapists, medical paraprofessionals).*



**Caution:**

Federal law restricts the device to sale by or on the order of a physician.

Cryo 6 cold air device is intended to minimize pain and thermal injury during laser and dermatological treatments and for the temporary topical anesthetic relief for injections.

## 6.1 Assembly

### Caution!

After horizontal transport or assembly, the Cryo 6 must stand upright for at least 30 minutes prior to being switched on.  
The compressor might otherwise be damaged.

### Connect the power cord

Connect the power cord to the socket (11) on the device and connect it to the mains.

### Notice:

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

### Switch on the device

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

### Switch off the device

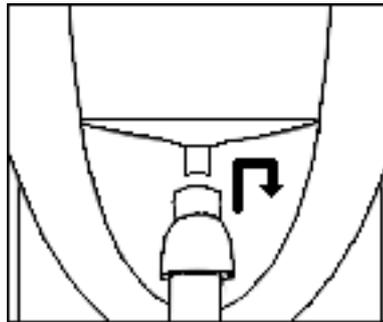
The device is switched off using the toggle switch (10).  
To completely disconnect the device from the mains (all poles), unplug the power cable.

### Caution!

All cables must be protected against getting clamped or other mechanical damage.

### Assemble the treatment tube

The treatment tube is inserted and locked into the connection piece (5) on the front of the device.



When not in use, the treatment tubes can be placed in the curved indent above the operating panel (3).

### Assemble the castor guards

The castor guards (2) are inserted into the castor holders.

### Assemble the glass plate

Four spacer bolts are already installed on the top of the device for installing the glass plate.

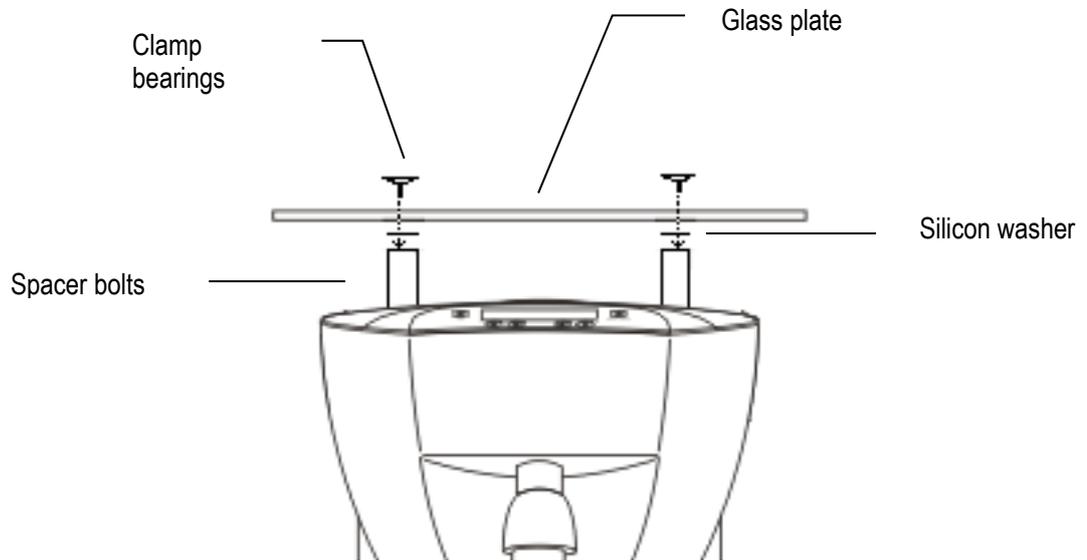
Place a silicon washer on each of the four spacer bolts.

Then place the glass plate on the spacer bolts.

Anchor the glass plate by screwing one of the provided clamp bearings into each of the 4 spacer bolts.

In order to not damage the glass plate, no tools are necessary.  
Tighten the clamp bearings by hand.

## 6.1 Assembly



To remove the glass plate, reverse these steps.

Do not lift the device by the glass plate.



*Notice:*

*The nozzles for the cold air discharge are attached to the therapy nozzle at the end of the tube.*

*The therapy nozzle and nozzle inserts can be stored in the toolbox.*

## 6.2 Assembling the Supporting Arm

### Supporting arm

The Cryo 6 device can be optionally equipped with a supporting arm. This arm allows a specific area of the body to be cooled without the therapist having to hold the tube.

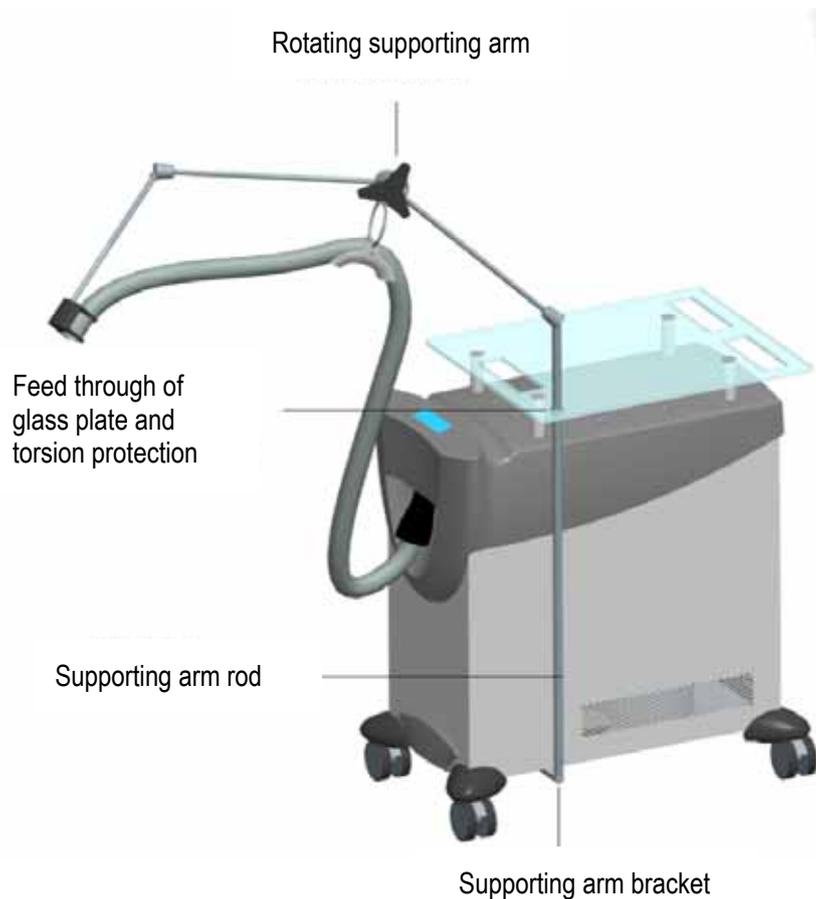
The supporting arm accessory set consists of:

- 1 supporting arm bracket
- 2 M6x16 screws and Allen wrench for tightening
- 1 torsion protection
- 1 supporting arm rod
- 1 rotating supporting arm
- 1 tube clip
- 1 tube bracket

in addition, the following are required

- glass plate
- insertion duct

### Picture of the assembled support arm



## 6.2 Assembling the Supporting Arm

### Assembly

In order to be able to assemble a support arm, the glass plate must be attached to the device (see 7.1 Assembly). The glass plate has an opening through which the support arm is guided.

### Notice:

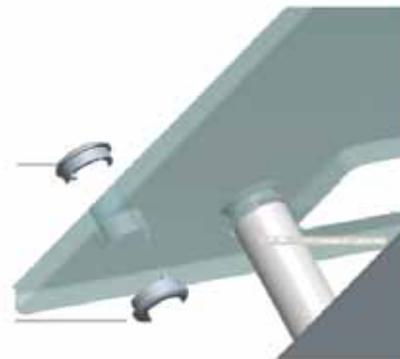
*The glass plate can be assembled symmetrically with the device. If a support arm is also installed, the glass plate is placed on the spacer bolts so the hole for positioning the support arm is on the desired side of the device.*

### Step 1 - Assemble the insertion duct

The insertion duct (included with the glass plate) is assembled in the provided hole.

Grommet  
Part 1

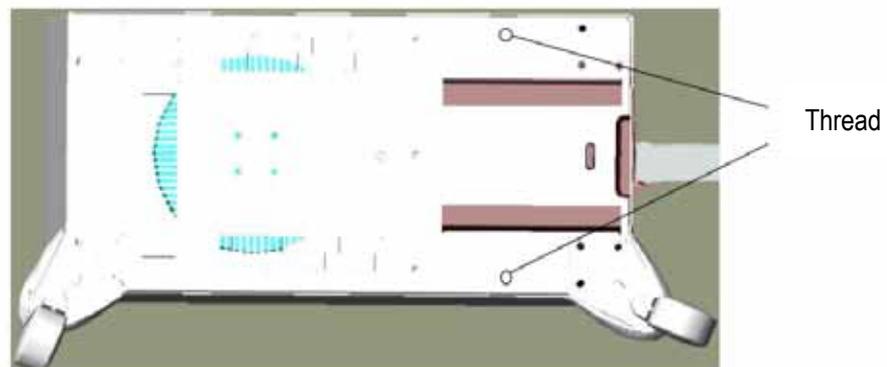
Grommet  
Part 2



### Step 2 - Assemble the support arm bracket

The mounting bracket is screwed to the bottom of the device using an Allen wrench and the M6x16 screws.

There are already threaded holes on the bottom of the device.



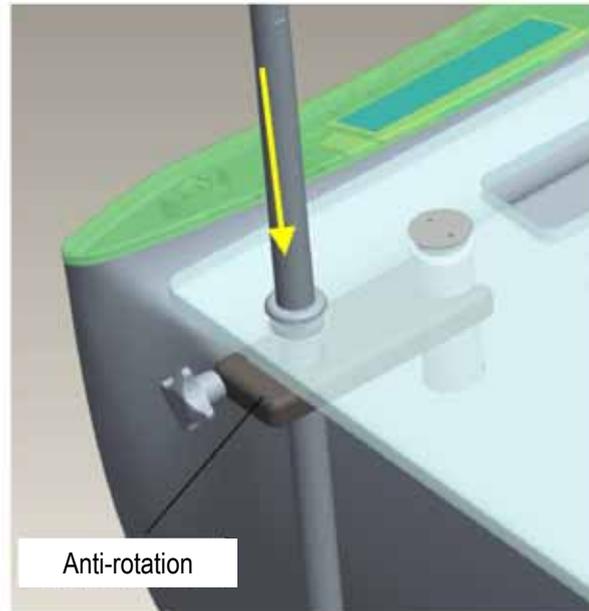
### Caution!

The illustration of the bottom of the device is only for a better view. Please do NOT lay the device down this way for assembly!

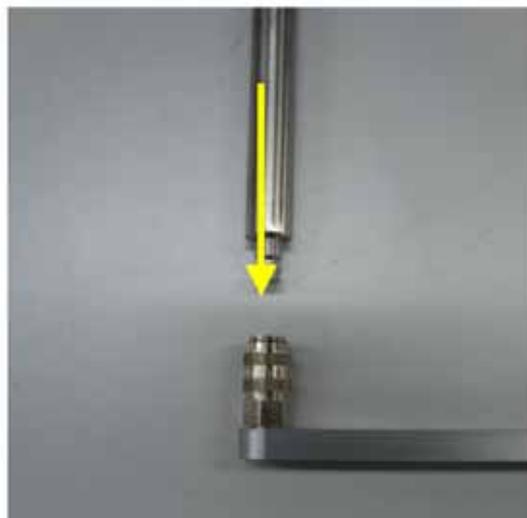
## 6.2 Assembling the Supporting Arm

### Step 3 – Attach the torsion protection and rod

The torsion protection is attached to the glass plate spacers as illustrated.



Then, the supporting arm rod is inserted from above through the insertion duct and torsion protection and locked into the supporting arm bracket.



## 6.2 Assembling the Supporting Arm

### Step 4 – Attach the supporting arm

The supporting arm is screwed to the assembled rod (a). To ensure that the supporting arm can move freely up / down, the notches must be adjusted. They must lie on an axis and allow the rod to move in the direction of the bend.



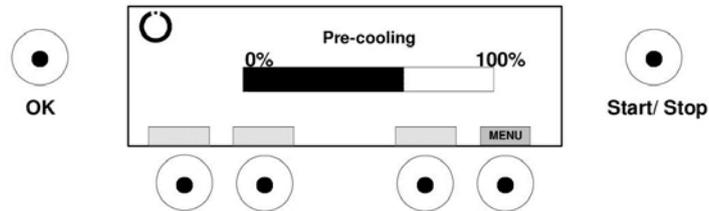
### Step 5 – Attach the tube clip / tube bracket

The tube clip is screwed to the supporting arm (b); the tube bracket is hung on the fixation screw on the supporting arm (c).

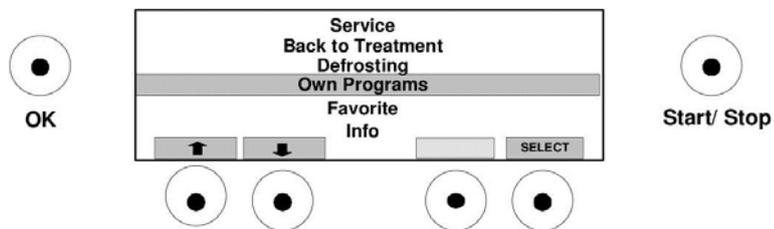
The treatment tube can now be guided over the tube bracket and the hand piece locked into the tube clip.

## 7.1 Device Menu

After being switched on, the Cryo 6 first performs a self-test. During the self-test and the subsequent pre-cooling of the device, changes can be made in the configuration menu.



To enter the menu, press the "Menu" key on the display during the self-test.



In the menu, technical information can be queried and factory default settings can be modified, a favorite program can be selected or own programs can be defined.

In total, 11 menu items are available:

- Service
- Back to treatment
- Defrost
- Own programs
- Favorite
- Info
- Automatic maintenance program S01
- Automatic maintenance program S02
- Cryo device type
- Device configuration
- Basic settings

Use the arrow keys (14 and 15) to navigate through the menu options.

Selecting the menu items

A menu item is selected using the "Select" key (17).

Exit menu

By selecting the menu option "Back to treatment" the menu will be closed and the treatment screen will be displayed.

## 7.2 Device Type and Device Configuration

**Device type** The Cryo 6 can be operated as "Cryo 6 Physio" and "Cryo 6 Derma".

Use the arrow keys (14 and 15) to navigate to the desired preset. Select the desired preset using the "Save" key.

**Device configuration** This menu point offers different settings options, e.g. the language or start sequence.

Use the arrow keys (14 and 15) to navigate through the sub-menu options. A menu option is selected using the "Select" key (17).

### Languages

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

*Notice:* The "External control input", "External control output" and "External start input" sub-menus are not active.

### Start sequence

The Cryo 6 offers two different options:

1. Direct start
2. Programs

Select the menu using the "Select" key.

Choose between direct start and programs using the "Change" key.

Save the desired start sequence using the "Save" key; this will be applied after confirmation by pressing the "Yes" key.

## 7.3 Basic Settings and Service

### Basic settings

In this menu option, the factory default settings can be restored.

By selecting the "YES" key, all modified parameters will be reset to the factory default settings.

Your own saved programs and the favorite program will not be affected.

If you select the "NO" key, the modified parameters will not be changed.

### Service

This area is password protected and is only accessible for trained Zimmer MedizinSysteme personnel.

Exit the menu using the "OK" key.

## 7.4 Defrosting

### Defrosting

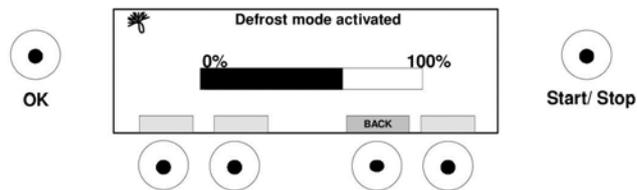
The defrosting process for the heat exchanger is activated under the "Defrost" menu item.

#### *Notice:*

*Defrost the device if the discharged air current is weaker than usual. The cause of this is often that the Cryo 6 is located in a humid environment (e.g. in balneotherapy suites, saunas). In addition, defrosting the Cryo 6 and emptying the water container is recommended if the device is not in use for a longer period of time (e.g. vacations periods).*

### Defrosting the device

When the defrost program is selected using the "Select" key, the defrosting process will start immediately. The defrosting process is executed in standby mode.



The therapy fan starts and runs until the cooling system reaches the defrost temperature. Then the fan switches off.

After the defrosting process is complete, the notification "Defrost complete" appears on the display.

Using the "Back" key, the defrosting process can be prematurely aborted.

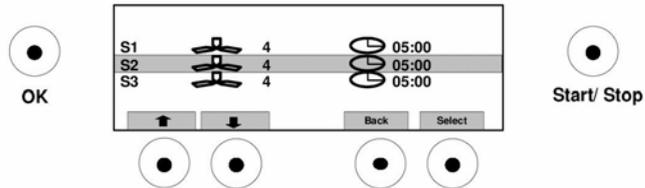
## 7.5 Own Programs and Favorites

*Notice:*

*Activating the menus in internal programs, programming 1 and 2-phase programs and the favorite program is only possible if "Programs" is activated as the start sequence (see chapter 7.2).*

### Own programs

In addition to the 6 factory default programs which cannot be permanently modified, the Cryo 6 offers storage options for 3 of your own therapy programs. The fan level and time can be individually assigned to a storage location. The programs can be programmed for both 1 phase and 2 consecutive phases.



### Programming a 1-phase program

Use the arrow keys (14 and 15) to navigate through the 3 storage locations. The desired storage program is selected using the "Select" key (17).

Then, the fan level can be selected using the arrow keys (15 and 16). The fan symbol (20) will blink.

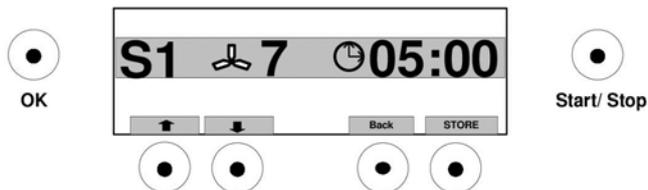
Save the fan level using the "Save" key.

The fan symbol will now be continuously displayed and the time symbol (22) will blink.

Use the arrow keys (14 and 15) to select the desired time.

Save the time using the "Save" key.

Pressing the "Back" key ends the programming of the 1-phase program. Exit the menu using the "Back" key.



### Programming a 2-phase program

Here, you have the option of letting 2 programs with different fan levels and times run consecutively during one treatment session.

Follow the first step for programming a 1-phase program. Instead of exiting the program using the "Back" key, the "Save" key is pressed again. The phase 1 parameters will now appear on the display in small print.

### Favorite

Here, you have the option of selecting from the 6 factory default programs P1 - P6 or a personal favorite program from your own special programs S1 - S3 to be automatically loaded every time the device starts up. Use the arrow keys (14 and 15) to navigate through the 3 program locations. Select the desired favorite program and confirm using the "Select" key.

## 7.6 Info and Maintenance Programs

**Info** Under this menu point, the technical information about different device components is displayed.

*Notice:* *No settings can be made.*

**Maintenance programs** The maintenance programs S01 and S02 simulate continuous operation and document the proper condition of the device. Potential faults are diagnosed and recorded.

**S01** This program simulates two 15 minute treatments and a defrosting process. During this, the program records the important parameters such as temperature and duration.

During the test, the current temperature of the compressor and the vaporizer can be checked.

**S02** The device cools to  $-43^{\circ}\text{C}$  /  $-38^{\circ}\text{C}$  and starts a 15 minute treatment at fan level 9.

This program is repeated until the "Stop/Start" key is pressed.

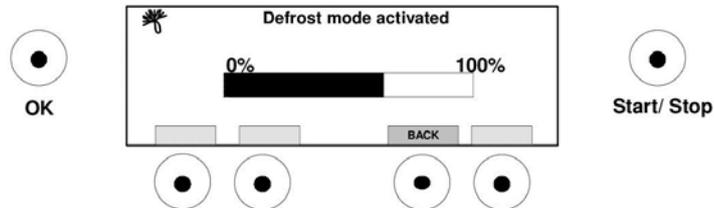
## 8.1 Device Description

|   |   |
|---|---|
| <b>Pre-cooling</b>                          | Once Cryo6 is turned on, the device starts to pre-cool to the minimum reachable temperature. During this phase, the compressor and the capacitor fan work together. In parallel, the device performs a self-test. During self-test or pre-cooling, no entries can be made on the display. Merely the "Menu" button (8) can be manipulated to reach the configuration menu. When the pre-cooling is sufficient, the display automatically returns to start screen. Cryo6 is now ready for use. |
| <b>Operation</b>                            | During therapy, the therapy fan blows cold air through the treatment tube. At the same time, the compressor / capacitor starts automatically during the treatment to ensure a constant cooling.   |
| <b>Stand-by mode</b>                        | If no therapy is performed, Cryo6 is in stand-by mode. In order to ensure that sufficient cool air can be provided at any time, the compressor starts automatically as soon as a certain temperature is exceeded. An immediate start of treatment is possible from the stand-by mode.   |
| <b>Recommendation for optimal treatment</b> | <p>Before starting treatment, a waiting time of about 10 min. is recommended after the precooling. This ensures that the device has reached its maximum cooling capacity.</p> <p>It is also recommended to turn off Cryo6 only for longer treatment breaks or at the end of the day.</p>  |

## 8.2 Performing Cold Treatment

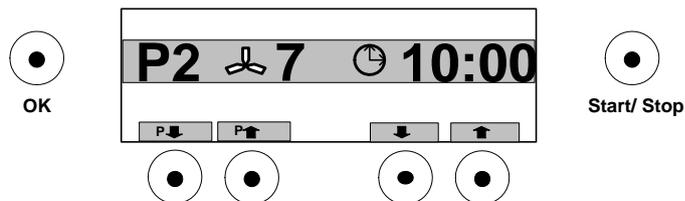
**Switch on the device** Switch the device on using the main switch (10); the display will illuminate.

**Initialization** During initialization, the current status can be seen on the display (self-test, pre-cooling).



*Notice:* Depending on the preset settings, Cryo 6 Physio or Cryo 6 Derma, the start screen or start sequence is represented differently as a factory default. Please see the next page for illustrations of the two start screens.

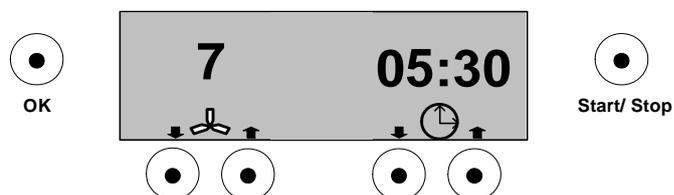
**Selection Program and therapy time** The device is operationally ready as soon as the therapy screen (here "Physio") appears.



Using the program selection keys (14 and 15), set the desired treatment program and using the timer keys (16 and 17), set the desired therapy time.

*Notice:* Prior to starting treatment, the fan level cannot be changed.

**Start of the treatment** The program is started by pressing the Start/Stop key (18). During treatment, the keys can be used to change fan level (14 and 15) and therapy time (16 and 17).



*Notice:* If parameters are changed during treatment, after the treatment, the system will restore the factory default settings or, if a favorite program is stored, the favorite program settings will be restored.

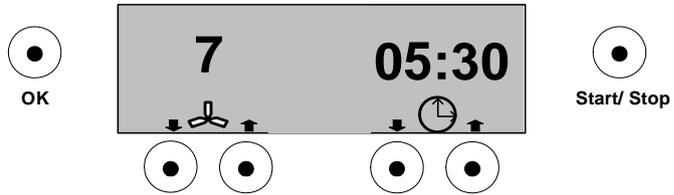
**End of the treatment** An acoustic signal indicates the end of treatment and the fan is automatically shut off. This also applies when prematurely aborting treatment using the "Start / Stop" key (18).

## 8.3 Start Screens

### Start screens

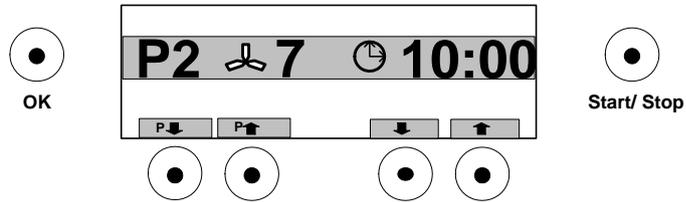
As a factory default, the start screens or start sequence are set differently for the Physio and Derma designs.

#### Start screen Derma / direct start



Direct start    Direct selection option for fan level and time.

#### Start screen Physio / programs



Programs:    Directly select between different preset programs and the use of interval programs.

**Notice:**

*In the device "Device configuration" menu, the desired start sequence can be set as desired. The settings procedure is described in Chapter 7.*

## 8.4 Default Parameters / Changes

- Preset parameters** Each unit leaves the manufacturer with a set of standard parameters preset. These may be restored at any time by selecting the “Basic Settings” function (see chapter 7.3).
- Adjustments to preset parameters** Cryo 6 allows the airflow and treatment time to be adapted to suit specific requirements and for the new values to be saved in the unit’s memory (see chapter 7 and 8).
1. Air flow rate: The treatment fan can be adjusted through nine levels.
  2. Treatment time: Treatment time may be set from 00:00 and 99:59 minutes.

|                                 |   |
|---------------------------------|---|
| Power supply                    | 100 - 120 V / 50 Hz / 60 Hz (9 – 11 A)  |
| Power Consumption               | standby: 2A<br>maximum: 9-11A   |
| Mains fuse                      | 16 A circuit breaker in power on/of switch  |
| Protection class                | I   |
| Applied part                    | Type B  |
| Dimensions                      | H 645 mm x W 390 mm x D 680 mm  |
| Weight                          | 60 kg   |
| Castor diameter                 | 75 mm   |
| maximum load on the glass plate | Devices (e.g. (lasers) with a maximum weight of 35kg and a maximum size of 50x50x35cm (WxDxH) can be placed on the glass plate. |
| Operation                       | +10°C to +35°C, 20 % to 80 % relative humidity without condensation at 700 to 1060 hPa  |
| Transport                       | -10°C to +50°C, 10 % to 90 % relative humidity without condensation at 600 to 1060 hPa  |
| Storage                         | -0°C to +40°C, 10 % to 90 % relative humidity without condensation at 600 to 1060 hPa   |

*Notice: Storage and transport only in original packaging.*

|  |                           |                                    |
|--|---------------------------|------------------------------------|
| Evaporation temperature                                    | minimum (standby)         | -38°C                              |
|  | maximum (standby)         | -25°C                              |
|  | maximum (operating)       | -22°C                              |
| Air outlet temperature<br>(ambient temperature up to 25°C) | average                   | - 25°C                             |
|  | at the start of treatment | - 31°C                             |
|  | maximum                   | - 18°C (after 15 min of treatment) |

Accuracy of the values +/- 10 %

max. therapy time setting 99:59 min

**Subject to technical modifications!**



- Before starting any maintenance and cleaning measures the device must always be turned off at the main switch and unplugged.
- 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 unit out of service, protect it from getting used again and contact your service representative.
- Make sure that when cleaning and disinfecting the labels of the device (such as warnings, labels of control devices, identification plate) are not damaged.
- The device and its applied part are considered non-critical in relation to hygiene when used on non-injured and healthy skin.

## Housing / Accessories

**Cleaning:** In the event of visible contamination, the housing, all cables and accessories can be cleaned using commercially available soft 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.

**Disinfection:** We recommend that disinfection be carried out at least once a week, as well as in the event of evidence of possible contamination. Consult with your health professional when doing so. Always perform cleaning prior to disinfection.

Housing, cables and accessories can be disinfected using disinfectant wipes. To do so, 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 cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or use pre-impregnated disinfectant wipes (so-called wipes).

If applicable, also observe requirements for drying or post-cleaning.

## Container for defrosted water

**Cleaning:** The container for defrosted water (7) should be cleaned after each draining of condensed water.

Proceed as indicated under "Housing / Accessories".

## Caution!

The device may only be operated with the container for defrosted water installed.

## Air filter

The air filter (9) should be cleaned regularly, however, after no later than 200 operating hours (maintenance notice appears on the display).

To do this, the air filter is vacuumed from outside using a conventional vacuum cleaner.

## Notice:

*Only use the device in a hygienic environment.*

The device bears the following UL Mark:



CLASSIFIED BY UNDERWRITERS LABORATORIES INC.  
WITH RESPECT TO ELECTRIC SHOCK, FIRE,  
MECHANICAL HAZARDS ONLY  
IN ACCORDANCE WITH UL 60601-1 AND CAN/CSA C22.2 NO. 601.1  
1KD1

### Scope of delivery

- 1 Neo light treatment tube
- 1 Instructions for use
- 1 Container for defrosted water

### Accessories

- Container for defrosted water
- Neo light treatment tube
- Castor  $\varnothing$ 75 mm

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

**Subject to change!**

The Cryo 6 can be used in combination with several laser devices. Please follow the operating instructions of the laser manufacturer.

Anyone who combines devices and thus operates a medical system does so at its own risk.

When combining devices please observe the requirements of the standard IEC 60601-1.

## 14.1 Safety

The Cryo 6 is manufactured in accordance with the safety regulations of DIN EN / IEC 60601-1.

Zimmer MedizinSysteme GmbH, as the manufacturer, can only be considered liable for the safety and reliability of the device if

- the device is operated using a proper power outlet that is properly grounded and the electrical installation complies with DIN VDE 0100 Section 710,
- the device is operated in compliance with the instructions for use,
- extensions, readjustments or modifications are only carried out by persons authorized by Zimmer MedizinSysteme GmbH ,
- the user is satisfied regarding the functional safety, the proper condition and mechanical integrity prior to using of the device, the device is only operated by properly trained personnel,
- the device is not operated in hazardous areas and / or combustible atmospheres,
- the device is immediately disconnected from the mains in the event of the penetration of liquids.

The device does not contain any user serviceable parts, with exception of the air filter and the container for defrosted water (see chapter 14.2).

**Cleaning the air filter** In order to clean the treatment air and necessary cooling air from dust particles, a filter element (9) is located on the rear of the device. Under normal use it is sufficient to clean the filter regularly by vacuuming the entire surface of the outer area using a commercial household vacuum cleaner, at the latest, when the software displays a corresponding request notification after 200 operating hours. In carpeted rooms or rooms in which other circumstances lead to increased dust generation, more frequently cleaning the filter element is recommended.

*Notice:* After cleaning the air filter, the notification from the software must be confirmed by pressing the "OK" key.

**Emptying the container for defrosted water** If the Cryo 6 is switched off after use or the defrost program is started, the cooling system heats up and generates condensate. The one liter container for defrosted water can be removed for draining by pulling it out of the device. The container must be put back into the device. Please also comply with the specifications for cleaning and disinfecting (Chapter 10).

### Functional test

After switching on the Cryo 6, it performs a self-test and checks the functionality of the technical components.

A functional test of the cooling equipment can be performed by the user as described below:

1. Switch the device on.
2. Wait until the device is operationally ready.  
This has been achieved when the device displays the program selection menu / direct start menu.
3. Start the Cryo 6 using the "Start / Stop" key (18).
4. Select the various air flow levels and check the air flow rate and the cooling achieved.

Mains fuse triggers

To protect the device from supply problems, the Cryo 6 is equipped with a 2-pole overload fuse integrated into the main switch (10). If the fuse is triggered, the device automatically switches off via the toggle switch (10). To restart the device, it must be switched back on using the toggle switch (10).

If the fault occurs frequently and successively, please notify customer service.

Decreased cooling capacity / reduced cooling capacity

If the cooling capacity decreases and the air current is significantly reduced, a polluted defrost drain (8) may be the cause. Dust particles collect in the heat exchanger through the treatment air. After a long time, these can clog the defrost drain and can lead to the condensate backing up.

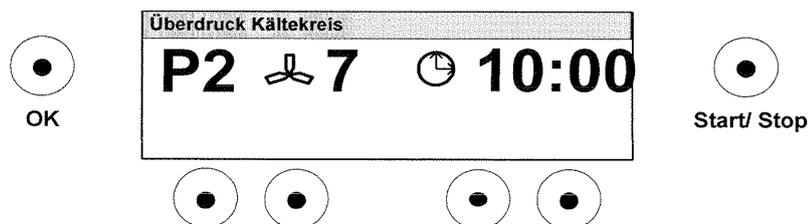
The defrost drain is above the container for defrosted water. To clean the defrost drain; the device has to be defrosted (see chapter 7 "Defrosting"). After defrosting, switch the device off and unplug the power supply from the outlet.

Remove the container for defrosted water and place a flat container beneath the device to collect the condensate. Slowly unscrew the defrost drain. Clean the defrost drain under running water and screw it back in.

Error Messages

When switching on the device and sometimes during ongoing operation, device components important for the program sequence are tested. If an error is determined, the treatment will be canceled, a fault notification appears in the top line of the display and an acoustic signal will sound.

The error message appears in clear text in the top line of the display. If treatment is no longer possible, the device can only be switched off.



Faults that do not impact further operation of the device can be repaired by switching the device off, waiting five seconds and switching it back on.

To remove fault notifications for overheating or excess pressure, the device should only be switched on after 30 minutes because the device requires time to cool down. The external and ambient temperatures, which impact the cooling capacity, can be the cause for this.

If the fault occurs frequently and successively, please notify customer service. You can reach customer service through your assigned field technician or the central office in Neu-Ulm.

For other functional faults, please contact the service department.

**Service department /  
Distributor**

Zimmer MedizinSystems  
25 Mauchly, Suite 300  
Irvine, CA. 92618  
800 327 3576  
949 727 2154 fax  
[www.zimmerusa.com](http://www.zimmerusa.com)  
[info@zimmerusa.com](mailto:info@zimmerusa.com)

**Manufacturer**

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Fax: +49 (0)731 / 9761-299  
[www.zimmer.de](http://www.zimmer.de)  
[export@zimmer.de](mailto:export@zimmer.de)

**Disposal**

Please observe the national regulations regarding disposal. Contact your distributor if necessary.

With regards to the EMC (electromagnetic compatibility), medical electrical devices such as the Cryo 6 are subject to special safety measures and must be installed and commissioned in accordance with the EMC instructions in the operating instructions or accompanying documents.

Portable and mobile HF communications equipment (e.g. mobile telephones, cell phones) can impact medical electrical devices.

The Cryo 6 may only be operated using the original power cable indicated in the scope of delivery list. Operating the device with another power cable can lead to increased emissions or reduced interference resistance of the device!

| Guidelines and manufacturer declaration - electromagnetic emitted interference  |                |   |
|---|----------------|---|
| The Cryo 6 device is intended for operation in an electromagnetic environment as indicated below. The Cryo 6 customer or user should ensure that it is operated in such an environment. |                |   |
| Emitted interference  | Compliance     | Electromagnetic environment - guideline   |
| HF emissions in accordance with CISPR 11  | Group 1        | The Cryo 6 device uses HF energy solely for its internal function. Therefore, its HF emissions are very low and it is improbable that it will interfere with neighboring electronic devices.                    |
| HF emissions in accordance with CISPR 11  | Class B        | The Cryo 6 device is suitable for use in all facilities, including residential spaces and areas directly connected to the public power supply grid which also supplies buildings used for residential purposes. |
| Harmonic emissions in accordance with IEC 61000-3-2   | Class A        |   |
| Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3   | not applicable |   |

The device must not be used directly next to or stacked on/under other devices. If operation near or stacked on/under other devices is necessary, the device should be observed to check for proper operation in this setup.

| Guidelines and manufacturer declaration - electromagnetic interference resistance   |  |  |   |
|---|--|--|---|
| The Cryo 6 device is intended for operation in the electromagnetic environment indicated below. The Cryo 6 customer or user should ensure that it is used in such an environment. |  |  |   |
| Interference resistance tests   | IEC 60601-Test level   | Compliance level   | Electromagnetic environment - guidelines  |
| Static electricity discharge (SED) in accordance with IEC 61000-4-2   | ± 6 kV contact discharge<br>± 8 kV air discharge   | ± 6 kV contact discharge<br>± 8 kV air discharge   | Floors should be made of wood or concrete or covered in ceramic tiles. If the floor is made of synthetic material, the relative humidity must be at least 30%.  |
| Rapid, transient electrical disturbance variables/bursts in accordance with IEC 61000-4-4   | ± 2 kV for mains cables<br>± 1 kV for input and output cables  | ± 2 kV for mains cables<br>± 1 kV for input and output cables  | The quality of the supply voltage should correspond with a typical business or hospital environment.  |
| Surges in accordance with IEC 6100-4-5  | ± 1 kV differential mode voltage<br>± 2 kV common mode voltage   | ± 1 kV differential mode voltage<br>± 2 kV common mode voltage   | The quality of the supply voltage should correspond with a typical business or hospital environment.  |
| Drops in voltage, temporary interruptions and fluctuations in the supply voltage in accordance with IEC 61000-4-11  | <5% $U_T$ (>95% drop in the $U_T$ for ½ period)<br>40% $U_T$ (60% drop in the $U_T$ for 5 periods)<br>70% $U_T$ (30% drop in the $U_T$ for 25 periods)<br><5% $U_T$ (>95% drop in the $U_T$ for 5 seconds) | <5% $U_T$ (>95% drop in the $U_T$ for ½ period)<br>40% $U_T$ (60% drop in the $U_T$ for 5 periods)<br>70% $U_T$ (30% drop in the $U_T$ for 25 periods)<br><5% $U_T$ (>95% drop in the $U_T$ for 5 seconds) | The quality of the supply should correspond with a typical business or hospital environment. If the Cryo 6 user requires continuous functionality even if there are interruptions in the power supply, powering the Cryo 6 using an uninterrupted power supply or battery is recommended. |
| Magnetic field at the supply frequency (50/60 Hz) in accordance   | 3 A/m  | 3 A/m  | Magnetic fields at the mains frequency should correspond with the typical values found in business or hospital environments.  |

|   |  |  |  |
|---|--|--|--|
| with IEC 61000-4-8  |  |  |  |
| Remark: $U_T$ is the mains AC voltage prior to applying the test level. |  |  |  |

Significant performance specifications of the Cryo 6 include: fault-free discharge of cold air, fault-free operation of all functions.

| Guidelines and manufacturer declaration - electromagnetic interference resistance  |   |   |  |
|--|---|---|--|
| The Cryo 6 device is intended for operation in the electromagnetic environment indicated below. The Cryo 6 customer or user should ensure that it is used in such an environment.  |   |   |  |
| Interference resistance tests  | IEC 60601 test level  | Compliance level  | Electromagnetic environment - guidelines   |
| <p>Conducted HF interference variables in accordance with IEC 61000-4-6</p> <p>Radiated HF interference variables in accordance with IEC 61000-4-3</p>   | <p>3 V<sub>Effective value</sub><br/>150 KHz to 80 MHz</p> <p>3 V/m<br/>80 MHz to 2.5 GHz</p> | <p>3 V<sub>Effective value</sub><br/>150 KHz to 80 MHz</p> <p>3 V/m<br/>80 MHz to 2.5 GHz</p> | <p>Portable and mobile radio devices, including the cables, should not be used at distances to the Cryo 6 less than the recommended safety distance which is calculated based on the applicable equation for the transmission frequency.</p> <p>Recommended safety distance:</p> <p><math>d = 1.17 \sqrt{P}</math></p> <p><math>d = 1.17 \sqrt{P}</math> for 80MHz to 800 MHz</p> <p><math>d = 2.33 \sqrt{P}</math> for 800 MHz to 2.5 GHz</p> <p>with P as the nominal output of the transmitter in watt (W) in accordance with the specifications of the transmitter manufacturer and d as the recommended safety distance in meters (m).</p> <p>The field strength of stationary radio transmitters should be lower than the compliance level<sup>b</sup> at all frequencies in accordance with an on-site test<sup>a</sup>.</p> <p>Interference is possible from nearby devices with the following symbol:</p>  |
| <p>NOTE 1 At 80 Hz and 800 MHz the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not be applicable in all cases. The expansion of electromagnetic variables is influenced by absorptions and reflections in the building, objects and people.</p> |   |   |  |

- a The field strength of stationary transmitters such as base stations for portable telephones and mobile land radios, wireless keyboard stations, AM and FM radios and televisions cannot be accurately theoretically predetermined. To determine the electromagnetic environment with regards to the stationary transmitters, a study of the electromagnetic phenomena of the location should be considered. If the measured field strength at the location in which the Cryo 6 device will be used exceeds the compliance level, the Cryo 6 device should be observed to verify proper functionality. If unusual performance characteristics are observed, additional measures may be required, e.g. modified layout or a different location for the Cryo 6 device.
- b Above the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

| Recommended safety distances between portable and mobile HF telecommunications devices and the Cryo 6 device   |   |   |  |
|--|---|---|--|
| The Cryo 6 device is intended for operation in an electromagnetic environment in which the HF interference variables are controlled. The Cryo 6 device customer or user can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunications devices (transmitters) and the Cryo 6 device, depending on the output capacity of the communications device, as specified below.   |   |   |  |
| Nominal output of the transmitter<br>W   | Safety distance based on the transmitter frequency<br>m |   |  |
|  | 150 kHz to 80 MHz<br>$d= 1,17 \sqrt{P}$                 | 80 MHz to 800 MHz<br>$d= 1.17 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d= 2.33 \sqrt{P}$ |
| 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 with a maximum nominal output not indicated in the table above, the recommended safety distance d in meters (m) can be determined using the equation in the respective column, where P is the maximum nominal output of the transmitter in watt (W) in accordance with the specification from the transmitter manufacturer.<br>NOTE 1 At 80 MHz and 800 MHz the higher frequency range applies.<br>NOTE 2 These guidelines may not be applicable in all cases. The expansion of electromagnetic variables is influenced by absorptions and reflections in the building, objects and people. |   |   |  |

# Cryo 6

## Instructions for Use

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