Zimmer MedizinSystems

Instructions for Use

Cryo 7

USA

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Detailed description – defrost container

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Fig. 2 Detailed description – defrost container

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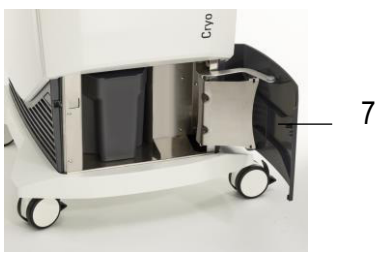
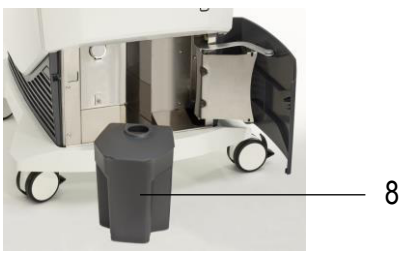
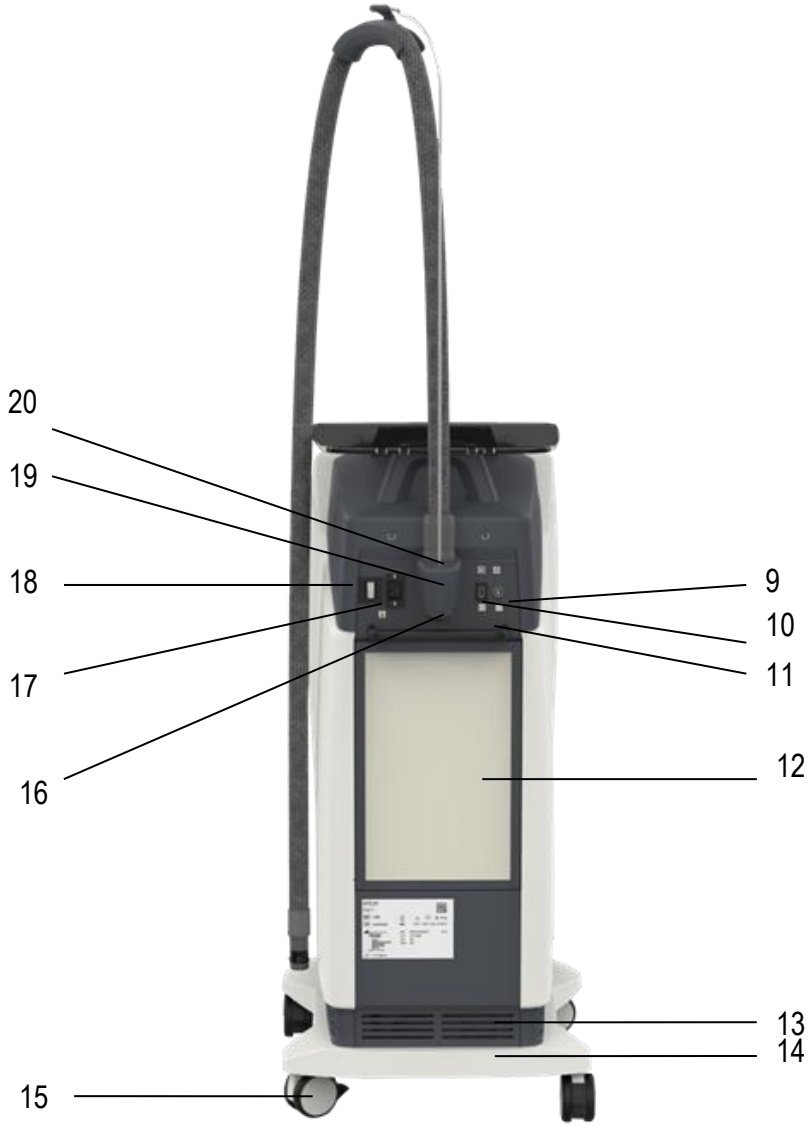




Figures

Rear of the device

Fig. 3 Rear of the device



9	RS232 connection port for data communication with medical technology devices
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Fig. 4 Detailed description **Air outlet with magnetic connection / Connection port for Cryo 7 therapy hose spring arm / Locking lever**

21	Air outlet with magnetic connection and treatment tube connection
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Figures

Accessories

Fig. 5 Accessories

24 Cryo 7 Therapy Hose 2.5m

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26 Cryo 7 Air filter

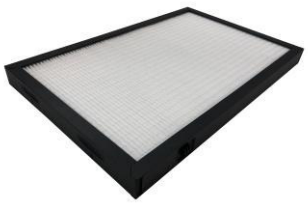
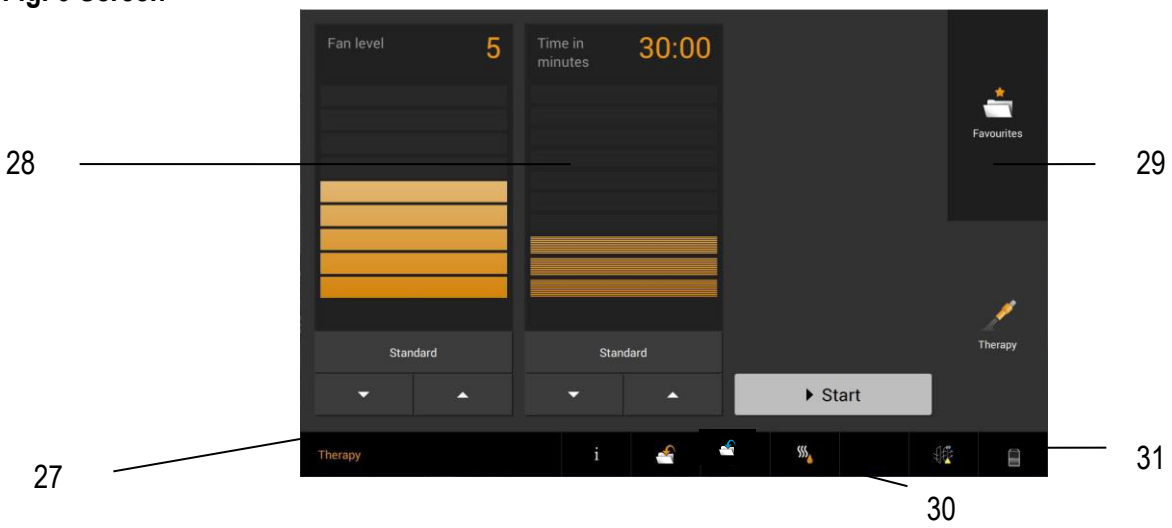


Fig. 6 Screen



Display views

27 Status bar
28 Buttons on the screen
29 Buttons in the navigation menu
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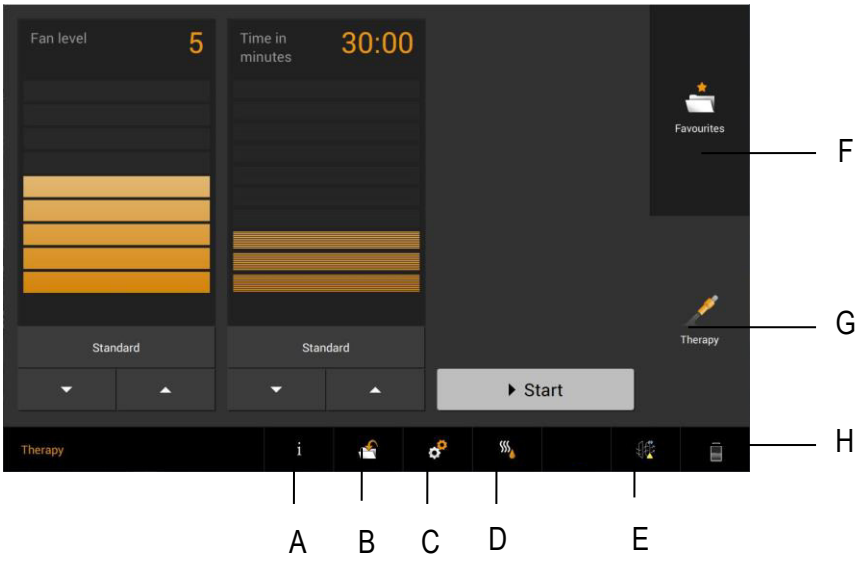
31 Fill level of defrost container; when defrost container is full, the icon switches to “Empty defrost container” (see Fig. 7 (I))

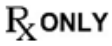
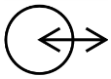
Fig. 7 Screen



Navigation bar/ Status bar
Function description

(A) Switches to the general information area
(B) Switches to the Memory area to save Favourites
(C) Switches to the Configuration area
(D) Starts the defrosting process
(E) Indication of dirt on air filter (only active in the case of dirt on the filter or if a filter change is needed – in this case, “Change needed” icon)
(F) Switches to the Favourites area
(G) Switches to the therapy screen
(H) Empty defrost container

Explanation of symbols

No.	Symbol	Description
1		In the United States of America, federal law restricts this device to sale by or on the order of a physician.
2		Medical device
3		This symbol indicates “Caution” with regard to possible material damage.
4		This symbol indicates “Danger” with regard to possible risks to people.
5		Follow instructions for use.
6		Instructions for use
7		Serial number
8		Article number
9		Manufacturer
10		Date of manufacture
11		RS232 interface
12		USB interface
13		Do not push
14		Maximum load of the shelf plate (35 kg)
15		Off (power supply)

Explanation of symbols

No.	Symbol	Description
16		On (power supply)
17		Disposal of electrical and electronic devices as well as used disposable and rechargeable batteries. Products which are marked with the adjacent symbol may not be discarded with household waste.
18		Do not stack
19		Protect from moisture
20		Transport upright
21		Fragile
22		Temperature limits
23		Air humidity limit
24		Air pressure limit
25		The UDI “Unique Device Identifier” is assigned for unique device identification and traceability.

Contents

Contents

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 2021.

If the instructions for use have become illegible, damaged, or are not accessible for the user for other reasons, a replacement is to be requested from the manufacturer for the safe use of Cryo 7 and made available to the user. This also includes the information on the labels on the device.
The instructions for use can also be downloaded from our website.

We reserve the right to revise this document at any time or change product specifications described. There is no obligation to provide information about the changes to the customer.

℞ ONLY In the United States of America, federal law restricts this device to sale by or on the order of a physician.

Intended use

1

1.1 Indications / Contraindications

Indications

Cryo 7 is indicated to be used to:

Minimize pain and thermal injury during laser and dermatological treatments and for 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-globulinema
- Cold agglutinin disease
- Systematic lupus erythematosus
- Vascular inflammation
- Allergies or hives
- Bronchospasm caused by the cold
- Acrocyanosis
- Sickle cell anaemia
- Circulation disorders of the skin
- Paroxysmal cold haemoglobinuria
- Cardiac arrhythmias
- Symptomatic cardiovascular or pulmonary diseases
- Uncontrolled hypertension
- Advanced diabetes mellitus
- Cutaneous hypoesthesia
- Scleroderma
- Spinal cord injury

Side effects Transient skin irritation due to the cold, especially in sensitive patients.

Intended purpose Cold air therapy devices are intended to minimize pain and thermal injury during laser and dermatological treatments and for the temporary topical anesthetic relief for injections.

Target patient group

Age	Age 3 years and over
Sex	No limitations
Potential patient group	The patients must be able to perceive pain and communicate. Patients who have at least one of the contraindications listed may not be treated.
Weight	No limitations

User Cold air therapy devices are intended exclusively for medical professionals, such as authorised physicians, therapists, and medical paraprofessionals. Cold air therapy devices are not intended for use by laypersons or in home care.
State of health: The user may not have any visual, hearing or colour vision impairment which interferes with safe device operation and use.

Residual risks: If the device is used within its intended purpose, no other residual risks are known besides the side effects and the warnings already mentioned

Anticipated clinical efficiency: Pain reduction through pain-relieving cold air therapy.

Application information and warnings

Do not place the device in the vicinity of heat sources (heater, hot medicinal mud products, sauna, etc.) and leave a distance of at least 50 cm between the device and a wall (to enable the supply of cool air).

If used in combination with a laser device, the laser ventilation system should not impair the cooling of the cold air therapy device.

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.

Children's body parts which are not being treated should be covered and kept warm. This is also recommended for adults who are undergoing longer cooling.

Treatment instructions regarding treatment location, duration and scope require medical knowledge and should only be given by authorised physicians, therapists and medical paraprofessionals. These instructions are mandatory.

During skin cooling with the cold air therapy device in combination with laser applications, the laser output may not be increased beyond the degree recommended by the manufacturer.

Frostbite can occur if the skin temperature falls to 0°C or below. This can happen if the nozzle is less than 10 cm from the skin. If it is not possible for therapeutic reasons to maintain this distance, it is recommended to move the nozzle dynamically over the area to be treated. An application in direct contact with the air outlet may not be performed.

The patient must not be left unattended during the therapy. The user must take note of the patient's feedback and react accordingly.

The user must ventilate the treatment room at the start and end of a workday. In rooms with a high level of air humidity, we recommend purging the treatment tube 3 minutes before the treatment at fan level 3 and not aiming it directly at the area to be treated.

The cold air therapy device should not be used in hygienically critical medical areas such as operating rooms, intensive care units or emergency departments.

Use in wet areas is not permissible and, in case of non-compliance, may lead to considerable damage and endanger both the patient and the user.

If the cold air stream reaches open wounds or comes into contact with skin compromised by the treatment, disinfection and, if applicable, wound care (bandage, wound dressing, etc.) must be performed in any case after the treatment is completed.

Dispose of the packaging material properly. Ensure that it is stored out of the reach of children.

During the application of cold to the face, the eyes and mucous membranes must be protected in general.

Do not switch Cryo 7 on and then immediately switch it off. Doing so could damage Cryo 7.

If the user identifies a potential safety problem or operating anomaly during use, the treatment must be immediately discontinued and the manufacturer must be contacted.

To transport over thresholds, Cryo 7 must be moved over a threshold backwards by lifting it at the handle.

After transport or storage on its side, Cryo 7 must be brought to an upright position and kept in an upright position for at least 30 minutes before it is switched on. Otherwise the compressor will be damaged.

Before use, ensure that Cryo 7 is supplied with power via a properly grounded power outlet. Cryo 7 may only be operated with the supplied power cable. The power cable must be protected against mechanical stress.

Magnetic and electrical fields can impair the function of the device. For this reason, do not operate Cryo 7 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.

Cryo 7 is not suitable for use in areas with an explosive, flammable or combustive atmosphere.

During use, Cryo 7 should be set up such that direct access to the central mains power of the device is possible and it can be disconnected from the mains at any time.

To avoid the risk of electric shock, the mains plug must be disconnected from the power supply before performing cleaning or maintenance work.

Check Cryo 7 before use. If it has any damage, it should not be used.

Only accessories provided by Zimmer MedizinSysteme GmbH should be used.

Objects must be placed in the centre of the shelf plate. Observe the maximum load! Do not place any liquids on the shelf plate.

Pushing Cryo 7 at the sides labelled with corresponding warnings is not permitted. Do not lean on the device.

Only USB sticks may be inserted in the USB port. It is prohibited to draw operating voltage for small devices or connect devices with an external power supply.

Cryo 7 performance features

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What is new?

The use of the latest technology to provide cold air.

Space-saving thanks to a slim housing type in a new design.
Ergonomic operation.

High-resolution display with touch operation.

All keys, menus and sub-menus, as well as buttons can be activated directly on the touch screen with finger pressure.

Swipe and drag function on the touch screen to select your user preferences with regard to fan level and therapy time.

The new, flexible spring arm assists and supports the user during therapy.

Energy-saving mode through standby operation.

Important notes

After transport/assembly or repair, Cryo 7 must be placed in and kept in an upright position for at least 30 minutes before being switched on. If Cryo 7 is switched on before the 30 minutes have elapsed, the compressor can become damaged.
The mains plug may be inserted only in a power outlet with a protective contact.

Removal from the packaging

Cryo 7 can be removed from the packaging by the user on site.

Cryo 7 is delivered in a box on a wooden pallet.
The device and accessories are housed in the box.
Open the box by lifting the lid.
To facilitate removing the device from the packaging, you can fold the lid of the box into a ramp.
You can roll Cryo 7 off the pallet using the ramp.

Converting the lid into a ramp

Follow the conversion instructions enclosed with the box or follow the conversion instructions in our YouTube video. To do this, scan the QR code (on the side of the lid of the Cryo 7 box) using your smartphone.
Remove the accessories box at the rear of Cryo 7.
Remove the white plastic protective inlay.
Lift the box upwards off the pallet.
Ensure that there is adequate space above the pallet and that there is nothing above the box which could be damaged.
Remove accessories box 2.
Attach the ramp (converted lid) to the pallet.
Release the brakes on the castors of Cryo 7. Roll the device out slowly and carefully.
It is important to support the device.

Risk of tipping!

Reassemble the box, following the steps in reverse order.
Keep the box.

Set-up

There is a handle (11) on the back of Cryo 7.
You can use this handle to push Cryo 7 and move it to its destination.

Assembly of the Cryo 7 therapy hose 2.5m

Mount the Cryo 7 therapy hose with the magnetic components at the air outlet (note the orientation relative to the indentation) at the rear of the device (19).
The Cryo 7 therapy hose is secured using the magnetic components on the air outlet.

Assembly of the Cryo 7 therapy hose spring arm

Insert the Cryo 7 therapy hose spring arm in the intended hole which is located at the top of the air outlet (20).
The Cryo 7 therapy hose spring arm holds the Cryo 7 therapy hose and assists the user by supporting the weight of the Cryo 7 therapy hose.

Assembly of the Cryo 7 therapy hose in the Cryo 7 therapy hose spring arm

Place the Cryo 7 therapy hose in the guide of the Cryo 7 therapy hose spring arm

Dismantling the Cryo 7 therapy hose

Remove the Cryo 7 therapy hose from the guide of the Cryo 7 therapy hose spring arm.
Remove the Cryo 7 therapy hose spring arm from the air outlet. Hold the Cryo 7 therapy hose on the device end at the plastic sleeve. Tilt the hose towards the left or right by pressing firmly with your thumbs and pull it out at an oblique angle.
Due to the strength of the magnets, a certain amount of resistance must be overcome.

All application parts which can come into contact with the patient must be cleaned before initial use and before the first patient contact in order to remove residues from production and packaging. No part of the device may be in the immediate vicinity of the patient since this is a contactless application.

AC mains connection

Guide the power cable under the handle.
Connect the power cable to the provided port on the device (17) and connect the cable to the mains.

Start-up

Switch on the device using the power switch (18).
After it is switched on, Cryo 7 performs a one-time initial set-up.
You are guided through a brief menu with the following questions:

1. Language selection
2. Temperature display selection

If you would like to make an entry, activate the desired button.

If you would like to enter distributor information
1. Distributor name,
2. Distributor telephone,
3. Distributor email

activate the desired button and enter the information using the keypad.

Activating the “Continue” button leads to the next screen page and activating the “Back” button leads to the previous screen page.
The “Continue” button jumps to the next screen page.
Swiping left or right on the screen is also possible and leads to the previous or next screen page.

The data in the initial set-up are accepted by activating the “Save” button.

Thereafter Cryo 7 switches to the “Precooling” cooling phase. The cooling phase is represented by an active bar display.
As long as the cooling phase is running and the bar display is active, no button entries can be made. If the cooling phase has completed, the bar display ends and Cryo 7 switches directly to the therapy screen.

Software

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IT safety measures and information

Cryo 7 is controlled via special device software.
The Cryo 7 device software is protected by special software protection measures against copying.
Only USB sticks may be inserted in the USB port. It is prohibited to draw operating voltage for small devices or connect devices with an external power supply.
The version number of the software can be found in the service screen for users in “software versions”.
Cryo 7 has 2 interfaces: an RS232 interface for possible device communication and a USB interface.
The USB interface is used for writing log files or for possible updates to Cryo 7.
The RS232 interface may be used only by technical personnel. The manufacturer of the connected device is responsible for this device combination (see chapter 11).

Note

Device-specific parameters and default settings are pre-set in the factory and can be changed only by factory support.
Basic user settings, such as fan levels and therapy time, are not affected by this. User parameters in the configuration can be changed and individually stored at any time.

Note

Changes are stored by activating the “Back” button.
Activating the “Reset” button restores the factory default settings.

Select configuration

Activating the “Configuration” button opens the “Configuration" screen.

The following default settings can be individually adjusted.
Standard:

Fan level at start of treatment	5
Treatment time at start of treatment	30 min
Screen colour scheme	Dark
Brightness	6
Volume of the button sounds	7
Standby operation	2 – 6 hours
Temperature unit	Degrees Celsius
Language	English

Adjusting the fan levels

The fan levels are adjusted using the arrow buttons or by scrolling directly in the bar graph.

Adjusting the treatment time

The treatment time is adjusted using the arrow buttons or by scrolling directly in the bar graph.

Screen colour scheme

Activating the “Bright or Dark” buttons switches between a bright and a dark screen and may be necessary, depending on the use of protective laser glasses.

Brightness

The brightness of the screen illumination can be adjusted.
The adjustment can be made using the arrow buttons.

Volume of the button sounds

The volume of the button sounds can be adjusted using the arrow buttons.

Standby operation

If therapy is not performed for a longer period of time, the cooling switches off depending on the setting in the configuration menu (2-6 hours) and Cryo 7 goes into “standby” energy-saving mode. The Cryo 7 cooling phase restarts by touching anywhere on the touch screen.
If the cooling phase is completed, Cryo 7 automatically switches to the therapy screen.

Note:

Cryo 7 is not switched off during standby operation.

Temperature unit

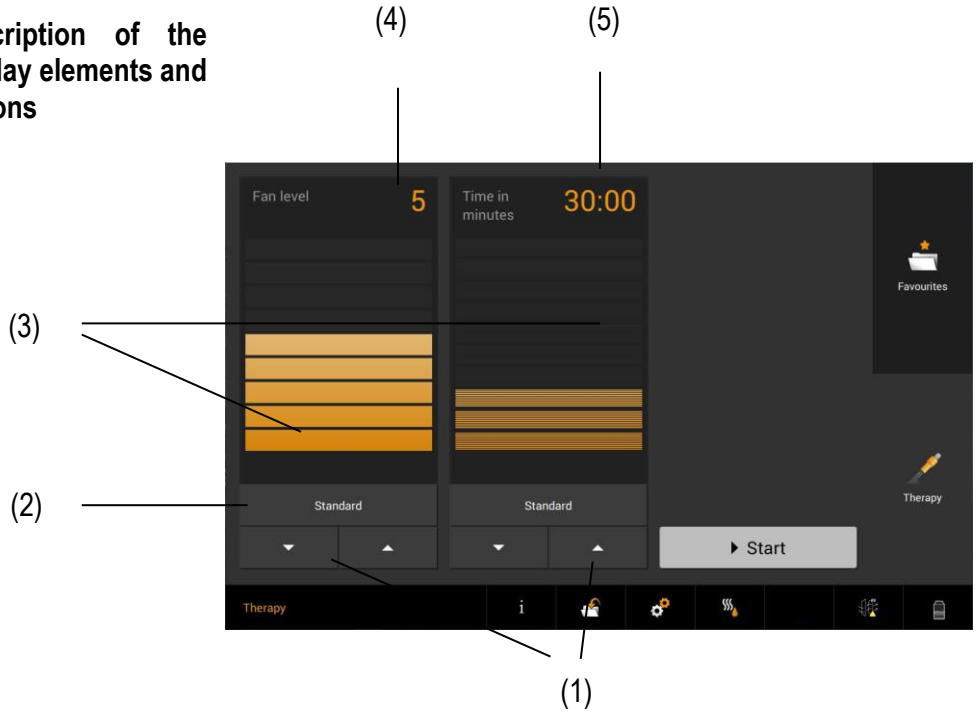
The temperature unit is set directly in the desired button.

Language

Activating the “Language” button opens a selection window with different languages. The language is selected directly in the line.
The list can be scrolled through using the scroll bar on the right-hand margin of the list.

Switch device on	Cryo 7 performs a “precooling” cooling phase after it has been switched on. If the cooling phase is completed, Cryo 7 automatically switches to the therapy screen.
Patient preparation	For standard procedures in your medical practice, we additionally recommend that the patient remove metal objects in the therapy area, if possible. The site to be treated must not be covered by clothing. Please observe the warnings.
Starting therapy	Select the fan level and therapy time. The therapy starts upon activation of the “Start“ button. The screen display changes during the cold air output.
Cold air output	During the cold air output, the “Start” button switches to “Stop”.
Interrupting the cold air output	Activating the "Stop” button interrupts the cold air output.
Resuming therapy	By activating the “Start” button again, the cold air output will be resumed with the automatically saved remaining therapy time.
End of therapy	After the therapy time has elapsed, the cold air output ends, the screen switches back to the start screen, and the “Stop” button turns to “Start”.
Touch screen operation	The touch screen can be operated with and without rubber gloves.

Description of the display elements and buttons



(1) Arrow buttons By tapping the arrow button, the fan level and therapy time values decrease or increase in single increments. If the arrow buttons are held down, the values are continuously increased or decreased.

(2) Standard Activating the “Standard” button restores the respective factory settings or the individual settings in the configuration menu.

(3) Display Visual display of the fan level and time set. Through direct selection in the display (held down for approx. 1 second), the fan level or time value jumps to the desired location. Hold down the value in the display and swipe up or down to change the values for time and fan level as desired. These functions are only available on the start screen.

(4) Fan level Numeric display of the fan level set.

(5) Therapy time Represents the current therapy time numerically.
A keypad opens by tapping on the currently set time.
The therapy time can be set using the keypad.

Favourites

The entries changed and saved in the start screen are filed in Favourites through the save procedure.

Favourites list

In the Favourites list, these can be:

1. called up for use.
To do this, the desired entry is selected directly in the corresponding line. Thereafter the screen display switches to the start screen with the Favourites parameters you stored.

2. edited, moved in the sequence, and deleted.
Activating the “Edit” button opens the editing mode.

2.1 Delete entry
Activating the “Wastebasket” button deletes the entry.

2.2 Changing the order of entries
By selecting and pressing the double bar, the entry can be moved to a different place.

2.3 Change entry
Activating the “Pen” button opens a keypad with which the entry can be individually changed. There are 50 characters available.

By activating the “Edit” button, you leave the editing mode.

Technical information

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Mains voltage	100V - 120V / 50-60Hz
Power consumption	max. 10 A
Protection class	I
IP protection class	IP20
Dimensions	H 1060 mm x W 500 mm x D 560 mm
Weight	60 kg (without accessories)
Environmental conditions Operation	Temperature: 10 to 35°C Air humidity: 20-80% relative air humidity without condensation Air pressure: 900-1030 hPa
Environmental conditions for storage and transport	Temperature: -10 to 50°C Air humidity: 10-90% relative air humidity without condensation Air pressure: 700-1060 hPa
Interfaces	USB 2.0, RS232
Temperature emitted at the device outlet	- 30°C ± 3°C
Fan levels	1-9
Therapy time	1:00 – 100:00 min
Load capacity of the shelf plate	Maximum 35 kg
Length of the treatment tube	2.5 m
Mains fuse	16 A

Subject to technical changes!

Cleaning / Disinfection

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General notes

Before starting maintenance and cleaning measures, the device must always be switched off at the main switch (18) and the power cable must be disconnected (17).
During cleaning and disinfection, make sure that the labels of the device (such as warnings, control unit signs, identification plate) are not damaged.
During cleaning and disinfection, make sure that no liquids penetrate the device. Do not use sprays.
If liquid gets into the device during cleaning or disinfection, take the device out of use, ensure that it cannot be used again, and contact your distributor.
Use the device only in a proper environment.

Housing / accessories

Cleaning: If there is visible soiling, the housing, cable, display and accessories can be cleaned with commercially available alcohol-free plastic cleaners. Wipe the surface until the dirt has been removed using a soft cloth which has been soaked according to the information from the manufacturer of the cleaning agent but not dripping wet.
Disinfection: We recommend performing disinfection at least once weekly and if there are any signs of contamination. Contact your hygiene specialist if necessary. 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 manufacturer's instructions for use. Wipe all surfaces with a soft cloth which has been soaked according to the disinfectant manufacturer's instructions but which is not dripping wet, or use presoaked disinfectant cloths (wipes).
Also observe the instructions for drying or post-cleaning, where applicable.

Defrost container

Cleaning: The defrost container should be cleaned whenever it has been emptied.
To do this, you can open the lid of the defrost container. Follow the procedure described under "Housing / Accessories".

Cryo 7 Air filter

To filter coarse dust particles from room air, there is a Cryo 7 air filter located at the back of Cryo 7.
If the icon to change the Cryo 7 air filter appears in the status bar, the Cryo 7 air filter along with the frame must be changed.
The Cryo 7 air filter cannot and should not be cleaned.

Notes

Use the device only in a properly hygienic environment.

Manufacturer / Distributor

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Manufacturer

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm
Germany

Distributor

Zimmer MedizinSystems
3 Goodyear, Suite B
Irvine, CA 92618

Scope of delivery

Item no.	Number	Device
7370	1	Cryo 7

Contains	Item no.	Description
1	6525226401	Cryo 7 Air filter
1	6525220401	Defrost container
1	93252210	Cryo 7 Therapy Hose Spring Arm
1	95252200	Cryo 7 Therapy Hose 2.5m
1	67300129	Power cable 3m
1	10105064	Instructions for use
4	80400752	Device castors

Optional items

Item no.	Number	Description
93252205	1	Cryo 7 Adjustable Therapy Hose Arm

* Individual power cable available. Please get in touch with your contact partner.

Subject to changes

Note: *The device may be operated only with original parts from Zimmer MedizinSysteme GmbH. Otherwise the function and safety of the patient, user and third parties cannot be guaranteed.*

Orders Contact your responsible contact person on site.

Device combinations

The RS232 interface of Cryo 7 can be used only in connection with medical devices according to ES60601-1 Ed 3.1. Please also follow the instructions for use of the other medical device.
Anyone (referred to as “organisation” below) who combines the devices must observe the requirements of standard ES60601-1 Ed. 3.1 listed below:

The organisation which combines the device and thus operates a medical system is itself responsible for the correct combination of the devices.

The Cryo 7 device may be combined only with a medical device which meets ES60601-1 Ed 3.1.

In the case of a combination, observe the instructions for use of the combined device.

If Cryo 7 is connected to an IT network (for example, to an aesthetic medical laser), previously unidentified risks to patients, operators, or third parties may arise.

The organisation should identify, analyse, evaluate, and monitor these risks.

Subsequent changes to the IT network could introduce new risks and necessitate an additional analysis.

Changes to the IT network include:

- changes to the IT network configuration;
- the connection of additional elements to the IT network;
- the disconnection of objects from the IT network;
- updating of devices which are connected to the IT network;
- upgrading of devices which are connected to the IT network.

Safety and maintenance

Cryo 7 was developed and manufactured in compliance with the safety regulations of ES60601-1.
Zimmer MedizinSysteme GmbH is responsible for the safety and reliability of the device only if

1. the device is operated using a proper power outlet with a protective contact.
2. the device is operated in accordance with the instructions.
3. expansions, readjustments or modifications are carried out only by persons authorised by Zimmer MedizinSysteme.
4. the user was instructed prior to use in the functional safety, the proper operating condition, and the mechanical integrity of the device and accessories.
5. the device is operated only by properly trained personnel.
6. the device is not operated in areas at risk of explosion and/or in a flammable atmosphere.

7. the device is immediately disconnected from the mains if liquid penetrates it.

8. the device does not contain any parts that can be serviced or repaired by the operator. This does not apply to the defrost container (emptying and cleaning) as well as to the replacement of the air filter. If the air filter needs to be changed, this is indicated in the status bar.
9. Replacement of the lithium battery by untrained personnel can lead to hazards.

Reporting

All serious incidents associated with the product are to be reported to the manufacturer and the competent authority of the state in which the user and/or the patient is located.

Service

Activating the “Service” button in the configuration menu opens the “User” service screen.

Defrost

We recommend daily defrosting (in the evening) if Cryo 7 is operated for several hours, since ice may have formed around the evaporator.
Please empty the defrost container before the defrosting process.

Activating the “Start” button in the “Defrost” display field starts the defrosting process.
While the defrosting process is running, no screen entries or therapy is possible.
After the end of the defrosting process, the defrost container must be emptied.

Capacity of the defrost container

The defrost container has a capacity of approx. 1.5 litres.

If the defrost container has reached a certain fill level, an acoustic signal sounds. In addition, the “Defrost container fill level” icon in the status bar switches to the “Empty defrost container” icon.

Maximum capacity reached

Cryo 7 also displays a message in the therapy screen to empty the defrost container.

Emptying

To remove the defrost container, open the maintenance door.
Remove the defrost container from the hatch and take the cover off the top of the defrost container.
After you have emptied the defrost container, ensure that the cover is positioned correctly on the defrost container.

Insertion

Insert the defrost container as follows:

- Opening is on top and facing the device.
- Because of the defrost valve, there is slight resistance when inserting the defrost container in the device; this can be overcome by gentle pressure.
- Push the defrost container all the way into the device.
- Close the maintenance door.

Note

The defrost container must always be in the device, except during emptying and cleaning.

S01 / S02

The S01 and S02 maintenance programs simulate long-term operation and document the proper condition of Cryo 7.
Any faults are recorded.

Note

Before starting the maintenance program, the defrost container must be emptied.

Performing S01

Activating the “Start” button under the “Run S01” display field starts the “Run S01” maintenance program.

Description of Run S01 (total time approx. 90 minutes):
This program simulates two 15-minute treatment sessions and three cooling processes, as well as a 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.

At the end, a summary appears on the screen. You should photograph or write down the summary of the data at the end of Run S01.
Caution! Run S01 lasts about 90 minutes. Afterwards, Cryo 7 restarts.

Performing S02

Activating the “Start” button under the “Run S02” display field starts the “Run S02” maintenance program.

Description of Run S02:
The device simulates a 15-minute therapy session.
Run S02 is repeated until the start/stop button is pressed.
Run S02 is a stress test for the cooling system.
Please use Run S02 only with instructions from a technician. Afterwards, Cryo 7 performs a restart.

Software versions

Activating the “Software versions” button displays a list of the software versions and serial numbers.

Operating hours

This display gives an overview of various operating hours, such as availability if service is needed and the Cryo 7 configuration.

Cryo 7 Air filter

An icon in the status bar indicates that the Cryo 7 air filter needs to be replaced.
We recommend keeping a replacement Cryo 7 air filter on hand in your medical practice (see air filter information in this chapter).

Note

Cryo 7 may not be operated without the original Cryo 7 air filter.

Only the original air filter from Zimmer MedizinSysteme GmbH may be used!

Replacing the Cryo 7 air filter

The Cryo 7 air filter is located at the rear of the Cryo 7.

Grasp with both hands from above through the handle.

Note

Press the air filter downwards with your fingers at the indentations, pull it forwards, and remove the air filter from the frame.
Insert the new air filter with the air filter frame first at the lower retaining support. Press the air filter frame into the housing until it clicks into place. The two arrows at the upper edge of the air filter must be pointing towards the device. The retaining lugs on the air filter frame must click into place on the side of the housing.

Resetting the Cryo 7 air filter

After the Cryo 7 air filter is replaced, the operating time counter of the air filter must be reset.
There are 2 options for performing this process:

Status bar

1. Activating the "Air filter” icon in the status bar opens a window with information on resetting the operating time counter.

Configuration menu, “user” service menu

2. Activating the “Air filter operating hours reset” button resets the operating time counter.

Please dispose of the used Cryo 7 air filter in household waste.

Export log	Cryo 7 provides data for error analysis. These data can be saved on a USB stick.
Creating the export log	Insert the USB stick in the port provided on the back of Cryo 7 (10). Activating the “Export log” button transfers the data (text file) to the USB stick. This text file supports the error analysis.
Note	The USB stick must be empty and formatted with FAT32.
Troubleshooting/ Service	May only be performed by trained staff.

Functional test

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

- Switch on the device.
- Wait until the device is ready for use.
- This is the case when the device switches to the start screen.
- Start Cryo 7 using the start button.

Select the various fan levels one after the other and check the strength of the air stream and the cold air output.

Function failure
Error message / Troubleshooting
Disposal

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Function failure Device

Mains fuse is activated
Cryo 7 is fitted with a bipolar overload protection element (triggered at 16 amperes) which is integrated into the main switch to protect the device in the event of supply problems.
If the fuse trips, the device automatically switches off via the toggle switch. The toggle switch jumps from I to 0.
The device can only be made ready for use again by switching it on via the toggle switch.

Reduced cold air output / reduction in cold air output

Reduced cold air output / reduction in cold air output
Icing of Cryo 7 may be the cause of a significant reduction in cold air output and a weak air stream.
You must defrost the device or manually trigger the defrosting process.
Before doing so, empty the defrost container.
The defrosting process may take up to 20 minutes.
Press the defrost icon on the start screen or select the icon for Configuration, then Service and finally Defrost.
Cryo 7 restarts after defrosting.

Error report

If an error is detected, this is shown via an error message in the display. Switch the device off and back on. If the error occurs repeatedly, contact customer service.

Instructions

If instructions are provided (e.g. change air filter, empty water container), follow the instructions on the screen and restart Cryo 7, if necessary.

Update Troubleshooting/ Service

A software update can be performed via the USB interface. You need an empty USB 3.0 or 2.0 stick which is formatted with FAT32 and has a storage capacity of 4 GB. Copy the *.tar file to this stick.

Switch off Cryo 7. Insert the USB stick (with the *.tar file) in the USB interface.
Switch on Cryo 7.
After it has been switched on, a message appears (“should an update be performed”).
If “ok” is pressed, the update runs.
Do not switch off the device while the update is running.
The device must be restarted afterwards (without the stick).

You will help us solve the problem if you have the following information at hand:

- Error ID
- Accurate description of the problem
- The Cryo 7 serial number + software version

Head office

In the event of malfunctions, contact your responsible sales representative or contact the following address:

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm
Germany
Tel. +49 731 / 9761-554
Fax +49 731 / 9761-273
Mail: service@zimmer.de
Web: www.zimmer.de

US office

Zimmer MedizinSystems
3 Goodyear, Suite B
Irvine, C 92618
Tel. (800) 327-3576
Fax (949)727-2154
E-Mail info@zimmerusa.com

Return shipment

The device may only be returned in the original packaging.

Disposal

Please refer to national regulations for disposal.
Contact your distributor if necessary.
Cryo 7 must not be disposed of in household waste under any circumstances.

Packaging materials must be kept out of the reach of children since there is a risk of suffocation!

Manufacturer's EMC declaration

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Cryo 7 was developed according to the state of the art. The information on use as intended of the components was taken into account.

Cryo 7 should not be operated near active HF surgical devices or magnetic resonance imaging devices which can cause a high degree of electromagnetic interference.

Cryo 7 is exclusively intended and has been tested for professional healthcare facilities, such as hospitals.

The electromagnetic compatibility of Cryo 7 device was tested on the original device with the Cryo 7 therapy hose.

Cryo 7 does not have any key performance features which could be impaired through electromagnetic interference.

WARNING: The use of this device next to or also stacked with other devices should be avoided since this could lead to faulty operation. If such use is necessary, the device as well as the other devices should be continuously observed to ensure that they are working normally.

WARNING: The use of accessories, converters and cables which are not specified or provided by the manufacturer of this device can lead to increased electromagnetic interference emissions or decreased electromagnetic immunity of this device, resulting in improper operation.

Cryo 7 device does not contain any exchangeable components, cables or other parts which lead to worsening of the EMC.

WARNING: Portable HF communication devices (including peripheral devices such as antennas) should not be used at a distance of less than 30 cm (12 inches) from any part of Cryo 7, including the cables indicated by the manufacturer. There may otherwise be a loss of performance of this device.

The device was tested for HF immunity with selected frequencies only. Transients with other frequencies occurring in the vicinity can lead to malfunctions. The tested frequencies are listed in Table 4.

Cryo 7 does not contain any components which can age during the life of the device and which can lead to worsening of the electromagnetic compatibility.
Thus no maintenance is necessary during the service life of the device to ensure basic safety.

All tests according to standard IEC 60601-1-2 Ed. 4.0 were performed. No other standards and regulations on electromagnetic compatibility were used.

Table 1

Guidelines and manufacturer's declaration – Electromagnetic emissions		
The Cryo 7 device is intended to be used in the electromagnetic environment as indicated below. The customer or user of the Cryo 7 device must ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – Guidelines**
HF emitted interference according to CISPR 11	Group 1	The Cryo 7 device must emit electromagnetic energy to guarantee its intended function. Electronic devices located in the vicinity may be impaired.
HF emitted interference according to CISPR 11	Class A	The Cryo 7 device is suitable for use in all establishments, including domestic establishments, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuations/flickers according to IEC 61000-3-3	Not applicable	

Table 2

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Cryo 7 device is intended to be used in the electromagnetic environment as indicated below. The customer or user of the Cryo 7 device must 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	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Floors should be made of wood, concrete or ceramic tiles. In the case of plastic coverings, the relative humidity must be at least 30%.
Rapid electrical transients/bursts according to IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The quality of the supply voltage must correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5 (external conductor – external conductor)	± 0.5 kV, ± 1 kV	± 0.5 kV, ± 1 kV	
Surges according to IEC 61000-4-5 (external conductor – ground)	± 0.5 kV, ± 1 kV, ± 2 kV	± 0.5 kV, ± 1 kV, ± 2 kV	
Voltage dips according to IEC 61000-4-11	0% UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The quality of the supply voltage must correspond to that of a typical business or hospital environment.
	0% UT; 1 cycle and 70% UT; 25/30 cycles	0% UT; 1 cycle and 70% UT; 25/30 cycles	

	Single phase: at 0°	Single phase: at 0°	When the user of the Cryo 7 device needs further operation even in the case of interruptions in the power supply, it is recommended to operate the Cryo 7 device from an uninterruptible power supply or a battery.
Voltage interruptions according to IEC 61000-4-11	0% UT; 250/300 cycles	0% UT; 250/300 cycles	
Magnetic field at power supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	Magnetic fields at mains frequency should correspond to the typical values found in business or hospital environments.
Note: U_T is the a.c. supply voltage prior to application of the test level.			

Table 3

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Cryo 7 device is intended to be used in the electromagnetic environment as indicated below. The customer or user of the Cryo 7 device must ensure that it is used in such an environment.			
Immunity test	**IEC 60601 – test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Conducted disturbances by HF fields according to IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	**In the environment of devices which bear the following symbol, interferences are possible:** 
Radiated electromagnetic HF fields according to IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM to 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	

Table 4

Electromagnetic immunity to HF radio equipment						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum energy (W)	Distance (m)	Test level immunity (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sinus	2	0.3	28
710	704 – 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Cryo 7

Instructions for Use

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