User Manual

CRYOFLOW ICE-CT

CE 0197

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CONTENTS

1 INTRODUCTION

Congratulations on the purchase of your new **CRYOFLOW ICE-CT**!

You have opted for the **CRYOFLOW ICE-CT**, a cold air therapy device with high levels of performance, an attractive and user-friendly design, and of the highest quality. The **CRYOFLOW ICE-CT** has already proven to be excellent in physiotherapy centres, local practices and clinics.

The **CRYOFLOW ICE-CT** determines the surface temperature of the skin without touching it, and maintains the set value as a condition for the application of the cold treatment. The patient will find that the control of the skin's surface temperature feels very comfortable, thus minimising the occurrence of cold pain. Combined with the supporting arm, longer treatments may be administered without incurring fatigue. The cold can penetrate the tissue deeply and evenly, without it being too unpleasant for the patient.

We have placed special emphasis on high levels of reliability, safety, ease of operation and extended service life.

Please read carefully these Operating Instructions before using the **CRYOFLOW ICE-CT** to ensure its proper application.

We wish you and your patients every success in your treatment with the **CRYOFLOW ICE-CT**.

2 DESCRIPTION OF CONTROLS, DISPLAYS, EQUIPMENT PARTS

1 Power supply cord

2 Filter mat

3 Power switch

4 Valve for water tank

5 Label

6 Mains fuses

8 Nozzle feed

9 Nozzle that is screwed on the nozzle feed

10 LED “SELECT”, yellow, select active

11 “DEFROST” button

12 “SYSTEM” button

13 “MAIN MENU” button

14 LED “POWER”, green, treatment active

15 “START/STOP” button

16 Knob, parameter setting

17 Display

18 Connection cable for the IR sensor

19 Supporting arm (option)

20 Handle, pivoting, with IR sensor, for the treatment hose (27)

22 M8x30 star grip on the handle holder

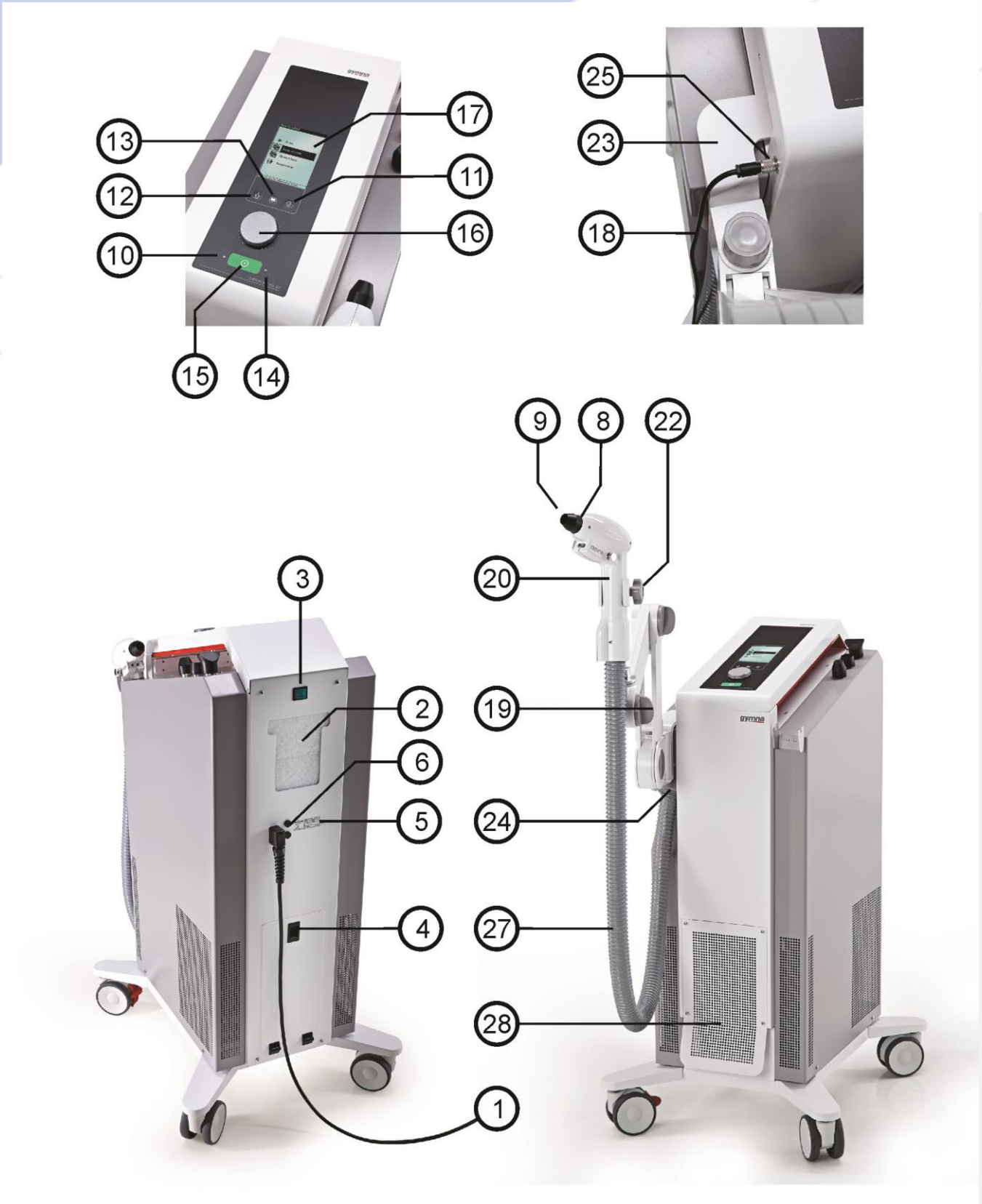
23 Support mounted on the **CRYOFLOW ICE-CT** for the supporting arm

24 Flange on the device for connecting the treatment hose (26) or (27)

25 Socket for the connection cable of the IR sensor

27 Treatment hose, for the handle with IR sensor (20)

28 Ventilation plate (unscrew to clean the cooler)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3 GENERAL INFORMATION

Purpose

Cryotherapy devices, with and without infrared option for manual cryotherapy, have been developed for the treatment of orthopaedic diseases, or treatment of traumatology, as well as those relating to sports medicine.

Cold air is generated by a cooling unit and heat exchanger, and delivered in doses by means of a fan (controlled in thermofeedback mode) via a nozzle to the place of treatment on the patient. The therapy occurs either in continuous or timed operation.

Cryotherapy devices are used for pain relief, anti-inflammation, relaxation, to reduce swelling or bleeding, as well as to reduce nerve conduction velocity on joints, tendons, muscles and nerves.

For specific indications and contraindications, please refer to Chapters 9.4 and 9.5 of these Operating Instructions.

3.1 Device

As a therapy device, the **CRYOFLOW ICE-CT** is not intended for the mobile or emergent use

Careful: Cryotherapy devices should be used exclusively by personnel trained or skilled in the fields of physiotherapy or other similar background, and the treatment must be monitored by this personnel!

The device is not intended to drive over obstacles, with the exception of transport to the destination for initial assembly. The movable rollers are only used for a better position change to optimize treatment in the room. The brakes on the two braked rollers must be released to change position and be locked again.

The device sucks in the ambient air via a filter mat **(2)** and cools it down to **-32 °C**. The ambient air looses humidity during cooling. The dried cold air passes through a nozzle **(9)** to the body part to be treated. The cold air flow is adjustable in 10 steps and may be changed even during the treatment.

Using the **CRYOFLOW ICE-CT**, the surface temperature can be selected and maintained automatically at a constant level.

Various nozzles **(9)** may be screwed on the angled nozzle feed **(8)** of the 360° pivoting handle **(7)** or **(20)**.
The flexible hose with the pivoting handle **(7)** or **(20)** and the additional **2nd joint** on the flange **(24)**, ensures a fatigue-free treatment for the user and a really wide range of action.

A supporting arm can be fitted on the device. It makes long treatments easier.

The easy adjustment and clear display of the parameter on the panel **(17)** allow for a straightforward treatment of the patient.

The nozzles (9) should not be touched during the treatment of a patient. The cold air flow could be considerably restricted or completely interrupted.

3.2 Installation of the device after delivery

The device is delivered completely assembled. If the optional supporting arm is included in the delivery, then it must be placed on the device on the holder for the supporting arm (23) and attached using the star grip (22).

If, in this context, a threshold crossing is required, this must be done with the aid of optional accessories "threshold ramp" (see Item 15 Accessories).

At the back of the device, open the valve **(4)** for the water tank and check that the tank is in its proper place. Any bits of paper or foam used to ensure a safe transport should be removed.

After unpacking the device, and before connecting it to the power supply, it is essential to make sure that no condensation remains and that the temperature of the device has been adjusted to the room temperature. In any case, you should wait at least **1 hour** before switching it on. Please also refer to Item 5 "Commissioning".

The device should be transported lying down, so to avoid any potential damage to the cooling circuit or to the compressor. After placing the device, wait at least 30 minutes before turning it on.

Careful! The device is not intended to be fitted or used in an environment that is rich in oxygen or in presence of anaesthetic gases (AP/APG environment)!

3.3 Directive for medical devices

The **CRYOFLOW ICE-CT** complies with the requirements outlined in Directive 93/42/EWG on medical devices.

The device may only be operated in accordance with the purpose described in these Operating Instructions.

We recommend that a safety-related inspection of the device be carried out every 2 years, by an authorised service (Item 11.3)

3.4 ESD guidelines

The following measures must be taken during installation:

- Before making the electrical connection, please touch only once the housing of the medical device in order to discharge it.
- Use no other accessories than those mentioned in the Operating Instructions.

We recommend that you train all relevant persons in matters of general ESD protection measures.

4 SHORT OPERATING INSTRUCTIONS

Careful: Before applying cryotherapy, first check that the patient does not have any potential intolerance and/or allergy!

First treatment

1 Switch on the power supply **(3)**
2 Select the operating mode, continuous operation, timed operation or thermofeedback, knob **(16)**
3 Select the parameters, knob **(16)**, to set air stages and/or treatment time and/or temperature, or to Item 4. Short Operating instructions
4 Start the treatment, Start/Stop button **(15)**
5 Adjust the air stages to the sensitivity of the patient using the knob **(16)**
(In thermofeedback operating mode, it is not possible to set programmes or have automatic mode.)
6 Treatment ends when:

Timed operation:	**-** Automatic after expiry of the set treatment time	
	- Interruption during the treatment when activating the Start/Stop button **(15)**	
Continuous operation:	**-** Start/Stop button **(15)**	
Thermofeedback:	**-** Automatic operation,	such as timed operation
	- Manual operation,	such as continuous operation
	- Set programme (indications),	such as timed operation

Upon the regular conclusion of the treatment or the interruption of the treatment using the Start/Stop button **(15),** the display of **Figure 2 "**Operating mode selection" can be brought up using the Main Menu button **(13)**, Item 2 short operating instructions

Other treatments

7 Return to Item 3 Short Operating Instructions (Operating mode is selected)
8 Return to Item 4 Short Operating Instructions (Parameters are selected)

Changing the operating mode

Press the Main Menu button **(13)**, **Figure 2** "Operating mode selection" appears, then proceed according to Item 2 Short Operating Instructions.

Recommended

Switch on the device 5 to 10 minutes prior to the treatment **(3)**.
Do not switch the device off for treatment pauses shorter than 30 minutes.

This enables a pre-cooling of the heat exchanger and the air exiting nozzle **(9)** at the start of the treatment is significantly colder.
The device is in standby mode.

System setup (see Item 5.4)

Press on the system button **(12)** and change the settings with the knob **(16)**, for example the language, sound of the button, sound volume, contrast of the Display **(17)**, or temperature unit in °C or °F.
Return by pressing on the Main Menu button **(13)** in **Figure 2 "**Operating mode selection"**.**

De-icing (see Item 7.)

On Display **(17),** if stars appear at the bottom or the air flow is significantly reduced, the heat exchanger is icing up.
Press on the Defrost button **(11)**. The "De-icing" process (**Figure 6**) will end automatically and the device will then switches to the standby mode.

Emptying the water tank (see Item 8.)

Figure 7 will appear on the Display **(17)** when the water tank is full.
Turn off the device with the power switch **(3)**. Open the valve **(4)** for the water tank, remove and empty the container.
Replace the container in the device and close the valve **(4)**.

Cleaning the cooler (see Item 12)

After an operating time of 500 hours, a notice will appear on the Display (17) regarding the cleaning of the cooler.
The ventilation plate (28) must be unscrewed and then you should proceed as per Item 12.

5 COMMISSIONING

Careful!
The device should not be used in explosive atmospheres.
There is a risk of explosion if the device is used in areas where flammable gases are present, or where they may be released during the operation of the device (e.g. anaesthesia rooms that use easily flammable anaesthetics).

5.1 Inspection on delivery

Check that the device has not been damaged during transport and that the accessories are intact and complete (see Item 15. Accessories and the delivery note).

In case of damages or defects, please promptly notify your supplier. In case of serious damage, do not turn the device on.

5.2 Connection to the power supply

The device is intended to be connected to a power supply of 230 V +/- 10 %, 50/60 Hz; special models may also be connected to 115 V +/- 10 %, 50/60 Hz.
Please refer to the information on the label **(5)** at the back of the device. Before connecting to the existing power supply, check its compliance with the label **(5)**.
Connecting to the wrong power supply can damage the device.

The connection must be made using only the firmly connected power supply cord **(1)** that comes with the basic equipment, to a properly fitted grounded power outlet. As regards fuses in the associated installation, we recommend using 16 A slow-blow fuse at 230 V and 20 A slow-blow fuse at 115 V.

Please also consider Item 3.2 “Installation of the device after delivery”.

Careful: Only the accessories specified in Chapter 15 should be used!

Caution! Avoid trapping & bruising during operation, and pay attention to the risk of jabbing or stabbing the patient when moving the supporting arm! Please refer to instructions in Item 11.4 “Handling the treatment hose/IR Cable” and in Item 11.5 “Handling the supporting arm”.

5.3 Switch on and Switch off

Switch on the device using the power switch **(3)** at the back of the **CRYOFLOW ICE-CT**. The Display **(17)** will briefly show the name of the device and its relevant software version. During that time, a device test will be performed. After this device test, the device goes into standby mode. The Display **(17)** shows **Figure 2** “Operating mode selection” (see Item 6.1). The compressor will be switched on. There is then a pre-cooling phase of the heat exchanger. Upon reaching the preset minimum temperature, the compressor switches off, and on again when it reaches the preset maximum temperature.

This process is repeated and will be called standby mode. The device can remain in that mode during treatment pauses.

Should the patient stop requiring treatments for longer periods of time, such as after work, during holidays or in case of need, then the device can be switched off using the power switch (3). Please refer to Items 11 and 12 of these Operating Instructions.
When the power switch (3) is “ON”, the light is green. When it is “OFF”, there is no light.

The device must be switched off for maintenance and service work, and the power plug of the power supply cord (1) must be pulled out of the power supply.

5.4 System setup

You can change the **language**, **contrast** of the Display **(17)** and the **volume** of the sound of the button, as well as turn the **sound of the button** on or off.

Using the system button **(12),** you can go from **Figure 2** “Operating mode selection” (see Item 6.1) in the system setup **(Figure 1)**. By turning the knob **(16)** either on the right or on the left, you can select the parameters to set. Pressing the knob **(16)** will activate this parameter and you can adjust it again by turning right or left. By pressing the knob **(16)** again, the set value will be saved.
Activating the Main Menu button **(13)** will get you back to **Figure 2 “**Operating mode selection” (see Item 6.1).

In the **CRYOFLOW ICE-CT**, you can select the unit for the temperature, either **°C** or **°F**. The sound at the end of the treatment is always activated by the **CRYOFLOW ICE-CT**.

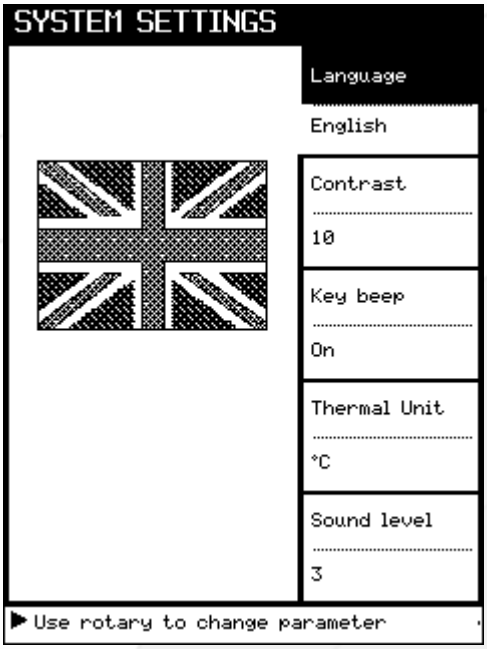

Figure 1.: “System setup”

6 TREATMENT

6.1 Operating mode selection

After the device initialisation, the **CRYOFLOW ICE-CT** starts with the Main menu, in which the desired operating mode can be selected. The choices will be determined by whether the device is operated with or without an IR sensor **(see Figure 2)**. The yellow LED **(10**) lights up. By turning the knob **(16)** right or left, you can choose between a timed operation, continuous operation or thermofeedback. The selected operating mode is highlighted on the Display **(17)**. Pressing the knob **(16)** will switch on the selected operating mode.

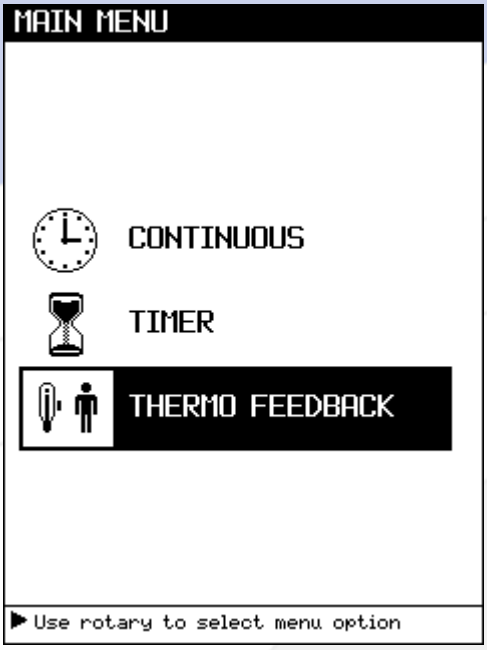

Figure 2: Operating mode selection with contact with IR sensor

6.2 Timed operation

The green LED **(14)** lights up. The Display **(17)** will show the values that were last selected for time and air flow. It is now possible to start the treatment. You can also set up the treatment time in 1-minute increments and the air flow in 10 steps. To set up, use the knob **(16),** turn it (selection) and press it (activation).

Activating the Start/Stop button **(15)** will start the treatment.
It is also possible to interrupt the treatment by activating that button.

During the treatment, the air flow can be adjusted to the patient's sensitivity to the cold using the knob **(16)**. The strongest sensitivity to cold may occur, for most patients, at **air stages 5** to **6** with the smallest possible distance of the largest nozzle **(9)** from the skin surface.

The end of the treatment time is indicated by a short visual and acoustic signal (can be switched off, see Item 5.4). The output picture will appear again on the Display **(17)** before the start of the treatment. A new treatment can be started.
After stopping the treatment, **Figure 2 "**Operating mode selection" can be called up again (see Item 6.1) by activating the Main Menu button (**13).**

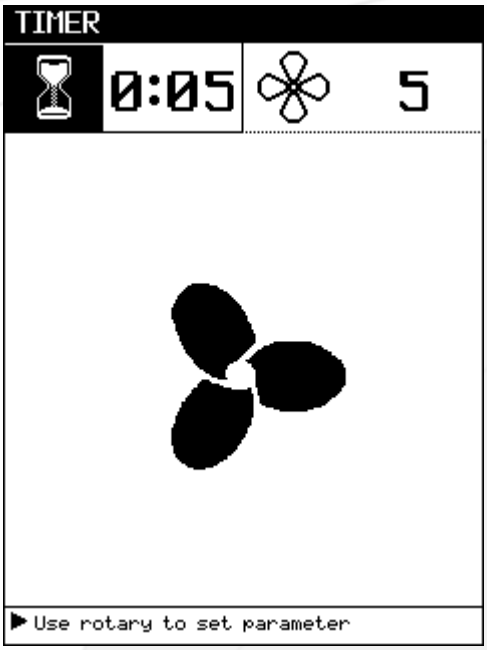

Figure 3: "Timed operation"

6.3 Continuous operation

The green LED **(14)** lights up. The Display **(17)** will show the values that were last selected for the air flow. It is now possible to start the treatment. You can also set the air flow in one of the 10 steps. To set up, use the knob **(16),** turn it (selection) and press it (activation).

Activating the Start/Stop button **(15)** will start the treatment. It is also possible to interrupt the treatment by activating this button **(15)**. The time will be reset to zero and a new treatment can be started.

During the treatment, the air flow can be adjusted to the patient's sensitivity to the cold using the knob **(16)**. The strongest sensitivity to cold may occur, for most patients, at **air stages 5** to **6** with the smallest possible distance of the largest nozzle **(9)** from the skin surface.

At the end of the treatment, **Figure 2** "Operating mode selection" can be called up again by activating the Main Menu button (**13)** (see Item 6.1).

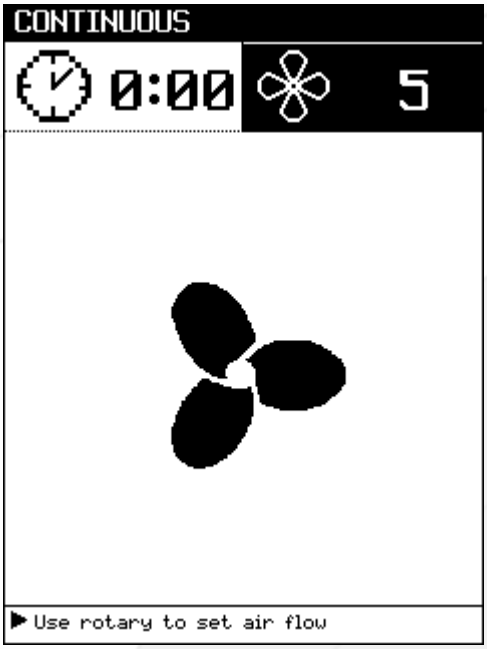

Figure 4: "Continuous operation"

6.4 Thermo feedback

Thermo feedback is the possibility to perform a controlled application of the cold air while determining and display the surface of the body part to be treated without any contact.

In Figure **5.1,** you can choose between the operating mode with freely adjustable parameters (freely selectable) and the operating mode with preset parameters (indications, goals). To go the desired programmes, use the knob **(16),** turn it (selection) and press it (activation). In the “Freely selectable” operating mode, you can choose between the manual operation (manual) and automatic operation (automatic) (**Figure 5.2).**

Use the knob **(16),** turn it (selection) and press it (activation) to go to the “automatic” operating mode in **Figure 5.3** (Item 6.4.1) and to the “manual” operating mode in **Figure 5.5** (Item 6.4.2).

Figure 5.1: “Thermofeedback”

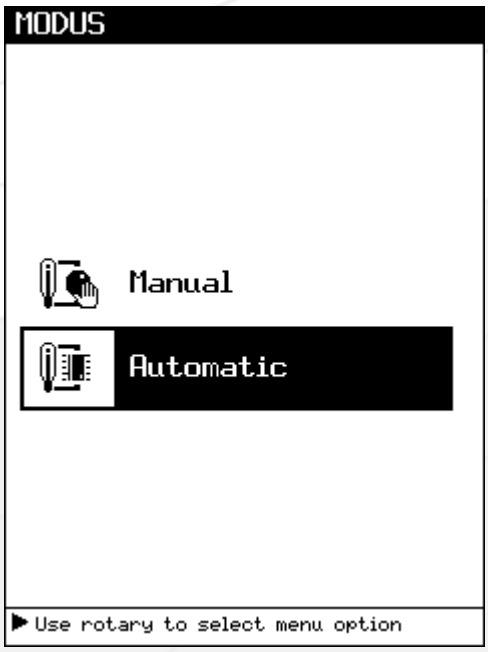

Figure 5.2: “Operating mode”

6.4.1 Automatic operation

The green LED **(14)** lights up. The Display **(17)** will show the values that were last selected for time and temperature. The red LED on the handle also lights up. The red ray of light serves for the topographic orientation of the IR sensor. The optimal distance for determining the skin temperature (as reference value) in the cold air flow is a distance ranging between 3 cm and 8 cm from the nozzle (9) to the skin surface.
It is possible to start the treatment. You can also set up the treatment time in 1-minute increments and the temperature in 1-degree increments. To set up, use the knob **(16),** turn it (selection) and press it (activation).

The treatment temperature can be adjusted between 12 °C and 25 °C.

Activating the Start/Stop **(15)** will start the treatment.
It is also possible to interrupt the treatment by activating this button.

During the treatment, the air flow is automatically controlled. If the preset surface temperature (reference value) is reached, it switches itself off and when it exceeds this temperature, it switches itself back on. The end of the treatment time is indicated by a short visual and acoustic signal. The Display **(17)** shows again the output picture just as it did at the start of the treatment. A new treatment can be started.
After the end of the treatment, or when the treatment is stopped, **Figure 2.2 "**Operating mode selection" can be called up again by activating the Main Menu button **(13)** (see Item 6.1).

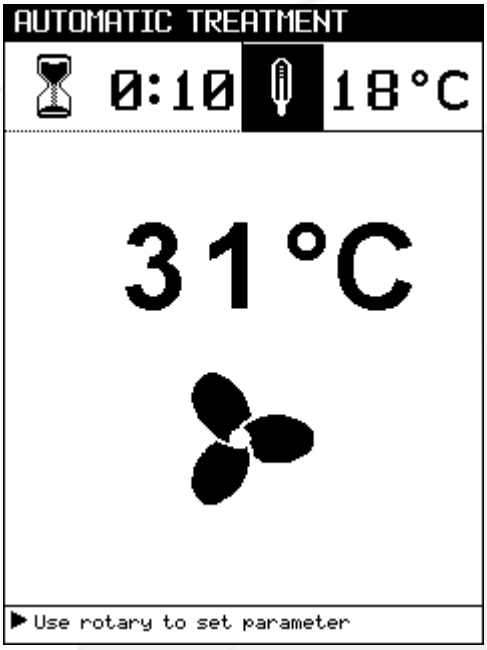

Figure 5.3: "Automatic operation""

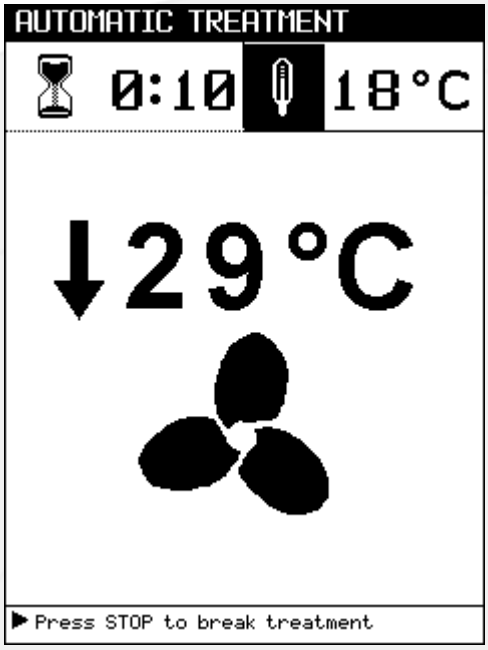

Figure 5.4: "Automatic operation", START

6.4.2 Manual operation

The green LED **(14)** lights up. The Display **(17)** will show the values that were last selected for time and air flow. The red LED on the handle also lights up. It shows the detection area of the IR sensor. The optimal distance for determining the skin temperature (as reference value) in the cold air flow is a distance ranging between 3 cm and 8 cm from the nozzle (9) to the skin surface.
It is now possible to start the treatment. You can also set up the treatment time in 1-minute increments and the air flow in 1 to 10 steps. To set up, use the knob **(16),** and turn it (selection) and press it (activation).

Activating the Start/Stop button **(15)** will start the treatment.
It is also possible to interrupt the treatment by activating that button.

During the treatment, the air flow can be adjusted to the patient's sensitivity to the cold. The strongest sensitivity to cold may occur, for most patients, at **air stages 5 to 6** with the smallest possible distance of the largest nozzle **(9)** from the skin surface.

The end of the treatment time will be indicated by a short visual and acoustic signal. The Display **(17)** shows again the output picture just as it did at the start of the treatment. A new treatment can be started.
Upon conclusion of the treatment or when the treatment is stopped, **Figure 2.2 "**Operating mode selection" can be called up again by activating the Main Menu button **(13)** (see Item 6.1).

Figure 5.5: "Manual operation"

Careful! Do not point the red LED light towards the eyes!

Careful! It is not recommended to remove or insert the IR plug connection when in operation.

6.4.3 Indications

Indications are suggestions of treatments for cases that are usually at the acute, sub acute and chronic stages. It is not possible to change individual parameters.

In each individual case, the treating specialist or treating physician must be the one deciding of the application of these indications.

You can access each programme by using the knob **(16),** turning it (selection) and pressing it (activation).

Activating the Start/Stop button **(15)** will start the treatment.
It is also possible to interrupt the treatment by activating this button.

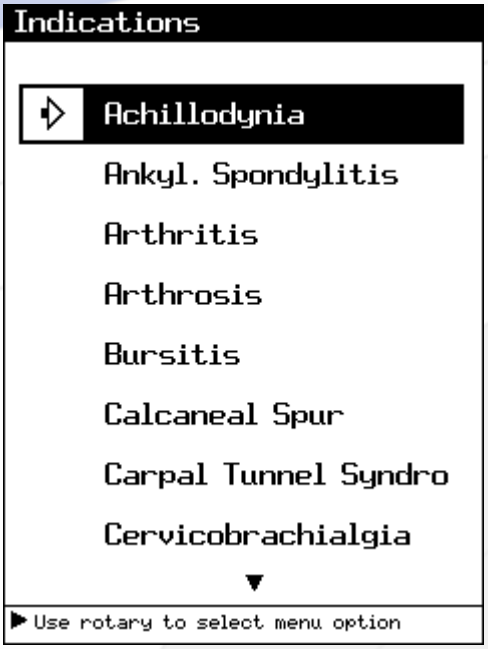

Figure 5.6: **“**Indications”

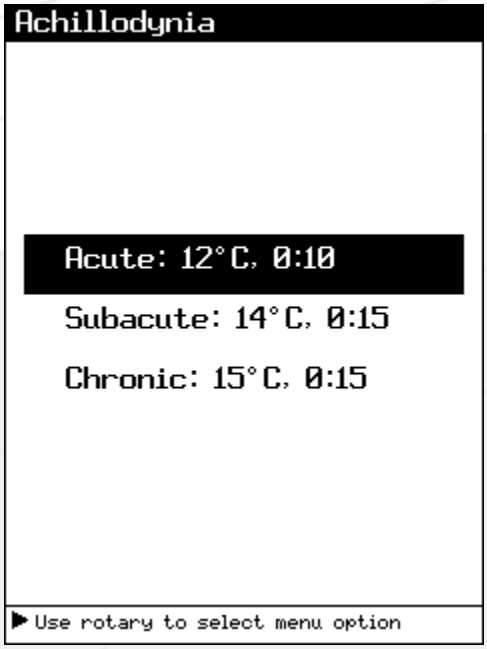

Figure 5.7: **“**Treatment suggested for achillodynia - acute”

6.4.4 Objectives

Objectives are suggestions of treatments for cases that are usually at the acute, sub acute and chronic stages. It is not possible to change individual parameters.

In each individual case, the treating specialist or treating physician must be the one deciding of the application of these indications.

You can access each programme by using the knob **(16),** turning it (selection) and pressing it (activation).

Activating the Start/Stop button **(15)** will start the treatment.
It is also possible to interrupt the treatment by activating this button.

Figure 5.8: "Shock wave therapy"

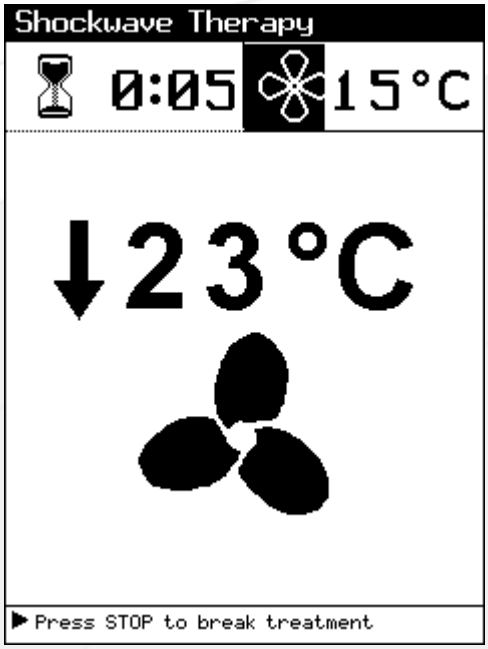

Figure 5.9: treatment suggestion "Shock wave therapy"

6.4.5 Skin Temperature

The skin temperature has an average (under the normal conditions) of 34°C. At a more acute phase, there are more inflammatory phenomenona and of course a higher skin temperature.

With use of the rotating knob **(16)** it is possible by turning it (selection) in Figure 5.1 and pressing it (confirm) to "Skin Temperature".

Point the IR-sensor at the area that needs to be evaluated. The optimal distance for temperature determining lies between 3 and 8 cm between Nozzle (9) and skin surface, the optimal is circa 6 cm. The temperature will be shown automatically in the Display (17).

In this manner the evolution of the therapy can be followed.

7 DE-ICING

During the treatment, the **CRYOFLOW ICE-CT** sucks in the ambient air via a filter mat **(2)** and cools it down in the heat exchanger to -32 °C. It is well known that the air will lose its moisture. This moisture condensates in the heat exchanger and freezes. The freezing process can take several hours depending on the level of moisture. The icing process occurs only during treatment, when the cold air is blown out. In standby mode, the level of icing remains unchanged. If the Display **(17)** shows a row of stars at the bottom or the air flow is significantly lower, then the heat exchanger freezes up.
You can start the de-frosting process by pressing the Defrost button **(11)**. **Figure 6** appears on the Display **(17).** The yellow LED **(10)** lights up. The compressor is turned off. The fan blows ambient air through the heat exchanger. The defrosting will end automatically. It can also be ended manually no less than 5 minutes after the activation of the Defrost button **(11)**. If the process is ended, the **CRYOFLOW ICE-CT** switches back to the standby mode and **Figure 2 "**Operating mode selection" appears on the Display **(17)**.

The de-icing process may only be started if the device is pre-cooled, for example after a treatment or in standby mode after about 20 min of operating time.

If the **CRYOFLOW ICE-CT** is turned off for an extended period of time, for example overnight, then the heat exchanger will self-defrost. Defrosting generates water. The water is conducted into a vessel, which is located behind the valve **(4)** on the back of the device. If the vessel fills up, this will be indicated on the Display **(17)** (see Item 8).

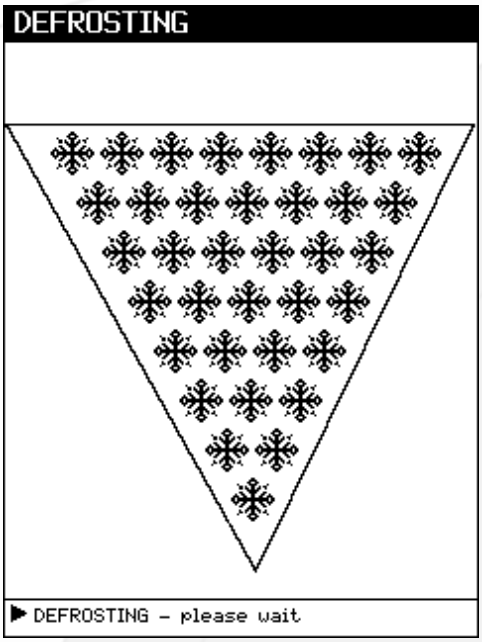

Figure 6: "De-icing"

8 DRAINING THE WATER TANK

The Display **(17)** shows when it is necessary to drain the water tank. A treatment can therefore not be started. Turn the device off using the power switch **(3)**.

Open the valve **(4)** on the rear panel of the **CRYOFLOW ICE-CT** and remove the water tank. After draining, clean the tank and replace it so that the drain pipe is located above the tank opening. The left side of the water tank must be positioned in parallel to the plastic housing of the filling level sensor. Close the valve **(4)**. The device is ready to be used again and the power can turned back on using the power switch **(3)**.

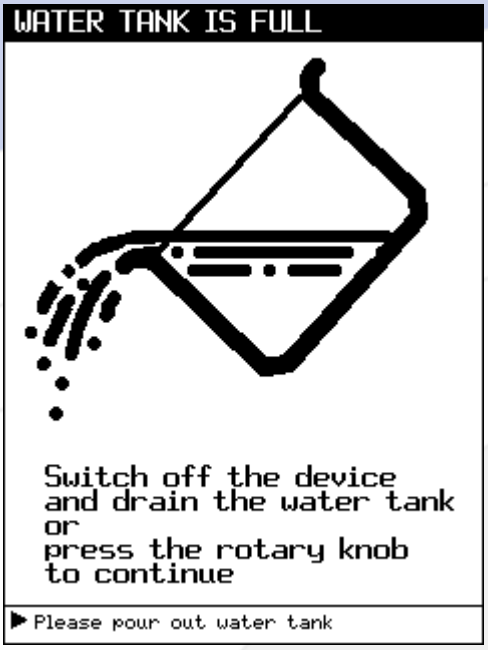

Figure 7.1: "Draining the water tank"

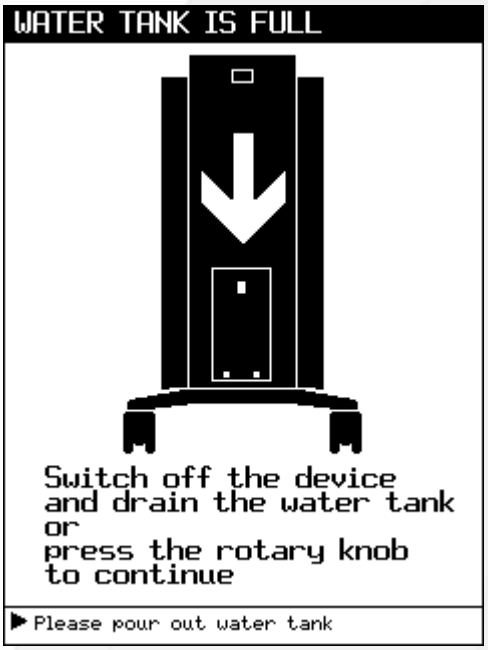

Figure 7.2: "Draining the water tank"

When the "Water tank is full" notice appears, the function locking can be skipped by pressing the knob. The treatment can be resumed without restriction by pressing the knob when prompted by the message "Continue pressing the knob" (can be construed as acknowledgement of information by the user).

Careful! Overflowing the water tanks may result in a risk of accident by slipping. Moreover it can also result in water damage. The maintenance instructions indicated (Display) must be complied with!

9 USING CRYOTHERAPY

Cryotherapy has been used since Ancient times as a proven method to relieve pain relief, inflammations and stimulate blood circulation.

Acute and chronic diseases are significant fields of application of cold air therapy.

9.1 Physiological effect of the cryotherapy

- Pain-relieving (analgesic)
- Anti-inflammatory (anti-phlogistic)
- Antispasmodic (muscle relaxant)
- Decongestant (prevents oedema)
- Reduce bleeding (anti-haemorrhagic)
- Reduce the nerve condition velocity

9.2 Significant medical effects

- Reduction of inflammatory metabolisms
- Significant analgesic effect
- Lower manifestation of post-traumatic and post-operative oedema
- Improvement of the condition of the musculoskeletal system and connective tissue
- Cryotherapy does not require any prior medicative treatment

9.3 Therapy advice as regards the use of cold air

1. With an air flow at stage 5-6 and the largest nozzle **(9),** as well as a short distance from the skin surface, you can ensure that most heat will be removed from the tissue. At **air stages 5** to **6,** the air flow is at its coldest.
2. The response to cold is unique to each patient. It also depends on the area to be treated. During the treatment, the air flow can be adjusted on manual operation to best suit the patient sensitivity.
   In thermofeedback, in automatic operation and for indications, a temperature is dependent on the control of the air flow.
3. In manual operation, the air flow should be applied with slight movements over the area to be treated. In automatic operation, the air flow should be applied with movement however. This is a more effective way to control the surface temperature.
4. During the dialogue with the patient, the therapy should be terminated if pain due to cold starts.
5. Cryotherapy is particularly effective when used daily. A course of treatment should include 10 sessions.
6. It is recommended to treat only one area at a time with cold area during one session.
7. The more sensitive the area to be treated, the shorter the treatment time.
8. For pain relief, a stronger air flow will be used for a shorter treatment time (about 2 to 5 minutes). The nozzle **(9)** will be brought closer to the skin surface and the recommended distance will be about 2 cm to 4 cm.
9. For a relaxing effect, a weaker air flow will be applied for a longer period of time (about 4 to 10 minutes) and the recommended distance is about 3 to 8 cm.
10. The cold is generated in the **CRYOFLOW ICE-CT** using a special compressor. For an optimum use of the cold air, we recommend to switch on the power switch (**3)** about 20 to 30 minutes before treatment. The device does into standby mode and the systems are pre-cooled. The air coming out is much colder, which is particularly advantageous for the treatment of larger areas.

9.4 Indications selected for local cryotherapy

Orthopaedics, sports medicine, traumatology

- Injuries: distortions, contusions, fractures, muscle sprains
- Post-traumatic conditions: lymphedema, joint contractions, haematoma
- Orthopaedic diseases: periarthropathy, active arthrosis, inflammations from swollen tendons and bursitis, myosclerosis, muscle gelling
- Post-operative conditions: Phase 1 (directly after operation), analgesia, prevention of oedema, Phase 2 (mobilisation) analgesia, muscle relaxation.

Rehabilitation

- Before physiotherapy and occupational therapy: for example for contractures, muscle hypertonia, limp paresis, trigger point treatment
- After orthopaedic-surgical interventions: joint surgery, synovectomy, arthroscopic interventions, tendon surgery
- After joint mobilisations: shoulder, elbow, knee, foot.

Rheumatology

- Inflammatory flares in: chronic polyarthritis, active arthrosis, acute attack of gout, mono-oligoarthritis, insertional tendinitis
- Acute inflammation of soft tissues: acute myositis, acute tendinitis, acute tendovaginitis, acute bursitis
- Acute periarthropathy: shoulder, knee, elbow
- Acute episodes of pain in the spine: acute torticollis, acute lower back pain
- Reflex Sympathetic Dystrophy(CRPS), stage 1: Sudeck's atrophy.

Dermatology and cosmetics

- Short-term cryotherapy best prepares the skin for other treatment procedures, such as masks, compresses, injections and physiotherapeutic treatments.
- The reduction of the nerve conduction velocity alleviates the pain of subsequent treatments.
- The application of cold is highly effective for the stabilisation of previous therapeutic or cosmetic treatments after operations or heat treatments, such as plastic surgery, laser or mechanical depilation, thermo coagulation, polishing and cleansing.
- Cold air is highly suitable for relieving pain during dermatological laser treatments.
  During a laser treatment, cold air must be applied by a skilled practitioner or at least monitored by one.

9.5 Contraindications

- Allergy to cold
- Cold haemoglobinuria (blood in urine after application of cold)
- Careful to angina pectoris in the thorax and more particularly in the left arm
- Deep aversion to cold
- Abdominal disorders (e.g. bladder and kidney diseases)
- Raynaud's disease
- Organic arterial circulatory disorders from stage 3 (arteriosclerosis)
- Patients, who are freezing and shivering (risk of hypothermia)
- Palpable protruding bones (e. g. olecranon)
- Eyes (eye socket, cornea).
- Use in emergency medicine
- Neuropathy (distorted sensitivity to cold)

Careful: The information in Items 9.4 and 9.5 do not claim to be complete.
For specific cases, and in particular when it comes to contraindications, the treatment physician must always be the one to decide on the use of cryotherapy.

10 SAFETY INSTRUCTIONS FOR THE OPERATION OF THE DEVICE

The cooling capacity of the **CRYOFLOW ICE-CT** depends also on the ambient conditions. It uses the ambient air to generate the cold air and to cool its own assembly.

Please comply with the following safety instructions:

- The device should not be placed near heat sources (heaters, ovens, stoves, saunas, windows with strong sunlight, etc.).
- The device should stand at least 40 cm from wall surfaces.
- For room temperatures above 30 °C and high levels of humidity, there might be limitations to the cooling capacity. This is normal and due to physical reasons. Under such extreme conditions, please switch on the device's power switch **(3)** about 20 to 30 minutes before treatment. This will allow the device' systems to pre-cool.
  Lower the cold air to a sufficient level (16) and reduce the distance between the nozzle (9) and the skin surface.
- The vent holes on the device should not be covered.

- No objects should penetrate the device either by the vent holes or by the open bottom part, or they may damage parts of the cooling circuit and coolant might escape. Nevertheless, should the cooling system be damaged, ventilate for a few minutes the treatment room where the device is located. Small amounts of fluid may have been released.

- Cryotherapy devices should be used exclusively by personnel trained or skilled in the fields of physiotherapy or similar background! The patient must be monitored by this personnel during the treatment!

- The device is not intended for installation and use in an environment that is rich in oxygen or in the presence of anaesthetic gases (AP/APG environment)!

- Before using cryotherapy, the patient must be consulted as regards any potential distorted sensitivity, intolerance or allergy to cold!

- Only accessories specified in Chapter 15 should be used!

- Avoid trapping & bruising the patient when actuating the supporting arm, and pay attention to the risk of jabbing or stabbing the patient when moving the supporting arm!

- Do not point the red LED light towards the eyes!

- It is not recommended to remove or insert the IR plug connection when in operation.

- Overflowing the water tank may result in a risk of accident by slipping. Moreover it can result in water damage. The maintenance instructions indicated in the Display and in these Operating Instructions must be complied with.

- Careful to the clamping points on the filter slot for the filter mat (2), to the valve for the water tank (4) and to the holder for the water tank (4)!

- If during the performance, a smell of ether occurs due to the potentially leaking coolant, make sure fresh air is brought in, switch the device off and lead people out of the treatment room!

-Only GymnaUniphy-authorised service personnel may open or repair the device and accessories, or perform the safety and technical inspection service on the device and accessories.

-Use only the type of fuses that is indicated on the label (6).

-A defective power supply cord **(1)** or a defective power switch **(3)** must be replaced only by service personnel authorised by GymnaUniphy or by the manufacturer.

-For all questions regarding service, please contact GymnaUniphy at the service address listed in Item 17.

-Please also refer to the instructions detailed in Items 11 "Fault, Service, Guarantee" and 12 "Maintenance and Cleaning".

-Do not move (drive) the unit between treatment rooms and do not use it in emergency medicine.

-Drive the device only for the purpose of driving over thresholds, initial setup/delivery transport and using the threshold ramp as a special accessory

11 FAULTS, SERVICE, GUARANTEE

11.1 Faults

Each time the switch on the power supply is turned on, the **CRYOFLOW ICE-CT** performs an inspection of the software. The device meets the accepted standards for interference resistance and emission of radiation. Faults that may affect the power supply cord **(1)** can cause indication errors. The device must then be switched off and switched on again at the power supply. You should always wait at least 3 minutes between switching off and on, in order to avoid any potential adverse effects on the compressor.

- THE DEVICE WILL NOT TURN ON.
  Check whether there is power at the mains, the power switch **(3)** is on, the power supply cord **(1)** and the fuses **(6)** are working. If the fuses **(6)** in the device are not working, you can replace them yourself. You may however only use the type of fuses specified on the label **(5)**. You can order fuses **(6)** from your supplier.

- A FOREIGN LANGUAGE appears on the Display **(17)**.
  Specify the desired language in the system menu setup (see Item 5.4). If the error persists, please contact your supplier.

- ALL CONTROLS WITHOUT FUNCTION.
  Switch off the device with the power switch **(3)** and turn it back on again after about 3 minutes. If the error persists, please contact your supplier.

- THE COOLING CAPACITY IS TOO LOW
  Check whether the filter mat **(2)** is dirty, the location of the device and the room temperature. Change the filter mat **(2)** and comply with instructions in Item 10.

- THE COLD AIR FLOW IS TOO WEAK
  If the cold air flow is too weak in air stages 10, then the heat exchanger is frozen.
  Please, follow Item 7.

- THE COLD AIR FLOW IS AT ROOM TEMPERATURE
  If the temperature of the cold air flow is still greater than 10°C even after 30 minutes or so and at air stage 5 (measured with a suitable thermometer in the nozzle (9)), please notify service.

- WATER LEAKS FROM THE DEVICE
  The water tank is filled. Please drain it as per Item 8.
  As a result from long standby and with high levels of humidity, small amounts of condensation may form in the device.
  This condensation evaporates in minutes during treatment. In rare cases, a few ml of condensation may also drip on the floor. This situation is a result of the functionality and does not constitute an error or indicates a leak in the device.

- THE “WATER TANK IS FULL” STATUS DOES NOT SHOW ON THE DISPLAY (16)
  The water tank must be placed in its holder behind the valve (4), so that it lies parallel to the left side on the plastic of the filling level sensor. The distance should be even and must not exceed 2 mm. The left side of the water tank is dirty or badly scratched.

- THE “WATER TANK IS FULL” MESSAGE REMAINS ON THE DISPLAY (16) EVEN AFTER DRAINING
  The device should be switched off with the power switch (3) and switched back on after 3 minutes or so.
  Please check that the water tank is properly placed and clean (see previous Item).
  If the message remains, then follow instructions specified in Item 8.

- ACCESSORIES ARE ICED UP
  This is normal during long operations or at high levels of humidity.

- THERMOFEEDBACK DOES NOT SHOW
  Check whether you have the right contact for the connecting cable for the IR sensor

- NO COLD AIR IS BLOWN OUT IN THERMOFEEDBACK, IN AUTOMATIC AND IN INDICATION OPERATION
  The specified treatment temperature is higher than the temperature on the surface of the body part

- THE TEMPERATURE DISPLAYED SEEMS UNREALISTIC

The distance for the reference value of the surface temperature is outside the optimum range (outside the skin surface). The red marking (LED spot) does not point to the desired area. The surface of the sensor is damaged, dirty or wet. The connection cable is not plugged in or defective.

- THE DEVICE CANNOT BE DE-ICED AFTER PRESSING THE BUTTON (11)
  The temperature in the heat exchanger must be lower than -10°C. Please leave the device in standby mode to cool down, until it shuts off automatically or de-ice after a treatment. Before de-icing with button (13), select the main menu.
  De-icing will occur automatically when the device is not switched on for a long time, e.g. overnight.

- THE TEMPERATURE SENSOR IN THE COOLING UNIT IS FAULTY
  Please notify service immediately.

- ERROR MESSAGE “IR SENSOR IN HANDLE FAULTY"
  If an IR sensor is plugged to your device, please check the plug connection.

- THE UNIT LOSES COOLING CAPACITY WITH CONTINUOUS OPERATION
  In the low probable case of continuous operation with simultaneous supply voltage on the upper tolerance limit, it may occur that the compressor unit will switch off of in the meanwhile. After about 10 minutes, the compressor unit connects again automatically. This condition is not a defect and does not constitute impairment of the purpose

11.2 Service

Your dealer proclaims his responsibility for proper functioning only if:

- The electrical installation of the relevant room complies with the applicable statutory provisions.
- Any repairs, modifications, extensions or settings on the device were performed by entitled personnel, in accordance with the requirements of these Operating Instructions.
- The device should be used for the purpose intended by the manufacturer.
- Maintenance is carried out regularly on the device and is done so in the prescribed manner.
- The legal requirements for the operation of the device have been complied with.

With the exception of the mains fuses **(6)**, filter mat **(2),** connection cable **(18)** for the IR sensor, nozzle **(9)**, water tank, located at the back behind the valve **(4)** and cleaning plate **(28),** there are no parts on the device that should be replaced by the user. Improper use or failure to carry out maintenance of the device in accordance with the provisions, releases GymnaUniphy and its representatives from liability with respect to all resulting damages, injuries, defects or malfunctions.
The expected life duration of the device is 10 years.

Please note that only the persons authorised by the manufacturer or by GymnaUniphy may open or repair the device and accessories, and carry out regular safety and technical inspections on the device and accessories. Please note also Items 10 and 11.

For all questions about the device, its use, defects, repairs and safety and technical inspections, please first contact the dealer from whom you purchased the device. Oftentimes, problems get solved more easily and faster that way.

You can also contact the service department of the manufacturer directly, as specified in Item 17 of these Operating Instructions.

Service and guarantee benefits will be lost if the device is not used in accordance with these Operating Instructions.

11.3 Guarantee

11.3.1 Guarantee conditions

The duration of the guarantee for the **CRYOFLOW ICE-CT** is based on the relevant national statutory regulations and shall start from the date of purchase (the date on the invoice will count as proof).
The guarantee covers all defects in material and build quality.

The guarantee applies only if the device is used as per the intended purpose and in compliance with the Operating Instructions.

The guarantee does not apply in case of poor maintenance and improper interpretation of faults, or in case of maintenance and repairs carried out by persons that were not authorised by GymnaUniphy, or for any accidents and damages arising thereof.

11.3.2 Limitation of liability of the manufacturer

The manufacturer is not liable for any potential complications to the therapists, patients or device, which have occurred after an incorrect diagnosis, improper use of the device or accessories, misinterpretation or failure to comply with the Operating Instructions, after poor maintenance of the device or if the maintenance or repair of the device was carried out by persons who were not authorised to do so by the manufacturer.

11.4 Handling the treatment hose/IR cableFaults

Figure 8.2.1: Cable on the handle

Do **not** rotate the handle > 360°!

Figure 8.2.2: Cable on the handle

If the cable twists around the hose, the handle must always be turned back.

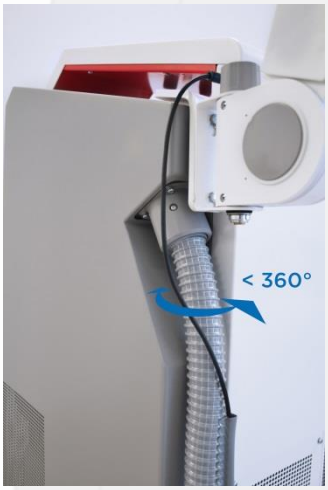

Figure 8.3:1 Cable on the device

Do **not** turn the hose > 360°!

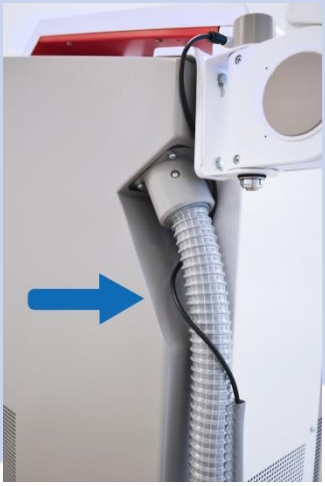

Figure 8.3.2: Cable on the device

If the cable twists directly around the device, the complete hose must always be turned back.

11.5 Handling the supporting arm

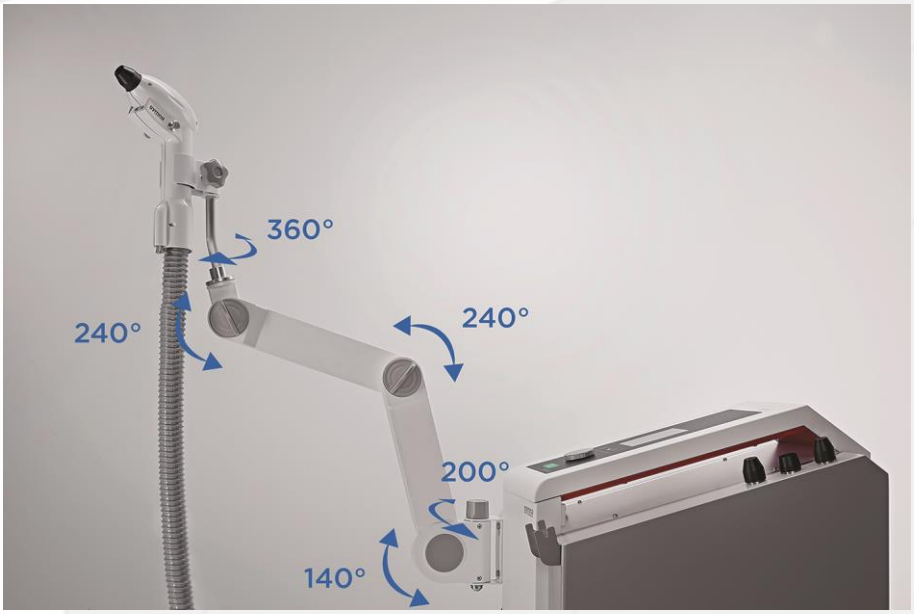

Figure 9.1: Supporting arm

Figure 9.2: Handle slot on the supporting arm

Figure 9.3: Axial adjustment of the supporting arm

Figure 9.4: Joints on the supporting arm

Figure 9.5: Adjustment of the rotor-joint on the supporting arm

Careful: Before adjusting the supporting arm, the joints must be loosened!

11.6 Relocating the device

The **CRYOFLOW ICE-CT** is fitted with 4 double rollers, to enable the easy positioning of the device at the place of treatment. Since the device is not earmarked for mobile use, no pushing into another treatment room can be done and it should not run over obstacles in the room (such as cable or similar). The alignment (positioning) are represented by the user as shown in Figure 9.6.
Before repositioning, please release the brakes on the wheels, by pulling the lever over the wheel and put the brakes back on by pressing on the lever after the change in position.
It is recommended to move items, such as cables, out of the way.

Figure 9.6: Touching the device when changing position in the room

12 MAINTENANCE AND CLEANING

Before carrying out any maintenance, cleaning or repair work on the **CRYOFLOW ICE-CT**, the device must be turned off **(3)** and disconnected from the electrical mains **(1)** (Item 5.3).

Cleaning the system regularly guarantees perfect hygiene and functionality of the **CRYOFLOW ICE-CT**.
The surface of the device, including the handle and the nozzle, should be cleaned every 14 days. Wipe the outside of the housing and the accessories with a damp, but not dripping wet, lint-free cloth. You can also use “Hexaquart S neutral” cleaning products and disinfectants from B. Braun Melsungen AG.
Make sure that no liquid penetrates the device and that no cleaning product residue remains on the housing.

Careful: No humidity should penetrate the device or the accessories and no cleaning product residue should remain on the housing or accessories.
Please dry all parts thoroughly.

At regular intervals, the filter mat **(2)** should be checked for soiling and changed as appropriate. It can be simply pulled out of its housing and put back into it.
Please insert only dry filter mats in the support. Wet filters will considerably reduce the amount of air blown to the patient and may even stop the flow in extreme cases.

At regular intervals, the water tank, located behind the valve **(4),** must be rinsed with simple tap water, at maximum room temperature, and cleaned with a brush as necessary. Heavy deposits in the tank can affect the measurement of the filling level. If despite intensive cleaning, the measurement of the filling level is impacted, we recommend using a new water tank.
Because of possible damage to the materials, the following is not suitable: halogen or oxygen releasing based compounds, strong organic acids, solvents, gasoline, acetone and similar substances. When disposing of the cleaning products or disinfectants, please comply with the instructions specified by each manufacturer.

Plastics, rubbers and materials with surface coatings may react to the application of cleaning products and disinfectants and be damaged accordingly. We therefore ask that before using any new product, you always read manufacturer’s information and conduct tests at appropriate locations.

Please note Item 11., in which it explicitly stated that only personnel authorised by GymnaUniphy or the manufacturer may open and repair the device or accessories. This also applies to the replacement of a damaged mains cable (1) or damaged power switch (3).

We recommend that a safety and technical inspection be conducted every 2 years on the device by service personnel authorised by GymnaUniphy or the manufacturer.

12.1 CLEANING THE COOLER

Caution: Careful to the clamping points on the filter slot and to the bottle holder!

The state of the cooler affects the functionality of the **CRYOFLOW ICE-CT**. Inside the device, a ventilator sucks in ambient air and blows it through the cooler and the round ventilation slots of the front wall to the outside. The environment will then be instrumental in how long it will take for the cooler to get dirty. If the cooling fins of the cooler become heavily covered with dirt, then the cooling capacity of the cryoflow is decreased and the cooler must be cleaned.
Before carrying out any maintenance work, and before unscrewing the ventilation plate **(28),** the power switch **(3)** must be switched off (Item 5.3) and the device disconnected from the mains at the power supply cord **(1)**.

For this purpose, the 4 screws of the ventilation plate **(28)** must be unscrewed on the front wall of the device using a Phillips screwdriver, and the ventilation plate removed. The cooler is now visible. The cooler can be cleaned using a normal vacuum cleaner. In order to better reach the edges and the covered areas of the cooler, a flexible vacuum cleaner nozzle can be plugged onto the hose of the vacuum cleaner. This flexible vacuum cleaner nozzle **(No 336.118)** can be ordered from GymnaUniphy (Customer Support Centre, Item 17). After cleaning, the ventilation plate must be screwed back on the front wall.

After **500** hours of operation, **Figure 10** appears on the Display **(17)** to indicate that a cleaning should be performed. If the cleaning is performed immediately, then **Figure 10** appears on the Display **(17)** and you can confirm the field "**performed'** with the knob **(16).** Then the Display **(17)** shows the next figure with the main menu (see Item 6.1) and a new treatment may be started. **Figure 10** will appear again after **500** hours of operation. The number of hours of operations corresponds to the switch-on times of the ventilator on the cooler.

If the cleaning is not performed immediately, then **Figure 10** appears on the Display **(17)** and you can confirm the field "**later"** with the knob **(16).** The next figure appears with the main menu (see Item 6.1) and a new treatment may be started. If the field "**later"** is confirmed, then **Figure 10** will always appear when switching on the device using the power switch **(3)**. It will show until **Figure 10** has confirmed the field "**performed"** with the knob **(16)**.

If compressed air is available, (you can also use small spray bottles that are commercially available and contain between 200 and 400 ml compressed air), we recommend blowing out the cooling fins after vacuuming. The result of the cleaning may be further improved with use of a vacuum cleaner and help remove easily the dust and fluff hidden on the corners.

With a regular cleaning of the cooler, the cooling performance of the cooling unit is maintained, the perfect function of the entire cooling system is supported and a thermal overload of the compressor as a result from a clogged cooler prevented.

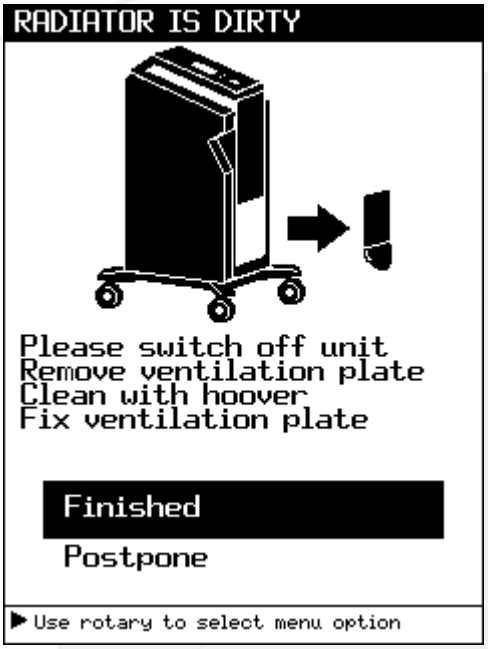

Figure 10: "Cleaning the cooler"

Caution! If during the performance, a smell of ether occurs due to the potentially leaking coolant, make sure fresh air is brought in, switch the device off and lead people out of the treatment room!

13 DECOMMISSIONING AND DISPOSAL

The device must be disposed of by an authorised company that is specialised in electronic and refrigeration products.
The device does not fall under household or bulk waste.

Please find out about the national regulations applicable in your country as regards disposal.
Information about the proper disposal may also be obtained from your supplier and local town and municipal administrations.

You may also contact your supplier in countries with a collection scheme.

Should you wish to dispose of the device yourself, or bear the responsibility of it, please bear in mind the following information about the materials used:

- Housing parts	among others	steel, zinc
- Electronic	among others	lead, tin, copper, steel, nickel, gold, various plastics
- Cooling unit	among others	steel, copper, tin, various plastics, coolant R404A or R410A, about 0.5 L with parts of CFCs (chlorofluorocarbons), lubricant, polyolester oil about 1 L
- Accessories	among others	steel, various plastics, tin, copper, nickel

The materials used for the packaging and operation instructions are recyclable.
You can place these materials in a suitable collection point or dispose of them with the household waste.
Please comply with the appropriate national regulations when disposing of packaging.

For the disposal of the cleaning products and disinfectants, please comply with the relevant instructions on the packaging or on the manufacturers‘ material data sheets included with the products!

14 TECHNICAL SPECIFICATIONS

Power supply	230 V, 50 Hz 115 V, 60 Hz (on request)
External electrical fuse	T 16 A at 230 V power supply T 20 A at 115 V power supply
Device fuse	T10A H 250 V at 230 V power supply T16A H 250 V at 115 V power supply
Maximum power consumption	1,2 kVA
Protection class	I
Protection degree	IP 21
Operating modes	• Automatic operation, 1 to 590 minutes • Manual operation, 1 to 590 minutes • Fixed programme
Absolute accuracy of infrared temperature measurement	+/- 2°C, at a distance of 4 cm from the nozzle (intersection of the IR spot and the middle of the cold air flow)
Optimum IR treatment distance	3 cm to 6 cm, nozzle to surface of the skin
Orientation aid for IR measurement	red LED, area of a circle
Time setting, increments	1 minute
Display	large LCD display, illuminated
Air control	10 stages in manual operation, or continuously in automatic operation
Maximum airflow	1000 l/min
Cold air	cooled down to –32 °C and blown on the skin via the treatment hose
Cooling circuit	maintenance-free, closed circuit, coolant R 404A or R 410 A
Hose	about 1,600 mm long with 2 joints (360°) for optimum flexibility
Power cord, average length	2,5 m
Dimensions (D x W x H)	687 mm x 569 mm x 1117 mm,
Average weight	90 kg
Maximum noise level	72 dBA, at air stage 10
Conditions of transport and storage	in the manufacturer’s packaging with the following limits: • -20 °C to +60 °C ambient temperature • 5 % to 95 % relative humidity, non-condensing • 500 hPa to 1060 hPa atmospheric pressure
Operating conditions	• +10 °C to +40 °C ambient temperature • 5 % to 90 % relative humidity, non-condensing • 500 hPa to 1060 hPa atmospheric pressure

15 ACCESSORIES

15.1 Scope of delivery

CRYOFLOW ICE-CT	Item number:	343.002
- User Manual		
- Nozzle 5 mm (distal cold air outlet on the handle)	Item number:	300.221
- Nozzle 15 mm (distal cold air outlet on the handle)	Item number:	300.222
- Nozzle 25 mm (distal cold air outlet on the handle)	Item number:	300.223

15.2 Optional accessories:

- Supporting arm	Item number:	343.035
- Filter mat	Item number:	300.275
- Threshold ramp (for the purpose of haulage/line-up in the treatment room)	Item number	333.210

We are constantly striving to keep our products at the cutting edge of technology. As a result, we reserve the right to make changes.

16 NOTES ON ELECTROMAGNETIC COMPATIBLITY (EMC)

Guidelines and manufacturer's declaration – Electromagnetic Interferences		
The **CRYOFLOW ICE-CT** is intended for use in an electromagnetic environment specified below. The customer or user of the **CRYOFLOW ICE-CT** must ensure that it is used in such an environment.		
Interference measurements	**Compliance**	**Electromagnetic Environment - guidelines**
HF emissions according to CISPR 11	Group 1	The **CRYOFLOW ICE-CT** uses HF energy only for its internal function. Therefore its HF emissions are very low and it is unlikely that nearby electronic devices would be disturbed.
HF emissions according to CISPR 11	Class B	The **CRYOFLOW ICE-CT** is suitable for use in all facilities, including living areas, and places directly connected to the public supply network, which supplies buildings used for domestic purposes.
Emissions of harmonics according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/ flicker according to IEC 61000-3-3	Met	

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The **CRYOFLOW ICE-CT** is intended for use in an electromagnetic environment specified below. The customer or user of the **CRYOFLOW ICE-CT** must ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 – test level**	**Level of compliance**	**Electromagnetic environment - guideline**
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be in wood or concrete, or covered with ceramic tiles. If the floor is covered with a synthetic material, the relative humidity should be at least 30%
Fast transient electrical disturbances/bursts according to IEC 61000-4-4	± 2 kV for mains cable ± 1 kV for input and output connections	± 2 kV for mains cable ± 1 kV for input and output connections	The quality of the supply voltage should correspond to that of a typical business or hospital environment
Surges according to IEC 6100-4-5	± 1 kV Normal mode voltage ± 2 kV Common mode voltage	± 1 kV Normal mode voltage ± 2 kV Common mode voltage	The quality of the supply voltage should correspond to that of a typical business or hospital environment.

Voltage dips, short-term interruptions and variations in the supply voltage in accordance with IEC 61000-4-11	<5% U_T (>95% Dip of the U_T for ½ period) 40% U_T (60% Dip of the U_T for 5 periods) 70% U_T (30% Dip of the U_T for 25 periods) <5% U_T (>95% Dip of the U_T for 5 seconds)	<5% U_T (>95% Dip of the U_T for ½ period) 40% U_T (60% Dip of the U_T for 5 periods) 70% U_T (30% Dip of the U_T for 25 periods) <5% U_T (>95% Dip of the U_T for 5 seconds)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the **CRYOFLOW ICE-CT** wishes the machine to keep functioning even during breaks in the power supply, we recommend powering the **CRYOFLOW ICE-CT** from an uninterruptible power supply or battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should have the same typical values as those found in business or hospital environments.
Note: U_T is the alternating mains voltage prior application of test levels.			

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The **CRYOFLOW ICE-CT** is intended for use in an electromagnetic environment specified below. The customer or user of the **CRYOFLOW ICE-CT** must ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 – test level**	**Level of compliance**	**Electromagnetic environment - guideline**
			Portable and mobile radio devices should not be used closer to the **CRYOFLOW ICE-CT**, including cables, than the recommended safety distance, which is calculated on the basis of the equation applicable to the transmission frequency. **Recommended safety distance**
Conducted HF disturbances in accordance with IEC 61000-4-6	3 V_{rms} 150 KHz to 80 MHz	3 V_{rms} 150 KHz to 80 MHz	$d = 1.17 \sqrt{P}$
Radiated HF disturbances in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.17 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz

			Where P is the power rating of the transmitter in Watt (W) according to the information of the transmitter's manufacturer and is the recommended safety distance in meter (m). The field strength of stationary radio transmitters should be [b] for all frequencies in accordance with a test of location [a] lower than the compliance level. Wherever the following symbol appears in the environment of the device, faults are possible 

NOTE 1 At 80 Hz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply to all cases. The propagation of electromagnetic quantities will be impacted by the absorptions and reflections of the building, objects and people.

[a] The field strength of stationary transmitters, such as base units of radio-telephone and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasts cannot, in theory, be predicted with accuracy. In order to ascertain the electromagnetic environment resulting from stationary transmitters, a study of the site's electromagnetic phenomena should be considered. If the field strength measured in a place where the **CRYOFLOW ICE-CT** is used, exceeds the aforementioned compliance level, the **CRYOFLOW ICE-CT** should be monitored to check its normal operation. If an abnormality is noted, additional measures may be required, such as changing the direction or place the **CRYOFLOW ICE-CT** somewhere else.

[b] For frequency ranges of 150 kHz to 80 MHz, the field strength should be lower than 3 V/m.

Recommended safety distances between portable and mobile HF telecommunication devices and the CRYOFLOW ICE-CT

The **CRYOFLOW ICE-CT** is intended for use in an electromagnetic environment, where the HF disturbances are controlled. The customer or user of the **CRYOFLOW ICE-CT** can help prevent electromagnetic faults, by maintaining a minimum distance between the portable and mobile HF telecommunications devices (transmitters) and the **CRYOFLOW ICE-CT** – depending on the output power of the communications devices, as specified below.

Rated output of the transmitter W	**Safety distance depending on the transmission frequency m**		
	150 KHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
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 whose maximum rated output is not stated in the table above, the recommended safety distance d in meter (m) can be ascertained using the equation in the corresponding column, where P is the maximum rated output of the transmitter in Watt (W) in accordance with the information of the transmitter's manufacturer.

NOTE 1 At 80 Hz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply to all cases. The propagation of electromagnetic quantities will be impacted by the absorptions and reflections of the building, objects and people..

17 SERVICE ADDRESS

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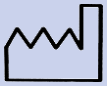
18 EXPLANATION OF SYMBOLS

Symbol:	Meaning:
	Year of manufacture
	CE marking, with the identification number of the notified body
	Mains fuse
	Manufacturer
	"DEFROST" button
	"SYSTEM" button
	"MAIN MENU" button
	"START/STOP" button
	Knob, parameter setting
	Follow operating instructions
REF	Item number
SN	Serial number
	Do not place the device in the general household waste
IP 21	Degree of protection against the intrusion of solids and moisture (1. Code number 2 = protected against solid foreign bodies with a diameter of 12.5 mm; Protected against access with a finger) (2. Code number 1 = protect against vertical falling drops)
	Safety signs “Do not push”
I	“ON”
O	“OFF”

	a  b c d	Warning label on the outer cardboard box of the packaging for: a) This side up b) Caution, fragile c) Protect from humidity d) Keep dry