ProSense™ Cryoablation System

User Manual

DMS-29361 Rev. A

CE 0482

Please read this document carefully before using the ProSense™ Cryoablation System. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your IceCure Medical representative.

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1 OVERVIEW

1.1 Introduction

ProSense™ Cryoablation System is a comprehensive system that is used in conjunction with an Imaging System (for example, Ultrasound) for cryotherapy of human tissue based on IceCure™ Medical's technology. All established cryotherapy techniques utilize a low temperature cryogen under pressure. The ProSense™ Cryoablation System utilizes Liquid Nitrogen that causes the cryoprobe to reach very low temperatures thereby freezing tissue with which it comes in contact.

1.2 Intended Purpose

ProSense™ cryoablation system is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. The ProSense™ cryoablation system is indicated for use as a cryosurgical tool in the fields of general surgery (including breast and liver tissue), dermatology, thoracic surgery (including lung tissue), gynecology, oncology (including Musculoskeletal tissue), proctology, and urology (including kidney tissue). The ProSense™ cryoablation system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

This cryotherapy should only be executed if the operative standard therapy and established therapies cannot be applied.

1.3 Indications for use

ProSense™ cryoablation system is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. The ProSense™ cryoablation system is indicated for use as a cryosurgical tool in the fields of general surgery (including breast and liver tissue), dermatology, thoracic surgery (including lung tissue), gynecology, oncology (including Musculoskeletal tissue), proctology, and urology (including kidney tissue). The ProSense™ cryoablation system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

<u>Urology</u>

- The system may be used to ablate prostatic tissue.
- The system may be used to ablate kidney tissue including renal cell carcinoma.
- The system may be used for the ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia.

<u>Oncology</u>

- The system may be used for ablation of cancerous or malignant tissue.
- The system may be used for ablation of benign and malignant breast tumors

- The system may be used for ablation of benign and malignant lung tumors
- The system may be used for ablation of benign and malignant musculoskeletal tumors
- The system may be used for ablation of benign and malignant liver tumors
- The system may be used for ablation of benign tumors.
- The system may be used for palliative intervention.

Dermatology

- The system may be used for the ablation or freezing of skin cancers and other cutaneous disorders.

Gynecology

- The system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.

General Surgery

- The system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions.
- The system may be used for the destruction of warts or lesions.
- The system may be used for the palliation of tumors of the oral cavity, rectum, and skin.
- The system may be used for ablation of breast fibroadenomas and breast tumors.

Thoracic Surgery

- The system may be used for the ablation of arrhythmic cardiac tissue.
- The system may be used for the ablation of cancerous lesions, including lung tissue.

Proctology

- The system may be used for the ablation of benign or malignant growths of the anus and rectum
- The system may be used for the ablation of hemorrhoids.

This cryotherapy should only be executed if the operative standard therapy and established therapies cannot be applied.

1.4 Clinical Benefit

The clinical benefits of ProSense™ cryoablation system include offering an alternative or additional therapy option .This procedure is minimally invasive and is intended for cryoablative tissue destruction in the fields of general surgery, dermatology, thoracic surgery, gynecology, oncology, proctology, and urology. The procedure is short, entails minimal risks and scarring, and is characterized by short recovery and hospitalization times. Cosmetic outcomes are exceptional, and in breast procedures with our technology, there is no need for post-procedure reconstruction surgery. Optimal patient-specific treatment, according to the expected application, is attained with IceCureTM's cryoprobes which are available in various diameters and lengths .The cryoprobes are chosen based on the tumor size, application, and surgery approach, creating a spheric or an elliptic iceball shape engulfing the tumor. In addition ,quick and safe navigation with reduced risk for infection ,bleeding ,and adjacent organs injury are attained with IceCureTM's introducer as it remains in position throughout the procedure allowing multiple passes of different surgical tools (e.g., biopsy needle, Cryoprobe) and substances (e.g., gelfoam).

1.5 ProSense™ Qualified users

Qualified ProSense™ cryoablation system user can perform cryoablation procedures in humans.

Qualified users are individuals who:

- Are a board-certified physician licensed in their country.
- Have been trained in ProSense Cryoablation System use by a certified trainer approved by IceCure Medical Ltd..
- Have read and understood all relevant material accompanying the ProSense™ cryoablation system.

Warning
If you do not meet the above criteria, do not use the ProSense™ cryoablation system.

Practitioners electing to be ProSense™ cryoablation system users must attend a training course prior to using the system. The course is taught by IceCure™ Medical certified personnel.

Warning
Do not use this system if you have not been adequately trained in its use.

1.6 Advanced Operator

Qualified ProSense Cryoablation System operators can operate the system for the qualified user during the clinical procedure and will operate the system for non-clinical purposes such demonstrations and training.
Qualified Operators are individuals who:

- Have been trained in ProSense Cryoablation System operation by a certified trainer approved by IceCure Medical Ltd.
- Have read and understood all relevant materials accompanying the ProSense Cryoablation System.

Warning
If you do not meet the above criteria, do not operate the ProSense™ cryoablation system.

1.7 Clinical decisions

The practitioner is solely responsible for all clinical use of the ProSense™ cryoablation system and for any results obtained with the device.

Cryotherapy is beneficial in a variety of applications as a minimally invasive approach However, sole responsibility for determining when and how to use the system with a given patient and for a particular medical condition lies with the practitioner.

Warning
In case of incomplete treatment, there is a chance that full destruction of the targeted area DIDN'T OCCURRED and therefore physicians must act accordingly.

Use of ProSense™ cryoablation system in special populations, such as pregnant women, pediatric has not been established.

For further details, refer to Section 1.3 – Indications for use.

1.8 Contraindications

Severe infection, uncorrectable coagulopathy, hemodynamic or respiratory instability.

1.9 Qualified technician

Only a technician trained by IceCure™ Medical is qualified to service the ProSense™ cryoablation system.

Servicing includes installation, periodic maintenance, and repair of the ProSense™ cryoablation system.

Warning

Do not modify this equipment without authorization of the manufacturer

2 SAFETY NOTES

While this manual is designed to provide instructions in the use of the ProSense™ cryoablation system, it is not intended to take the place of the user training course which must be completed before using the system.

This chapter defines the different types of safety notices that appear in the manual.

2.1 Warnings and Cautions

Safety notices appear throughout the manual and take one of the following forms:

Warning
This notice warns of situations that could result in loss of life or severe injury. Be sure to read and follow all information presented.

Caution
This notice warns of actions that can result in severe damage to the system and/or to the data stored on the system.

2.2 Basic safety principles

All safety issues explained in this manual are grouped within the following areas of responsibility:

2.2.1 Ownership

Caution
U.S. federal law restricts this device to sale by or on order of a physician.

2.2.2 Qualification

Warning
Any procedures using this system must be performed by licensed practitioners or board-certified doctors who are trained and experienced in the use of this system.

Warning
Do not attempt to perform any troubleshooting or corrective action beyond those specified in the following guide. Any malfunction not listed in the guide, or one that persists after the recommended action has been taken, must be referred to IceCure™ Medical.

Warning

Never allow untrained personnel to operate the ProSense™ cryoablation system.

Warning

Never enter the Technician mode screen. Only an IceCure™ Medical technician or authorized representative is allowed to use the technician mode for maintenance or repair of the system.

Warning

Never open the console. Only an IceCure™ Medical technician or authorized representative is allowed to open the console for maintenance or to repair the system.

2.2.3 Training

Warning

Do not use this system if you have not been adequately trained in its use.

2.2.4 Clarity

Warning

Do not use this system until you have read the User Manual in its entirety and fully understand its contents.

While every effort has been made to make this User Manual comprehensive, certain sections may be unclear or difficult to understand depending on the user's background and experience. Do not use this system if there is any instruction, direction, precaution or note which you do not understand, or which is unclear. Never hesitate to contact an authorized IceCure™ Medical representative for further information and clarification before using the system.

2.2.5 Clinical Assessment

Warning

Ensure that cryoprobes are used with matching introducers. Use of longer cryoprobes may result in undesired tissue perforation.

Warning

Practitioners should be aware of the possibility of imaging findings at the site of a cryoablated area. Practitioners should inquire if a patient has a history of cryoablation.

Warning

Exercise caution when treating patients who have had previous difficulty with surgical procedures or local anesthesia.

Warning

Safety and effectiveness of the ProSense™ cryoablation system in pregnant women has not been established. Physicians should exercise caution when using the cryoablation system in pregnant women.

Caution

The cryohandle and hose may become cold during the cryoablation procedure. Consider insulating these parts in order to prevent discomfort to the patient or the physician.

Warning

The supplier and manufacturer of the ProSense™ cryoablation system do not claim that it will be useful for assisting with the treatment of any particular condition or set of circumstances. Full responsibility for assessing the potential benefit of the system for a given medical condition lies with the practitioner.

While experience has shown that the system is useful for certain applications in cryosurgery, no representation or warranty is made that the system is useful for any specific person or condition.

Warning

Practices of cryoablation for women with breast implants have not been established. For patients with breast implants, you must document that adequate distance exists between the lesion and the implant to ensure that the ablated lesion will not contact or jeopardize the implant, and there is enough space to create the required margins.

Warning

Artifacts from the devices may appear in the Ultrasound or CT image.

Warning
Introducer and cryoprobe insertion and navigation within tissue must be done under guidance of an appropriate imaging device.

Warning
Do not start the **Freeze** step before the cryoprobe active area is within the target tissue.

Warning
Make sure the cannula is placed in the desired place after extracting the mandrel.
Verify under imaging that the ice ball forms at the desired location at the beginning of the freeze step

2.2.6 Voltage and power ratings

Caution
Verify that the ProSense™ cryoablation system complies with the local voltage line.

2.2.7 Installation and Setup

Caution
The ProSense™ cryoablation system must be unpacked, installed, and tested by an IceCure™ Medical technician or by a technician authorized by IceCure™ Medical to perform installation and testing on ProSense™ system.

Caution
After positioning the main chassis, lock the front roller brakes. Failure to do so may result in damage to the system or to other equipment in the clinic room.

Warning
The cryoablation system should be operated in an adequately ventilated room. Failure to do so may result in risk of suffocation due to increased levels of nitrogen in the room.

⚠	**Warning** Do not use the ProSense™ Cryoablation System in an oxygen-rich environment

⚠	**Caution** There are no user-serviceable parts in the system. Refer all service issues to IceCure™ Medical's Customer Service Department.

⚠	**Caution** Make sure the time is set according to local time zone before executing a cryotherapy procedure.

⚠	**Caution** The ProSense™ cryoablation system must be installed according to the Electromagnetic emissions guidance and declaration provided in chapter 14 of this manual.
⚠	**Caution** To avoid portable and mobile RF communications equipment effect on the ProSense™ cryoablation system, it is recommended to work according to Recommended separation distances between portable and mobile RF communications equipment provided in section 14.4 of this manual.

⚠	**Warning** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ProSense, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠	**Caution** The ProSense™ should not be used stacked on other equipment and if stacked use is necessary, the ProSense™ should be observed at all times to verify normal operation in the configuration in which it will be used.

Caution

After transporting the ProSense™ Cryoablation System, check the device's temperature. If the temperature is below 10°C or above 40°C, allow one hour for every 2.5 degrees before the System is used.

2.2.8 Proper use

Warning

The ProSense™ cryoablation system must be operated only with IceCure™ cryoprobes.
IceCure™ cryoprobes must be used only with the ProSense™ cryoablation system.

Warning

Do not remove any of the system's panels and do not open any of the system's covers.

Warning

Do not disconnect the cryoprobe from the system during **Freeze**, **Extraction**, or **Thaw** unless you are instructed to do so by the system.

Caution

Do not use the workstation or the Liquid Nitrogen Dewar for any purpose other than operating the ProSense™ cryoablation system.

Caution

The Liquid Nitrogen Dewar supplied with the ProSense™ cryoablation system is a dedicated system part and should not be used for any other purpose. Make sure to use only IceCure™ approved and labeled Dewars for your system.

Caution

Dewars should always be stored with their dedicated lids in place.

Caution

Only Dewars and lids supplied by IceCure™ Medical may be used with the ProSense™ cryoablation system. Make sure to use only an approved IceCure™ Dewar for your system.

Caution

Turn off the cryoablation system and lock the rollers when the system is not in use.

Before you start a procedure, lock at least two of the four rollers.

Caution

The ProSense™ cryoablation system should be moved with care in order to avoid damage to the system or other clinical equipment. When moving the system, use the dedicated handle.

Caution

If one or more of the rollers is damaged, do not use the system.

Warning

Cryoprobes are fragile and can be damaged if mishandled. Do not use a cryoprobe that has been bent, dropped, hit against a hard surface or compromised in any manner, as damage to the cryoprobe may have occurred. If any mechanical damage (such as bent) is identified during any phase of the procedure, press the emergency stop button immediately, and extract the cryoprobe (if not possible, wait for passive thaw).2.9

Warning

1. Surgical instruments must be handled with care to avoid damage to the cryoprobe.
2. Avoid pinching, cutting, or pulling the cryoprobe. Do not use damaged cryoprobes
3. Do not grasp cryoprobes with auxiliary instruments, as this may cause damage to the cryoprobe shaft.

Warning
If a sterile product packaging is compromised in any way, do not use the product.

Caution
The system will not allow additional treatment when zero procedures are left to maintenance. Make sure to call IceCure™ Medical service representatives in time.

Warning
The system and its accessories are not compatible with magnetic resonance imaging.

Warning
The use of accessories, transducers, and cables other than those specified or sold by the manufacturer of the ProSense™ as replacement parts for internal components, may result in increased emissions or decreased immunity of the ProSense™.

Warning
Follow the EMC guidance provided in Chapter 14 of this manual when installing or servicing the system during expected service life. Failure to follow these instructions may result in degrading in basic safety and essential performance of the system.

Caution
Do not use acetone to clean the labels' area (Holder and ProSense™ system).

2.3 Cyber security

The ProSense™ Cryoablation System has no Bluetooth or WiFi devices installed and cannot be connected to any networks or devices using Bluetooth or WiFi protocols.

Caution

Use USB2.0 flash drives only to export reports or log files. Importing any data or software may corrupt the ProSense™ Cryoablation System.
Do not connect any other USB devices to the ProSense™ Cryoablation System USB port.

Caution

Do not use USB extension cables to connect a USB flash drive to the ProSense™ Cryoablation System USB port. Using USB extension cables may cause electromagnetic emissions exceeding regulatory limits.

Caution

Do not connect Ethernet cables to the ProSense™ Cryoablation System and do not connect the system to any internal or external networks.
Connecting external equipment to the system can only be done by individuals trained and certified by IceCure™ Medical company.

2.4 Operating warnings

Warning

Ensure that the cryoprobe is securely connected to avoid leakage of Liquid Nitrogen.

Warning

Insertion of the introducer or cryoprobe into the target tissue is performed under the guidance of an appropriate imaging device and by an authorized practitioner trained by IceCure™ Medical.

Warning

when the cryoprobe is already connected to the cryohandle, exercise caution to prevent a stabbing injury from the cryoprobe and maintain sterility.

Warning
Do not tap the **Extraction** button when the cryoprobe is not within the target tissue, as skin burns could occur.

Warning
Do not tap the **Extraction** button before the freezing protocol is completed unless you want to shorten the procedure due to clinical judgment.

Warning
After Extraction step, before removing the cryoprobe and/or Introducer from the tissue, make sure that the freeze effect has been thawed out so that the cryoprobe and/or Introducer can be easily and safely removed from the tissue.
Do not force removal of the cryoprobe and/or Introducer from the tissue as it might increase the risk of tissue damage. Continue the Extraction step or wait for passive thaw until the cryoprobe and/or Introducer can be withdrawn easily.

Warning
Never detach the cryoprobe from the cryohandle if you are not clearly instructed to unscrew or disengage it.

Warning
Verify cryoprobe S/N registration by double checking the serial number on the package and on the cryoprobe itself. Entering an incorrect cryoprobe S/N registration will result in cryoprobe nullification or incomplete treatment.

Warning
Entering an incorrect cryoprobe S/N during registration can affect the calculation for the cryoprobe placement, System performance and treatment outcome.

Warning
Do not allow any liquid or humidity to enter the Cryohandle. Always keep the handle plug on the Cryohandle.

Warning
In case the Extraction process isn't available, Wait for passive Thaw.

Warning
Pay attention to the cryoprobe during functional test: if bubbles, leak or frost on shaft or no ice are observed do not use the cryoprobe.

Warning
If you don’t press **Skip** after replacing Dewar, the system will stay in **Thaw** mode.

Warning
Do not try to disengage a cryoprobe before instructed since the system is under pressure and you can be hurt by the sharp cryoprobe ejected under pressure. In addition, the hose and the cryoprobe still contain Liquid Nitrogen that can be spilled out.

Caution
The maximum Holder arm load is 3Kg.

2.5 Danger - explosion and fire hazard

Warning
The ProSense™ cryoablation system includes electronic devices that may emit sparks, and therefore, should not be operated in the presence of flammable materials.

ProSense™ cryoablation system should be kept away from flammable fumes, e.g., flammable anesthetics or volatile substances. An easily accessible fire extinguisher in the vicinity of the ProSense™ cryoablation system is recommended.

2.6 Liquid Nitrogen

Nitrogen gas is a potential asphyxiant. In the event of a large Liquid Nitrogen spill, personnel should adhere to a predetermined evacuation plan. Seek medical help immediately if breathing problems occur.

Warning

Press the emergency stop button immediately in case of emergency situation which is related to system's fault (for example nitrogen leak / fire / electrical fault) or cryoprobe's fault (for example nitrogen leak / frost on shaft and so on). Wait for passive thaw until the cryoprobe and/or Introducer can be withdrawn easily. Do not force removal of the cryoprobe and/or Introducer from the tissue as it might increase the risk of tissue damage.

Warning

At the beginning of the procedure the Dewar should be filled around 1 cm below the neck of the bottle.
Do not overfill a Dewar with Liquid Nitrogen; it will reduce performance of the system.

2.6.1 Opening the Dewar compartment

Warning

Never open the Dewar compartment while running a cryoablation procedure unless you are instructed to do so by the system interface.

Warning

Follow the specific instructions on how to fill and transfer a Dewar as described in section 5.2.6.1.

2.6.2 Liquid Nitrogen Safety

Warning

Removing the Dewar or placing it back within the system after refilling it must only be done according to system instructions and with the carriage in the bottom position. If the carriage is not in the bottom position, Liquid Nitrogen may spill out.

Caution

When replacing the Dewar, follow detailed on-screen instructions on opening the Dewar compartment.

Warning

Do not move the system when the Dewar contains Liquid Nitrogen.

Warning

Liquid Nitrogen may cause, if there is not sufficient ventilation in the room, serious injury or burn if handled improperly. Local laws and safety rules regarding the maintenance and handling of Liquid Nitrogen Dewars should always be observed. Maintenance of Liquid Nitrogen Dewars should be performed by authorized personnel only.

Warning

To avoid spillage and cold burns, do not transfer a Dewar containing Liquid Nitrogen unless it is covered with its designated lid.

Warning

If there is not sufficient ventilation in the room, the ProSense™ cryoablation system cannot be used due to risk of suffocation due to increased levels of nitrogen in the room.

Warning

Standard guidelines for safe handling and storage of Liquid Nitrogen are available from the supplier and must be carefully followed.

Warning

Handle Liquid Nitrogen with care. Contact with skin may cause serious frostbite. Do not allow objects cooled by Liquid Nitrogen to touch your bare skin. Objects cooled by Liquid Nitrogen may stick to the skin and tear flesh when attempting removal.

Warning

Protective clothing can reduce the hazards of handling Liquid Nitrogen. Insulated or heavy leather gloves should always be worn when handling any object that has been in contact with Liquid Nitrogen. Loose fitting gloves are recommended so that they may be discarded quickly in the event that any Liquid Nitrogen splashes into them. If you are working with open containers of Liquid Nitrogen, boots should be worn and trousers should not be tucked into boots but worn outside.

Warning

Personal protective equipment is essential and can save you from the risk of Liquid Nitrogen. Full face shield and safety glasses are recommended for eyes/face protection.

Warning

Fill the Dewar slowly to avoid the expansion stress that occurs as a result of the rapid cooling. Too much pressure can damage the container.

Warning

Do not seal the Dewars tightly. The use of a tight-fitting stopper or plug that prevents the adequate venting of gas allows a build-up of pressure that could severely damage or even burst the container. Even an accumulation of ice or frost on the lid can interfere with proper venting. To assure safe operation, only use the original sponge lid supplied with the Dewar.

Warning

Liquid Nitrogen Dewars must always be stored in an upright position. Tipping the Dewar or letting it lie on its side can result in spillage and may damage the Dewar. Dropping the or subjecting it to severe vibration may damage the vacuum insulation system.

Warning

Transfer Liquid Nitrogen with care. Spilling and splashing are the primary hazards of transferring Liquid Nitrogen from one container to another. never overfill the containers. Filling above the specified level is likely to produce spillage when the lid is replaced. Transportation of Liquid Nitrogen must always be done in the original container and in accordance with local laws and safety rules.

Warning

Do not attempt to dispose of residual or unused quantities of Liquid Nitrogen. For safe disposal contact your supplier. For emergency disposal, discharge slowly to the atmosphere in a well-ventilated room or outdoors.

If spilled Liquid Nitrogen causes a cloud to form, the room must be evacuated and ventilated immediately. Anyone experiencing headache, dizziness, difficulty breathing, or other symptoms of hypoxia should receive immediate medical attention.

Warning

Do not use a Liquid Nitrogen Dewar if it is damaged. You can tell that a Dewar is damaged if after filling it, frost appears on the outer wall of the container. Return the Dewar to an IceCure™ Medical technician or an authorized distributor for inspection.

Warning

Before beginning a procedure on a new patient, the Dewar MUST be properly filled and placed in the system as described in section 5.2.6.1 of this manual.

2.6.3 Burn hazards

The Cryoprobe tip can reach very low temperatures.

Warning

Portions of the cryoprobe other than the freeze zone, including the plastic cover that is located near the cryoprobe handle, may become cold and cause tissue damage. If unwanted freezing occurs, stop the functional test process by pressing "Cancel".

Warning

. If unwanted freezing occurs, immediately stop the freeze step. In case of cryoprobe fault such as frost on shaft, or nitrogen leak, press the emergency stop button.

To prevent injury, ice ball growth must be monitored under imaging guidance.

2.7 Grounding

Warning

To avoid risk of electric shock, this equipment must only be connected to an electricity network with protective grounding.

2.8 Sterility

Warning

Cryoprobes, introducers, and sterile sleeves are single-use devices supplied in single use sterile packaging.

Reuse of single-use devices affects their performance and can cause cross-contamination.

Warning

Never reuse a single-use cryoprobe, introducer, or a single-use sterile sleeve.

Warning

After finishing the cryoablation procedure on a patient, remove and safely discard the single-use cryoprobe, introducers, and sterile sleeve.

Warning

For each new procedure, ensure that the previously used single-use cryoprobe, introducers, and sterile sleeve have been removed and discarded. Any used cryoprobe and introducer must be disposed of as used sharp biohazard waste. Any used sterile sleeves must be disposed of as used biohazard waste.

Warning

Do not use IceCure™ sterile products after their expiration date, which can be found on their labels.

2.9 Mechanical handling of hose and cryohandle

Warning

Do not try to disengage a cryoprobe before instructed since the system is under pressure and you can be hurt by the sharp cryoprobe ejected under pressure.

Warning

The hose and the cryoprobe still contain Liquid Nitrogen that can be spilled out if you disengage the cryoprobe before you get proper system instructions to disengage the cryoprobe.

Warning

Do not use the system if the hose is damaged. Pay attention to the hose and to the interface between the system and the hose during functional test: if leak or frost on hose do not use the system.

Caution

Never use excessive force to insert or remove a cryoprobe from the cryohandle.
If moderate force is not sufficient, contact IceCure™ Medical for advice.

Caution

Do not pull the system by the cryohandle or hose.
Do not bend the hose to sharp angles during the procedure. .

2.10 Emergencies and errors

2.10.1 Emergency Stop button

Warning

Press the emergency stop button immediately in case of emergency situation which is related to system's fault (for example nitrogen leak / fire / electrical fault) or cryoprobe's fault (for example nitrogen leak / frost on shaft and so on). Wait for passive thaw until the cryoprobe and/or Introducer can be withdrawn easily. Do not force removal of the cryoprobe and/or Introducer from the tissue as it might increase the risk of tissue damage.

Warning

In case of environmental or medical emergency, extract the cryoprobe from the patient. If the cryoprobe is in the frozen tissue, tap the **Extraction** button for quick cryoprobe removal.
Hold the cryohandle steady as the cryoprobe may move due to the tension and weight of the hose.

2.10.2 Emergencies causing procedure halt

Warning

When a procedure halts due to an error, switch OFF the system. Call IceCure™ Medical and describe the error shown on the screen as precisely as possible.
Do NOT attempt to reuse the system before contacting IceCure™ Medical.

Warning

When an error message is displayed and a procedure is aborted, disengage the cryoprobe only after you are instructed to do so by the system. Alternatively, follow the instruction provided in section 5.3.5. Failure to follow the system instructions increases the risk of a Liquid Nitrogen related accident.

Warning

In case of software crash, switch OFF the mechanical ON/OFF switch and unplug the electrical cable.
Call IceCure™ Medical for technical service before restarting the ProSense™ cryoablation system.

Warning

When the system shuts itself down due to an error, contact IceCure™ Medical and describe the error message shown on the screen as precisely as possible. Do not attempt to reuse the system before contacting IceCure™ Medical. After reporting or making note of the error message, switch OFF the mechanical ON/OFF switch and unplug the electrical cable.

2.11 Potential Adverse Events

Warning

Users must notify IceCure™ Medical of all serious adverse events, including serious adverse device reactions, as soon as they become aware.

2.11.1 General surgery/ minimal invasive procedures

- **Mild/moderate adverse events**

Adjacent organs injury, alanine aminotransferase level elevation, anesthesia related adverse effects in cases used (cough, hypotension, hypoxia, residual neuromuscular block in recovery, slow to regain consciousness), aspartate aminotransferase level elevation, asthenia/fatigue bleeding, bowel stoppage, CPK elevation deep vein thrombosis, diarrhea, dimpling, edema, erythema, fever, flushing, heart rhythm disorder, hematoma, hemorrhage, hypertension, hypothermia, infection, intra adhesions, leucocytosis, liver transaminase elevation, local neuropathy, malaise, mild renal failure, minimal self-limited serum bilirubin level elevation, muscle twitching, myoglobinemia, nausea, pain, needle seeding, nerve injury, peripheral nerve impairment (paresthesia, peripheral nerve palsy), , pleural effusion, pneumonia, pneumothorax, pruritus, rash acneiform, skin burns, skin induration, thermal injury, thrombosis, transient ischemic attack, treatment site reaction, user accidental injury, vagal reaction, vomiting.

- **Severe adverse events**

Abscess, adjacent organ injury, anesthesia related adverse effects in cases used (cough, hypoxia, hypotension, residual neuromuscular block in recovery), angina/coronary ischemia, arrhythmia, atelectasis, bleeding, cardiac arrhythmias, congestive heart failure, CPK elevation, cryoshock (hypotension), death, disseminated intravascular coagulation, heart rhythm disorder, hemorrhage, hemothorax, hematoma, infection, life threatening serum bilirubin level elevation, liver transaminase elevation, multi organ failure, myocardial infarction, nerve injury, peripheral nerve impairment (paresthesia, peripheral nerve palsy), perirenal fluid collection, pneumomediastinum, pneumothorax, pulmonary emboli, respiratory compromise, rhabdomyolysis, severe elevation in aspartate aminotransferase, severe elevation in alanine aminotransferase, severe renal failure, stroke, skin burns, thermal injury, thrombosis, thrombosis of the portal vein branches.

2.11.2 Percutaneous ablation procedure

- **Mild/moderate adverse events**

Adjacent organ injury, asthenia/fatigue, bleeding, CPK elevation, dimpling, edema, erythema, flushing, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), infection, liver transaminase elevation, malaise, mild renal failure, muscle twitching, nerve injury, pain, percutaneous hematoma, peripheral nerve impairment (paresthesia, peripheral nerve palsy), pruritus, puncture of adjacent organs, rash acneiform, skin burns, skin induration, tumor recurrence.

- **Severe adverse events:**

Adjacent organ injury, CPK elevation, death, hematoma, infection, liver transaminase elevation, nerve injury, percutaneous bleeding, peripheral nerve impairment (paresthesia, peripheral nerve palsy), pneumomediastinum, puncture of adjacent organs, rhabdomyolysis, sepsis, severe renal failure, skin burns, tumor seeding.

2.11.3 Oncology/Breast, Liver, Musculoskeletal

2.11.3.1 Breast (malignant and benign, including fibroadenoma):

- **Mild/ moderate adverse events**

Adjacent organ injury, bleeding, breast skin bruising, breast swelling, ecchymosis, edema, fat necrosis, headache, heat sensation, hematoma, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), local breast infection, local pain, nerve injury, pneumothorax, puncture of adjacent organs, skin burns, skin necrosis, tethering, thermal injury to the breast skin or pectoralis muscle, tumor recurrence, vasovagal reaction.

- **Severe adverse events**

Adjacent organ injury, bleeding, death, hematoma, infection, nerve injury, pneumothorax, sepsis, skin burns, skin necrosis, puncture of adjacent organs, thermal injury to the breast skin or pectoralis muscle, tumor seeding.

2.11.3.2 Liver

- **Mild/moderate adverse events**

Adjacent organ injury, asthenia/fatigue, bleeding, CPK elevation, edema, hematoma, hematuria, burns, hemorrhage, hemothorax, hypotension, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), infection, liver transaminase elevation, malaise, mild renal failure, muscle twitching, myoglobinuria, nerve injury, pain, peripheral nerve impairment (paresthesia, peripheral nerve palsy), pneumothorax, pleural effusion, puncture of adjacent organs.

- **Severe adverse events**

Adjacent organ injury, arteriovenous fistula, bile peritonitis, bleeding, CPK elevation, bowel stoppage, death, hemothorax, hematoma, hematuria, infection, liver abscess, liver transaminase elevation, nerve injury, peripheral nerve impairment (paresthesia, peripheral nerve palsy), pleural effusion, pneumomediastinum, pneumothorax, puncture of adjacent organs, rhabdomyolysis, sepsis, severe renal failure, skin burns, tumor seeding.

2.11.3.3 Musculoskeletal

- **Mild/moderate adverse events**

Asthenia/fatigue, bleeding, bowel stoppage, chondrolysis, early-onset degenerative arthritis, edema, fracture, hematoma, hydronephrosis, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), increase CPK, infection, liver transaminase elevation, local pain, malaise, mild renal failure, motor dysfunction, muscular injury, muscle twitching, nerve injury, nerve palsy, nontarget ablation of adjacent neurovascular structures, osteomyelitis, peripheral nerve impairment (paresthesia, peripheral nerve palsy), skin burns, swelling, osteonecrosis, peri-ablational neuropathies, tumor recurrence.

- **Severe adverse events**

Avascular necrosis of bone, bleeding, chondrolysis, compartment syndrome, death, fracture, hematoma, hemorrhage, hydronephrosis, incomplete hemiplegia, increase CPK, infection, liver transaminase elevation, motor dysfunction, nerve injury, nerve palsy, nontarget ablation of adjacent neurovascular structures, osteomyelitis, osteonecrosis, peri-ablational neuropathies, pericardial effusion (in chest wall ablations), peripheral nerve impairment (paresthesia, peripheral nerve palsy), pneumomediastinum, puncture of adjacent organs, sepsis, severe renal failure, skin burns, radiculopathy, rhabdomyolysis, tumor seeding.

2.11.4 Urology/Renal and Prostate:

- **Mild/moderate adverse events**

Acute urinary retention, adjacent organ injury, anemia, asthenia/fatigue, bleeding, bowel stoppage, CPK elevation, cystitis, edema, ejaculatory dysfunction, erectile dysfunction, hematoma, hematuria, hydronephrosis, hypotension, idiosyncratic reaction, ileus, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), liver transaminase

elevation, malaise, mild renal failure, nerve injury, non–life-threatening pulmonary embolism, pain, pelvic pain, penile paresthesia, peripheral nerve impairment (paresthesia, peripheral nerve palsy), perineal pain, probe site paresthesia, pyelo-ureteral junction obstruction/ stenosis, renal infarct, skin burns, urinary tract obstruction, tumor recurrence, urinary tract infection, voiding dysfunction.

- **Severe adverse events**

Anaphylactic reaction, adjacent organ injury, arteriovenous fistula, bladder neck contracture, bleeding, chronic hypertension due to page kidney, CPK elevation, death, deep vein thrombosis, gastrointestinal tract injury, hematuria, hydronephrosis, hypotension, hypertensive emergency, idiosyncratic reaction, ileus, infection, liver transaminase elevation, lumbar radiculopathy, muscle twitching, myocardial infarction, need for transfusion due to hemorrhage, nerve injury, pelvic vein thrombosis, peripheral nerve impairment (paresthesia, peripheral nerve palsy), pneumomediastinum, puncture of adjacent organs, rectourethral fistula, renal artery/ vein injury, renal fracture, renal hemorrhage, renal infract, renal vein thrombosis, retroperitoneal hematoma, , rhabdomyolysis, scrotal edema, sepsis, severe renal failure, severe urinary tract obstruction, skin burns, splenic infarction, tumor seeding, urethral sloughing, ureteral stricture, urinary fistula, urinary frequency/ urgency, urinary incontinence, urinary retention, urinary tract infection, urinary tract leak, urinoma.

2.11.5 Thoracic/Lung and cardiac arrhythmia

- **Mild/moderate adverse events**

Adjacent organ injury, alveolar hemorrhage, arm paresis, arteriovenous fistula, back pain, bleeding, bronchial injury, cough, damage to the kidneys from dye used during the procedure, diaphragmatic paralysis, heamatoma, hematoma, hemothorax, hemoptysis, hemorrhage, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), infection, loss of speech (temporary aphasia from laryngeal nerve damage), nerve injury, new or worsening arrhythmia, pain, partial/total lung collapse, pericardial effusion, phrenic nerve palsy, pleural effusion, pneumonia, pneumonitis, pulmonary emboli, respiratory failure, rib fracture, silent microemboli, skin burns, skin injury, small pneumothorax, subcutaneous emphysema, thrombosis, transient ischemic attack, tumor seeding, vascular access problems.

- **Severe adverse events**

Acute respiratory distress syndrome, adjacent organ injury, air embolism, arteriovenous fistula, atelectasis, atrioesophageal fistula, bleeding, broncho-cutaneous fistula, bronchial injury, broncho-pleural fistula, cardiac arrest, cardiac tamponade, chest wall abscess, death, deep vein thrombosis, diaphragmatic paralysis, dyspnea, empyema, endocarditis, esophageal injury, femoral pseudoaneurysm, hematoma, hemopneumothorax, hemoptysis, hemorrhage, hemothorax, infection, lung collapse, myocardial infarction, nerve injury, perforation of the heart, persistent empyema, phrenic nerve palsy, pleural effusion, pneumonia, pneumothorax, prolonged chest tube drainage, prolonged

intubation, pulmonary emboli, pulmonary insufficiency/failure, puncture of adjacent organs, respiratory failure/arrest, sepsis, skin burns, stroke, subcutaneous emphysema, superior vena cava syndrome, thromboembolic complications, thrombosis, tumor seeding, valve damage, venous stenosis.

2.11.6 Gynecology

- **Mild/ moderate adverse events**

Adjacent organ injury, bleeding, genitourinary perforation, hematoma, hematuria, hydronephrosis, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), nerve injury, non-target ablation of adjacent structures, pain, pelvic pain, skin burns, treatment site infection, tumor recurrence, urinary tract infection.

- **Severe adverse events:**

Bleeding, death, hematoma, hemorrhage, hydronephrosis, infection, non-target ablation of adjacent structures, nerve injury, puncture of adjacent organs, sepsis, sigmoid colon perforation, skin burns, tumor seeding, ureteral stricture.

2.11.7 Dermatology:

- **Mild/ moderate adverse events:**

Adjacent organ injury, bleeding, Fasciitis, hemorrhage, , hematoma, hematuria, incomplete treatment (see the definition in section 2.11.8) related adverse effects (cancer recurrence due to residual malignancy), infection, local pain, motor dysfunction, muscular injury, nerve injury, nerve palsy, nontarget ablation of adjacent structures, peri-ablational neuropathies, skin burns, swelling, tumor recurrence.

- **Severe adverse events**

Bleeding, death, hemorrhage, hematoma, infection, motor dysfunction, nerve injury, nerve palsy, non-target ablation of adjacent structures, puncture of adjacent organs, sepsis, skin burns, tumor seeding.

2.11.8 Incomplete treatment – definition

Incomplete treatment is an adverse event which may occur due to device malfunction, aborted procedure, poorly planned cryoablation procedure (lack or insufficient of freezing time, early cryoprobe withdrawal), imprecise Cryoprobe location, improper patient selection pertaining to the tumor size or allowed margins or any circumstances preventing sufficient tumor engulfment and proper completion of cryoablation procedure.

Warning

In case of incomplete treatment, there is a chance that full destruction of the targeted area DIDN'T OCCURRED and therefore physicians must act accordingly.

Incomplete treatment may be detected during cryoablation procedure or immediately after it, or at follow up visits (via imaging). Incomplete treatment may require additional

cryoablation or other methods of treatment. If unrevealed, incomplete treatment may lead to residual malignancy and/or death.

2.11.9 Excessive freezing time

Excessive freezing time may result in ice-ball growth beyond the recommended margins and damage to healthy tissue therefore, monitoring ice ball growth is required.

2.12 Disposal

2.12.1 The System

Follow local regulations and hospital internal procedures concerning equipment disposal.

The WEEE symbol indicates that this system contains electrical and electronic components that must be collected and disposed of separately. Never dispose of electrical and electronic components in general municipal waste receptacles. Electrical and electronic equipment contain hazardous substances which, when disposed of incorrectly, may leak into the ground. This can contribute to soil and water pollution which is hazardous to human health and endangers wildlife. Therefore, such equipment must not be disposed of in landfill sites or incinerators.

Contact your local authority or place of purchase regarding responsible disposal/recycling.

2.12.2 Single Use Items

Follow local regulations and hospital internal procedures concerning disposal of single use items.

Warning

For each new procedure, ensure that the previously used single-use cryoprobe, introducers, and sterile sleeve have been removed and discarded. Any used cryoprobe and introducer must be disposed of as used sharp biohazard waste. Any used sterile sleeves must be disposed of as biohazard waste.

2.13 Compliance

2.13.1 Compliance with international safety standards

The cryoablation system was designed and built according to international standards.

- EN 60601-1 Standard for safety of Medical equipment
- European MDD 93/42/EEC
- EN 60601-1-2 Standards for Electromagnetic compatibility of medical electrical equipment (See chapter 14- Manufacturer's Declaration of the EUT)

2.14 Equipment classification

- Electric shock protection: Class I, Type BF.

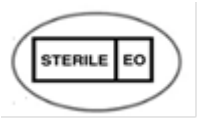
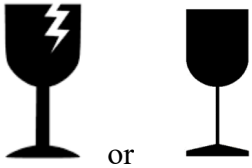
- Protection against ingress of liquids: IPX0 (no protection against contact and ingress of liquids). Not suitable for use in presence of volatile substances or flammable anesthetic mixture with air or nitrous oxide.

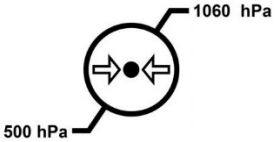
2.15 Important Symbols

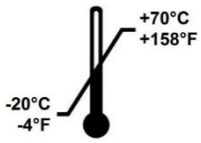
A number of symbols relating to safety requirements and standards are found on the ProSense™ cryoablation system. These symbols are listed in the table below.

Table 1: Symbols on ProSense™ cryoablation system and Accessories

Symbol	Meaning
	Caution/Warning
	Consult instructions for use
	Applied parts
	Serial number
	Manufacturer
	Date and country of manufacture
	Do not reuse
	Use- by Date
	Catalogue number

Symbol	Meaning
	Do not re-sterilize
	Single sterile barrier system, sterilized using ethylene oxide
	Sterilized using ethylene oxide, single sterile barrier system with protective packaging outside
	Batch code
	The WEEE symbol indicates that this system contains electrical and electronic components that must be collected and disposed of separately. Never dispose of electrical and electronic components in general municipal waste receptacles. Electrical and electronic equipment contain hazardous substances which, when disposed of incorrectly, may leak into the ground. This can contribute to soil and water pollution which is hazardous to human health and endangers wildlife. Therefore, such equipment must not be disposed of in landfill sites or incinerators. Contact your local authority or place of purchase regarding responsible disposal/recycling.
	Fragile, handle with care
	Do not use if package is damaged

Symbol	Meaning
	Cold area
	Consult instructions for use
 Oxygen depleting	Oxygen depleting
	This side up
EC REP	Authorized representative in the European community
CH REP	Swiss Authorized Representative
CE 0482	CE mark- mandatory conformity mark for products placed on the market in the European Economic Area
MD	Medical Device
	Transportation and storage atmospheric pressure limits
	Transportation and storage humidity limits

Symbol	Meaning
	Storage temperature limits
	Keep away from sunlight
	Keep dry
	CAUTION: US Federal law restricts this device to sale by or on the order of a physician
	Mandatory conformity mark for electronic products placed on the market in the USA
	Lock; tighten two parts together in a fixed position
	MR safety warning: system materials are not compatible with magnetic resonance imaging
	Equipotentiality: Indicates terminal to be used for connecting equipotential conductors when interconnecting (grounding) with other equipment as described in IEC60601-1.
IPX0	Degree of protection (access to hazardous parts inside the enclosure, ingress of solid foreign objects, harmful effects due to the ingress of water)
	Open here The location where the package can be opened and indication of the opening method
	Unique device identifier
	Outer diameter

Symbol	Meaning
	Nominal dimensions
	Inner diameter
c.z.	Cool zone center
	One unit in the package

3 SYSTEM DESCRIPTION

3.1 Introduction

This chapter contains the following:

- Concept of operation – ProSense™ cryoablation system intention for use
- Major components – description of the main system parts
- Operational details – system processes that occur as a result of user actions

3.2 Concept of operation

The ProSense™ cryoablation system is intended for cryogenic destruction of tissue during surgical procedures. It is indicated for use as a cryosurgical tool in a number of medical fields.

The system is designed to destroy tissue by the application of extreme cold temperatures. ProSense™ cryoablation system is indicated for patients whom the practitioner has designated as eligible for cryotherapy.

ProSense™ cryoablation system has 3 modes of operation:

1. Waiting (standby) mode – power cord is plugged in and the system is turned on; SW allows moving to procedure preparation, time set, log extraction, technician actions; the LN2 Dewar is disengaged from the system and the pneumatic circle is open. Active modules are panel PC and controller.
2. Freeze mode – as long as the system is turned on, Cryoprobe and LN2 Dewar are plugged into the system. In this mode, the Dewar is pressurized and LN2 is supplied to the Cryoprobe. Active modules are panel PC, controller, valves, compressor, exhaust heater.
3. Extraction (Heating) mode - as long as the system is turned on, Cryoprobe and LN2 Dewar are engaged with the system. In this mode, the Dewar is not pressurized and heated N2 is supplied to the Cryoprobe. Active modules are panel PC, controller, valves, compressor, warm heater.

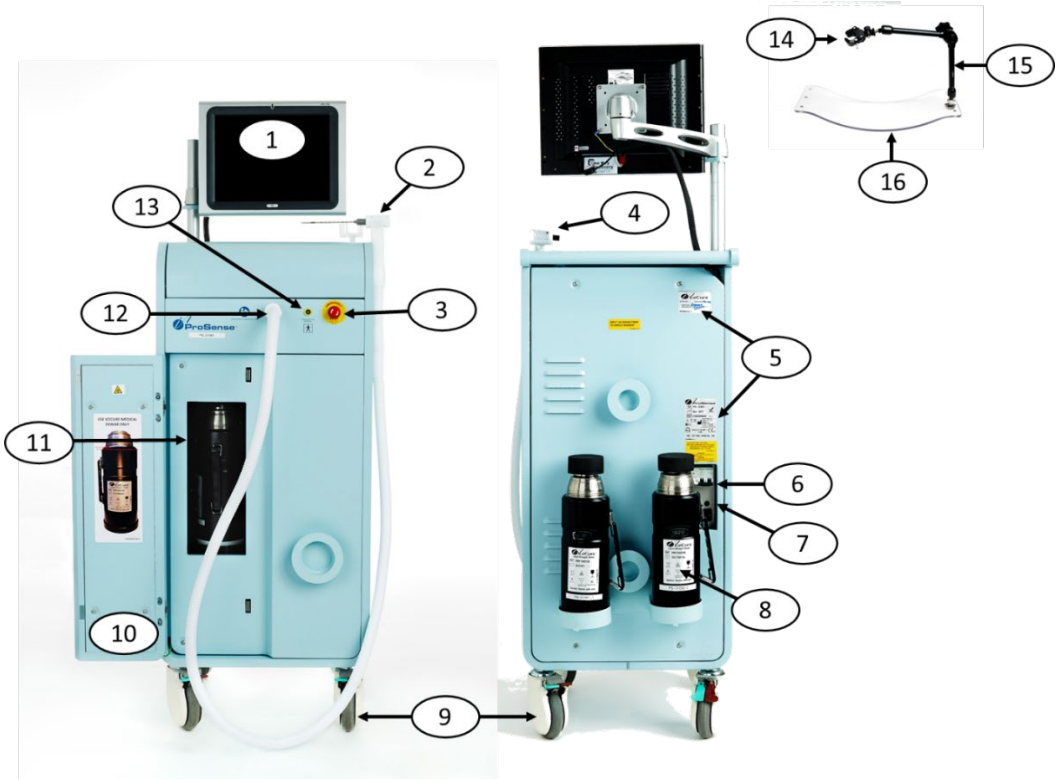
During Freeze step, the Cryoprobe tip temperature should reach at least -150 Degree Celsius. The temperature of the returning pipe is controlled by the software and depends on the type of Cryoprobe connected to the system.

During Extraction step, the Cryoprobe tip temperature must not be higher than 35 Degree Celsius. The temperature of the warm pipe is controlled by the software and depends on the type of Cryoprobe connected to the system.

The pressure in the 2-liter Dewar and Cylinder is controlled by the software and depends on the type of Cryoprobe connected to the system. The Cylinder and Dewar pressure is limited by the compressor power and the safety mechanical relief valves.

3.3 Major components

The following figure illustrates external features of the cryoablation system:



1. Touch screen
2. Cryohandle
3. Emergency Stop button
4. Cryoprobe cradle
5. System labels
6. ON-OFF switch
7. Potential Equalization pin (POAG)
8. Dewar
9. Rollers
10. Dewar positioning door/Elevator door
11. Dewar elevator compartment
12. Flexible hose connection
13. Temperature sensor port
14. Adjustable clamp
15. Holder adjustable arm
16. Holder base

Figure 1: Front and back view of the ProSense™ cryoablation system with numbered components

The ProSense™ Cryoablation system includes:

- Main chassis
- Adjustable touch screen
- Accessories: introducers, Holder (may not be available in some regions), and cryoprobes.
- External components: 2 liter Liquid Nitrogen Dewar, foot pedal (may not be available in some regions).

Product Name	Description	Part Number
Cryoablation Console (90 degrees handle)	100-127 VAC	FAS3000000
	220-240 VAC	FAS3100000
	100-127 VAC	FAS3000000-2

Cryoablation Console (straight handle)	220-240 VAC	FAS3100000-2

3.3.1 Main chassis

The ProSense™ Cryoablation system is housed within a chassis mounted on four rollers for ease of movement. Each roller is equipped with directional and rotational brakes for system immobilization. Located on the top of the chassis are a touch screen control panel and a Cryohandle cradle. On the right upper part of the chassis is the Emergency Stop button - a round red button that shuts down the system immediately in an emergency situation. On the back of the chassis are two hooks used for hanging the electric cable, and a grip handle for ease of system transportation.

The ProSense™ Cryoablation System has a potential equalization pin (POAG) located next to the Main rear ON/OFF switch. If required, connect the POAG to the hospital socket or to the site connection marked with green/yellow circles, using an appropriate wire (wire is not provided by IceCure™ Medical).

Figure 2: ProSense™ transportation rollers & brakes

3.3.2 Emergency Stop button

The Emergency Stop button is a red knob located on the right upper side of the chassis. It is designed for emergency shutdown of the ProSense™ Cryoablation System. Pressing this button immediately turns OFF the electrical power supply to the system. To release the Emergency Stop button, turn it in the direction of the arrows.
Note: Pressing the emergency stop button is the same as turning off the system via the ON\OFF button at the rear of the system and also the same as disconnecting the power cord from the AC line (mains).

Figure 3: Emergency Stop button

Warning

Press the emergency stop button immediately in case of emergency situation which is related to system's fault (for example nitrogen leak / fire / electrical fault) or cryoprobe's fault (for example nitrogen leak / frost on shaft and so on). Wait for passive thaw until the cryoprobe and/or Introducer can be withdrawn easily. Do not force removal of the cryoprobe and/or Introducer from the tissue as it might increase the risk of tissue damage.

Warning

In case of environmental or medical emergency, extract the cryoprobe from the patient. If the cryoprobe is in the frozen tissue, tap the **Extraction** button for quick cryoprobe removal.
Hold the cryohandle steady as the cryoprobe may move due to the tension and weight of the hose.

3.3.3 Flexible hose

The hose joins the cryohandle to the siphon inside the chassis. This permits Liquid Nitrogen to flow from the main chassis to the cryoprobe.

Caution

Do not pull the system by the cryohandle or hose.
Do not bend the hose to sharp angles during the procedure. .

Warning

Do not use the system if the hose is damaged. Pay attention to the hose and to the interface between the system and the hose during functional test: if leak or frost on hose do not use the system.

3.3.4 Touch screen and User Manual activation

The touch screen is located on top of the main chassis and allows for operating and monitoring of the system. It is designed for users and technicians.
Do not connect any signal input/output port to the touch panel PC except certified equipment provided by IceCure™ Medical.

Caution

Do not connect Ethernet cables to the ProSense™ Cryoablation System and do not connect the system to any internal or external networks.
Connecting external equipment to the system can only be done by individuals trained and certified by IceCure™ Medical company.

A sample touch screen display is represented by the figure below. For further information about computer interface and operating the system, see Chapter 6.

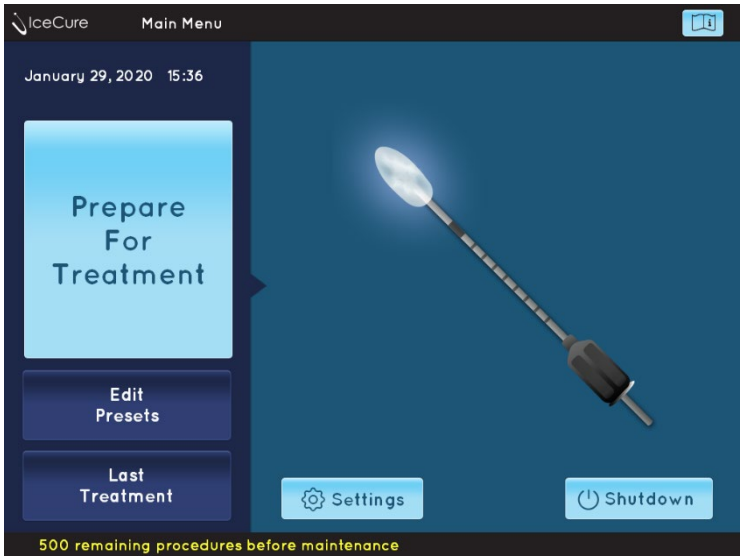


Figure 4: Touch screen display before a cryoablation procedure

The User Manual can be accessed from the Main menu by pressing on the User Manual icon in the top-right corner of the screen.

The User Manual is displayed by embedded Adobe Acrobat Reader. You can choose topics from the Table of Contents or use the Acrobat Reader navigation panel.

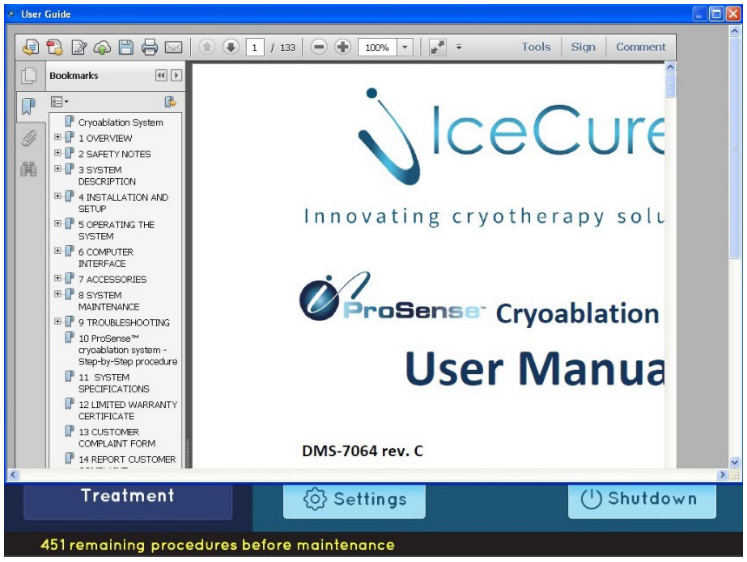


Figure 5: User Manual navigation panel

You can select a **page number**, **zoom out** or **zoom in**, **scroll** along the document

By pressing on the x (right corner), you will exit the User Manual.
If you prefer, you can also download the User Manual from our website:

http://www.icecure-medical.com

If you would like to acquire a printed copy of the User Manual, please contact us directly and one will be sent to you within 7 working days.
We can be reached via email at icecuresupport@icecure-medical.com

3.3.5 Cryohandle and cryoprobe

The cryohandle is situated at the end of the hose that projects through the upper area of the front panel of the ProSense™ cryoablation system. The cryoprobe is connected to the cryohandle. The cryohandle allows for maneuvering of the cryoprobe within the target tissue.

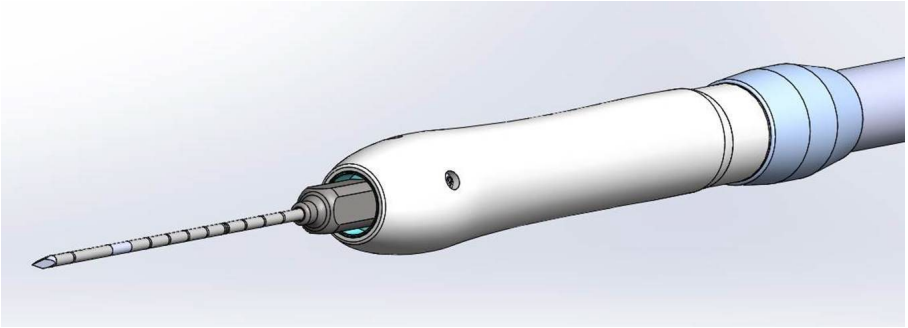


Figure 6: Straight cryohandle and connected Cryoprobe

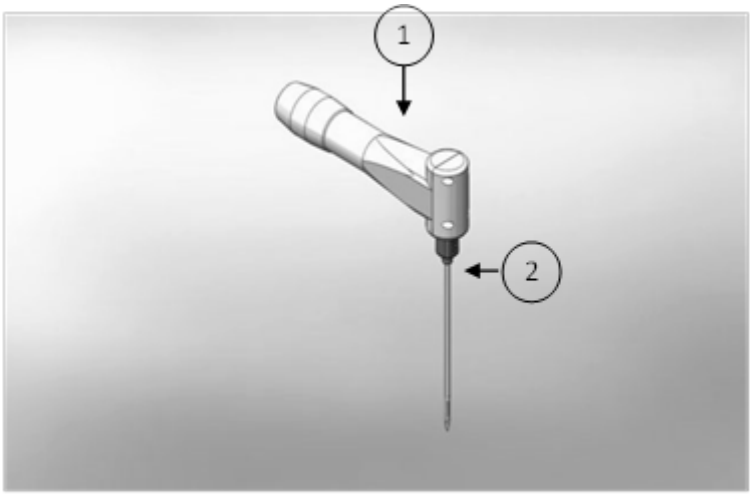


Figure 7: 90 degrees Cryohandle (No 1) and connected Cryoprobe (No 2)

Warning

Cryoprobes, introducers, and sterile sleeves are single-use devices supplied in single use sterile packaging.

Reuse single-use devices affects their performance and can cause cross-contamination.

Warning

After finishing the cryoablation procedure on a patient, remove and safely discard the single-use cryoprobe, introducers, and sterile sleeve.

3.3.5.1 Handle plug holder and handle plug

The handle plug holder is located on the top of the main chassis and allows a place for keeping the plug while performing the procedure.
Humidity is a crucial issue to address in cryosurgery systems.

- After every procedure, close the handle plug on the Cryohandle.
- Perform functional test at close proximity to the procedure treatment.

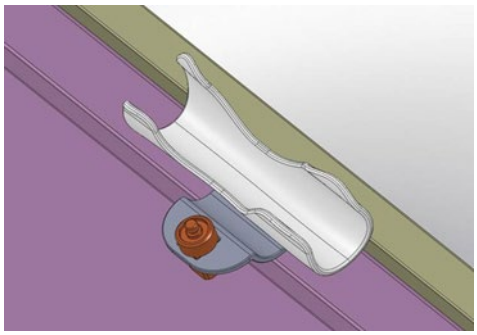


Figure 8: Handle plug holder and handle plug.

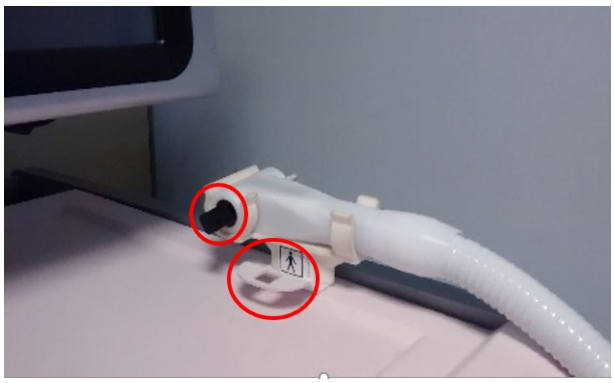


Figure 9: Cryohandle closed with the plug on the Handle holder

When using a 90 degrees cryohandle, make sure that the cryohandle is directed towards the system when laid down on the handle plug holder on main chassis.

3.3.6 Holder – Optional (May not be available in some regions)

The Holder is an optional accessory (may not be available in some regions), that stabilizes the hose in a specific position during the procedure.
The holder is adjustable in height and length and should be adjusted by the user as required.
The hose can be safely put on the Holder arm once positioning of the Cryoprobe in the tissue is completed.

Caution

The maximum Holder arm load is 3Kg.

The Holder base is designed to be positioned under the patient body while the holder arm is adjustable at the side of the table.

The Holder is designed to adjust to a CT or other patient table.

It is the consideration of the user on which side and where to position the holder arm according to the room and patient table conditions, except under the CT machine gantry.

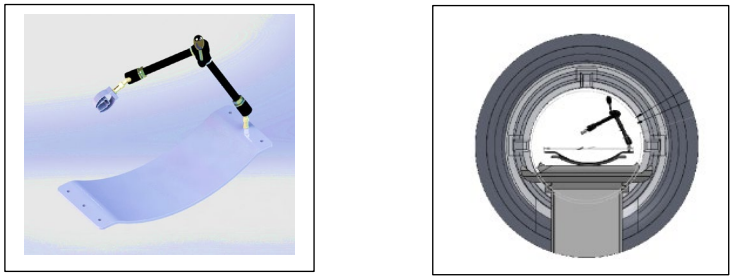


Figure 10: Holder and its position within the CT machine (may not be available in some regions)

3.3.7 Foot pedal (May not be available in some regions)

Pushing the pneumatic foot pedal is identical to activating/deactivating the **Freeze** step and confirming actions of the active buttons on the screen:

Figure 11: Action button as displayed on screen (several of the options)

Figure 12: Foot pedal

3.3.8 Dewar Holders

The Dewar holders are located at the back of the chassis, providing storage for the Dewars. When placing the Dewars inside the storage shelf, make sure they are well installed (see fig. below).

Figure 13: Dewar storage cases – the correct way to put the Dewars inside the storage shelf.

Warning
Do not move the system when the Dewar contains Liquid Nitrogen.

3.4 Operational details

This section describes the operational actions of the ProSense™ cryoablation system that support the functional operations described in Chapter 5.

- Order Liquid Nitrogen in advance based on projected case load
- Industrial grade Liquid Nitrogen should be delivered to the user's site in a standard cryogenic Dewar
- Follow standard guidelines for the safe handling and storage of the Dewar. These guidelines are provided by the supplier.

Warning
The ProSense™ cryoablation system must be operated only with IceCure™ cryoprobes.
IceCure™ cryoprobes must be used only with the ProSense™ cryoablation system.

Warning
Liquid Nitrogen may cause, if there is not sufficient ventilation in the room, serious injury or burn if handled improperly. Local laws and safety rules regarding the maintenance and handling of Liquid Nitrogen Dewars should always be observed. Maintenance of Liquid Nitrogen should be performed by authorized personnel

3.4.1 Starting the system

Before turning on the system, confirm the following conditions:

- Previously used cryoprobe and sleeves have been removed and the system has been cleaned of any residue and dried off.
- The system is connected to the electrical outlet.

To switch the system on, turn on the mechanical button at the back of the system, the touch screen will turn on and the following screen will appear:

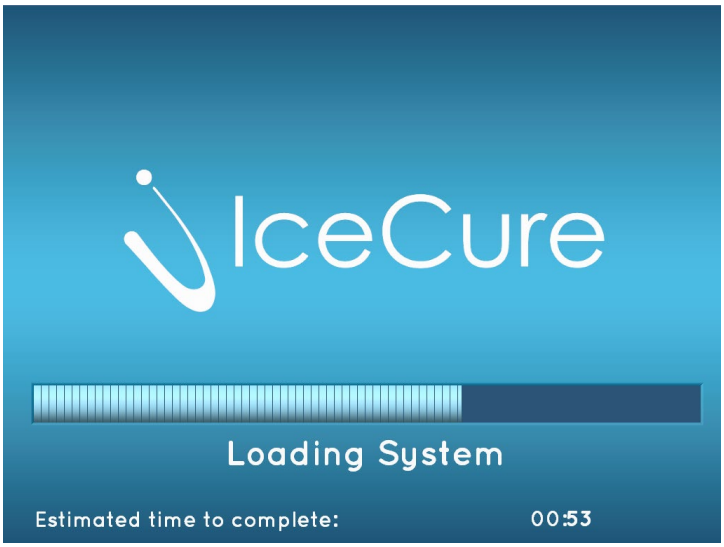


Figure 14: System is loading screen

Wait for the Main Menu screen to load.

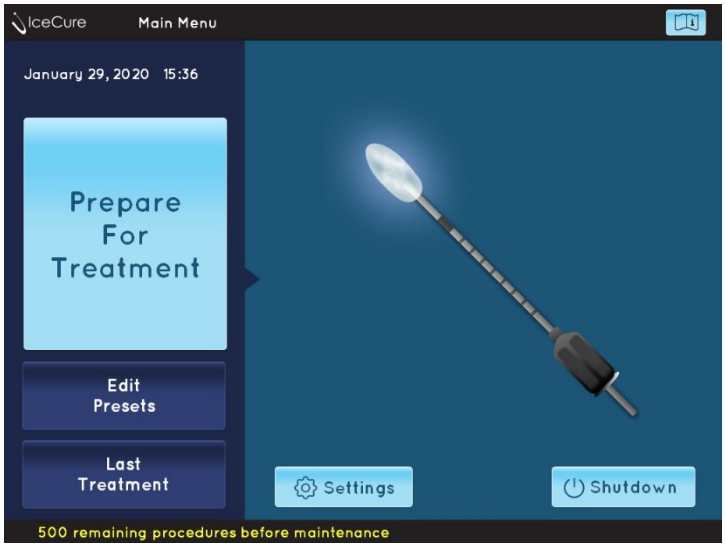


Figure 15: Main Menu screen

3.4.2 System functional tests

As the system uploads, several internal built-in tests are performed automatically in order to verify that the system is safe for use. Additional specific tests will be made upon visual inspection by the user, following instructions on the graphic interface. Each cryoprobe must be tested before use.

3.4.3 Cryoablation procedure

The cryoablation procedure can only be performed after the cryoprobe has been inserted in the target tissue. It can be activated by **Manual mode** (controlled by the user) or by **Automatic mode** (pre-programmed and monitored by the computer). During the entire procedure, the system continues its internal check. In case of system error, the user will be instructed as to the appropriate solution.

3.4.4 Extraction step

Extraction is a process activated automatically by the system at the end of every automatic protocol, or manually by the user at any time in the process. During this process, the cryoprobe tip is heated by warmed Nitrogen gas, enabling fast and safe removal of the cryoprobe.

4 INSTALLATION AND SETUP

ProSense™ Cryoablation System installation can be performed only by IceCure™ Medical authorized service engineers according to approve installation procedures. The system will be approved for use after the installation and acceptance tests have been completed successfully.

The installation procedure is required after each transportation.

4.1 Space and positioning requirements

The work area for the ProSense™ Cryoablation System should be prepared as per the dimensions described in the system specifications (chapter 11). In order to guarantee sufficient ventilation, always maintain a clearance distance of at least 0.5 meters (20 inches) between the system and walls or other objects that may obstruct air flow.

Adequate ventilation and air circulation are major considerations when working with Liquid Nitrogen.

For more details, refer to Environmental and Electromagnetic restrictions in this manual.

Caution

After transporting the ProSense™ Cryoablation System, check the device's temperature. If the temperature is below 10°C or above 40°C, allow one hour for every 2.5 degrees before the System is used.

Warning

Do not use the ProSense™ Cryoablation System in an oxygen-rich environment

Warning

Liquid Nitrogen may cause, if there is not sufficient ventilation in the room, serious injury or burn if handled improperly. Local laws and safety rules regarding the maintenance and handling of Liquid Nitrogen Dewars should always be observed.

4.2 Setup warnings and cautions

Warning

If there is not sufficient ventilation in the room, the ProSense™ cryoablation system cannot be used due to risk of suffocation due to increased levels of nitrogen in the room.

Caution

The ProSense™ cryoablation system must be unpacked, installed, and tested by an IceCure™ Medical authorized technician or by technician authorized by IceCure Service Manager to perform installation and testing on ProSense™ system.

Caution

After positioning the main chassis, lock the front roller brakes. Failure to do so may result in damage to the system or to other equipment in the clinic room.

Warning

Do not move the system when the Dewar contains Liquid Nitrogen.

4.3 Electrical requirements

The ProSense™ cryoablation system is pre-wired for the local line voltage as specified by the user.

The ProSense™ Cryoablation System is grounded through the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation.

The ProSense™ Cryoablation System has a potential equalization pin (POAG) located next the Main ON/OFF switch. If required, connect the ProSense System's POAG to the hospital socket or to the site connection marked with green and yellow circles, using an appropriate wire (not provided by IceCure Medical).

The System has high Inrush Current during Power Up due to the System input Transformer stage, at sites where the electrical infrastructure does not have a Type-D fuses (as specified below), an add-on Inrush Current Limiter can be used (Such as Renkforce 62421 or similar for 220 VAC) to overcome replacement of the site fuse. Such device is not generally required on sites and is not considered part of the System, but part of the site infrastructure. However, for safety reasons, it must connect/pass the FGND (AC Line grounding).

Table 2 below summarizes the electrical requirements for the dedicated wall outlet for ProSense™ Cryoablation System installation.

Table 2: Electrical Power Requirements

Local line voltage	Frequency	Current	Main circuit breaker	Type-D fuse
100-127 VAC	50/60 Hz	12 A	0.1 A	32 A
220-240 VAC	50/60 Hz	7 A	0.1 A	16 A

4.4 Shipment components

The ProSense™ cryoablation system is packed and shipped as follows:

- Main system
- Two empty Dewars (available is several colors)
- Foot pedal (may not be available in some regions)
- Installation kit

The following products are not supplied with the ProSense system and should be ordered independently from IceCure Medical:

- Sterile single use Cryoprobes
- Sterile single use Introducers
- Demo Cryoprobe
- Holder (Optional – May not be available in some regions)
- Dewar for liquid Nitrogen (Large volume)
- Liquid Nitrogen withdrawal device
- Roller base for large Dewar
- Hand pump for immediate pressure
- Cryo-Gloves Mid-arm length, large, waterproof, pair
- Face shield up to LN2 protection

The following products shall be available for the procedure. These are not supplied by IceCure Medical:

- Sterile sleeves for the hose
- Sterile cover for the cryoprobes cradle
- Disinfecting wipes
- Liquid Nitrogen

4.5 Installation

Caution

The ProSense™ cryoablation system must be unpacked, installed, and tested by an IceCure™ Medical technician or by a technician authorized by IceCure™ Medical to perform installation and testing of the ProSense™ system.

Any damage to the container or to the ProSense™ Cryoablation System discovered upon unpacking, installing, or testing should be immediately reported to your cryoablation system distributor.

The installation will be performed by an IceCure Medical authorized service engineer and the system will be approved to use after the installation is completed successfully.

5 OPERATING THE SYSTEM

This chapter explains how to use the cryoablation system and includes pre-operational, operational and post-operational steps.

Note: This User Manual describes how to operate the device with a percutaneous cryoprobe that requires imaging device for its clinical application.

The device can be used with a blunt cryoprobe for topical indications that are performed without ultrasound imaging. For topical applications the practitioner should follow standard clinical procedures that are not within the scope of this user manual.

The device can also be used for open surgical applications performed without the use of imaging device. For these applications the practitioner should follow standard clinical procedures that are not within the scope of this user manual.

The device materials are not compatible with magnetic resonance imaging; thus, it is not MR safe and should not be used in MRI procedures.

TRAINING: Practitioners electing to be cryoablation system users must attend a training course prior to using the system. The course is taught by IceCure™ Medical certified personnel.

5.1 Procedure Overview

- Patient and system preparation
- Cryoprobe selection
- System set-up and functional test
- Cryoprobe placement
- Cryoablation cycle
- End of procedure

5.2 Pre-operational stages

5.2.1 Preparing the system for procedure

1. Make sure you have enough Liquid Nitrogen available for the procedure:
    - The ProSense™ 2-liter dewar should be filled with Liquid Nitrogen. For that purpose, a large dewar (for example, 20 or 25 Liter) of Liquid Nitrogen must be prepared according to the manufacturers IFU attached to the product.
    - The larger dewar should be equipped with a withdrawal device, to allow safe, efficient, and precise delivery of Liquid Nitrogen from the larger dewar to the ProSense™ 2L dewar.
    - **It may take 12-24 hours to build up sufficient pressure to withdraw Liquid Nitrogen. Therefore, it Is recommended to fill the larger dewar about a day prior to the procedure**

.

2. If a cryoprobe is still connected to the cryohandle, remove used cryoprobe from the handle and safely discard it.
3. Remove previously used single-use sterile sleeve from the cryohandle.
4. Close the cryohandle with the covering plug.
5. Arrange a sterile work environment in accordance with accepted standards.

5.2.2 Preparing the patient for procedure

1. Always position the patient in a comfortable way.
2. If you use a Cryohandle holder, position patient comfortably on the holder base so that the target area is easily accessible and trajectory of the cryoprobe is safe (make sure that Holder adjustable arm is not in the way of the user or CT gantry). For example: in the treatment of Breast tumor, it is desirable that the cryoprobe will be placed parallel to the chest wall.
3. Measure the lesion with an imaging device in all dimensions prior to procedure to determine long axis and point of entry.
4. See Figure below for a schematic illustration of the placement of the system and the patient in the treatment room.

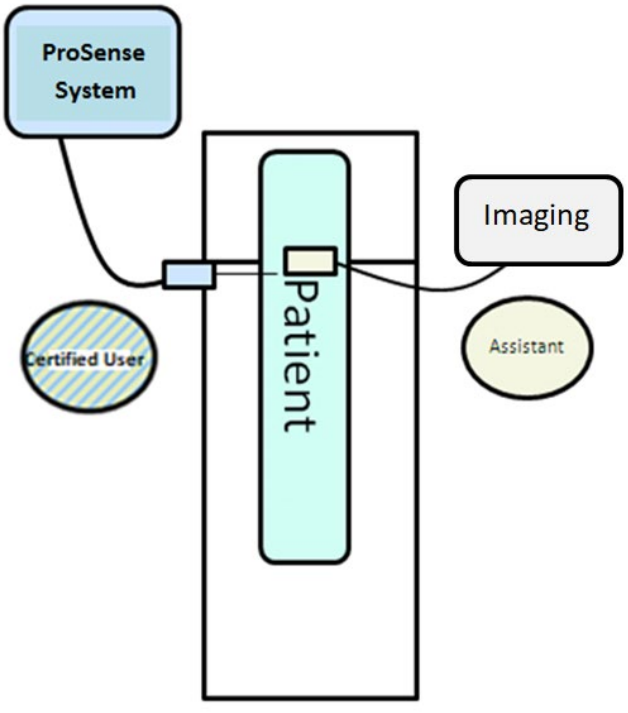


Figure 16 : Schematic illustration of placement of the system and patient.

Use of ProSense™ Cryoablation system in special populations, such as pregnant women or pediatric has not been established.

Caution

The cryohandle and hose may become cold during the cryoablation procedure. Consider insulating these parts in order to prevent discomfort to the patient or the physician.

Warning

Practices of cryoablation for women with breast implants have not been established. For patients with breast implants, you must document that adequate distance exists between the lesion and the implant to ensure that the ablated lesion will not contact or jeopardize the implant, and there is enough space to create the required margins.

5.2.3 Switching on the ProSense™ cryoablation system

Before operating the system, make sure the following conditions are in place:

- Ultrasound, CT or other appropriate imaging system is available for monitoring the medical procedure.
- The mechanical power switch is OFF.
- The cryohandle, hose and cradle are all clean and dry.

To Switch on the ProSense™ cryoablation system:

To switch the system on, connect the power cable and turn on the mechanical button at the back of the system, the touch screen will turn on and the following screen will appear:

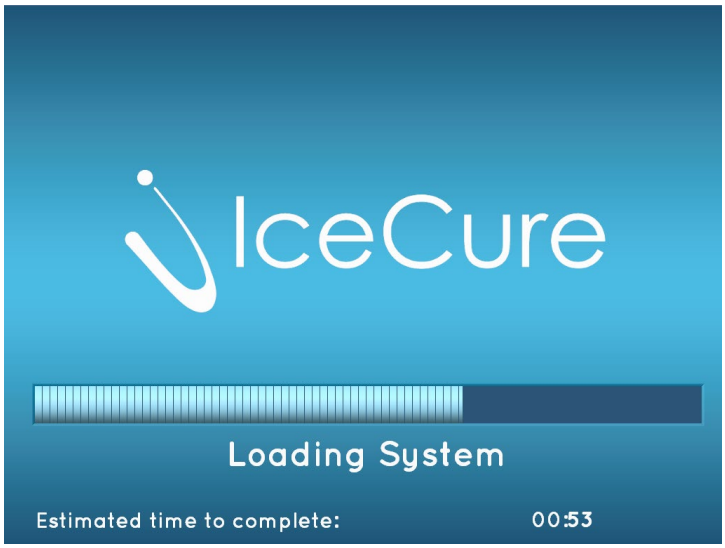


Figure 17: System is loading screen

Wait for the Main Menu screen to load.

Make sure the time is set according to local time zone before executing a cryotherapy procedure, as explained in 5.2.5.4.

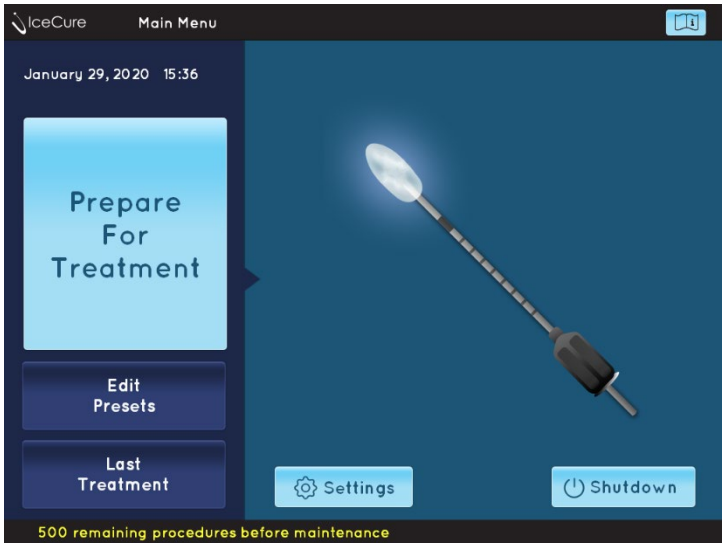


Figure 18: Main Menu screen

5.2.4 Cryohandle

The cryohandle allows the user to easily and safely handle the cryoprobe. The cryohandle parts are detailed in Chapter 3 - System description.

The cryohandle can be safely put on the adjustable Holder arm once positioning of the Cryoprobe is completed.

5.2.5 General settings

The system general settings and technician mode are available by choosing the “Settings” button at the bottom of the touch screen.

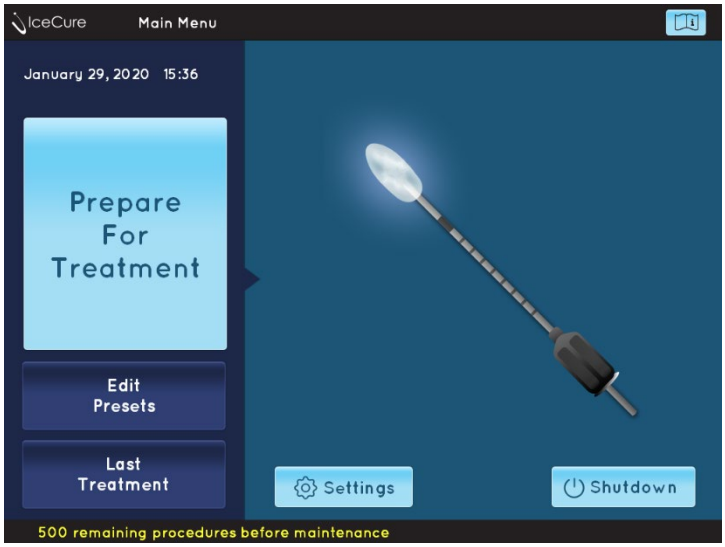


Figure 19: Activating the Settings option from the Main Menu screen

Choosing the “Settings” button will load the settings screen with four icons representing different options. Pressing any of these icons will open a new settings screen pertaining to that option.

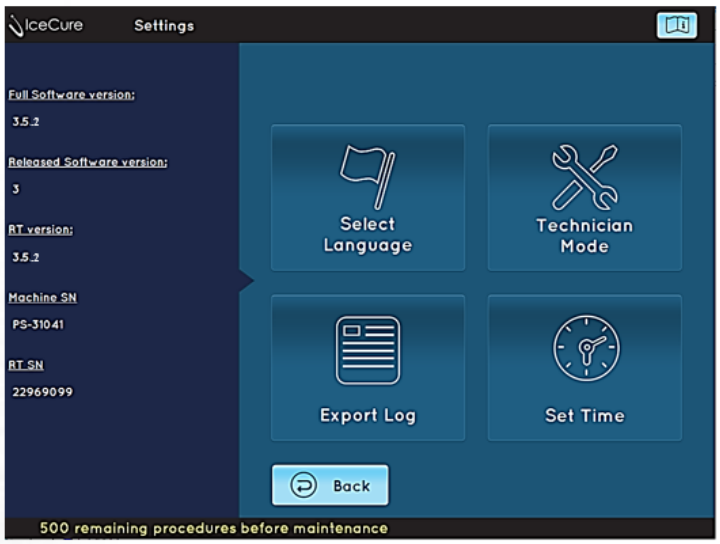


Figure 20: Settings screen

5.2.5.1 Select Language

This screen allows you to select your preferred language.

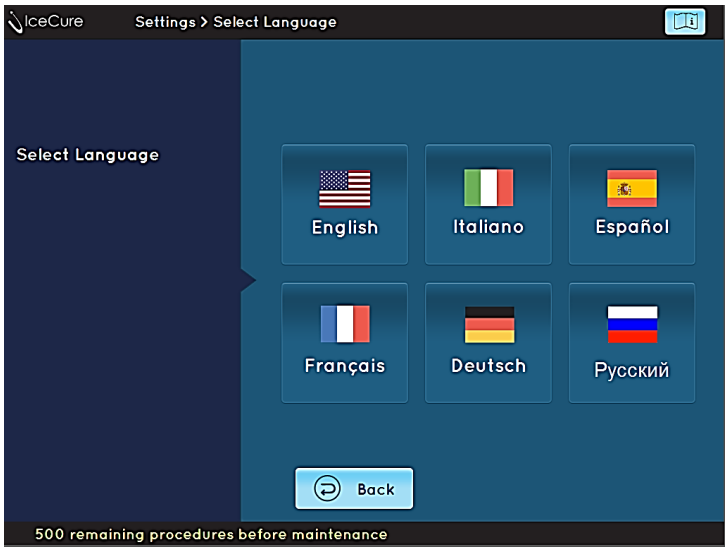


Figure 21: Language Selection screen

5.2.5.2 Log-in to Technician mode

Choosing the “Technician Mode” icon will load a Technician Mode entry screen that is used for maintenance of the system. The technician mode can only be accessed by an IceCure™ Medical authorized technician and is restricted by a password.

Warning

Never enter the Technician mode screen. Only an IceCure™ Medical technician or a technician authorized by IceCure™ Medical is allowed to use the technician mode for maintenance or repair of the system.

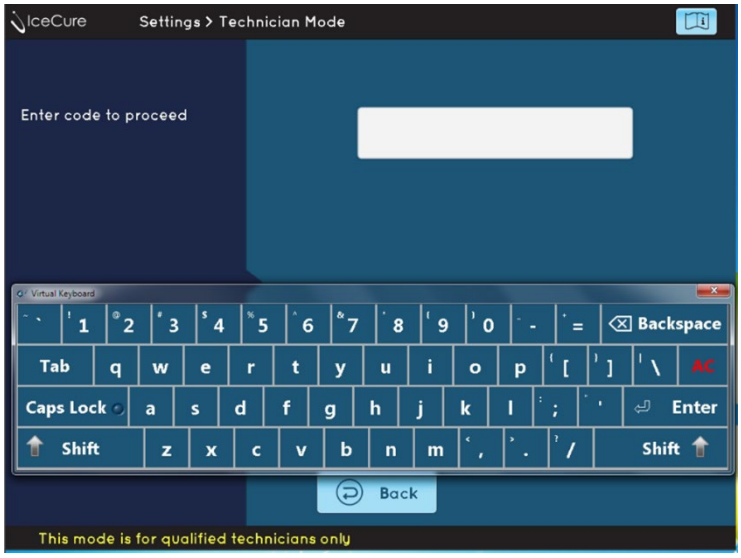


Figure 22: Technician Mode screen

5.2.5.3 Export Log

This screen allows you to export any procedure data to a USB removable storage device in an easy and convenient way. When you press the Export Log icon, a popup window appears with the following message:

Connect a USB flash drive and press OK

- Press **OK** to export the log file to the USB drive
- Press Cancel to return to Settings screen

If export fails, the message in the status area reads: ***Export failed; make sure a flash drive is connected.***

Before using a flash drive, check that it contains enough free space for file storage, and make sure it's clean of viruses. Connect the USB storage device to the USB 2.0 port with white marking at the bottom of the touch screen.

Note: Avoid using USB 3.0 ports (blue).

Caution

Use USB2.0 flash drives only to export reports or log files. Importing any data or software may corrupt the ProSense™ Cryoablation System.
Do not connect any other USB devices to the ProSense™ Cryoablation System USB port.

Caution

Do not use USB extension cables to connect a USB flash drive to the ProSense™ Cryoablation System USB port. Using USB extension cables may cause electromagnetic emissions exceeding regulatory limits.

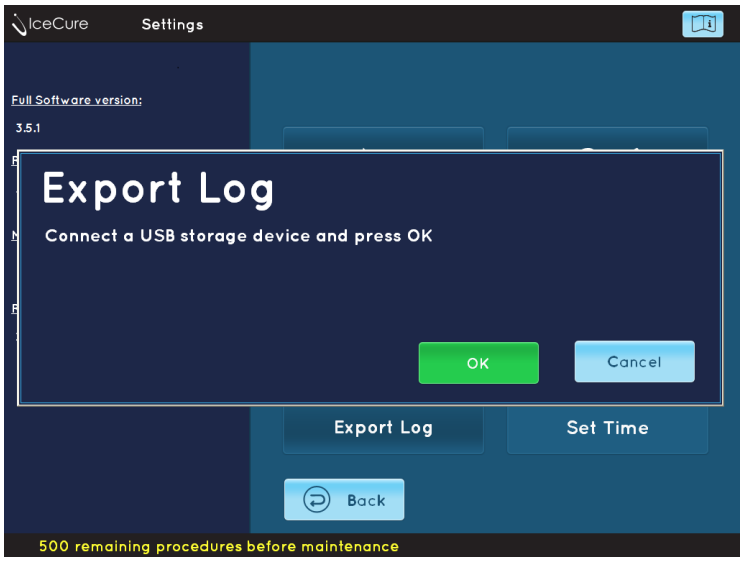


Figure 23: Export Log screen

5.2.5.4 Set time

This screen allows you to set the date and time.

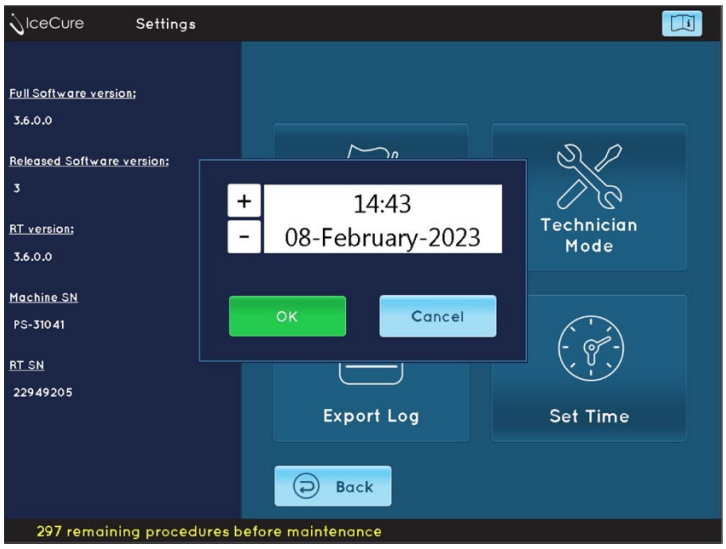


Figure 24: Windows® Date and Time Properties screen

Set the date and time according to your time zone and approve it by pressing **OK**. ⚠	**Caution** Make sure the time is set according to local time zone before executing a cryotherapy procedure.

5.2.6 Preparing the system for treatment

The system will guide the user through a system preparation process; following the system instructions is essential. Preparation includes technical steps and tests to make sure the system is ready for a cryotherapy procedure. It includes:

1. Dewar refilling and replacement
2. Maintain Sterility (Use of sterile sleeves)
3. Cryoprobe registration and connection
4. System tests

To prepare the system for treatment, choose the option Prepare for Treatment in the Main Menu as shown in the figure below.

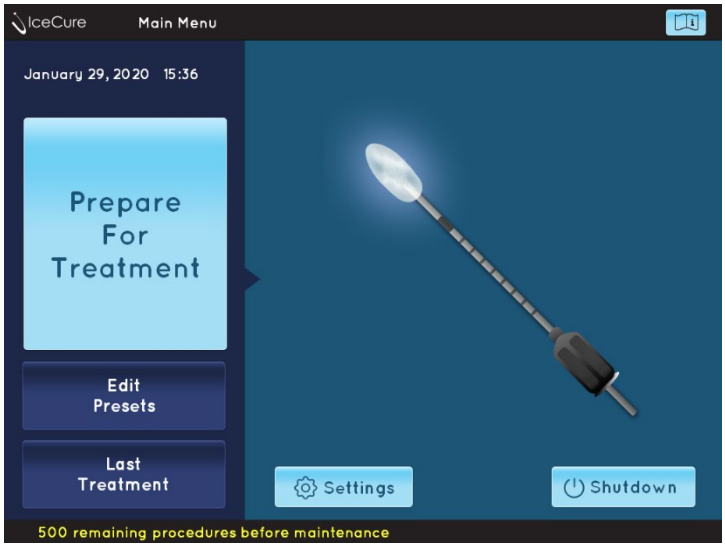


Figure 25: Preparing the system for treatment by tapping Prepare for Treatment on Main Menu screen

5.2.6.1 Dewar

Prepare the Dewar for treatment as per the following instructions and as detailed on the system screen (see Fig. below).

Filling the Dewar

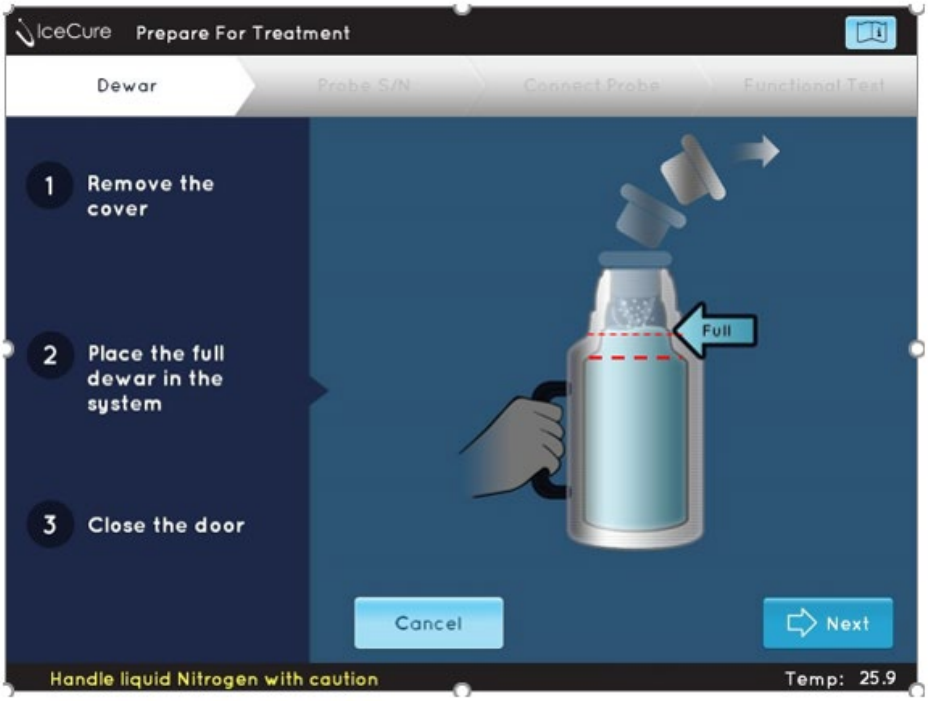


Figure 26: Dewar preparation screen

The upper line is the maximum level of Liquid Nitrogen that should be filled, and the lower line is the minimum level of Liquid Nitrogen that should be filled. Do not overfill the Dewar.

Figure 27: Frost on the Dewar opening

Be aware that frost or ice on the Dewar opening or not completely filled Dewar as shown on system screen and inner system door may result in a lower performance because of low pressure in the Dewar. Make sure you insert a full Dewar and wipe the Dewar opening of ice using a dry cloth before you insert it into the system.

During the Freeze step, the system monitors the pressure in the Dewar and if the pressure is insufficient, the following message is displayed:

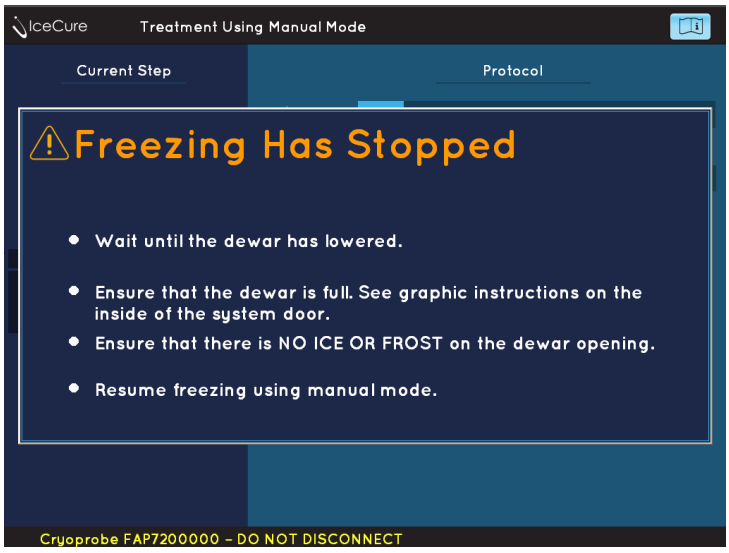


Figure 28: Freezing Has Stopped Pop-up Message

If such message appears, remove the Dewar from the system, clean its opening from ice and reinsert a full Dewar.

Caution

When replacing the Dewar, follow detailed on-screen instructions on opening the Dewar compartment.

- The Dewar must be properly filled prior to inserting the system.
- In each Dewar fill, make sure that you are performing it properly.
- The Dewar should never be stored with Liquid Nitrogen inside the system at the *end* of the working day.
- For proper handling in order to ensure safety, please follow the cryogen supplier instructions.

Warning

Liquid Nitrogen may cause, if there is not sufficient ventilation in the room, serious injury or burn if handled improperly. Local laws and safety rules regarding Liquid Nitrogen Dewars should always be observed. Maintenance of Liquid Nitrogen Dewars should be performed by authorized personnel only.

- Check that the Dewar is filled properly and cover it with its sponge lid to transfer it back to the system.
- Check there is no frost on the Dewar after you filled it. If there is a frost on the Dewar opening, wipe gently the Dewar opening prior to insertion to the system.
- In the event that a Dewar is damaged, use another Dewar to continue the procedure and contact support@Icecure-medical.com in order to replace the damaged one.

Warning

To avoid spillage and cold burns, do not transfer a Dewar containing Liquid Nitrogen unless it is covered with its designated lid.

Warning

Do not use a Liquid Nitrogen Dewar if it is damaged.

You can tell that a Dewar is damaged if after filling it, frost appears on the outer wall of the container. Return the Dewar to an IceCure™ Medical technician or an authorized distributor for inspection.

Warning

At the beginning of the procedure the Dewar should be filled around 1 cm below the neck of the bottle.
Do not overfill a Dewar with Liquid Nitrogen; it will reduce performance of the system.

- Take off the lid and place the Dewar in its position into the system; bottom first. Make sure the Dewar moves freely (right-to-left) when you move the Dewar-handle (see pictures below).

Figure 29: Correct insertion and positioning of the Dewar – bottom first

Make sure the Dewar positioned freely in the base.

Figure 30: Insertion of the Dewar – head first, leaning forward

Such insertion might cause wrong positioning of the Dewar, leaning forward.

Figure 31: Insertion of the Dewar - bottom first, leaning backwards

Wrong bottom first positioning of Dewar on the back of the elevator might cause Dewar leaning backwards.

> **Warning**
> Removing the Dewar or placing it back within the system after refilling it must only be done according to system instructions and with the carriage in the

	bottom position. If the carriage is not in the bottom position, Liquid Nitrogen may spill out.

- Close the compartment door and tap **Next** on the screen.

Dewar door is open

If the system detects that the Dewar compartment door is open when it tries to move the Dewar carriage up or down, the following popup message will appear:

Dewar door is open. Close the door to continue.

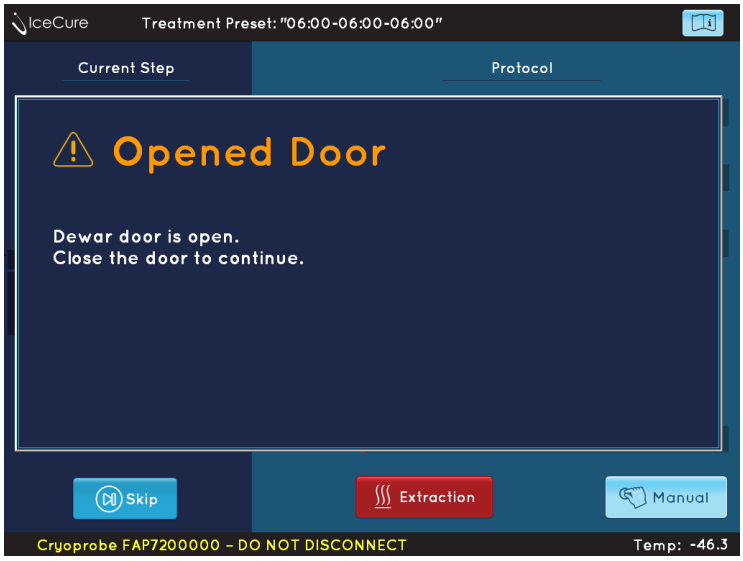


Figure 32: Dewar door open warning

5.2.6.2 Sterile sleeves

After filling the Dewar and placing it in its compartment, please work under sterile conditions. Cover all relevant accessories in the sterile area with the suitable single-use sleeves, to ensure sterility.

5.2.6.3 Cryoprobe Selection

Select a cryoprobe according to your clinical judgment and target tissue.

The ice ball size is a function of the freezing time and is also affected by the tissue and blood flow (see Figure 343).

On the label of the cryoprobe packaging, the specification of the cryoprobe is clearly mentioned, with reference to the following elements:

* Diameter (2.4 or 3.4mm)
* Shaft length (defined in mm)
* Ice ball shape (spherical or elliptic).
* Tip shape (trocar or pencil or blunt)

Figure 33: Cryoprobe identification label

Always monitor the ice ball growth with adequate imaging techniques.

If an introducer to guide the cryoprobes to the tissue location is used, make sure to choose an introducer with tight dimensions.

> **Warning**
> The system and its accessories: cryoprobes, introducersand holder are not compatible with magnetic resonance imaging.

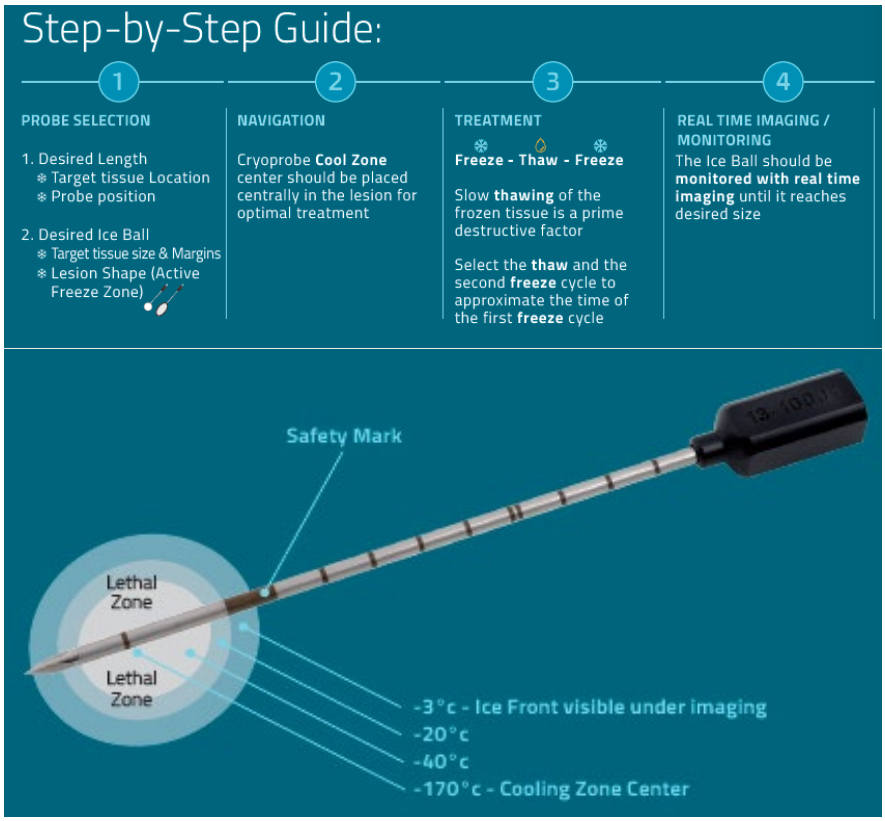


Figure 34: Ice ball measurement ranges

Ice-ball dimensions are based on bench testing done at room temperature gel Aquasonic clear ultrasound gel (Parker laboratories, INC.). Isotherm measurements in soft tissue tumors may vary depending among others on clinical applications, patient condition, tumor location, proximity of blood vessels. Ice-ball dimensions per freezing duration (±3 mm) are approximate and should not preclude ice-ball monitoring and physician clinical judgment.

Table 3 through Table 6 below represent ice ball isotherms of ProSense™ cryoprobe from experiments in gel at room temperature.

Table 3: 2.4 mm/13G Cryoprobe Spheric (ice ball shape) FAP7600000

	Ice Ball Dimensions at Various Temperatures over Time					
	-3°C*		-20°C		-40°C	
Time (minutes)	Width (mm)	Length (mm)	Width (mm)	Length (mm)	Width (mm)	Length (mm)
2	20	24	16	20	12	17
3	23	27	18	22	14	18
4	24	30	20	24	15	18
5	28	31	22	25	16	19
6	30	32	23	26	16	20
8	33	36	24	27	17	20
10	35	38	26	29	17	21
15	39	42	29	31	19	21

*The ice front of the ice ball visible under imaging is around -3°C. The same results were obtained when using Cryoprobes thread into introducers.

Table 4: 2.4 mm/13G Cryoprobe Elliptic (ice ball shape) FAP7800000

	Ice Ball Dimensions at Various Temperatures over Time					
	-3°C*		-20°C		-40°C	
Time (minutes)	Width (mm)	Length (mm)	Width (mm)	Length (mm)	Width (mm)	Length (mm)
2	19	34	16	30	13	27
3	24	36	20	32	16	28
4	28	38	23	34	17	28
5	30	41	24	35	18	29
6	32	43	26	36	19	29
8	35	46	28	38	21	30
10	38	47	30	39	22	31
15	46	51	34	39	24	32

*The ice front of the ice ball visible under imaging is around -3°C. The same results were obtained when using Cryoprobes thread into introducers.

Table 5: 3.4 mm/10G Cryoprobe Spheric (ice ball shape) FAP7100000

	Ice Ball Dimensions at Various Temperatures over Time		
	-3°C*	-20°C	-40°C

Time (minutes)	Width (mm)	Length (mm)	Width (mm)	Length (mm)	Width (mm)	Length (mm)
2	23	30	19	25	15	21
3	25	32	22	27	17	22
4	28	34	24	29	18	24
5	31	36	25	29	19	24
6	33	38	27	31	20	25
8	36	40	29	32	21	26
10	38	43	30	33	22	27
15	44	48	33	36	24	28

*The ice front of the ice ball visible under imaging is around -3°C. The same results were obtained when using Cryoprobes thread into introducers.

Table 6: 3.4 mm/10G Cryoprobe Elliptic (ice ball shape) FAP7200000; FAP7410000; FAP7400000

	Ice Ball Dimensions at Various Temperatures over Time					
	-3°C*		-20°C		-40°C	
Time (minutes)	Width (mm)	Length (mm)	Width (mm)	Length (mm)	Width (mm)	Length (mm)
2	22	37	18	32	15	28
3	26	40	23	34	18	30
4	30	41	25	36	19	31
5	32	42	27	36	21	30
6	35	46	29	38	23	32
8	37	46	31	37	23	32
10	41	48	33	38	25	33
15	46	52	36	41	26	35

*The ice front of the ice ball visible under imaging is around -3°C. The same results were obtained when using Cryoprobes thread into introducers.

5.2.6.4 Cryoprobe registration

Identify the cryoprobe serial number (S/N). It appears on the cryoprobe package and/or cryoprobe plastic cover as shown in the figure below.

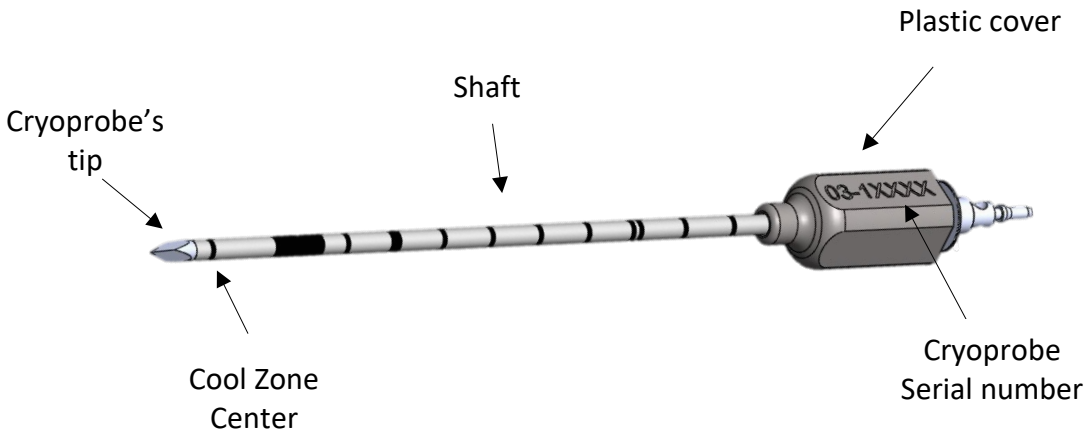


Figure 35: Cryoprobe (the figure is for illustration only)

Enter the serial number of the cryoprobe on the screen.

When done, verify the entered number is correct and tap **Next** on the touch screen.

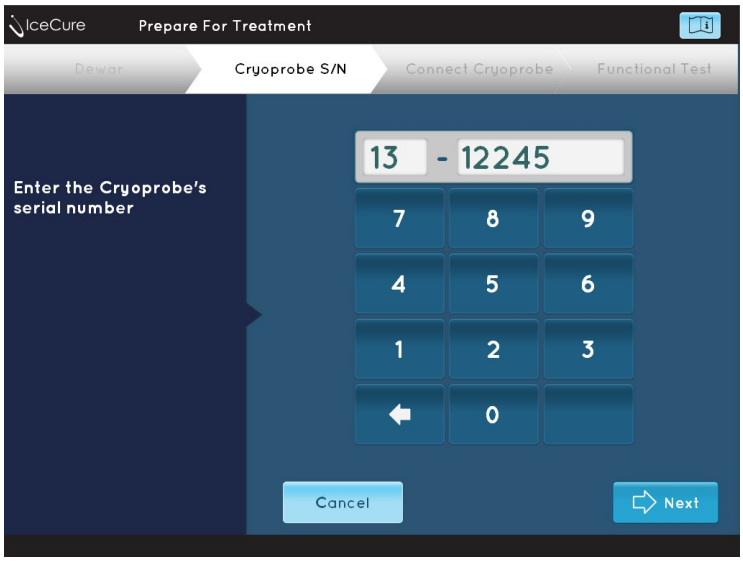


Figure 36: Cryoprobe registration screen

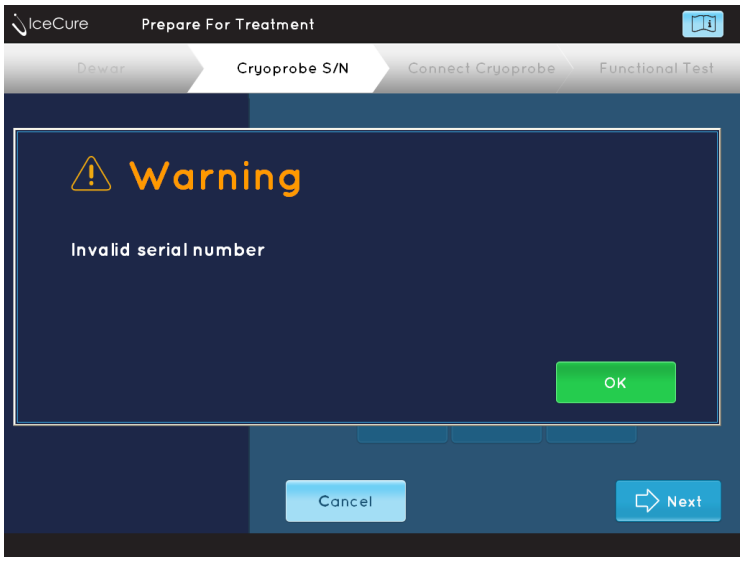


Figure 37: Invalid serial number warning

Warning

Verify cryoprobe S/N registration by double checking the serial number on the package and/or on the cryoprobe itself. Entering an incorrect cryoprobe S/N registration will result in cryoprobe nullification or incomplete treatment.

Warning

	Entering an incorrect cryoprobe S/N during registration can affect the calculation for the cryoprobe placement, System performance and treatment outcome.

5.2.6.5 Cryoprobe connection

Connect the cryoprobe to the cryohandle as follows, while maintaining sterility of the cryoprobe:

1. Open the cryoprobe pouch in accordance with the “Open here” label. 
2. Remove the plug that covers the cryoprobe connection point.
3. Insert the cryoprobe into the insertion point in the handle as shown on screen and screw it until it cannot be turned anymore, insuring it has been securely attached. .
4. Tap **Next** on the touch screen.
5. After tapping **Next**, a “Do not disconnect” message will appear

Figure 38: Cryoprobe connection screen

⚠	**Warning** Never reuse a single-use cryoprobe, introduceror a single-use sterile sleeve.

⚠	**Warning** Never “unscrew” the cryoprobe if you are not clearly instructed to unscrew or disengage it.

⚠	**Warning**

	Before beginning treatment of a patient, you MUST ensure that the previous single-use cryoprobe and sterile sleeve have been removed.

⚠	**Warning** Cryoprobes are fragile and can be damaged if mishandled. Do not use a cryoprobe that has been bent, dropped, hit against a hard surface or compromised in any manner, as damage to the cryoprobe may have occurred. If any mechanical damage (such as bent) is identified during any phase of the procedure, press the emergency stop button immediately, and extract the cryoprobe (if not possible, wait for passive thaw)..

⚠	**Warning** 1. Surgical instruments must be handled with care to avoid damage to the cryoprobe. 2. Avoid pinching, cutting or pulling the cryoprobe. Do not use damaged cryoprobes. 3. Do not grasp cryoprobes with auxiliary instruments, as this may cause damage to the cryoprobe shaft.

⚠	**Warning** If a sterile product packaging is compromised in any way, do not use the product.

5.2.6.6 Handling Cryoprobe Mechanical Failure

During any phase of the procedure, if the cryoprobe is identified to have any mechanical damage, please follow the instructions below:

1. Press the red emergency stop button.
2. Wait for 60 seconds.
3. If the cryoprobe is in the patient's body, wait for passive **Thaw** if necessary and remove the cryoprobe gently.
4. Pay attention that the cryoprobe is removed completely.
5. Securely disengage the cryoprobe into sterile sheets – Make sure the tip is pointed in a safe direction.
6. If the cryoprobe cannot be screwed out of the cryohandle. The system should not be turned on before disengaging the cryoprobe.
7. Close the handle plug on the cryohandle.
8. To release the Emergency Stop button, turn it in the direction of the arrows

9. Start the system, using the ON/OFF switch on the back side of the system.

10. If required, wait for the Dewar to lowered down and perform a new procedure with full Dewar and a new cryoprobe while maintaining sterility.

5.2.6.7 System functional test

Perform a functional test to ensure system efficacy and safety per the following instructions and per the screens presented in the figures below:

- Prepare a container full of **sterile** water/saline.
- Remove the cryoprobe cover that protects the tip.
- Insert the cryoprobe into the container and press TEST on the touch screen.

Figure 39: Wait for Functional test screen

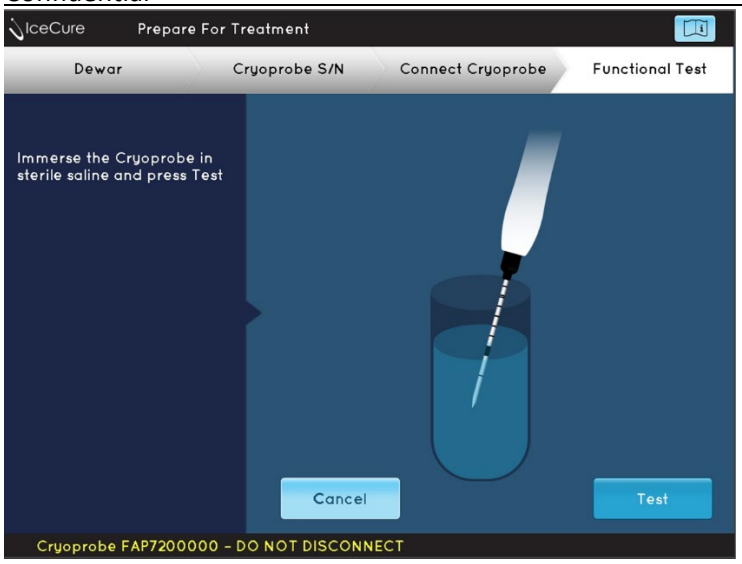


Figure 40: Functional test screen

- The system will check essential parameters.
- A failure of any internal test will result in, an error message displayed on screen. Please record the error number and follow system instructions until you are requested to remove the cryoprobe safely from the cryohandle. You will then be returned to the Main Menu screen. Contact IceCure™ Medical technical service.

  After successful internal test, the system will display the visual inspection screen. You will be prompted to inspect the following:

  - The cryoprobe tip – make sure a small ice ball forms
  - The cryoprobe shaft – check that there is no ice on it
  - The saline – check that there are no bubbles
- Illustrations of potential functional failures will appear on screen. Please refer to these illustrations while inspecting the cryoprobe.

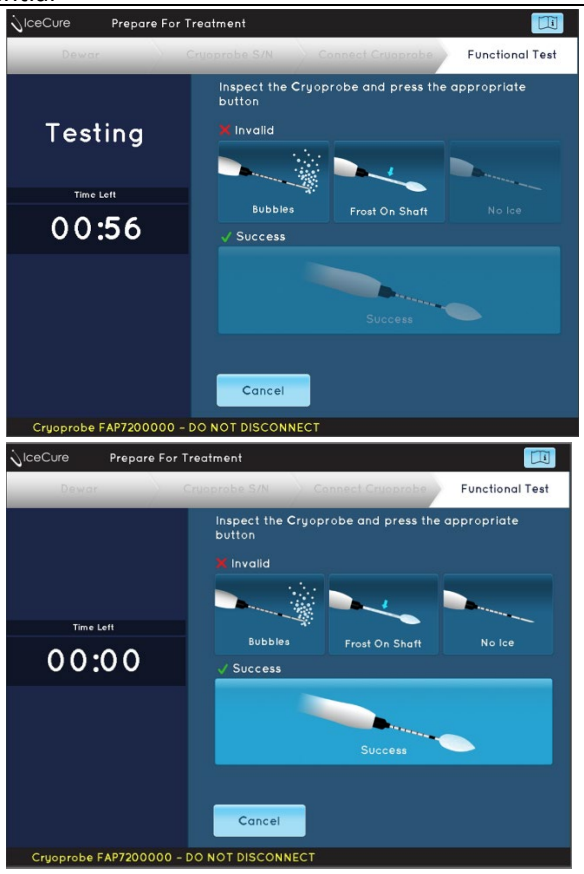


Figure 41: Functional test - visual inspection screens

- If no failure occurs, tapping **Success** will load the treatment selection screen.
- If a functional problem occurs or there is any unusual appearance (such as bubbles, frost on shaft, or no ice) and it is not represented by one of the Illustrations, tap **Cancel**. Follow system instructions until you are required to safely remove the cryoprobe from the cryohandle. You will then be returned to the Main Menu screen. To start again, check that the Dewar is full and replace the cryoprobe. If the problem recurs, do not proceed with treatment. Turn OFF the system and contact IceCure™ Medical.
- If for any other reason you decide to stop the procedure, tap **Cancel**. Follow system instructions until you are required to safely remove the cryoprobe from the cryohandle. You will then be returned to the Main Menu screen.

Warning

Do not try to disengage a cryoprobe before instructed since the system is under pressure and you can be hurt by the sharp cryoprobe ejected under pressure. In addition, the hose and the cryoprobe still contain Liquid Nitrogen that can be spilled out

⚠	**Warning** During functional test, portions of the cryoprobe other than the freeze zone, including the plastic cover that is located near the cryoprobe handle, may become cold due to malfunction. If unwanted freezing occurs, stop the – functional test process by tapping **Cancel**.
⚠	**Warning** Pay attention to the cryoprobe during functional test: if bubbles, leak or frost on its shaft or no ice are observed do not use the cryoprobe.

5.2.7 Cryoprobe Positioning

5.2.7.1 Placement Calculation

The cryoprobe specification defines the distance from the tip to the center of the cooling zone.

- Place the center of the cooling zone in the center of the target tissue to achieve accurate killing zone.
- Use the below formula to calculate the position of the cryoprobe relative to the target tissue.

Verification of proper positioning should be made via imaging tools in real time (i.e. measuring the distance from the cryoprobe tip till the target tissue outline (including the tumor and the safety margins to be treated).

$$\textit{Cool zone center} - \frac{(\textit{target tissue large dimension})}{2} = \textit{Distance to penetrate beyond needle tip}$$

Example 1:

Cryoprobe 3.4 elliptic shape (FAP7200000)

Cool zone center of cryoprobe 3.4 elliptic = 20 mm

Lesion size: 15 mm in its largest dimension

Lesion shape: oval/elliptic

20 – (15/2) = 12.5 mm

Correct placement of the cryoprobe inside the lesion requires that the tip goes beyond the lesion by 12.5 mm.

Example 2:

Cryoprobe 2.4 elliptic shape (FAP7800000)

Cool zone center of cryoprobe 2.4 elliptic = 14.5 mm

Lesion size: 20 mm in its largest dimension

Lesion shape: oval/elliptic

14.5 – (20/2) = 4.5 mm

Correct placement of the cryoprobe inside the lesion requires that the tip goes beyond the lesion by 4.5 mm.

Pre-plan your trajectory needle insertion and the needle point of entry prior to the treatment on baseline tumor measurements.

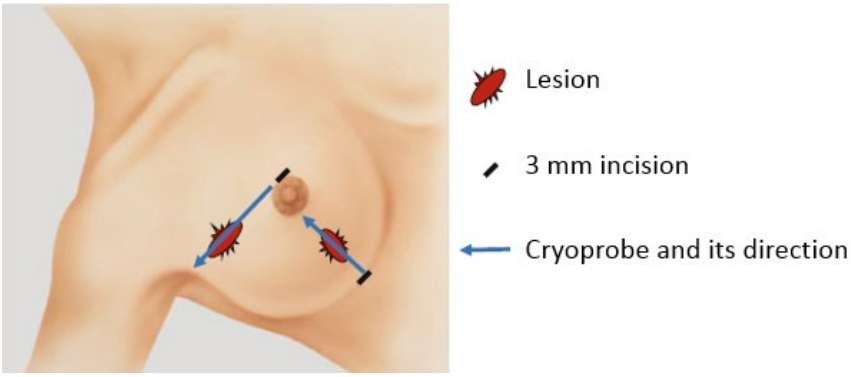


Figure 42: Pre-Planning trajectory needle insertion in breast applications

5.2.7.2 Cryoprobe Placement Calculation during a procedure

After the system test is successfully completed, you can use the Cryoprobe Placement Calculation screen to calculate the cryoprobe placement.

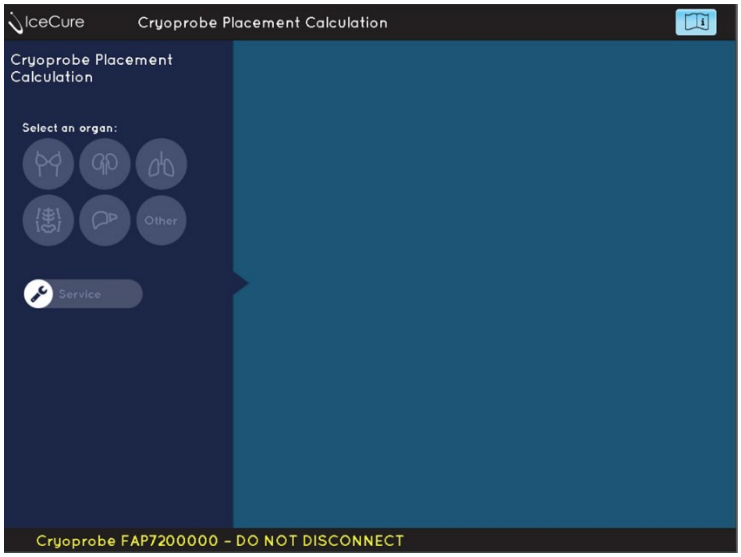


Figure 43: Select Organ

1. Select the organ for treatment. Once the organ is selected, the right pane of the screen will display the Lesion size field and a keyboard.

2. If you wish to proceed without placement calculation, tap **Next**. For cryoprobe placement calculation, perform steps 3 though 4 below.

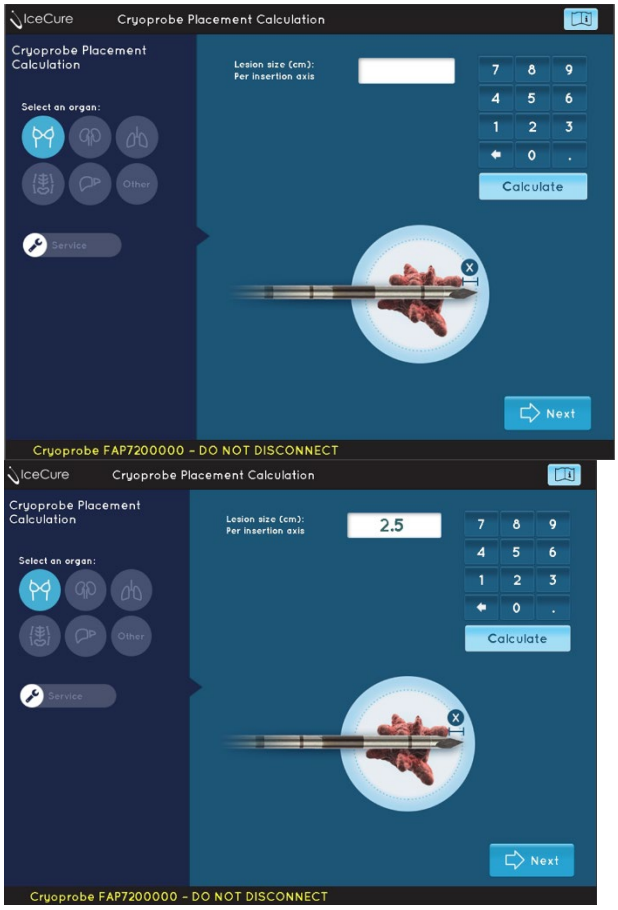


Figure 44: Lesion size value

3. Enter the Lesion size value in centimeters.

4. Press **Calculate** to calculate the cryoprobe placement. The calculated result (X) that will appear is the distance the Cryoprobe should pass through to ensure that the center of the lesion is aligned with the center of the Cryoprobe cooling area.

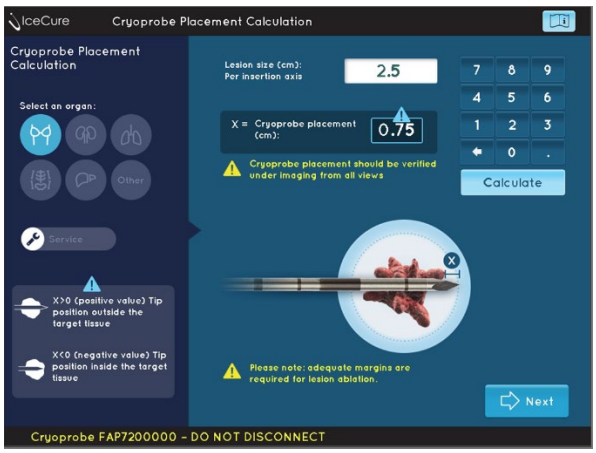


Figure 45: Calculated Result

If the entered lesion size value equals to or is larger than maximum (6 cm) or the calculated cryoprobe placement value is less than -1 cm (Cryoprobe tip is likely inside the lesion), “N/A” (not applicable) will appear in the calculation result field.

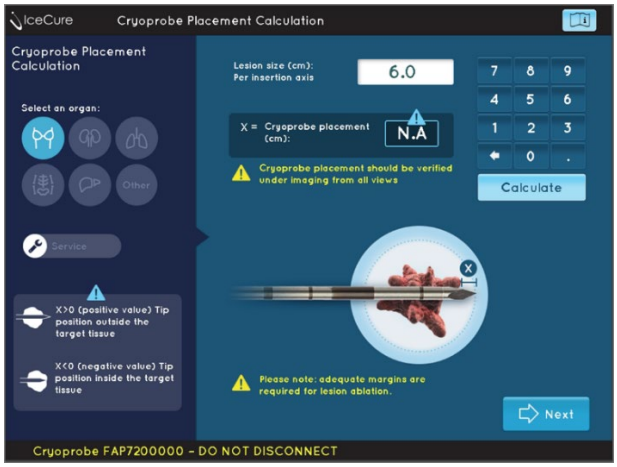


Figure 46: Calculated Result N/A

5.2.8 Treatment Selection

The system allows you to choose between manual mode and automatic mode using preset protocols.

To choose automatic mode, select one of the preset protocols from the Treatment Selection screen as shown below.

Type of treatment is determined by the number and duration of **Freeze** and **Thaw** steps and depends also on the practitioner’s preferred way of work.

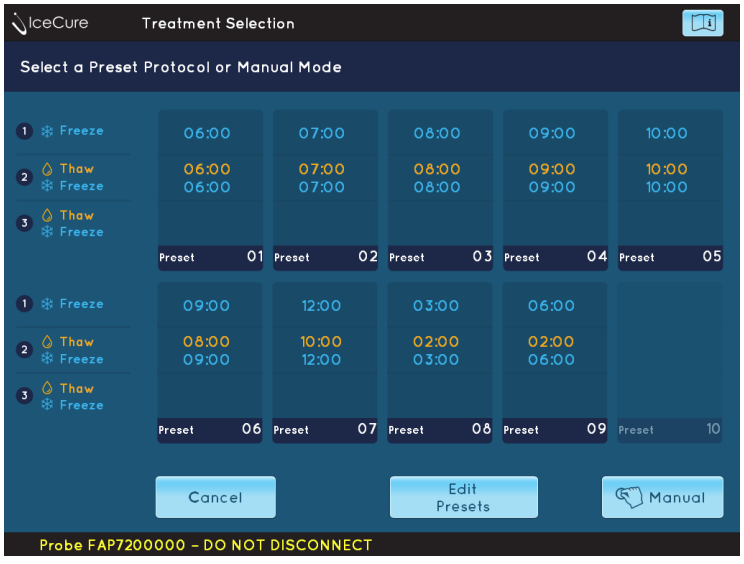


Figure 47: Treatment Selection screen

5.2.8.1 Automatic Freeze mode

Each preset protocol icon displays the number and duration of **Freeze** and **Thaw** steps as shown in Fig. above. Select a protocol by tapping the desired icon on the touch screen. A

procedure screen will open. After inserting the cryoprobe into the tissue, you will be able to start the cryoablation procedure.

5.2.8.2 Define treatment protocols

ProSense™ cryoablation system allows you to define specific treatment protocols by tapping the SETUP PRESETS icon at the bottom of the Treatment Selection screen. Additional option to define treatment protocol is available before “system test” by using EDIT PRESETS in the Main Menu screen (As shown in the figure below).

Choosing either option will open the PRESET SETUP screen and you will be able to add a specific protocol by tapping one of the empty Preset icons or edit an existing protocol by tapping one of the pre-defined Preset icons.

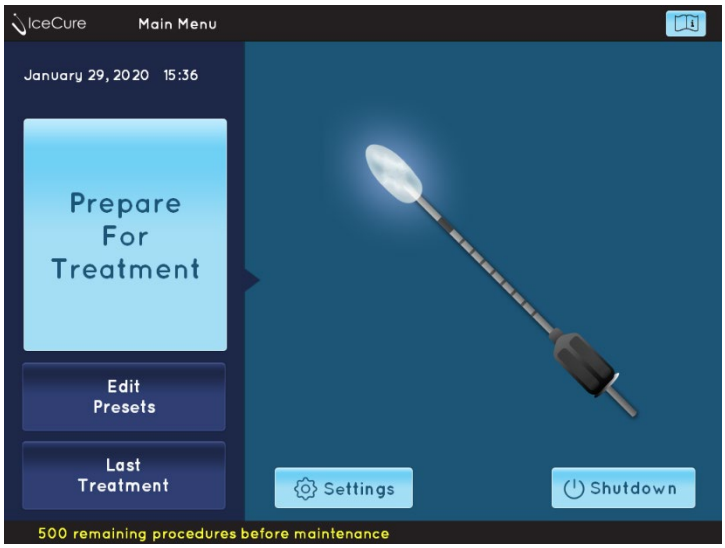


Figure 48: Edit Presets in the Main Menu screen

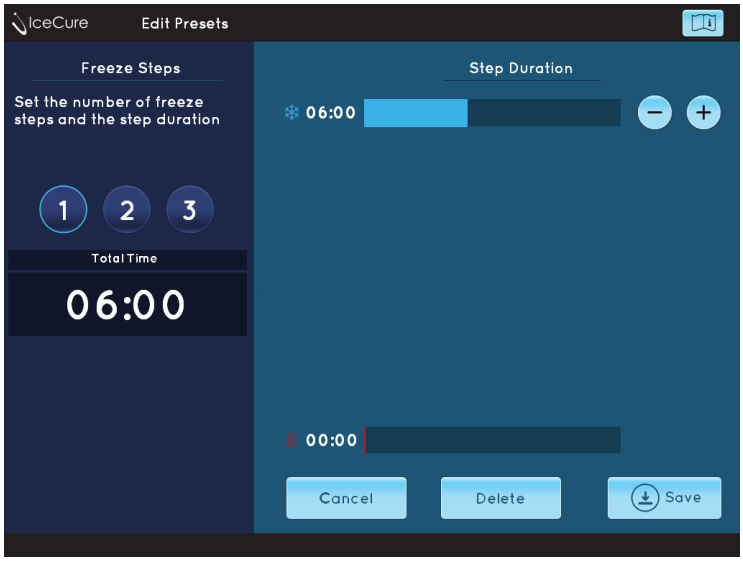
Figure 49: Define a treatment protocol by choosing Setup Presets on the Treatment Selection screen

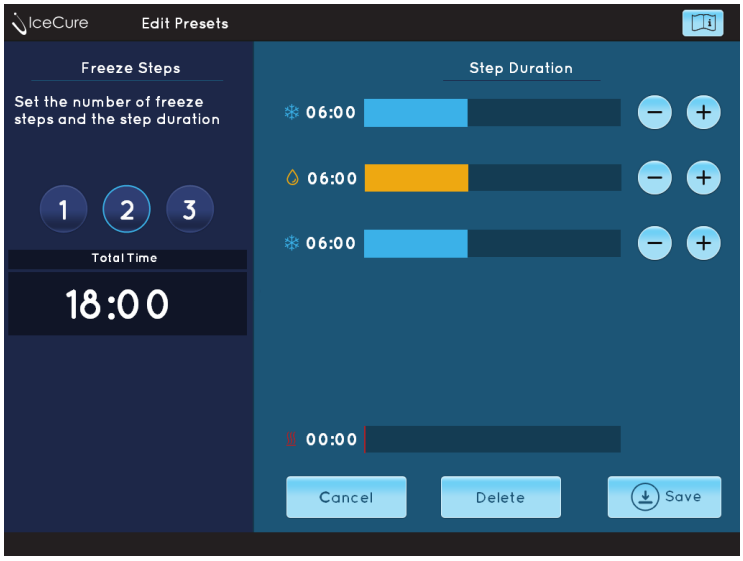
5.2.8.3 Adding a protocol

If you choose to add a protocol, tap one of the empty slots in the screen: the **Edit Presets** screen will load.

Perform the following steps:

1. Choose the number of **Freeze** steps in the left side of the screen.
2. Decrease/increase the time for every step using +/- icons. Each step will increase/decrease 15 seconds of the step time.
3. Save the protocol by tapping the SAVE icon.





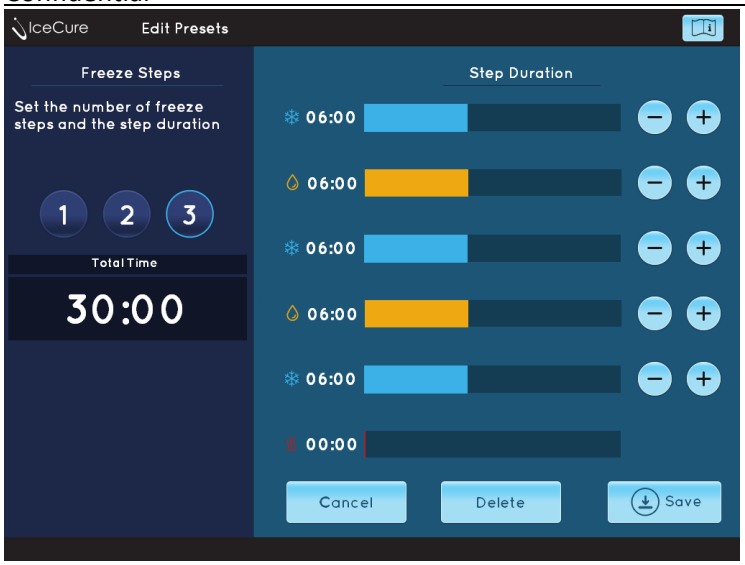


Figure 50: Steps for adding a protocol

The calculated total time of all steps is displayed on the left pane of the screen.

5.2.8.4 Editing a protocol

If you choose to edit an existing protocol (see Figure 49), the EDIT PRESET screen will load. The process is very similar to that of adding a new protocol.

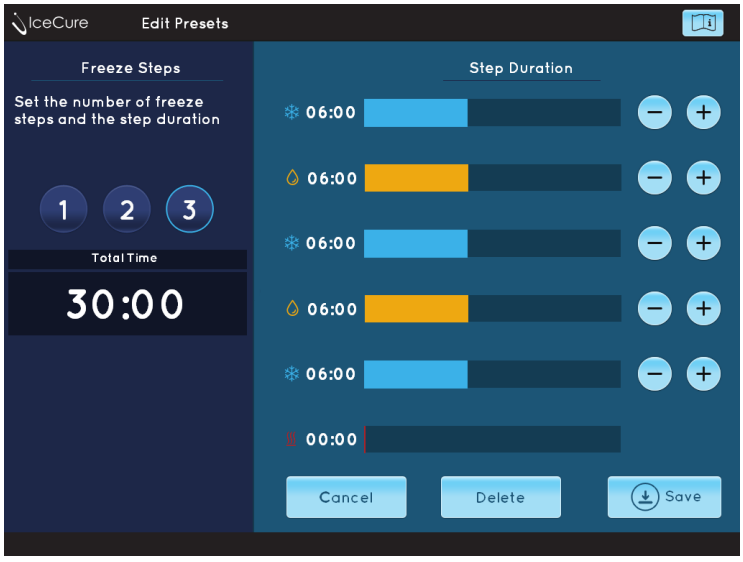


Figure 51: Edit Preset screen

5.2.8.5 Manual Freeze mode

The manual freeze mode allows you to perform a Cryoablation procedure without setting its duration or the number of **Freeze**-**Thaw** cycles in advance. You can choose manual

freeze mode by tapping the Manual Mode icon at the bottom of the Treatment Selection screen.

Figure 52: Choosing the Manual Mode option

5.3 Operational stages

5.3.1 Safe Operation in Percutaneous Procedures

When performing percutaneous cryotherapy procedures, meticulous observation of the incision site and the skin overlying the treatment site is required. Skin protection techniques must be implemented to avoid thermal injury to the skin.

Skin protection techniques include, but are not limited to: dripping room-temperature sterile saline on these areas; continuous monitoring of the growing ice ball by ultrasound; utilizing an external thermocouple to measure skin temperature; injecting sterile saline or local anesthetic between the skin and the ice ball formation; and placing moist gauze between the skin and the cryoprobe.

5.3.2 Preliminaries

Before operating ProSense™ cryoablation system, make sure you have completed all pre-operational stages.

Warning

Insertion of the introducer or cryoprobe into the target tissue is performed under the guidance of an appropriate imaging device and by an authorized practitioner trained by IceCure™ Medical.

Warning

Do not start the **Freeze** step before the cryoprobe cool zone center is aligned with the center of the target tissue.

Warning

Make sure the cannula is placed in the desired place after extracting the mandrel.
Verify under imaging that the ice ball forms at the desired location at the beginning of the freeze step

Warning

Cryoprobe, introducerand holder materials are not compatible with magnetic resonance imaging

Before activating the **Freeze** step, insert the cryoprobe into the target tissue according to the following steps:

1. Plan the trajectory of the cryoprobe prior to placement. Cryoprobe penetration direction shall be along the longest dimension of the target tissue as possible (if required parallel to the chest wall in breast applications).
2. Center of the cool zone must be in the center of the tissue to be ablated (see Figure 54 for the distance of the cool zone from the tip).
3. In percutaneous procedures, insert introducer or cryoprobe under ultrasound guidance or other appropriate imaging guidance:
    - Confirm longest dimension of the target tissue
    - Perform a 3 mm skin incision (for example using #11 blade)
    - Position the tip of the cryoprobe according to Cryoprobe placement calculation shown on the screen

Warning

Artifacts from the devices may appear in the Ultrasound or CT image.

4. When an introducer is used to guide the Cryoprobes to the tissue location, an introducer with matching dimensions should be used.

Warning

Ensure that cryoprobes are used with matching introducers. Use of longer cryoprobes may result in undesired tissue perforation.

For optimal cryoprobe positioning please note the following:

Cryoprobe Diameter/ Gauge	Shaft Length + Tip ±3mm	Tip Shape	Ice Ball Shape	Cool Zone Center From needle tip [mm]	Part Number
3.4 mm / 10G	127 mm	Trocar	Spheric	12 mm	FAP7100000
3.4 mm / 10G	140 mm	Trocar	Elliptic	20 mm	FAP7200000
3.4 mm / 10G	185 mm	Pencil	Elliptic	20 mm	FAP7400000
3.4 mm / 10G	185 mm	Trocar	Elliptic	20 mm	FAP7410000
2.4 mm / 13G	124 mm	Trocar	Spheric	10 mm	FAP7600000
2.4 mm / 13G	134 mm	Trocar	Elliptic	14.5 mm	FAP7800000

- Cryoprobe and matching introducers are marked in the same color.
- Cryoprobe and matching introducers are marked with tag labels in the same color.

Introducer Shaft Length	Description	Tip Shape	Part Number
115 mm	Fit to needle diameter 13G (FAP7800000)	Trocar	FAC9000000
122 mm	Fit to needle diameter 10G (FAP7200000)	Trocar	FAC9100000
167 mm	Fit to needle diameter 10G (FAP7400000 and FAP7410000)	Trocar	FAC9200000

*IceCure™ Medical systems, needles, introducers, cryoprobes and accessories may not be available in all regions.

Refer to Cryoprobe and Introducer IFUs for further details.

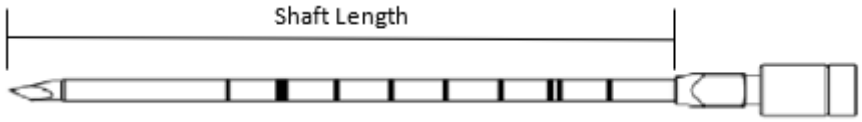


Figure 53: Introducer shaft length

The order in which you follow these steps is essential for maintaining sterility and patient safety.

First, insert the cryoprobe tip into the target tissue. Be aware of the markings on the cryoprobe: the wide mark closest to the tip is the safety mark. In percutaneous procedures **it must be completely inside the tissue** to avoid skin burns. The rest of the

marks indicate depth of cryoprobe insertion: each mark equals one centimeter with distinctive markings at 5 and 10 cm as shown in Fig. below.

Figure 54: Illustration of FAP7200000 cryoprobe Markings on the cryoprobe.

Main marks indicate safety zone, 5 cm (slightly thick third mark from the left) and 10 cm (double mark in circle).
Once you have verified the cryoprobe is located in the correct place, you may begin freezing.

5.3.3 Freeze Step

Selecting the type of treatment, Manual or Automatic, is discussed in section 5.3.3.2 and 5.3.3.3.

Warning
If unwanted freezing occurs, immediately stop the freeze step.
In case of cryoprobe fault such as frost on shaft, or nitrogen leak, press the emergency stop button.

To prevent injury, ice ball growth must be monitored under imaging guidance.

Warning
Do not start the **Freeze** step before the cryoprobe cool zone center is aligned with the center of the target tissue.

The practitioner can hold the cryohandle for the duration of the cryoablation procedure or use a hose support device.

5.3.3.1 Pause Option

The **Pause** enables the user to halt the freezing step for a short period of time. The tissue is naturally reheated, which creates a passive thaw state. The Pause option is available at any **Freeze** step of the cryoablation procedure, in Manual or in Automatic mode.
The use of the **Pause** button is according to clinical judgment (for example, inject saline to create buffer between the ice ball and the skin, perform a CT scan to evaluate ice ball dimension). Using the pause option should be as minimal as possible. Consider additional freeze time in the next freezing step.
The pause duration is not calculated in the total cryoablation cycle time. Pay attention to the pause time counter that appears on the screen during pause.

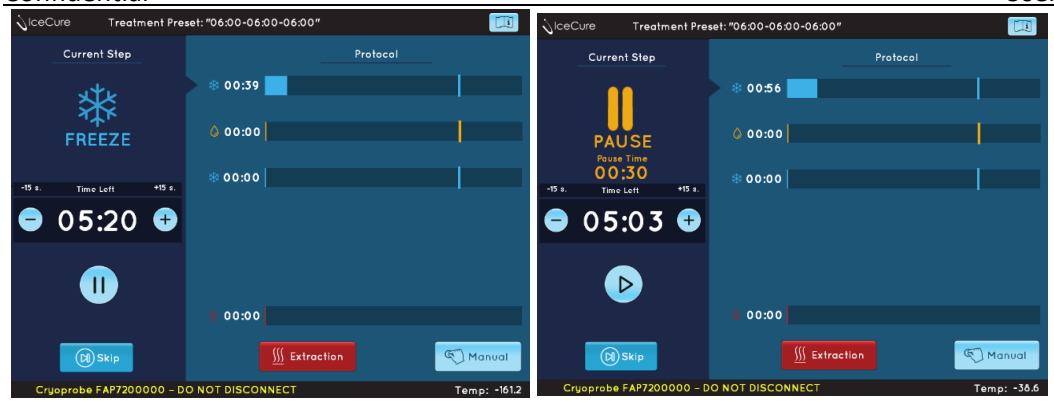


Figure 55: Left: Pause button available; Right: Pause in progress, Play button available

Depending on when and how long the pause time is defined, it may affect the ice ball characteristics (size, temperature, etc.).

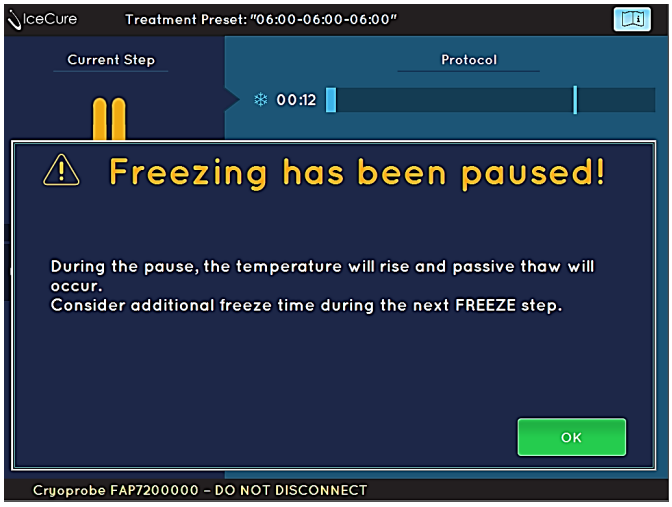


Figure 56 : Informative Pop when activating the pause

> **Warning**
> Always monitor the ice ball size during the entire procedure using proper imaging modalities.

5.3.3.2 Manual Freeze mode

Choosing the Manual freeze mode will open the treatment screen for manual mode as show in Fig. below. To **activate** the **Freeze** step, tap the **Freeze** icon on the screen.

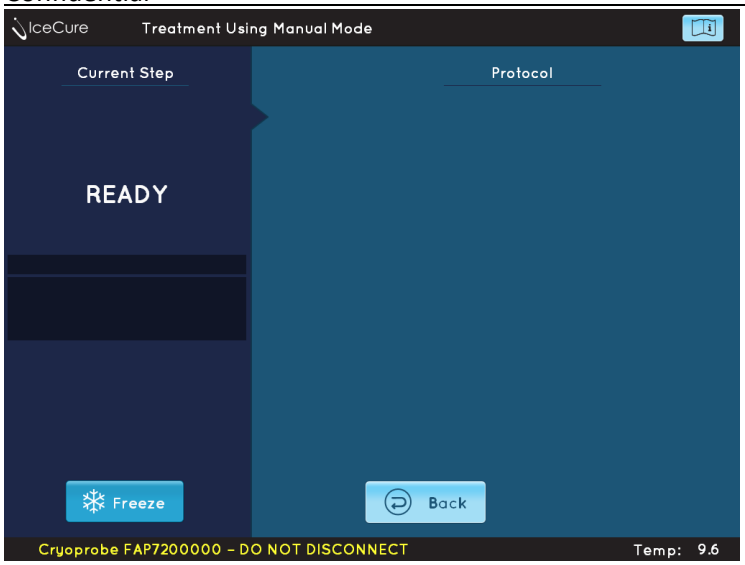


Figure 57: Manual Mode screen: tap on Freeze to start the Freeze step.

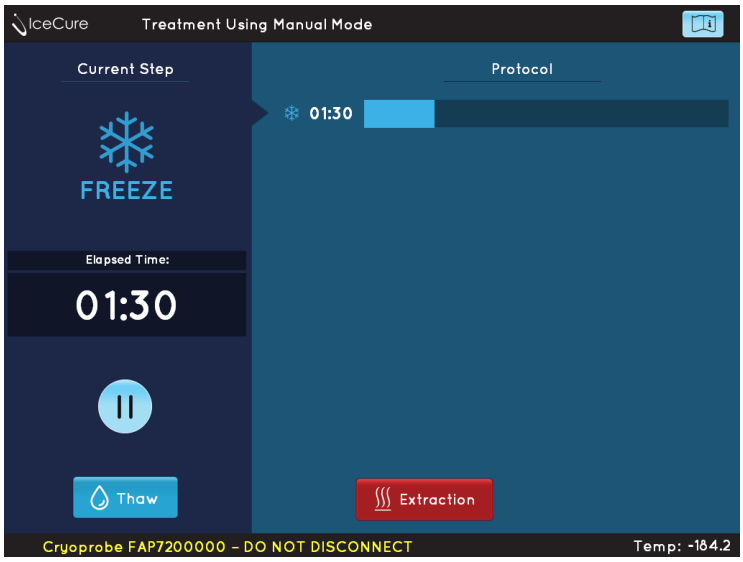


Figure 58: Freeze screen in Manual Mode

- The progress of the **Freeze** step will be shown on the screen with a second counter and a blue active progress line.

- The **Freeze** icon will change to a **Thaw** icon and will allow you to move from **Freeze** step to **Thaw** step by tapping the **Thaw** icon.

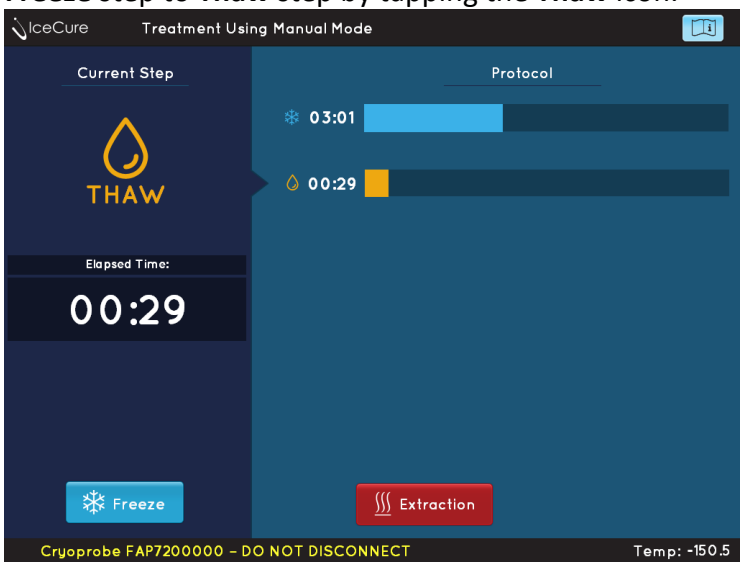


Figure 59: Thaw screen in Manual Mode

- You can continue to move between steps using the same method.
- To **end** the procedure, and extract the cryoprobe, tap the **Extraction** icon on the screen. Freezing will cease and the warming will be activated.

- When the Extraction is done, you may try to extract the cryoprobe from the tissue as described in the Extraction section below.
- Tapping the **Finish** icon will terminate the procedure.

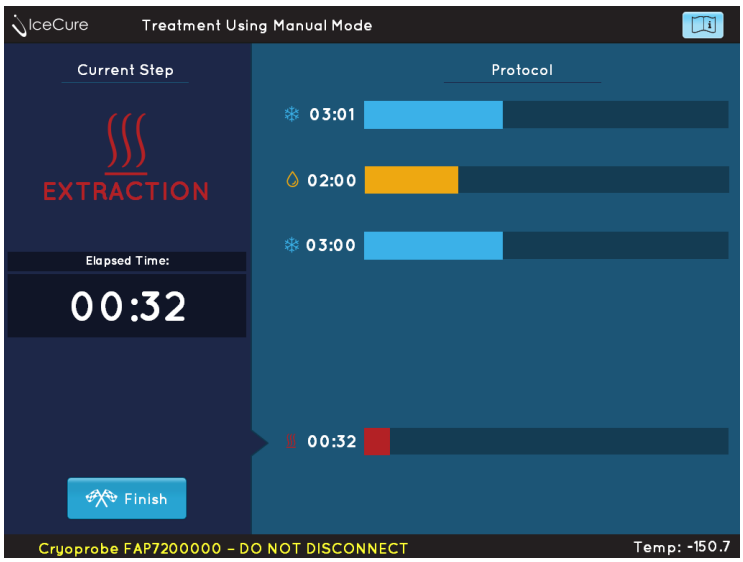


Figure 60: Extraction screen in Manual Mode

During the manual procedure, the system provides information regarding treatment progress:

- The left side of the screen displays the Current step (**Freeze**, **Thaw** or **Extraction**) and time elapsed for this specific step.
- The right side of the screen displays information on the entire Protocol as total elapsed time and treatment format.
- If you perform more than 3 consecutive **Freeze/Thaw** steps, the right side will only display the last 5 actions due to screen size limitation (3 **Freeze**-**Thaw** steps).
- The system allows up to 7 **Freeze/Thaw** steps

5.3.3.3 Automatic Freeze mode

Choosing one of the suggested protocols from the Treatment Selection screen will open the automatic protocol screen.

- To activate the **Freeze/Thaw** preprogrammed steps, tap the **Freeze** icon on the left lower corner of the screen.
- The **Start** icon will change to a **Skip** icon.
- The skip icon enables the user to skip from the current step in the cycle to the next step as preprogrammed.
- Within a given protocol, if you want to increase/decrease the preprogrammed time of a step when the step has already started, use the +/- icons on the left side of the screen to add/subtract 15 seconds with each push.
- At the end of the last **Freeze** step in automatic mode, the **Extraction** step will begin and the **Extraction** screen will be displayed.
- **You can move from the automatic mode AT ANY TIME by tapping the Manual mode button on the screen, without interrupting the procedure. When in Manual, you can't go back to Automatic mode.**
    - If you choose to do so, proceed as explained in section "Manual freeze mode": tap **Next** on the touch screen to move from **Freeze** to **Thaw** and monitor the process under ultrasound or other imaging modality.

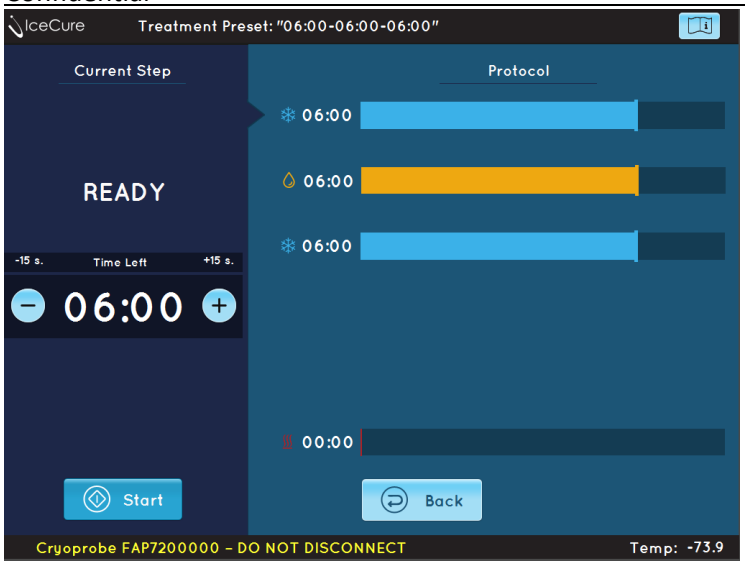


Figure 61: Automatic Mode screen: tap on Start to begin the Freeze step.

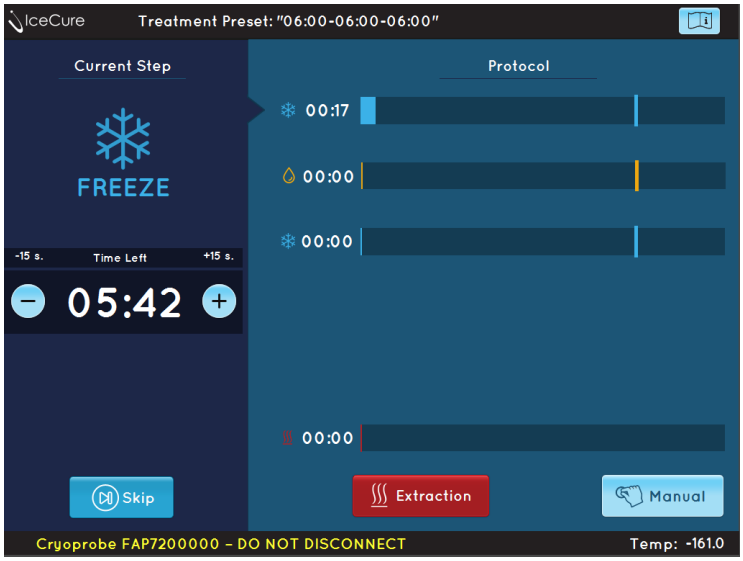


Figure 62: Freeze screen in Automatic mode

During the preprogrammed procedure, the system provides information regarding treatment progress:

- The left side of the screen displays the Current step (**Freeze**, **Thaw**, or **Extraction**) and time left for this step.
- The right side of the screen displays information concerning the overall Protocol, including total protocol time, time elapsed, protocol format, and changes you have made, if any, to the preprogrammed protocol.

5.3.4 Thaw

During **Thaw**, the ice ball melts partially or totally depending on the **Thaw** time and the tissue properties.

Since the **Thaw** step is a primary destructive factor in cryoablation mechanism it is important to have a **Thaw** step between two **Freeze** steps and to keep the cryoprobe location steady in the target tissue during all of the **Thaw** period. Monitor the process under ultrasound or other imaging modality.

5.3.5 Extraction

The **Extraction** step occurs at the end of every treatment. Its purpose is to allow the cryoprobe's removal from the target tissue in the fastest and safest way.

The **Extraction** step occurs at the end of every treatment, when you use the automatic mode. Its purpose is to allow the cryoprobe's removal from the target tissue in the fastest and safest way.

In order to be able to get the **Extraction** option, the **Freeze** time should have been at least 2 minutes.

If you did not previously freeze for 2 minutes, the system may update you to wait for a passive thawing process (Figure 66) before you can extract the cryoprobe.

- To activate the **Extraction**, press on the **Extraction** icon on screen as previously shown.
- The **Extraction** screen will be displayed and a time count will appear.
- At the end of the **Extraction** step, a message will be displayed on screen informing the user that the **Extraction** step is done.
- Wait for the message, then gently remove the cryoprobe from the target tissue and then tap **Finish**. Do not force removal of the cryoprobe from the tissue as it might increase the risk of tissue damage.
- If the cryoprobe cannot easily be extracted from the tissue, tap the**Extraction** icon on screen to initiate another **Extraction** step.
- After the cryoprobe has been removed from the tissuetap the "Finish" icon on screen to complete the procedure.
- After the cryoprobe has been removed, apply momentary pressure to the insertion site. You may apply adhesive skin closure to the incision and cover it with a 4x4 gauze dressing.
- The system will then perform several verification steps and it will inform you when it is safe to disengage the cryoprobe.
- In case the **Extraction** process isn't available, wait for passive **Thaw**.

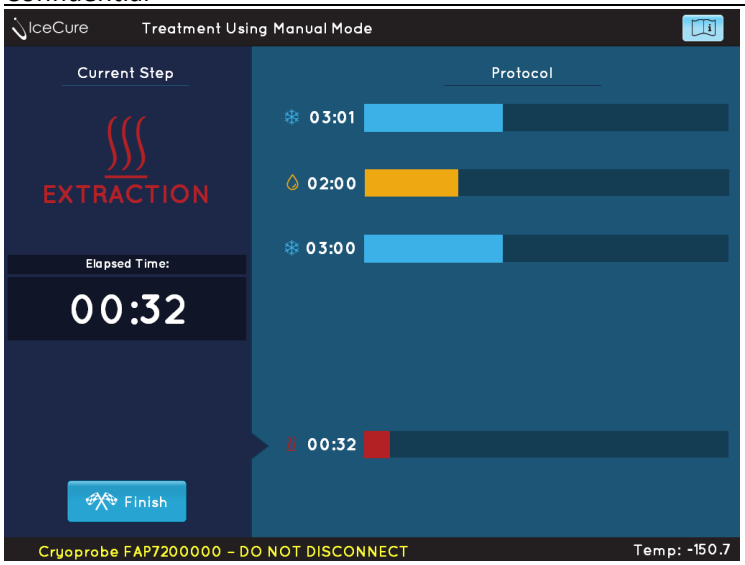


Figure 63: Extraction screen during procedure

At the end of the **Extraction** step, unless you tap **Finish**, one of the two screens below will be displayed automatically:

Extraction

Figure 64: Extraction screen

The Extraction screen appears for a few seconds and is replaced automatically by the ‘Completed’ screen.

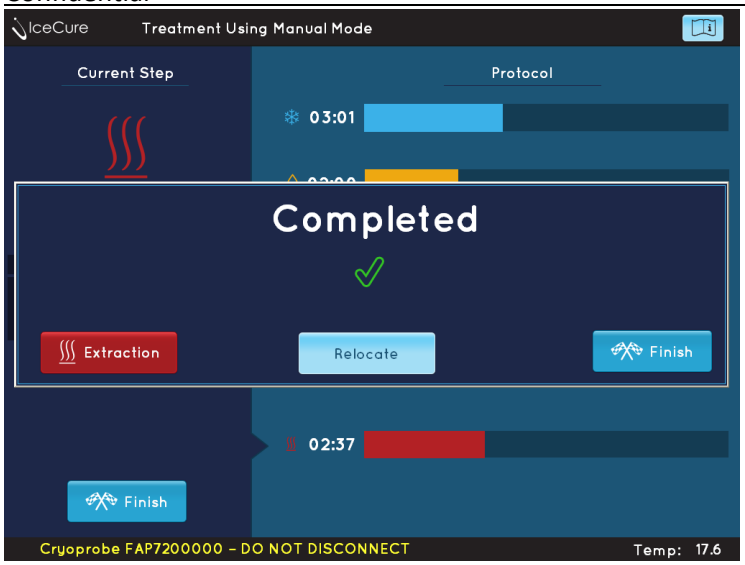


Figure 65: Completed screen with 3 options: Extraction, Relocate and Finish.

- To continue warming, tap the **Extraction** icon.
- For an additional **Freeze** step - tap the RELOCATE icon and select a treatment cycle.
- To end procedure, tap **Finish**.

The use of RELOCATE option is according to clinical judgment (for re-positioning the cryoprobe in case additional freezing step is required).

Note: You can only use the relocate option twice, thus, the system enables to Freeze only 3 locations per a given procedure.

⚠	**Warning** After Extraction step, before removing the cryoprobe and/or Introducer from the tissue, make sure that the freeze effect has been thawed out so that the cryoprobe and/or Introducer can be easily and safely removed from the tissue. Do not force removal of the cryoprobe and/or Introducer from the tissue as it might increase the risk of tissue damage. Continue the Extraction step or wait for passive thaw until the cryoprobe and/or Introducer can be withdrawn easily.

⚠	**Warning** Do not tap the **Extraction** button before the freezing protocol is completed, unless you want to shorten the procedure due to clinical judgment. Monitor the cryoprobe positioning during Extraction and make sure it is still in the target tissue.

Passive Thaw screen appears if the cryoprobe tip is too cold to disconnect the cryoprobe from the tissue. Press **OK** after the cryoprobe is disconnected from the tissue.

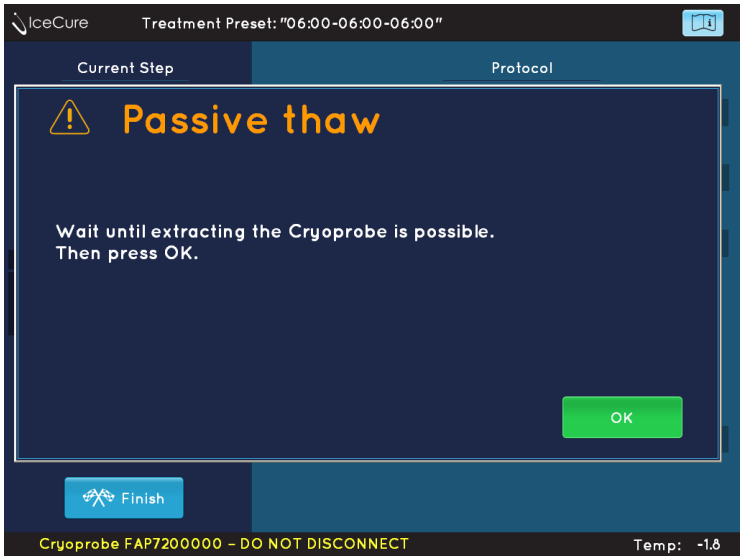


Figure 66: Passive Thaw screen

For an additional **Freeze** step, tap the RELOCATE icon and select a treatment cycle.
To end procedure, tap **Finish**.

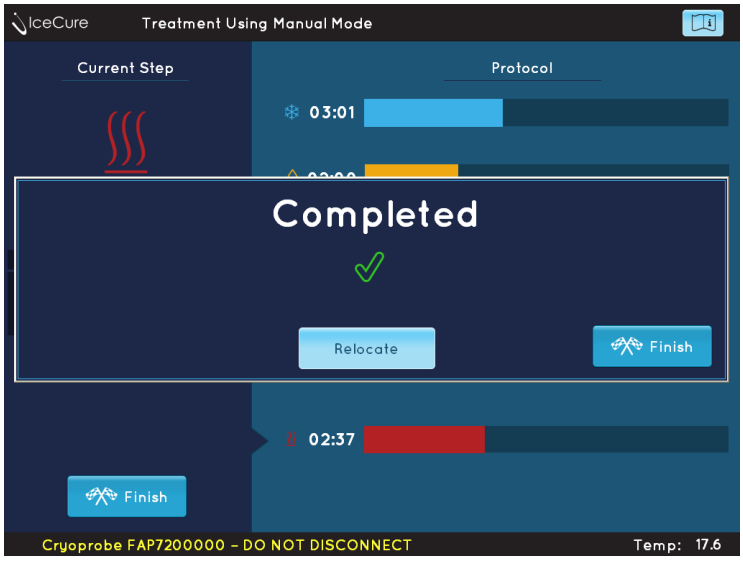


Figure 67: Completed screen without Extraction option

In case Relocate is tapped, the Cryoprobe Placement Calculation screen appears and the Dewar needs to be refilled:

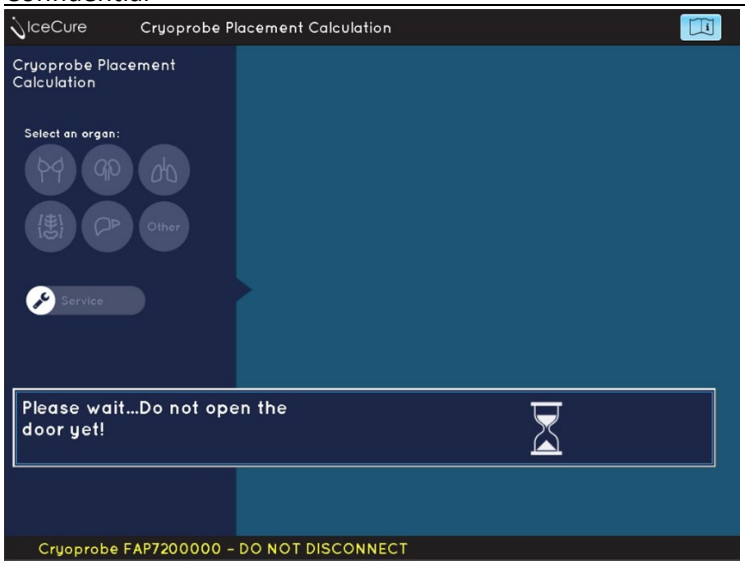


Figure 68: Cryoprobe Placement Calculation screen during relocate

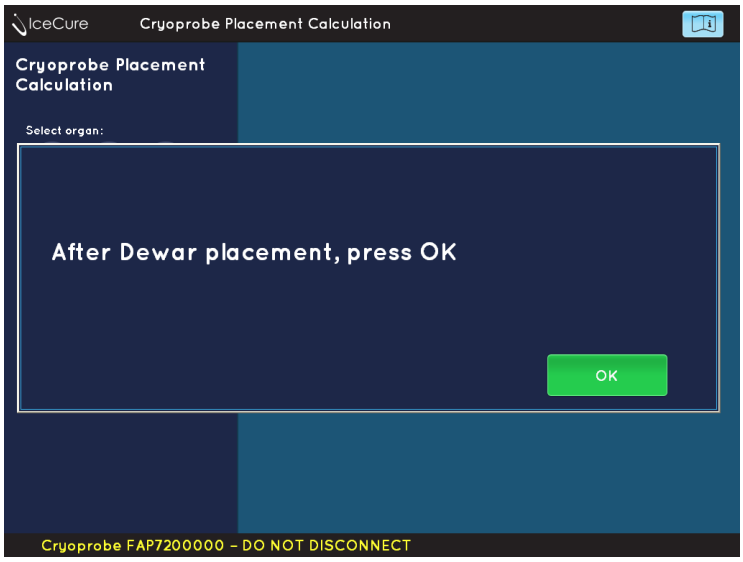


Figure 69: Dewar Replacement screen

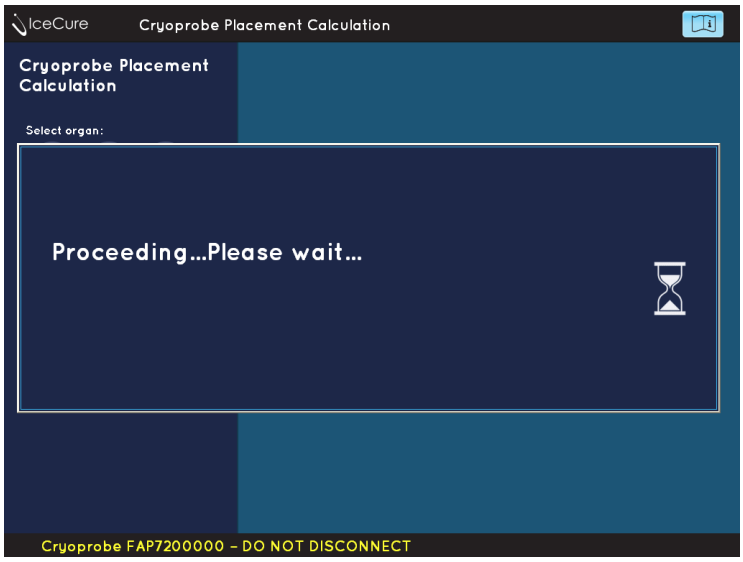


Figure 70: Dewar Replacement finished screen

After each relocation, replace the Dewar when required and follow on-screen instructions for the additional **Freeze** step.

5.3.6 Show Last Treatment

The last treatment will be displayed by choosing LAST TREATMENT icon on the Main Menu screen.

In this screen, you can see details of the last procedure that was performed including date, time, treatment mode, cryoprobe type and duration of treatment.

Figure 71: Last Treatment screen after relocation

Figure 72: Last Treatment screen after more than 3 Freeze steps without relocation.

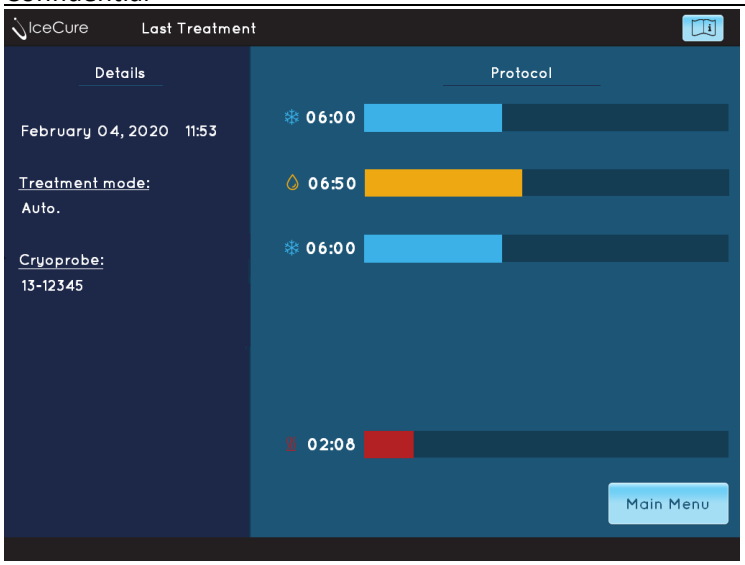


Figure 73: Last Treatment screen after up to 3 Freeze steps

5.3.7 Replace (refill) the Dewar during a cryoablation procedure

Option to refill the Dewar is available at each **Thaw** step.

If the Freeze step is 5 minutes or longer, the system will request Dewar refill between the steps.

It is recommended to have an additional full Dewar ready, in case you need it for a longer freeze time.

- At every **Thaw**, the system will automatically ask if you want to replace the Dewar (see figure below):

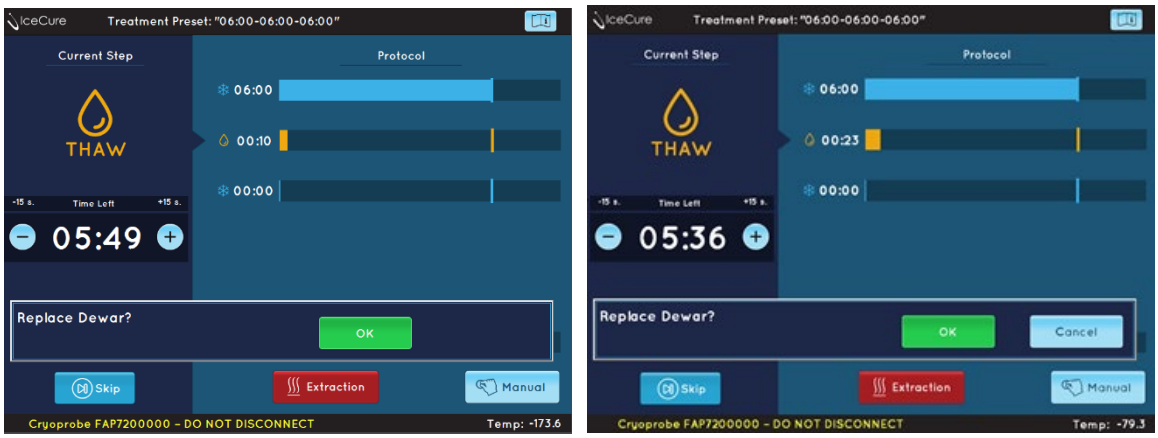


Figure 74: Replace Dewar option question

- Press **OK** to replace the Dewar.

Note: If the Freeze step was shorter than 5 minutes, **Cancel** button will appear on the screen.

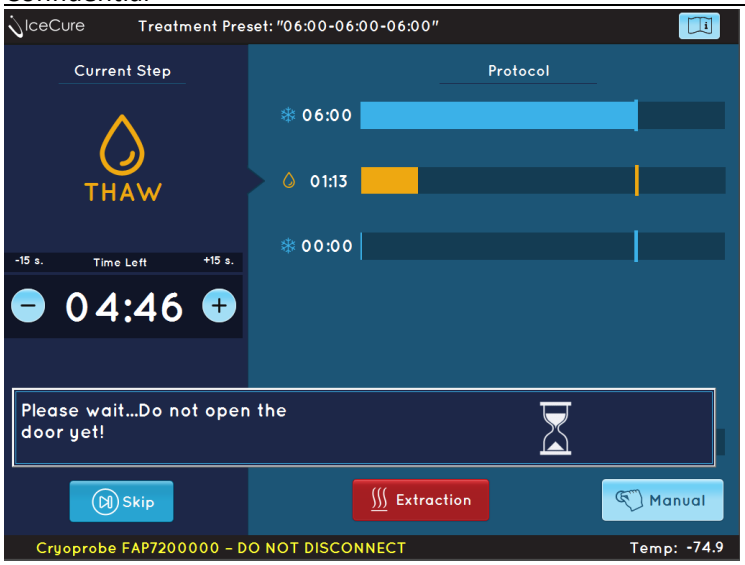


Figure 75: Lowering the Dewar during Thaw screen.

The message "Please wait…Do not open the door yet!" will appear.

- The system will perform several steps, and then it will inform you that it is safe to replace the Dewar and you will get the Replace Dewar screen (figure below).
- Please insert a full Dewar in place of the old one and only then tap **OK** to continue.
- At the same time, you will get an interactive update of the Thawing time.

Figure 76: Replace Dewar screen

- After tapping the **OK** button, the system will proceed and prepare the new Dewar that was inserted. The screen will show "Proceeding, please wait… " (figure below)

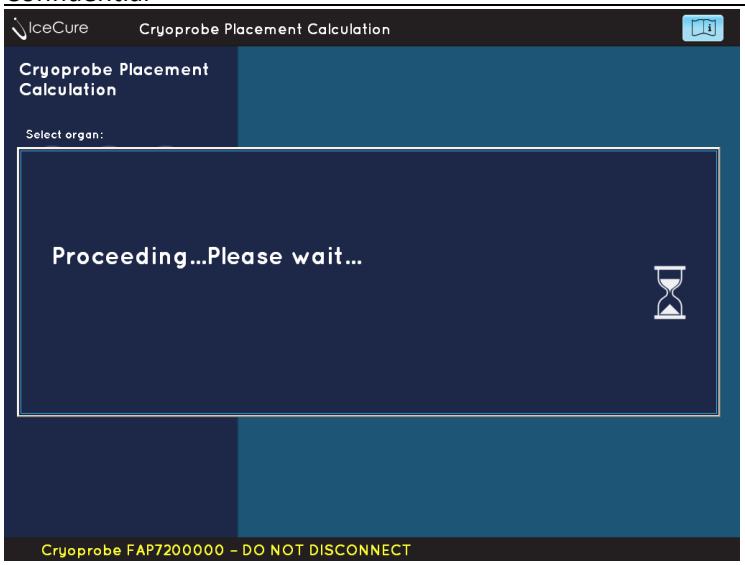


Figure 77: Replacement done follow up screen

- When preparation of the new Dewar is complete, the system will resume the **Thaw** step (figure below).
- **To go to the next Freeze step, you have to tap Skip –** even if the time to complete the replacement exceeded the preset **Thaw** time (figure below).

Warning

If you don't tap **Skip** after replacing Dewar, the system will stay in **Thaw** mode.

Figure 78: Replacement was completed before the Thaw ended

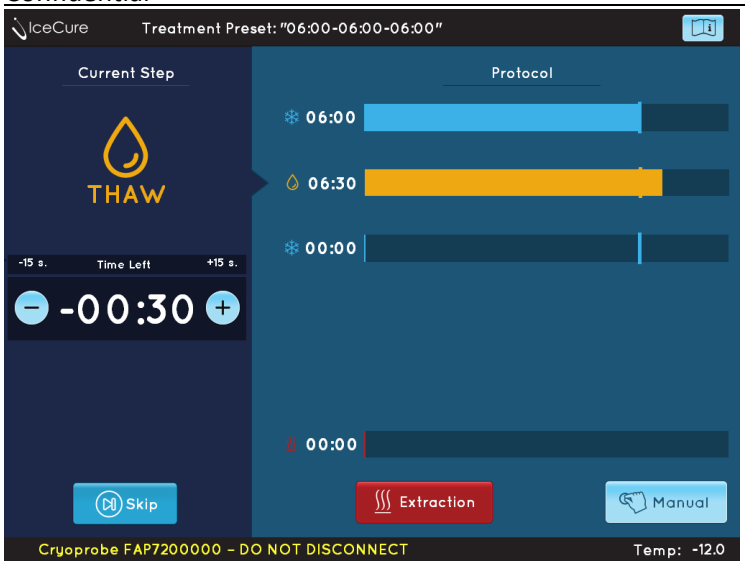


Figure 79: Replacement was completed <u>after</u> the Thaw ended

5.3.7.1 Replace the Dewar during Freeze

In case of low level of Liquid Nitrogen or ice on top of the Dewar, the system can't continue to Freeze. It will ask to refill the Dewar in Freeze step (see fig. below)

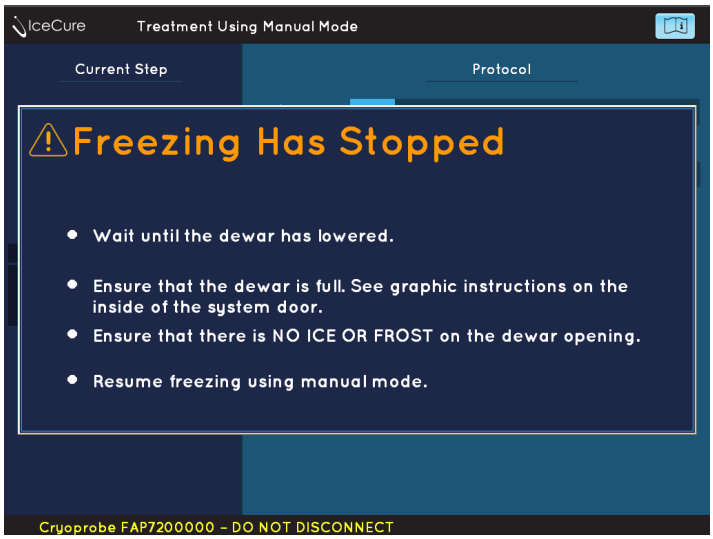


Figure 80: Replacement during Freeze, in case of empty Dewar.

- <u>If you tap **OK**, you can replace the Dewar and continue the procedure. The system will move to Manual mode and wait in a **Thaw** step for instruction.</u>

  <u>Pay attention that in Manual mode, you need to tap the icon on the screen for each **Freeze** or **Thaw** step.</u>
- Replace Dewar as in paragraph 5.3.8.
- If you tap **Cancel**, you will get a message of "Low Liquid Nitrogen Level" (See a figure below).

Figure 81: Procedure stopped due to Low Liquid Nitrogen.

If you tap **OK**, you will get an "Extraction Completed screen" with 3 options: Extraction, Relocate and Finish.

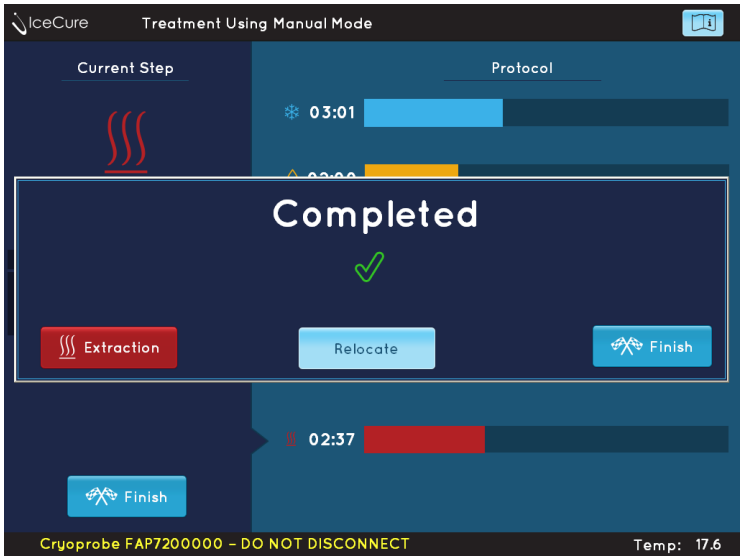


Figure 82: Extraction Completed screen.

5.4 Post-operational stages

5.4.1 Removing the cryoprobe from the cryohandle

When a Cryohandle holder is used during the procedure, safely disengage the hose from the Holder device.

After removing the cryoprobe from the target tissue, and the message that it is safe to disengage the cryoprobe is displayed, detach the cryoprobe from the cryohandle as follows:

1. Unscrew the used cryoprobe from the cryohandle and dispose of it appropriately.
2. Remove the single-use sterile cover from the cryohandle.

3. Close the cryohandle with the covering plug.

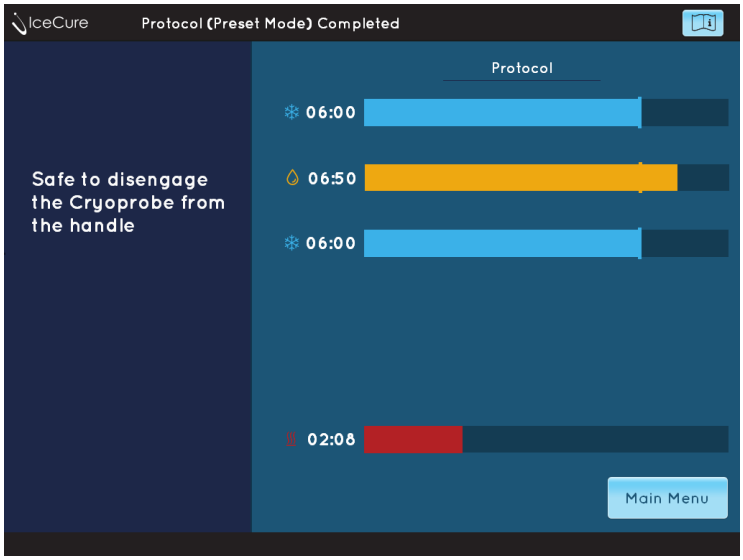


Figure 83: Safe to Remove cryoprobe

Warning

Dispose of the cryoprobe, introducer and cryohandle sleeve in accordance with institutional policy.

Do not reuse, do not re-sterilize.

5.4.2 Exiting the ProSense™ cryoablation system treatment mode

At the end of the treatment and after removing and disassembling the cryoprobe return to the Main Menu screen by tapping the MAIN MENU icon on the right lower corner.

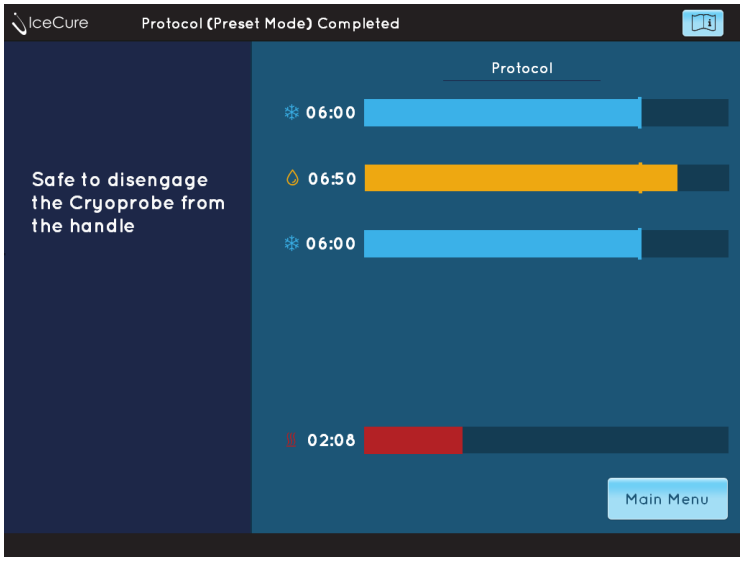


Figure 84: Protocol Completed screen.

Press the Main Menu icon to load the Main Menu screen.

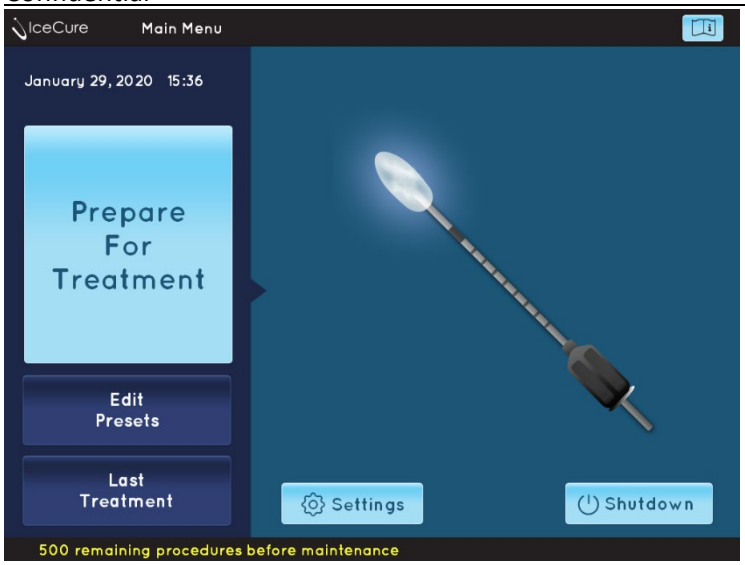


Figure 85: Main Menu screen.

To shut down the system, tap the Shutdown icon

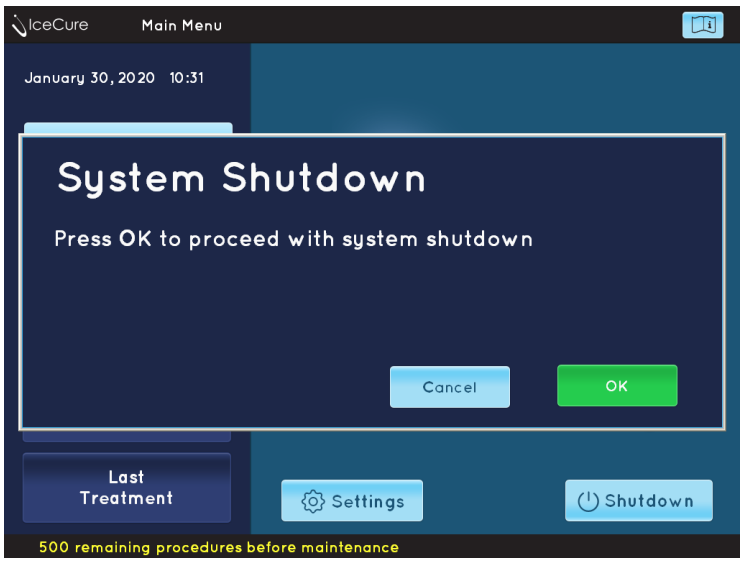


Figure 86: System Shutdown screen.

Press OK to proceed.

At the end of the last treatment of the day, Switch OFF the mechanical ON/OFF switch and unplug the electrical cable. Clean the system following instructions in section 8.1 and move the system to its storage location, using the dedicated handle.

5.4.3 General advice for patients

Instruct patients as follows:

- Remove gauze dressing after 24 hours and expect minimal discharge.
- Adhesive skin closure should be removed after 7 days if it has not already fallen off
- They may need over-the-counter pain relievers for mild discomfort after procedure

- After breast procedures, swelling and moderate ecchymosis may be present for several weeks

5.5 System failures

5.5.1 ProSense™ cryoablation system failure

When the ProSense™ cryoablation system detects an **error**, the following will occur:

- A **failure** message will appear.
- The procedure will be aborted.

When the above occurs, take action as follows:

1. Write down the error message and number, follow the system instructions.

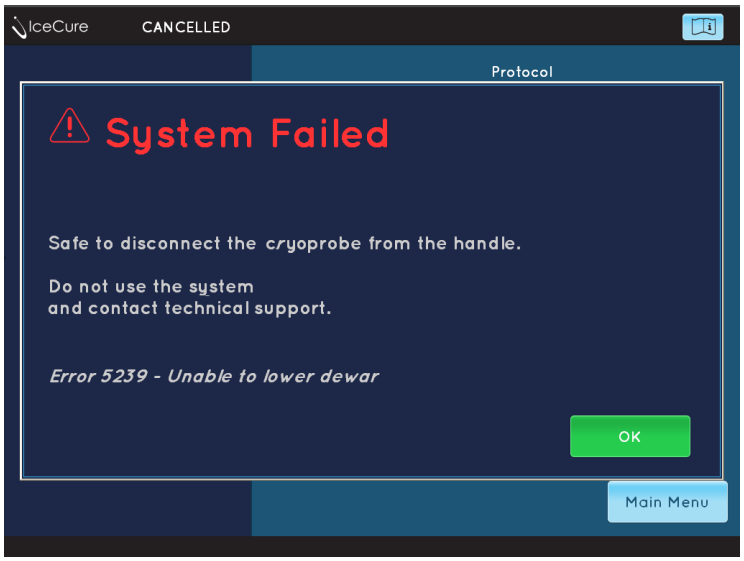


Figure 87: System Fail example screen

2. If you are in the middle of a cryotherapy procedure, **wait for passive Thaw** and then carefully **remove the cryoprobe** from the tissue. Replace the cryoprobe when required automatically by the system.
3. **Disengage the cryoprobe** from the cryohandle **only** after the system instructs you that it is safe to do so.
4. If system shut down is required, **shut OFF the ProSense™ cryoablation system** by pressing the mechanical ON/OFF switch on the main chassis and then remove the plug from the power supply.
5. Contact support@Icecure-medical.com

5.5.2 ProSense™ cryoablation system touch screen failure

If the touch screen shuts down, you will need to shut OFF the system with the mechanical ON/OFF switch and remove the plug from the power supply. This will end the cryoablation procedure.

Caution

In case of software crash, switch OFF the mechanical ON/OFF switch and unplug the electrical cable.
Call IceCure™ Medical for technical service before restarting the ProSense™ cryoablation system.

5.5.2.1 Emergency Stop button

The fastest way to end a procedure is to tap EXTRACT on the screen (or the RED HANDLE button). However, in case of electrical emergency, press the RED ROUND Emergency Stop button located on the right side of the main chassis. The Emergency Stop button is designed for emergency shutdown of the ProSense™ Cryoablation System. Pressing this button immediately turns OFF the system.

Switch OFF the mechanical ON/OFF switch and unplug the electrical cable.

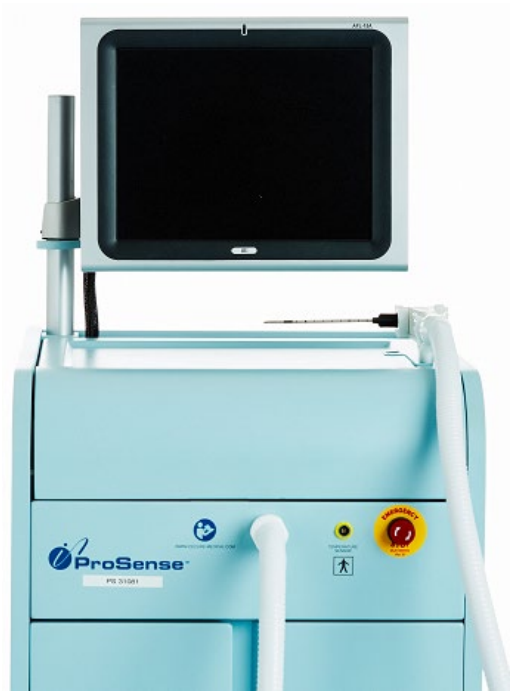


Figure 88: Emergency Stop button located on the main chassis

Warning

Press the emergency stop button immediately in case of emergency situation which is related to system's fault (for example nitrogen leak / fire / electrical fault) or cryoprobe's fault (for example nitrogen leak / frost on shaft and so on). Wait for passive thaw until the cryoprobe and/or Introducer can be withdrawn easily. Do not force removal of the cryoprobe and/or Introducer from the tissue as it might increase the risk of tissue damage.

Warning

In case of environmental or medical emergency, extract the cryoprobe from the patient. If the cryoprobe is in the frozen tissue, tap the **Extraction** button for quick cryoprobe removal.
Hold the cryohandle steady as the cryoprobe may move due to the tension and weight of the hose.

After pressing the emergency stop button, wait for "passive **Thaw**" before extracting the cryoprobe from the tissue.

To release the Emergency Stop button, turn it clockwise (as the direction of the arrows).

If emergency stop button was *accidently* pushed, the procedure is cancelled but can start again with a new cryoprobe.

6 COMPUTER INTERFACE

6.1 The technician menu

The technician menu/screen can be accessed by tapping the SETTING icon on the left lower corner of the main menu screen and then tapping the Technician icon.

The technician mode can only be accessed by an IceCure™ Medical authorized technician and is restricted by a password. It is used for maintenance of the system.

> **Warning**
> Never enter the technician mode screen. Only an IceCure™-Medical technician or an authorized representative can access this mode for maintenance or repair of the system.

6.2 Reading the screen

The screen within the control panel is represented by the picture below:

Figure 89: A sample touch screen

6.3 System messages

Messages can appear in one of three modes: status, warning or error messages.

6.3.1 Status messages

Information that is valuable to the user will appear in the status bar area at the bottom of the screen.

Status messages, such as the type of cryoprobe currently connected will be displayed in the left bottom corner. For Example:

Figure 90: Status message example

6.3.2 Warning messages

Critical information will appear as a pop-up dialog with an **OK** button for acknowledging the message.

When such a message appears, the user should carefully follow system instructions.

If a warning message appears during a treatment, it will appear in the following format:

Figure 91: Warning message format example

Pressing the **OK** button will indicate you have read this message and will dismiss the popup.

6.3.3 Error messages

Information that prevents the user from continuing the operation of the system will appear as a dialog box that cannot be closed, stating the problem and possible solutions.
When such a message appears, the user should carefully follow system instructions.
If an error appears during a treatment, it will appear in the following format:

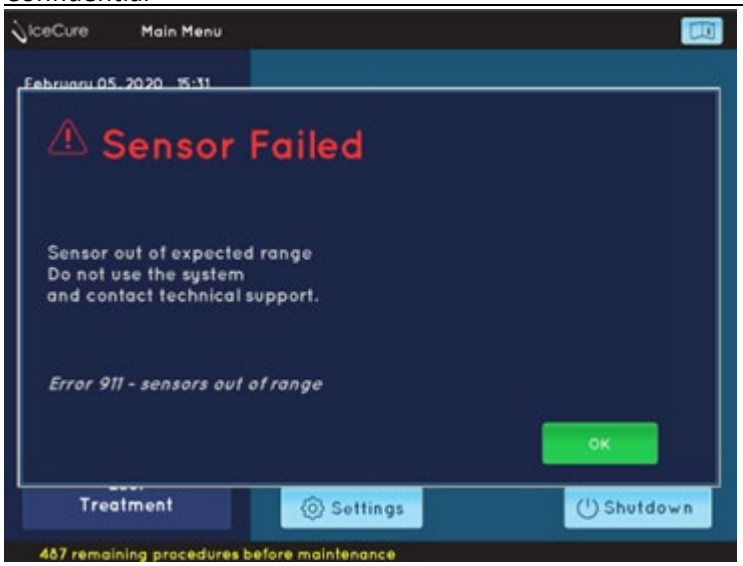


Figure 92: Error message format example

⚠	**Warning** When the system shuts itself down due to an error, contact IceCure™ Medical and describe the error message shown on the screen as precisely as possible. Do not attempt to reuse the system before contacting IceCure™ Medical. After reporting or making note of the error message, switch OFF the mechanical ON/OFF switch and unplug the electrical cable.

7 ACCESSORIES

Expiration dates of all IceCure™ sterile accessories are specified by the appropriate labels on the external package as well as on the internal package.

7.1 Cryoprobe

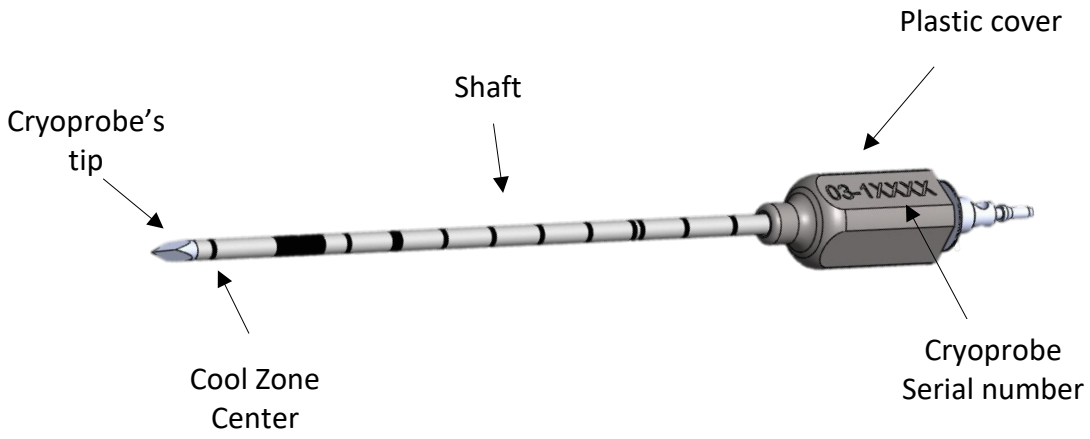


Figure 93: Cryoprobe components (the figure is for illustration only).

There are various cryoprobe configurations. For example:

Cryoprobe Diameter/ Gauge	Shaft Length + Tip ±3mm	Tip Shape	Ice Ball Shape	Cool Zone Center From needle tip [mm]	Part Number
3.4 mm / 10G	127 mm	Trocar	Spheric	12 mm	FAP7100000
3.4 mm / 10G	140 mm	Trocar	Elliptic	20 mm	FAP7200000
3.4 mm / 10G	185 mm	Pencil	Elliptic	20 mm	FAP7400000
3.4 mm / 10G	185 mm	Trocar	Elliptic	20 mm	FAP7410000
2.4 mm / 13G	124 mm	Trocar	Spheric	10 mm	FAP7600000
2.4 mm / 13G	134 mm	Trocar	Elliptic	14.5 mm	FAP7800000

* Certain configurations are not available in some regions.

The ProSense™ cryoprobes are available in various diameters (2.4 mm to 3.4 mm), various ice ball shapes (Spheric, Ellipsoid), various tips (trocar, blunt and pencil) and various lengths according to the expected application, treated tumor size and surgery approach.

Cryoprobes of 185 mm length are intended for penetrating and freezing soft tissue and can be used in laparoscopic procedures, while shorter cryoprobes are typically used for percutaneous procedures under reduced mechanical stress. It is preferred to use the adapted lengths according to the superficiality of the lesions.

Select the cryoprobe based on ice ball size you want to obtain and the cooling zone location as defined in the table above.

Always monitor the ice ball engulfment with appropriate imaging modality.

Marks on the cryoprobe shaft aid in determining the depth of cryoprobe insertion. The first mark (closest to the tip) is thicker and represents the minimum insertion depth of the cryoprobe for a percutaneous procedure. Before starting the freezing procedure, the user must verify that this mark is fully inserted into the skin.

Ensure that Cryoprobes are used with matching introducers.

Warning

Cryoprobe, introducerand holder materials are not compatible with magnetic resonance imaging.

7.2 Introducer

The needle guide, named Introducer consists of two main parts made of stainless steel:

a. Mandrel – a needle attached to a standard female Luer
b. Cannula – a fitting trocar attached to a standard lock hub
c. The notch on the mandrel is visible under imaging systems and facilitates positioning of the introducer inside the target tissue. The mandrel notch must be positioned at the center of the target tissue.

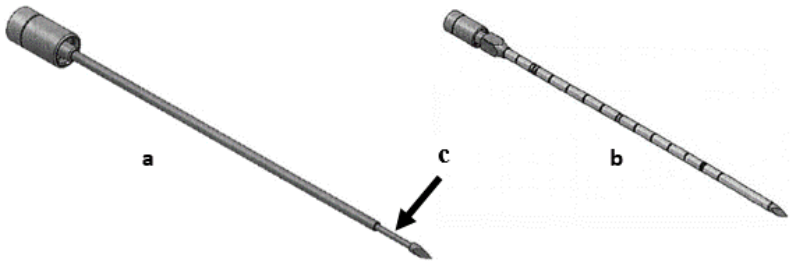


Figure 94: Illustration of Mandrel with the notch (a+c) the Cannula with the Mandrel inserted (b)

7.3 Foot pedal (Not available in some regions)

The foot pedal (Not available in some regions, e.g. China) is a pneumatic accessory, external to the main chassis and is not essential for normal functioning of the system. It

serves as an alternative way to select actions displayed on the screen, instead of tapping the active buttons on the screen.

To use the foot pedal (Not available in some regions, e.g. China), connect it to the console by plugging its cable into the footswitch connector located on the back panel. The foot pedal action is equal to the action of the optional **BLUE** button.

7.4 Holder (Not available in some regions)

The Holder is a re-usable external accessory that can be used for safely positioning the Cryohandle during cryoablation procedure in order to ensure stability during the procedure.

It is the consideration of the user on which side and where to position the holder arm according to the room and table conditions.

To use the holder, safely position the Holder base on the CT or other patient table under the patient body and tighten the nuts to the table. Once positioning of the Cryoprobe is completed, carefully place the Cryohandle in the Holder clamp and tighten the clamp.

8 SYSTEM MAINTENANCE

8.1 General cleaning

Warning

Do not allow any liquid or humidity to enter the cryohandle. Always keep the handle plug on the cryohandle.

Caution

Do not use acetone to clean the labels' area (Holder and ProSense™ system).

Following each cryosurgical procedure, discard the single use devices (single-use cryoprobe, cryohandle handle plug, and sleeves for the hose and touch screen). Carefully clean the hose and the cryohandle according to the cleaning instructions acceptable for permanent equipment in your institution.

All single use devices are considered to be medical waste and must be disposed of in accordance with medical waste laws and hospital standards. Sharp objects such as the cryoprobe and introducer must be disposed of in an adapted container.

Following a cryosurgical procedure, it is recommended to wipe the pedal with a damp cloth and WARM soapy water to remove visible soil. Dry it with a clean cloth or with forced air and wrap it in another clean cloth until disinfecting it according to the disinfection acceptable standards in your institution.

Before and after every procedure wipe the holder gripper arm and base with gauze pads soaked with 70% alcohol to ensure no remnants of blood or tissue are present, according to the disinfection standards acceptable in your institution. Afterwards, dry it with a clean cloth. Check the ProSense™ Cryoablation System for any remaining blood or tissue. In case blood or tissue remnants are detected, wipe the contaminated area with gauze pads soaked with 70% alcohol. Verify that no visible remnants remain. Wipe the initially cleaned area with approved medical grade surface disinfecting wipes and allow it to air dry. Please note that using a high concentration of chlorine solution might damage the paint.

Thoroughly clean the ProSense™ cryoablation system with a damp cloth and warm soapy water. Dry it with a clean cloth. Clean the monitor screen with a soft cloth and a mild window cleaning solution. Take special care to avoid spilling liquid onto the system.

At the end of the day, carefully dry all items and store the system in an appropriate place.

8.2 Sterility

Warning

Cryoprobes, introducers, and sterile sleeves are single-use devices supplied in single use sterile packaging.
Reuse single-use devices affects their performance and can cause cross-contamination.

Cryoprobes and Introducers are single use products sterilized using ethylene oxide.

The sterile sleeves and covers are single-use and are not supplied by IceCure™ Medical in single use packaging.

The sterile single use sleeves are used to cover the hose up to the cryoprobe and maintain sterility.

8.3 Periodic servicing

Caution

The ProSense™ cryoablation system is not user-serviceable. Refer all service issues to IceCure™ Medical's Customer Service Department.

If there is any malfunctioning of the ProSense™ cryoablation system, please contact IceCure™ Medical technical support.

The technician should disconnect the system from the electrical outlet before removing external covers of the system.

Periodic servicing will only be performed by IceCure™ Medical authorized service representatives in compliance to the company service procedures and according to the procedure counter that can be seen in the bottom of the main menu screen (see figure below).

Figure 95: Counter of the remaining procedures before maintenance at the bottom of the main menu screen.

Hospital bio-engineering teams should follow local regulations and hospital internal procedures concerning periodic maintenance of medical devices. IceCure™ Medical recommends performing periodic maintenance once or twice a year according to warranty or service agreement between IceCure™ Medical and the customer.

Caution

The system will not allow additional cryoablation procedures when zero procedures are left to maintenance. Make sure to call IceCure™ Medical service representatives in time.

9 TROUBLESHOOTING

9.1 General

Warning
Do not modify this equipment without authorization of the manufacturer.

Warning
Never open the console. Only an IceCure™ Medical technician or authorized representative is allowed to open the console for maintenance or to repair the system.

Warning
Do not attempt to perform any troubleshooting or corrective action beyond those specified in the following guide. Any malfunction not listed in the guide, or one that persists after the recommended action has been taken, must be referred to IceCure™ Medical.

9.2 Troubleshooting guide

Table 7: Troubleshooting guide

Problem	Probable Cause	Action
Main chassis does not move	Rollers are locked	Unlock the rollers, transport the system and lock them again. If the problem persists, contact IceCure™ Medical service.
No system power	AC power is not connected to the system; power supply malfunction	Check that the power cable is connected to the inlet and the wall outlet. Check that Emergency button is released. Check that main switch is on. If still there is no power, contact IceCure™ Medical service.
Electrical short circuit	The electrical infrastructure of the site does not have a 16 A (for 220-240 VAC countries) or 32 A (for 100-120 VAC countries) Type-D fuse or greater.	An add-on Inrush Current Limiter can be used to overcome replacement of the site fuse.

Problem	Probable Cause	Action
AC power is on but the screen does not turn on	Computer power supply malfunction or computer error	Check if the computer power cable is connected to the screen and turn the screen on. If the screen still does not turn on contact IceCure™ Medical service.
The system and screen turn on but the screen does not change	Computer LAN cable is not connected correctly.	Contact IceCure™ Medical service
Dewar compartment door does not open	Door held shut by magnet	Try to open the door using reasonable force. If door will not open, contact IceCure™ Medical service.
The door is open but the Dewar is not visible	Carriage is not in correct position.	Turn the system OFF and try to restart the system. If the Dewar is still in its upper position contact IceCure™ Medical service.
Dewar is jammed and cannot be removed.	Dewar is not in place or is blocked by an unknown object.	If Dewar cannot be removed, close the door, and contact IceCure™ Medical service.
"Dewar is empty" pop-up during **Freeze** step while Dewar is NOT empty.	Machine or Cryoprobe blockage	The system will alert of "Dewar is empty" and elevator will descent. This is proper system function to release the clog. Please continue according to system automatic instructions.
System provides "Invalid serial number" message.	System identifies wrong or double use of the cryoprobe.	Verify that the number you entered matches the one on the cryoprobe and the package. If S/N is correct, re-enter it into the system. If the message reappears, change the cryoprobe and call IceCure™ Medical service.
"Connect the cryoprobe" message displayed constantly on the screen	Faulty microswitch	Ensure that the cryoprobe is fully inserted (can't screw it in any more with reasonable force). If "**Next**" button doesn't appear, change cryoprobe. If the problem persists, contact IceCure™ Medical service.

Problem	Probable Cause	Action
Cryoprobe mechanical damage	Bent or pinched cryoprobe.	1. Press the red emergency stop button 2. Wait for 60 seconds. 3. If the cryoprobe is in the patient's body, wait for passive thaw if necessary and remove the cryoprobe gently. • Make sure that the cryoprobe is removed intact. 4. Make sure that the tip is pointed in a safe direction and then securely disengage the cryoprobe. 5. The system should not be turned on until disengaging the cryoprobe from the cryohandle. The cryoprobe should be screwed out of the cryohandle. 6. Close the handle plug on the cryohandle, by screwing it in. 7. Start the system, using the on-off switch on the back side of the system. 8. If required, wait for the Dewar to be lowered down and perform a new procedure with full Dewar and a new cryoprobe while maintaining sterility.
Freeze/Extraction icon does not initiate the operation	Faulty icon or operator misuse.	Try tapping the **Freeze/Extraction** icon again. It is only activated if pressed for 1 second. Check the user manual to ensure that you can indeed use the icon in the present screen. If the problem persists contact IceCure™ Medical service.
LED does not light up	Burned out LED, or it should not be lighting up at given time.	Check user manual to verity that the LED should light up. If yes, contact IceCure™ Medical service.
Ice formation on the hose, the cryohandle and sterile sleeve	Low temperature and long freezing steps may cause moisture to form ice particles.	This is not an operational problem. Wipe OFF accumulated ice with clean sterile gauze.

Problem	Probable Cause	Action
Liquid Nitrogen leaks from cryoprobe, cryohandle or system during the cryotherapy procedure.	Cryoprobe is not well connected or pipes are faulty.	Press the **Extraction** button or emergency button and contact IceCure™ Medical service.
Cryoprobe cannot easily be removed from target tissue.	EXTRACTION (WARM) process malfunction	Do not use force in attempt to extract the cryoprobe from the tissue. Wait a few minutes and try removing it gently again. If problem persists, contact IceCure™ Medical service.
Cryoprobe is difficult to disengage from cryohandle.	Parts are frozen together	Try again after five minutes. If it still cannot be disengaged, contact IceCure™ Medical service.
Liquid Nitrogen leak when trying to remove the cryoprobe	Excess pressure on the pipes, main valve open, procedure not completed, or Dewar relief valve malfunction.	When initial leak is detected, screw the cryoprobe back in place. Make sure that the procedure has ended, wait 3 minutes and try removing the cryoprobe again. If Liquid Nitrogen is still leaking contact IceCure™ Medical service.
Computer failure due to hardware fault	Unknown	Mechanical shut down of the system using the ON/OFF switch at the back of the system or emergency stop button. Then turn on the system (after releasing the emergency stop button, if pressed) and wait for computer re-boot. If this occurs during a procedure, replace the cryoprobe when required to do so by the system, according to training materials provided by IceCure™ Medical.
Screen is stuck/ Controller stops working/ Controller is stuck	Unknown	Mechanical shut down of the system using the ON/OFF switch at the back of the system or emergency stop. Then turn ON the system (after releasing the emergency stop button, if pressed) and wait for computer re-boot. If there is a cryoprobe in the target tissue, refer to training materials provided by IceCure™ Medical for further details.

Problem	Probable Cause	Action
Interference in adjacent devices such as image artifacts on screen	Unknown	First make sure the problem is related to the system by examine the interference after turning the system off. If the interference is still observed: ▪ Re-orient or relocate the other device(s). ▪ Increase the separation between the equipment. ▪ Connect the system into an outlet on a circuit different from that to which the other device(s) are connected. If the problem persists, contact IceCure™ Medical service.
"Long wash" popup message	System pipes blockage	The user will have to wait until the wash ends. In order to have better indication in regards to the end of the long wash procedure, it's better not to click "O.K" when the message pops up, but to wait until the message disappear by itself. In case you clicked "O.K" the screen freeze till the end of the "long wash" procedure.
Prepare for Treatment button in the Main Menu screen is disabled	• Maintenance is needed • Washing is in progress	1) Contact IceCure™ Medical service representative. 2) Wait until the button becomes enabled.

10 ProSense™ cryoablation system - Step-by-Step procedure

Before starting the procedure, a functional test **must be** carried out!

System preparation and Functional test

1. On the console touch screen, tap **Prepare for Treatment**.
2. Remove the Dewar's cap and fill the Dewar with Liquid Nitrogen **in a safe manner.**
3. Place the Dewar inside the system and close the door.
4. Tap **Next**.
5. Enter the cryoprobe serial number. **Each procedure must be carried out with a new sterile cryoprobe. Press the Next button on the screen.**
6. Remove the handle's cap, and attach the cryoprobe to the handle and tap **Next**. The **Next** button will be shown only when the cryoprobe is connected properly.
7. The following message will appear **"Inspect the cryoprobe and tap the appropriate button".** When the system is ready, place the cryoprobe inside a sterile Saline or water cup.
8. Tap TEST. **Make sure that you don't see any bubbles, that the shaft is not frozen, and that a small ice-ball is created at the tip of the cryoprobe.**
9. If the test was successful, tap SUCCESS. If not, start over with a new sterile cryoprobe.

Procedure

10. Select treatment modality: Preset Cycles/ Manual Mode. You can modify the steps as needed **during procedure.**
11. Insert the cryoprobe into the tissue, and navigate with the help of Ultrasound or CT to pierce through the lesion center.
12. Once positioning of the Cryoprobe is completed, the hose can be safely mounted on the Holder arm (optional).
13. Activate treatment cycle: Tap **Freeze** on the console touch screen.
    - Monitor ice-ball under ultrasound at all times.
    - Inject saline buffer as needed to protect the skin.
    - You may manually stop the first **Freeze** step and start the **Thaw** process by tapping **Skip**.
    - You may manually stop the second **Freeze** step and start the **Extraction** process by tapping **Extraction**.
14. During the **Extraction** process, gently remove the cryoprobe. When the **Extraction** process is finished you can tap **Finish** if you have managed to remove the cryoprobe from the body. If not, continue the **Extraction** process by tapping **Extraction** and try again to gently remove the cryoprobe. In some cases, you can choose the relocate option for additional freezing steps.

- **in some cases, the following message may appear - "Please wait for passive Thaw"**
  In this case, wait for passive **Thaw** and gently extract the cryoprobe from the tissue**.**

15. Do not disengage the cryoprobe from the handle until the following message appears - **"Safe to disengage the cryoprobe from the handle"**

16. After disengaging the cryoprobe, immediately replace the handle's plug.

Warning messages - Critical information will appear as a pop-up dialog with an "OK" button for acknowledging the message.
Error messages- Information that prevents the user from continuing the operation of the system will appear as a dialog box that cannot be closed, stating the problem and possible solutions. **When such a message appears, the user should carefully follow system instructions.**

11 SYSTEM SPECIFICATIONS

Physical properties	Dimensions (excluding the screen) Weight	Height: 120 cm (47.24 inches) Depth: 70 cm (27.56 inches) Width: 50 cm (19.68 inches) 150kg
Electrical requirements		**100-127 VAC** 12 A 50/60 Hz, single phase **OR** **220-240 VAC** 7 A 50/60 Hz, single phase
Operating pressure	Pressure range	0-100 psi
Cryogen	Liquid Nitrogen	Boiling point: -196° C
Type of cryometer		thermocouple type K
Environmental conditions Temperatures:	Operating	10° C; +40° C (50° F; 104° F)
	Transportation and Storage	-20° C; +70° C (-4° F; 158° F)
Relative Humidity:	Operating	30% to 85% not condensing at room temperature
	Transportation and Storage	30% to 85% not condensing
Atmospheric pressure:	Operating	700 hPa; 1060 hPa
	Transportation and Storage	500 hPa; 1060 hPa
Temperature reading range of cryoprobe:		-196° C to +40° C
Pressure sensor		Power supply 24 V Pressure range: 0.1 - 145 psi Accuracy 1% Repeatability ≤ ± 0.1

12 ICECURE'S DISCLAIMER OF WARRANTY

ICECURE'S WARRANTY CONSTITUTES THE SOLE AND EXCLUSIVE LIABILITY FOR DEFECTIVE OR NONCONFORMING PRODUCTS, INCLUDING SOFTWARE. SUCH WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES EXPRESSED, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND IS IN LIEU OF ALL OBLIGATIONS OR LIABILITIES ON THE PART OF ICECURE FOR DAMAGES.

For complete warranty information, please see accompanying limited warranty documents provided with purchase.

13 REPORT CUSTOMER COMPLAINT

In case any deficiencies that are related to the identity, quality, durability, reliability, usability, safety (any serious incident that has occurred in relation to the device), effectiveness or performance of IceCure products, please gather as much information as possible and report to IceCure representative as soon as possible including the details listed below:

- Complainant name, position, and contact details
- Complaint date
- Site name
- System serial number
- software version
- Cryoprobe batch and/or serial number (if relevant),
- Does a sample available for inspection,
- Under what circumstances did the deficiency occur (during Installation, pretest, procedure, follow up, other)?
- Detailed description of complaint (If possible, please provide pictures for better explanation)
- What was the clinical procedure being performed (if relevant)?
- If a clinical procedure was being performed, was it completed?
- What was the initial outcome (No Harm, Injury, Death)?
- If death or injury occurred, please describe in detail.

Please contact IceCure™ Medical for a designated form to collect the above information.

You can contact IceCure™ Medical in your area using the contact information given below:

IceCure™ Medical, Inc. support@icecure-medical.com US/Canada Toll Free 1-888-902-5716	IceCure™ Medical Ltd. HaEshel 7 street, 2nd Floor, POB 3163, 3079504 Caesarea, Israel support@icecure-medical.com Tel: +972-4-623 0333 Fax: +972-4-623 0222
MedNet EC-REP GmbH – Authorized Representative of IceCure Medical Ltd. Borkstraße 10 48163 Münster Germany Tel +49 (0) 251 32266-0 Fax +49 (0) 251 32266-22	MedNet SWISS GmbH – Swiss Authorized Representative of IceCure Medical Ltd. D4 Platz 4 6039 Root D4 Switzerland

14 Manufacturer's Declaration of the EUT

14.1 Guidance and manufacturer's declaration-electromagnetic emission- for all equipment and systems

The model ProSense™ Cryotherapy product is intended for use in the electromagnetic environment specified below. The customer or the user of the model ProSense™ Cryotherapy product should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ProSense™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ProSense™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The ProSense™ is intended for use in any professional healthcare environment.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

ProSense™ is intended for use in professional healthcare facility environment (such as physician offices, clinics, limited care facilities, freestanding surgical centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, office procedure, surgery rooms except near HF SURGICAL EQUIPMENT, etc.)

14.2 Electromagnetic immunity guidance and declaration

The ProSense™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ProSense™ should assure that it is used in such an environment.

Immunity test	**IEC 60601 level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 5 %.
Electrical fast transient/burst, IEC 61000-4-4	2 kV for power supply lines	2 kV for power supply lines	Mains power quality should be that of a

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
	1 kV for SIP/SOP lines		typical commercial or hospital environment
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

14.3 Guidance and manufacturer's declaration-electromagnetic immunity for PROFESSIONAL HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz)	[V] = 3 Vrms [V] = 6 Vrms
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.7 GHz	[E] = 3 V/m
Proximity fields from RF wireless	385 MHz	27 V/m
	450 MHz	28 V/m

Immunity test	IEC 60601 level	Compliance level
communications equipment	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	

14.4 Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM- for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the model ProSense™ Cryotherapy product			
The model ProSense™ Cryotherapy product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model ProSense™ Cryotherapy product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model ProSense™ Cryotherapy product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	$d = [\frac{3,5}{V_1}]\sqrt{P}$ MHz	$d = [\frac{3,5}{E_1}]\sqrt{P}$ MHz	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Recommended separation distances between portable and mobile RF communications equipment and the model ProSense™ Cryotherapy product

The model ProSense™ Cryotherapy product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model ProSense™ Cryotherapy product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model ProSense™ Cryotherapy product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	$d = [\frac{3,5}{V_1}]\sqrt{P}$)MHz	$d = [\frac{3,5}{E_1}]\sqrt{P}$) MHz	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Warning

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ProSense, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.