USER MANUAL

3-100176, REV E

NICE1 Cold + Compression Therapy System

THIS IS NICE

Thank you for choosing the NICE1 Cold + Compression Therapy System. The NICE1 uses advanced technology to significantly improve the convenience and efficacy of cold + compression therapy.

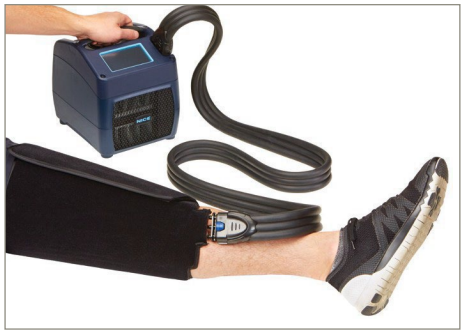
This manual has all the information you need to properly and effectively operate the NICE1.

Consult a healthcare professional before using NICE1.

QUICK START GUIDE

Consult a healthcare professional before using NICE1.

- Connect the power cord to the external power supply.
- Plug the circular connector into the back of the Cooling Unit. You will hear a click when properly connected.
- Plug the power cord into the wall outlet.



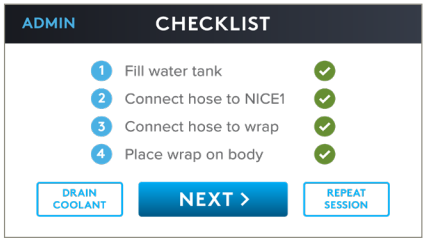
- Place the wrap on the appropriate body part. Secure with hook and loop.
- Connect the hose to the wrap. You will hear a click when properly connected.

Caution: Therapy wraps are non-sterile and should never be directly applied to an open wound or breached skin

- Connect the hose to the Cooling Unit. You will hear a click when properly connected.

It is recommended to read entire user manual before beginning. Refer to the individual wrap guides for specific information regarding wrap use.

Settings for temperature, compression, and duration should be used as directed by your physician or medical professional.



STEP 1

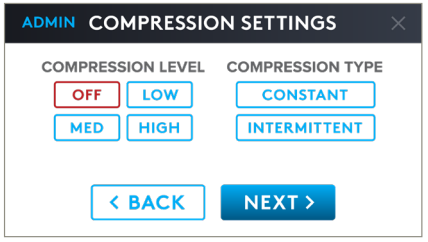
Turn on the power switch on the back of the device. The touch screen will illuminate and display the "Nice" logo. Push NEXT. Review the checklist on the touch screen. Confirm and press NEXT.

STEP 2

Select desired COLD LEVEL and press NEXT.

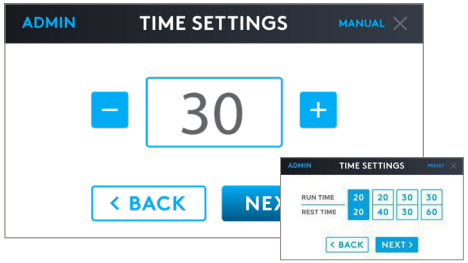
Cold Settings are as follows:

Level 1 = 58F (14.4C)
Level 2 = 54F (12.4C)
Level 3 = 50F (10C)
Level 4 = 46F (7.7C)
Level 5 = 42F (5.5C)



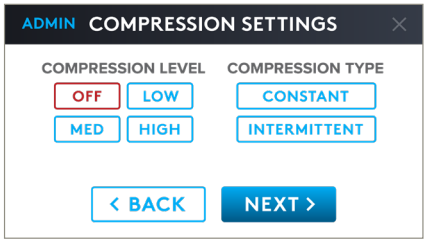
STEP 3

Select desired COMPRESSION LEVEL and COMPRESSION TYPE and press NEXT.



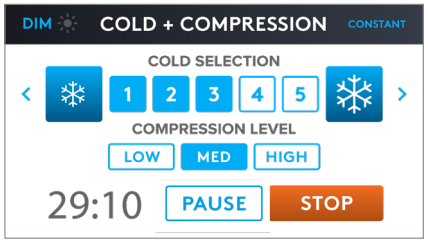
STEP 4

Choose a MANUAL time setting of 5 – 40 minutes for a single therapy session OR choose a PRESET PROGRAM for multiple sessions and press NEXT.



STEP 5

Review and confirm your settings by pressing START or press BACK to change the settings.



STEP 6

During your therapy session you can change the cold or compression settings simply by pressing 1 – 5 or HIGH, MED or LOW. To Dim, Press Dim switch, to brighten - touch screen.

3-100176, REV E

COOLING

State-of-the-art technology delivers therapeutic cooling without ice. The most convenient way to apply cold therapy.

COMPRESSION

Programmable intermittent and constant compression significantly improves the effectiveness of cold therapy and promotes healing.

RECOVERY

By combining the therapeutic benefits of cooling and compression in a single easy-to-use device, recovery times are significantly improved.

TABLE OF CONTENTS

1 INTRODUCTION

NICE1 is designed to provide cold and compression therapy as specified in this manual. If the system is used in a manner other than as specified, its operation or the safety protection may be impaired.

Please read the entire manual carefully before operating the NICE1. The patient is the intended operator. The patient can safely use and maintain the NICE1 following these instructions.

CAUTION: Federal law restricts this device for sale by or on the order of a physician.

2 NICE1 DESCRIPTION

NICE1 is a cold and compression therapy device used to aid recovery and reduce pain associated with soft tissue injuries. The device works by circulating cooled water and air through a therapy wrap that is placed on the injured body part. The cooled water circulates through the therapy wrap and provides cold therapy; the air inflates the therapy wrap causing it to compress around the injured body part. The NICE1 is a non-transit-operable medical device.

2.1 FEATURES

- Fluid therapy temperature range between 42°F - 58°F (14.4°C - 5.5°C)
- Treatment for edema in the upper and lower extremities with alternating compressions of Low (20 mmHg), Medium (35 mmHg) and High (50 mmHg)
- Programmable therapies
- Lightweight and portable package
- User-friendly interface
- Easy to use and read touch screen display

2.2 GENERAL SPECIFICATIONS

- Weight: 10 lbs. when full of water
- Hose Length: 6 ft.
- Specified Medical Grade Power Supply (supplied with the system)
- Dimensions: 8.6" W x 8.6" H x 9.0" D
- Operating Fluid: Distilled water or tap water
- Flow Rate: .5 liters per minute
- Water Pressure: <30 PSI
- Water Reservoir Capacity: 300 mL
- Safety: IEC 60601-1: Ed 3.1 and IEC 60601-1-2 Ed 4.1
- Air Pump Pressure: 0-50 mmHg
- Intermittent Compression Setting:
  - o High: inflate to 50 mmHg for 2 minutes and then deflate to 5 mmHg for 30 seconds.
  - o Medium: inflate to 35 mmHg for 2 minutes and then deflate to 5 mmHg for 30 seconds.
  - o Low: the NICE1 inflate to 20 mmHg for 2 minutes and then deflate to 5 mmHg for 30 seconds.
- Cooling Temperature Range:
  Level 1 = 58F (14.4C) Level 4 = 46F (7.7C)
  Level 2 = 54F (12.4C) Level 5 = 42F (5.5C)
  Level 3 = 50F (10C)
- User Operating Temperature: +5°C to 40°C
- Relative Humidity: 15% to 90%, non-condensing
- Storage/Transportation Temperature Range: -25°C to +5°C, and +5°C to 35°C at RH up to 90% non-condensing, and >+35°C to 70°C at water vapor pressure 50hPa
- Atmospheric pressure range: 700 to 1060hPa (13801ft)
- Maximum Sound Pressure Level: 75dBA (with air pump running)
- Maximum Altitude: 4000m (13,123 ft)
- Display accuracy: +/- 2%
- Expected Service Life of the NICE1 Unit: 3 years
- Expected Service Life of the NICE1 accompanying Accessories: 3 years.
- Expected life of Disposable Wraps 1 User, 3 Months
- Expected Service Life of the NICE1 Training Room Wraps: 1-year operational use.

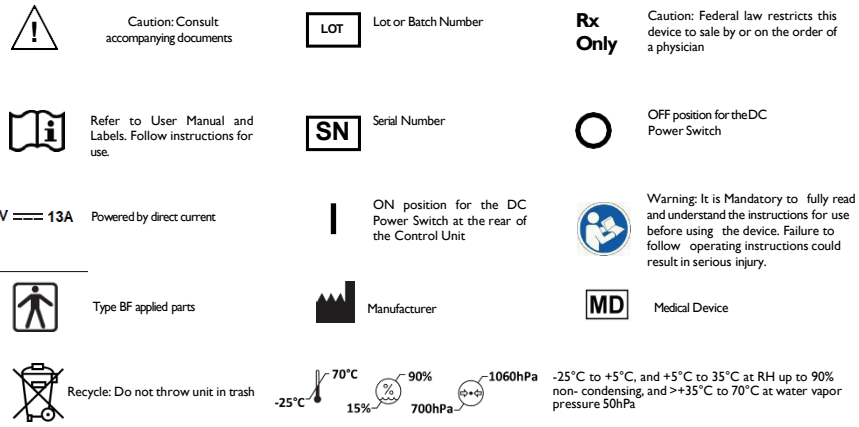
2.3 MEDICAL SYSTEM SPECIFICATIONS

- Specified Medical Grade Power Supply. The following Power Supply is specified for use with the NICE1 unit:
  - o Class II Power Supply: DC output rated 15Vdc 12A
    NOTE: A detachable type power supply cord (rated 125V 10A) is provided with each power supply, suitable for use in the USA and Canada.
- NICE1 Cooling Unit: Electrical Input Rating of 15Vdc 12A
- Patient Therapy Wrap (patient applied part): Classification of Patient Applied Part, Type BF
- Insulated Air/Water Hose Assembly for connection between Control Unit and Patient Therapy Wrap

2.4 OPTIONS

- Non-Sterile Patient Therapy Wraps (knee wrap, etc.)
- Carrying Case

2.5 SYMBOLS



3 INDICATIONS FOR USE

NICE1 combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of a healthcare professional in hospitals, outpatient clinics, athletic training settings, or home settings.

4 CONTRAINDICATIONS, CAUTIONS, AND WARNINGS

PRECAUTIONS

- Basic safety precautions should always be followed when using NICE1 to reduce the risk of fire, electric shock, and personal injury.
- Please read the entire User Manual carefully before operating the unit.

MEDICAL

CONTRADICTIONS FOR COLD THERAPY

- NICE1 or any cold therapy device should not be used by patients that:
  - have significant vascular impairment in the affected region (e.g., from prior frostbite, diabetes, arteriosclerosis, or ischemia).
  - have acute paroxysmal cold hemoglobinuria or cryoglobulinemia.
  - have Raynaud's disease or cold hypersensitivity (cold urticarial).

WARNINGS

- Do not use over sensitive skin areas or in the presence of poor circulation.
- Therapy wraps are non-sterile and should never be directly applied to an open wound or breached skin.
- Dressings used under the therapy wrap should be applied lightly. Do not use pins to secure the therapy wraps or hoses.
- Do not apply the therapy wrap so tightly as to restrict blood or fluid flow.
- Follow the prescribed instructions of your physician for area, frequency, and duration of treatment.
- If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of NICE1 and consult a healthcare professional.
- Immediately stop compression therapy if you experience any sense of discomfort, numbness or tingling of the limb.

POTENTIAL HARM FROM MISUSE

WARNINGS

- Use of this device may also cause frostbite or tissue damage if used incorrectly.
- Use carefully. May cause serious burns.
- The unattended use of NICE1 by children or incapacitated persons may be dangerous.
- Do not drink or ingest the coolant or water that has been circulating in the system.
- Observe all warning and caution labels. Never remove the caution/warning labels.

POWER SUPPLY AND ACCESSORIES

CAUTION

- Only use the supplied power supply and power cord.
- Do not operate the unit with a damaged or frayed power cord.
- A multiple socket outlet (power strip) or extension cord will not be used to power the NICE1 unit.

WARNINGS

- Connect only items that have been specified as part of the ME equipment for NICE1 including the specified external Medical Grade AC/DC power supply.
- Use only NICE1 approved therapy wraps.

ENVIRONMENT AND OPERATING CONDITIONS CAUTION

- Do not operate the unit if it has any noticeable or physical damage or is leaking fluid.
- Do not smoke while using therapy wraps or use wraps by an open flame.
- Do not use near equipment that generates electromagnetic or other interference, as this may be harmful to the therapy unit.
- The therapy unit is not intended to be used in a wet environment.
- The NICE1 has an IPx1 rating and can tolerate light rain during movement or storage. If the unit gets wet, unplug the unit from the wall and allow the unit to dry before use.
- The NICE1 has an IP2x rating and can tolerate and prevent foreign object intrusion such as a finger. Do not stick foreign objects into the reservoir, fan protective covers, or power connectors
- Never push objects of any kind into the therapy unit through the frame.

WARNINGS

- Do not simultaneously touch parts of other electrical equipment when using the NICE1 unit.
- Slots and openings in the cabinet are provided for ventilation to protect the unit from overheating. These openings must not be blocked or covered at any time except by the supplied air filter.
- Do not allow the therapy wrap or hoses to contact sharp objects that could puncture it.
- Monitor all hose and cord placement when in use to avoid tripping and strangulation hazards for children and pets. Store hoses and cords when not in use to avoid hazardous situations.
- Keep the system, including hoses and cords, away from children and pets. No parts of the system are to be used as toys.
- Keep the system away from pest. If your home has problems with insects, please keep the unit away from problem areas and off the floor.
- All compression therapies must be turned OFF when the unit is not in use, the wrap is removed from the patient for prolonged periods, or for repositioning of the wrap.

POTENTIAL DAMAGE TO UNIT FROM MISUSE CAUTION

- Do not overfill the water reservoir.
- Never spill liquid of any kind on the therapy unit.
- Do not drop the therapy unit or cause impact to the unit.
- Do not pull or otherwise put undue stress on the hoses.
- Do not spray the unit with any water solvents or cleaners.
- Do not service or perform maintenance while the equipment is in use.

WARNINGS

- Do not attempt to sterilize this device by any means.
- No modification of this equipment is allowed.

WRAPS WARNINGS

- The NICE1 contains multiple sensors that monitor device performance and issues error messages. If the wrap does not become cold, makes unusual noises, or becomes unresponsive, please turn the device off and contact your NICE representative.
- Disposable therapy wraps are designed for single patient use only and may only be used on the same patient for the length of the treatment.
- The therapy wrap should be periodically cleaned if it is used on the same patient for an extended period.

DISPOSAL

CAUTION

- The NICE1 and accompanying Power Supply must not be disposed of with your household waste. To learn where to drop off your electrical and electronic waste, please contact your local city/municipal waste disposal service office or contact Nice Recovery Systems for assistance.

5 UNPACKING NICE1

The following instructions apply to all users and settings as described in section 2 Indications for Use: healthcare professional in hospitals, outpatient clinics, athletic training settings, or home settings.

When you first unpack the NICE1 carrying case you should have the following items:

1. NICE1 Cooling Unit
2. Power Supply
3. Power Cord
4. Hose
5. Drain
6. Wrap (optional)

All these items are needed for safe system operation. If any of these items are missing, please contact the clinic or hospital that prescribed the unit, or your Durable Medical Equipment (DME) supplier or provider or Nice Recovery Systems.

Immediately upon unpacking your NICE1, inspect your unit. If the unit shows shipping damage, contact your Durable Medical Equipment (DME) provider. Be sure to retain all packing material and the original box or case.

Along with NICE1 you should have received a non-sterile disposable therapy wrap(s) necessary for your prescribed treatment in an individually sealed, unopened bag.

Therapy wraps should never be directly applied to an open wound or breached skin.

6 ENVIRONMENTAL CONDITIONS

NICE1 is intended for indoor use only. Do not operate NICE1 in or near a wet environment.

NICE1 is not to be used in a confined space. Adequate airflow is necessary for the proper functioning of the device. It is recommended that the device have at least 12 inches of clearance in the front and back for adequate airflow. Inadequate airflow can result in overheating of internal electrical components and undesirable or excessive noise.

Although the NICE1 unit can be used between +5°C to 40°C ambient and RH 90% non-condensing, for optimal performance use the system between +15.5°C to 27.7°C (60°F to 80°F) at 15% to 90% relative humidity.

Failure to meet these operating environment conditions may result in:

- Condensate buildup inside the unit.
- Overheating or freezing of the unit.
- Internal electronics malfunction.
- A reduction in the heating or cooling capabilities of the unit.
- The inability of the unit to properly regulate and administer fluid temperature during heat or cold therapies.
- The inability of the unit to properly regulate and administer pneumatic compression as specified in the indications for use.

Which may void the warranty.

7 HOW TO SET UP YOUR NICE1 FOR THERAPY

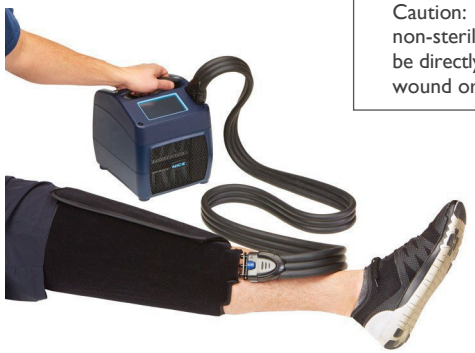
- Remove the NICE1 Cooling Unit, external power supply, power cord, and hose from the box or carry case. The wrap is separate and may not be packaged with the unit. Verify that all the necessary equipment is present and not damaged.
- Find a stable location for the Cooling Unit and ensure that nothing is blocking the airflow in the front and back of the device.
- Open the water reservoir and fill with water. Replace reservoir cap after filled.

- Connect the power cord to the external power supply.
- Plug the circular connector into the back of the Cooling Unit. You will hear a click when properly connected.

- Plug the power cord into the wall outlet.
- Connect the hose to the Cooling Unit. You will hear a click when properly connected.

- Place the wrap on the appropriate body part. Secure with hook and loop.
- Connect the hose to the wrap. You will hear a click when properly connected.
- See wrap specific instructions for use for additional information.

Caution: Therapy wraps are non-sterile and should never be directly applied to an open wound or breached skin



8 OPERATING INSTRUCTIONS

NOTE: Do not use this device without your physician's specific recommendations for the frequency, temperature, and duration of your treatments.

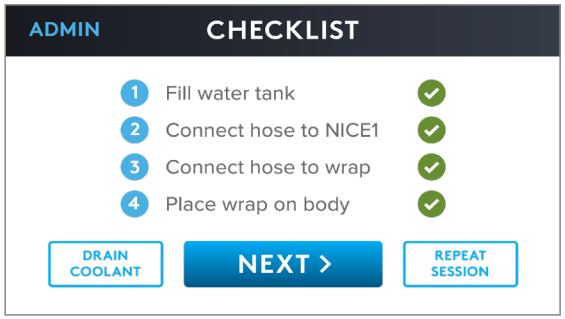
The patient MUST be familiar with all warnings and cautions listed in Section 4 before attempting to operate the unit.

NICE1 can perform therapies for the following:

- Cold Therapy
- Cold Therapy + Compression

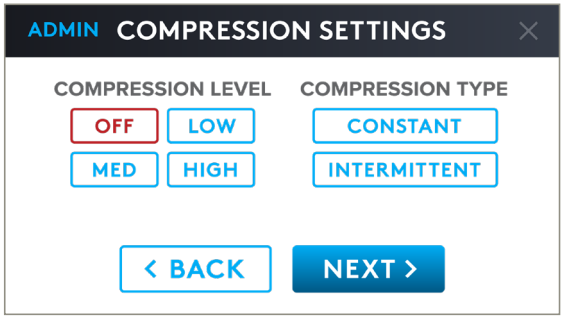
8.1. TURNING THE UNIT ON FOR THE FIRST TIME

STEP 1 Turn on the power switch on the back of the device. The touch screen will illuminate and display the "Nice"

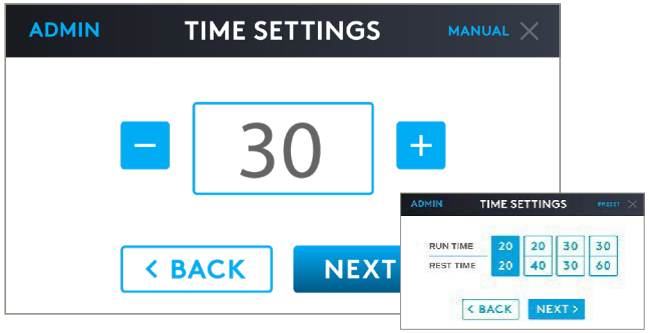


STEP 2 Review the checklist on the touch screen. Confirm and press "NEXT".

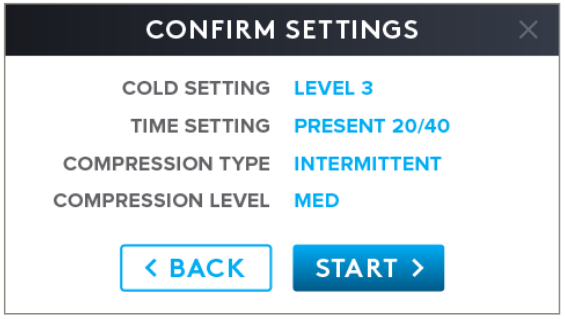
STEP 3 Select desired COLD LEVEL and press NEXT. (Level 5 is the coldest setting)



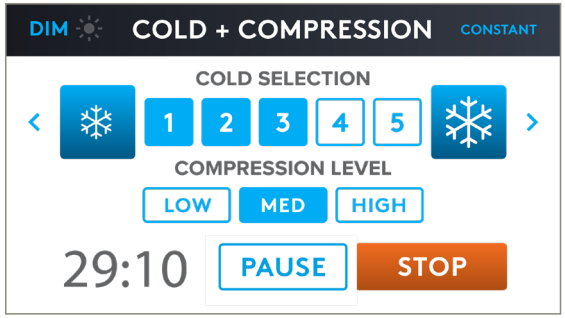
STEP 4 Select desired COMPRESSION LEVEL and COMPRESSION TYPE and press NEXT.



STEP 5 Choose a MANUAL time setting of 5 – 40 minutes for a single therapy session OR choose a PRESET PROGRAM for multiple sessions and press NEXT.



STEP 6 Review and confirm your settings by pressing START or press BACK to change the settings.



STEP 7 During your therapy session you can change the cold or compression settings simply by pressing 1 – 5 or HIGH, MED or LOW.

STEP 8 When the therapy session is complete turn the unit OFF. Once the unit is OFF, you may now remove your therapy wrap.

NOTE: Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way can cause damage to the wrap and will reduce the life of the wrap and may void the warranty.

9 MAINTENANCE AND CLEANING

9.1. COOLING UNIT

- There are no user serviceable internal parts. The system warranty is voided if the tamper resistant screws are breached or removed.
- Keep water away from vents, power supply, and the power cord connection of the unit.
- To avoid possible electric shock, do not remove the cover of the unit.
- Do not immerse the Cooling Unit in water or any liquid.
- If the water becomes discolored or offensive to smell, contact supplier or Durable Medical Equipment (DME) provider for assistance. If microbial growth is present, the unit should not be used.
- Wipe the exterior of the unit with a damp cloth to clean.
- Do not use abrasive or solvent-based cleaners on the unit.

9.2. WRAPS

- Clean the therapy wrap if used for longer than 2 weeks or when noticeably dirty.
- Clean exposed surfaces of the therapy wrap with either a mild anti-bacterial soap and water solution or an isopropyl alcohol and water solution (90:10).
- Do not use abrasive or solvent-based cleaners on the wrap.
- Do not use bleach on the wrap.
- See wrap specific instructions for use for additional information.

10 DRAINING WATER FROM THE UNIT

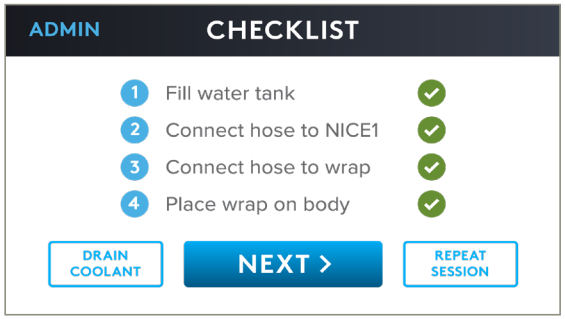
Between uses or if the Cooling Unit is going to be stored for a long period of time, the water reservoir should be drained.

1. Turn the Cooling Unit OFF.
2. Disconnect the therapy wrap from the hose.
3. Connect the Drain Fitting to the end of the hose.

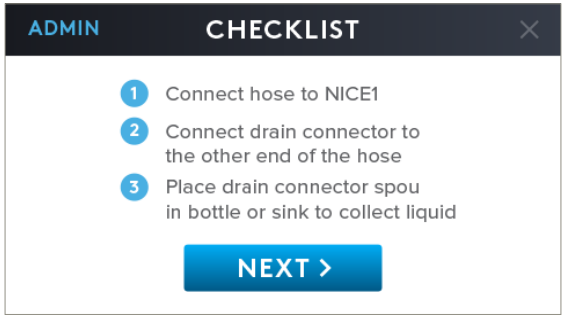
Note: Drain completely before traveling on an airplane or shipping.

4. Place the tapered end of the drain fitting in bottle or another receptacle, capable of holding a minimum of 350mL.

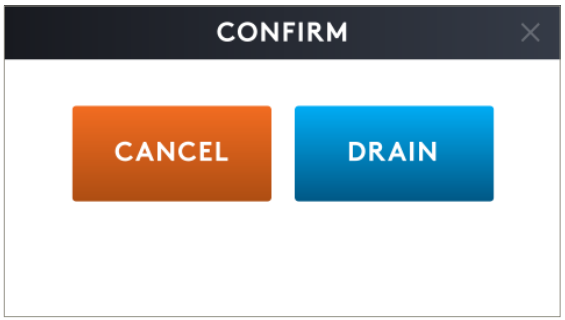
5. Turn the Cooling Unit ON.
6. Press the DRAIN COOLANT button.



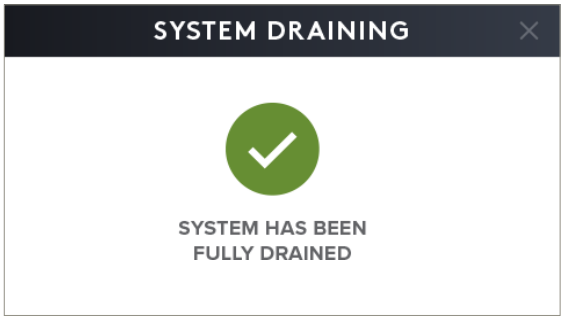
7. Review the checklist and press NEXT.



8. Press the DRAIN button to continue with draining the unit or press CANCEL to go back to the beginning.



9. The Cooling Unit will display confirmation that the unit has been fully drained.



11 STORAGE AND RE-PACKING THE UNIT

When therapy is complete, and it is time to return or store NICE1.

- Turn the unit OFF and unplug from the electrical source.
- Remove all therapy wraps.
- Disconnect all fittings from the rear and front panel of the unit.
- Follow the "Draining Fluid from the Cooling Unit" instructions in Section 10.
- Leave reservoir cap off to allow the unit to dry completely. replace cap upon completion.
- Collect the following items together:
  - Cooling Unit
  - Power Supply
  - Power Cord
  - Hose
  - Wrap
  - Padded Carrying Case
  - Optional Shipping Box
- Store the above items in the original box or in the travel case you received.
- Store indoors in an ambient environment of the following ranges: -25°C to +5°C, and +5°C to 35°C at RH up to 90% non-condensing, and >+35°C to 70°C at water vapor pressure 50hPa.

Failure to properly store the unit and wraps may result in damage to the unit, hoses and/or wraps.

12 TROUBLESHOOTING GUIDE

NICE1 has many internal software safeguards to help protect the users and the unit from unsafe operation. In this section you will find a list of system warnings and errors that may occur if a potentially unsafe situation arises while using NICE1. Neither the unit nor the wraps are intended for field repair. Do not attempt to service the unit in any way. Troubleshooting steps are included.

Errors indicate the system has detected an issue and has stopped to protect the user. The error state must be corrected before any therapy can be restarted. An audible notification is also initiated as a beeping noise.

System errors indicate that an error has been detected and all current therapies are halted to protect the user. System errors typically require service to the Cooling Unit to correct the problem. If you encounter a system error, notate code indicated on the display and contact the supplier or Durable Medical Equipment (DME) provider. If assistance is not available, please contact NICE Recovery technical assistance.

Below is a list of common user-related warnings and errors that may occur during therapy operation of the unit.

TYPE OF ERROR AND SCREEN MESSAGE	ADDITIONAL SUGGESTED ACTION OF USER
Error 101: Low Voltage Turn off unit and disconnect power. Ensure the unit is not limited by surge protector or long extension cord. If error persists contact service provider.	Re-seat all electrical plugs leading to unit before restarting it. Ensure firm positive contact. If the error persists, contact service provider.
Error 103: Air Pump Error Restart unit. If error persists contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 104: Low Air Pressure Error Disconnect hose from unit and wrap and reapply. Ensure wrap has a snug fit before session start. If error persists contact service provider.	Turn off device. Remove wrap. Disconnect hose from device and wrap. Push excess air from the wrap. Reconnect hose to device and wrap and make sure you hear audible click to indicate proper connection. Reapply wrap, ensure a snug fit and restart therapy session. If the error persists, contact service provider.
Error 105: Low Liquid Flow Disconnect hose from unit and wrap. Check for kinks and reapply wrap with a snug fit. Restart session. If error persists contact service provider.	Turn off device. Remove wrap. Disconnect hose from device and wrap. Reconnect hose to device and wrap and make sure you hear audible click to indicate proper connection. Reapply wrap and ensure a snug fit. Check wrap and hose for kinks. Restart therapy session. If the error persists, contact service provider.
Error 106: Low Liquid Level Check water level in tank. Ensure the tank is halfway full. Do not fill to threads. If error persists contact service provider.	If the wrap and hose are applied do not fill tank completely again. This will prevent water in the wrap from overfilling the tank when the session is complete. If the error persists, contact service provider.
Error 107: Water Pump Error Restart unit. If error persists contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 108: Fan Obstruction Error Check fan for obstructions. Restart unit. If error persists contact service provider.	Ensure that the front and back of the unit has at least 12 inches of clearance for proper air flow and that no small, thin objects that can fit through the grills are near.
Error 109: Fan Error Restart unit. If error persists contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 111: Cooling System Error Restart unit. If error persist contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 112: High Temperature Error Unit environment is too hot to provide therapy. Bring to room temp, wait 5 minutes, and restart. If error persists contact service provider.	Also ensure that the front and back of the unit has at least 12 inches of clearance for proper air flow and that no small, thin objects that can fit through the grills are near.
Error 113: Low Temperature Error Unit environment is too cold to provide therapy. Bring to room temp, wait 5 minutes, and restart. If error persists contact service provider.	No additional action needed. If the error persists, contact service provider.

TYPE OF ERROR AND SCREEN MESSAGE	ADDITIONAL SUGGESTED ACTION OF USER
Error 114: Temperature Sensor Error Restart unit. If error persists contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 115: High Air Pressure Error Disconnect hose from unit and wrap and reapply. Ensure wrap has a snug fit before session start. If error persists contact service provider.	Movement of the limb in the wrap should be slow and persistent if necessary. Fast compression and release of the of the wrap repeatedly can cause this error.
Error 201: Low Voltage Turn off unit and disconnect power. Ensure the unit is not limited by surge protector or long extension cord. If error persists contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 203-216: System-Off Current Error Restart unit. If error persists contact service provider.	Restart unit. If the error persists, unplug the unit and contact service provider.
Error 212: High Temperature Error Unit environment is too hot to provide therapy. Bring to room temp, wait 5 minutes, and restart. If error persists, unplug and contact service provider.	Repeat at least twice to allow unit to cool. Ensure that the front and back of the unit has at least 12 inches of clearance for prop- per air flow. If the error persists, contact service provider.
Error 217: Cooling Sensor Startup Error Contact service provider.	No additional action needed. If the error persists, contact service provider.
Error 218: Low Temperature Error Unit environment is too cold to provide therapy. Bring to room temp, wait 5 minutes, and restart. If error persists contact service provider.	Repeat at least twice to allow unit to cool. If the error persists, contact service provider.

13 SERVICE AND CUSTOMER SUPPORT

Nice Recovery Systems, LLC is committed to servicing our NICE1 both during and after sale to the customer. If you have any questions concerning the operation of your Nice Recovery Systems, please contact us at:

Nice Recovery Systems LLC
2205 Central Ave, Suite A Boulder,
CO 80301

Info@NiceRecovery.com
888.815.9907

14 SERIOUS INJURY REPORTING

If a serious incident has occurred, please report to Nice Recovery Systems, LLC using the contact information noted in Technical Support section of this User Manual. If in the European Union, please also report to your Competent Authority where the serious incident has occurred.

15 WARRANTY AND DISCLAIMER INFORMATION

Limited Warranty Terms: Nice Recovery Systems LLC ("Nice Recovery") warrants to the immediate purchaser from Nice Recovery or an immediate purchaser of an unused unit from an authorized distributor of Nice Recovery products, that any Nice Recovery Systems will be free from defects in workmanship and material under normal use for one year (1) after the date of purchase. Nice Recovery warrants to the immediate purchaser from Nice Recovery, or an immediate purchaser of an unused wrap from an authorized distributor of Nice Recovery products, that Nice Recovery single patient use wraps will be free from defects in workmanship and material under normal use for only the first use of the wrap.

This Limited Warranty covers only defects in material or workmanship. Therefore, it does not cover any other claim, service, defect, condition, or damage, including: installation, set-up, instructions, recommendations on use; accidents, tampering, improper product selection, misuse, neglect, or abnormal use; use of parts, accessories or fluids that are incompatible or adversely affect operation, performance, or durability; unauthorized service, repair or alteration; excessive moisture or humidity; cleaning or any condition caused by any dirt or foreign substance on or in the product; or damages resulting from shipping. Installation or use of the product or any portion thereof in a manner that does not comply with the Operating Instructions voids the warranty. Any alteration or modification that changes the product's effectiveness or intended use voids the warranty.

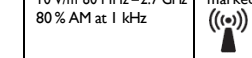
Nice Recovery will, at its discretion, repair or replace within a reasonable time any product that is found to have a defect in material or workmanship under normal use during the applicable warranty period. This is the immediate purchaser's sole remedy. Any warranty on a repair or replacement expires the same time as the warranty expires or would have expired on the original product. The product must be returned at the immediate purchaser's expense to an authorized Nice Recovery Service Center for warranty service.

Because Nice Recovery Systems updates and advances its products and technology, Nice Recovery Systems reserves the right to modify or improve the design of any product without assuming any obligation to modify any product previously manufactured.

16 ELECTROMAGNETIC COMPATIBILITY

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY AND EMISSIONS

The NICE1 is intended for use in the electromagnetic environment specified below. The customer or the user of the NICE1 should assure that it is used in such an environment.

EMC TEST	IEC 60601-1-2 LEVEL	TESTED COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	CISPR 11:2009+A1:2010 Class B, Group 1; IEC 60601-1-2:Ed.4.1 (4th Edition)	CISPR 11:2009+A1:2010 Class B, Group 1; IEC 60601-1-2:Ed. 4.1 b:2014 (4th Edition)	The NICE1 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.
AC Power Line Conduct- ed Emissions, 150 kHz – 30 MHz	CISPR 11:2009+A1:2010 Class B, Group 1	CISPR 11:2009+A1:2010 Class B, Group 1	The NICE1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public mains that supplies buildings used for domestic purposes.
AC Harmonic current emissions	IEC 61000-3-2:2005 +A1:2008+A2:2009	IEC 61000-3-2:2005 +A1:2008+A2:2009	The NICE1 power supply electrical harmonics are very low and is suitable for use in all establishments, including domestic establishments and those directly connected to the public mains that supplies buildings used for domestic purposes.
Voltage changes, fluctuations, and flicker	IEC 61000-3-3:2013	IEC 61000-3-3:2013	Mains power quality can be that of a typical hospital, commercial, or home environment.
ElectrostaticDischarge immunity	IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	While this testing level is high it is not the maxi- mum observed in some areas with very low humidity. If used in a known very dry location the user should try to discharge/ground themselves before using the unit.
Radiated RF Immunity	IEC 61000-4-3:2006 +A1:2007+A2:2010 10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	IEC 61000-4-3:2006 +A1:2007+A2:2010 10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	While tested to a high level, interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical Fast Transients /Bursts Applied to AC input no I/O 3 M or longer	IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition frequency	IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition frequency	Mains power quality can be that of a typical hospital, commercial, or home environment.
Surge immunity test Applied to AC input	IEC 61000-4-5:2005 Line to Line: ± 0,5 kV, ± 1 kV Line to Gnd: ± 0,5 kV, ± 1 kV, ± 2 kV	IEC 61000-4-5:2005 Line to Line: ± 0,5 kV, ± 1 kV Line to Gnd: ± 0,5 kV, ± 1 kV, ± 2 kV	Mains power quality can be that of a typical hospital, commercial, or home environment.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY AND EMISSIONS

The NICE1 is intended for use in the electromagnetic environment specified below. The customer or the user of the NICE1 should assure that it is used in such an environment.

EMC TEST	IEC 60601-1-2 LEVEL	TESTED COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Immunity to conducted Disturbances induced by RF fields Applied to AC input, No I/O 3 M or longer	IEC 61000-4-6:2013 3 V - 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz modulation	IEC 61000-4-6:2013 3 V - 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz modulation	Portable and mobile RF communications equipment should be used no closer to any part of the NICE1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Power Frequency H-Field Immunity Applied around full system	IEC 61000-4-8:2009 30 A/m – 50 or 60 Hz	IEC 61000-4-8:2009 30 A/m – 50 or 60 Hz	NICE1 Does not contain magnetically sensitive components.
Voltage Dips and Interruptions	IEC 61000-4-11:2004 Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruptions: 0 % UT; 250/300 cycle h)	IEC 61000-4-11:2004 Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruptions: 0 % UT; 250/300 cycle h)	Mains power quality can be that of a typical hospital, commercial, or home environment.

NOTE 1 At 80 MHz and 800 MHz, 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.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 006 is used exceeds the applicable RF compliance level above, the Model 006 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 006.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE NICE1

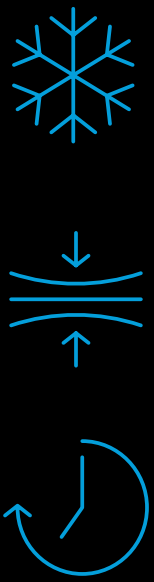
The NICE1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NICE1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NICE1 as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER M		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
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

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.



NICERECOVERY.COM

NICE1 IS MANUFACTURED BY:

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info@nicerecovery.com 888.815.9907

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