NeuWave™

NEUWAVE™ Microwave Ablation System*
User Reference Manual
Software Version 3.2.X

**Formerly known as Certus 140*

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ETHICON™

Johnson&Johnson SURGICAL TECHNOLOGIES

User Responsibility

This Product will perform in conformity with the description thereof contained in this User's Reference manual and accompanying labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. Should repair or replacement become necessary, NeuWave Medical recommends that a written request or request by phone for service advice be made to the nearest Ethicon™ Customer Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by NeuWave Medical and by NeuWave Medical trained personnel. The Product must not be altered without the prior written approval of NeuWave Medical. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than NeuWave Medical.

NeuWave Ablation Probes are provided sterile. Follow facility procedures for sterile device handling.

Not all products are available in all markets.

CAUTION Federal law restricts this device to sale by or on the order of a physician. Outside the U.S.A., check local laws for any restrictions that may apply.

NeuWave products have unit serial numbers with coded logic which indicates a product group code, the year of manufacture, and a sequential unit number for identification.

Serial Numbers are formatted in the following manner:

SN: MMYYZDDXXXXX

Where: MM is a two-digit code identifying the manufacturer and YY is the last two digits of the year of manufacture. Z is a one character code identifying the unit as new (N) or remanufactured (R). DD indicates the product indicator and XXXXX is the sequential unit number.

pat. www.ethicon.com/patentmarking

Company Contact Information

Contact the Ethicon Customer Service Department or your local representative for any customer or technical support.

USA/Canada: +1-877-ETHICON (384-4266)
USA/Canada: +1-513-337-8901 (English)

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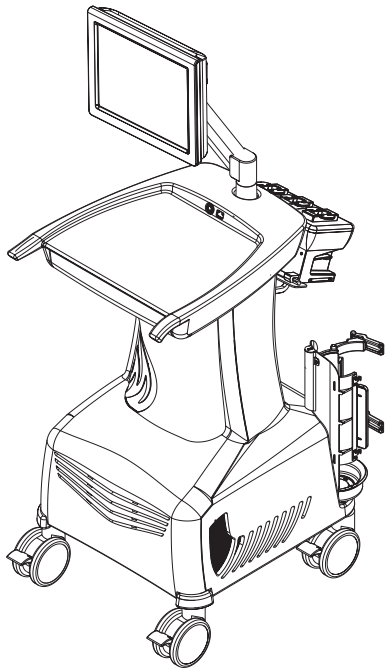
Table of Contents

1

1 Introduction

Intended Use, Device Description and Performance Characteristics



The NEUWAVE Microwave Ablation System is intended to be used for the ablation (coagulation) of soft tissue.

Microwave energy refers to a specific subset of the radio frequency (RF) spectrum operating between 300 MHz to 300 GHz. The NEUWAVE™ Microwave Ablation System (NEUWAVE System) is a fully featured soft tissue ablation system that uses small diameter ablation/surgical accessories, a single microwave source with three (3) 140 W microwave power amplifiers operating at 2.45 GHz, a CO_2 based cooling system and Power Distribution Module or PDM. Microwave energy is applied to the target tissue, heating the tissue to the point of necrosis.

One, easy to use, touch-screen user interface controls the system. The User Interface can be set for either Ablation Mode or Surgical Mode. An optional footswitch can be connected to the system to control power delivery in Surgical Mode.

Microwave energy is delivered through three distinct channels. A single system is capable of powering up to three energy delivery accessories at one time. The cooling system helps limit the temperature of the handle and cable.

The PDM is designed to minimize user set-up time, improve operator and patient safety, and improve power delivery efficiency. The PDM interface utilizes connections that allow the user to connect the power, electrical signals, and cooling lines of the NEUWAVE System energy delivery accessories in one simple step. In percutaneous applications, the PDM can mount directly to the CT table and therefore can move with the CT table during imaging. This allows the probe and probe cables to move with the patient, greatly reducing the potential for patient injury due to accidental probe or probe cable movement. In open surgical applications, the PDM can mount directly to the NEUWAVE System or to the surgical table. The PDM also uses a larger, more efficient cable from the PDM to the power amplifier. This increased efficiency of the larger cable enables more energy to be sent to the energy delivery accessory.

A variety of energy delivery accessories are available for use with the NEUWAVE System. All are comprised of a sharp trocar on the end of a cannula, a handle, a cable and a connector assembly.

Ablation probes include Models NEUWAVE LN, NEUWAVE LK, NEUWAVE SR and NEUWAVE PR.

Models NEUWAVE LK and NEUWAVE PR are available in 15 gauge and 17 gauge cannulas and in 15 cm and 20 cm lengths. These probes have a cable length of 1.4 m.

Model NEUWAVE LN has a 17 gauge cannula and is available in 15 cm and 20 cm lengths. These probes have a cable length of 1.4 m.

Model NEUWAVE SR has a 13 gauge cannula and is available in a 25 cm length only. These probes have a cable length of 1.4 m.

Model NEUWAVE PRS15 (Surgical PR Probe) is available in a 15 gauge cannula and in 15 cm length only. This Probe has a cable length of 2.9 m.

Model NEUWAVE PRS35 (Surgical PR Probe) is available in a 11 gauge cannula that tapers down to a 13 gauge tip and in a 35 cm laparoscopic shaft length only. This Probe has a cable length of 2.9 m.

Each energy delivery accessory contains temperature measurement sensors that help monitor performance and ensure patient and operator safety.

Additionally, the different percutaneous ablation probes have been designed to optimize the energy transfer efficiency from the probe into different types of tissue based on known electrical properties of each tissue.

The NEUWAVE System also uses the CO_2 cooling system to control the cable and handle temperatures and also to enable Tissu-Loc™. The Tissu-Loc feature is available on all NeuWave Ablation Probes. The Tissu-Loc feature produces a “stick” function that lowers the temperature near the tip of the probe to temporarily adhere the probe to tissue. This feature helps prevent the probe from moving once it has been placed in the desired location.

The NEUWAVE System can be used in either Ablation Mode or Surgical Mode. These two modes deliver power the same way, but the user interface and workflow in the two modes are different and optimized for different applications.

- Ablation Mode is used for Target Ablation. Target ablation involves placing a probe into a substantial target and then ablating for up to several minutes until the target tissue is necrotic. This is done either percutaneously, via a laparoscopic port or in open surgical settings.
- Surgical Mode is used for Surgical Coagulation. Surgical Coagulation involves using an energy delivery accessory to ablate/coagulate for shorter periods of time, while moving the energy delivery accessory frequently. This is often done using the technique called “Planar Coagulation” to create a plane of coagulated tissue in an organ prior to resection. Surgical Mode can incorporate the use of a footswitch, which connects to the USB port next to the System ON/OFF switch.

The NEUWAVE System has several safety features which monitor system performance. The NEUWAVE System will automatically stop delivering energy to the patient in response to system performance issues.

The system is designed for facility use and should only be used under orders of a physician.

Indications For Use:

The NEUWAVE Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors.

The NEUWAVE Microwave Ablation System is not indicated for use in cardiac procedures.

Patient Target Groups:

The NEUWAVE Microwave Ablation System (NEUWAVE System) is intended to be used on the general population, undergoing ablation of soft tissue in percutaneous, open surgical or in conjunction with laparoscopic surgical settings.

The system should not be used on:

- pregnant patients, and,
- patients with implantable pacemakers or other electronic implants.

Intended Users:

The NEUWAVE System should only be used by licensed physicians.

Expected Clinical Benefit:

The expected clinical benefits of the NEUWAVE System is the minimally invasive coagulation of soft tissue.

Undesirable Side Effects and Residual Risks:

Undesirable side effects and risks associated with microwave ablation devices may include bleeding, pain, soft tissue injury, unintended thermal damage to adjacent structures/organs, infection, and post ablation syndrome. Serious complications, including organ injury, dysfunction or failure; cardiac arrhythmia; vessel or nerve injury; pleural effusion, pneuomothorax/hemothorax, gas embolism, thromboembolism, and fistula, are uncommon, but possible. There is also potential for failure to achieve desirable ablation therapy, which may require additional surgery or lead to inadvertent tumor seeding, foreign body retention, magnetic resonance incompatibility, or electric shock. Additionally, there may be unknown side effects associated with use of the device. All of these undesirable side effects and risks have been classified as remote.

Risk Grading	*Grading Range*
Remote	≤ 23 in 100,000

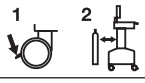
Using this Manual

This manual uses text formatting to identify different aspects of the product and its use.

Warnings and Cautions tell about the dangerous conditions that can occur if the instructions in the manual are not followed. Read and follow all warnings and cautions.

WARNING	Warnings tell about a condition that can cause injury to the operator or the patient. In the manual, the word **WARNING** is in all caps and bold text with additional text indented. If more than one warning is listed in a row, the word **WARNINGS** is only printed once.
CAUTION	Cautions tell about a condition that can cause damage to the equipment. In the manual, the word *CAUTION* is presented in italics and in all caps. If more than one caution is listed in a row, the word *CAUTIONS* is only printed once.
Important	Important statements provide tips on device operation or settings. In the manual, the word *Important* is presented in italic text.
Device command	Device commands are written in bold typeface, for example **Ablate**.
Menu tab	Menu tabs on the system display are presented in bold, italic text. For example, ***Ablation***.
‘Message’	Messages that appear on the system display are presented in single quotation marks, for example, ‘Check Probe 1 connection at the PDM’.
Section and Heading	When referring to different sections or headings in this manual, the text is presented in the color green, for example, System Controls and Menus.

System and Accessories Symbols Used in Manual, Equipment and Packaging

Symbol	Symbol Description
	Manufacturer
	Date of manufacture
	Sterilized using irradiation
	Use-by date
	Do not re-use
	Single sterile barrier system with protective packaging inside
	Do not resterilize
	“ON”/“OFF” (push-push)
	USB Port
	Ethernet port
	Type BF applied part
SN	Serial number
LOT	Batch code
REF	Catalogue number
UDI	Unique Device Identifier
	Set caster brake before changing CO_2 tanks.
	Caution, hot surface

Symbol	Symbol Description
	Non-ionizing electromagnetic radiation
	Refer to instruction manual/booklet (blue color represents a mandatory action)
	Do not use if package is damaged
	Caution
	Consult instructions for use or consult electronic instructions for use
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Separate Collection
	No stepping on surface
	Keep dry
	Keep away from heat
	Humidity limitation
	Temperature limit
	Packaging unit
	Equipotentiality

Symbol	*Symbol Description*
	Reset settings to default power and time settings.
	Input
	A footswitch is connected to the system and is active (system is in Surgical Mode).
	A footswitch is connected to the system and is not active (system is in Ablation Mode).
	Indicates a reflected power error has occurred.
	Press this icon to return to the Tissue Selection screen. This icon is not active when the system is delivering power.
	Use these buttons to increase or decrease settings.
	Denotes a procedure performed only in Ablation Mode.
	Denotes a procedure performed only in Surgical Mode.
	Denotes a procedure performed using both Ablation and Surgical Mode.
	Press this icon to adjust the system audio settings.

2 Warnings and Cautions

Users should be familiar with all warnings and cautions prior to using the NEUWAVE™ System. The warnings and cautions listed in this chapter also appear in the relevant sections of the manual.

WARNINGS

- The NEUWAVE System should not be used in the following situations:
  - Pregnant patients – potential risks to patient and/or fetus have not been established.
  - Patients with implantable pacemakers or other electronic implants. Implanted electronic devices may be adversely affected by microwave power.
  - Use on the central nervous system.
- The NEUWAVE System should only be used by physicians and staff properly trained in the use of this technology and its associated warning and cautions. Physicians should avail themselves of preclinical training, a review of pertinent literature, and other appropriate education before attempting to use the NEUWAVE System.
- Use only one NEUWAVE System at a time and never use additional ablation systems in combination with the NEUWAVE System. Doing so may result in excess energy delivery to the patient.
- Do not operate the NEUWAVE System near life-support equipment that is sensitive to 2.45 GHz microwave energy.
- Electrosurgical/electrocautery devices may interfere with the NEUWAVE System and cause system errors. Ensure that all NeuWave probes are removed from the patient prior to using electrosurgical/electrocautery devices.
- Use only NeuWave Ablation Probes from NeuWave Medical with the NEUWAVE System. Probes from other manufacturers may cause patient injury or fail to function properly.
- Do not perform microwave procedures on patients with cardiac pacemakers or other implanted electronic devices.
- Remove hearing aids and all metal jewelry from the patient prior to a procedure. Ensure there are no metallic buttons, snaps, or other metallic items in direct contact with the patient.

WARNINGS

- The NEUWAVE System and accessories are NOT MRI compatible.
- Any part of the patient's body containing metal implants should not be treated with microwave energy unless specialized medical advice is obtained.
- Do not direct the NeuWave Ablation Probes toward the eyes or testes.
- Use medical imaging devices to verify proper probe placement prior to starting an ablation.
- Do not reuse or re-sterilize any product labeled "SINGLE USE". Doing so may result in cross-contamination, injury to the patient or medical staff, or equipment malfunction.
- Connect only medical grade CO_2 cylinders to the NEUWAVE System. Connecting a different gas to the NEUWAVE System will result in system malfunction and may lead to patient and/or user injury.
- No modification of this equipment by the user is authorized by NeuWave Medical.
- Do not connect ablation probes directly to the back of the cart as potential injury to the patient or user is possible.
- Use caution when adjusting the moveable display arm to avoid pinching hands or fingers.
- Do not attach any device to the USB port while delivering therapy. The USB port is for the connection of approved accessories only, including the footswitch. USB memory sticks may be connected to the USB port when the system is not delivering power for the purposes of removing/saving system information (i.e. procedure logs). Do not attach any unapproved devices to the USB port as this may cause a device malfunction.
- During initial set-up, inspect the system and accessories for any damage that may have been caused during shipping and transportation. If damaged, do not use or attempt to repair. Call Ethicon Customer Service for service assistance.
- Inspect the system and accessories before each use. If there is evidence of damage, do not use the system or accessories. Call Ethicon Customer Service for service assistance.
- The NEUWAVE System has no parts that can be serviced by the user. To avoid electric shock, do not remove system covers or attempt repairs.
- Electromagnetic interference (EMI) produced by the NEUWAVE System may adversely affect performance of other equipment during normal operation. Precautions should be taken to ensure that the well being of the patient is maintained in the event of such interference. Increase the distance between the NEUWAVE System and other electronic equipment. Plug devices into separate branch circuit outlets. Call Ethicon Customer Service for assistance.

WARNINGS

- Heating associated with microwave power can provide an ignition source. Observe fire precautions at all times. Avoid the accumulation of flammable gases that may collect in body cavities such as the bowel. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks. When using microwave power in the same room as any of these substances or gases, prevent their accumulation under surgical drapes, or within the area where microwave procedures are performed.
- **Fire/Explosion Hazard:** Verify that all oxygen circuit connections are leak free before and during the use of microwave power. Verify that endotracheal tubes are leak free and that the cuff is properly seated to prevent oxygen leaks. Enriched oxygen atmosphere or the presence of any flammable/oxidizing gases and liquids may result in fires and burns to the patient or medical team.
- A non-functioning system may cause an interruption in a procedure. A back-up system should be available for use.
- Do not stack other equipment on the NEUWAVE System.
- Keep fluids away from the NEUWAVE System and prevent liquids from dripping or spilling onto the system during use and storage.
- Do not use two- or three-prong adapters with the system power cord. The power cord assembly should be checked periodically for damaged insulation or connectors. Do not use damaged cords.
- Reliable grounding can only be achieved when the equipment is plugged into a receptacle marked “Hospital Grade.” Any interruption of the Protective Earth conductor will result in a potential shock hazard, which could cause injury to patient or operator.
- Do not use power strips.
- NEUWAVE System components (microwave power amplifiers, PDM, probes and other accessories) are designed to be used as a single unit. Failure to understand and follow instructions provided may result in improper functioning of the system and cause injury to the patient or user.
- Intraprocedure and/or post ablation imaging are recommended to assess the extent of tissue coagulation.
- Always inspect probes and cables for chips, cracks, or other damage before each use. Do not use damaged probes.
- Do not defibrillate a patient with a probe inserted. Completely remove the probe from the patient before defibrillation.
- Do not obstruct the system display or speakers providing activation tones. These are important safety features that must be visible and audible at all times.
- Ensure the radiating section of the probe is always fully inserted into tissue to prevent elongated waveform fields that can cause unintended thermal energy delivery to the user or patient. The characteristics of microwave fields differ based on the permittivity of the local environment around the radiating section of the probe.

WARNINGS

- Energy delivery will automatically cease if a serious error is detected by the system. If this occurs, follow instructions on the display.
- The CO_2 cooling system does exhaust CO_2 into the procedure room. Ensure that the procedure room has adequate ventilation/room air exchanges.
- Prior to moving patient into a CT imager, ensure the placed probes have sufficient clearance from the CT bore. Patient injury can result if the probe handles contact the CT bore while moving the patient in and out of the CT scanner.
- Do not place probes so that the probe cables are draped on or near the patient's head or neck.
- Prior to starting the ablation, use imaging to confirm proper probe placement and that the probe is not bent or broken.
- In the event of a display failure, use the System ON/OFF switch to turn the system OFF. Discontinue use of the system until repair services are obtained.
- Do not attempt to remove an ablation probe from the PDM while the probe is active.
- Failure of the NEUWAVE System may lead to an unintended increase in output power.
- Do not use damaged probes and probes beyond the expiration date noted on the packaging.
- Examine each probe prior to use. Do not use probes with obvious visual damage. Injury to the user or patient may occur.
- Do not attempt to bend or reshape probes as they may malfunction when attached to the NEUWAVE System.
- Probes are provided sterilized. Follow your facility sterile handling guidelines.
- Probe tips are sharp. Handle with care.
- Do not use any probes that fail to pass the system test or show evidence of a CO_2 leak. Use of a faulty probe could lead to user or patient injury.
- Never press the Test button when the probe tip is in air. Testing in air does not allow for the check of a CO_2 leak. Use of a faulty probe could lead to user or patient injury.
- The probe cable can heat and reach 60° C during energy delivery. When placing the probe, verify that the probe cable does not rest on the patient's skin. Use the included clips to secure the probe cable away from the patient's skin as needed.
- Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.

WARNINGS

- NeuWave Ablation Probes can be used with needle introducers. If a needle introducer is used, it must be retracted so that it doesn't interfere with the planned ablation zone prior to delivering energy. Failure to retract the needle introducer a sufficient distance may impact energy delivery. Introducers used with 17 gauge probes must be 14 gauge introducers or larger to help minimize the risk of probe damage.
- The NEUWAVE System is not a cryogenic ablation device. The CO_2 supplied provides sufficient coolant to enable the Tissu-Loc™ function and to cool an active probe. The CO_2 supplied is not sufficient to ablate tissue.
- If the CO_2 gas is not released through the bleed valve the CO_2 fitting will contain high-pressure CO_2 which may pose a hazard to users when removing the CO_2 fitting from the CO_2 cylinder.
- If the bleed valve is not closed when the cylinder is open, CO_2 gas will be released through the bleed valve.
- Never remove a probe from the patient while Tissu-Loc™ mode is enabled or the displayed temperature is below 0° C. Serious internal injuries may result.
- Do not activate the Tissu-Loc™ function when the probe is not placed in tissue.
- Never begin delivering energy to a probe when the probe tip is in the air. The system will detect a "reflected power" error and stop delivering energy.
- CO_2 cylinders contain high pressure. Ensure the cylinders are closed prior to removing the yokes.
- Repairs should only be attempted by trained NeuWave Medical Inc. personnel or by persons having completed NeuWave Medical Inc. approved service training.
- The battery should not be repaired or replaced except by trained NeuWave Medical personnel. Replacement by inadequately trained personnel could result in excessive temperatures, fire or explosion.
- The NEUWAVE System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.
- Portable RF communications (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NEUWAVE System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Failure to use this equipment in the specified shielded location could result in degradation of the performance of this equipment, with other equipment or interference with radio services.
- The NEUWAVE System should not be used adjacent to or stacked with equipment other than specified in this user manual. If adjacent or stacked use is necessary, the NEUWAVE System should be observed to verify normal operation in the configuration in which it will be used.

WARNINGS

- The NEUWAVE System intentionally applies RF/Microwave energy for ablation during activation. Observe other electronic medical equipment in the vicinity during NEUWAVE System activation for any possible adverse electromagnetic effects. Ensure adequate separation of electronic medical equipment based on observed reactions.
- The NEUWAVE System was tested using NeuWave Ablation Probes. The use of accessories other than those listed in this user manual may result in increased emissions or decreased immunity of the NEUWAVE System.
- Probes removed from the body may be hot. Handle with care to avoid user and/or patient injury.
- Do not handle probes that appear excessively cold.
- System, probes, and accessories should be placed appropriately to prevent cable tripping hazard.
- Do not apply a clamp or hemostat to the probe shaft or cable as this may damage the probe and cause a malfunction.
- Probe movement during ablation is possible. Probe movement can be caused by patient movements from breathing, coughing, etc. and also by pressure applied to the probe when target tissue contracts in response to the ablation. To help prevent probe movement, hold the probe handle in place during the initial period of the ablation (at least 45 seconds). Monitor the probe for movement throughout the procedure and hold the probe in place as needed. If repositioning of a probe is required, stop energy delivery prior to repositioning the probe.
- Charred tissue may accumulate on the probe tip during planar coagulation. As needed, use a sterile soft cloth or soft pad to remove any tissue build up on the probe tip. Probe tip may be hot. Never use a rough surface or scratch pad to clean the probe tip as this may damage the probe and result in errors or malfunction.
- System or probe malfunction can result in a delay of surgical procedures. Always ensure that an alternative coagulation method and additional NeuWave probes are available.
- When using a probe in or near rigid structures such as bones and cartilage, use care not to apply excessive lateral force or excessively bend the probe. Near the probe tip, the probe shaft is made of ceramic, which may break if excessive force is applied. This may result in the probe tip being detached from the probe and possibly remaining in the patient.
- There are temperature sensors on the outside of the probe shaft. If the temperature sensors are damaged during placement or use of the probe, the NEUWAVE System will generate an error and disable the probe. To minimize the risk of damaging the temperature sensors during placement, avoid penetrating rigid structures such as bones and cartilage without the use of an introducer. Sharp instruments and hemostats/clamps should never be used along the probe shaft. Ultrasound guides and needle introducers should be used with caution.

WARNINGS

- The Surgical Clip (DR-001193) is designed for use with either 15 or 17 gauge probes. To avoid damage to the surgical clip and/or the probes, do not use 11/13 gauge (PRS35) or 13 gauge (SR) probes with the Surgical Clip (DR-001193).
- Use only NeuWave approved accessories listed in this manual. Use of other accessories may impact system performance.
- Never bend or apply excessive force to the probe. Probe malfunction may occur, possibly causing user and/or patient injury.
- Cauterizing track sizes are dependent on probe temperature and probe removal rate. Cauterizing with probes at higher temperatures and/or with slower rates of removal may result in larger cautery tracks.
- The NEUWAVE system must be pulled from the handles through doorways to prevent damage to the PDM and tank heaters.

CAUTIONS

- Lock caster brakes during procedures.
- The PDM mount uses a spring loaded lever which could cause a pinch point. Use caution when attaching the PDM to the CT table mounting bracket or system cart storage location.
- A system error could result if power is disconnected while the system is shutting down.
- Do not use abrasives, sharp tools, or any methods that may damage the surface of the parts.
- Flexible connection covers (3) protect the PDM from dirt, debris and liquids. Ensure the covers remain in place when the system is not in use.
- Lock caster brakes before installing or changing CO_2 cylinders.
- Do not use if the product sterile barrier system or its packaging is compromised.
- Removing the probe too slowly while cauterizing may result in a probe temperature error.
- When the NEUWAVE System and physiological monitoring equipment are used simultaneously on a patient, any monitoring electrodes should be placed as far away as possible from the ablation area.
- When performing target ablation procedures, always use the lowest power setting and shortest time that will achieve the intended results. Refer to the NeuWave Ablation Probe Instructions for Use for example ablation sizes based on power and time settings.
- Do not use abrasive or sharp tools or any other methods that may damage the surface of the parts.
- Ensure PDM covers (3) are in place to prevent liquid from collecting in the PDM connectors. Do not immerse the system or any of its accessories or parts.

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3 System Overview and Setup

Read this entire manual and any accessory documents prior to use.

Several minor aspects of the System Cart design will depend on the age of the cart. Where these differences are significant, they will be shown in this manual.

System Display

The system display is a touch screen, and is the user interface for the NEUWAVE™ System. Use the system display to access all controls and settings.

The system display is mounted on a moveable arm that allows the display to be easily positioned and repositioned as needed.

Instructions on using the user interface are provided throughout this manual.

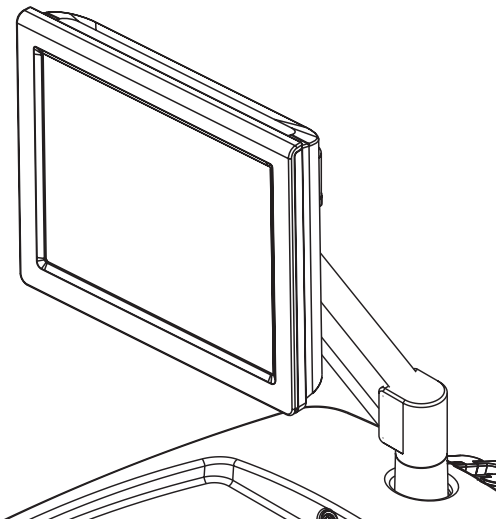


Figure 3-1: System Display

WARNING Use caution when adjusting the moveable display arm to avoid pinching hands or fingers.

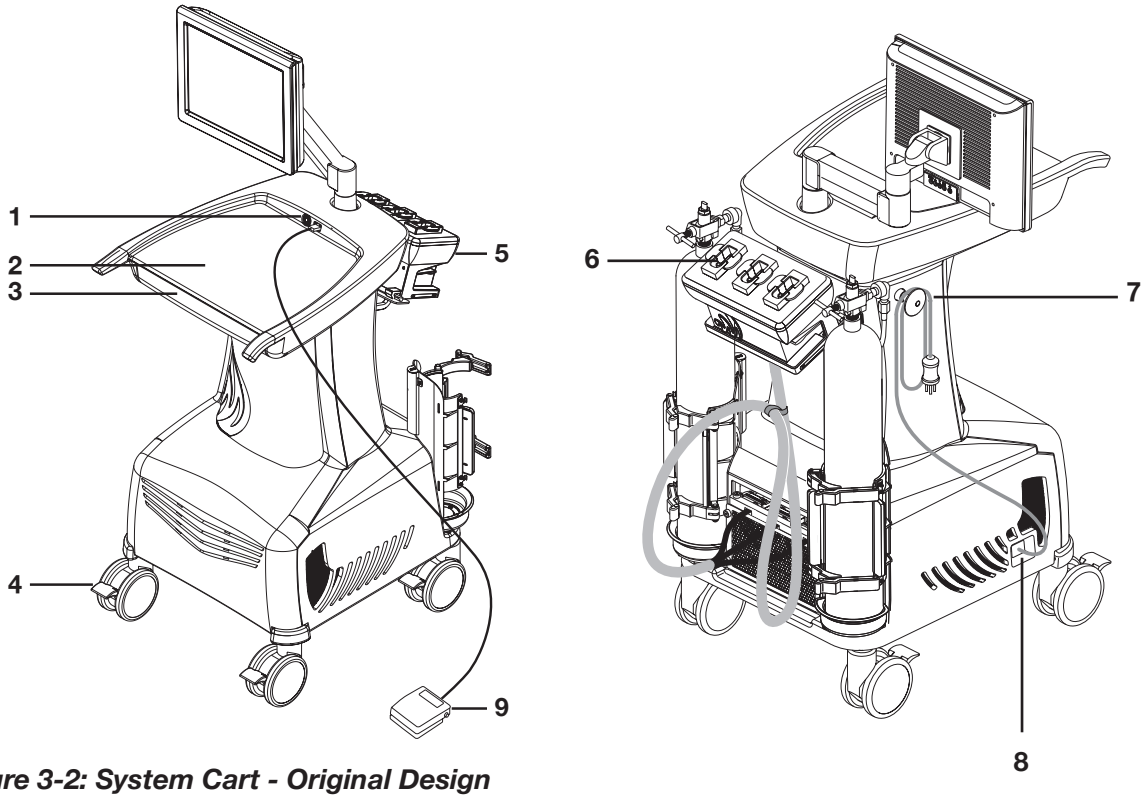


Figure 3-2: System Cart - Original Design

System Cart

The NEUWAVE System cart contains the microwave power amplifiers and cooling system.

The system ON/OFF switch is located on the cart just below the system display arm.

The cart holds 2 CO_2 cylinders.

A cylinder wrench for opening and closing the CO_2 cylinders is provided in the drawer.

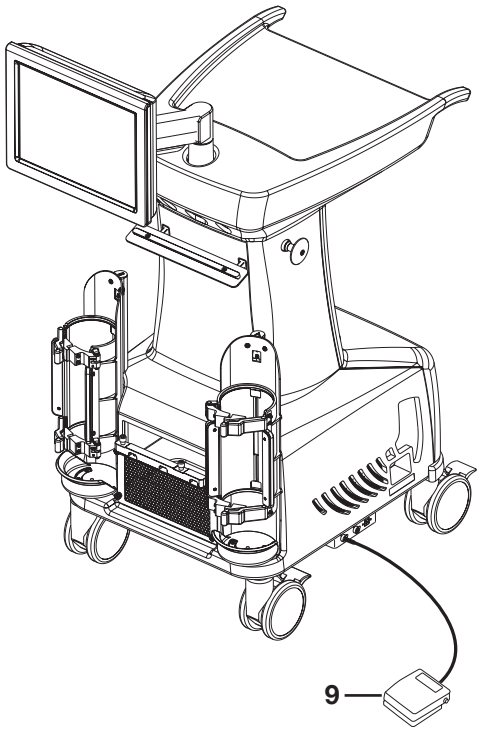
The PDM mounting bracket allows the PDM to be easily stored on the cart for transport and storage.

Follow facility procedures for storing the CO_2 tanks. Local regulations may prohibit storing the CO_2 tanks with the NEUWAVE System when not in use.

All four casters can lock.

The cart includes:

1. System ON/OFF Switch
2. Writing Surface
3. Drawer
4. Casters/Caster Locks
5. PDM/Cable Assembly Mount/Cable Wrap
6. Probe PDM Connection
7. AC Power Cable Wrap
8. AC Power Inlet
9. Footswitch (Optional Accessory)



System Cart - Current Design

USB Ports

A USB port (next to the ON/OFF switch) is available to download system data. It can also be used to connect the Standard USB Footswitch.

There are two Locking USB connectors on current version system carts for connecting Locking USB Footswitch. The data port is not currently functional.

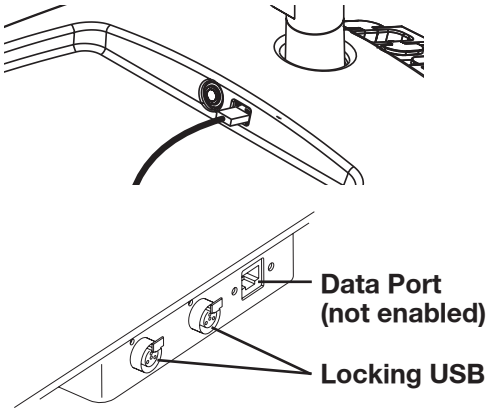


Figure 3-3: NEUWAVE System USB Port and Footswitch Connection.

PDM/Cable Assemblies

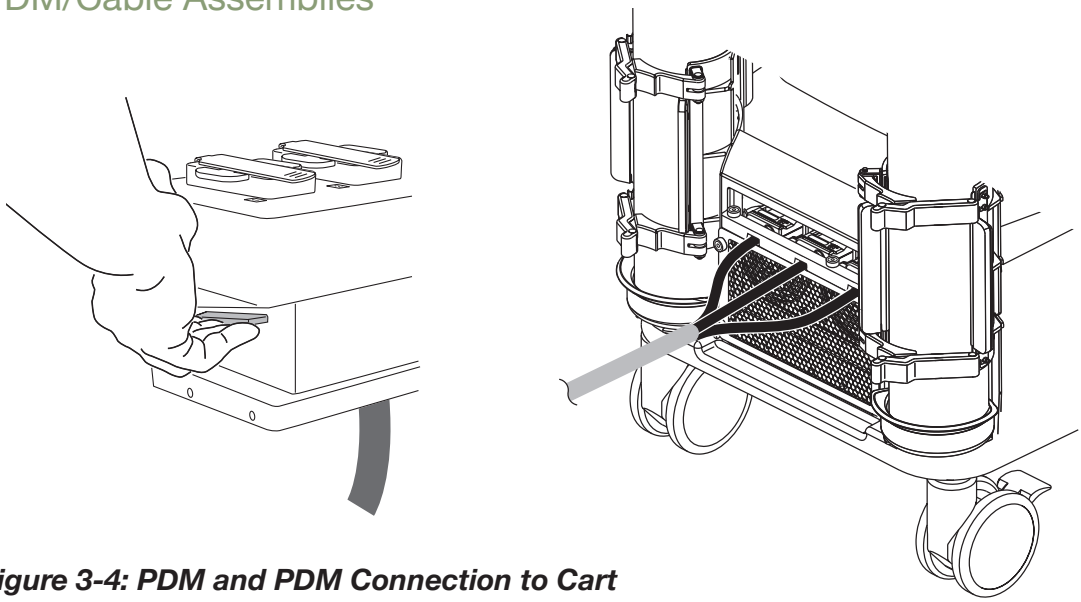


Figure 3-4: PDM and PDM Connection to Cart

The PDM provides a single connection point for up to three ablation probes while minimizing cabling to the cart. The PDM Connections are identified as channels 1, 2 and 3.

CAUTION Flexible connection covers (3) protect the PDM from dirt, debris and liquids. Ensure the covers remain in place when the system is not in use.

The PDM cable connects to the cart. The three PDM connectors and the three channels are numbered to ensure proper connection. The connectors attach to the corresponding cart channel.

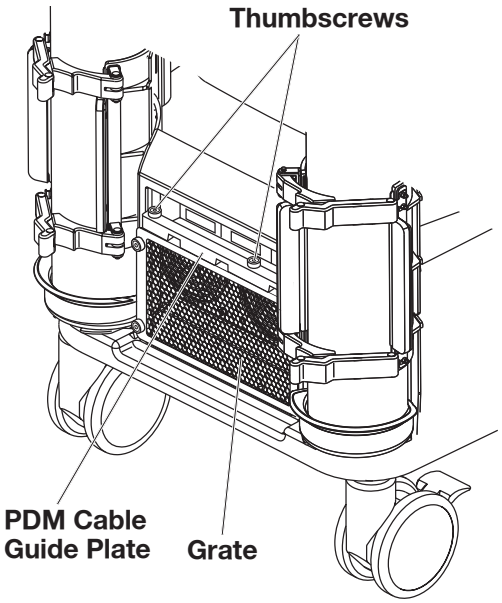
The PDM and cable assembly enable energy delivery, CO_2 cooling and temperature monitoring while minimizing cable clutter and cable management issues.

The PDM mounts directly to the rail on the CT scanner table or to the NEUWAVE CT table bracket.

NeuWave recommends leaving the PDM connections connected to the cart between uses. This will reduce wear and extend the life of the PDM and cable assembly.

Connecting PDM to the System Cart

The PDM Connections are identified as channels 1, 2, and 3. The PDM cable connects to the cart. The three PDM connectors and the three channels are numbered to ensure proper connection. Attach the connector to the corresponding cart channel.



1. Loosen the thumbscrews on the PDM cable guide plate (2) and grate (4), and remove the cable guide plate and grate.
2. Position a PDM connector to the corresponding channel port, making sure the rounded end of the connector aligns with the rounded end of the port.
3. Press and hold the connector release tabs.
4. Insert the PDM connector fully into the port.
5. Release the connector release tabs and listen for an audible click.
6. Verify the integrity of the connection by gently attempting to remove the connector.
7. Repeat steps 2-6 with the remaining PDM cables.
8. Reinstall the grate on the cart and secure in place with the thumbscrews (4).
9. Place the PDM cable guide plate such that each cable rests in one of the three guides.
10. Press the plate against the cart and secure with thumbscrews (2).

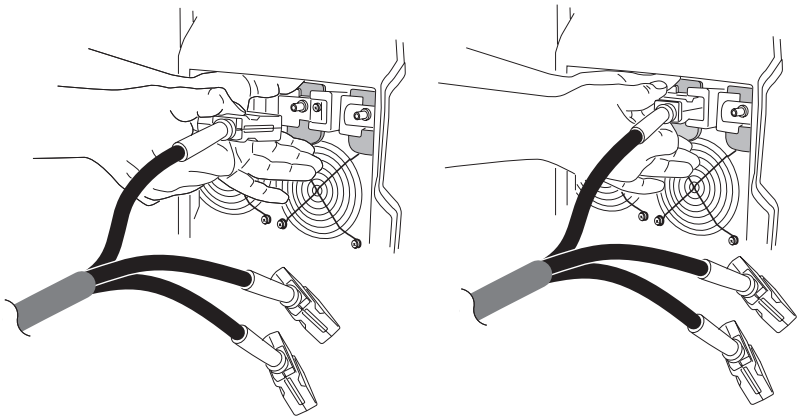


Figure 3-5: Connecting PDM Cables to the Cart

Important: Once properly connected, it is not necessary to remove the PDM cable connections after each use. Keeping the PDM cables connected to the system cart reduces wear and tear on the PDM cable connections.

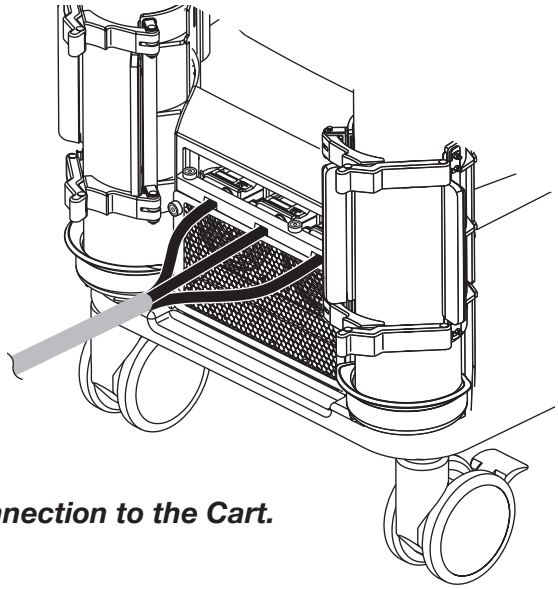


Figure 3-6: Full PDM Connection to the Cart.

Connecting the PDM to a Rail Mount

Important: The NEUWAVE System is not provided sterile. Do not place the system or PDM in the sterile field.

For percutaneous procedures, connect the PDM to the CT bed using the CT system's rail mount or by using a NEUWAVE CT Rail Mount option.

Installing a NEUWAVE CT Rail Mount

1. If your CT system has an integrated rail mount, the PDM can connect directly to it.
2. If your CT system does not have an integrated rail mount, NeuWave has multiple CT rail mount bracket options available to fit a variety of CT beds. Contact Ethicon Customer Service to determine which mount option will fit your CT system.
3. Fold the CT bed mattress back as shown in Figure 3-7.
4. Place the NEUWAVE CT Rail Mount bracket onto the CT bed. The bed may have velcro. NEUWAVE Rail Mount brackets have velcro and will engage the CT bed. However, the NEUWAVE Rail Mounts will mount and secure properly on CT beds without velcro.
5. Fold the CT mattress back down to cover the Rail Mount bracket.

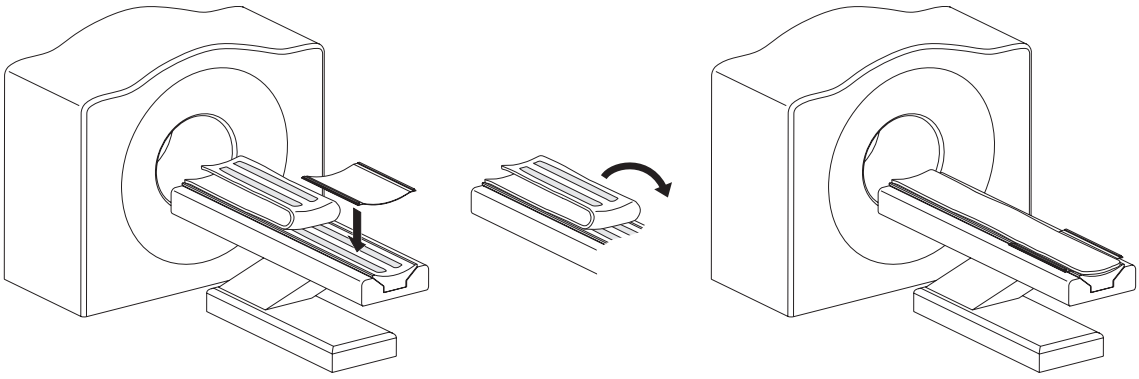


Figure 3-7: Installing a NEUWAVE CT Rail Mount

Installing a NEUWAVE Bed Rail Mount

For open surgical procedures, the PDM can remain mounted to the NEUWAVE Storage Bracket or it can be mounted to the surgical table by using the PDM Bed Rail Mount.

1. Install the Bed Rail mount to the surgical table rail as shown in Figure 3-8.

Important: When not in use, the Bed Rail Mount can be stored on the NEUWAVE System as shown in Figure 3-9.

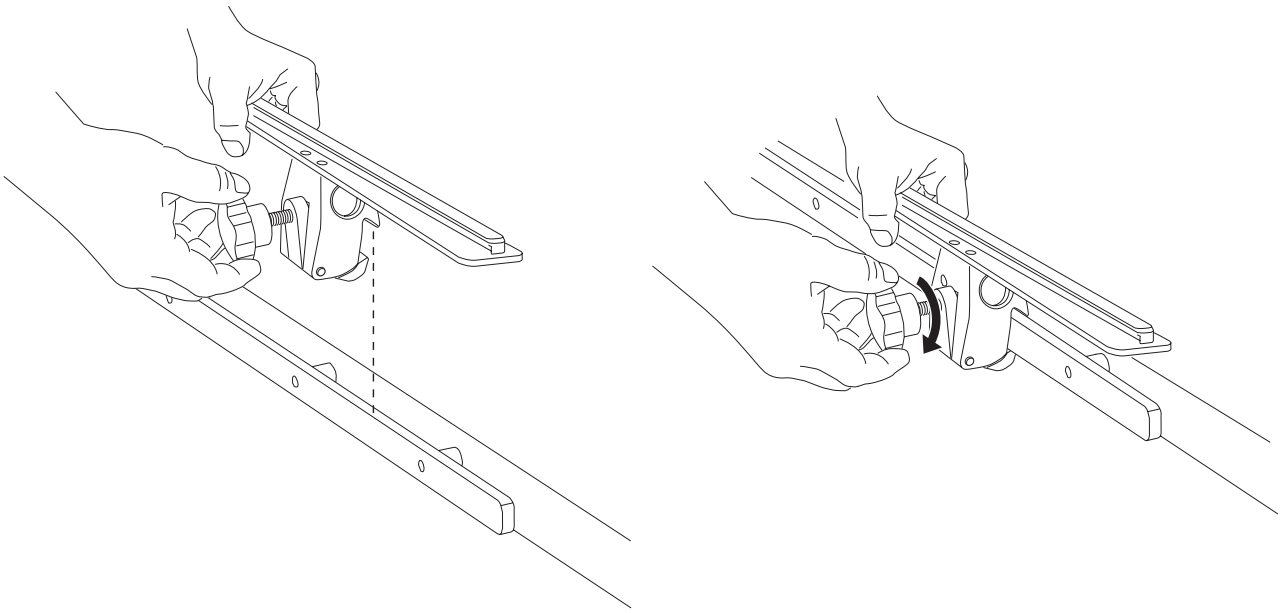


Figure 3-8: Installing a NEUWAVE Bed Rail Mount

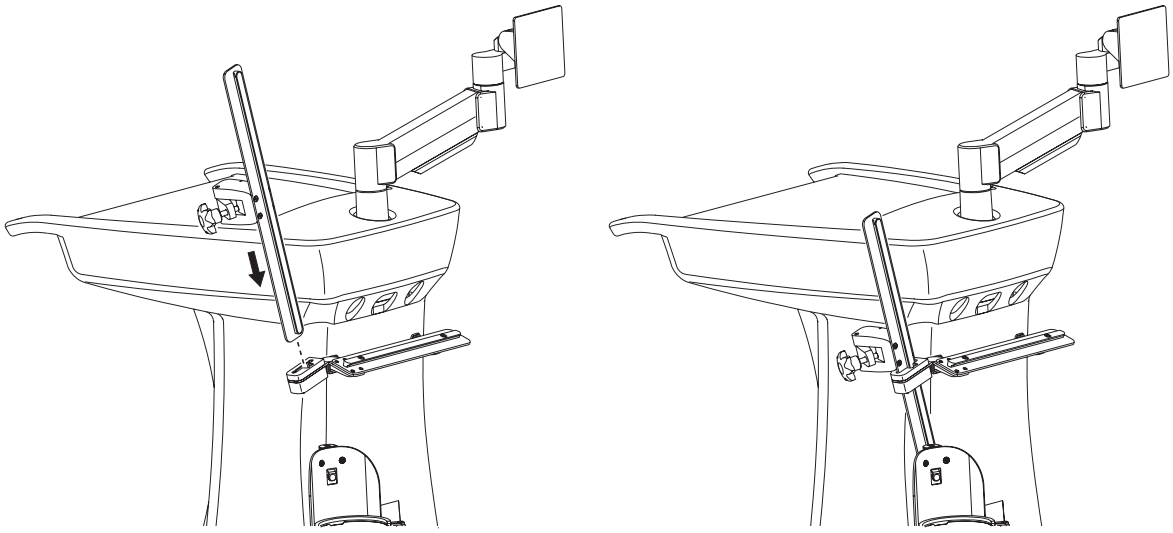


Figure 3-9: Storing a NEUWAVE Bed Rail Mount

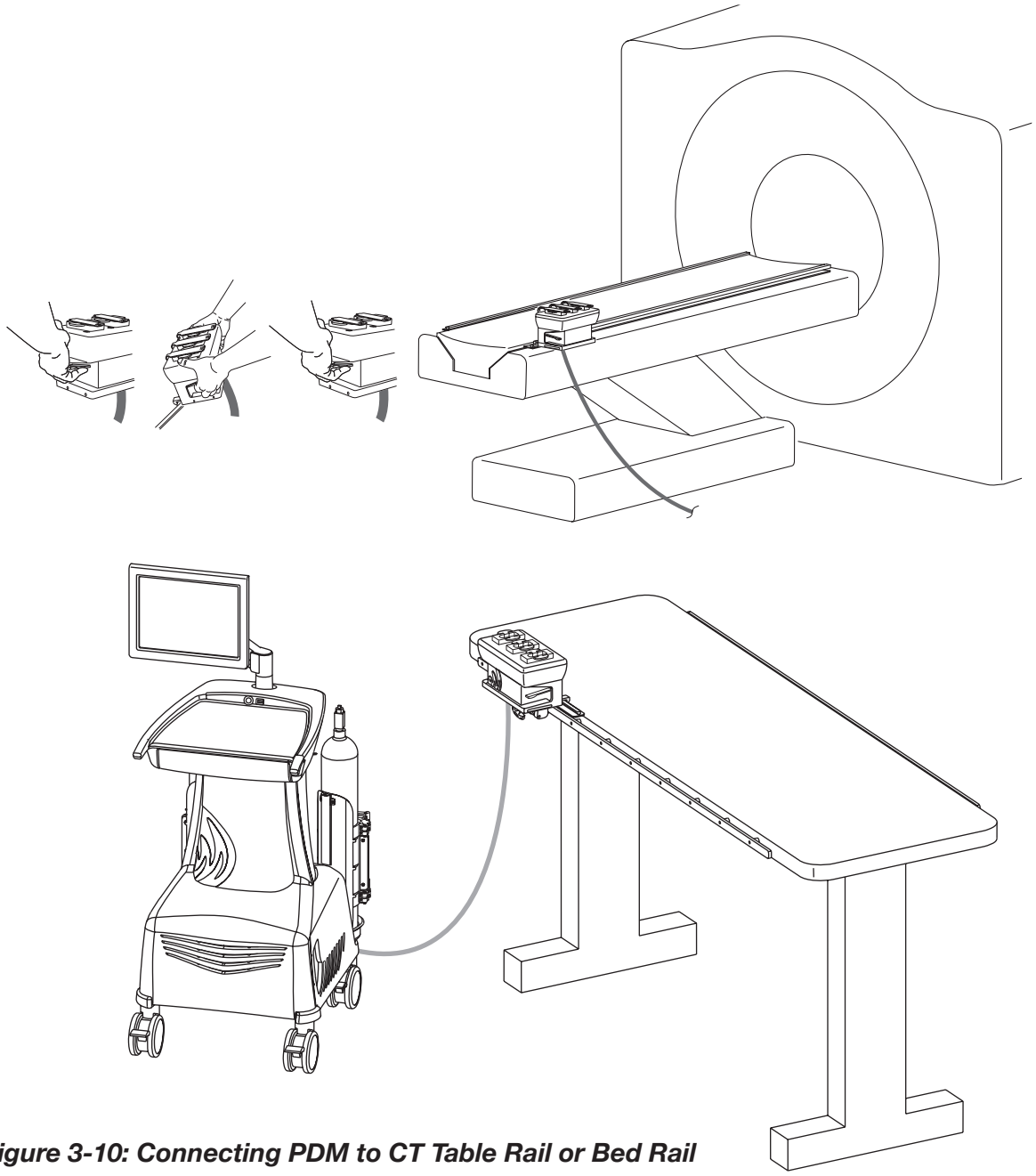


Figure 3-10: Connecting PDM to CT Table Rail or Bed Rail

CAUTION The PDM mount uses a spring loaded lever which could cause a pinch point. Use caution when attaching the PDM to the CT table mounting bracket or system cart storage location.

1. Raise and hold both PDM release levers.
2. Tilt the PDM up to remove it from the PDM storage bracket.
3. While holding the PDM release levers, angle the PDM slightly upward; position the PDM mounting bracket on the CT table dovetail rail.
4. Lower the PDM and visually verify that the bracket is properly positioned on the dovetail rail.
5. Release the PDM release levers to lock the PDM to the dovetail rail.

Connecting AC Power

Connect the provided power cord to a hospital-grade AC wall outlet.

The power cord is detachable, but is secured in place by a clip. To remove the power cord, lift the clip (as shown in Figure 3-11). When installing the power cord, plug the female end into the NEUWAVE System and secure the cord by lowering the clip (as shown in Figure 3-12). Plug the male end of the power cord into the AC wall outlet.

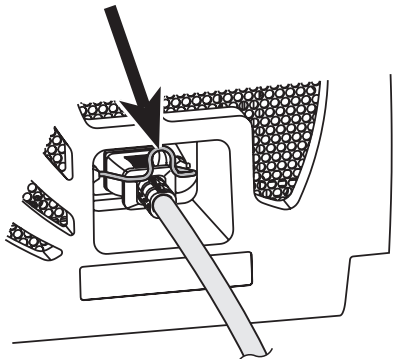


Figure 3-11: Power Cord Clip in Up Position.

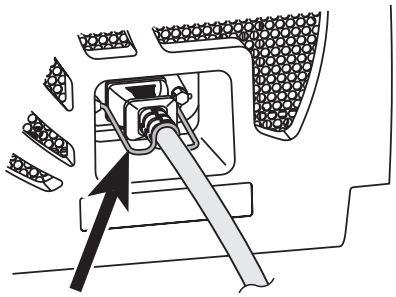


Figure 3-12: Power Cord Clip in Down Position.

WARNINGS

- Do not use two- or three-prong adapters with the system power cord. The power-cord assembly should be checked periodically for damaged insulation or connectors. Do not use damaged cords.
- Reliable grounding can only be achieved when the equipment is plugged into a receptacle marked “Hospital Grade.” Any interruption of the Protective Earth conductor will result in a potential shock hazard, which could cause injury to the patient or operator.
- Do not use power strips.

Residual Pressure Valve (RPV)

What is a Residual Pressure Valve?

A residual pressure valve is a type of one-way check valve. They are used to always maintain a small positive pressure in the CO_2 cylinder, while preventing any unwanted material from inadvertently being backed into the cylinder.

How to Identify a RPV

To determine if the fitting has a RPV, look at the center of the fitting. If there is a pin present, the fitting has a RPV as shown in Figure 3-13.

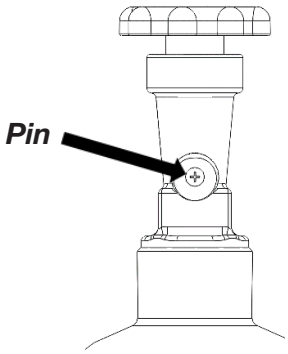


Figure 3-13: Example of a valve with a RPV, arrow is indicating the pin.

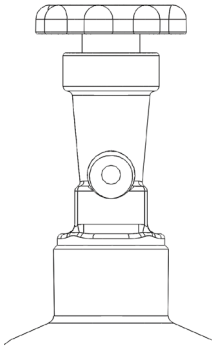


Figure 3-14: Example of a valve without a RPV.

RPV Selection

If it is determined that a RPV is present, when the system is powered on, follow these steps from the ***Tools*** tab, as shown in Figure 3-15.

1. Select the ***Tools*** tab.
2. Select the ***Tanks*** tab.
3. Select Residual Pressure Valve: **Yes**
4. **Save and close** the ***Tools*** display.

Important: It is normal and expected to hear gas vent shortly after making this selection. The sound will be similar to a probe test. This vent will occur twice, once for Tank A and Tank B.

The system will vent for the following conditions:

- System Start-Up
- When a pressure sensing error is detected.

Figure 3-15: RPV Selection Screen

Cooling System Connections

Installing CO_2 Cylinders

Important: The system will not use coolant from a tank that is not at proper temperature. To help ensure that the system is available for use with minimal delay, ensure that the cylinders are at or near room temperature prior to starting the NEUWAVE System.

CAUTION Lock caster brakes before installing or changing CO_2 cylinders.

WARNING CO_2 cylinders contain high pressure. Ensure the cylinders are closed prior to removing the yokes.

CO_2 cylinders must be obtained locally. They are not provided as part of the NEUWAVE System.

1. Lock Casters.

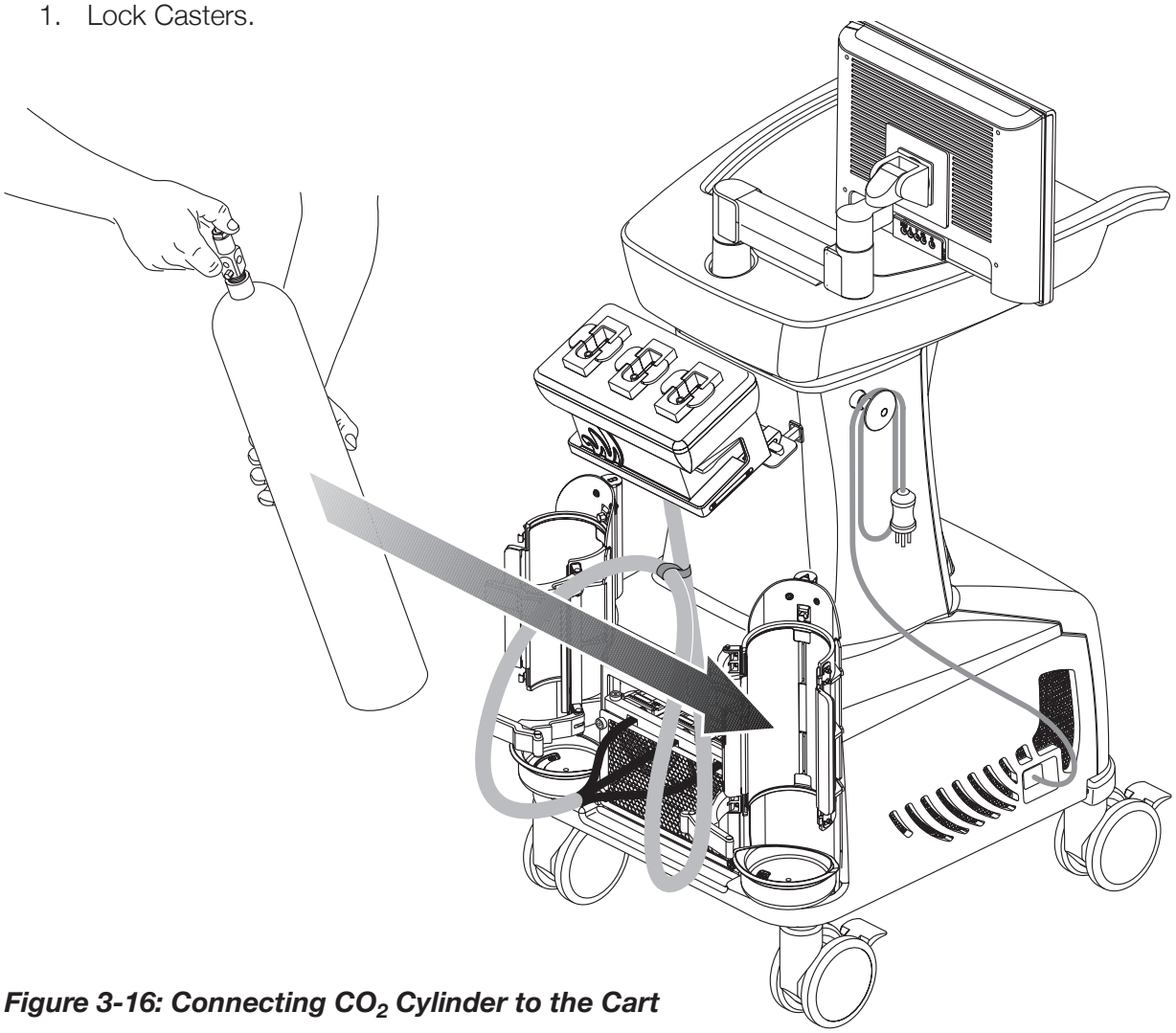
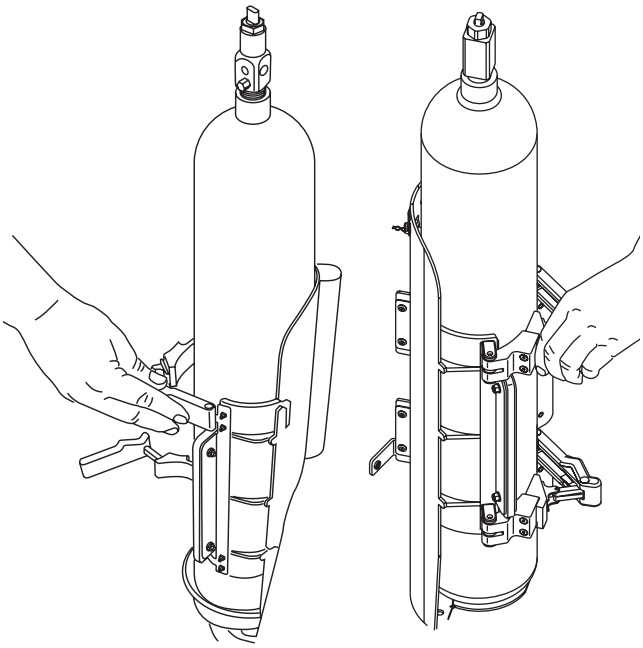


Figure 3-16: Connecting CO_2 Cylinder to the Cart

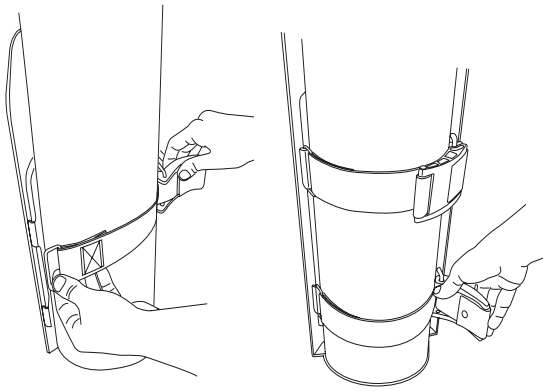
2. Ensure the black clamps (2 per tank holder) are open.
3. Angle the cylinder slightly away from the cart and place it in the cylinder bracket.
4. Ensure the cylinder valve opening is facing the cart, and push the cylinder upright.

5. Secure cylinders by connecting both black clamps. Failure to connect clamps may inhibit system performance.

Important: Different cylinder bracket styles exist. Both are shown in the graphics.



Latches



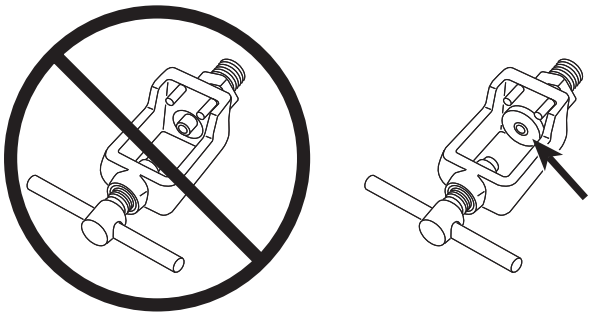
Straps

Supported CO_2 Cylinder Size and Fittings by Product Code

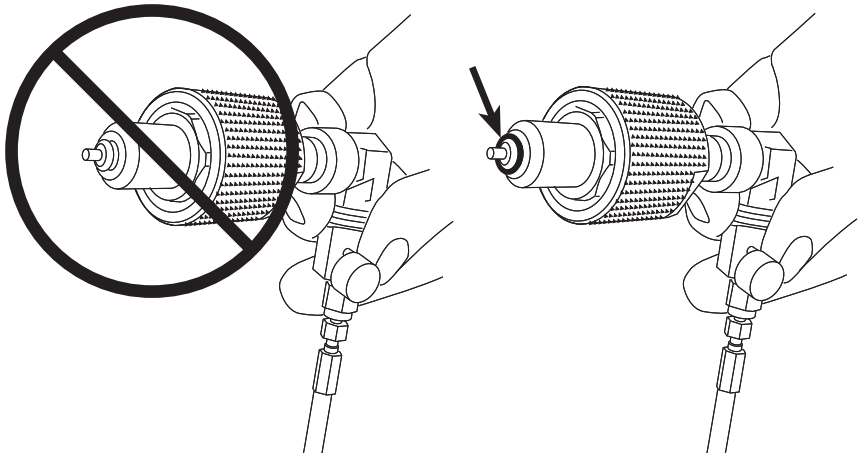
*Product Code**	*Volume (L)*	*Diameter (mm)*	*Fitting*
NWC1US1N / NWC1CA1N / NWC2SG1N	4.5-5.0 (E-Size)	100-111	Pin Index CGA-940 / ISO 407
NWC2IT1N	10	140	ISO5145 (W27x2)
NWC2DE1N	10	140	DIN477 (W21.8x1.814)
NWC2FR1N	5	140	DIN477 (W21.8x1.814)
NWC2NL1N / NWC1BA2N	10	140	Pin Index CGA-940 / ISO 407
NWC2KR1N	5	140	JIS B 8246 (W22x1.814)
NWC2HK1N	13.4	175-180	Pin Index CGA-940 / ISO 407

*Please check your system product code and contact your NeuWave distributor with questions.

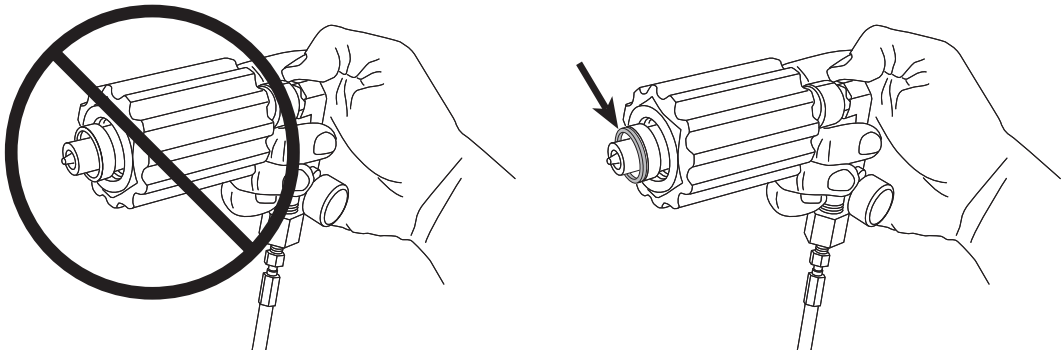
6. Inspect the CO_2 fitting and ensure the gas seal is in place. If the gas seal is not in place, the fitting will leak. See the CO_2 Cylinder Table for the fitting supported in your region and refer to the applicable image.



Pin Index CGA-940 / ISO 407



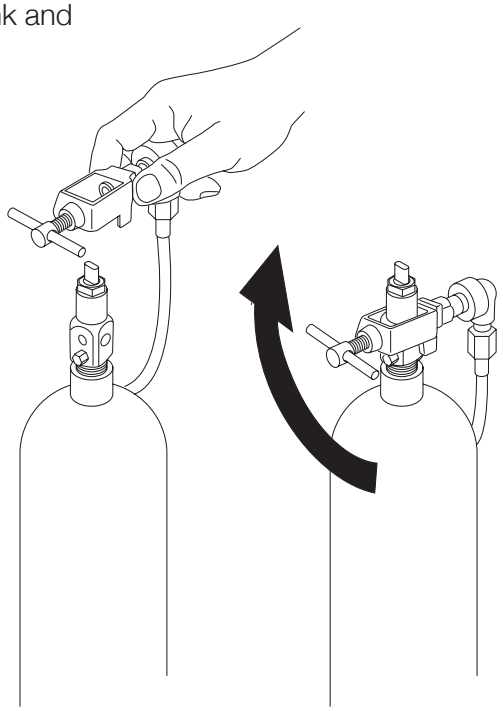
ISO5145



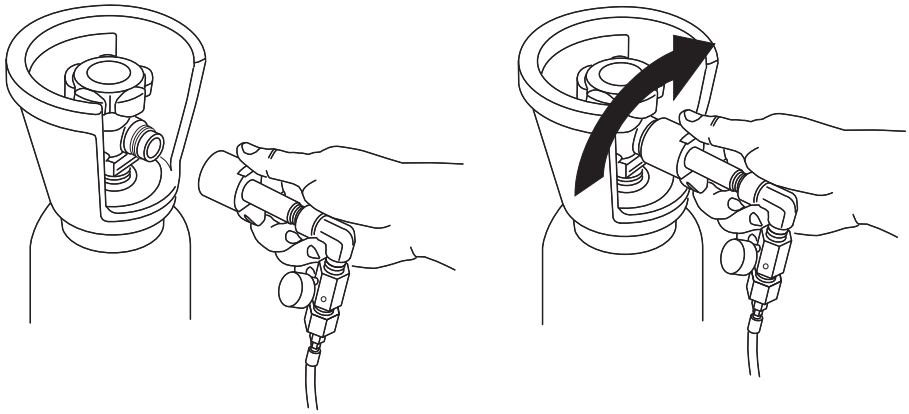
DIN477 / JIS

7. Connect the CO_2 fitting to the tank and turn it clockwise until tight.

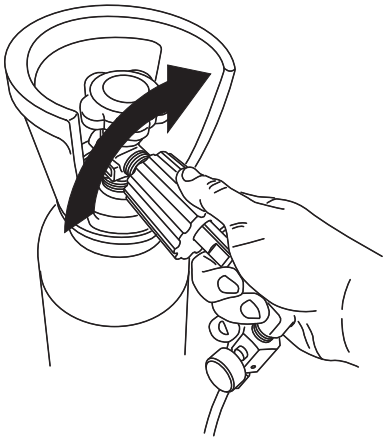
Pin Index CGA-940 / ISO 407



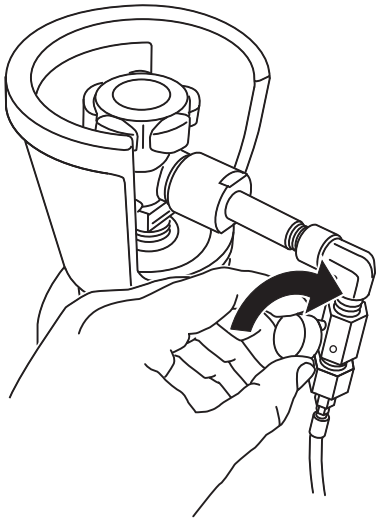
ISO5145



DIN477 / JIS



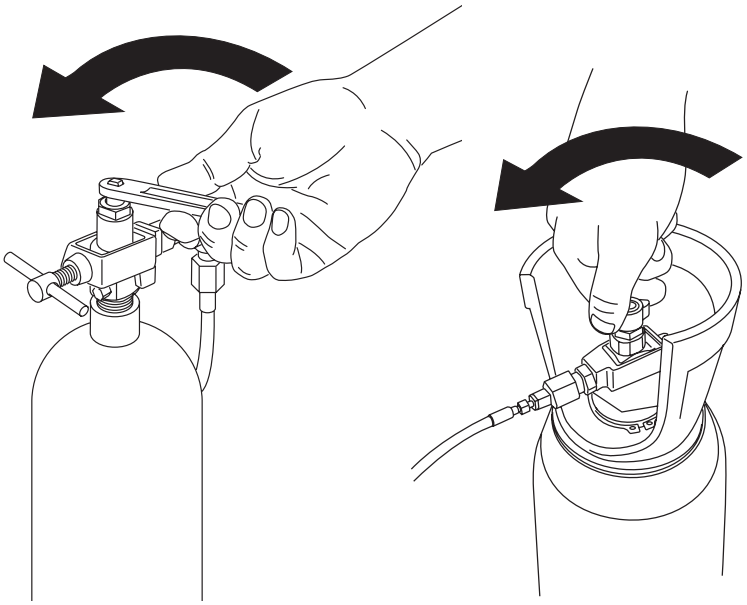
8. If CO_2 fitting is equipped with one, turn the bleed valve clockwise until tight. This closes the bleed valve.



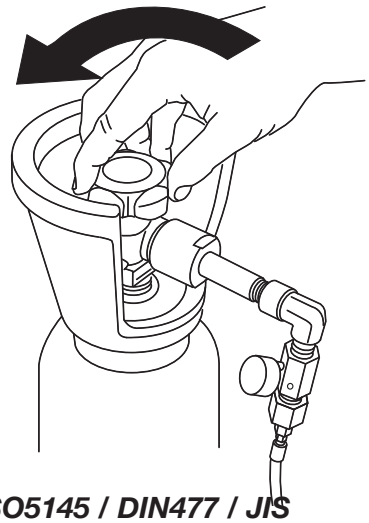
ISO5145 / DIN477 / JIS

WARNING If the bleed valve is not closed when the cylinder is open, CO_2 gas will be released through the bleed valve.

9. Fully open the CO_2 cylinder by turning the knob counter-clockwise fully or utilizing the wrench provided in the drawer.



Pin Index CGA-940 / ISO 407



ISO5145 / DIN477 / JIS

10. Repeat steps 2-9 for the second cylinder.

CO_2 Cylinder Management Tips

CO_2 Tank Management Steps (5L and less):

1. Best practice is to start the case with two new, full tanks. If that is not practical, be sure to allow time at the beginning of the procedure for the tanks to stabilize prior to use and have several new tanks easily accessible. Open the valves on both tanks to allow the system to manage tank switching.
2. When the active tank is nearly empty  , be sure to have a new, full tank ready for replacement.
3. When the active tank is empty  , disconnect the empty tank and replace it with the new, full tank, as soon as it is reasonable.
4. Make sure the new, full tank is connected and opened.
5. Repeat steps 2-4 as necessary.

Large CO_2 Tank Management Steps (7-13L):

1. Start with at least one unused tank. The green icon  means there is enough gas for a typical ablation. Open the valves on both tanks to allow the system to manage tank switching.
2. When the tank status changes to nearly empty  , make sure there is a full, replacement tank ready. (***Important:*** A nearly empty  tank can still be used if the other tank is full  . It is common for an empty  or nearly empty  tank's icon to change to a green icon  when cooling after use.)
3. When the tank status changes to empty  , disconnect and replace it with a full tank as soon as reasonable.
4. Connect the new tank and open it.
5. Repeat steps 2-4 as necessary.

Additional CO_2 Tank Management Tips:

- For optimal performance, NeuWave recommends the system start with two new, full CO_2 tanks before each case. Make sure these are new, and not just displayed as full in the tank icon. A new, full tank can be verified by utilizing the CO_2 tank supplier tags. Make sure each tank is fully opened.
- During multiple probe ablations and cases involving significant usage of Tissu-Loc, the system will consume more gas. Be prepared to go through more gas cylinders and replace them more often in such cases. During these types of cases, it is even more critical to have a new CO_2 tank ready as a replacement or the procedure may be interrupted.
- NeuWave recommends that the system be turned on as early as reasonable before use. This will allow the system to acclimate to the procedure room temperature and regulate the CO_2 tanks to the proper temperature. There is no downside to starting the NEUWAVE system early and letting it sit idle.
- When the NEUWAVE system indicates that a CO_2 tank is empty  , the CO_2 tank is NOT completely drained of CO_2. The NEUWAVE system needs each CO_2 tank to deliver CO_2 at a minimum pressure level. When the pressure of the CO_2 tank is no longer enough to perform the required functions of the system, the tank is marked as empty although there is some amount of CO_2 still in the tank.
- Some CO_2 tank suppliers will provide tags that can be attached to the CO_2 tank to show tank status. These tags allow the tanks to be labeled as FULL, IN USE, and EMPTY. If available, use these tags as a high-level indication of tank status.

- NeuWave recommends that the CO_2 tanks only be disconnected and/or replaced when the status is empty .
- NeuWave recommends that the CO_2 tanks are not vented, in other words, disconnecting the entire CO_2 tank yoke and then reconnecting it, in order to alter the tank's temperature and status. Venting the CO_2 tanks can cause other system issues.
- If at any point a tank reads empty , it should be replaced with a new, full tank.
- When replacing tanks on a NEUWAVE system, it may take some time for the tanks to register as full. The system should be allowed time to register new tanks, without venting them.
- It is possible for a CO_2 tank to go from a full state to a nearly empty state and then back to a full state. If a tank changes from the full to nearly empty state during an ablation and the ablation is stopped shortly after, the system may be able to heat the tank such that the pressure is increased, and the state may change back to full. If this occurs, the tank will become nearly empty very quickly once an ablation or Tissu-Loc is started. A back-up tank should be available when a tank shows nearly empty.

Connecting the Footswitch

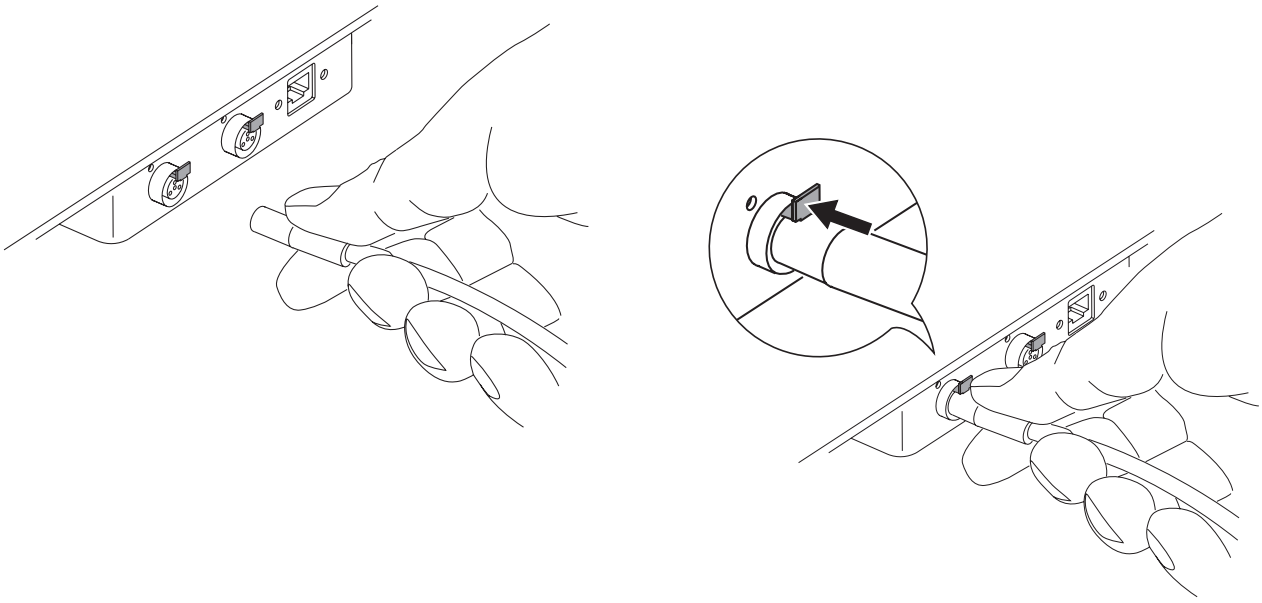
WARNING Use only NeuWave approved accessories listed in this manual. Use of other accessories may impact system performance.

1. Connect Footswitch to the USB port.

When the system is powered on and in Ablation Mode, the Footswitch Inactive Icon will appear on the green status bar at the bottom of the page. The Footswitch Active Icon will only appear when the system is in Surgical Mode. The Standard USB Footswitch can connect to the USB port near the System ON/OFF switch.

The Locking USB Footswitch only can be connected on systems with locking USB ports near the AC Power inlet.

1. To connect, align the connector and insert until it clicks into place.



2. To remove the Locking USB, press the metal tab and remove the connector. The connection cannot be removed unless the metal tab is pressed.

Position System for Use

Move the NEUWAVE System into position for the procedure.

A detachable power cord and an appliance coupler are used for electrical isolation means. Position the device so that it is not difficult to disconnect the power cord during operation.

If desired, place a sterile drape over the system display. The touch screen controls will function through the sterile drape.

WARNINGS

- Electromagnetic interference (EMI) produced by the NEUWAVE System may adversely affect performance of other equipment during normal operation. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interference. Maintain a maximum distance between the NEUWAVE System and other electronic equipment. Plug devices into separate branch circuit outlets. Call Ethicon Customer Service for assistance.
- Heating associated with microwave power can provide an ignition source. Observe fire precautions at all times. Avoid the accumulation of flammable gases that may collect in body cavities such as the bowel. Some materials, such as cotton, wool, and gauze, when saturated with oxygen, may be ignited by sparks. When using microwave power in the same room as any of these substances or gases, prevent their accumulation under surgical drapes, or within the area where microwave procedures are performed.
- **Fire/Explosion Hazard:** Verify that all oxygen circuit connections are leak-free before and during the use of microwave power. Verify that endotracheal tubes are leak-free and that the cuff is properly seated to prevent oxygen leaks. Enriched oxygen atmosphere or the presence of any flammable/oxidizing gasses and liquids may result in fires and burns to the patient or medical team.
- A non-functioning system may cause an interruption in a procedure. A back-up system should be available for use.
- Do not stack other equipment on the NEUWAVE System.
- Keep fluids away from the NEUWAVE System, and prevent liquids from dripping or spilling onto the system during use and storage.

CAUTIONS

- Lock caster brakes during procedures.
- When the NEUWAVE System and physiological monitoring equipment are used simultaneously on a patient, any monitoring electrodes should be placed as far away as possible from the ablation area.

Turning System On

Important: System and coolant performance can be impacted by temperature. For optimal coolant performance and longevity and to ensure that the system is available for use with minimal delay, ensure that the system and the CO_2 cylinders are at or near room temperature prior to starting the NEUWAVE System. Additionally, avoid placing the system near air conditioning vents during use.

The system ON/OFF switch is a push-button type switch that controls AC power to the NEUWAVE System. The ON/OFF switch blinks while the system is starting up or shutting down. The ON/OFF switch is steadily illuminated when the system is ON.

Pressing the ON/OFF switch starts the system boot-up process. While booting, the system display will show the product name and software version number.

During boot-up, the system runs several self-tests. When these self-tests have been successfully completed, the Select Profile and Tissue window is shown on the system display. If the self-tests fail, error messages will appear on the system display. Follow the instructions on the system display if an error occurs.

Select Profile and Tissue

The Select Profile and Tissue window is displayed when the system is turned on, as shown in Figure 3-17. When ready to begin the procedure, use this window to select the tissue in which probes will be inserted during the procedure. The ***Ablation*** and ***Surgical*** tabs cannot be accessed until a tissue selection is made. The user needs to select the appropriate Profile and Tissue type when the system is turned on in order to proceed to the next step in the process.

Tissue type buttons may be selected with tissue(s) and segment(s) turning pink when individually selected. More than one organ, tissue or tissue segment can be selected for targeted ablation. When selections are complete, press the **Close** button. To return to the Select Profile and Tissue window, select the body torso icon at the bottom of the display.

The Select Profile and Tissue window also appears each time the **Close Procedure** button is pressed or to configure Profiles use the **Edit Profiles** button.

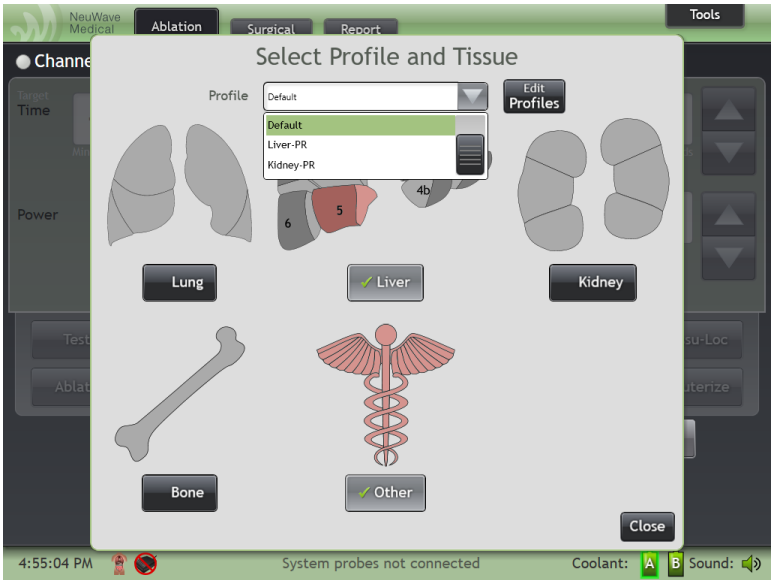


Figure 3-17: Select Profile and Tissue Window

Edit Profile

The NEUWAVE System can create and store multiple Profiles with the number of Profiles not limited.

To configure the system default settings for Profiles, use the **Edit Profiles** button next to the Profile selection on the Select Profile and Tissue window. The Profiles window appears in Figure 3-18.

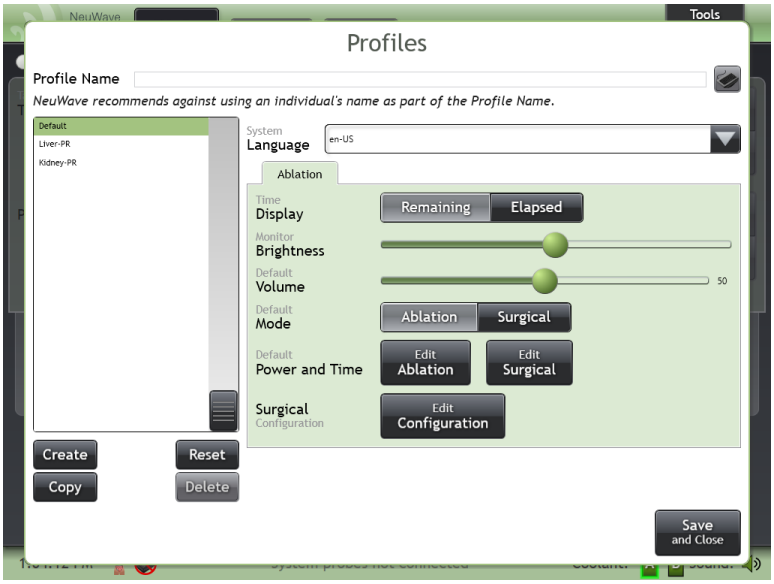


Figure 3-18: Profiles Window

Profiles

Profiles allow the operator to customize their Profile Name and ***Ablation*** tab setting preferences. System Language, Time Display, Monitor Brightness, system's volume, ablation approach (Default Ablation or Surgical Mode), default ablation time (min) and ablation power (W), as well as Surgical Configuration max ablation time can all be preselected and stored in a single profile.

The last Profile used by the system will revert to Default upon re-start unless creating a new Profile or changed to another existing profile. Use **Create**, **Copy**, **Reset** and **Delete** buttons to Edit Profile or Profile Name.

Important: NeuWave recommends against using an individual's name as part of the Profile Name.

Selecting the **Keyboard** icon  will enable an on-screen keyboard allowing the user to type the Profile Name.

If there are multiple profiles stored on the NEUWAVE System, press the drop-down arrow and select a user Profile Name from the list. When the Profile Name is highlighted and selected, the Profile Name will appear in the Profile Name field and the stored settings specifically configured for that user will appear.

Important: Editing profile only edits selected Profile Name default settings; to select the Profile to be used for the procedure, the user must return to the Select Profile and Tissue window and select the desired Profile.

To set the System Language, use the drop down menu provided.

Ablation Tab

The Edit Profiles window includes the following additional settings on the ***Ablation*** tab:

- **Time Display** - Select the default time displayed in Time boxes: Remaining (Count Down) or Elapsed (Count Up) from target time for the NEUWAVE System Ablation Channel display areas.
- **Monitor Brightness** - Drag the slider to adjust the default brightness of the user display.
- **Default Volume** - Drag the slider to adjust the volume of the System.
- **Default Mode** - Select the NEUWAVE System's default mode of Ablation or the Surgical Mode.
- **Default Power and Time** - Edit and set default Ablation Power (W) and Ablation Time (min) for the Ablation and/or the Surgical mode selected.
- **Surgical Configuration** - Edit the Max Auto-Shut Off Value (Set to 1:00 minute).

Default Power and Time Configuration Edits

Press the Default Power and Time **Edit Ablation** or **Edit Surgical** buttons to display a window in which default settings can be made using the arrow buttons on the right-hand side of the window. See Figure 3-19.

- Select the appropriate probe type tab.
- Touch a Default Time or Default Power box corresponding to the number of probes being used.

*Important: The numbers at the top of the window are for the number of probes in use, **NOT** for the Channel Numbers in use.*

- The box selected becomes outlined in green highlight.
- Use the arrow buttons to set the desired value for the box selected.
- To close the Default Time and Power window, press the **Close** button.
- Press the **Save and Close** button to save the desired settings.

Figure 3-19: Windows displayed when Default Power and Time Edit Ablation (left) and Edit Surgical (right) buttons are pressed.

Surgical Configuration Edits

Press the Surgical Configuration **Edit Configuration** button to display a window in which Automatic Shutoff time can be set using the arrow buttons in the window. The Automatic Shutoff time is the maximum time that power can be delivered in a single delivery in the Surgical Mode. For example, if 15 seconds is set as the automatic shut off time, the power will be turned off automatically after 15 seconds of delivery if the user does not manually stop delivery first. This applies to when power delivery is started from the system display or from the Footswitch. Power will be automatically stopped when the time limit is reached, even if the user keeps the Footswitch engaged. The maximum time available for this setting is 1 minute. Multiple power deliveries are available in Surgical Mode, but no delivery can last longer than the Automatic Shutoff time. See Figure 3-20.

- There are two different sound tones that can be selected to sound when power is being delivered in the Surgical Mode. Press the **Enabled** button to use a double-beep tone. Press the **Disabled** button to use the default gurgling tone. The selected tone is not audible until surgical power is being delivered.

Important: Only the default gurgling tone is available in the Ablation Mode.

- To close the Surgical Configuration window, press the **Close** button.
- To save these settings as defaults, press the **Save and Close** button.
- Close the Select Profile and Tissue window by pressing the **Close** button. To access the Profiles and Tissue window again after initial Profile and Tissue selection, select the body torso icon at the bottom left of the screen next to the clock to access both Profile and Tissue or to access just Profile you can Edit Profiles through the ***Tools*** tab at top right of the screen.

Figure 3-20: Window displayed when the Surgical Configuration Edit Configuration button is pressed.

Planning: Time and Power Guide without Probe

When a probe is not connected to the NEUWAVE System, a **Plan** button can be selected for each channel. Planning will allow you to run a simulation algorithm to estimate the approximate ablation dimensions for different types of ablation probes. The software will first prompt you to select the type of probe to simulate. To view the projected ablation dimensions, select the probe type and the **Simulate** button. A simulation Ablation Visualization Window will be displayed showing the predicted ablation dimensions. The simulations ran by the software are based on data obtained from ex vivo testing of ablation probes in bovine liver and may differ from actual in vivo ablation dimensions in human tissues.

Figure 3-21: Ablation Channels Screen / Ablation Planning.

Figure 3-22 (A, B, C) shows the workflow to access the on-screen power and time. (A) Select a Probe type to simulate an ablation. This will activate the time and power settings screen. (B) Enter desired time (min:sec) and power (W). When the Ablation Visualization Window appears (C) Entering incremental units of time and power will depict the predicted ablation zone for the procedure.

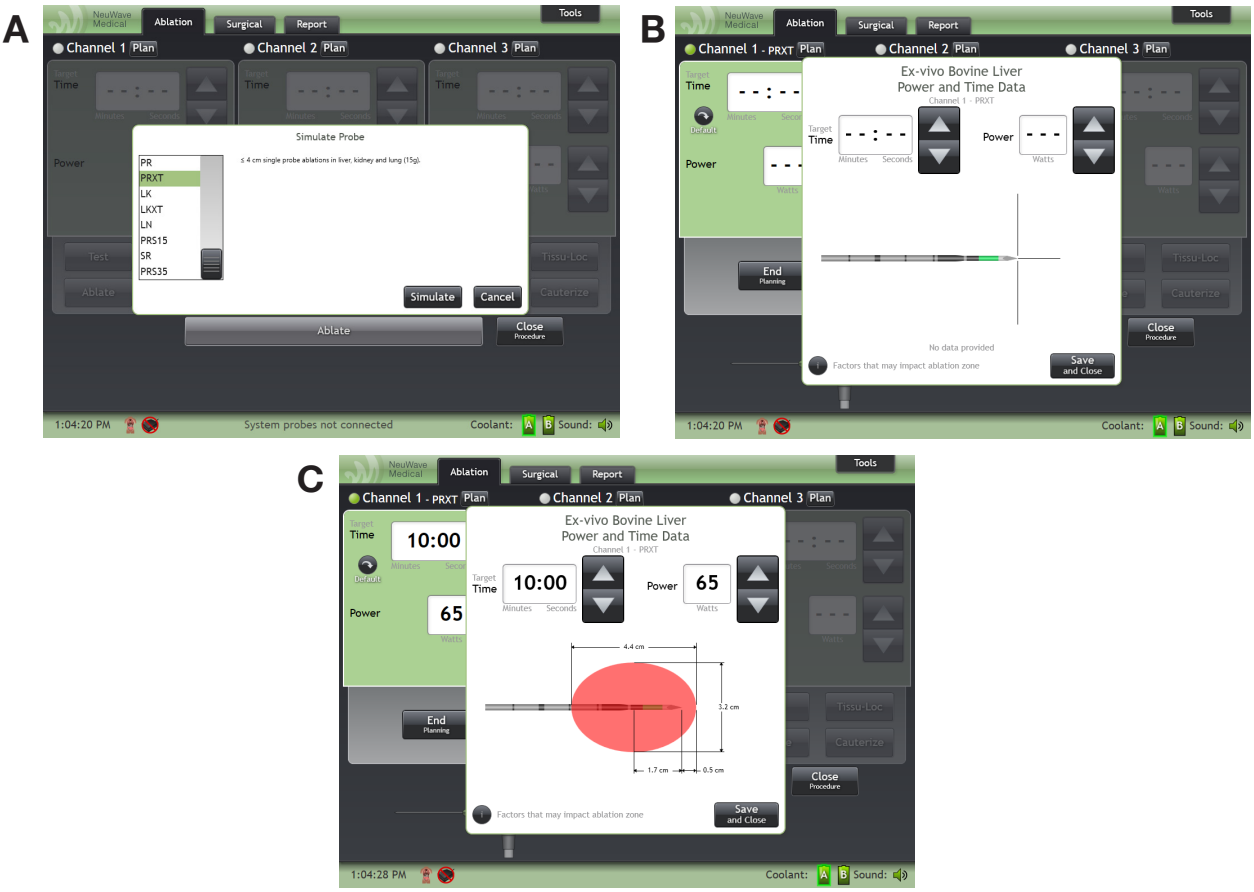


Figure 3-22: A, B, and C show the planning screens for a software simulation to project the ablation zone dimensions using a PRXT probe at 65 W for 10 min.

Select **Save and Close** and **End Planning** to move to actual ablation or plunging in probe turns planning off automatically.

Ablation Visualization Window

When the **Plan** button is selected, if data is available for the current combination of active probe(s) and selected tissue, the simulated ablation size is shown over the enlarged probe tip view.

Important: If more than a single tissue type is selected, the default tissue type displayed will be as follows: Liver (unless not selected), then Kidney (unless not selected), then Lung (unless not selected). No data is provided for Bone or Other.

For single probe ablations (available only when one probe is active), the ablation size shown in the Ablation Visualization Window is based on the current power and time settings. The power and time settings can be changed in the Ablation Visualization Window and the ablation size will update automatically. To save the settings and return to the main screen, press the **Save and Close** button.

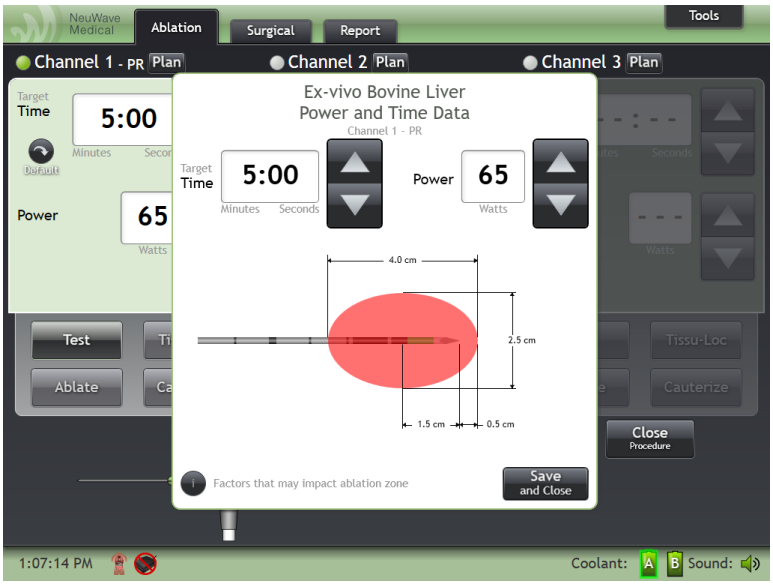


Figure 3-23: Example of Ablation Visualization Window for a single probe ablation

For multiple probe ablations (available when two or more probes are active), the ablation size shown in the Ablation Visualization Window is for the simulated maximum power and time settings only and assumes a 2 cm spacing between probes. The power and time settings cannot be changed in the Ablation Visualization Window and must be set on the main screen. To return to the main screen, press the **Close** button.

Figure 3-24: Example of Ablation Visualization Window for a multiple probe ablation

Important: The ablation zone sizes shown in the Ablation Visualization Window are representative of the data found in the probe Instructions for Use. The measurement data is based on ablations performed in ex-vivo animal tissue. There are many factors that may impact the ablation zone.

Ablation Zone Guidance Factors

Important: This guidance factor information is also available onscreen by selecting the ⓘ *button at the bottom of the Ablation Visualization Window.*

The ablation zone data provided onscreen and in the Instructions for Use are from ablations performed in ex-vivo animal tissue and do not account for the cooling effects of blood flow.

Blood flow will generally result in a smaller ablation.

Lower power ablations are more impacted by the cooling effects of blood flow.

Additional factors that may impact the final ablation zone include but are not limited to:

Factors that may result in a smaller ablation	*Factors that may result in a larger ablation*
Increased/high level of vascularity	Decreased/low level of vascularity
Proximity to large blood vessels	Prior treatments such as TACE or embolization

Physicians should consider all factors when determining the appropriate ablation parameters for each case.

General User Interface Features

This section discusses the features that are common to most user interface screens.

Read this entire manual before using the NEUWAVE™ System for an actual procedure.

Once the Select Profile and Tissue window that appears upon start-up is closed, the user is able to select from four tabs: ***Ablation, Surgical, Report***, and ***Tools***. The ***Report*** and ***Tools*** tabs are discussed in this chapter. The ***Ablation*** and ***Surgical*** tabs are discussed in Chapter 4.

User Interface Information Bar

A green information bar appears at the bottom of most display screens and shows (from left to right):

- Current Time.
- Torso Icon: Touch this icon to display the Select Profile and Tissue window.

Important: This selection is not available when any probe is actively delivering power.

- Footswitch Status: This icon always appears when the Footswitch is connected to the system and available for use. The icon has an overlaid universal no symbol when the Footswitch is connected but not available for use.
- A 'System probes not connected' message appears when probes are not connected to the system. There is no text in this space when probes are connected.
- Coolant System Tank Status: Touch an A B icon to see the corresponding tank's status details.

Important: This selection is not available when any probe is actively delivering power.

- System Sound Volume: Press the icon to display a slide-bar volume control for system sounds.

CO_2 Cooling System Icons

The status of the two (2) coolant tanks is always shown in the green bar at the bottom of the display. The tank currently supplying the CO_2 cooling system is highlighted in green.

Tank Status Icons	Definitions
Coolant: A B	Both tanks are connected and at acceptable pressures and temperatures. Tank A is currently supplying the system.
Coolant: A B	Tank A is supplying the system but is nearly out of CO_2. Tank B is at an acceptable pressure and temperature. The system will automatically switch to using Tank B when Tank A is empty.
Coolant: A B	Tank A is currently supplying the system. Tank B is empty or not connected.
Coolant: A B	Tank A is currently supplying the system. Tank B is connected but is not yet at an acceptable temperature or pressure. Tank B will switch to a different icon when it reaches an acceptable pressure and temperature.
Coolant: A B	Tank A is currently supplying the system but is not at an acceptable temperature or pressure. Tank B is empty. Replace Tank B. System will automatically switch to using Tank B when available.
Coolant: A B	Tank A is currently supplying the system. The system detects an error with Tank B. An error message is displayed when this icon is present.

Figure 3-25: CO_2 Cooling System Icons

A summary of this information is available on the system. Touch a tank icon on the screen to display a legend explaining the meaning of the icons.

Report Tab

The ***Report*** tab is *only* accessible when energy ***is not*** being delivered by the system. It provides detailed information about the current procedure.

The ***Report*** tab displays Delivery Reports using two side-by-side windows, as shown in Figure 3-26. The window to the left provides probe data (Channel Number, Power, Elapsed Time, and Target Time) for each probe connected during a delivery. The window to the right provides system operation message entries as described below in the Delivery Report Entries Section.

The ***Report*** tab display has a main scroll bar along the right-hand side, which permits the user to scroll through the numbered Delivery Report windows. Each individual Message window has its own scroll bar, which permits the user to scroll through lines of an individual delivery report.

Figure 3-26: Report Tab Showing Three Delivery Report Windows

Delivery Report Entries

An individual Delivery Report is generated each time energy delivery is started, and concludes when energy delivery is stopped. Transition points within each Delivery are posted sequentially, and are stamped with the date and time they occurred.

The following message entries are recorded for both ablation and surgical deliveries, and appear one time each in a single Delivery Report:

- 'Delivery Started'
- 'The user has stopped ablating on channel [number]'
- 'Delivery Stopped'

Also included in a Delivery Report are:

- Probe identification message entries, which describe a probe's size, connection channel, serial number, and usage count.
- Transitional message entries, which relate to the **Test, Tissu-Loc™,** and **Ablate** buttons. This type of message entry is displayed for each time one of these functions is activated. The text for these types of entries reads:

  'The probe on channel [number] has transitioned from [button name] to idle.'

  'The probe on channel [number] has transitioned from idle to [button name].'

Error Message Entries

Important: Warning message entries are preceded by a triangular green alert icon and Error message entries are preceded by a triangular red alert icon.

Selecting a Warning or Error icon displays the pop-up message window which was displayed when the warning or error occurred during the procedure.

The pop-up message window also displays the actions that should have been taken for the warning or error to be properly addressed. Press the **OK** button to close the Warning or Error message window.

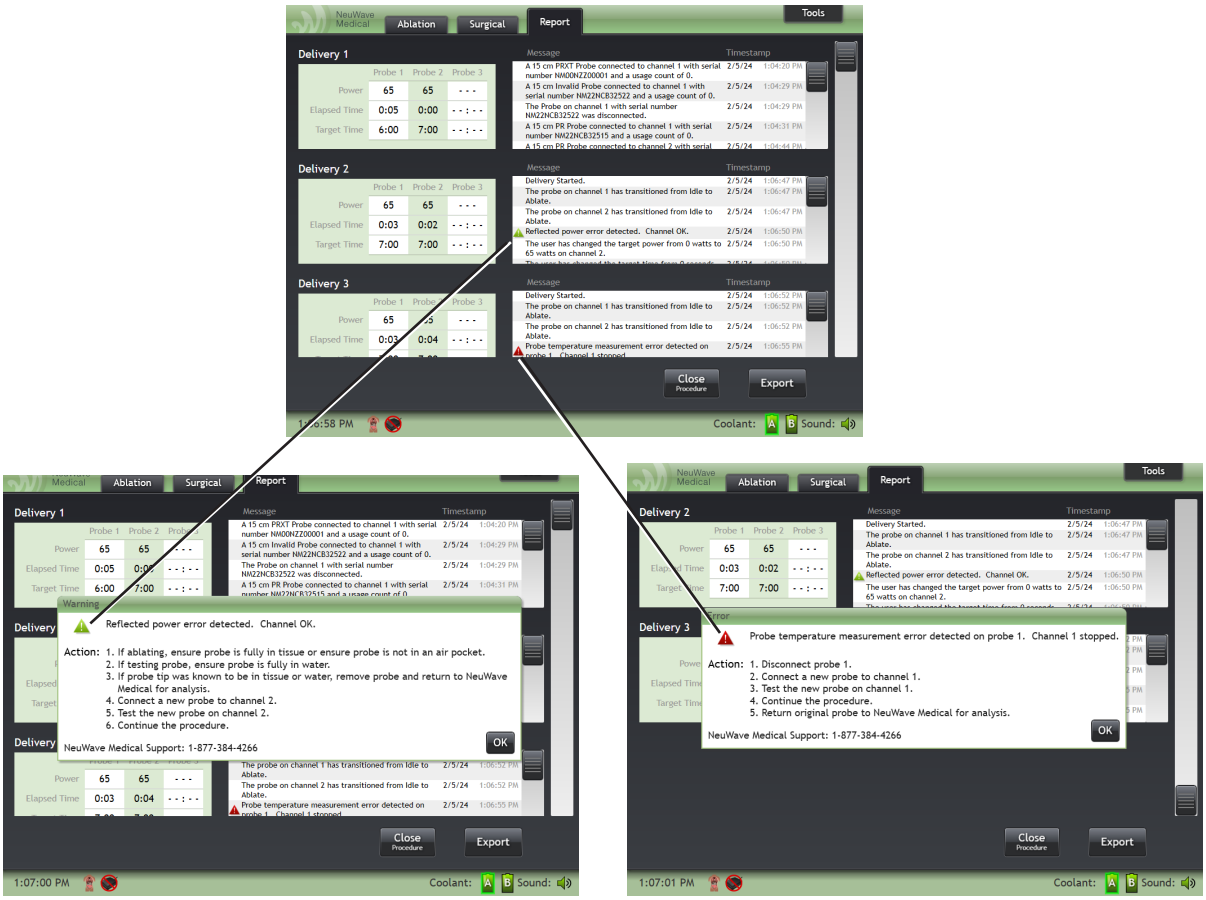


Figure 3-27: Types of Windows that pop up when Warning and Error icons are touched in Delivery Report Window.

Close Procedure Button

Once the **Close Procedure** button is pressed, no new data is saved to that procedure file. Any new actions are saved in a new procedure file.

When the **Close Procedure** button is pressed, a progress bar is momentarily displayed. An information window appears once the procedure is successfully closed. Select **OK** to close this window.

Export Button

Press the **Export** button to send the closed Delivery Reports to the USB port.

Similar to pressing the **Close Procedure** button, when the **Export** button is pressed, a progress bar is momentarily displayed. An information window appears once the export is successfully completed. Select **OK** to close this window.

Tools Tab

The ***Tools*** tab has four sub-tabs: ***System Logs***, ***Procedure History***, ***Tanks*** *and* ***Licenses***. Selecting a sub-tab changes the window that appears in the upper portion of the ***Tools*** tab display. These windows look and operate differently, as explained later in this section.

The controls displayed below all sub-tabs are the same. Toggling between sub-tabs has no effect upon settings established using controls in the lower portion of the screen.

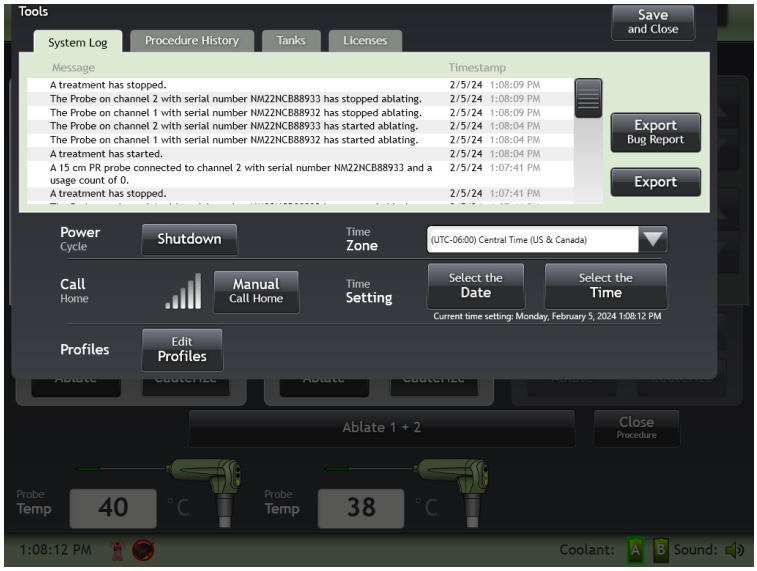


Figure 3-28: Tools Tab with System Log Sub-Tab selected, Procedure History, Tanks and Licenses Tabs

Tools Tab Controls

The following describes how to set controls in the ***Tools*** tab.

- Pressing the **Shutdown** button will display an on-screen dialog window to instruct the user how to properly turn the system off. This button should only be pushed when instructed to do so by NeuWave Medical personnel as part of system troubleshooting. If probes are connected when this button is pressed, they will need to be re-tested prior to use.
- To select the correct Time Zone, use the drop down menu provided.
- To initiate system contact with NeuWave Medical, press the **Manual Call Home** button when instructed to do so by NeuWave Medical Support. This will enable system data to be sent to NeuWave Medical via cellular modem.
- To select the current date, press the **Select the Date** button and select the correct date from the pop-out menu that appears.
- To select the current time, press the **Select the Time** button and select the correct time from the pop-out menu that appears.

Important: The current set date and time settings are displayed below the **Select the Date** *and* **Select the Time** *buttons.*

- To access Profiles use the **Edit Profiles** button.

System Log Sub-Tab

See Figure 3-29.

The ***System Log*** sub-tab window has a layout similar to the layout of Delivery Report windows but is not divided into distinct Delivery Report windows. The System Log scroll bar permits access to a chronologically sequenced and cumulative set of message entries about system procedures. There are also alert icons to designate when Warning and Error messages occurred during the procedure, but these icons are ***not*** touch-sensitive, and touching them does ***not*** display the corresponding Warning or Error window.

To send the System Log to a connected USB memory stick, press the **Export** button. A progress bar is momentarily displayed. An Information window appears once the export is successfully completed. Select **OK** to close this window.

A bug report may be generated in the same way by pressing the **Export Bug Report** button. A bug report is meant for NeuWave Medical personnel when troubleshooting system issues.

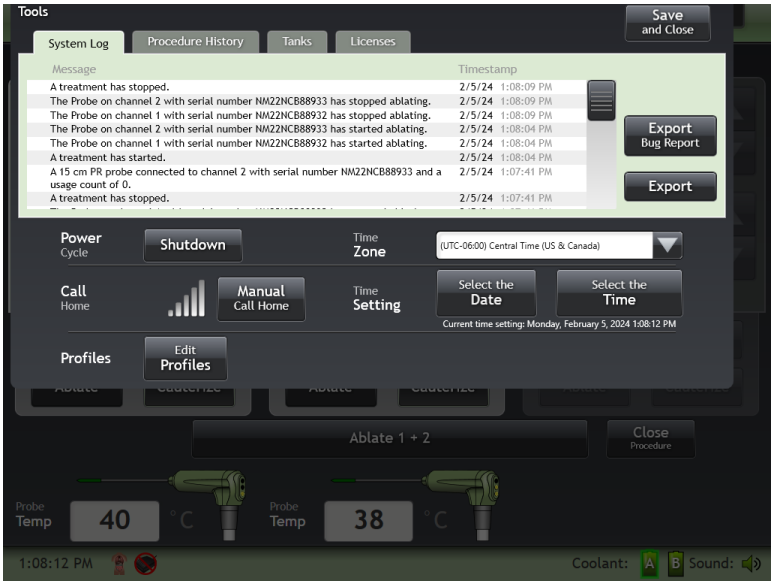


Figure 3-29: Tools Tab showing active System Log Sub-Tab.

Procedure History Sub-Tab

See Figure 3-30.

The ***Procedure History*** sub-tab window shows a chronologically sequenced set of message entries about probe use during a procedure. Each message entry shows:

- An icon which indicates what sort of probe data has been recorded.

Important:  icon denotes procedure performed only in Ablation Mode.

 icon denotes procedure performed only in Surgical Mode.

 icon denotes procedure performed in both Ablation Mode and Surgical Mode.

- The time at which a probe action took place.
- The duration of time energy was delivered to the probe.

In front of each entry is a gray button which, when touched, selects the entry. A selected entry button turns green. Pressing the button when it is green de-selects the entry.

- To select all the entries in the ***Procedure History*** sub-tab, press the **Select All** button. All entry buttons turn green.
- To de-select all entries, press the **Unselect All** button. All entry buttons turn gray.
- To send the Procedure History to a connected USB memory stick, press the **Export** button. A progress bar is momentarily displayed. An Information window appears once the export is successfully completed. Select **OK** to close this window.

Figure 3-30: Tools Tab showing Procedure History Sub-Tab and Procedure History

Tanks Sub-Tab

Refer to Residual Pressure Value (RPV) Section in Chapter 3.

Licenses Sub-Tab

Licenses vary based on software configuration. Please contact Ethicon Customer Service if additional support is needed.

4 Ablation and Surgical System Use

Tab Selection and Layout

When the system is turned ON and the tissue type has been selected, either the ***Ablation*** or ***Surgical*** tab may be selected, but no system functions or controls are fully usable until probes have been connected to the system and the connected probes have been properly tested. The functional probe test is described later in this chapter.

- ***Ablation*** Mode is used for Target Ablation. Target ablation involves placing a probe into a substantial target and then ablating for up to several minutes until the target tissue is necrotic. This is done either percutaneously, via laparoscope or in open surgical settings. In Ablation Mode, power delivery times can be set from 1 to 10 minutes per delivery.
- ***Surgical*** Mode is used for Surgical Coagulation – Surgical Coagulation involves using the probe(s) to ablate/coagulate for shorter periods of time, while moving the probe(s) frequently. This is often done using the technique called planar coagulation to create a plane of coagulated tissue in an organ prior to resection. In Surgical Mode, power delivery can be set for a maximum of 1 minute per delivery.

The ***Ablation*** tab and the ***Surgical*** tab have a similar, but not identical, appearance. Each display has:

- Three numbered Channel Setting areas
- A Control Button area for each channel
- One Control Bar
- One **Close Procedure** button

The ***Ablation*** tab's Channel Setting areas are displayed horizontally (left to right). The ***Surgical*** tab's Channel Setting areas are displayed vertically (top to bottom). These areas and controls remain shaded until one or more probes are connected to the system. See Figure 4-1.

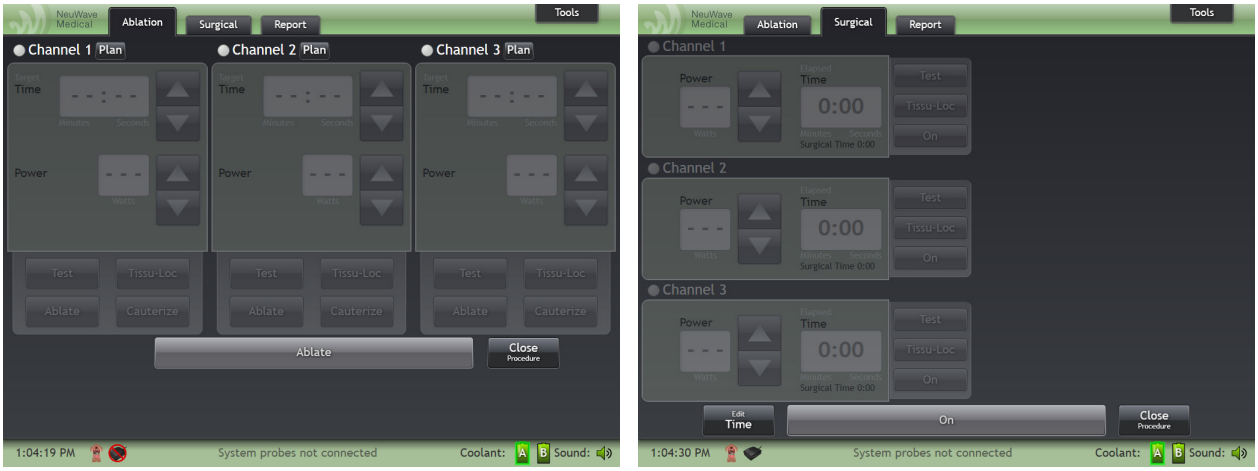


Figure 4-1: Ablation (left) and Surgical Tab (right) appearance when no probes are connected to the system. Controls are shaded in gray when they are inactive.

When a probe is connected to the system, its corresponding Channel setting area brightens, and the **Test** button activates (darkens) as shown in Figure 4-2.

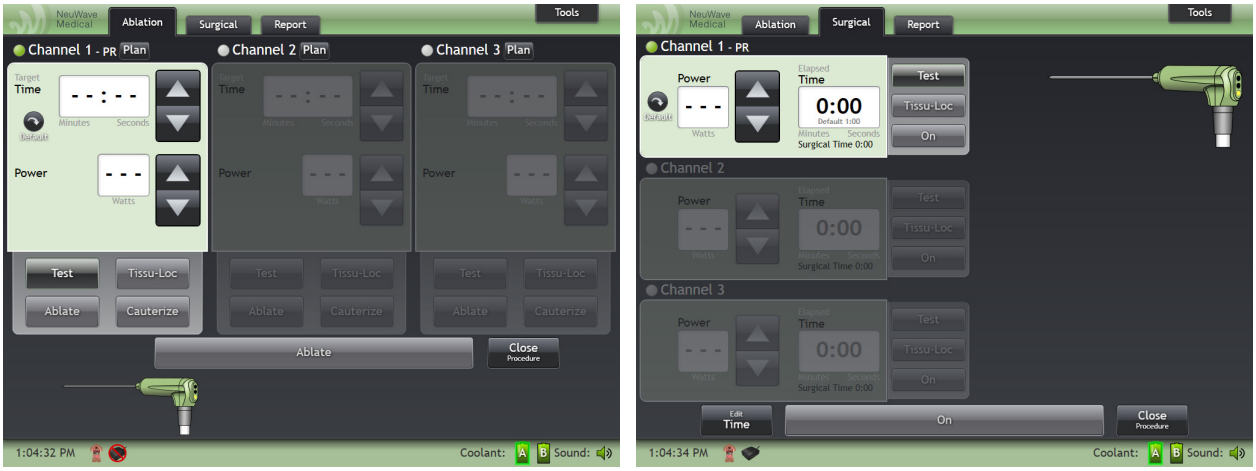


Figure 4-2: A Channel Setting area brightens when a probe is connected to the corresponding channel outlet

When multiple probes are connected to the system, each probe's corresponding Channel setting area brightens, and the **Test** button activates (darkens) for each probe, as shown in Figure 4-3.

Figure 4-3: Ablation and Surgical tab appearance when multiple probes are connected. Probe images are displayed for each connected probe.

When a probe is connected to the channel outlet, a color image of the probe handle appears within the corresponding channel area indicating that the connected probe is able to be tested and subsequently used.

The number of enabled probes affects the maximum amount of power that can be delivered by each probe, as described in the Probe Power Section of this chapter. Disabling a probe (or probes) increases the maximum power limits for the remaining active probe(s). To change a probe's status to 'Not Enabled', touch the probe icon within the corresponding probe channel area. The probe image will change from color to black-and-white, and a probe status box will appear over the probe's channel area, as shown in Figure 4-4.

Figure 4-4: Ablation and Surgical Tab appearance when the probe connected to Channel 2 is not enabled.

To enable a probe that is in 'Not Enabled' status, touch the black-and-white corresponding probe image.

Important: If additional probes are connected while another probe is actively delivering power, the status of the newly connected probe(s) will automatically be 'Not Enabled,' and can only be enabled when power delivery is stopped.

Ablation Probes

Before using the system for an actual procedure, it is important to know specific information about the ablation probes that can be used with the system and how using multiple probes in various combinations affect system operation.

See the Instruction for Use included with NeuWave Ablation Probes for complete probe information.

Visually inspect all packaging for damage, including a careful inspection of all sterile barrier systems for breaches in package integrity, immediately prior to use.

CAUTION Do not use if the product sterile barrier system or its packaging is compromised.

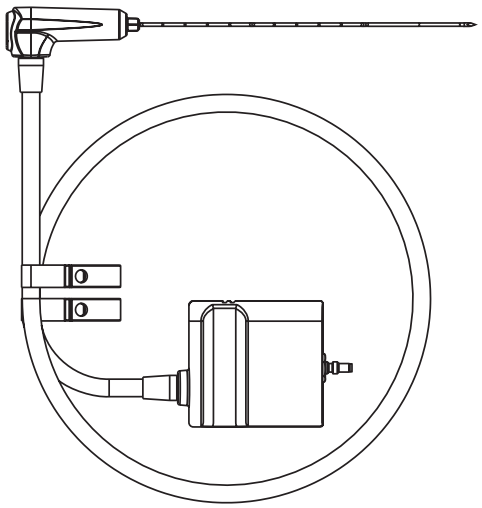


Figure 4-5: NEUWAVE Ablation Probe

Ablation probes are single patient use only. Do not attempt to reuse or re-sterilize ablation probes. Ablation probes connect to the PDM.

WARNING Do not connect ablation probes directly to the back of the cart as potential injury to the patient or user is possible.

LEDs in the probe handle light up to indicate which channel the probe is connected to. A probe plugged into channel 1 will have one (1) LED light up. A probe plugged into channel 2 will have two (2) LEDs light up and so on. The LEDs also pulse as a visual indicator when energy is being delivered.

Temperature sensors are placed in three locations on the probe: the probe handle, the Tissu-Loc™ zone and between the Tissu-Loc™ zone and the microwave emitting point.

The Tissu-Loc™ zone is the area of the cannula that cools down to adhere to tissue prior to applying energy. This enables the desired position of the probe to be maintained while using imaging to verify probe placement or when placing additional probes.

A protective sheath is provided installed on the ablation probe to protect the user from the sharp probe tip during removal from the package and to prevent accidental contact of the probe tip from non-sterilized surfaces during setup. The probe protective sheath must be removed prior to probe testing.

Selecting an Ablation Probe

WARNINGS
- Use only NeuWave Ablation Probes from NeuWave Medical with the NEUWAVE™ System. Probes from other manufacturers may cause patient injury or fail to function properly.
- Do not use damaged probes and probes beyond the expiration date noted on the packaging.

Several different models of ablation probes are available from NeuWave Medical.

Reference	*Model / Description*
LN15	NEUWAVE LN Probe 15 CM 17 ga
LN20	NEUWAVE LN Probe 20 CM 17 ga
LK15	NEUWAVE LK Probe 15 CM 17 ga
LK15XT	NEUWAVE LK XT Probe 15 CM 15 ga
LK20	NEUWAVE LK Probe 20 CM 17 ga
LK20XT	NEUWAVE LK XT Probe 20 CM 15 ga
PR15	NEUWAVE PR Probe 15 CM 17 ga
PR15XT	NEUWAVE PR XT Probe 15 CM 15 ga
PR20	NEUWAVE PR Probe 20 CM 17 ga
PR20XT	NEUWAVE PR XT Probe 20 CM 15 ga
PRS15	NEUWAVE Surgical PR Probe 15 CM 15 ga
PRS35	NEUWAVE Surgical PR Probe 35 CM 11/13 ga
NWSR25	NEUWAVE SR Probe 25 CM 13 ga

The different probes have different performance specifications.

Target Ablation Use Guide

Single Probes								
	LK	**LN**	**SR**	**PR**	**LKXT**	**PRXT**	**PRS15**	**PRS35**
Lung Tissue	✓	✓	See 4 below	✓	See 4 below	See 4 below	See 4 below	See 4 below
Liver Tissue	✓	See 3 below	✓	✓	✓	✓	✓	✓
Kidney Tissue	✓	See 3 below	✓	✓	✓	✓	✓	✓
Other Soft Tissue	See 1 below	See 3 below	See 1 below	See 1 below	See 1 below	See 1 below	See 1 below	See 1 below
Multiple Probes								
	LK	**LN**	**SR**	**PR**	**LKXT**	**PRXT**	**PRS15**	**PRS35**
Lung Tissue	See 4 below	See 4 below	See 4 below	See 4 below	See 4 below	See 4 below	See 4 below	See 4 below
Liver Tissue	✓	See 3 below	✓	✓	✓	✓	✓	✓
Kidney Tissue	See 1 and 2 below	See 3 below	See 1 and 2 below	See 1 and 2 below	See 1 and 2 below	See 1 and 2 below	See 1 and 2 below	See 1 and 2 below
Other Soft Tissue	See 1 below	See 3 below	See 1 below	See 1 below	See 1 below	See 1 below	See 1 below	See 1 below

Surgical Coagulation Use Guide

	LK	LN	SR	PR	LKXT	PRXT	PRS15	PRS35
Planar Coagulation Technique	Single-Probe Only	See 5 below	Single-Probe Only	Single-Probe or Two-Probe	Single-Probe Only	Single-Probe or Two-Probe	Single-Probe or Two-Probe	Single-Probe Only

1. Performance characteristics of NeuWave Ablation Probes have not been established in all probe and tissue type combinations.
2. Multiple probes make larger ablations than single probes. When using multiple probes, ensure that the target tissue is an appropriate size to limit the risk of unintended thermal damage to non-target tissue.
3. Use model NEUWAVE LN Probes only in lung tissue.
4. Performance characteristics of multiple probes and 15 ga or larger probes have not been established for lung tissue.
5. NeuWave does not recommend the planar coagulation technique in lung tissue.

All NeuWave Ablation Probes are intended for use in soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings.

The efficiency at which different types of soft tissue receive microwave energy differ based on the electrical properties of the tissue. The design differences in certain NeuWave Ablation Probes are intended to optimize the efficiency of energy transferred from the probe into different tissue types.

NEUWAVE LN Probes were designed to optimize energy transfer efficiency in lung tissue based on tissue properties. NeuWave recommends using NEUWAVE LN Probes only for lung.

Performance characteristics of multiple probes has not been established for lung tissue.

NEUWAVE LK Probes (LK, LKXT) were designed to optimize energy transfer efficiency in liver and kidney tissue based on tissue properties. However, NEUWAVE LK Probes can be used in all soft tissue.

NEUWAVE PR Probes (PR, PRXT, PRS15, PRS35) were designed to limit the length of the ablation for instances when a shorter ablation zone is desired. NEUWAVE PR Probes were developed to provide physicians with an additional ablation probe designed specifically for ablating smaller targets. The NEUWAVE PR Probes are designed to produce ablations that quickly encompass the tip of the probe while limiting the overall length of the ablation.

NEUWAVE SR Probes were designed for use in laparoscopic applications.

As always, use imaging to confirm desired ablation results for percutaneous applications. See the appropriate Instructions for Use for tables of ex-vivo ablation results.

Up to three (3) probes can be connected to the NEUWAVE System and powered at any time. This can be done to create one, larger ablation or three (3) independent ablations. Refer to the appropriate Instruction for Use for a table of ex-vivo ablation results and guidelines for minimum and maximum probe separation distances.

Bone Ablation

It is common to use bone introducers when ablating soft tissue lesions within a bone or when needing to penetrate cartilage. NeuWave recommends the following guidance when using the NeuWave Ablation Probes with introducers in these types of procedures to help avoid damaging the probe.

WARNINGS
- When using a probe in or near rigid structures such as bones and cartilage, use care not to apply excessive lateral force or excessively bend the probe. Near the probe tip, the probe shaft is made of ceramic, which may break if excessive force is applied. This may result in the probe tip being detached from the probe and possibly remaining in the patient.
- There are temperature sensors on the outside of the probe shaft. If the temperature sensors are damaged during placement or use of the probe, the NEUWAVE System will generate an error and disable the probe. To minimize the risk of damaging the temperature sensors during placement, avoid penetrating rigid structures such as bones and cartilage without the use of an introducer. Sharp instruments and hemostats/clamps should never be used along the probe shaft. Ultrasound guides and needle introducers should be used with caution.

1. When placing or removing NeuWave Ablation Probes into introducers, avoid placing excessive force on the side of the ablation probe. This lateral force can result in the probe being damaged.
2. Two techniques are recommended for placing and removing the NeuWave Ablation Probes when used in concert with bone introducers.
   a. Technique 1 (Introducer Removed for Ablation)
      - Use introducer to create access to lesion. Auger to distal aspect of the lesion in the direction of vital structures, if possible.
      - Remove introducer.
      - Guide NeuWave Ablation Probe into tract created by introducer. It is recommended that the guidance be directed initially from the tip of the probe. With finger tips at the surface of the skin, slowly guide the probe through the soft tissue and then bone.
      - Check probe placement with imaging.
      - Perform ablation.
      - Remove ablation probe by pulling straight back out of the bone and the lesion. Avoid moving probe from side to side during removal.
   b. Technique 2 (Introducer Present for Ablation)
      - Use introducer to create access to lesion.
      - Pull back introducer to distance where the end of the introducer (> 6 cm) will not be in the desired ablation zone.
      - Guide NeuWave Ablation Probe into introducer and into lesion.
      - Perform ablation.
      - Remove introducer and NeuWave Probe simultaneously. Do not push introducer back over NeuWave Ablation Probe prior to removal. Avoid moving probe or introducer from side to side during removal.
      - Because of the withdrawal technique, it is recommended to use a 20 cm probe when possible.

Probe Power

The maximum power is dependent on both the number of probes and probe types in use.

For LK, LN and SR Probes, the maximum power limits are as follows:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	140 Watts	140 Watts
Two	95 Watts	190 Watts
Three	65 Watts	195 Watts

For PR Probes, the maximum power limits are as follows:

When NEUWAVE PR Probes are Connected to the System and used in Ablation Mode:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	65 Watts	65 Watts
Two	65 Watts	130 Watts
Three	65 Watts	195 Watts

When NEUWAVE PR Probes are connected to the System and used in Surgical Mode:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	95 Watts	95 Watts
Two	95 Watts	190 Watts
Three	65 Watts	195 Watts

For Surgical PR probes, the maximum power limits are as follows:

When Surgical PRS15 Probes are Connected to the System and used in Ablation Mode:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	80 Watts	80 Watts
Two	80 Watts	160 Watts
Three	80 Watts	240 Watts

When Surgical PRS15 Probes are Connected to the System and used in Surgical Mode:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	110 Watts	110 Watts
Two	110 Watts	220 Watts
Three	80 Watts	240 Watts

When Surgical PRS35 Probes are Connected to the System and used in Ablation Mode:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	140 Watts	140 Watts
Two	110 Watts	220 Watts
Three	80 Watts	240 Watts

When Surgical PRS35 Probes are Connected to the System and used in Surgical Mode:

Number of Probes	*Maximum Power per Probe*	*Maximum Total System Power*
One	140 Watts	140 Watts
Two	110 Watts	220 Watts
Three	80 Watts	240 Watts

Connecting Ablation Probes

WARNINGS
- Examine each probe prior to use. Do not use probes with obvious visual damage. Injury to the user or patient may occur.
- Do not attempt to bend or reshape probes as they may malfunction when attached to the NEUWAVE System.
- Probes are provided sterilized. Follow your facility sterile handling guidelines.
- Probe tips are sharp. Handle with care.

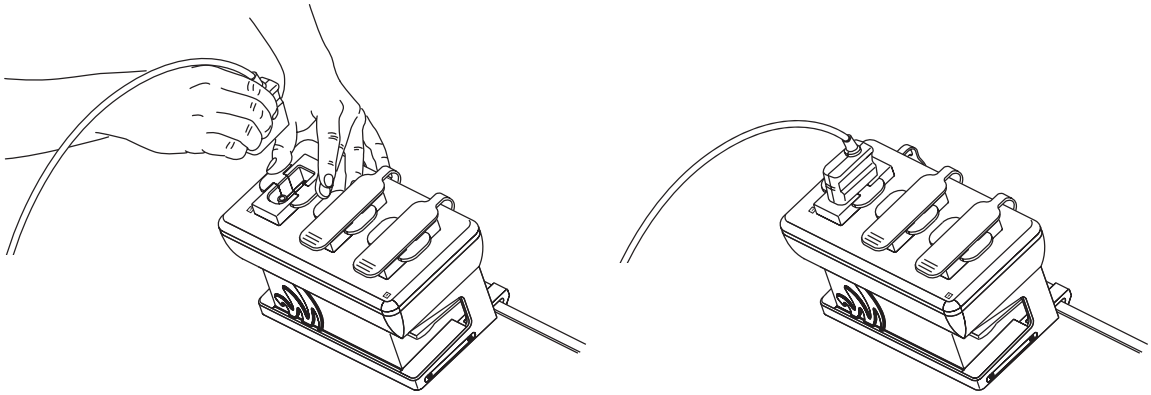


Figure 4-6: Connecting NEUWAVE Ablation Probe to PDM

1. Remove the PDM connector cover for the channel being used.
2. Align the probe connector with the desired channel on the PDM. The channel connection number will correspond to the controls on the system display.
3. Press the two connector release tabs on the PDM channel and push the probe connector into the PDM channel.
4. Release the metal tabs.
5. If a proper connection was made, the metal tabs will return to their original position and the system display will indicate a connected probe. If not, remove the probe and repeat steps 1-3.

Figure 4-7: Ablation Tab After Channel 1 Probe connected to PDM.

Functional Test of Connected Probe

WARNINGS

- Do not use any probes that fail to pass the system test or show evidence of a CO_2 leak. Use of a faulty probe could lead to user or patient injury.
- Never press the **Test** button when the probe tip is in air. Testing in air does not allow for the check of a CO_2 leak. Use of a faulty probe could lead to user or patient injury.

Conduct this test for all probes connected to the system whether using the ***Ablation*** or ***Surgical*** modes.

System controls remain disabled until a connected probe successfully passes a system test. To test a probe:

1. Remove the probe's protective sheath.
2. Place the probe tip into a clear container of sterile water. See Figure 4-8.
3. On the User Interface Tab Display, press the **Test** button for the channel to which the probe is connected. After pressing the **Test** button, the button turns green and a Test Status area appears in place of the probe image that was previously displayed. See Figure 4-9.
4. The Test Status area shows two bottle icons and three rows of text that relate to the test status. The three lines of text above the bottle icons do the following:
   a. The first line indicates that the actual probe tip is in the water bottle.
   b. The second line, Self Diagnostic, is followed by a pin-wheel icon which spins as the system performs power delivery and temperature sensing functions. The pin-wheel changes to a check mark once the system has performed these functions.
   c. The third line requires the user to answer a question regarding the results of the actual probe test.

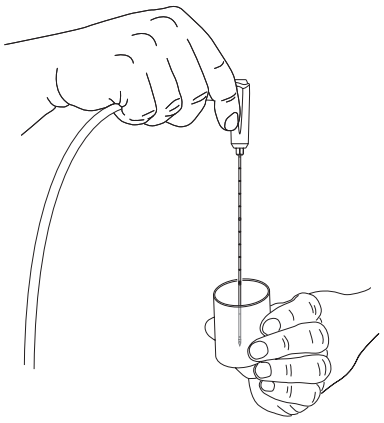


Figure 4-8: Probe tip placed in sterile water bottle

Important: The system's functional probe test may be stopped by pressing the green **Test** *button.*

1. During the test, observe the actual probe tip in the sterile water bottle. Verify that no bubbles appear in the water. The presence of bubbles indicates a leak in the CO_2 cooling system or a faulty probe that should not be used.
2. Press the bottle icon that matches what you see happening in the actual water bottle.
   a. Selecting the bottle icon that has bubbles displays a **Warning** window. See Figure 4-10. Follow the instructions in the Warning window,
   b. Selecting the bottle icon without bubbles indicates that the user did not see bubbles when the actual probe tip was immersed in the actual water bottle. The functional probe test area is replaced with the probe image.

Figure 4-9: Probe on Channel 1 is being tested (Ablation Tab).

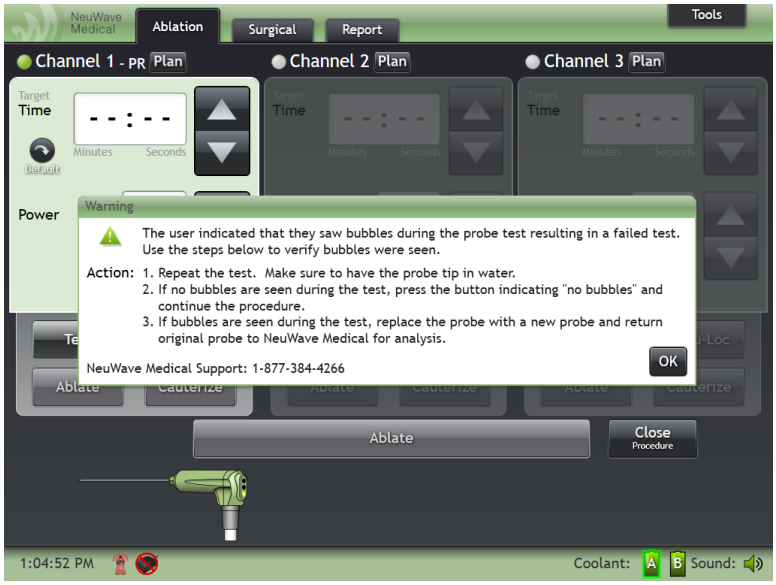


Figure 4-10: When the bottle icon with bubbles is selected, a 'Replace this probe' Warning window is displayed.

Figure 4-11: Ablation Tab with probe on Channel 1 successfully tested

The NEUWAVE System requires a test in sterile water or saline when probes are first connected to the system. In addition to the initial test, there may be instances during the procedure where another test is required, such as error conditions, moving a probe between channels, or a system reboot.

Should a retest be required after a probe is placed in the patient/target tissue, a decision must be made by the physician whether to remove the probe from the patient and test it in sterile water or saline as is required for the first test of a probe, or to repeat the probe test with the probe in the tissue. NeuWave provides the following information to physicians when assessing the relative risks of each:

Probe Test Overview:

The probe test involves the NEUWAVE System delivering a small amount of power to the probe and measuring the probe response to ensure proper energy delivery and temperature measurement functions. Additionally, a small amount of CO_2 cooling is sent to the probe. This is done only to confirm the mechanical integrity of the probe tip area. When tested in water, a damaged probe will produce bubbles. If a probe is found to be damaged, it should not be used in the procedure and should be replaced with a new probe.

Risk Summary:

No studies have been done to investigate the effects of testing a probe in tissue, though there is no known risk to the patient from the small amount of microwave energy delivered to the tip during a probe test. If the probe seal is uncompromised, there is also no known risk to the patient when the small amount of CO_2 is delivered to the probe.

However, the integrity of the probe cannot be guaranteed as it could have been damaged after initial testing if significant force was applied to it. If the probe cannula was damaged after the initial probe test, there is a risk of gas embolus to the patient from the CO_2 used during the probe test. If a user believes damage has occurred to the probe, it is recommended to remove the probe and test again in sterile water.

Probes that require a retest cannot perform other energy delivery functions until they have passed test. This means that tract cautery function cannot be used when removing the probe from the target tissue, which could present risk of bleeding or seeding, depending on the specific biology of the target tissue.

All NeuWave Probes are 100% tested for CO_2 leaks during manufacture. Additionally, all NeuWave Probes are 100% tested by users before use. If a probe passes the initial user test, significant physical force to the probe tip/shaft would be required to create a CO_2 leak scenario.

When a probe is successfully connected:

1. Its corresponding Channel Setting area activates (brightens), and an image of the probe is displayed below the Channel controls. The handle of the probe image (and the actual probe handle) has a single yellow LED lit for Channel 1, two LEDs lit for Channel 2, and three LEDs lit for Channel 3.
2. The circle to the left of the Channel Number turns green.
3. The text to the right of the Channel Number automatically indicates the probe type (NEUWAVE LK, NEUWAVE LN, NEUWAVE SR or NEUWAVE PR) connected to the channel.
4. "--:--" remains displayed in the Time box, and "- - -" in the Power box until desired values have been set.

*Important: Pressing the **Default** button will set both the power and time to default values in selected Profiles.*

Figure 4-12: Ablation Tab with one probe connected (left) and with two probes connected (right)

Figure 4-13: Touch the Channel Number to see probe identification information.

Probe Identification

When a probe is connected to the system, probe identification information can be viewed by touching the corresponding Channel Number as shown in Figure 4-13.

Using Ablation Mode/Percutaneous Applications

Placing a Probe

Standard biopsy technique is recommended for placement of the NeuWave Ablation Probes. Verify proper placement of the probe.

WARNINGS

- Prior to starting an ablation, use imaging to confirm proper probe placement and that the probe is not bent or broken.
- Never activate power to a probe when the probe tip is in the air. The system will detect a “reflected power” error and stop delivering energy.
- Probe movement during ablation is possible. Probe movement can be caused by patient movements from breathing, coughing, etc. and also by pressure applied to the probe when target tissue contracts in response to the ablation. To help prevent probe movement, hold the probe handle in place during the initial period of the ablation (at least 45 seconds). Monitor the probe for movement throughout the procedure and hold the probe in place as needed. If repositioning of a probe is required, stop energy delivery prior to repositioning the probe.
- There are temperature sensors on the outside of the probe shaft. If the temperature sensors are damaged during placement or use of the probe, the NEUWAVE System will generate an error and disable the probe. To minimize the risk of damaging the temperature sensors during placement, avoid penetrating rigid structures such as bones and cartilage without the use of an introducer. Sharp instruments and hemostats/clamps should never be used along the probe shaft. Ultrasound guides and needle introducers should be used with caution.

WARNINGS
- The probe cable can heat and reach 60° C during energy delivery. When placing the probe verify that the probe cable does not rest on the patient's skin. Use the included clips to secure the probe cable away from the patient's skin as needed.
- Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.
- Never bend or apply excessive force to the probe. Probe malfunction may occur, possibly causing user and/or patient injury.
- NeuWave Ablation Probes can be used with needle introducers. If a needle introducer is used, it must be retracted so that it doesn't interfere with the planned ablation zone prior to delivering energy. Failure to retract the needle introducer a sufficient distance may impact power delivery. Introducers used with 17 gauge probes must be 14 gauge introducers or larger to help minimize the risk of probe damage.
- Do not apply a clamp or hemostat to the probe shaft or cable as this may damage the probe and cause a malfunction.

Important: When using probes in situations that require repositioning the probe during use, always press the Stop Ablate button prior to removing the probe from tissue. If the probe is removed from the tissue while ablating, the system will detect an error and stop delivering energy.

Important: Probe temperatures are highly dependent on tissue variables such as perfusion and vasculature. Probe temperatures are likely to vary from procedure to procedure based on these tissue variables. These temperature variations do not, by themselves, indicate a malfunctioning probe or system.

The NEUWAVE System automatically controls the flow of CO_2 to maintain safe temperatures. When ablating, the system will increase and decrease CO_2 flow based upon temperature measurements. At moments of initial CO_2 flow increase, the temperature displayed on the screen may momentarily drop and then return to higher temperatures (above 60° C). This is normal behavior and does not impact ablation size or indicate a malfunctioning probe or system.

Reflected Power Error

If the probe is not in tissue while energy is being delivered, the system will detect a reflected power error and stop delivering energy. This applies to probes whether used in ***Ablation*** or ***Surgical*** modes. If this occurs:

1. Power delivery is stopped.
2. This icon  appears on the channel box. Pressing the icon displays additional information.
3. The reflected power error tone (a sound distinct from other errors) indicates that power delivery has stopped on the probe experiencing reflected power. If multiple probes are ablating when the error occurs, power delivery will continue on any probes not experiencing reflected power.
4. The green highlight around the Time Remains box disappears and is replaced by a purple box.
5. The green circle to the left of the probe number stops pulsing.
6. The tip of the graphic probe turns green and stops pulsing.
7. The LEDs in the graphic probe handle stop pulsing.
8. The **Stop Ablate** and **Stop All Ablation** buttons change to **Ablate**.

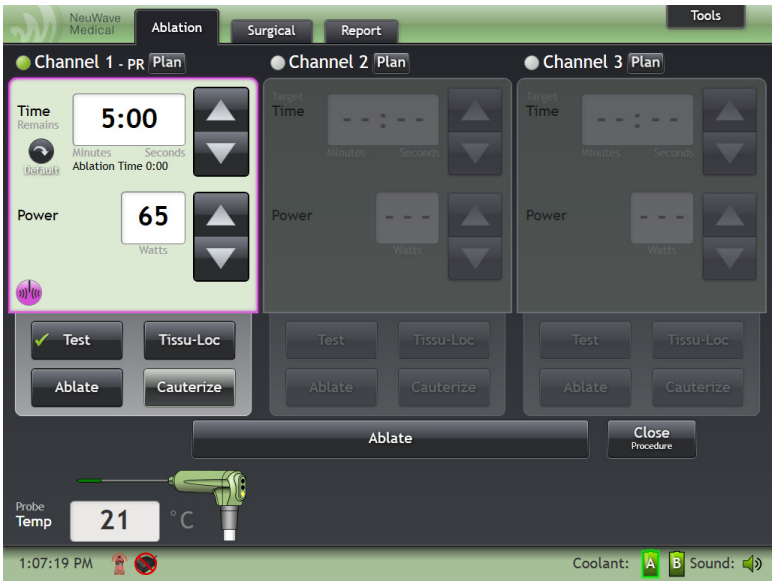


Figure 4-14: Channel Settings Area if trying to deliver energy with probe not in tissue

Ablation Time and Power Setting Buttons

Pressing the ▲ and ▼ buttons next to the Time box adds or subtracts from the Target Time in 1 minute increments.

The ▲ and ▼ buttons next to the Power box add or subtract from the Power in 5 W increments.

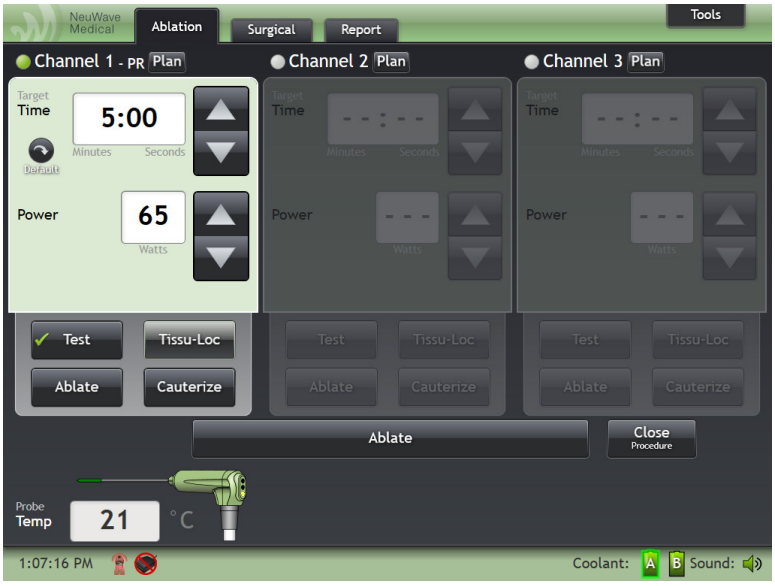


Figure 4-15: Channel 1 with Target Time and Power Value settings entered

Important: If planning and incorporating single or multiple probe simulation, reference Chapter 3 Ablation Visualization Window and Ablation Zone Guidance Factors sections in Chapter 3 for details for using with or without probe(s) connected.

Ablation Probe Function Buttons

For each connected probe, **Test, Tissu-Loc™, Ablate,** and **Cauterize** buttons are present. Use of the **Test** button was explained earlier in the Functional Test of Connected Probe Section of this chapter. Use of the other three buttons is explained in the following sections.

*Important: Each connected probe must successfully pass a functional test before **Tissu-Loc™, Ablate, or Cauterize** buttons are activated. The functional test must be conducted and passed before a probe can be used for ablation or surgical functions. Once a probe passes, the functional controls in both Ablation and Surgical tabs become active.*

Ablation Tissu-Loc™ Button

Pressing the **Tissu-Loc™** button starts the CO_2 cooling system to cool the Tissu-Loc™ Zone in the probe to between 0 and -15° C (-20 to -25° C for NEUWAVE PR Probes).

When the **Tissu-Loc™** button is pressed:

1. The Tissu-Loc™ Zone temperature is displayed below the probe image.
2. The Tissu-Loc™ area of the probe image is shown in blue.
3. The **Tissu-Loc™** button briefly turns green, and its text changes to **Stop Tissu-Loc™**. The button does not respond to touch while it is green.
4. Once the Tissu-Loc™ Zone temperature reaches -5° C, the button turns gray, a green check mark appears on the button, and the button text reads **Stop Tissu-Loc™**.
5. Pressing the **Stop Tissu-Loc™** button having the green check mark, briefly changes the button to green, and then returns the button to its idle condition (no green check mark).

Figure 4-16: Probe connected to Channel 1 is in Tissu-Loc™ and probe connected to Channel 2 is idle.

*Important: Pressing any active button automatically stops the current active function and initiates the requested control function. For example, if the **Tissu-Loc™** function is active and the **Ablate** button is pressed, the **Tissu-Loc™** function turns off and the system begins delivering energy to the probe.*

Ablate and Stop Ablate Button and Bar

Pressing the **Ablate** button within an individual Channel Setting area starts the system delivering energy to the probe connected to that channel.

When more than one probe is connected, the long gray Control Bar just above the probe images becomes an **Ablate** control that can simultaneously send energy to *all* connected and function-tested probes.

The text in the **Ablate** controls changes, based on which probes are in use, as shown in Figure 4-17 and Figure 4-18.

Figure 4-17: Channel 1 Ablate Button has been pressed.

Figure 4-18: Ablate Bar has been pressed for Channels 1 and 2.

When a channel's **Ablate** button is pressed:

1. The text on the button changes to **Stop Ablate** and the button turns green.
2. The Probe Temp (probe temperature) is displayed below the probe image.
3. A green highlighted outline appears around the Time box to indicate that power is being delivered.

Important: The Time box changes to either a Time Remains box or an Elapsed Time box once power delivery has been initiated. This is a user-selectable option. Refer to the Edit Profiles Section in Chapter 3 for more information.

4. The green circle to the left of the probe's Channel Number pulses.
5. The Time display begins to count down from the Target Time or count up to the Target Time.
6. The starting Target Time is shown below the Time box.
7. A green highlighted outline appears around the upper portion of the Channel Setting area.
8. The **Test, Tissu-Loc™**, and **Cauterize** buttons are disabled and appear in faded gray.
9. The tip of the probe image alternates color.
10. The green LED or LEDs in the probe handle image (and actual probe handle) pulse.
11. An audible tone sounds continuously to indicate that power is being delivered. If more than one probe is delivering power, the audible tone changes pitch.

Figure 4-19: Channel 1 probe ablating and Channel 2 probe ready for use but not delivering energy.

When the **Stop Ablate** button or **Stop All Ablation** bar is pressed:

1. Energy delivery is stopped.
2. The green highlight around the Time box disappears.
3. The Ablation Time is displayed below the Time box. This indicates the total time that power has been delivered via that probe.
4. The green circle to the left of the probe number stops pulsing.
5. The tip of the probe image turns green and stops pulsing.

6. The LEDs in the probe handle image (and the actual probe handle) stop pulsing.
7. The **Stop Ablate** and **Stop All Ablation** controls change to **Ablate**.
8. The **Tissu-Loc™** and **Cauterize** buttons are active.
9. The Probe Temp remains on the display.

Using Cauterize Feature

A cauterizing feature is available to cauterize the insertion track when removing the probe from the patient. This feature is to cauterize the insertion track only and should not be used to ablate or cauterize target tissue. Only one probe can be used in Cauterize mode at a time. No other probes can be delivering energy when cauterizing with a probe.

Pressing the **Cauterize** button sets the generator to a specific power level. The power level is designed to cauterize the insertion track and approximately 1-4 mm of tissue around the insertion track when used appropriately. Only one probe at a time delivers energy when using the **Cauterize** button.

WARNING Cauterizing track sizes are dependent on probe temperature and probe removal rate. Cauterizing with probes at higher temperatures and/or with slower rates of removal may result in larger cautery tracks.

CAUTION Removing the probe too slowly while cauterizing may result in a probe temperature error.

1. Press the **Cauterize** button.
2. The Probe Temp is displayed on the screen. When the probe temperature reaches at least 60° C, begin slowly (approximately 1 cm every 5 seconds) pulling the probe from the patient.
3. Closely watch the probe and slowly remove it.
4. Refer to the probe Instructions for Use to locate the End Cauterize Marking. When the End Cauterize Marking is visible, stop removing the probe from the patient.
5. Press the **Stop Cauterize** button.
6. Fully remove the probe from the patient.

WARNINGS
- Probes removed from the body may be hot. Handle with care to avoid user and/or patient injury.
- Do not handle probes that appear excessively cold.

Changes on the display screen when the **Cauterize** button is pressed:

1. The text on the **Cauterize** button changes to **Stop Cauterize** and the button turns green.
2. The Probe Temp is displayed below the probe image.
3. The **Test, Tissu-Loc™**, and **Ablate** functions are disabled and are in faded gray for the probe actively cauterizing. For other enabled probes, the **Ablate** and **Cauterize** functions are disabled and are in faded gray.
4. A green highlighted outline appears around the Power and Target Time boxes to indicate power delivery.
5. The green circle to the left of the probe's Channel Number pulses.

6. The tip of the probe image alternates colors.
7. The LED on the probe handle image (and the actual probe handle) pulses.
8. The power and time settings are inactive and show dashes.
9. The Probe Temperature remains on the display.

Figure 4-20: Ablation Tab with Cauterize Button in use for Channel 1 probe.

When the **Stop Cauterize** button is pressed, the probe data returns to Default Power and Time settings of the selected Profile.

Ablation Close Procedure Button

The **Close Procedure** button (to the right of the Control Bar) is only available when there are no connected probes actively delivering energy. When the **Close Procedure** button is pressed, a message window indicating that the procedure was successfully closed appears on the display. Closing the procedure creates a data record about the procedure. When the procedure has successfully closed, the system will return to the Tissue Selection screen.

Using Surgical Mode

If a Footswitch is connected to the system, it will be active when the ***Surgical*** tab is selected.

In the Surgical tab, three Channel Setting areas remain shaded in gray until one or more probes are connected to the system and pass the probe function test.

When a successfully tested probe is connected:

1. Its corresponding Channel Setting area activates (brightens), and an image of the probe is displayed below the Channel controls. The handle of the probe image (and the actual probe handle) has a single yellow LED lit for Channel 1, two LEDs lit for Channel 2, and three LEDs lit for Channel 3.
2. The circle to the left of the Channel Number turns green.
3. The text to the right of the Channel Number automatically indicates the probe type (NEUWAVE LK, NEUWAVE LN, NEUWAVE SR, or NEUWAVE PR) connected to the channel.
4. “0:00” is displayed in the Time box, and “- - -” in the Power box until the desired settings are made.

Important: Pressing the Default button will set Power to the default value of the Profile selected. The default value is set in the Profiles window. See the Edit Profiles Section in Chapter 3 for instructions on how to set Surgical default Power values.

5. Surgical Time elapses and probe activation is ***not*** cumulative. Each instance of probe activation resets the Time to "0:00."

Figure 4-21: Surgical Tab Display showing probe connected to Channel 1.

Probe Identification

In the **Surgical** tab display, when a probe is connected to the system, probe identification information can be viewed by touching the corresponding Channel Number.

Figure 4-22: Touch the Channel Number to see probe identification information.

Surgical Power Setting Buttons

The  and  buttons next to the Power box add or subtract from the Power in 5 W increments.

Figure 4-23: Surgical Tab with Power settings selected.

Surgical Probe Control Buttons

For each connected probe, **Test, Tissu-Loc™**, and **On** buttons are present.

*Important: Each connected probe must successfully pass a functional test before the **On** button is activated. The functional test must be conducted and passed before a probe can be used for ablation or surgical functions. Once a probe passes, the functional controls in both **Ablation** and **Surgical** tabs become active.*

Surgical Tissu-Loc™ Button

Pressing the **Tissu-Loc™** button starts the CO_2 cooling system to cool the Tissu-Loc™ Zone in the probe to between 0 and -15° C (-20 to -25° C for NEUWAVE PR Probes).

When the **Tissu-Loc™** button is pressed:

1. The Tissu-Loc™ Zone temperature is displayed below the probe image.
2. The Tissu-Loc™ area of the probe image is shown in blue.
3. The **Tissu-Loc™** button briefly turns green, and its text changes to **Stop Tissu-Loc™**. The button does not respond to touch while it is green.
4. Once the Tissu-Loc™ Zone temperature reaches -5° C, the button turns gray, a green check mark appears on the button, and the button text reads **Stop Tissu-Loc™**.
5. Pressing the **Stop Tissu-Loc™** button (which has a green check mark) briefly changes the button to green, and then returns the button to its idle condition (no green check mark).

Figure 4-24: A NEUWAVE PR Probe is connected to Channel 1 and the Tissu-Loc button is enabled and active.

Important: Pressing any active button automatically stops the current active function and initiates the requested control function. For example, if the Tissu-Loc™ function is active and the ***Ablate*** *button is pressed, the Tissu-Loc™ function turns off and the system begins delivering energy to the probe.*

Surgical On and Stop Controls

Power delivery can be controlled via the system display or the footswitch, if connected.

Pressing the Surgical **On** button within an individual Channel Setting area starts the system delivering energy to the probe connected to that channel.

When more than one probe is connected, the long gray Control Bar at the bottom of the display becomes an **On** control that can send energy to *all* connected and function-tested probes.

Depressing the Footswitch or Fingerswitch mimics the action of pressing the long gray Control Bar; however, the Footswitch or Fingerswitch must be depressed and held down for power to be delivered. If power delivery is initiated by the Footswitch or Fingerswitch, power delivery will stop when the Footswitch or Fingerswitch is released.

The Automatic Shutoff setting determines how long power can be delivered. See Chapter 3 for more details.

The text within the **On** buttons changes based on which probes are in use as shown in Figure 4-25 and Figure 4-26.

Figure 4-25: Surgical Tab with 1 probe connected on Channel 1 and the On Button has been pressed

When a channel's **On** button is pressed:

1. The **On** button text changes to **Off** and the button turns green.
2. The Probe Temp is displayed below the probe image.
3. The Time box changes to an Elapsed Time box, and time is automatically reset to "0:00" and begins counting up.
4. A green highlighted outline appears around the Power box and Time box to indicate power is being delivered.
5. The green circle to the left of the probe's Channel Number pulses.
6. The Time display begins to show elapsed time.
7. A green highlighted outline appears around the Power box and Time box.
8. The tip of the probe image alternates color.
9. The green LED or LEDs in the probe handle image (and actual probe handle) pulse.
10. An audible tone sounds continuously to indicate power is being delivered.
11. If more than one probe is delivering power, the audible tone changes pitch.

Figure 4-26: Surgical Tab with two probes connected and Control Bar has been pressed.

When the **Off** button or **Stop All** bar is pressed:

1. Energy delivery is stopped.
2. The green highlight around the Time box disappears.
3. The green circle to the left of the probe number stops pulsing.
4. The tip of the probe image turns green and stops pulsing.
5. The LEDs in the probe handle image (and the actual probe handle) stop pulsing.
6. The **Off** and **Stop All** controls change to **On**.
7. The **Tissu-Loc™** button is active.
8. The Probe Temp remains on the display.
9. The Surgical Time display changes to show the cumulative time for which power has been delivered to that probe in the current procedure.

Figure 4-27: Surgical Tab showing Off/Stop controls.

Surgical Close Procedure Button

The **Close Procedure** button (to the right of the Control Bar) is only available when there are no connected probes actively delivering energy. When the **Close Procedure** button is pressed, a message window indicating that the procedure was successfully closed appears on the display. Closing the procedure creates a data record about the procedure. When the procedure has successfully closed, the system will return to the Select Profile and Tissue window.

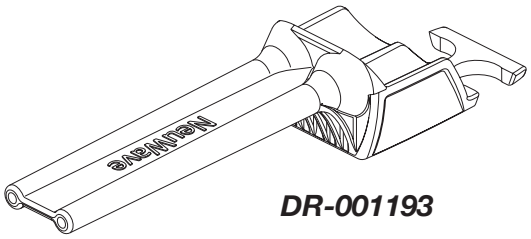
Planar Coagulation Technique

NeuWave Ablation Probes can be used for planar coagulation, a technique designed to create a line of ablated tissue through an organ, often prior to resection. See the probe Instructions for Use for information regarding planar coagulation performance of different probe types.

Planar coagulation can be achieved using either one or two probes.

Two-Probe Technique

The two-probe technique involves the use of a Surgical Clip accessory and two probes. The data included in the probe Instructions for Use was generated using the following picket-fence pattern.



DR-001193

Probe/Clip Compatibility Guide

Probe Models	*DR-001193 / RCPK*
17 ga probes (PR15, PR20, LK15, LK20)	Acceptable for use
15 ga probes (PR15XT, PR20XT, PRS15, LK15XT, LK20XT)	Acceptable for use
13 ga probes (NWSR25)	Not compatible; probe damage likely
11/13 ga probe (PRS35)	Not compatible; probe damage likely

WARNING • The Surgical Clip (DR-001193) is designed for use with either 15 or 17 gauge probes. To avoid damage to the surgical clip and/or the probes, do not use 11/13 gauge (PRS35) or 13 gauge (SR) probes with the Surgical Clip (DR-001193).

1. Use the NEUWAVE System in Surgical Mode.
2. Perform **Test** of each probe intended to be utilized.
3. Insert two (2) NeuWave Ablation Probes into the Surgical Clip. Using the surgical clip ensures both a 1.5 cm spacing between the probes as well as parallel probe placement.
4. Use Figure 4-28 as guidance for probe placement. Insert the two (2) probes into the target tissue. This first placement will correspond to the two probes labeled “1” in Figure 4-28.

Important: For all probe insertions, ensure that the probes are inserted at least 1 mm beyond the solid green area of the probe as noted in Figure 4-28. If the probes are inserted to a more shallow depth, a reflected power error may occur.

5. Deliver power at the desired power and time settings by pressing the **On** button or depressing and holding the footswitch.
6. Remove the probes from the target tissue and move the probes linearly such that one probe is placed between the coagulation zones created by the first probe placement, corresponding to the probes labeled “2” in Figure 4-28.

Important: Coagulation areas will be highly dependent on tissue characteristics such as tissue depth/thickness and vascularity. Visually assess the coagulation zones created by the initial few insertions/deliveries and adjust the power and time settings or probe spacing as needed to achieve the desired results.

WARNING Charred tissue may accumulate on the probe tip during planar coagulation. As needed, use a sterile soft cloth or soft pad to remove any tissue build up on the probe tip. Probe tip may be hot. Never use a rough surface or scratch pad to clean the probe tip as this may damage the probe and result in errors or malfunction.

7. Deliver power at the desired power and time settings by pressing the **On** button or depressing and holding the footswitch.
8. Remove the probes from target tissue and move the probes linearly such that one probe is placed approximately in the same location as the previous placement and one probe is in uncoagulated tissue, corresponding to probes labeled “3” in Figure 4-28.

9. Deliver power at the desired power and time settings by pressing the **On** button or depressing and holding the footswitch.
10. Continue moving probes and delivering power using Figure 4-28 as a guide.
11. Figure 4-28 shows placement guidance for 6 distinct probe placements during the procedure. The same pattern can be used for procedures that require an additional number of placements.

Important: NEUWAVE PR Probes are designed to produce ablations that quickly encompass the tip of the probe. Other NeuWave probes may not encompass the probe tip when performing planar coagulation.

Important: Use of different probe placement patterns will result in different ablation zone characteristics. For example, probe placement patterns with more overlapping placement will likely result in a wider plane of coagulation, depending on power and time settings.

Important: NeuWave does not recommend the use of NEUWAVE LN Probes for planar coagulation.

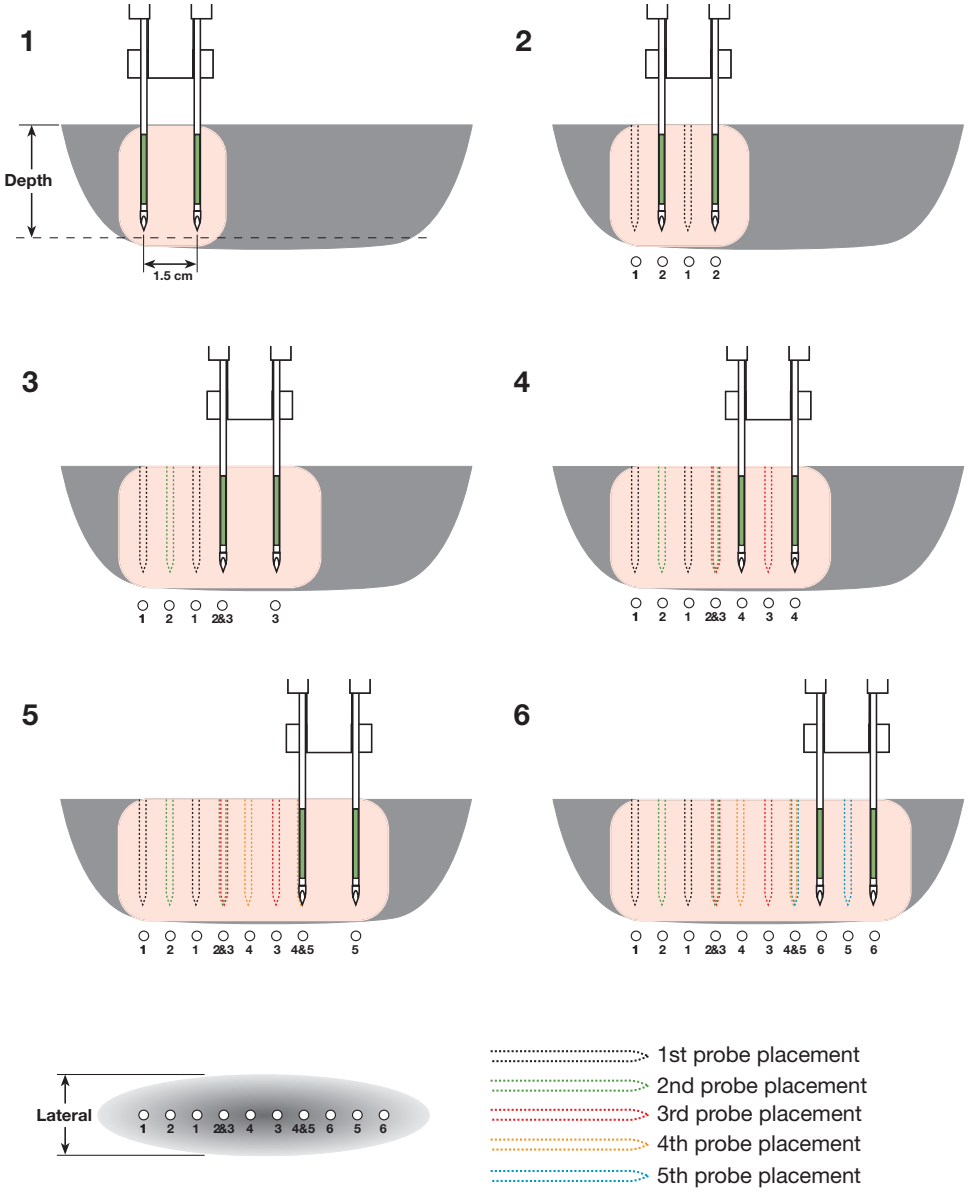


Figure 4-28: Two-Probe Planar Coagulation probe placement

Single-Probe Technique

When using a single probe, either a 17 gauge (NEUWAVE LK or NEUWAVE PR), 15 gauge (NEUWAVE LK, NEUWAVE PR or NEUWAVE Surgical PRS15 probe), or 13 gauge (NEUWAVE SR), or 11/13 gauge (NEUWAVE Surgical PRS35 probe) can be used. NeuWave recommends the following procedure:

1. Use the NEUWAVE System in Surgical Mode.
2. Perform **Test** for the probe to be utilized.
3. Use Figure 4-29 as guidance for probe placement. Insert the probe into the target tissue.

Important: Ensure that the probe is inserted at least 1 mm beyond the solid green area of the probe as noted in Figure 4-29. If the probe is inserted to a more shallow depth, a reflected power error may occur. If a more shallow insertion depth is used, a reflected power error may occur.

4. Deliver power at the desired power and time setting by pressing the **On** button or depressing and holding the footswitch or fingerswitch.
5. Remove the probe from the target tissue and move the probe linearly approximately 0.75 cm.

   WARNING Charred tissue may accumulate on the probe tip during planar coagulation. As needed, use a sterile soft cloth or soft pad to remove any tissue build up on the probe tip. Probe tip may be hot. Never use a rough surface or scratch pad to clean the probe tip as this may damage the probe and result in errors or malfunction.

6. Repeat steps 3-5 until the desired plane of coagulation is achieved.

Important: Coagulation areas will be highly dependent on tissue characteristics such as tissue depth/thickness and vascularity. Visually assess the coagulation zones created by the initial few insertions/deliveries and adjust the power and time settings or probe spacing as needed to achieve the desired results.

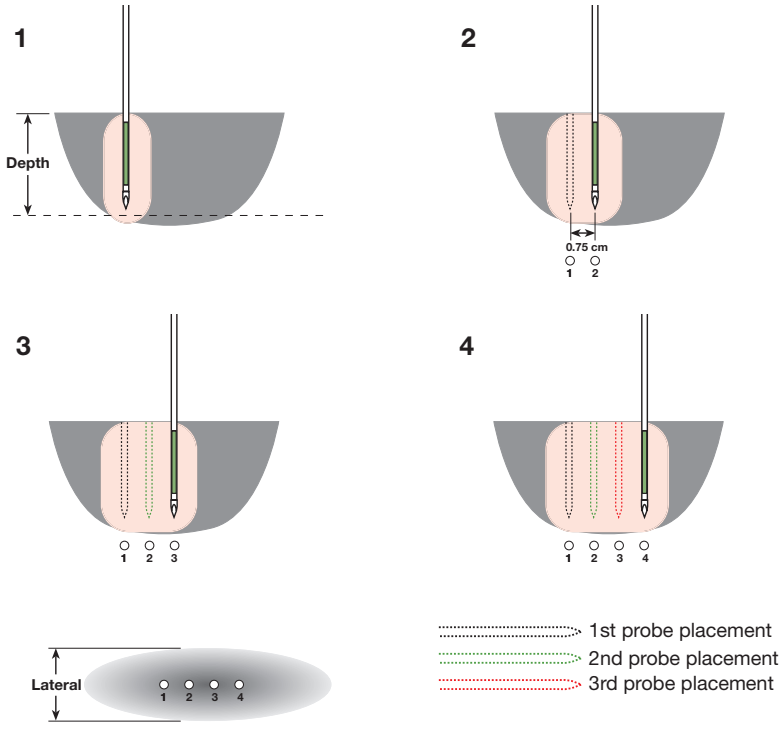


Figure 4-29: Single-Probe Planar Coagulation probe placement

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5 After a Procedure

End Procedure

At the conclusion of the procedure, press the **Close Procedure** button.

Turning the System Off

When done using the system, press the System ON/OFF switch to turn the system off.

When turning off the system, the LEDs in the ON/OFF switch will blink while the internal system safely shuts down. Wait for the LEDs to extinguish completely (should take less than 30 seconds) before disconnecting the power cord.

CAUTION A system error could result if power is disconnected while the system is shutting down.

Probe Disposal

Disconnect all NeuWave Ablation Probes from the PDM and dispose of probes according to local requirements and regulations for sharps. Probes which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

Some internal components of this device contain lead. Disposal should be performed according to local requirements and regulations.

Dispose of all opened instruments whether used or unused. This device is packaged and sterilized for single use only.

Serious Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation EU 2017/745); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

AC Power Cord

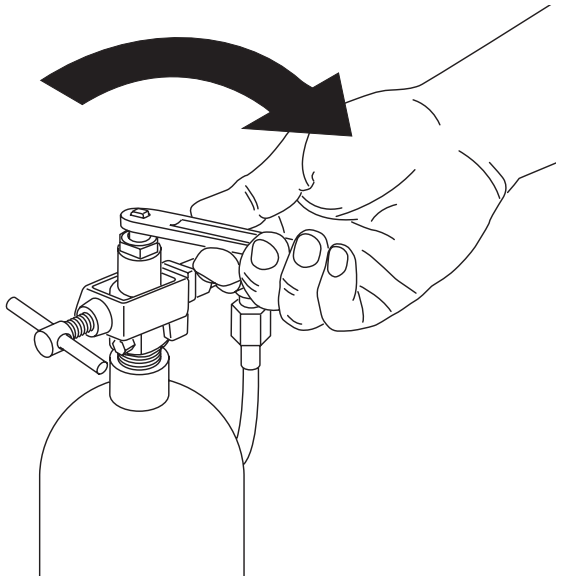
Remove the AC power cord from the wall outlet. Wrap the power cord on the side of the system cart using the cord wrap provided.

Position System Display for Transport/Storage

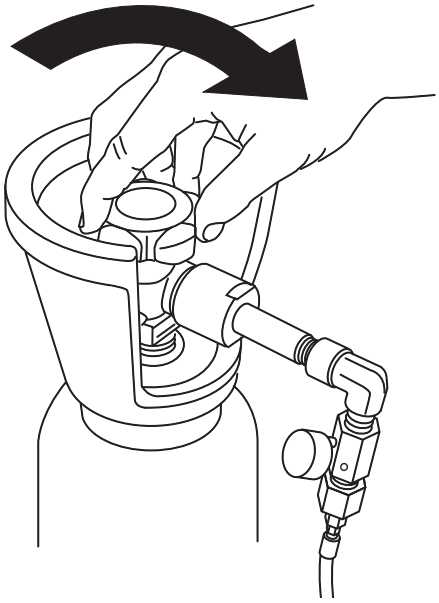
Position the system display over the writing surface to help prevent damage during transport and storage.

Disconnecting CO_2 Cylinders

1. Close the CO_2 cylinder by turning the knob clockwise fully or utilizing the wrench provided in the drawer.



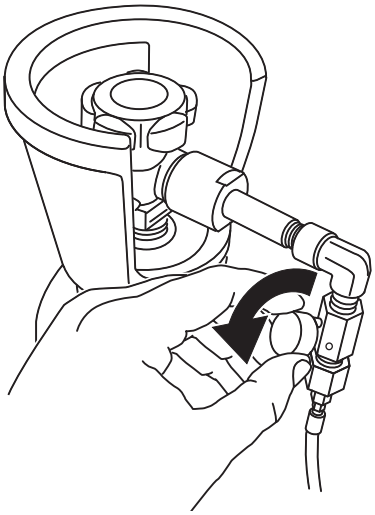
Pin Index CGA-940 / ISO 407



ISO5145 / DIN477 / JIS

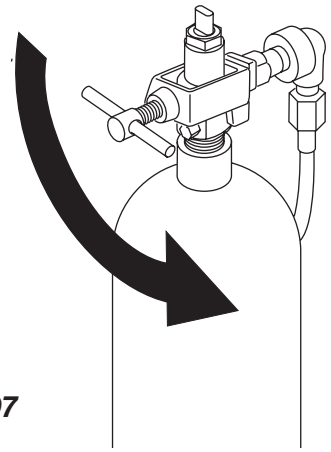
2. If CO_2 fitting is equipped with one, open the bleed valve by slowly turning the knob counter-clockwise fully.
3. CO_2 gas will be released through the bleed valve, reducing gas pressure in the CO_2 fitting.
4. Wait until no more CO_2 gas is being released through the bleed valve, then close the bleed valve by turning it clockwise until tight.

WARNING If the CO_2 gas is not released through the bleed valve the CO_2 fitting will contain high-pressure CO_2 which may pose a hazard to users when removing the CO_2 fitting from the CO_2 cylinder.

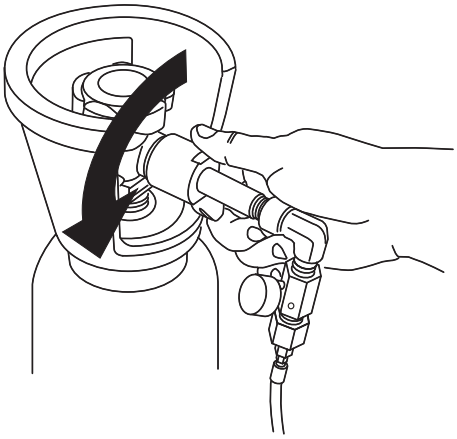


ISO5145 / DIN477 / JIS

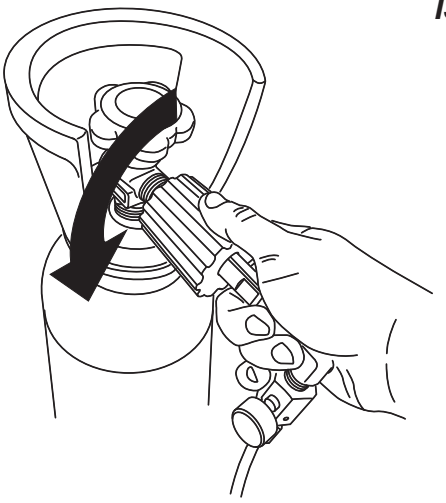
5. Remove the CO_2 fitting from the CO_2 cylinder by turning it counter-clockwise fully.



Pin Index CGA-940 / ISO 407



ISO5145



DIN477 / JIS

6. Unlatch the clamps holding the CO_2 cylinder in the bracket.
7. Remove CO_2 cylinder.
8. Repeat steps 1-7 for the second CO_2 cylinder.
9. Store CO_2 cylinder per your local facility guidelines.

WARNING CO_2 cylinders contain high pressure. Ensure the cylinders are closed prior to removing the yokes.

Follow your facility procedures for storing the CO_2 tanks. Local regulations may prohibit storing the CO_2 tanks with the NEUWAVE System when not in use.

PDM Disconnection and Storage

Secure the PDM connector covers on the PDM connectors.

Disconnect the PDM from the CT rail.

Attach the PDM to PDM mounting bracket on the rear of the NEUWAVE System as shown. Using the attached Velcro strap secure the PDM cable to help prevent damage during transport and storage.

Footswitch

Remove the Footswitch from the USB port. Store the Footswitch in the NEUWAVE System drawer.

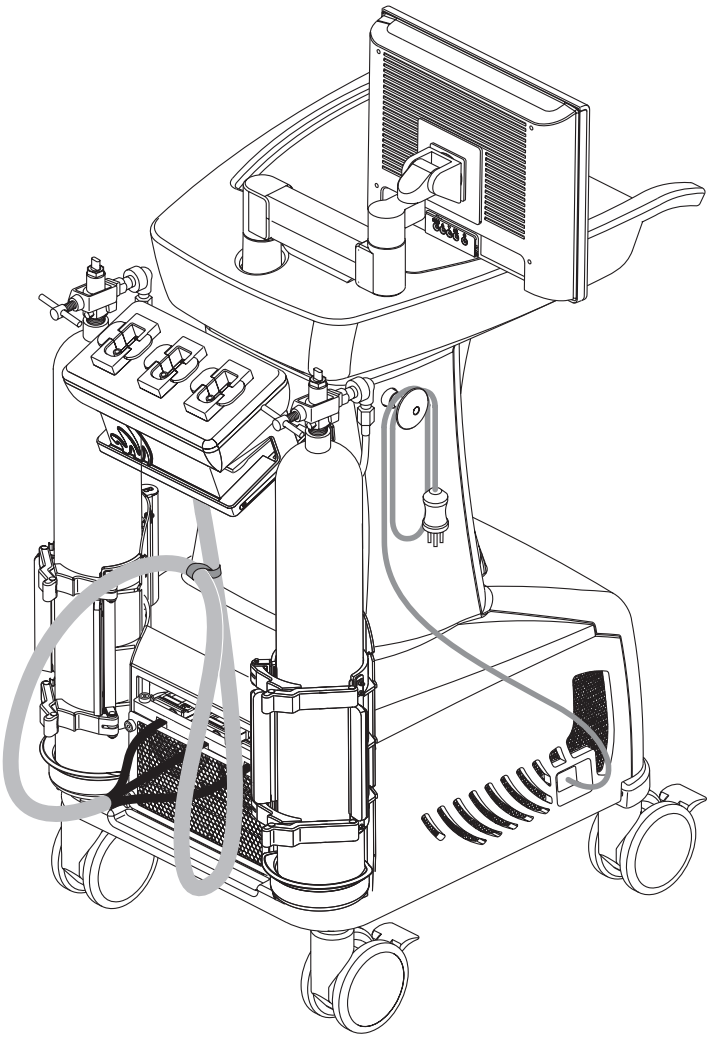


Figure 5-1: Cart with PDM on storage bracket

It is not necessary to disconnect the PDM cables from the system cart between each use. Keeping the cables connected to the system will reduce normal wear and tear and help to extend the useful life of the PDM.

Set the caster brakes during storage to help prevent unintended system movement.

6 Cleaning and Maintenance

Before cleaning and disinfecting, thoroughly inspect the device(s) for any signs of damage, cracks, or improper mechanical function. Do not use the device(s) if there are signs of damage. Contact Ethicon Customer/Technical Service for any service or repair needs if damage or degradation is present.

- Operators in North America should refer to appropriate sections of AORN Standards & Recommended Practices for additional guidance on cleaning. All other localities should refer to appropriate guidelines; e.g., KRINKO-BfArM-Empfehlung zu Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten in Germany).
- The operator must qualify cleaning effectiveness when deviating from the instructions in this manual.

CAUTION Do not use abrasive or sharp tools or any other methods that may damage the surface of the parts.

CAUTION Ensure PDM covers (3) are in place to prevent liquid from collecting in the PDM connectors. Do not immerse the system or any of its accessories or parts.

Clean the NEUWAVE™ System and accessories following the hospital protocol and any other applicable local guidelines and regulations. Before cleaning, turn the main power off and unplug the power cord from the grounded electrical outlet.

It is recommended that the NEUWAVE™ System and accessories be cleaned and disinfected between patient use to minimize risk to patients and health care workers. Cleaning agents that are indicated for both cleaning and disinfection are recommended for use on the system. CaviWipes™ were utilized to support the cleaning and disinfection validation activities. Similar products may be used to clean and disinfect the system components.

Disinfectants that demonstrate effective kill against Mycobacterium, fungi, vegetative bacteria and viruses should be used. Refer to hospital protocol and local guidelines and regulations for requirements of appropriate disinfectant label claims for use. It is important to understand the disinfectant label claims to ensure that contact times are appropriate to meet these requirements.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Follow the cleaning and disinfection steps below.

1. Pre-clean all surfaces by thoroughly wiping down the system and accessories with unused Wipe(s); e.g., CaviWipes™, following the manufacturer's instructions.
2. Inspect the equipment to ensure that all soil, blood, or debris have been removed. If needed, repeat the cleaning steps and re-inspect.

3. Using new unused wipe(s); e.g., CaviWipes™, thoroughly wipe down the system and accessories following the manufacturer's instructions for surface contact time to ensure effective disinfection.
4. Follow manufacturer's instructions on required drying time to allow the system and accessories' surfaces to dry.

Maintenance and Calibration

There is no preventative maintenance or calibration required on the NEUWAVE System.

Servicing

Contact Ethicon Customer Service for any service needs.

Expected Device Lifetime

The expected service life of the NEUWAVE System and accessories is 8 years.

System Decommissioning and Disposal

Contact Ethicon Customer Service for assistance in decommissioning the software and disposing of the NEUWAVE System, accessories and PDM.

Monitor Arm Adjustment

The LCD arm should not sag or slip from a desired position or angle. If the monitor or LCD Arm sags or slips, adjust the arm tension set screw per Figure 6-1, Figure 6-2 and Figure 6-3.

H = 7/32" (5.663) Allen wrench

I = 3/32" (2.388) Allen wrench

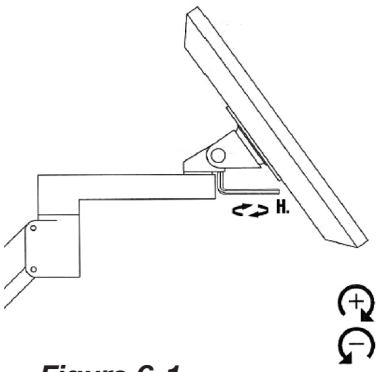


Figure 6-1

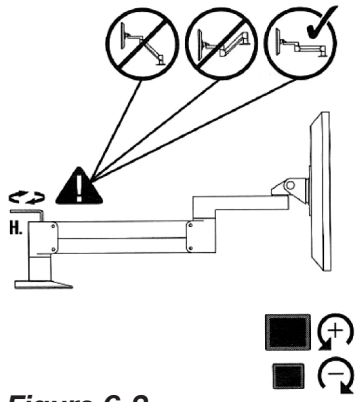


Figure 6-2

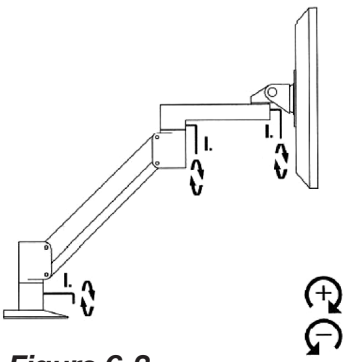


Figure 6-3

If the arm is not staying in the horizontal or fully extended position after performing the above step, follow Figure 6-4 to make additional adjustment to the counterbalance of the LCD arm.

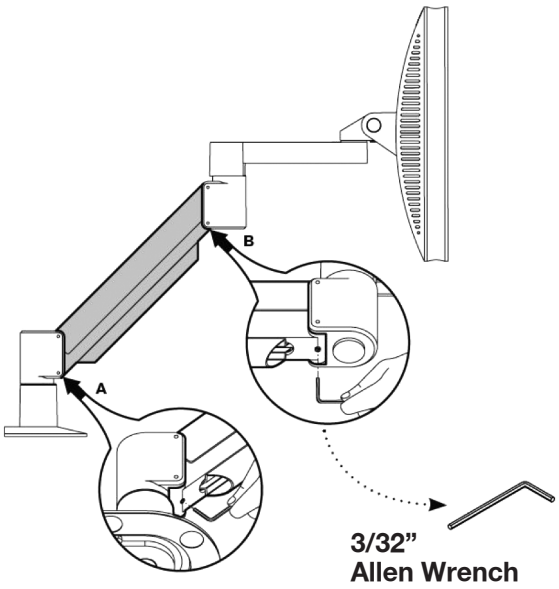
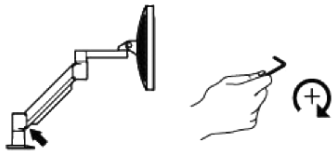


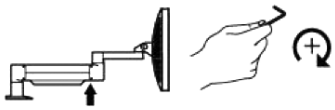
Figure 6-4

In some instances, further counterbalance adjustments are needed to allow the arm's instant height adjustment function to work properly.

If your arm is not staying in position after performing the previous steps, follow these steps:



With arm in raised position, tighten set screw (A).



With arm in horizontal position, tighten set screw (B).

Do not over tighten screws.

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7 Alarms and Troubleshooting

WARNING Repairs should only be attempted by trained NeuWave Medical Inc. personnel or by persons having completed NeuWave Medical Inc. approved service training.

System Messages

The system will display informational messages and alarms and provide guidance on what actions to take.

All alarms are considered equal priority and are displayed as pop-up messages on the screen. Alarm messages disable the display until the message is confirmed.

Informational message are shown on the bottom of the display in the green horizontal bar.

A history of all alarm messages and information messages for a given procedure can be viewed in the ***Report*** tab. Selecting an error message in the ***Report*** tab displays the message again if a review of the message or actions is required.

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8 Principles of Operation

System Overview

The system has a single microwave source with 3 microwave amplifiers capable of producing up to 140 W each operating at 2.45 GHz. Generator power is limited based upon the number of probes selected and the types of probes used. One easy to use touch-screen user interface controls the system. Up to 3 microwave ablation probes can be connected to and powered by the system at one time.

Cooling System Overview

A CO_2 based cooling system ensures the non-active portion of the probe does not exceed temperature requirements. Additionally, the CO_2 enables the Tissu-Loc™ function, which can be used to adhere or stick the probe in place prior to starting ablation therapy. This function is identical in use to the stick function available on cryogenic ablation systems.

The system uses two (2) CO_2 cylinders to supply gas to the cooling system. When a tank in use empties, the system will automatically switch to using the other tank and notifies the user to replace the empty tank.

The cooling system regulates the flow of high pressure CO_2 in a cooling gas tube to the PDM and eventually to the probe. Inside the tip of the probe, the cooling gas tube expands from high pressure to low pressure. As the gas pressure reduces quickly, the Joule-Thompson effect causes the probe shaft to cool. This is used for both the Tissu-Loc™ function and to keep probes at a safe temperature while energy is being delivered to the patient.

The PDM is designed to improve the usability of the system by reducing set-up complexity while also helping to minimize the cabling from the probe to the generator. The PDM also allows a larger, lower-loss cable to be used between the microwave generator and PDM. The increased efficiency of the larger cable and PDM allow more power to be safely sent to the ablation probe without an unsafe heating of the probe cable or handle.

System performance is constantly monitored. The NEUWAVE™ System will automatically discontinue delivering microwave energy in the event of system failures.

Triaxial Probe Design

Probes are provided sterile and are intended for single patient use only. Ablation probes are comprised of a sharp trocar on the end of a cannula, a probe handle, a 1.4 meter or 2.9 meter cable and a connector assembly.

Models NEUWAVE LK and NEUWAVE PR are available in 17 gauge and 15 gauge cannulas and in 15 cm and 20 cm lengths.

Model NEUWAVE LN has a 17 gauge cannula and is available in 15 cm and 20 cm lengths.

Model NEUWAVE SR is 13 gauge and is available in a 25 cm length only.

Model NEUWAVE PRS15 (Surgical PR Probe) is available in a 15 gauge cannula and in 15 cm length only.

Model NEUWAVE PRS35 (Surgical PR Probe) is available in a 11 gauge cannula that tapers down to a 13 gauge tip and in a 35cm laparoscopic shaft length only.

Each probe contains three (3) temperature measurement sensors that help monitor performance and ensure patient and operator safety.

The ablation probe assembly contains 4 main sections: a handle, a cannula, a radiating section and a faceted tip for insertion. The probes have a triaxial antenna design. The triaxial antenna design is created from a coaxial monopole antenna passed through a hollow needle. The needle creates the triaxial structure and its tip is positioned approximately 1/4 of a wavelength proximal to the monopole base. This positioning improves antenna efficiency and reduces fields flowing back on the coaxial outer conductor. In turn, more energy is deposited in the tissue. Additionally, different ablation probes have been designed to optimize the energy transfer efficiency from the probe into different types of tissue based on known electrical properties of each tissue.

NEUWAVE LK probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in liver and kidney tissue. NEUWAVE LN probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in lung tissue.

The antenna of the NEUWAVE SR probe is designed to limit the length of the ablation for instances when a shorter ablation zone is desired. NEUWAVE PR Probes were developed to provide physicians with an additional ablation probe designed specifically for ablating smaller lesions. The NEUWAVE PR probes are designed to produce ablations that quickly encompass the tip of the probe while limiting the overall length of the ablation. NEUWAVE PR probes will enable physicians to ablate smaller lesions while limiting necrosis of adjacent tissue when compared to other NeuWave probes.

9 Specifications

System Dimensions

Width: 23” (58.4 cm)

Depth: 28” (71.1 cm)

Height with Monitor: 52” (132 cm) Min, 59” (150 cm) Max

Weight (unloaded): 280 lb (127 kg)

Weight (max load): 382 lb (173 kg)

Alternate configuration with 180mm tank bracket:

Width: 29.5” (75 cm)

Depth: 36” (91.4 cm)

Height with Monitor: 52” (132 cm) Min, 59” (150 cm) Max

Weight (unloaded): 328 lb (149 kg)

Weight (max load): 443 lb (201 kg)

Environmental Specifications

Operating Conditions:

Temperature: 18° to 28° C,

Humidity: 10 to 90% RH, non-condensing

Altitude: 106 to 70 kPa (-440 to 3040 m reference)

Transport and Storage Conditions:

Temperature: -22° C to 60° C,

Humidity: 10 to 90% RH, non-condensing

Altitude: 106 to 50 kPa (-440 to 5860 m reference)

Keep dry

Keep away from heat

MRI Safety

NeuWave Ablation devices are not intended to be used in an MR environment. Do not use the NeuWave Ablation System, Accessories, and Probes in an MRI Scanner.

Measurement Accuracy

Temperature Measurements +/-1.5° C

Essential Performance

The Essential Performance of the NEUWAVE System includes the following functions:

1. Accurate and consistent microwave power delivery from the system power amplifiers.
2. Delivery of CO_2 gas to the probe to maintain safe probe temperatures.
3. Ongoing communications between the user interface software and the control system software.
4. Ongoing and accurate temperature measurements from the probe to the control system.
5. Ongoing and accurate temperature and pressure measurements from the cooling system to the control system.
6. Maintaining a hermetic seal on the probes to prevent gas from entering the patient.
7. Functional user interface to set, change and activate system controls.

Safe Working Load

The safe working load for the cylinder holders is no more than 48 lbs (22 kg) each or 96 lbs (44 kg) total.

The safe working load for the drawer and all configurations is 5 lbs (2.2 kg).

Alternate configuration with 180 mm tank bracket: The safe working load for the cylinder holders is no more than 55 lbs (25 kg) each or 110 lbs (50 kg) total.

Electrical Specifications

Operating Range 100-120 VAC, 12 A,
220-240 VAC, 6 A,
50 Hz-60 Hz

Alternate configuration with 180 mm tank bracket:

Operating Range 110-120 VAC, 12 A,
220-240 VAC, 6 A,
50 Hz-60 Hz

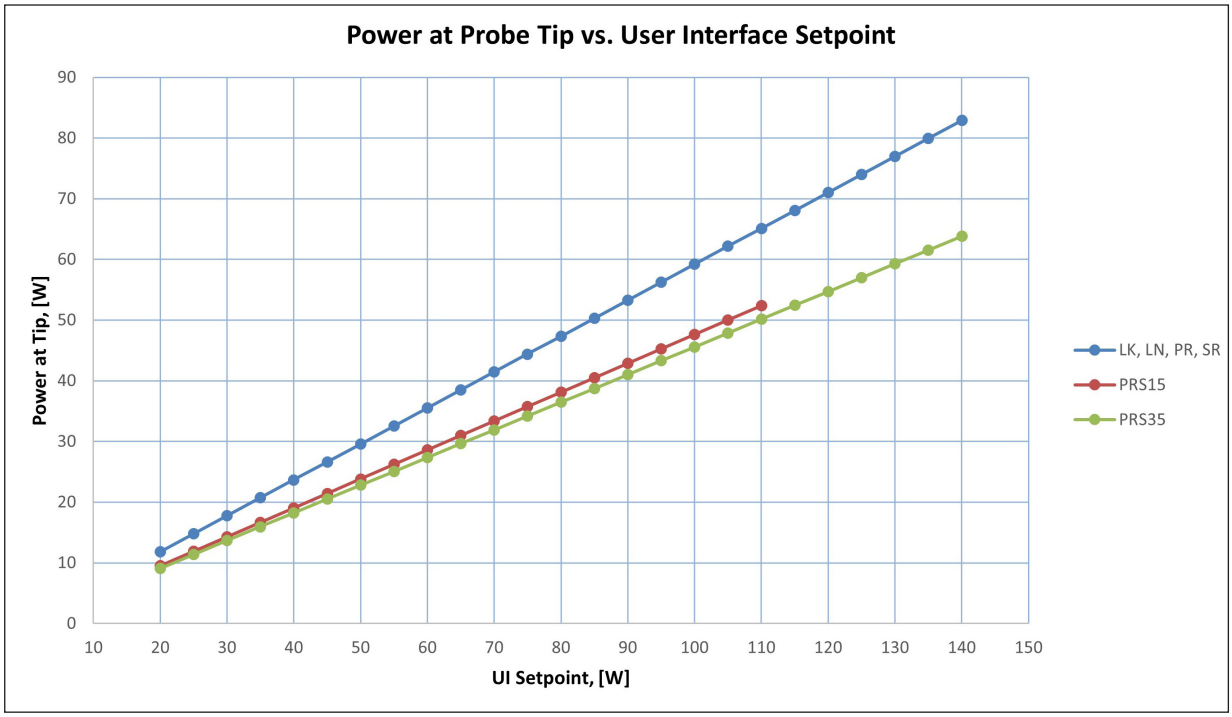
In the US, plug the NEUWAVE System into only 120 VAC outlets. Leakage currents are within limits of Class BF equipment per IEC 60601-1 System is designed for continuous use.

Fuses

The system is provided with replacement fuses. Contact Ethicon Customer Service for any service needs, including fuse replacement. Fuses should only be replaced by service personnel.

Parameter	100-120 VAC Units	220-230 VAC Units
Manufacturer & P/N	Schurter 0034.3129	Schurter 0034.3127
Dimensions	5 x 20 mm	5 x 20 mm
Rated Voltage	250 VAC	250 VAC
Rated Current	16 A	10 A
Breaking Capacity	160 A	100 A
Speed	20-300 ms @ 160 A	20-300 ms @ 100 A

Power Output Chart



System Security

The cart should be stored in a locked/secured area.

Potential Equalization Terminal

The NEUWAVE System may contain a Potential Equalization Terminal on the bottom of the system. This is provided for compatibility with other medical systems requiring such connections. This conductor is not intended for protective earthing. This terminal should be connected as per standard hospital procedure. Refer to 60601-1 clause 16 when connecting the Potential Equalization Terminal of the NEUWAVE System to other equipment.

Cybersecurity Information

The NEUWAVE System was designed with the cybersecurity needs of the Hospitals, Medical Centers, and Healthcare Providers that are marketed to by NeuWave.

Key security features of the NeuWave device include:

- Secure communications
- Application whitelisting
- Digitally signed code
- Software upgrades
- Independent vulnerability and penetration testing has been performed on the NeuWave device to verify security features.
- Users are not allowed access to the Operating System.
- Encryption at rest using Microsoft Bitlocker

The NeuWave System SBOM (Software Bill of Materials) may be requested by contacting customer service.

The following is additional cybersecurity information for the NEUWAVE System:

- Users are not allowed to download NeuWave system software updates. Ethicon customer service will notify the users if there is an update to the software and will install the updated version.
- NeuWave System does not notify users when there is a security event, but events are logged in the system. System runs in Kiosk mode, so login attempts are not applicable. Key security features of the system prevent the unauthorized configuration changes, network anomalies, or anomalous traffic.
- The NeuWave System protects system integrity starting with a secure boot process. Data is encrypted at rest. Hardware is selected to resist physical and side channel attacks. The System monitors for hardware and software tampering. The NeuWave system firmware and software are monitored for vulnerabilities on an ongoing basis.
- System configuration is backed up during installation by Ethicon customer service. Contact Ethicon Customer service for support related to restore the system configuration.
- Contact the Ethicon Customer Service Department for support related to recovery of device configuration.
- NeuWave Microwave Ablation System security configuration is pre-configured and has no user adjustable security features. Third party utilities cannot be installed and are not necessary to ensure system functionality or security.
- System log files are maintained in the NeuWave call home server, the event log proprietary format is not intended for analysis by third party software. Contact Ethicon Customer Service for support related to event log.
- Ethicon customer service or sales will contact users as the device approaches end of support. This notification will describe risks involved with the continued use of an unsupported system.

Below are the recommended cybersecurity best practices to follow when setting up and using the NeuWave device:

- Control and monitor physical access to the NeuWave device and other medical devices. Proper physical security is necessary to prevent tampering of the device.
- If you believe you have identified a potential security vulnerability that you would like to report, please access http://productsecurity.jnj.com to review our disclosure and response processes.
- The Microsoft Bitlocker feature of the Windows operating system has been enabled to encrypt the contents of the hard drive. This increases the security and protection of the ablation system against data theft or modification by unintended actors. To support this feature, a password key will be written to the software USB stick during the system upgrade process. The key allows the NEUWAVE System software to decode the encrypted data during maintenance or software update activities. This USB stick should be kept in a safe place, not with the cart, and must be available to a NeuWave representative to service the system.

Call Home Modem

System may be equipped with GX440, GX450, RV50X, or RV55 modems, depending on manufacturing date. Refer to the tables below for information specific to each modem.

GX440 Modem

GX440 Verizon Wireless—MC7750 Conducted Transmit Power

Band	Average Conducted Tx Power (dBm)
LTE	
Band 13	+23 ±1
CDMA	
CDMA Band Class 0 (Cellular)	+23.5 ±1 (channel 1175) +24±1 (other channels)

GX440 AT&T, Bell, and Canada—MC7700 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 1	+22±1	
Band 4 Band 17	+23±1	
UMTS		
Band 1 (IMT 2100 12.2 kbps) Band 2 (UMTS 1900 12.2 kbps) Band 5 (UMTS 860 12.2 kbps) Band 6 (UMTS 800 12.2 kbps)	+23±1	Connectorized (Class 3)
Band 1 (IMT 2100 MHz) 12.2 kbps	+23±1	Connectorized (Class 3)
GSM / EDGE		
GSM 850 CS GSM 900 CS	+32±1	GMSK mode, connectorized (Class 4)
	+27±1	8 PSK mode, connectorized (Class E2)
DCS 1800 CS PCS 1900 CS	+29±1	GMSK mode, connectorized (Class 4)
	+26±1	8 PSK mode, connectorized (Class E2)

GX440 Verizon Wireless—MC7750 Frequency Band Support

Radio Technology	Band	Frequencies
LTE	Band 13 (700 MHz)	Tx: 777–787 MHz Rx: 746–756 MHz
CDMA/EV-DO	BC0 (Cellular) (800 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	BC1 (PCS) (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz

GX440 AT&T and Canada—MC7700 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 1 (2100 MHz)	Tx: 1920 –1980 MHz Rx: 2110–2170 MHz
	Band 4 (AWS) 1700/2100 MHz	Tx: 1710– 1755 MHz Rx: 2110– 2155 MHz
	Band 17 (700 MHz)	Tx: 704 – 716 MHz Rx: 734–746 MHz
HSPA	Band I (2100 MHz)	Tx: 1920 –1980 MHz Rx: 2110–2170 MHz
	Band 2 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz
	Band 5 (850 MHz)	Tx: 824 –849 MHz Rx: 869 –894 MHz
	Band 6 (800 MHz)	Tx: 830 –840 MHz Rx:875– 885 MHz
EDGE	GSM 850 (850 MHz)	Tx: 824–849 MHz Rx: 869– 894 MHz
	EGSM 900 (900 MHz)	Tx: 880– 915 MHz Rx: 925–960 MHz
	DCS1800 (1800 MHz)	Tx: 1710–1785 MHz Rx: 1805–1880 MHz
	PCS 1900 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930– 1990 MHz

GX450 Modem

GX450 North America— MC7354 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 1 Band 4 Band 13 Band 17 Band 25	+23±1	
UMTS		
Band 1 (IMT 2100 12.2 kbps) Band 2 (UMTS 1900 12.2 kbps) Band 4 (AWS 1700/2100 12.2 kbps) Band 5 (UMTS 850 12.2 kbps) Band 8 (UMTS 900 12.2 kbps)	+23±1	Connectorized (Class 3)
GSM / EDGE		
GSM 850 CS GSM 900 CS	+32±1	GMSK mode, connectorized (Class 4)
	+27±1	8 PSK mode, connectorized (Class E2)
DCS 1800 CS PCS 1900 CS	+29±1	GMSK mode, connectorized (Class 4)
	+26±1	8 PSK mode, connectorized (Class E2)
CDMA		
Band Class 0 (Cellular)	+24+0.5/-1	
Band Class 1 (PCS)		
Band Class 10 (Cellular)		

GX450 International— MC7304 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 1 Band 3 Band 8 Band 20	+23±1	
Band 7	+22±1	
UMTS		
Band 1 (IMT 2100 12.2 kbps) Band 2 (UMTS 1900 12.2 kbps) Band 5 (UMTS 850 12.2 kbps) Band 6 (UMTS 800 12.2 kbps) Band 8 (UMTS 900 12.2 kbps)	+23±1	Connectorized (Class 3)
GSM / EDGE		
GSM 850 CS GSM 900 CS	+32±1	GMSK mode, connectorized (Class 4)
	+27±1	8 PSK mode, connectorized (Class E2)
DCS 1800 CS PCS 1900 CS	+29±1	GMSK mode, connectorized (Class 4)
	+26±1	8 PSK mode, connectorized (Class E2)

GX450 North America— MC7354 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 2 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz
	Band 4 (AWS) (1700 / 2100 MHz)	Tx: 1710–1755 MHz Rx: 2110–2155 MHz
	Band 5 (850 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	Band 13 (700 MHz)	Tx: 777–787 MHz Rx: 746–756 MHz
	Band 17 (700 MHz)	Tx: 704–716 MHz Rx: 734–746 MHz
	Band 25 (1900 MHz Block G)	Tx: 1850–1915 MHz Rx: 1930–1995 MHz
CDMA/EV-DO	BC0 (Cellular 800 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	BC1 (PCS 1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz
	BC10 (Secondary 800 MHz)	Tx: 817–824 MHz Rx: 861–869 MHz
HSPA	Band 1 (2100 MHz)	Tx: 1920–1980 MHz Rx: 2110–2170 MHz
	Band 2 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz
	Band 4 (AWS 1700/ 2100 MHz)	Tx: 1710–1755 MHz Rx: 2110–2155 MHz
	Band 5 (850 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	Band 8 (900 MHz)	Tx: 880– 915 MHz Rx: 925– 960 MHz
EDGE	GSM 850 (850 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	GSM 900 (900 MHz)	Tx: 880–915 MHz Rx: 925 –960 MHz
	DCS 1800 (1800 MHz)	Tx: 1710–1785 MHz Rx: 1805–1880 MHz
	PCS1900 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz

GX450 International — MC7304 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 1 (2100 MHz)	Tx: 1920–1980 MHz Rx: 2110–2170 MHz
	Band 3 (1800 MHz)	Tx: 1710 –1785 MHz Rx: 1805–1880 MHz
	Band 7 (2600 MHz)	Tx: 2500–2570 MHz Rx: 2620– 2690 MHz
	Band 8 (900 MHz)	Tx: 800–915 MHz Rx: 925 – 960 MHz
	Band 20 (800 MHz)	Tx: 832 – 862 MHz Rx: 791–821 MHz
HSPA	Band 1 (2100 MHz)	Tx: 1920–1980 MHz Rx: 2110 –2170 MHz
	Band 2 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz
	Band 5 (850 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	Band 8 (900 MHz)	Tx: 880 –915 MHz Rx: 925–960 MHz
EDGE	GSM 850 (850 MHz)	Tx: 824–849 MHz Rx: 869–894 MHz
	GSM 900 (900 MHz)	Tx: 880– 915 MHz Rx: 925–960 MHz
	DCS 1800 (1800 MHz)	Tx: 1710–1785 MHz Rx: 1805–1880 MHz
	PCS1900 (1900 MHz)	Tx: 1850–1910 MHz Rx: 1930–1990 MHz

RV50X Modem

RV50X North America and EMEA — MC7455 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 1	Tx: 1920 – 1980 MHz Rx: 2110 – 2170 MHz
	Band 2	Tx: 1850 – 1910 MHz Rx: 1930 – 1990 MHz
	Band 3	Tx: 1710 – 1785 MHz Rx: 1805 – 1880 MHz
	Band 4	Tx: 1710 – 1755 MHz Rx: 2110 – 2155 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 7	Tx: 2500 – 2570 MHz Rx: 2620 – 2690 MHz
	Band 8	Tx: 880 – 915 MHz Rx: 925 – 960 MHz
	Band 12	Tx: 699 – 716 MHz Rx: 729 – 746 MHz
	Band 13	Tx: 777 – 787 MHz Rx: 746 – 756 MHz
	Band 20	Tx: 832– 862 MHz Rx: 791 – 821 MHz
	Band 25	Tx: 1850 – 1915 MHz Rx: 1930 – 1995 MHz
	Band 26	Tx: 814 – 849 MHz Rx: 859 – 894 MHz
	Band 29	Tx: N/A Rx: 717 – 728 MHz
	Band 41	Tx/Rx: 2496 – 2690 MHz| (TDD)
HSPA+	Band 1	Tx: 1920 – 1980 MHz Rx: 2110 – 2170 MHz
	Band 2	Tx: 1850 – 1910 MHz Rx: 1930 – 1990 MHz
	Band 3	Tx: 1710 – 1785 MHz Rx: 1805 – 1880 MHz
	Band 4	Tx: 1710 – 1755 MHz Rx: 2110 – 2155 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 8	Tx: 880 – 915 MHz Rx: 925 – 960 MHz

RV50X Asia Pacific — MC7430 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 1	Tx: 1920 – 1980 MHz Rx: 2110 – 2170 MHz
	Band 3	Tx: 1710 – 1785 MHz Rx: 1805 – 1880 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 7	Tx: 2500 – 2570 MHz Rx: 2620 – 2690 MHz
	Band 8	Tx: 800 – 915 MHz Rx: 925 – 960 MHz
	Band 18	Tx: 815 – 830 MHz Rx: 860 –875 MHz
	Band 19	Tx: 830 – 845 MHz Rx: 875 –890 MHz
	Band 21	Tx: 1447.9 – 1462.9 MHz Rx: 1495.9 – 1510.9 MHz
	Band 28	Tx: 703– 748 MHz Rx: 758 –803 MHz
	Band 38	Tx/Rx: 2570 – 2620 MHz
	Band 39	Tx/Rx: 1880 – 1920 MHz
	Band 40	Tx/Rx: 2300 – 2400 MHz
	Band 41	Tx/Rx: 2496 – 2690 MHz
HSPA+	Band 1	Tx: 1920 – 1980 MHz Rx: 2110 – 2170 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 6	Tx: 830 – 840 MHz Rx: 875– 885 MHz
	Band 8	Tx: 880 – 915 MHz Rx: 925 – 960 MHz
	Band 9	Tx: 1749.9 – 1784.9 MHz Rx: 1844.9 – 1879.9 MHz
	Band 19	Tx: 830 – 845 MHz Rx: 875 – 890 MHz
TD-SCDMA	Band 39	Tx/Rx: 1880 – 1920 MHz

RV50X — MC7455 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 1 Band 2 Band 3 Band 4 Band 5 Band 8 Band 12 Band 13 Band 20 Band 25 Band 26	+23±1	
Band 7 Band 30 Band 41	+22±1	
HSPA+		
Band 1 (IMT 2100 12.2 kbps) Band 2 (UMTS 1900 12.2 kbps) Band 4 (AWS 1700/2100 12.2 kbps) Band 5 (UMTS 850 12.2 kbps) Band 8 (UMTS 900 12.2 kbps)	+23±1	Connectorized (Class 3)

RV50X — MC7430 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 1 Band 3 Band 5 Band 8 Band 18 Band 19 Band 21 Band 28 Band 39	+23±1	
Band 7 Band 38 Band 40 Band 41	+22±1	
HSPA+		
Band 1 (IMT 2100 12.2 kbps) Band 5 (UMTS 850 12.2 kbps) Band 6 (UMTS 800 12.2 kbps) Band 8 (UMTS 900 12.2 kbps) Band 9 (UMTS 1700 12.2 kbps) Band 19 (UMTS 850 12.2 kbps)	+23±1	Connectorized (Class 3)
TD-SCDMA		
Band 39	+23±1	

RV55 Modem

RV55 – WP7610 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 2 Band 4 Band 5 Band 12 Band 13 Band 17 Band 66	+23±1	Connectorized (Class 3)
WCDMA		
Band 2 Band 4 Band 5	+23±2	Connectorized (Class 3)

RV55 North America – WP7610 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 2	Tx: 1850 – 1910 MHz Rx: 1930 – 1990 MHz
	Band 4	Tx: 1710 – 1755 MHz Rx: 2110 – 2155 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 12	Tx: 699 – 716 MHz Rx: 729 – 746 MHz
	Band 13	Tx: 777 – 787 MHz Rx: 746 – 756 MHz
	Band 17	Tx: 704 – 716 MHz Rx: 734 – 746 MHz
	Band 66	Tx: 1710 – 1780 MHz Rx: 2110 – 2200 MHz
WCDMA	Band 2	Tx: 1850 – 1910 MHz Rx: 1930 – 1990 MHz
	Band 4	Tx: 1710 – 1755 MHz Rx: 2110 – 2155 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz

RV55 – EM7565 Conducted Transmit Power

Band	Conducted Tx Power (dBm)	Notes
LTE		
Band 1 Band 2 Band 3 Band 4 Band 5 Band 8 Band 9 Band 12 Band 13 Band 18 Band 19 Band 20 Band 26 Band 28 Band 30 Band 66	+23±1	
Band 7 Band 41 Band 42 Band 43 Band 48	+22±1	
UMTS		
Band 1 (IMT 2100 12.2 kbps) Band 2 (UMTS 1900 12.2 kbps) Band 4 (AWS 1700/2100 12.2 kbps) Band 5 (UMTS 850 12.2 kbps) Band 6 (UMTS 800 12.2 kbps) Band 8 (UMTS 900 12.2 kbps) Band 9 (UMTS 1700 12.2 kbps) Band 19 (UMTS 800 12.2 kbps)	+23±1	Connectorized (Class 3)

RV55 Global – EM7565 Frequency Band Support

Radio Technology	Band	Frequency
LTE	Band 1	Tx: 1920 – 1980 MHz Rx: 2110 – 2170 MHz
	Band 2	Tx: 1850 – 1910 MHz Rx: 1930 – 1990 MHz
	Band 3	Tx: 1710 – 1785 MHz Rx: 1805 – 1880 MHz
	Band 4	Tx: 1710 – 1755 MHz Rx: 2110 – 2155 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 7	Tx: 2500 – 2570 MHz Rx: 2620 – 2690 MHz
	Band 8	Tx: 880 – 915 MHz Rx: 925 – 960 MHz
	Band 9	Tx: 1749.9 – 1784.9 MHz Rx: 1844.9 – 1879.9 MHz
	Band 12	Tx: 699 – 716 MHz Rx: 729 – 746 MHz
	Band 13	Tx: 777 – 787 MHz Rx: 746 – 756 MHz
	Band 18	Tx: 815 – 830 MHz Rx: 860 – 875 MHz
	Band 19	Tx: 830 – 845 MHz Rx: 875 – 890 MHz
	Band 20	Tx: 832 – 862 MHz Rx: 791 – 821 MHz
	Band 26	Tx: 814 – 849 MHz Rx: 859 – 894 MHz
	Band 28	Tx: 703 – 748 MHz Rx: 758 – 803 MHz
	Band 29	Tx: N/A Rx: 717 – 728 MHz

Radio Technology	Band	Frequency
LTE	Band 30	Tx: N/A Rx: 2350 – 2360 MHz
	Band 32	Tx: N/A Rx: 1452 – 1496 MHz
	Band 41	Tx/Rx: 2496 – 2690 MHz (TDD)
	Band 42	Tx/Rx: 3400 – 3600 MHz (TDD)
	Band 43	Tx/Rx: 3600 – 3800 MHz (TDD)
	Band 46	n/a
	Band 48	Tx/Rx: 3550 – 3700 MHz (TDD)
	Band 66	Tx: 1710 – 1780 MHz Rx: N/A
HSPA	Band 1	Tx: 1920 – 1980 MHz Rx: 2110 – 2170 MHz
	Band 2	Tx: 1850 – 1910 MHz Rx: 1930 – 1990 MHz
	Band 4	Tx: 1710 – 1755 MHz Rx: 2110 – 2155 MHz
	Band 5	Tx: 824 – 849 MHz Rx: 869 – 894 MHz
	Band 6	Tx: 830 – 840 MHz Rx: 875 – 885 MHz
	Band 8	Tx: 880 – 915 MHz Rx: 925 – 960 MHz
	Band 9	Tx: 1749.9 – 1784.9 MHz Rx: 1844.9 – 1879.9 MHz
	Band 19	Tx: 830 – 845 MHz Rx: 875 – 890 MHz

Power Cord

Maximum Power cord length: 20 ft.

Power Output Specifications

Microwave energy is produced at 2.450 GHz +/- .025 GHz, Nominal

20 Watt minimum setting

140 Watt maximum power output at 50 ohms

5 Watt power increments

1 minute timer increments

Maximum open-circuit voltage = 33 V

Cauterize Power Setting: NEUWAVE LK, NEUWAVE LN, NEUWAVE SR = 80 W; NEUWAVE PR = 60 W; Surgical PRS15 = 75 W; Surgical PRS35 = 80 W

PDM Power

The following table defines the power at the PDM related to the Generator Power displayed on the User Interface:

Generator Power (W)	PDM Power (W)
20	16
25	21
30	25
35	29
40	33
45	37
50	41
55	45
60	49
65	53
70	57
75	62
80	66

Generator Power (W)	PDM Power (W)
85	70
90	74
95	78
100	82
105	86
110	90
115	94
120	98
125	103
130	107
135	111
140	115

IEC 60601-1 Classifications

Class 1, Type BF Product

IEC 60601-1-2 Specifications

Electromagnetic Compatibility (EMC)

WARNINGS

- The NEUWAVE System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.
- Portable RF communications (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NEUWAVE System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Failure to use this equipment in the specified shielded location could result in degradation of the performance of this equipment, with other equipment or interference with radio services.
- The NEUWAVE System should not be used adjacent to or stacked with equipment other than specified in this user manual. If adjacent or stacked use is necessary, the NEUWAVE System should be observed to verify normal operation in the configuration in which it will be used.
- The NEUWAVE System intentionally applies RF/Microwave energy for ablation during activation. Observe other electronic medical equipment in the vicinity during NEUWAVE System activation for any possible adverse electromagnetic effects. Ensure adequate separation of electronic medical equipment based on observed reactions.
- The NEUWAVE System was tested using NeuWave Ablation Probes. The use of accessories other than those listed in this user manual may result in increased emissions or decreased immunity of the NEUWAVE System.
- The battery should not be repaired or replaced except by trained NeuWave Medical personnel. Replacement by inadequately trained personnel could result in excessive temperatures, fire or explosion.

Guidance and manufacturer's declaration – electromagnetic emissions

The system is suitable for use in the specified electromagnetic environment. The customer and/or the user of the system should assure that it is used in an electromagnetic environment as described below.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF/Microwave emissions CISPR 11	Group 1 While Device is Idle Group 2 During Microwave Power Delivery	The NEUWAVE System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be effected.
RF/Microwave emissions CISPR 11	Class A	The NEUWAVE System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - Electromagnetic immunity

The system is suitable for use in the specified electromagnetic environment. The customer and/or the user of the NEUWAVE System should assure that it is used in an electromagnetic environment as described below.

Transient EM Disturbances may result in temporary interruptions to the Essential Performance of the system causing power and/or cooling delivery to be halted. In some cases this may require a restart of the system and/or retest of the probe. Severe or constant EM Disturbances may render the system unusable.

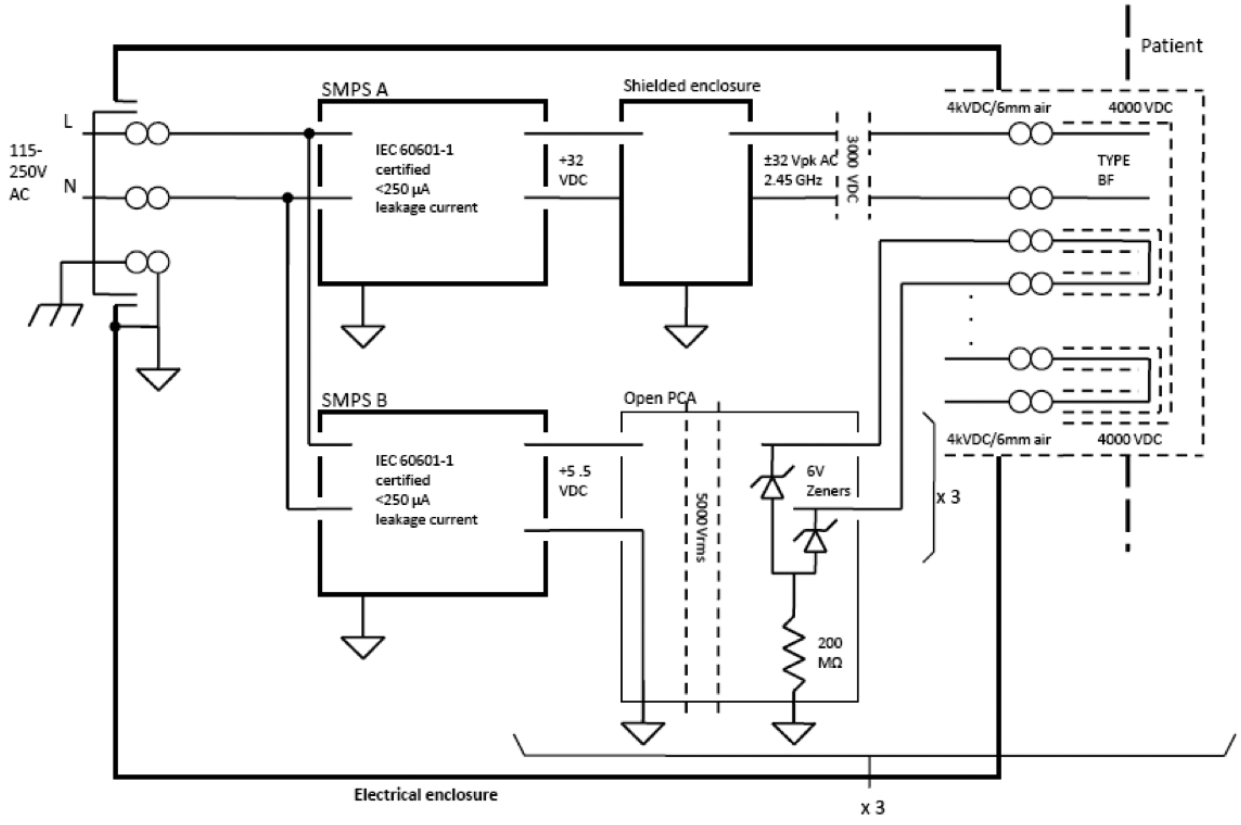
Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels / Conformance Levels
ENCLOSURE PORT		
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz

Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels / Conformance Levels
Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3	27 V/m at 385 MHz 28 V/m at 450 MHz 9 V/m at 710, 745 and 70 MHz 28 V/m at 810, 870 and 930 MHz 28 V/m at 1 720; 1 845; and 1 970 MHz 28 V/m at 2 450 MHz 9 V/m at 5 785 MHz
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
INPUT A.C. POWER PORT		
Electrical Fast Transients/Bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-Line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-Ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage Dips	IEC 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage Interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycle
PATIENT COUPLING PORT		
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
SIGNAL INPUT/OUTPUT PARTS PORT		
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical Fast Transients/ Bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency

Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels / Conformance Levels
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Electrical Diagram

NEUWAVE: Applied Part Grounding & Patient Isolation Diagram



NeuWave Open Source Software Notice

The NeuWave Medical, Inc. Microwave Ablation System (the "**NEUWAVE System**") contains software that is provided to you under open source licenses ("**OSS**"). For a list of the OSSs that may be included in the NEUWAVE System and the applicable license terms and attribution notices for such OSS, please visit www.e-ifu.com ("**Component Terms**"). The Component Terms may also contain required licenses and notices for third party commercial software used in this product. NeuWave Medical, Inc. may update the list and the Component Terms at any time in its sole discretion, so you should check the Component Terms periodically.

In the event of a conflict between the software license in the NeuWave Medical, Inc. commercial agreement applicable to the NEUWAVE System and the open source license applicable to such OSS, the open source license will prevail, solely with respect to that OSS.

Microsoft Software License Terms

See www.e-ifu.com for applicable Windows License Terms.

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ETHICON™
Johnson & Johnson SURGICAL TECHNOLOGIES

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