Navigator™ 2.0

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CE 0459

IMPORTANT NOTES

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PART NUMBER

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1. INTRODUCTION

1.1 Purpose

The purpose of this document is to provide comprehensive instructions for the safe and effective use of the Dilon Navigator 2.0. This manual serves as a guide for users, including healthcare professionals, by outlining proper setup, operation, maintenance, and troubleshooting procedures. It ensures compliance with industry standards and regulatory requirements while promoting optimal performance and patient safety.

1.2 Intended Audience

This document is intended for healthcare professionals, including surgeons, physicians, nurses, and medical technicians, who are trained in the use of the Dilon Navigator 2.0 system. It provides essential guidance on proper setup, operation, maintenance, and troubleshooting to ensure safe and effective use. This manual is not intended for patients or individuals without medical training.

1.3 Safety Information

Safety information for the Navigator System can be found throughout this manual. Refer to sections below for areas of safety information.

- **Section 4** – Indications for Use
- **Section 5** – Contraindications for Use
- **Section 6.1** – Radiation Safety Guidelines
- **Section 6.2.4** – Electromagnetic Compatibility
- **Section 9** – Device Cleaning and Decontamination
- **Section 12** – Adverse Events and Reporting

1.4 Product Lifetime

The product's lifetime is based on the rate of usage, wear, abrasion and damage and varies among users. For practical purposes of record keeping, Dilon Technologies further defines the “Product lifetime” of the product components to these time periods given below:

- Navigator 2.0 Control Unit and Probes 7 Years
- Rechargeable Battery Pak 3 Years
- Cable 2 Years

2. DEVICE DESCRIPTION

2.1 Product Name and Model Number

Table 1 – Product Name and Model Number

Product	Model Number
Navigator 2.0 System- Includes the following: 2-bay battery charger and line cord (N2-8000-00) and 2X Control Unit Batteries (N2-8500-02)	N2-9800-00

2.2 General Description and Components

The Navigator 2.0 System is a portable battery powered system used for non-imaging

procedures. The system consists of the control unit, one or more probes, and the system accessories. The System includes the following principal items:

Table 2 – Component Name and Model Number

Probe	Model Number
Wireless Pilot Probe (Straight): 2 Wireless Probe Batteries included	WP-9000-14S
Wireless Pilot Probe (Angled): 2 Wireless Probe Batteries included	WP-9000-14
Standard Lymphatic Mapping Probe (Straight)	SP-2A14-67
Standard Lymphatic Mapping Probe (Angled)	SP-2S14-67
Superficial Head & Neck Probe	SP-2S11-53
Daniel Lung Probe™	SP-2S10-31D
Laparoscopic Probe	SP-2S10-31

NOTE: Cable Sold Separately (GP-4001-00)

2.3 Principles of Operation (Gamma Radiation Detection)

The Navigator 2.0 System detects the presence of gamma rays emitted from radioactive isotopes in body organs or tissue. System use requires the Navigator 2.0 Control Unit, which allows the user to adjust the system's settings and produces a variety of signal outputs. The control unit is powered by a rechargeable battery. The system provides an increasing or decreasing sound and visual counts that vary as the level of gamma radiation increases or decreases.

The control unit works in conjunction with a hand-held probe that is connected to the control unit either via a cable or wireless technology. Placing the probe close to a radiation source increases the number of counts detected and localization occurs. As the distance between the probe and the radiation source increases, the number of gamma rays detected decreases.

The Navigator Control Unit is used with any of the following Navigator™ hand-held probe models. The probes differ primarily in their size, shape, detector technology, and connection to the control unit.

The system is supplied non-sterile. This manual includes guidelines for the use of the probes and accessories within the sterile field.

2.4 Device Specifications

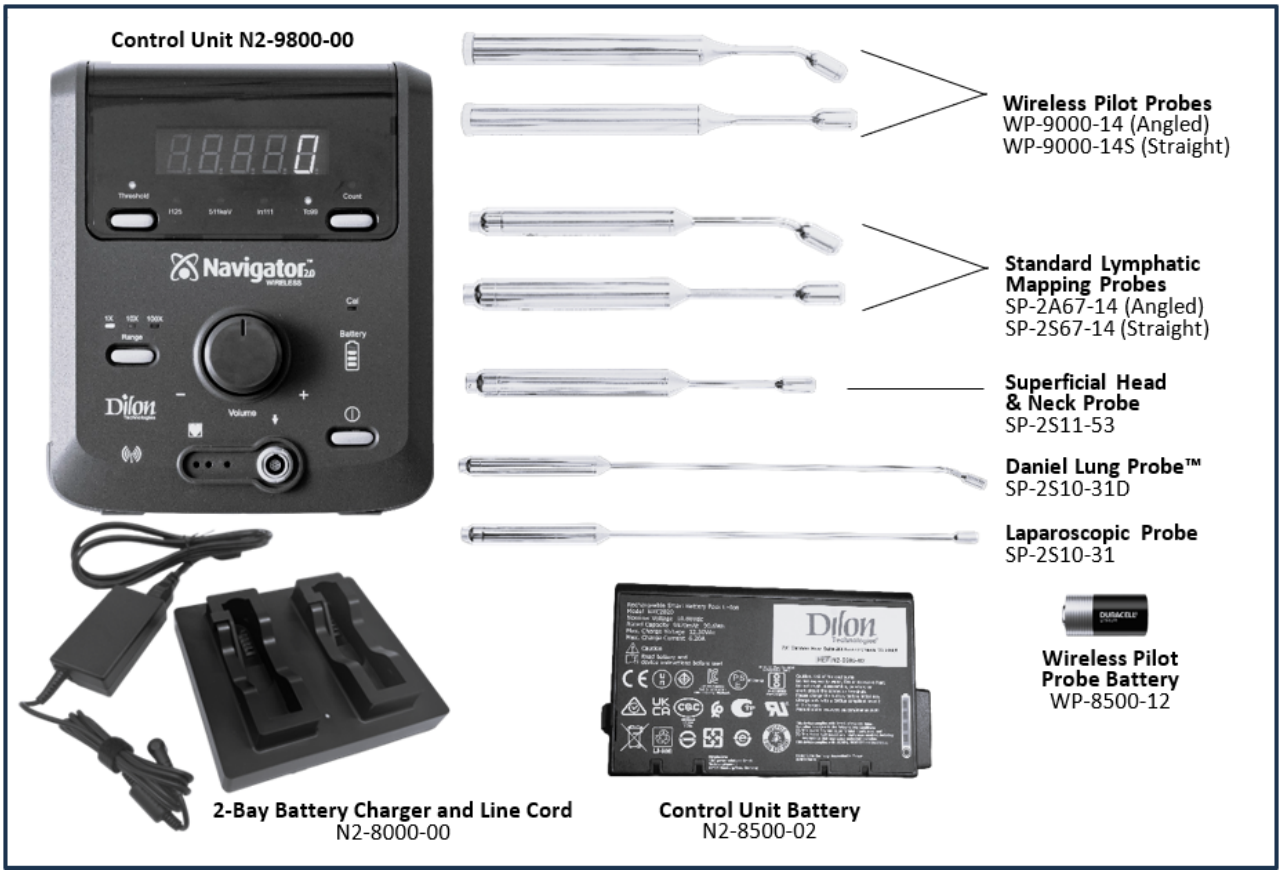


Figure 1 – System Overview and Components

Table 3 – Navigator 2.0 System Specifications

Item	Description
Control Unit Power Source	Replaceable, internal battery
Battery	Rechargeable Smart Lithium-Ion Battery; 10.8V (nominal) voltage, 8.7Ah (nominal) capacity, 99.6Wh SOC (state-of-charge) indicator. Approximate weight: 470g
New Battery Charge Life – full charge	Approximately 10-12 hours continuous use (nominal)
Battery Recharge Cycle -100% discharge	300 full charge/discharge cycles at room temperature and under normal discharge rates.
Wireless Pilot Probe Power Source	Duracell Battery. Single use CR2, 3V Lithium; capacity 750-850 mAh
Wireless Pilot Probe Transmission Distance	Up to 5 meters
Industry Standard Wireless Operating Frequency	2.4 GHz.

Table 3 – Navigator 2.0 System Specifications

Item	Description
Fuse – Control Unit	UL/CSA (198G) standards; 0.80 amp. Glass housing. 250-volt rating. 5x20m. (REF: SC-0099-00) IEC 127 standard : Type 7. 0.80 amp, 250 volts. 5x20m T0.63AL250V.
Sound Indicators	Pitch variations - Frequency proportional to event rate. Upon completion of 10-second count, device emits double-beep sound.
Visual Indicators	**Control Unit:** • Digital count – Vacuum fluorescent display • Single count – LED • Calibration-check - LED • 10-second count – LED • Battery energy level – LED • Range 1X/10X/100X – LED • Isotope – LED (four) **Battery:** • Battery state-of-charge – 4 LED' **Wireless Pilot Probe**: • Probe connection and battery voltage– LED
Energy Range	0 - 650 keV
Maximum Count Rate	99,999/s
Color of Housing	Purple
Control Unit Dimensions	20cm W x 24cm H x 12cm D
Control Unit Weight w/Battery	2.0kg

Table 4 – Probe Specifications

Probe	Tip Diameter	Tip Angle (Degrees)	Weight (grams)	Length (mm)
Wireless Pilot Probe (Straight) WP-9000-14S	14mm	0	255	257
Wireless Pilot Probe (Angled) WP-9000-14	14mm	30	255	260
Standard Lymphatic Mapping Probe (Straight) SP-2A14-67	14mm	0	185	224
Standard Lymphatic Mapping Probe (Angled) SP-2S14-67	14mm	30	185	220
Superficial Head & Neck Probe SP-2S11-53	11mm	0	161	207
Daniel Lung Probe™ SP-2S10-31D	10mm	30	195	465
Laparoscopic Probe SP-2S10-31	10mm	0	195	467

2.5 Accessories

Accessories may be purchased from the local Dilon Technologies Navigator representative.

CAUTION: *Only approved Accessories listed above should be used with the Dilon Navigator and Probes. Use of unapproved accessories may result in damage to the Navigator Control Unit and Probes.*

CAUTION: *Use of unapproved accessories may alter the performance of the Navigator Control Unit and Probes.*

Table 5 – Accessories and Dilon Part Numbers

Accessory Item (*Included with N2-9800-00)	Dilon Part Number
Navigator 2.0 Battery	N2-8500-02
2-Bay Battery Charger	N2-8000-00
Battery Charger Power Cord*	SC-2000-00
Batteries for Wireless Pilot Probe (12/pack)	WP-8500-12
Flexible Probe Cable	GP-4001-00
Optional Storm Case	N2-8000-07
Optional Top Gun Collimator	SP-1800-00
End Cap for Wireless Pilot Probe	WP-2000-10
Battery Holder for Wireless Pilot Probe	WP-9050-01
Sterilization Tray 2.6” x 12” (6.6 cm x 30.5cm)	WP-9000-TR
Sterilization Tray 6.5” x 18” (16.6cm x 45.7cm)	SP-9000-TR
Navigator 2.0 Pole Clamp	N2-8800-00
Rolling Pole	108-00001
Wireless Probe Cover (10/pack)	WP-9003-DRT
Cabled Probe Cover (10/BX)	SP-9004-DRC

2.5.1 Battery Charger

Place the charger on a flat, level surface, away from sources of heat and moisture. Plug the DC connector from the power supply into the back of the charger, and connect the power supply to the main AC, using only the cable provided.

All the LEDs will flash momentarily to indicate that power is present.

Figure 2 – 2-Bay Battery Charger (N2-8000-00) & Navigator 2.0 Battery (N2-8500-02)

Place the battery into either battery bay, ensuring that the 5-way connector is fully seated. The LEDs in the battery status window will provide charge status, and the charger will automatically begin charging. Each charge bay operates independently, providing simultaneous charge of each battery inserted.

⚠ **CAUTION:** *To avoid the risk of electric shock, the battery charger cord must only be connected to a Supply Mains with protective earth ground.* Main power quality should be that of a typical commercial or hospital environment.

Table 6 – Charger Bay LED Indications

Indication	Battery Charge Status
One Time- Red/Orange/Green	Self-test: Charger is ready for use.
Red/Green Blinking	Battery recognition and initialization
Orange blinking	The battery is currently being calibrated.
Orange light	The inserted battery is the correct type and is charging.
Green light	The battery is charged and is ready for use
Red blinking	The battery is too hot or too cold to charge safely. • If too cold, charging will resume once it warms up. • If too hot, remove the battery and allow it to cool before charging.
Red light	The battery is either damaged or a non-rechargeable conventional battery.

NOTE: *Use only batteries supplied by Dilon Technologies. No unauthorized accessories should be used.*

NOTE: *Approximately 3.5 hours are required to charge a completely drained battery.*

NOTE: *Recalibration time is approximately 18-26 hours.*

CAUTION: *Do not expose the charger or power supply to water or liquids.*
Do not open the charger or power supply case. No user-serviceable parts. Refer to Charger Operators Manual for further instruction on installation.

2.5.2 Flexible Probe Cable Assembly

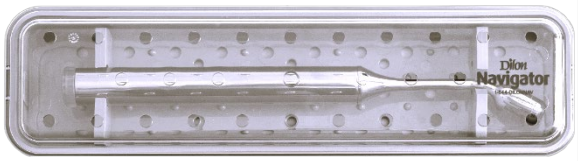
The Flexible Probe Cable (GP-4001-00) is necessary for connecting cabled probes to the Control Unit. Refer to Figure 6 for a list of compatible cabled probes. For connection and disconnection instructions, see Section 7.1.4.

2.5.3 Sterilization Trays

The sterilization tray is available in two sizes, designed for use with both cabled and wireless probes, see figure 2A. (Probe not included)

- Sterilization Tray (2.6” x 12” / 6.6 cm x 30.5 cm) (WP-9000-TR)
- Sterilization Tray (6.5” x 18” / 16.6 cm x 45.7 cm), (SP-9000-TR)

Refer to Section 8.2.5 for sterilization instructions.



Sterilization Tray (2.6” x 12” / 6.6 cm x 30.5 cm) (WP-9000-TR)

Sterilization Tray (6.5” x 18” / 16.6 cm x 45.7 cm), (SP-9000-TR)

Figure 2A

3. DEVICE DESCRIPTION

3.1 General Purpose

For the detection and quantification of gamma radiation from gamma-emitting isotopes in the body or tissues. Used for non-imaging procedures to measure the amount of radionuclide absorbed by a particular organ or body region.

3.2 Functional Overview

The Navigator 2.0™ Control Unit with Wireless Probe detects gamma photons during surgery. Before the procedure, a radiopharmaceutical is injected into the patient, concentrating at specific sites that emit gamma photons. During surgery, the handheld probe is used to scan areas both in and outside of the patient. The control unit displays the detected event rate and emits an audible pitch proportional to signal intensity.

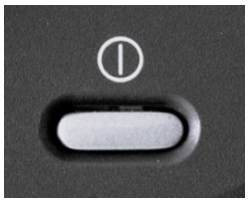
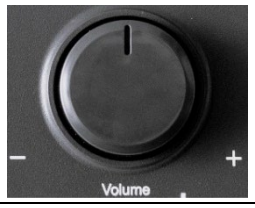
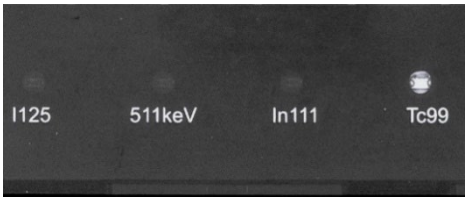
The Navigator 2.0 ™ Control Unit:

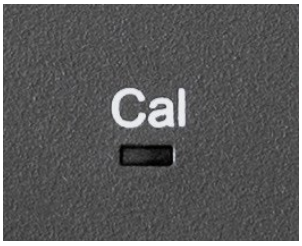
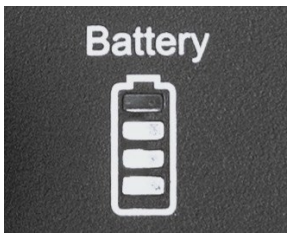
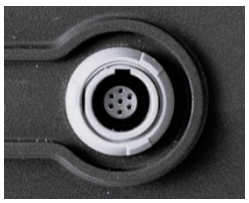
- Provides electrical power for the cabled probes.
- Receives wireless transmissions from the wireless probe
- Accepts a signal from the probe.
- Performs energy analysis of the probe signal.
- Provides audible and visual signal output for the probe signal based on user selected settings.

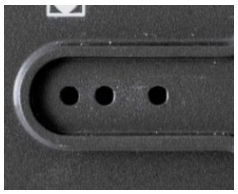
3.3 Control Unit Instructions and Features

The control unit houses the display, battery, and the majority of the system controls, which are positioned on both the front and rear panels. It enables the user to adjust system settings and generates signal outputs—displaying a count rate on the screen and producing an audible tone that corresponds to the intensity of detected gamma photons. The number of gamma photons, or "events," displayed is primarily influenced by the probe and its position relative to the radioactive source, and secondarily by the control unit's settings.

Table 7 – Control Unit Front Panel Displays and Controls

Control Display	Description
	**Power B:** Turns power on and off.
	**Volume Knob:** Increases/decreases the volume of the audible signal.
	**Display Screen:** When turned on, displays the photon count per second. Upon completion of a 10-second count, the total number of photons detected will show on the display screen for 4 seconds, and then the display returns to showing counts per second.
	**Isotope Indicator:** Indicates the isotope selected. Isotopes detected on the Navigator 2.0 are I125, 511keV (for I-131 or FDG-18), In111, and Tc99.
	**Range Button and Indicator Settings:** Adjusts the audible signal based on the density of detected events. It defaults to 1X, where the audible signal fluctuates with every detected event. 1X – All events are heard (low event rates). 10X – Every 10th event is heard (medium event rates). 100X – Every 100th event is heard (high event rates). Pressing the Range button cycles through these settings, allowing selection based on the procedure. ***NOTE**: The Range setting only affects the audible signal and does not impact on the count displayed or signal processing.*
	**Threshold Control**: For Cabled Probes only, the Threshold feature controls the range of photon energy detected. It defaults to ON, allowing only events within a narrow, preconfigured energy range to be counted and displayed, reducing or eliminating scattered photon detection. The indicator is illuminated in this setting. When OFF, all detected photon energy, including

Control Display	Description
	scattered photons, is counted, expanding the value range. The indicator is not illuminated in this setting. For Wireless Probes only, the Threshold functionality is integrated into the probe, and the Control Unit setting does not affect its operation.
	**Count Button**: Initiates a 10-second photon count. When Count has been pressed, the count indicator on the display screen is illuminated and the display screen will show increasing counts. Probe must be held in a fixed position for entire duration of 10-second count. When the 10 seconds are complete, the control unit beeps, and the total count is shown in the display. After displaying the total count for four seconds, the display shows the counts per second.
	**Calibration-Check Mode Indicator**: This light indicates when the system is in 'Calibration-Check' mode on the rear of the unit. The light will be illuminated when in any of the 3 calibration-check settings and will not be illuminated when the system is set to the 'Scan' mode. **The SCAN / Calibrate Control must be set to the SCAN position only, for all probes for all procedures. In this mode, the 'Cal' light will be turned off.** See Section 11.2 Verification of Standard Gain (Calibration Quick Test) for more information on Calibration.
	**Battery Charge Status Indicator:** Shows the charge status of the battery in use. When the indicator level on the Control Unit is at 50%, the battery should be replaced with a fully charged battery to prevent any interruptions during use. Please note that the charge status on the control unit may differ from charge status reflected on the battery.
	**Signal Input (Cable Port):** For cable connection. For all cabled probes, connect the probe cable matching the arrow on the cable connector to the arrow above the signal input port. See Section 4.7 Flexible Probe Cable for more information. The signal input port is not applicable when using the Wireless Pilot Probe with the Navigator 2.0.

Control Display	Description
	**Co-Pilot Receptacle:** Connection port for the optional Co-Pilot accessory.

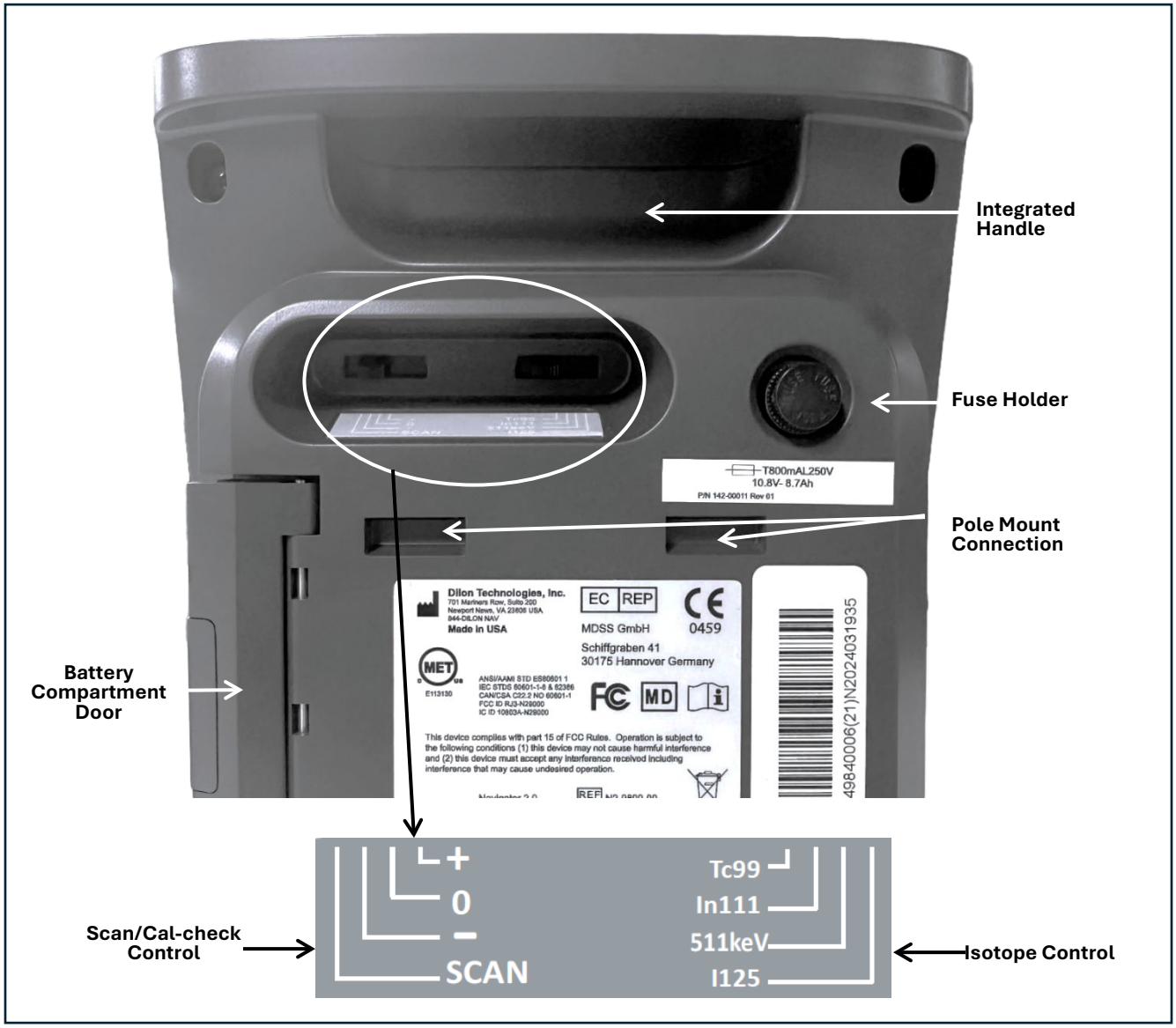
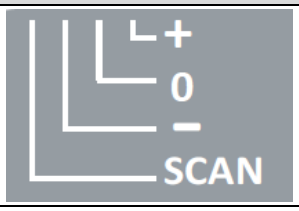
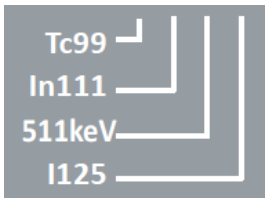


Figure 4– Control Unit (Back)

Table 8 – Control Unit Front Panel Displays and Controls

Control Display	Description
	**The SCAN/Calibrate Control** has four positions. Set the control unit switch to SCAN for normal use. In SCAN mode, the CAL indicator will remain off. For details on the '+,' '0,' and '-' positions, contact Dilon Customer Service or your local distributor.
	**Isotope Control Setting**: Allows the user to designate the specific isotope in use. • I125 – Iodine-125 **(For use with cabled probes only. Not compatible with wireless probes.)** Commonly used to locate I125 seed implanted prior to surgery. • 511keV – 18F-FDG (and I131) **(For use with cabled probes only. Not compatible with wireless probes.)** • In111 – Indium **111 (For use with cabled probes only. Not compatible with wireless probes.)** • Tc99 - Technetium-99m
	The **Isotope Selection** and **SCAN/Calibrate Control** switch on the rear activates the corresponding **Isotope Indicator** light and the **SCAN/Calibrate** function on the front of the control unit.

NOTE: If the front panel CAL indicator is flashing before a procedure, move the control to the SCAN position.

3.4 Wireless Probe Connectivity and Use

The Wireless Pilot Probe is used in various procedures. The Wireless Pilot Probe is used only for a procedure with a Technetium-99m isotope (such that may be used in a lymphatic mapping procedure for a sentinel node biopsy) Probes are Type CF Applied Parts.

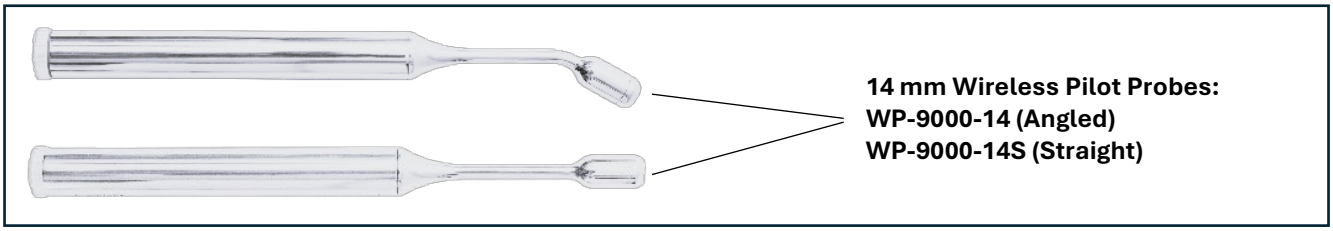


Figure 5 – Wireless Probes

Table 9 – Pilot Probe LED Indicator

Indication	Status
On/Slow Blink	Probe is in pairing mode, looking for a Control Unit to connect to.
On/Static Light (Version 2.7.0) On/Blink (Version REV5)	Probe has paired with Control Unit and is ready for use.
On/Fast Flash	Battery is low. Probe should not be used until the battery is replaced.
Off	The probe enters a resting mode to conserve power when the Control Unit is off. To reactivate the LED indicator, turn on the Control Unit and lightly shake the probe. If the probe does not power on when ready for use, the battery may need to be installed or replaced.

3.5 Cabled Probes

The Navigator 2.0 may be used with cabled Standard Lymphatic Mapping Probes (straight or angled), Superficial Head & Neck Probe, Laparoscopic Probes, or the Daniel™ Lung Probe. The Flexible Probe Cable (GP-4001-00) is required to connect the cabled probes to the Control Unit. Probes are Type CF Applied Parts.

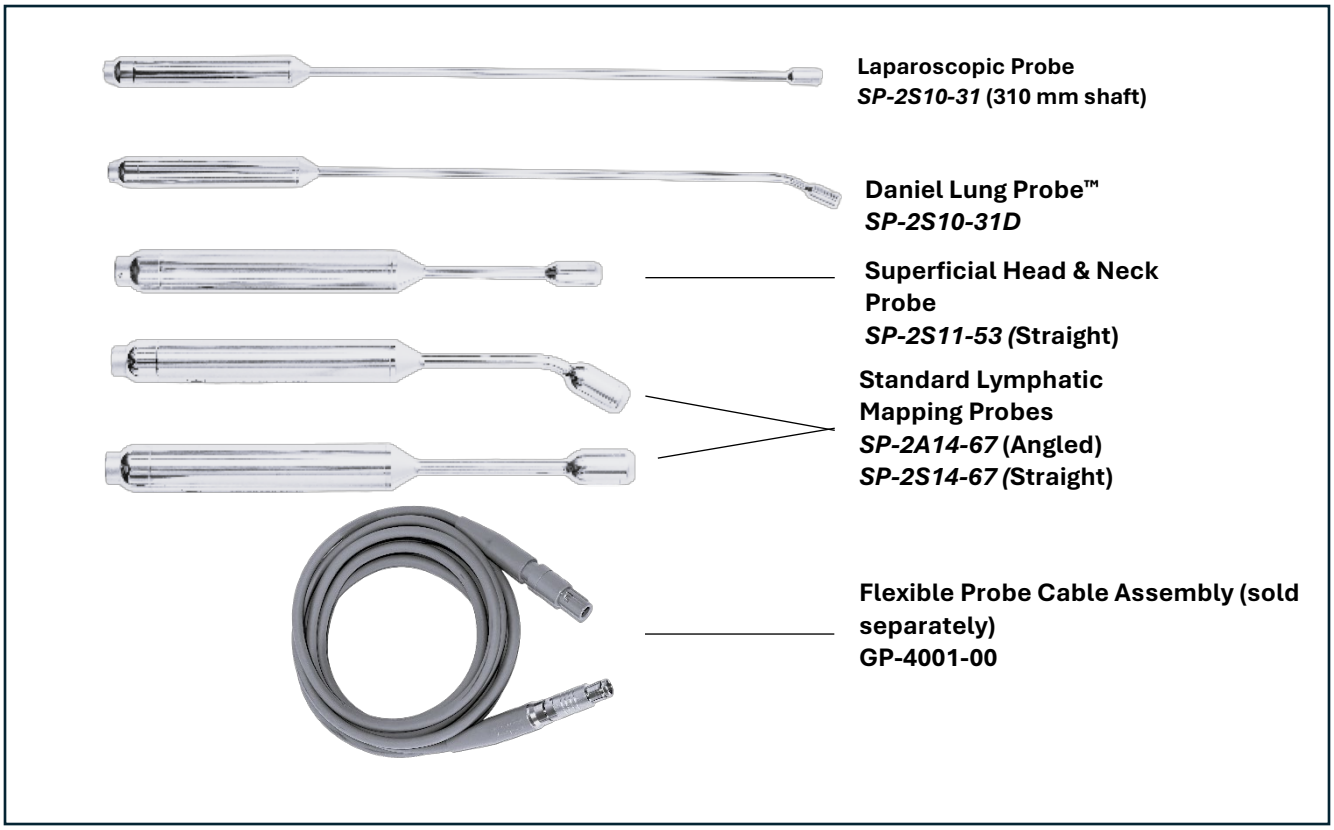


Figure 6 – Cabled Probe Family

4. INDICATIONS FOR USE

4.1 Specific Applications

For the detection and quantification of gamma radiation from gamma-emitting isotopes in the body or tissues. Used for non-imaging procedures to measure the amount of radionuclide absorbed by a particular organ or body region in open-surgical, laparoscopic or thoracoscopic surgical procedures.

4.2 Target Population

Gamma probes are intended for use in both invasive and non-invasive procedures by positioning the probe near or in contact with the targeted area of the body. The duration of probe contact typically does not exceed 15 minutes. The Navigator 2.0 is designed for patient comfort and does not require any unusual, awkward, or painful positioning during operation.

Thus, the intended patient population is not restricted to age, weight, health, nationality, or patient state.

5. CONTRAINDICATIONS

5.1 Situations Where the Device Should Not Be Used

- The output of this system is not to be considered a diagnostic measure of the extent of disease in the patient, nor the recommended source of therapy.
- The Navigator 2.0 system is not intended for use in the central nervous system.
- This User/Service manual is designed to assist the use of the Navigator 2.0 system and is not a reference to surgical techniques.
- Do not use products near sources of extreme magnetism, such as MRI equipment.
- Do not modify this equipment without the authorization of the manufacturer.

6. WARNINGS, CAUTIONS, AND PRECAUTIONS

6.1 Radiation Safety Guidelines

The Navigator 2.0 System is designed solely to measure radiation and does not emit any form of radiation. The device functions as a passive detection system, ensuring safe operation without radiation exposure to users or the environment.

6.2 Potential Risks and Error Mitigation

6.3 General

- Failure to thoroughly review and adhere to the information contained in this User and Service Manual may pose a potential hazard to the patient and/or user and may void the warranty.
- Keep the control unit within the line of sight of and facing the surgeon, and within 15 feet (~5m) of the patient.
- Be sure the wireless probe's end cap is clear of obstructions, such as a misplaced hand. The probe should be held like a stylus or fine surgical instrument.
- Upon startup, the control unit displays the software version (e.g., 270 for version 2.7.0). For REV 5 units, the screen will display 0.
- The second set of numbers is the wireless channel the probe and the control unit are

communicating on (e.g. 11).

- Contact your Dilon Technologies representative to report any incidents or injuries that occur during use of the Navigator 2.0 System and its accessories.
- Operation near X-ray equipment may cause incorrect counts.
- Incorrect counts can occur in the vicinity of individuals exposed to radiation therapy.

CAUTION: *To avoid malfunction of the system, only the manufacturer's approved system components and replacement parts shall be used. This includes the manufacture's approved replacement parts such as the fuse, control unit battery, 2-bay battery charger, power supply line cord, wireless pilot probe battery, and probe cable.*

CAUTION: *To avoid fire hazard, do not insert a fuse with higher rating than the manufacturer's specification (0.8A).*

6.4 Control Unit, Battery, and Charger

- During system use, maintain electrical isolation of the patient. Do not connect the probe, cable (if used), or the internal circuit of the control unit to earth ground, or to other voltage potentials.
- Maintain patient electrical isolation. Do not defeat the electrical isolation of the surface of a probe cable (if used), and the control unit housing. These isolate the battery-power circuit inside the control unit, the conductors inside the probe cable, the probe surface, and the patient.
- The Line Cord of the 2-bay battery charger is used as the disconnect device for the charger.
- When optional system components are used with the system, maintain probe and patient electrical isolation from earth ground. The optional components include the probe drape, the Top Gun™ Collimator, Sterilization Trays, and Navigator 2.0 Roll Stand.
- In the operating room, use the charger at a distance of six feet or greater from the patient.
- Fully charge the Control Unit battery before each use.
- Replace the wireless probe battery before each surgical procedure or prior to sterilization.
- This system is not designed for use in an around flammable or combustible materials.
- Keep the control unit off when changing connections between the probe, cable, and control unit. The control unit should also be off when inserting a battery into the Wireless Pilot Probe.
- The control unit, cables, batteries, charger, and probes are sold non-sterile and all items should remain outside the sterile field except for the probe after proper sterilization.

CAUTION: Service activities should not be performed when the Navigator System is in use.

6.5 Probe

- DO NOT put any probe or probe cable in an autoclave.
- With the exception for the Wireless Pilot Probe's End Cap, (for battery access), DO NOT attempt to open probes.
- All probes are tested and sealed at the factory. Attempting to open the probe may cause damage and will void the warranty.
- DO NOT drop or strike the probe tip against a hard surface; this may result in damage to the probe.
- It is recommended to use only one wireless probe within range of the control unit at a time.

6.6 Electromagnetic Compatibility

This equipment has been certified to be protected to emissions and immunity according to EN/IEC-60601-1-2:2015.

CAUTION: *Medical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Operation Manual.*

CAUTION: *Portable and mobile RF communications equipment can affect medical electrical equipment.*

The Navigator Control Unit and Probes are ME EQUIPMENT (Medical Electrical Equipment) that is intended to be used for patients under medical supervision. Trained and qualified medical personnel must operate the Navigator Control Unit and Probes only.

WARNING: The use of accessories other than those specified may result in increased emissions or decreased immunity of the equipment and may void the warranty.

WARNING: The Navigator Control Unit and Probes should not be used adjacent to or stacked with other equipment.

WARNING: Electrosurgical equipment intentionally applies RF energy for diagnosis or treatment during activation. Observe the Navigator performance if it is in the vicinity of the electrosurgical equipment during activation for any possible adverse electromagnetic effects. Ensure adequate separation of the Navigator based on observed reactions.

Table 10 – Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11 Radiated	Group 1 Class A	The Navigator Control Unit and Probes uses RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Conducted	Class A	The Navigator Control Unit and Probes are suitable for use in all establishments other than domestic 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

Table 11 – Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec cycle	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec cycle	Mains power quality for the Battery Charger should be that of a typical commercial or hospital environment. The Navigator Control Unit is powered from the internal battery. The Navigator 2.0 met criteria C.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 3 V/m 80 MHz to 2.7 GHz 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 3 V/m 80 MHz to 2.7 GHz 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	Recommended separation distance d = $1.2\sqrt{p}$ d = $1.2\sqrt{p}$ 80 MHz to 800 MHz d = $2.3\sqrt{p}$ 800 MHz to 2.7 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of the equipment marked with the following symbol: 

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Guideline Notes **NOTE 1** - At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Assessment of the Electromagnetic Environment Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Navigator Control Unit and Probes are used exceeds the applicable RF compliance level above, the Navigator Control Unit and Probes should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Navigator Control Unit and Probes. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

7. DEVICE SETUP AND PREPARATION

7.1 Unpacking and Inspection

- Inspect the control unit, probe, and cable for signs of visual damage. If damage is noticed, discontinue use and contact Dilon Technologies for service.
- Confirm that the device serial number matches the accompanying documentation.
- Ensure all regulatory markings (e.g., CE, FDA, or other required symbols) are present and legible.
- Check for the presence of an up-to-date Instructions for Use (IFU) manual. Most current revisions available at www.dilon.com.

7.2 Inspection of Control Unit

- Inspect the device housing for any cracks, scratches, or signs of damage.
- Ensure all connectors, ports, and buttons are free of debris and appear undamaged.
- Verify that all accessories (cables, power adapters) are included and in good condition.
- Power on the device and confirm that it boots up properly.
- Verify that the display screen (if applicable) is clear and free of defects.
- Check that any indicator lights function as described in Table 7.

7.3 Inspection of Probes and Cables

- Probe faces are free of cracks
- Probe pins are intact (for cabled probes)
- Cables are free of cracks and cuts

WARNING: Do not drop the Navigator probe. The reusable Navigator probe is a delicate surgical instrument. Mechanical shock can result in permanent damage to the probe.

WARNING: Follow universal, generally accepted practices when handling components that have come in contact with blood or tissue.

7.4 Installation and Removal of Control Unit and Probe Batteries

To install battery:

1. Open the door to the battery port, located on the side of the control unit.
2. Insert a charged battery (Part #: N2-8500-02) into the battery port. The battery label should be facing toward the rear of the unit. The battery contacts will be inserted first. The tab on the side of the battery is positioned outward. Use the direction indicator arrow on the battery label for guidance. See figure 7.
3. Close the battery door. The door will “click” when closed properly.

CAUTION: The battery must be removed prior to installing the Pole Mount.

Figure 7 – Control Unit Battery Installation

To remove battery:

1. Turn off the Navigator Control Unit.
2. Open the door to the battery port, located on the side of the control unit.
3. The battery should partially eject when the door is opened. Use the tab attached to the end of the battery to slide the battery out of the Control Unit as shown in figure 8.

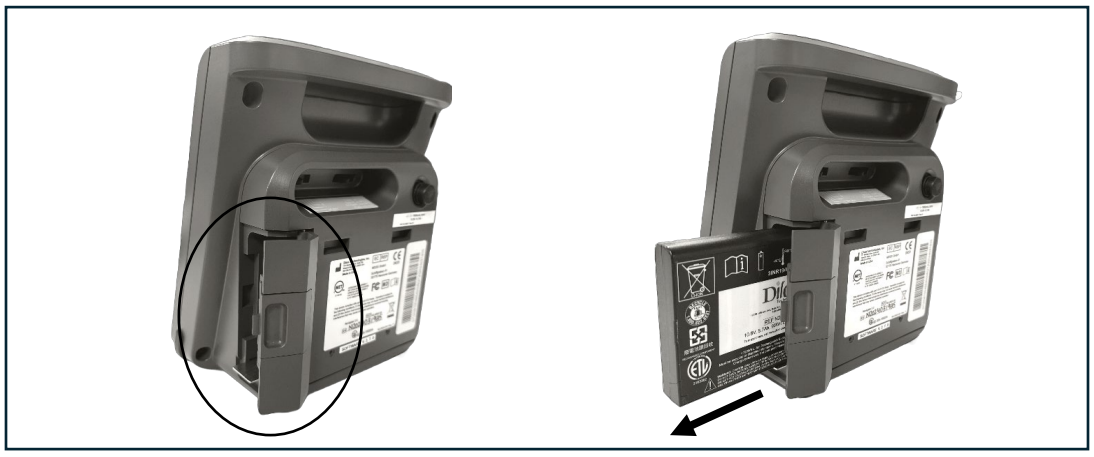


Figure 8 – Control Unit Battery Removal

To install the Wireless Pilot Probe Battery:

1. Install 3V CR2 Duracell battery (Part # WP-8500-01) into the Wireless Battery Holder with positive (+) end of the battery aligned with the (+) as shown on the label.

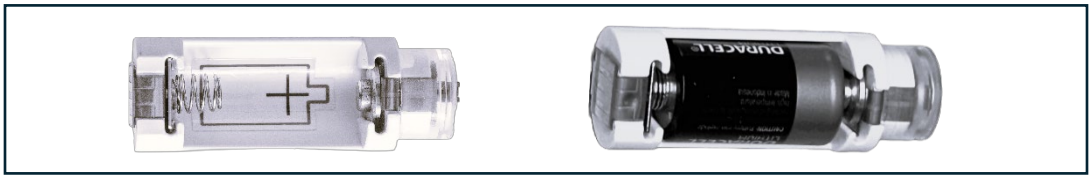


Figure 9 – Battery Holder

2. Insert Wireless Battery Holder into probe with battery aligned with the serial number of the probe. Lightly turn until battery holder lowers into place.

   Note: *The wireless antenna is located on the battery holder. Do not insert the antenna end of the battery holder into the probe. This will damage the antenna and may lead to wireless communication failures*

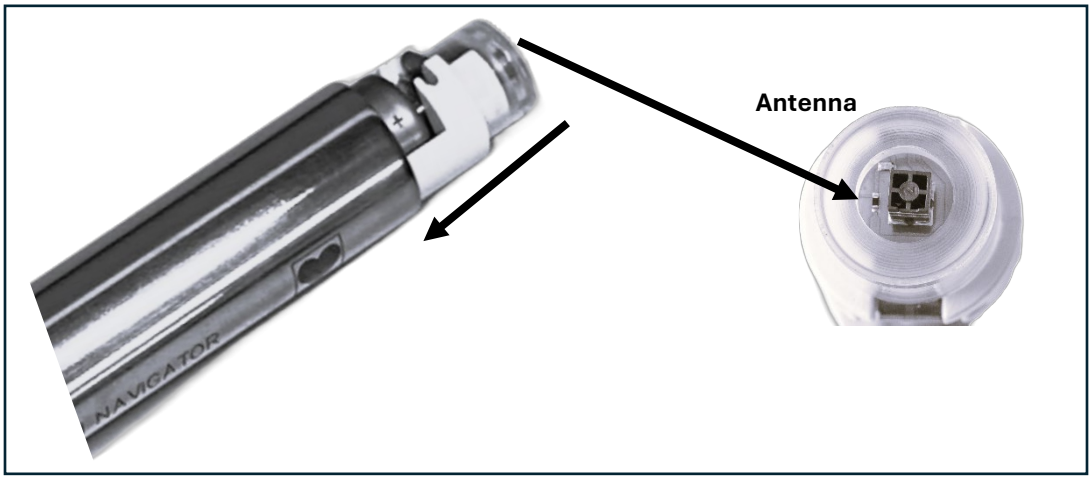


Figure 10 – Inserting Battery Holder

3. Inspect the rubber O-ring on the cap. If O-ring is missing or damaged, do not use the Battery Cap. Contact Dilon Technologies or your distributor for a new cap, if required.

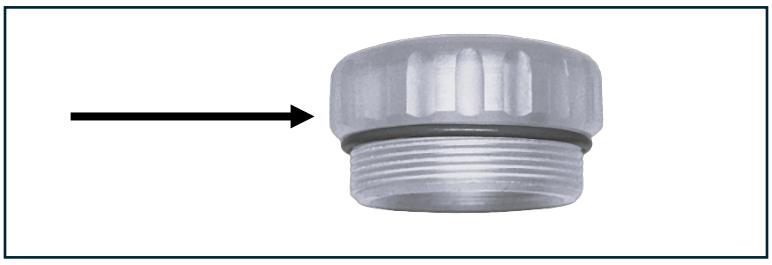


Figure 11 – Rubber O-ring

4. Install battery cap onto probe and turn clockwise until O-ring is no longer visible.

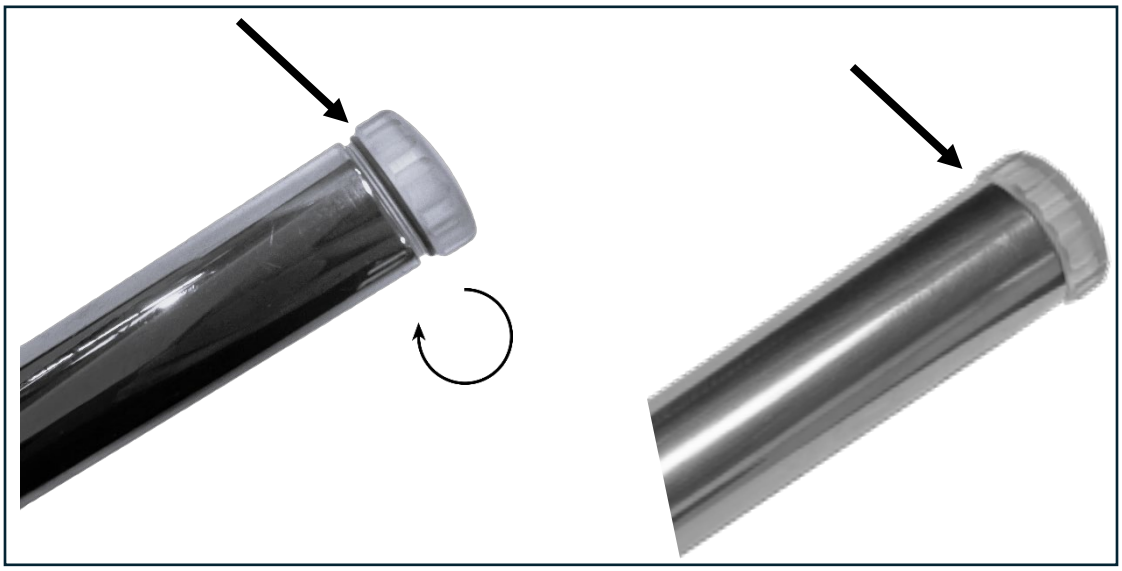


Figure 12 – Installing Battery Cap

To remove the Wireless Pilot Probe Battery:

Figure 13 – Removing Battery Cap

1. Remove the Wireless Battery Holder (Part # WP-9050-00) from the probe.
2. Hold the Wireless Pilot Probe firmly while turning the battery cap counterclockwise until the cap is removed.
   NOTE: Recommended installing a new battery before each procedure and prior to sterilization

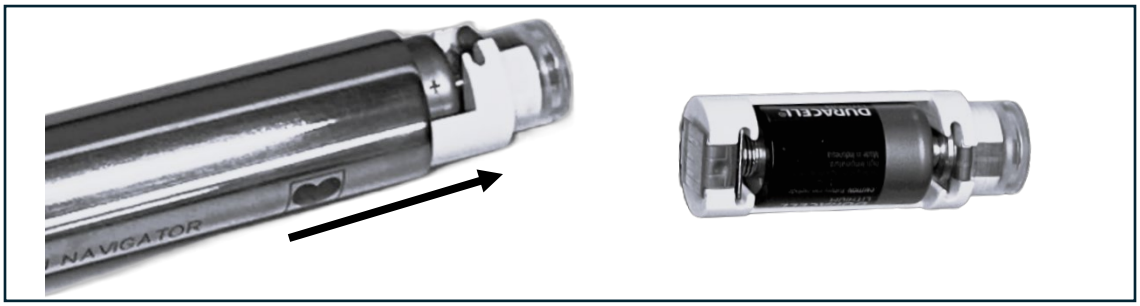


Figure 14 – Removing Battery Holder

7.5 Cabled Probe Flexible Cable Assembly Connection Instructions

Connecting and disconnecting the flexible cable assembly to the control unit:

To Connect: Match the arrows on the plastic cable connector to the arrow above the signal input port on the control unit, then gently push the connector in until it clicks into place.
To Disconnect: Gently pull back on the hood at the end of the cable assembly until it releases from the control unit.

Note: *Keep Control Unit powered off until all components are connected.*

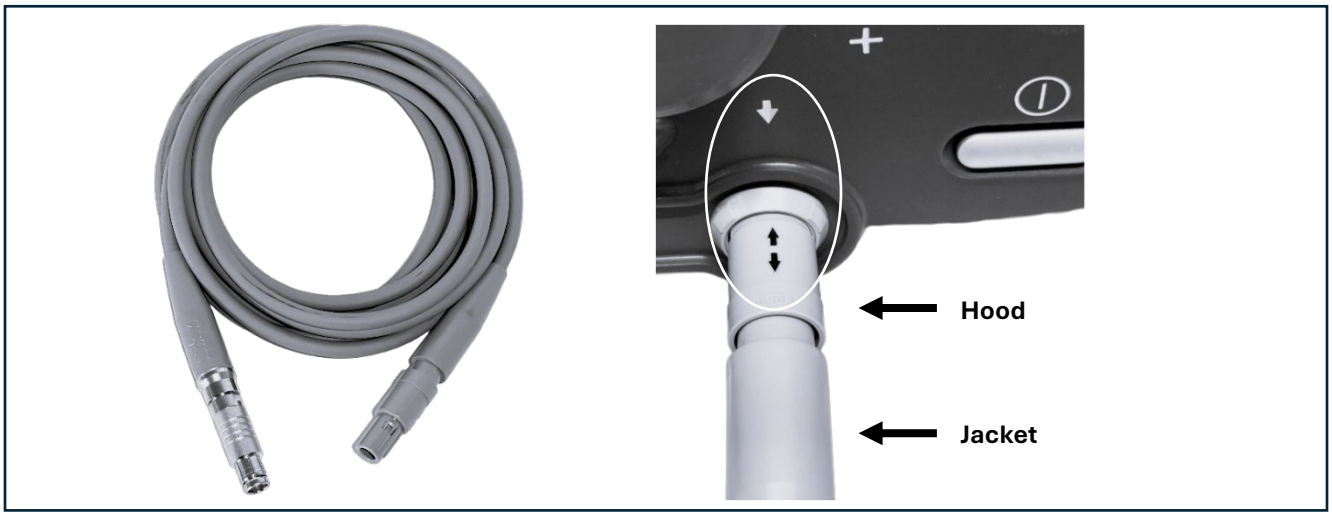


Figure 15- Removing Cable from Control Unit

⚠ **CAUTION: Do not pull or twist the jacket of the cable**. Pulling or twisting the jacket may damage the cable and render it unusable.

Connecting and disconnecting the flexible cable assembly to the cabled probe:

To connect: Align the metal connectors and the alignment dots on both ends, then gently push together until they click securely into place.

To disconnect: Gently pull back on the metal connector, then pull straight out to release the connection—**Do not twist.**

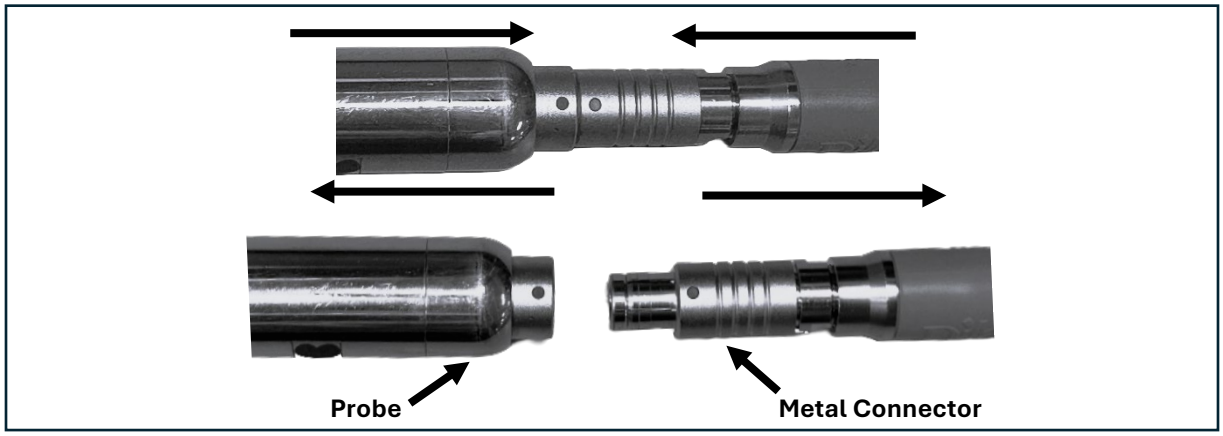


Figure 16 – Removing Battery Holder

⚠ **CAUTION: Do not pull or twist the probe or metal connector**- this may damage the cable and/or probe and render it inoperable.

7.6 Prior to Surgery- Surgical Set Up Sequence Example

Cabled and Wireless Navigator probes are used in various procedures.

*The typical setup sequence for procedures using a **Technetium-99m** isotope is as follows:*

- Refer to Section 8.4 for Probe and Cable Cleaning
- Insert a fully charged battery into control unit. See section 7.4
- Cabled Probe
  - Connect the cabled probe and Flexible Probe Cable (Part # GP-4001-00) to Navigator Control Unit. See Section 7.4
  - Connect the connected cabled probe and Flexible Probe Cable (Part # GP-4001-00) to Navigator Control Unit. See Section 7.4
  - Reference Control Unit settings in *Table 12*.
- Wireless Pilot Probe
  - Insert a fully charged battery into wireless probe. See section 7.4
  - With the Control Unit on, lightly shake the Wireless Pilot Probe to activate. The LED on the probe will illuminate when the probe is on and connected to the Control Unit.
  - Reference Control Unit settings in Table 13.
- During Surgery
  - Reference useful adjustments in Table 14
- After Surgery
  - Refer to Section 8 for Probe and Cable Cleaning

Table 12 – Navigator 2.0 with Standard Lymphatic Mapping Probes, Superficial Head & Neck Probe, Daniel Lung Probe, and Laparoscopic Probes - Settings and Indicators

Control / Indicator	Setting
Controls (Rear of Control Unit)	
SCAN/Calibrate:	SCAN
Isotope:	Switch to isotope of choice-Tc99, I125, 511keV In111
Indicators (Front of the Control Unit)	
Range:	1x
Threshold:	Illuminated
Display:	0
Isotope:	Selected Isotope Illuminated- Tc99, I125, 511keV In111

Table 13 – Navigator 2.0 with Wireless Pilot Probe – Settings & Indicators

Control / Indicator	Setting
Controls (Rear of Control Unit)	
SCAN/Calibrate:	SCAN
Isotope:	Tc99
Indicators (Front of the Control Unit)	
Range:	1x
Threshold:	Illuminated

Display:	0
Isotope:	Tc99 Illuminated
Indicator (On the Wireless Pilot Probe handle)	
Probe LED:	Illuminated

Table 14 – Useful adjustments

Adjustment	**Benefit**
Threshold	*For **Cabled Probes** only*, this feature increases specificity when only a low number of events are observed. Threshold control defaults to ON. When ON, the system counts only the events in a narrow energy range around the signal. Change Threshold to OFF to allow the system to count all signals it detects, opening the value range to scatter. For ***Wireless Pilot Probe*** only. The Threshold feature is integrated into the probe. The Control Unit setting will not affect the wireless probe functionality.
Range	The Range function defaults to 1X. When Range is set to 1X, the audible signal fluctuates according to every event detected. The 10X position will fluctuate the audible signal every 10th event. The 100X position will fluctuate the audible signal every 100th event. **NOTE**: The Range control only affects the sound. The count shown in the display is independent of the range setting.
10-Second Count	Press to obtain a 10-second count, keeping the probe in a fixed position each time. The 10 second count total is displayed for four seconds.
Volume	Adjust to desired volume.
Power	Press to turn on the control unit or to safely turn off the device.

8. POST-USE HANDLING AND DATA MANAGEMENT

8.1 Recording and Storing Measurement Data

The **Navigator 2.0 System** does not store, record, or have the capability to retain any form of data. The system operates in real-time without saving user inputs, patient information, or device settings.

8.2 Device Cleaning and Decontamination

The cleaning instructions provided have been validated by the manufacturer as being capable of preparing the medical device for re-use. It remains the responsibility of the re-processor to ensure that the reprocessing is performed using equipment, materials, and personnel to achieve the desired result. This requires validation and routine monitoring of processes, and any deviation from the instructions provided should be properly evaluated for effectiveness and potential adverse effects.

Failure to obey these safety instructions may cause permanent damage to the systems and/or lead to inadequate cleaning and sterilization. The probes should be sterilized after each case. Cleaning agents or techniques not specified are the sole responsibility of the user to adequately assess and validate.

WARNING: The Probes and cables must be cleaned and sterilized only by qualified personnel.

8.3 Control Unit Cleaning

To clean the Navigator Control Unit use any germicidal disposable wipe containing less than 35% Ethanol and less than 56% Isopropanol. Avoid excessive moisture and allow the device to air dry completely before use.

CAUTION: *The Navigator Control Unit should be cleaned prior to and after use.*

CAUTION: *To prevent damage to the control unit, use only the cleaning methods specified in this manual.*

CAUTION: *Do not sterilize the Navigator Control Unit or immerse it in fluids. Attempting to do so will cause permanent damage to the Control Unit*

CAUTION: *Do not clean control unit or accessories when energized. Remove battery from control unit prior to cleaning.*

NOTE: Avoid cleaning products with high levels of ethyl alcohol.
NOTE: If residue is observed, use a dry cloth to remove.

8.4 Probe and Cable Cleaning

CAUTION: Probes and cables should be cleaned prior to and after use.

CAUTION: *To avoid damage to the probe and cable, do not use cleaners or other methods not stated in this manual.*

CAUTION: *Disconnect cables and probes from other accessories and power sources prior to cleaning.*

WARNING: Do not clean or sterilize when the cap of the wireless probe is missing or not completely tightened. Attempting to do so will cause permanent damage to the probe.

WARNING: Do not scratch or abrade the probe when cleaning or sterilizing. Scratching / abrading the probe surface will damage the probe.

WARNING: Failure to thoroughly clean the device prior to sterilization may lead to inadequate sterilization.

WARNING: The handling and storing of clean and sterile probes and cables should be conducted per your facility's guidelines.

WARNING: Do not immerse probe and cable in fluids, or place in an automated cleaning system as it may cause permanent damage to the probe and cable.

Probe Preparation Steps:

Ensure the following for wireless probes, cabled probes, and cables:

1. The probes are free of any damage.
2. The cables are free of cracks or cuts.
3. The connectors of the probe and cable are completely dry.
4. The cable is detached from the probe and the Navigator Control Unit.
5. (If available) The top gun collimator is removed from the probe.

For wireless probe only:

1. Prior to each cleaning, insert a new CR2 Duracell battery, part number WP-8500-00.
2. Ensure the cap is securely tightened to the Wireless Pilot Probe. The O-ring on the cap should not be visible. See Figure 12.

Table 15 – Instructions for Cleaning Probes and Cables with Enzymatic Detergent

No.:	Cleaning with Enzymatic Detergent
1.	Probes and cables should be inspected according to section 8.4
2.	Prepare an enzymatic cleaner, suitable for surgical instruments, according to the manufacturer's recommendation.
3.	Rinse the outside surfaces of the probe with a brisk stream of lukewarm tap water (98°F to 105°F / 36.5°C to 40.5°C). Wipe with soft cloth or sponge soaked in enzymatic cleaner. Repeat separately for collimator cleaning, if used.
4.	Visually inspect device(s) for contaminated areas.
5.	Repeat steps 1 & 2 until visual inspection reveals the instrument(s) is clean.
6.	Rinse equipment with a brisk stream of lukewarm tap water (98°F to 105°F / 36.5°C to 40.5°C) for 30-seconds.
7.	Air-dry or dry with clean towel.

8.5 Sterilization of Navigator Probes and Cables

Dilon has identified that Navigator Gamma Probes that enter sterile tissue are to be considered critical devices and treated according to guidelines for this category as established by:

CDC Publication: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
Update May: 2019

ISO 17664: 2021 Processing of health care products

Joint Commission Standards Related to Disinfection and Sterilization found in: Joint-Commision-HLD-and-Sterilization-BoosterPak.pdf

Before sterilization, devices must be properly cleaned as outlined in section 8

*Table 16– Systems Approved for Use in Sterilization of Navigator **Probes and Cable***

STERRAD®
STERRAD® NX - Standard Cycle
STERRAD® 100NX - Standard Cycle
STERRAD® 100S - Short Cycle
Steris V-Pro®
Steris V-PRO® 1 Plus - Non-Lumen Cycle
Steris V-PRO® maX - Flexible Cycle
Steris V-PRO® 60 - Non-Lumen Cycle
Steris V-PRO® maX - Non-Lumen Cycle
STERIZONE®
STERIZONE® VP4 Sterilizer - Cycle 1

*Table 17 – Additional Cleaners Approved for Use in Sterilization of Navigator **Probes Only***

Steris V-Pro®
Steris V-PRO® 1 - Standard Cycle
Steris V-PRO® 1 - Standard Cycle
Steris V-PRO® maX – Lumen Cycle
Steris V-PRO® 60 – Lumen Cycle

WARNING: To avoid permanent damage of the cable, do not process the cable in the V-PRO 1 Standard Cycle or the VPRO-1 Plus, VPRO maX, or V-PRO 60 Lumen Cycles because the cable contains polyurethane.

WARNING: DO NOT put any probe or probe cable in an autoclave.

8.6 Sterilization Trays

Customized Navigator sterilization trays are available as additional accessories to properly store the Navigator probe and/or cable in the facilities' sterilization processing department. See Figure 2A for reference.

Wireless Probe Tray:

1. Secure cleaned wireless probe in Dilon Navigator tray in the customized rubber inserts. Secure cover and wrap tray per hospital and manufacturer's sterilization system guidelines. Tray may only contain one probe.

Cabled Probe Tray:

2. Place the cleaned cabled probe in the Dilon Navigator tray using the customized rubber inserts. Lightly coil the cleaned cable and position it alongside the probe. Secure the tray cover and wrap according to hospital and manufacturer sterilization system guidelines. Only one cleaned probe and one cleaned cable may be placed in each tray.

Table 18 – Systems for Use in Sterilization of Navigator Probes

No.:	Instruction Step
1.	Probes and cables should be inspected according to section 8.4
2.	Please refer to the sterilization equipment manufacturer's instructions to properly conduct the sterilization procedure. The probe cable can be loosely coiled in the sterilization tray and then placed together with the probe.
3.	After the sterilization procedure is completed, handle and store the probes and cables per your facility's guidelines for packaging and storing sterile products.
4.	The wireless probe, containing a battery, has a two-week shelf-life following sterilization. If this period is exceeded, the battery must be replaced and the probe re-sterilized before use.

WARNING: Do not use a wireless probe beyond its two-week shelf life after sterilization, as the battery may become depleted, affecting functionality. If the probe has been stored for more than two weeks, replace the battery and re-sterilize before use.

8.7 Navigator Probes Used in Non-Critical Environments

Noncritical items as identified by CDC Publication, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 Update May: 2019., are those that come in contact with intact skin but not mucous membranes.

Navigator Gamma Probes Used in Non-Critical Environments, such as to perform pre-operative scans, should first be processed using the cleaning and preparation instructions identified in Section 8.4

Sterile Dilon Probe Covers, part number WP-9003-DRT and SP-9004-DRC can also be used after cleaning, disinfection, and/or sterilization of probes.

9. MAINTENANCE AND CALIBRATION

9.1 Routine Maintenance Schedule

While the Navigator 2.0 System is virtually maintenance-free, the user should routinely inspect their equipment to ensure proper performance.

- Prior to each use, check each system component for any visible signs of damage or wear. This includes checking the following components and features.
- Additional service plans and warranties are available for purchase. For more information contact your Dilon representative.

Table 19 – Component Check

Component Check	Feature Check
Control Unit	Housing, integrity of switches and integrity of connections.
Battery Charger	Housing and integrity of connections.
Cabled Probe	Visual damage, probe tip and connector.
Wireless Probe	Visual damage, probe tip, battery cap and O-ring, battery holder
Cable (if used)	Each connector, the connector pins, and integrity of cable.

- Discontinue use if abnormalities are observed. Contact your sales representative or Dilon Technologies directly for repair.

CAUTION: *Do not use damaged equipment.*

CAUTION: *Disconnect cables and probes from other accessories and power sources prior to cleaning.*

- Check each battery for function and charge before use. Discontinue use if abnormalities are observed.
- In addition to the above, preventive maintenance suggests that every two years a new battery, fuse, and cable (if used) might be considered.
- User maintenance for the Wireless Pilot Probe is restricted to battery and battery cap replacement. There are no user serviceable components or items on the Pilot Probe. Do not attempt to repair.

WARNING: No modification of this equipment is permitted. Any modification to the Navigator Control Unit, Probes, or accessories may cause increased risk to user and patient.

WARNING: Modifications will void the warranty.

9.2 Performance and Calibration Procedures

The Navigator 2.0 system is designed to minimize periodic maintenance, such that would be performed by a clinical engineering department or the manufacturer. Depending on the probe used, the user can perform one of two procedures.

9.3 Verification of Standard Gain (Calibration Quick Test)

Table 20 – Applicable Probes for Standard Gain Verification

Probe	Model Number
Standard Lymphatic Mapping Probe (Straight)	SP-2A14-67
Standard Lymphatic Mapping Probe (Angled)	SP-2S14-67
Superficial Head & Neck Probe	SP-2S11-53
Daniel Lung Probe™	SP-2S10-31D
Laparoscopic Probe	SP-2S10-31

Some institutions perform this Verification of Standard Gain every six months or every year. The procedure does not calibrate the system; it simply reveals whether or not the probe and control unit are set to a common gain standard (calibration). That common standard relates the gamma photon energy detected by the probe to an energy window inside the control unit.

The Verification of Standard Gain uses 122 keV energy photons produced by the Isotope of Cobalt- 57, to create a known signal in the probe. The control unit expects these detected photons to be in an energy window corresponding to the CENTERED (>0<) position of the test. The control unit also has a test setting for an energy window BELOW (-) the expected signal, and an

energy window for a signal ABOVE (+) the expected signal. The desired outcome of the test is that the signal is greatest in the CENTERED (>0<) position, as revealed by the highest count rate seen in the control unit's display. The details of the test are given below.

9.4 Verification of Standard Gain (Calibration Quick Test)

Procedure is for Cabled Probes ONLY

1. Clean the PROBE and, if used, the CABLE.
2. Charge the BATTERY and install it into the CONTROL UNIT.
3. Place the system controls as indicated in Table 21, "System Configuration - Cobalt-57 Alignment".
4. Align a 57 Cobalt-57 source directly with the probe tip. Maintain this exact position between the source and the probe tip for the duration of the test.
5. Place the system controls as indicated in Table 21 "System Configuration - Cobalt-57 Alignment."
6. Place the SCAN/Calibrate Control in the CENTERED position, which is indicated by the following symbol on the SCAN/Calibrate Control (>0<). Obtain a ten-second count. Record this total.
7. Place the SCAN/Calibrate Control in the BELOW position which is indicated by the following symbol on the SCAN/Calibrate Control (-). Press the COUNT control to obtain a ten-second count. Record this total.
8. Place the SCAN/Calibrate Control in the ABOVE position which is indicated by the following symbol on the SCAN/Calibrate Control (+). Obtain a ten-second count. Record this total.
9. The highest count should be when the SCAN/Calibrate Control is in the CENTERED (>0<) position. The count in the ABOVE position (+) and the count in the BELOW position (-) should be less than the count in the CENTERED (>0<) position. The observance of these relationships verifies that the probe and control unit have the same standard gain.
10. Return the SCAN/Calibrate Control to the SCAN position.
11. Return the other system controls to the settings for normal use.

Table 21 – System Configuration – Cobalt-57 Alignment During Calibration Quick Test

Component/Feature	Setting
Cabled Probe	Cable connected to probe input
CALIBRATE control (rear panel)	(>0<), (-), (+)
ISOTOPE control (rear panel)	Technetium-99m
THRESHOLD control	As desired (no effect)
POWER switch	ON
RANGE control	As desired
VOLUME control	As desired

NOTE: Because the system is designed to detect slight changes in the location and intensity of radioisotopes, the test source must be maintained in the same direct alignment and distance from the probe tip throughout the three calibration tests.

NOTE: The front panel calibration–check mode indicator **Cal** blinks when the SCAN/Calibrate Control is in either the BELOW (**-**), CENTERED (>**0**<), or ABOVE (**+**) test position. The CALIBRATION-CHECK MODE INDICATOR is OFF when the CALIBRATION control is in the SCAN position.

NOTE: All cabled Navigator 2.0 probes are compatible with any Navigator 2.0 control unit. Wireless probes require software that matches the console software version

9.5 Navigator Control Unit Fuse Replacement

The Navigator 2.0 fuse may be replaced, when necessary, by the user.

WARNING: Only approved replacement part should be used with the Dilon Navigator. Use of an unapproved fuse may result in damage to the Navigator Control Unit.
WARNING: Use of an unapproved replacement fuse may alter the performance of the Navigator Control Unit.

1. Locate the fuse holder on the rear of the Navigator Control Unit.

Figure 17– Fuse holder cap above fuse label

2. Push-in and twist the fuse holder cap counterclockwise to remove to remove the fuse holder and fuse from the Control Unit and discard damaged fuse.

Figure 18 – Fuse holder cap removed from control unit

3. Insert a new fuse (Part # SC-0099-00) into the holder.

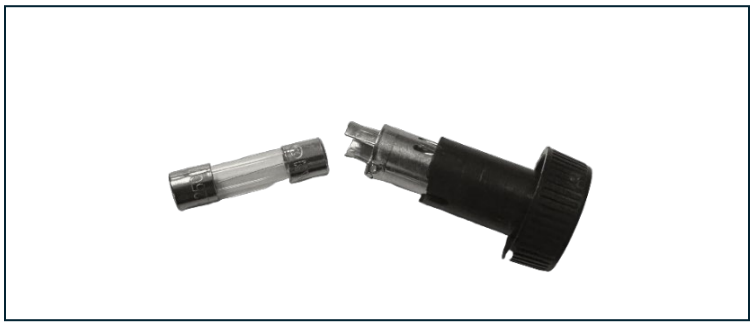


Figure 19 – Fuse holder cap above fuse label

4. Press-in and twist the fuse holder cap clockwise to lock in place.

9.6 Operating and Storage Conditions

9.6.1 Operating Conditions

- Temperature: -15°C to 40°C (5°F to 104°F)
- Relative Humidity: 0%-80% relative humidity, non-condensing
- Atmospheric Pressure: 80 kPa to 106 kPa

9.6.2 Storage Conditions

- Temperature: -15°C to 40°C (5°F to 104°F)
- Relative Humidity: 5%-95%, non-condensing relative humidity
- Atmospheric Pressure: 50 kPa to 106 kPa

10. TROUBLESHOOTING AND ERROR HANDLING

10.1 Common Errors and Resolutions

The Navigator Control Unit, Probes, and Cables contain no user serviceable parts. Dilon offers Wireless Pilot Probe Battery Holders, Wireless Pilot Probe Batteries, and Navigator Control Unit Batteries and Fuses for sale for use with the Navigator System.

Contact your local representative or Dilon Technologies for additional assistance if more detail is required.

Table 22 – Navigator Control Unit – Settings and Indicators

Problem	Possible Causes	Remedies
1. Display is dark; No power to unit.	- Power switch is off; - Switch is broken. - Unit may be damaged.	- Turn power on. - Contact Dilon Technologies for assistance.
	Battery is completely discharged or not installed.	Recharge battery or replace with new battery.
	Fuse is blown or missing.	Replace fuse.
	Damaged PCB (board) in control unit	Contact Dilon Technologies for assistance.

2. Incomplete digits in display.	- Display, or display driver, is damaged. - Unit may be damaged.	Contact Dilon Technologies for assistance.

Table 23 – Navigator Control Unit with Wireless Pilot Probe – Settings and Indicators

Problem	Possible Causes	Remedies
1. Zero in display; No signal under the presence of a radioactive source.	No wireless connection between probe and control unit.	- Replace the probe battery. - Verify that battery was inserted correctly into the battery holder. ('+' should face toward battery cap).
	Isotope control is set to incorrect isotope.	Change isotope control (on rear of control unit) to Tc99.
	The circuit inside the control unit has been damaged.	Try a different control unit. Contact Dilon Technologies for assistance.
	Probe LED is illuminated but not transmitting signal to unit (LED flashes when transmitting).	- Turn off the probe and turn it back on. - Contact Dilon Technologies if problem persists.
	Probe is damaged / battery cap not secure.	Check that cap is on properly. Try a different probe. Contact Dilon Technologies for further assistance.
2. LED on pilot probe does not illuminate	Probe battery is dead or installed incorrectly.	- Replace with new battery. Probe must be re-sterilized - Verify that battery was inserted correctly into battery holder ('+' should face toward battery cap).
	Battery was not installed.	Install a new battery.
	LED on probe is damaged.	Contact Dilon Technologies for assistance.
3. False counts, when probe not located adjacent to radiopharmaceutical	Radiopharmaceuticals may be present on probe.	Clean probe with Radiacwash or equivalent. Refer to radiation decontamination solution manufacturer's cleaning instructions.

Table 24 – Navigator Control Unit with Cabled Probe – Settings and Indicators

Problem	Possible Causes	Remedies
1. Zero in display. No signal under the presence of a radioactive source.	No connection between probe, cable, and control unit.	Check that all connections are secure.
	Isotope Control is set to incorrect isotope.	Change Isotope Control (on rear of control unit) to appropriate setting for radiopharmaceutical in use.
	There is an open circuit in the probe cable.	Replace cable.
	Circuit inside the control unit has been damaged.	- Try a different Control Unit or contact Dilon Technologies for assistance.
	Probe is damaged / probe cap not secure / detector	Try a different probe or contact Dilon Technologies for assistance.

	damaged.	
2. False high counts, such as 80,000 counts a second (when probe is held in air, for example).	Intermittent short in the cable.	Replace cable.
3. Spurious counts, when probe ***not*** located adjacent to radiopharmaceutical	Radiopharmaceutical may be present on probe.	Clean probe with Radiacwash or equivalent. Refer to radiation decontamination solution manufacturer's cleaning instructions.

10.2 System Alerts and Error Messages

The Navigator 2.0 with software version 2.7.0 or later includes warning and error message features not available in previous versions of the Navigator 2.0 system.

The warning and error message features are intended to notify users of conditions that may impact the operation of the device. In a warning condition, the controller will automatically attempt normal operation. In an error condition, the system will require a reboot or user intervention as described in table 20. The Navigator 2.0 system enters the warning or error mode and displays a specific value on the display that is outside the range of normal operations of the gamma probe count value.

10.3 Software Version

Software version can be identified by a label on the back of the control unit. For systems with version 2.7.0 or later, you can also display the software version using the following steps:

1. Ensure the control unit is in the Off state.
2. Set the Isotope Selection Switch to TC-99.
3. Turn the control unit On.

Three digits will appear on the display. These digits represent the software version. For example, if 270 is displayed, it indicates version 2.7.0.

Table 25 – Alarm Mode Indications

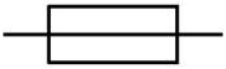
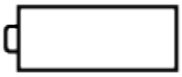
Warning Mode ID (Counts)	**Alarm State**
888X*	If the system disconnects from its wireless probe, it will automatically attempt to reconnect. If it is unable to reconnect after 4 seconds, the display will show 888X* while continuing to reconnect. During this time, the display will show '0' as it is not picking up additional data. *X can range from 0 to 9.
3333	While in normal operating mode, the system communicates with one probe. If this probe is inadvertently turned off and another unpaired probe is powered on in the vicinity, the controller will display 3333 to indicate a new probe is attempting to connect. When the original probe is powered back on and establishes a connection with the controller, normal operational mode will resume. If you want to use a different wireless probe the Control Unit must be turned off and restarted to pair to the different probe.

Warning Mode ID (Counts)	Alarm State
ERROR Mode ID (Counts)	**Error State**
7777	System Software version mismatch – the controller and wireless probe software versions are incompatible.
6666	The EEPROM (memory) in the control unit has been damaged. If this error occurs, please contact Dilon
5555	Wireless Probe Low Battery – Indicates a low battery condition on the wireless probe.
4444	The EEPROM (memory) in the wireless prove unit been damaged. If this error occurs, please contact Dilon

NOTE: Additional warning and error mode IDs may be added in future software versions.

11. SYMBOLS, GLOSSAY, AND ABBREVIATIONS

11.1 Explanation of Symbols Used

	Type-CF Applied Part		RX only Caution: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.
	Medical device		Follow Instructions for Use
	Manufactured		Consult instructions for use or consult electronic instructions for use
	ON/OFF		Caution
	Temperature limit		Serial number
	Humidity limitation		Catalogue number
	Wireless Capability		Authorized representative in the European Community/ European Union
	Fuse		WEEE
	Battery		Model number
	Keep dry		Country of manufacture
	Federal Communications Commission		Japan Radio Law and Ordinance Concerning Technical Regulations Conformity Certification of Specified Radio Equipment
	Fragile, handle with care		Do not use if package is damaged

12. MANUFACTURING AND REGULATORY INFORMATION

12.1 Repair

Serviceable parts for the Wireless Pilot Probes include a replaceable battery, battery holder, and end cap. The Wireless Pilot Probe contains no additional user serviceable parts.

The Cabled Probe contains no user serviceable parts. Damage to a probe may result if a probe is opened by the user and will void any remaining warranty, if attempted.

Serviceable parts on the Navigator 2.0 control unit include a fuse and a replaceable battery. The control unit contains no additional user serviceable parts and should not be opened by the user.

Please contact Dilon Technologies for service or to purchase user replaceable items. An authorization number is required for return to Dilon for service.

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⚠ **CAUTION**: *Before using loose packing materials, such as foam pellets, shredded paper, or excelsior, be sure to wrap the component(s) separately in protective bags or other protective wrapping upon return for repair.*

⚠ **CAUTION**: *If a system, or system components, are to be shipped from your institution for repair, then please clean and disinfect the components as described in this manual before packing for shipment.*

⚠ **CAUTION**: *Dilon Technologies require that the Navigator Service Sheet be attached to the outside of the shipping box, certifying that the items have been cleaned and disinfected to manufacturer's specifications. This form can be found on the Dilon Technologies website (**www.Dilon.com**) or by contacting your distributor or Dilon Technologies directly.*

12.2 Repair

Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.

WEEE Directive 2012/19/EU - Do not dispose of WEEE products in general waste. At the end of life of the product, contact Dilon Technologies for return instructions.

Ensure the cleaning of the device and/or accessories prior to shipment.

12.3 Regulatory and Safety Information

The Dilon Navigator 2.0™ System including Probes complies with the following standards:

EC Directives
EMC Directive 89/336/EEC Group l, Class B
EN 55011
EMC Directive 89/336/EEC IEC 60601-1-2 : 3rd Edition

Reciprocal Interference

This product has been tested and verified to ensure that there are no issues or concerns regarding reciprocal interference. This includes EMI, EMC, and RF. This product has been certified and tested by 3rd party testing facilities. List of standards is as follows:

- Medical Electrical Equipment - Part 1: General requirements For Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems – IEC 60601-1-1: 3Ed: Amendment 1.
- Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility – IEC 60601-1-2: 4th Ed.

Safety

- Medical Electrical Equipment - Part 1: General requirements For Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems – IEC 60601-1: 3rd Ed.
- Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – IEC 60601-1-2: 3rd edition.
- Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability - IEC 60601-1-6: 2010 + Am. 1: 2013.
- CAN/CSA C22.2 No. 60601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety & Essential Performance; issued 2008-02-01 Ed. 2
- AS/NZS 3200-1-0, Deviations to IEC 601-1 for Application in Australia and NewZealand

CE 0459

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

FCC statements: “This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.”

IC statements: “This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause interference and (2) this device must accept any interference, including interference that may cause undesired operation of the device.”

12.4 Limited Warranty

Dilon Technologies (Dilon), warrants to its customers that, subject to the below provisions, the Navigator 2.0 system and probes will be free from defects in materials and workmanship for twelve (12) months, commencing upon the date of shipment from Dilon.

Replacement parts and products are warranted to be free from defects in material and workmanship for a period equal to the balance of the warranty period remaining on the original part or product.

Dilon will repair or replace, at its option and without charge, any of the above products which are returned to Dilon or its designated repair site, within the applicable warranty period, with prepayment of shipping costs, and which are determined by Dilon to be defective in materials or workmanship.

This Limited Warranty does not apply to any product or replacement part or replacement product which has been subjected to any damage as a result of an accident or abuse, or that has not been used and maintained in accordance with the information contained in the literature accompanying the product, or that has been modified, repaired or serviced by any person or company other than Dilon or its authorized representative.

Dilon's sole liability for any defective product shall be repaired or replaced as set forth above. Dilon shall not be liable to anyone, under any circumstances, for any special, punitive, incidental, or consequential damage whatsoever, including without limitation any costs, expenses, lost profits, or other losses however designated. EXCEPT AS STATED ABOVE, NO WARRANTIES ARE EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND, EXCEPT AS STATED ABOVE, DILON EXPRESSLY DISCLAIMS ALL WARRANTIES.

EC REP

MDSS
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Made in USA