Navigator™ 2.0

User/Service Manual

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EC REP

CE 0459

Important Note

All personnel that will interact with this Navigator 2.0 System and Probes should read this Manual and Service Guide to ensure proper use, handling, storage and maintenance.

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User Manual: Table of Contents

1. Introduction 5

Description 5

Intended Use 5

Indications for Use 5

Manufacture and Distribution 5

Trademarks 5

Regulatory and Safety Requirements 6

EC Directives 6

Reciprocal Interference 6

Safety 6

2. System Overview and Components 9

3. Precautions 10

3A. General 10

3B. Control Unit, Battery, and Charger 10

3C. Probe 10

4. Control Unit, Battery, Cables, and Co-Pilot 12

4A-1. Control Unit Features: Front 12

4A-2. Control Unit Features: Back 15

4B. Battery (Part # N2-8500-00) 17

4C. Cables 19

4D. Optional Co-Pilot™ Device (Part # GP-6801-00) 20

4E. Useful Adjustments That Can Be Made During Procedures 22

5. Cleaning, Disinfection, and Sterile Use of Navigator Probes and Cables 23

5A. Cleaning Probes 23

5B. Radioactive Decontamination Procedure – OPTIONAL 25

5C. Cleaning/Storing Control Unit & Gain Module 25

6. Probe Connectivity and Use 26

6A. Navigator 2.0 with Wireless Pilot Probe 26

6B. Navigator 2.0 with Standard Lymphatic Mapping Probes, Superficial Head & Neck Probe, Daniel Lung Probe, and Laparoscopic Probes 29

6C. Navigator 2.0 with 12mm Lymphatic Mapping Probe (Part # N2-9001-12) 31

7. Running the Peak Procedure: 12mm Lymphatic Mapping Probe Only 33

7A. Running a Peak Procedure 33

Service Manual

8. Troubleshooting 35

9. Specifications 37

9A. Navigator 2.0 System Specifications 37

9B. System Accuracy 38

10. Support Items 39

10A. Product Part Numbers 39

10B. Sterile Drape 39

11. Maintenance 40

11A. Overview 40

11B. Verification of Standard Gain (Calibration Quick Test) 40

11C. Fuse Replacement Procedure 42

12. Repair 44

13. Recycling 45

14. Limited Warranty 46

USER MANUAL

1. Introduction

Description

The Navigator 2.0 System detects gamma photons, such as those produced by radioactive decay. The Navigator 2.0 System is a portable, battery powered system.

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 battery.

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

- 14mm Wireless Pilot Probe™ (angled tip)
- 14mm Standard Lymphatic Mapping Probes (angled tip & straight tip)
- 12 mm Lymphatic Mapping Probe (angled tip)
- 11mm Superficial Head & Neck Probe (straight tip)
- 10mm Daniel Lung Probe™ (straight tip)
- 10mm Laparoscopic Probes (310mm & 190mm Lengths, straight tips)

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

Intended Use

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

Indications for Use

For the detection and quantification of gamma radiation from gamma-emitting isotopes in the body or tissues. Use 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.

Manufacture and Distribution

The system is manufactured and distributed by Dilon Technologies of Newport News, VA. Please direct all inquiries about the Navigator 2.0 to Dilon Technologies.

Trademarks

The following are trademarks of Dilon Technologies: Navigator 2.0™, Wireless Pilot Probe™, Dilon Navigator GPS™, Dilon Navigator™, Dilon Technologies Navigator GPS™, Dilon Technologies Navigator™, Dilon Technologies Navigator 2.0™, Daniel Lung Probe™, and Navigator™ when used in context with the above.

Navigator GPS® is a registered trademark of Dilon Technologies.

Regulatory and Safety Requirements

The Dilon Navigator GPS™ System including Probes and accessories 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: 3rd Ed.
- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – IEC 60601-1-2: 3rd Ed.

Safety

- Medical Electrical Equipment - Part 1: General requirements For Safety 1: Collateral Standard: Safety Requirements For Medical Electrical Systems – IEC 60601-1: 2nd & 3rd Ed.
- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – IEC 60601-1-2: 3rd Ed.
- Medical Electrical Equipment - Part 1-6: General Requirements For Safety - Collateral Standard: Usability - IEC 60601-1-6: 3rd Ed.
- Information supplied by the manufacturer of medical devices- EN 1041:2008
- Symbols for use in the labeling of medical devices - EN 980 :2008
- 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 New Zealand

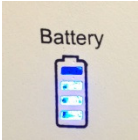
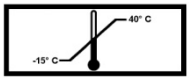
CE 0459

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

Table 1A. Explanation of Symbols

	Type-CF Equipment	Rx only	RX only Caution: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.
	Probe		Date of Manufacture
	Data Port		Manufactured by
	Eject	or	Consult instructions for use
	Attention, consult accompanying documents		Temperature limitation
	Remote Count Control		Humidity limitation
Tc99 In111 511keV I125	Isotope Control	SN	Serial number
+ 0 − SCAN	Calibrate Control	REF	Catalogue number
	Fuse	EC REP	European Authorized Representative
+	Battery	LOT	Batch code

Table 1A. Explanation of Symbols (Continued)

	Battery Power Level		Caution: High Voltage
	Acceptable shipping/storage conditions: -15° C to 40° C		
	WEEE Symbol (EU only)		

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."*

Cet appareil est conforme avec Industrie Canada RSS exemptes de licence standard (s). Son fonctionnement est soumis aux deux conditions suivantes: (1) Ce dispositif ne doit pas causer d'interférences, et (2) cet appareil doit accepter toute interférence, y compris les interferences qui peuvent causer un mauvais fonctionnement de l'appareil.

2. System Overview and Components

Table 2A. Probe Dimensions

Probe	Tip Diameter	Tip Angle	Length	Weight
Wireless Pilot Probe	14mm	30	260mm	255g
Standard Lymphatic Mapping Probes	14mm 14mm	0 35	224mm 220mm	185g 185g
12mm Lymphatic Mapping Probe	12mm	35	242mm	235 g
Superficial Head & Neck Probe	11mm	0	207mm	161g
Daniel Lung Probe™	10mm	30	465mm	195g
Laparoscopic Probes	10mm 10mm	0 0	467mm 347mm	195g 190g

3. Precautions

3A. General

- 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.
- 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.

3B. 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.
- When optional system components are used with the system, maintain probe and patient electrical isolation from earth ground. The optional components include the Co-Pilot™ Device, the probe drape, the Top Gun™ Collimator, and Navigator 2.0 cart.
- In the operating room, use the charger at a distance of six feet or greater from the patient. The charger has a rating in the United States of a "patient proximity charger."
- Fully charge the battery before use in the system.
- Replace the wireless probe battery with a new battery on EACH day of use, before the first surgical procedure.
- This system is not designed for use in an explosive atmosphere.
- Keep the control unit off when changing connections between the probe, cable, control unit and gain module, when used. Control unit should also be off when inserting battery into Wireless Pilot Probe.
- The control unit, cables, batteries, charger, and probes are sold non-sterile.

3C. Probe

- DO NOT put any probe or probe cable in an autoclave.
- With the exception of the Wireless Pilot Probe's battery bay, 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.
- Remove probe battery before cleaning Wireless Pilot Probe.
- DO NOT drop the probe.
- DO NOT strike the probe tip against a hard surface; the detector element may become damaged and no longer be able to measure radiation.
    - This will also void the warranty.
- When using the 12mm probe, DO NOT place it on, or near, a magnetic instrument pad.

3C-1. Laparoscopic and Thoracoscopic Probe Use

- This User/Service manual is designed to assist the use of the Navigator 2.0 system and is not a reference to surgical techniques. For information on endoscopic procedures, techniques, complications and hazards, please reference the following publications: *Surgical Laparoscopy* (Zuker KA ed. St. Louis MO 1991) and *Endoscopic Surgery* (White RA Klein SR, Mosby Year Book Inc. St Louis MO 1991).

- This device is intended for use only as indicated. It is not intended for use when endoscopic

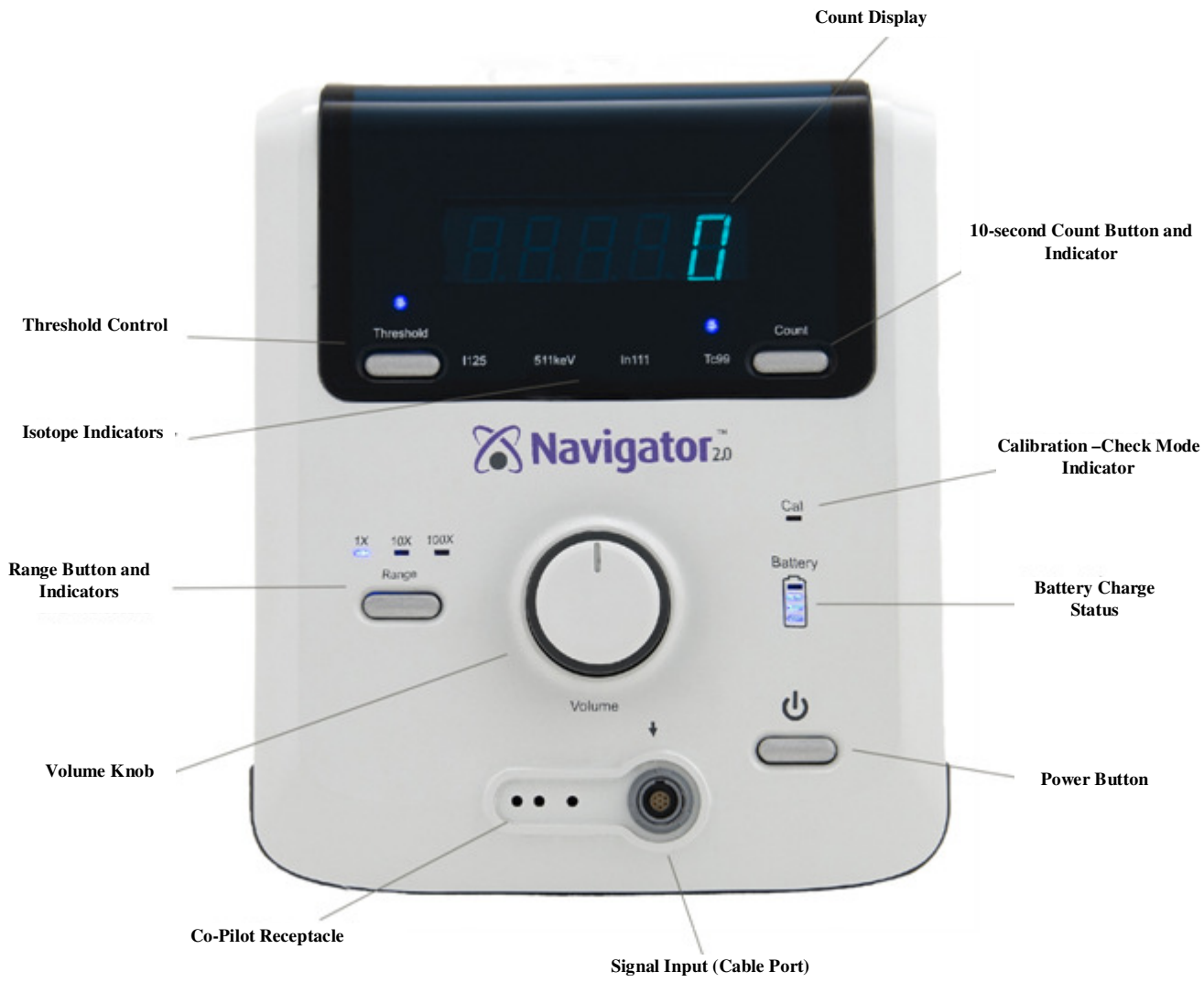
techniques are generally contraindicated. Please reference *Textbook of Laparoscopy* (Hulka JF. Grunda and Stratton, Inc. Orlando FL 1985 op114-116) for information on absolute contraindications, high-risk patients and low-risk patients.

- The use of the Navigator 2.0 system with laparoscopy should only be attempted where there is adequate visualization of the target tissue.
- Trocars should be placed in accordance with standard laparoscopic and thoracoscopic techniques, with specific regard to target organ geometry to assure probe access to the target organ. Please reference current trocar labeling, suggesting working knowledge of laparoscopic techniques and familiarization with trocar placements under direct visualization through a laparoscope.

CAUTION: *Endoscopic procedures should be performed only by physicians with adequate training and familiarity with endoscopic techniques. Medical literature should be consulted relative to techniques, complications, and hazards, prior to the performance of endoscopic procedures.*

4. Control Unit, Battery, Cables, and Co-Pilot

4A-1. Control Unit Features: Front

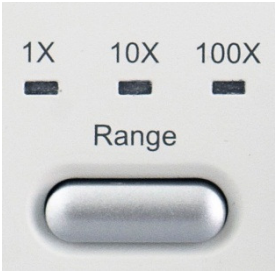


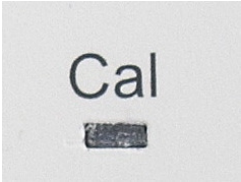
The control unit contains the display, the battery, and most of the system controls. These system controls are located on the front and back of the control unit.

The control unit allows the user to adjust the system's settings and produces signal outputs in the form of a count rate, viewable in the display, as well as an audible pitch that represents the intensity of a probe's signal.

The number of gamma photons (called "events") shown in the control unit display is determined primarily by a probe and the probe's position (with respect to the radioactively-tagged tissue), and secondarily by the position of the controls on the control unit.

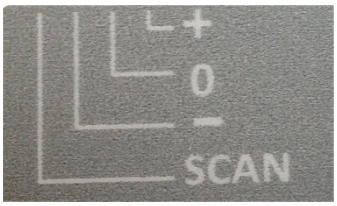
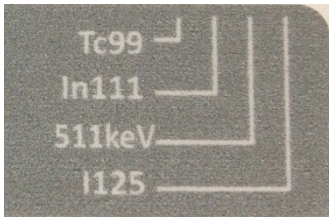
Table 4A-1. Controls and Displays on the Front of the Control Unit

Control Display	Description
	Power button: 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 Settings:** Adjusts the audible pitch, based on density of events detected: *1x* – Low event rates; all events are heard. *10x* – Medium event rates; 1 in 10 events are heard. *100x* – High event rates; 1 in 100 events are heard. Pressing the Range button cycles through the ranges; Select the one most useful to the procedure being performed. **NOTE**: ***Range selection only controls pitch of the sound generated by the unit; it has no effect on count rates displayed or signal conditioning***.
	Threshold: *For **CABLED PROBES** only*, it controls the count range of photon energy detected by the probe. When the Threshold is off, the indicator is not illuminated, and all photon energy, including scattered photons, is detected. When the Threshold is on, the indicator is illuminated. In this setting, the detection of scattered photons is reduced or eliminated. Signals of amplitude outside the pre-configured energy range are discarded. Only those events within the particular energy range are counted and displayed. NOTE: *The Threshold is normally on when using probes. The Threshold may be set to off to count **all** events detected by a cabled probe. (The Wireless Pilot Probe features integrated threshold)*

Control Display	Description
	Count: 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 goes back to showing counts per second.
	**Cal-check:** This light indicates when the system is in 'Calibration-Check' mode on the back 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 "Verification of Standard Gain (Calibration Quick Test)" in Section 11B for more information on Calibration.
	The **Battery indicator** shows the charge status of the battery in use. When the indicator level on the control unit is at 25%, the battery should be replaced immediately with a fully-charged battery. Please note that the charge status on the control unit may differ from charge status reflected on the battery, due to a higher power requirement on the control unit. Refer to charge status on control unit rather than the battery itself.
	Signal input port, for cable connection. The signal input port is **not** applicable when using the Wireless Pilot Probe with the Navigator 2.0. For the 12mm Lymphatic Mapping Probe, connect the cable attached to the Gain Module here, matching the arrows on the cable connector to the arrow above the signal input port. See "3mm Diameter Cable" in Section 4C for more information. For all other cabled probes, connect the probe cable here, matching the arrow on the cable connector to the arrow above the signal input port. See "6mm Diameter Cable" in Section 4C for more information.
	Connection port for the optional **Co-Pilot** accessory. See "Optional Co-Pilot Device" in Section 4D for more information.

4A-2. Control Unit Features: Back

Table 4A-2. Controls and Displays on the Back of the Control Unit

Control Display	Description
	*For **CABLED PROBES** only*. The SCAN position is the only correct position when a probe is being used during a procedure. When set to SCAN, the CAL indicator on the front of the control unit will not illuminate. For instructions on use of the '+', '0', and '-'positions, see "Verification of Standard Gain (Calibration Quick Test)" in Section 11B.
	Selects the isotope to be detected by the control unit.

SCAN/Calibrate Control

*For **CABLED PROBES** only**. The SCAN/Calibrate Control has FOUR POSITIONS.*** **During all surgical procedures, this control should be in the SCAN Position. During the calibration verification procedure, this control uses the remaining three settings, "+", "0", and "-".**

NOTE: *See "Verification of Standard Gain (Calibration Quick Test)" in Section 11B for information on calibration verification.*

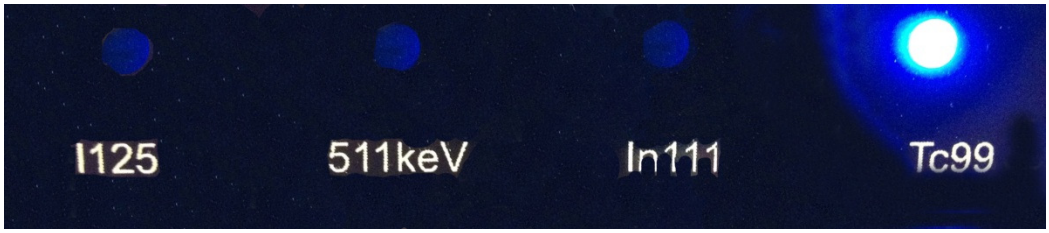
NOTE: *If the front panel CAL indicator is flashing before a procedure, move the control to the SCAN position.*

Isotope Control

The Isotope Controls allow the user to designate the specific isotope in use.

Switch set on: I125	Switch set on: 511keV	Switch set on: In111	Switch set on: Tc99
Iodine-125	^{18}F-FDG *(and I131)*	*Indium111*	*Technetium-99m*

The Isotope Control setting on the back of the control unit illuminates the corresponding light on the Isotope Indicator on the front of the control unit.



CAUTION:
It is important that the isotope control is set to the isotope that is going to be used in the procedure. Setting the isotope control incorrectly will result in incorrect detection.

4B. Battery (Part # N2-8500-00)

4B-1. Inserting the Battery

Open the door to the battery port, located on the right side of the control unit. Insert a fully charged battery with the battery label facing toward the rear of the unit, with battery contacts inward and tab on side of battery positioned outward. Use direction indicator arrow on battery label for guidance.

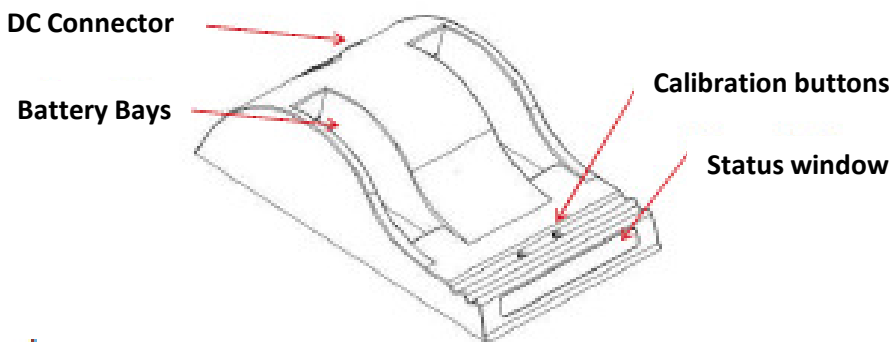
Shut the door of the battery port. The door will “click” when closed properly.

4B-2. Removing the Battery

Open the door to the battery port, located on the right side of the control unit. To remove the battery, pull the tab attached to the end of the battery.

4B-3. Charging the Battery (Battery Charger Part # N2-8000-02)

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 mains AC, using the cable supplied. All of the LEDs will flash momentarily to indicate that power is present.



Recharge Time: Approximately 3.5 hours

Place the battery into either battery bay, ensuring that the 5-way connector is fully seated. The battery should feel secure once inserted correctly. 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.

While there is a calibration button for each bay, **calibration is not necessary for use with the Navigator 2.0.** If calibration button is inadvertently pressed, either a flashing blue or solid blue light will illuminate. Simply remove battery and reinsert in order to resume charge. A green light will indicate that it is in charge mode.

If charger has flashing red light, the battery fuel gauge requires calibration. Only in this case, should the calibration button be pressed. Recalibration can take 10-13 hours.

If charger lights solid red, please refer to troubleshooting guide.

Table 4B-4. Charge Bay LED Indications

Indication	Battery Charge Status
Green Flashing	Battery Charging
Green Solid	Battery Fully Charged
Blue Flashing or Solid	Calibration mode: UNNECESSARY. Do not use.
Red Flashing	Battery fuel gauge in need of calibration
Red Solid	Error

NOTE: *Use only batteries supplied by Dilon Technologies. The Dilon Technologies control unit battery has the proper dimensions and a key feature that holds it securely in the Navigator 2.0 control unit.*

NOTE: *Approximately 3.5 hours are required to charge a completely drained battery. Having a second, fully charged battery available while the first battery is in use, is recommended.*

CAUTION:
Do not expose the charger or power supply to water or liquids; the case is not sealed.
Do not open the charger or power supply case; no user-serviceable parts are inside.
Do not cover the fan exhaust or obstruct the airflow; this will cause overheating.
Place the charger in a cool spot, away from external heat sources.

4C. Cables

In addition to the Wireless Pilot Probe, the Navigator 2.0 may also be used with cabled probes. One of the following two cables is used, depending on the wired probe selected.

4C-1. *3mm Diameter Cable (Part # PM-4000-20) and Gain Module (Part # PM-0400-40)*

The 12mm Lymphatic Mapping Probe uses a cable that has two conductors and an outside diameter of approximately 3mm. It also uses a Gain Module (pictured below), which connects the control unit to the probe cable.

1. Connect the 3mm Diameter Cable to the probe, matching the red indicator dot on the probe to the red indicator dot on the cable.
2. Connect the other end of the 3mm Diameter Cable to the gain module, matching the red indicator dot on the cable to the gain module's cable input port.
3. Connect the gain module to the control unit, matching the arrows on the gain module cable connector to the arrow above the signal input port. The gain module connector will "click" when it is seated properly.

The connector has a locking mechanism. To **disconnect** the cable from the probe and from the gain module, **pull directly back on the hood; DO NOT pull or twist the connector jacket.**

4C-2. *6mm Diameter Cable (Part # GP-4001-00)*

A different cable is used for the standard lymphatic mapping probes (straight or angled), Superficial Head & Neck Probe, laparoscopic probes, and the Daniel™ Lung Probe. This cable has five receptacles inside the probe end, and seven pins inside the plug, that connect to the control unit. The cable is approximately 6mm in diameter.

Connect the cable to the control unit, matching the arrows on the cable connector to the arrow above the signal input port.

The connector is a locking connector. To **disconnect** the cable from the probe and from the control unit, **pull directly back on the hood**; **DO NOT pull or twist on the jacket**.

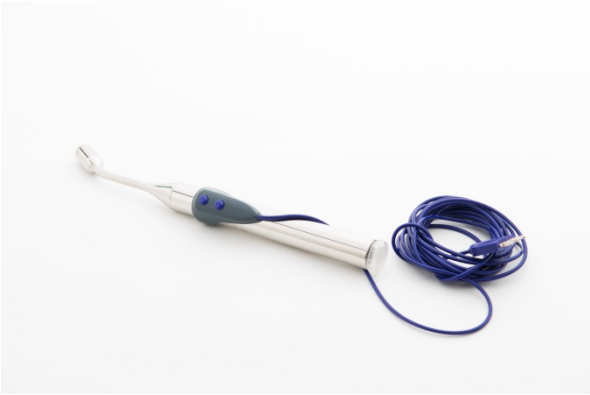
WARNING! Do not pull or twist the *jacket* of the cable, to remove from control unit. You must pull on the *hood* at the end of the cable. Pulling or twisting the jacket may damage the cable and render it unusable.

4D. Optional Co-Pilot™ Device (Part # GP-6801-00)

The optional Co-Pilot is a single-use device used for initiating counting periods and adjusting the audible range from the probe, inside the sterile field. It includes two small buttons, and a long, small-diameter cable.

To plug in the Co-Pilot, match the spacing of the prongs with the spacing of the receptacles on the control unit. It should then be clipped onto the base of the probe.

The Co-Pilot is supplied sterile and may be used inside or outside of the sterile drape.



R Button (Range)

C Button (Count)

The “C” button is the COUNT Button. Obtain a one-second count by pushing and releasing this button once. Obtain a ten-second count by pushing this button twice, in quick succession. Each time, total counts are shown in the display screen on the control unit.

The “R” button is the RANGE Button. This button operates the Range control mentioned above on the control unit. Push and release the RANGE Button to select an audible range, appropriate to the signal detected by the system.

CAUTION:
The Co-Pilot can only be attached to the control unit one way – the prongs are not evenly spaced (see image below).

4E. Useful Adjustments That Can Be Made During Procedures

Table 4D-1. 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. (NOTE: The Wireless Pilot Probe features integrated threshold.)
Range	The Range function defaults to 1X, meaning that the audible signal fluctuates according to every single count it detects. In the 10X position, every 10th event produces an audible output. In 100X, only every 100th event produces an audible output. 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 probe in fixed position each time. The total is displayed for at least four seconds, allowing time to record the total.
Volume	Adjust to desired volume.
Power	Press to turn on the control unit or to safely turn off the device.

5. Cleaning, Disinfection, and Sterile Use of Navigator Probes and Cables

All probes and probe cables require cleaning and disinfecting immediately after use. Follow these steps to ensure that cleaning and disinfection are done correctly.

- **Before Use**, visually inspect probe and probe cable to ensure that it is free of contamination.
- Place probe and cable in a sterile drape while in use.
- **After Use**, Clean/Disinfect/Store Probe and Probe Cable.
- Radioactive Decontamination Procedure – OPTIONAL (see section 5C).

CAUTION: *All Dilon probes and probe cables must be used inside a sterile drape. The control unit, gain module (if used), and battery/charger are used outside of the sterile field. Probes and probe cables should be cleaned and disinfected separately from the other components.*

5A. Cleaning Probes

- Visually inspect the probe and cable for contamination before storing. If the probe or cable show visual signs of contamination, or may possibly be contaminated, then proceed to Table 5A-1, "Cleaning & Disinfection".

WARNING! Do not scratch or abrade the probe when decontaminating. Scratching / abrading the probe will make future decontamination difficult, if not impossible.

Table 5A-1. Cleaning & Disinfection

Preparation for cleaning:	Remove battery from Wireless Pilot Probe, and secure battery cap to the bottom of probe before cleaning.
Cleaning Equipment:	Enzymatic detergent, OPA high-level disinfectant, running water
Cleaning Method:	1. 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). Prepare enzymatic cleaner, suitable for surgical instruments, according to the manufacturer's recommendation. Wipe with soft cloth or sponge soaked in enzymatic cleaner. Repeat separately for collimator cleaning, if used. 2. Visually inspect device(s) for contaminated areas. 3. Repeat steps 1 & 2 until visual inspection reveals instrument(s) is clean. 4. 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.
Disinfection:	1. Prepare Mixture according to manufacturer's instructions 2. Immerse probe and cable completely for a minimum of 12 minutes at 68°F (20°C or higher), to destroy all pathogenic microorganisms. • Note that probes that are compromised can be damaged if detergent seeps into them. 3. Rinse equipment with a brisk stream of lukewarm tap water (98°F to 105°F / 36.5°C to 40.5°C) for approximately1 minute. Repeat rinse two additional times.
Drying:	Air-dry or dry with clean towel. Flush the probe connector with 70% isopropyl or ethyl alcohol, and then flush with air. Ensure that the connector ends of the probe and cable are completely dry before storing.

5B. Radioactive Decontamination Procedure – OPTIONAL

An increase in background counts may signal radioactive contamination of the probe or the environment. If a process of elimination shows the probe to be contaminated with radioactive material, the probe must be decontaminated.

1. Decontaminate the probe using standard Nuclear Medicine Department techniques, which may involve washing the probe with a solution such as Radiacwash™.
2. Ensure that all recesses, crevices, and mating surfaces are clean.
3. Dispose of pads and cleaning solution in approved containers.

5C. Cleaning/Storing Control Unit & Gain Module

1. If unclean, wipe control unit and gain module (if present) with a soft cloth moistened with mild soap and water. Dry with a soft cloth.
2. Store the control unit and gain module in a clean, safe environment.

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

6. Probe Connectivity and Use

6A. Navigator 2.0 with Wireless Pilot Probe

The Wireless Pilot Probe is used in various procedures. A typical sequence of setting up the Wireless Pilot Probe for a procedure with a Technetium-99m isotope (such that may be used in a lymphatic mapping procedure for a sentinel node biopsy) is as follows:

6A-1. Before Surgery

- Insert a charged battery into control unit (see Section 4B-1).
- Upon initial insertion of new Wireless Pilot Probe battery, probe may need to be lightly shaken to activate LED in probe base.
- LED on the Pilot Probe indicates that it is linked with control unit and ready for use. When placed in a resting position, the LED turns off within seconds, to save energy. When the Pilot Probe is moved, it instantly powers up for immediate use.
- For intraoperative use, insert the Wireless Pilot Probe into a sterile drape.
- **Insert a probe battery into the Pilot Probe as follows:**
    1. Hold probe firm; turn battery cap counterclockwise and remove from probe. Inspect O-ring integrity. If O-ring is missing or damaged, use new battery cap. Contact Dilon Technologies or your distributor for battery cap reorder information.

2. Install 3V CR 2 lithium battery in Pilot Probe battery holder with **positive (+) end facing toward the base of the probe and negative (-) end toward the middle of the probe.** Incorrect placement of battery into battery holder for extended periods of time will cause battery to drain quickly.

3. Insert battery holder into probe negative (-) end in. Lightly turn until holder lowers into place.

4. Hold probe firm; push battery cap into probe and turn clockwise until O-ring is no longer visible.

Table 6A-1. Pilot Probe LED Indicator

Indication	Status
On/Flashing	Probe is linked and ready for use.
Off	Probe is in a resting position to conserve power; to reactivate LED indicator, simply pick up probe, or if needed, lightly shake probe. If no power upon ready to use, the battery needs to be installed or replaced. If battery has been replaced and LED light is still off, contact your distributor or Dilon Technologies directly.

6A-2. During Surgery

- See '*Useful Adjustments that can be made During Procedures*' (Section 4E).

NOTE: *For Technetium-99m (Tc99), the control unit settings are given in the following table.*

NOTE: *Follow the instructions in the section on 'Cleaning, Disinfection, and Sterile Use of Probe' (Section 5).*

Table 6A-2. Navigator 2.0 with Wireless Pilot Probe – Settings & Indicators (just prior to surgery)

Control / Indicator	Setting
Controls (back of Control Unit)	
SCAN/Calibrate:	SCAN
Isotope:	Tc99
Indicators (front of the Control Unit)	
Range:	1x
Threshold:	Illuminated
Display:	0
Isotope:	Tc99
Indicator (top of the Pilot Probe handle)	
Probe LED:	Illuminated; flashing.

6A-3. After Surgery

- See: '*Cleaning, Disinfection, and Sterile Use of Navigator Probes & Cables*' (Section 5).

6B. Navigator 2.0 with Standard Lymphatic Mapping Probes, Superficial Head & Neck Probe, Daniel Lung Probe, and Laparoscopic Probes

Standard Lymphatic Mapping Probe:	*SP-2A14-67* (Angled)
	SP-2S14-67 (Straight)
Superficial Head & Neck Probe:	*SP-2S11-53*
Daniel Lung Probe:	*SP-2S10-31D*
Laparoscopic Probe:	*SP-2S10-31* (310 mm shaft)
	SP-1S10-19 (190 mm shaft)

These Navigator probes are used in various procedures. A typical sequence of setting up these probes for procedures with a Technetium-99m isotope (such as may be used in a lymphatic mapping procedure for a sentinel node biopsy, localization of a parathyroid adenoma, or localization of a sub-centimeter lung nodule) is as follows:

6B-1. Before Surgery

- See: '*Cleaning, Disinfection, and Sterile Use of Probes and Cables'* (Section 5).
- Insert a fully charged battery into control unit (Section 4B-3).
- Connect the probe and cable to control unit (Section 4C-2).
- For intraoperative use, insert probe and cable in a sterile drape.

Table 6B-1. Navigator 2.0 with Standard Lymphatic Mapping Probes, Superficial Head & Neck Probe, Daniel Lung Probe, and Laparoscopic Probes - Settings and Indicators (just prior to surgery)

Control/Indicator	**Setting (with Tc99 example)**
Controls (back of Control Unit)	
SCAN/Calibrate:	SCAN
Isotope:	Tc99
Indicators (front of the Control Unit)	
Range:	1x
Threshold:	Illuminated
Display:	0
Isotope:	Tc99

6B-2. During Surgery

- See '*Useful Adjustments that can be made During Procedures'* (Section 4E).
- See '*Optional Co-Pilot Device' (Section 4D)*.

6B-3. After Surgery

- See: '*Cleaning, Disinfection, and Sterile Use of Probes and Cables'* (Section 5).

NOTE: *The time to charge a battery by the charger may take as long as 3.5 hours.*

NOTE: *Keep control unit powered off until all components are connected. This helps preserve component life.*

Cautions for Thoracoscopic, Laparoscopic, and Endoscopic Procedures:

CAUTION:
Trocars should be placed in accordance with standard laparoscopic and thoracoscopic techniques, with specific regard to target organ geometry to assure probe access to the target organ. Please reference current trocar labeling suggesting working knowledge of laparoscopic techniques and familiarization with trocar placements under direct visualization through a laparoscope.

CAUTION:
Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards, prior to the performance of endoscopic procedures.

6C. Navigator 2.0 with 12mm Lymphatic Mapping Probe (Part # N2-9001-12)

The Navigator 12mm lymphatic mapping probe is used in various lymphatic mapping procedures. Please note that the system pictured above also includes battery and charger.

6C-1. Before Surgery

- Charge and insert the battery into control unit (Section 4B-3).
- Connect the probe, cable, and gain module to control unit (Section 4C-1).
- Run a Peak Procedure (Section 7A).

Table 6C-1. Navigator 12 mm Probe - Settings and Indicators for use with Tc99 (just prior to surgery)

Control/Indicator	Setting
Controls (back of Control Unit)	
SCAN/Calibrate:	SCAN
Isotope:	Tc99
Indicators (front of the Control Unit)	
Range:	1x
Threshold:	Illuminated
Display:	0
Isotope:	Tc99
Gain Module	
Dial at Peak Setting:	Perform peak procedure (See Section 7A)

NOTE: *Keep control unit power off, until all components are connected.*

NOTE: *A 'peak procedure' must be performed before using the probe in the first surgical procedure of the day* (see Section 7A).

NOTE: *Although the 'peak procedure' is typically performed with no sterile drape around the probe and cable, it may also be performed with the probe and cable inside a sterile drape.*

NOTE: *After a 'peak procedure' has been performed, the control unit and gain module settings are given in the table above.*

NOTE: *Follow the instructions in Section 5 on 'Cleaning, Disinfection, and Sterile Use of Probe and Cable'.*

CAUTION:
For intraoperative use, insert probe and cable in a sterile drape.

6C-2. During Surgery

- See '*Useful Adjustments that can be made During Procedures*' (Section 4E).

6C-3. After Surgery

- See: '*Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables*' (Section 5).

7. Running the Peak Procedure: 12mm Lymphatic Mapping Probe Only

It is important to note that the 12mm Lymphatic Mapping Probe DOES NOT use the 'Calibration Verification Quick Test' referenced later in section 11B – instead, the probe-control unit configuration is brought to its highest sensitivity point via the 'Peak Procedure,' described below.

7A. Running a Peak Procedure

A Peak Procedure finds the best "sensitivity" of a probe when "paired" with a control unit. The setting on the gain module at which the probe counts the most events.

Adjusting the gain module dial increases/decreases the count rate in the Navigator 2.0 Display. Starting with the control unit turned **on** and the dial in the **full counter-clockwise position (0)**, the location on the gain module **dial** where the count rate reaches its **maximum value** is called the *Peak Setting*. The system should then be left in this setting for any subsequent procedures that day.

The probe *must* be held in a fixed position with respect to an isotope source during a Peak Procedure. This source can be either a check source or the injection site (or some other region of high activity) of the patient.

Only the Navigator 12mm Lymphatic Mapping Probe requires a Peak Procedure, because it is the only probe that uses the gain module. The Peak Procedure should be performed on EACH day of use, before the first surgical procedure.

Above: Example of a Peak Procedure using a Cobalt-57 check source

Table 7A-1. Example: Using and "pairing" multiple 12mm Sentinel Node Mapping Probes during one surgical day with the same control unit

1. **Probe A** is going to be used on Monday for all surgical procedures scheduled on that day.
2. Peak Procedure is run on **Probe A** before the first surgical procedure of that day.
3. **Probe A** counts are highest when the Gain Module dial is set to about 4.5. The dial is left at that location.
4. **Probe A** is ready for all surgical cases for the day.
5. **Probe A** is dropped and damaged. It cannot be used again until tested and/or repaired.
6. The Surgical Team chooses to use **Probe B** for the rest of the case and for all others scheduled on that day.
7. A Peak Procedure is run on **Probe B** before the next case or before continuing the current surgical procedure to "pair" it with the control unit.
8. **Probe B** counts are highest when the Gain Module dial is set just above 6. The dial is left at that location.
9. **Probe B** is ready for all surgical cases for the day.

SERVICE MANUAL

8. Troubleshooting

With the exception of the Wireless Pilot Probe's battery holder, no serviceable components are located inside the control unit or probes. Contact your representative or Dilon Technologies for additional assistance if more detail is required.

Table 8A-1. Control Unit Only - Settings and Indicators

Problem	Possible Causes	Remedies
1. Display is dark; No power to unit.	Power switch is off; Switch is broken. Unit may have been dropped.	Turn power on; Contact Dilon Technologies for assistance.
	Battery is dead.	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 have been dropped.	Contact Dilon Technologies for assistance.

Table 8A-2. Navigator 2.0 Control Unit with WIRELESS PILOT PROBE- Settings and Indicators

Problem	Possible Causes	Remedies
1. Zero in display. No signal under presence of a radioactive source.	No wireless connection between probe and control unit.	Replace the probe battery. Verify that battery was inserted correctly into probe ('+' should face toward base of probe).
	Isotope control is set to incorrect isotope.	Change isotope control (on back of control unit) to Tc-99.
	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).	Gently shake probe to activate connectivity.
	Probe is damaged / probe cap not secure.	Try a different probe, or contact Dilon Technologies for assistance.

Problem	Possible Causes	Remedies
2. LED on Pilot Probe does not illuminate.	Probe battery is dead or installed incorrectly.	Replace with new battery. Verify that battery was inserted correctly into probe ('+' should face toward base of probe).
	Battery was not installed.	Install new battery.
	LED on probe is damaged.	Contact Dilon Technologies for assistance.

Table 8A-3. Control Unit with CABLED PROBE- Settings and Indicators

Problem	Possible Causes	Remedies
1. Zero in display. No signal under presence of a radioactive source.	No connection between probe, cable, gain module (if present), and control unit.	Check that all connections are secure.
	Isotope control is set to incorrect isotope.	Change Isotope Control (on back of control unit) to Tc-99.
	Gain module, if used, is set to zero.	Run Peak Procedure (Sec. 7A).
	There is an open circuit in the probe cable.	Replace cable.
	Circuit inside the control unit has been damaged.	Try a different control unit. Contact Dilon Technologies for assistance.
	Probe is damaged / probe cap not secure / detector damaged.	Try a different probe or contact Dilon Technologies for assistance.
2. Spurious high counts, such as 80,000 counts a second (when probe is held in air, for example).	Intermittent short in the cable.	Replace cable.

9. Specifications

9A. Navigator 2.0 System Specifications

The Navigator 2.0 system consists of the control unit, one or more probes, and the system accessories.

Table 9A-1. 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, 94Wh 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	Battery. Single use CR2, 3 V Lithium; capacity 750-850 mAh
Wireless Pilot Probe Transmission Distance	Up to 9 meters
Industry Standard Wireless Operating Frequency	2.4 GHz.
Fuse – Control Unit	UL/CSA (198G) standards; 0.75 amp. Glass housing. 250 volt rating. 5x20m. IEC 127 standards: Type 7. 0.63 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's **Wireless Pilot Probe**: • Probe connection – LED • Isotope Indicator – LED

Item	Description
Energy Range	0 - 650 keV
Operating Conditions	Operating Temperature Range: 15°C to 40°C (5°F to 104°F)
Storage	Temperature: -10°C to 85°C (15°F to 185°F) Humidity: 0%-80% relative humidity Atmospheric Pressure: 50 kPa to 106 kPa
Maximum Count Rate	90,000/s
Color of Housing	Light gray and dark gray
Control Unit Dimensions	20cm W x 24cm H x 12cm D
Control Unit Weight w/Battery	2.0kg
Accuracy	95%-99% across the dynamic range of the instrument with probes

9B. System Accuracy

The Navigator 2.0 System with Probe counts gamma photons that proceed from radioisotopes. At event rates around 20,000 counts per second, the event rate shown in the display may be slightly less than the event rate seen by the probe. This is due to the possible occurrence of a second gamma photon during the short time period (a few microseconds) it takes the system to count a detected gamma photon.

The Navigator 2.0 Device exhibits at least 95% accuracy across its dynamic range.

10. Support Items

The Navigator 2.0 control unit is typically supplied with a complete system. Support items may be purchased from the local Dilon Technologies Navigator representative. At time of publication of this manual, the primary support items have the following part numbers. Feel free to contact your local representative for additional information.

10A. Product Part Numbers

Table 10A-1. Navigator 2.0 System Support Items with Part Numbers

Item	Dilon Part Number
Navigator 2.0 Battery	N2-8500-00
2-Bay Battery Charger	N2-8000-02
Battery Charger Power Cord	SC-2000-00
Batteries for Wireless Pilot Probe (pack of 10)	WP-8500-01
Navigator 2.0 Stand with Pole Clamps	N2-8800-00
6mm Diameter Cable (for CdTe Probes)	GP-4001-00
3mm Diameter Cable (for 12mm Lymphatic Mapping Probe)	PM-4000-20
Optional Storm Case (for travel and storage)	N2-8000-07
Gain Module for 12mm Probe	PM-4000-40
Optional Top Gun Collimator	SP-1800-00
End Cap for Wireless Pilot Probe (pack of 10)	WP-2000-10
Battery Holder for Wireless Pilot Probe (pack of 5)	WP-9050-00
Optional Co-Pilot Devices	GP-6801-00

10B. Sterile Drape

A sterile drape is an additional accessory, but it is not sold or supported by Dilon Technologies. Typical characteristics of a suitable intra-operative probe drape are as follows:

- Universal gamma probe cover, 5 x 24
- Sized with tapered tip to fit both straight and flexible probes
- Low density, soft polyethylene
- Telescopically folded w/rubber bands and medical grade tape strips
- Drape features:
    - 100% guaranteed latex-free - All components, including rubber bands
    - All available EtO Sterile
    - Strong and durable Anti-Static material

11. Maintenance

11A. Overview

While the Navigator 2.0 System is virtually maintenance-free, the user should follow a number of steps to ensure proper performance prior to each use.

1. Check each system component for any visible signs of abuse, neglect, or wear, before each use and storage. This includes checking the following components and these features:

Table 11A-1. Component Check

Component Check	Feature Check
Control Unit	Overall check - Housing, integrity of switches and integrity of connections.
Battery Charger	Overall check - Housing and integrity of connections.
Probe (Wireless or cabled)	Overall check. Also tip and connector.
Cable (if used)	Each connector, the connector pins, and integrity of cable.
Gain Module (if used)	Dial, cable and connector.

- *Should abnormalities be discovered, contact your sales representative or Dilon Technologies directly.*
- *Do not use a damaged control unit, battery, battery charger, probe, cable, or gain module.*

2. Check each battery for function and charge before use. Should abnormalities be discovered, contact your sales representative or customer support person.
3. To ensure proper functionality, follow each step as outlined in Section 4: "Control unit, Battery, and Co-Pilot," and the section in the manual pertaining to the relevant probe.
4. In addition to the above, preventive maintenance suggests that every two years a new battery, fuse and cable (if used) might be considered.
5. 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 damaged battery contacts, or any other damage to the probe.

WARNING! No modification of this equipment is allowed. Any modification to this will void any remaining warranty, if attempted.

11B. Verification of Standard Gain (Calibration Quick Test)

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, one of two procedures can be performed by the user.

11B-1. Verification of Standard Gain (Calibration Quick Test) - Background

*For **CABLED PROBES** only.* Applies to the Standard Lymphatic Mapping Probes (SP-2A14-67 & SP-2S14-67), Superficial Head & Neck Probe (SP-2S11-53), Laparoscopic Probes (SP-2S10-19 and SP-2S10-31), and the Daniel™ Lung Probe (SP-2S10-31D).. 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.

11B-2. Verification of Standard Gain (Calibration Quick Test) – Procedure. *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 11B-2, "System Configuration - Cobalt-57 Alignment".
4. Align a 57 Cobalt 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 11B-2 "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.
12. End of Test.

Table 11B-2. 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 INDICATOR blinks when the SCAN/Calibrate Control is in either the BELOW (-), CENTERED (>0<), or ABOVE (+) test position. The CALIBRATION INDICATOR is OFF when the CALIBRATION control is in the SCAN position.*

NOTE: ***All Dilon Technologies probes can be used with any Navigator 2.0 control unit. The 12mm Lymphatic Mapping Probe, used with a Gain Module, requires a different method of peak calibration assurance, detailed in the section 7A, entitled "Running a Peak Procedure"."***

11C. Fuse Replacement Procedure

The fuse is to be replaced when necessary by the user (when the fuse is "blown"). The Navigator 2.0 fuse is to be replaced as follows:

1. Push-in and twist the fuse holder cap counter-clockwise.

2. Remove the fuse from the fuse holder.

3. Insert a new fuse into the holder.

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

12. Repair

Probes are sealed at the factory. No user serviceable parts are inside the probes. 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, which may be inspected and replaced by the user, and a replaceable battery. Beyond these two items, the control unit contains no user serviceable parts and should not be opened by the user.

Please contact Dilon Technologies for additional service. An RMA number is required upon return for service.

If the device cannot be repaired and or it is determined that its useful life is at an end, contact Dilon Technologies for proper disposal of the unit.

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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. ***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.DilonProducts.com) or by contacting your distributor or Dilon Technologies directly.***

13. Recycling

At the end of the device life and/or accessories, please send the device and/or its accessories back to Dilon Technologies Authorize Representative in Europe.

Ensure the cleaning of the device and/or it accessories before shipment.

The disposables of the product are made out of plastic and cannot be reused and must be disposed as standard disposables.

14. 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.

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