Navigator GPS™ System

User and Service Manual

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User Manual

1. Introduction

Description

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

System use requires the Navigator GPS™ Control Unit: The Control Unit allows the user to adjust the system's settings and produces a variety of signal outputs. The Control Unit is powered by the PowerPak (battery).

- Navigator GPS ™ Control Unit ("Control Unit")
- PowerPak and Charger

The Control Unit is used with any of eight Navigator™ probe models. The probes differ primarily in their shape, which the user may prefer for a particular procedure.

- Dilon Navigator™ 12 mm Probe
- Gamma-PET™ Probe
- Standard Lymphatic Mapping Probe (angled tip)
- Straight Lymphatic Mapping Probe (straight tip)
- Superficial Head and Neck Probe
- Abdominal Probe
- Thoracic Probe
- Daniel-Probe™

The system is supplied non-sterile. This manual includes guidelines for the use of the Probe and Probe Cable in 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. Please direct all inquiries about the Navigator GPS™ System to Dilon Technologies.

Standards

The Dilon Navigator GPS™ System including Probes and accessories complies with the following standards:

EC Directives

EMC Directive 89/336/EEC
Group I, 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 60601-1-1: 3rd Ed.
- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – IEC 60601-1-2: 3rd Ed.
- 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

Other

CE 0459

The following are trademarks of Dilon Technologies, Inc.: Dilon Navigator™, Dilon Navigator GPS™, Navigator GPS™, Dilon Navigator™ 12 mm Probe, Gamma-PET™ Probe, Beta-PET™ Probe, Daniel-Probe™, and Navigator™ when used in context with the above.

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

Explanation of Symbols

Table 1. Symbols

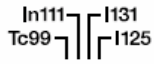
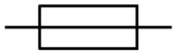
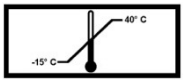
	Type-CF Equipment		RX only Caution: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.
	Probe		Date of Manufacture
	Data Port		Manufactured by
	Eject		Consult instructions for use
	Attention, consult accompanying documents		Temperature limitation
	Remote Count Control		Humidity limitation
	Isotope Control		Serial number
	Calibrate Control		Catalogue number
	Fuse		European Authorized Representative
	PowerPak		Batch code

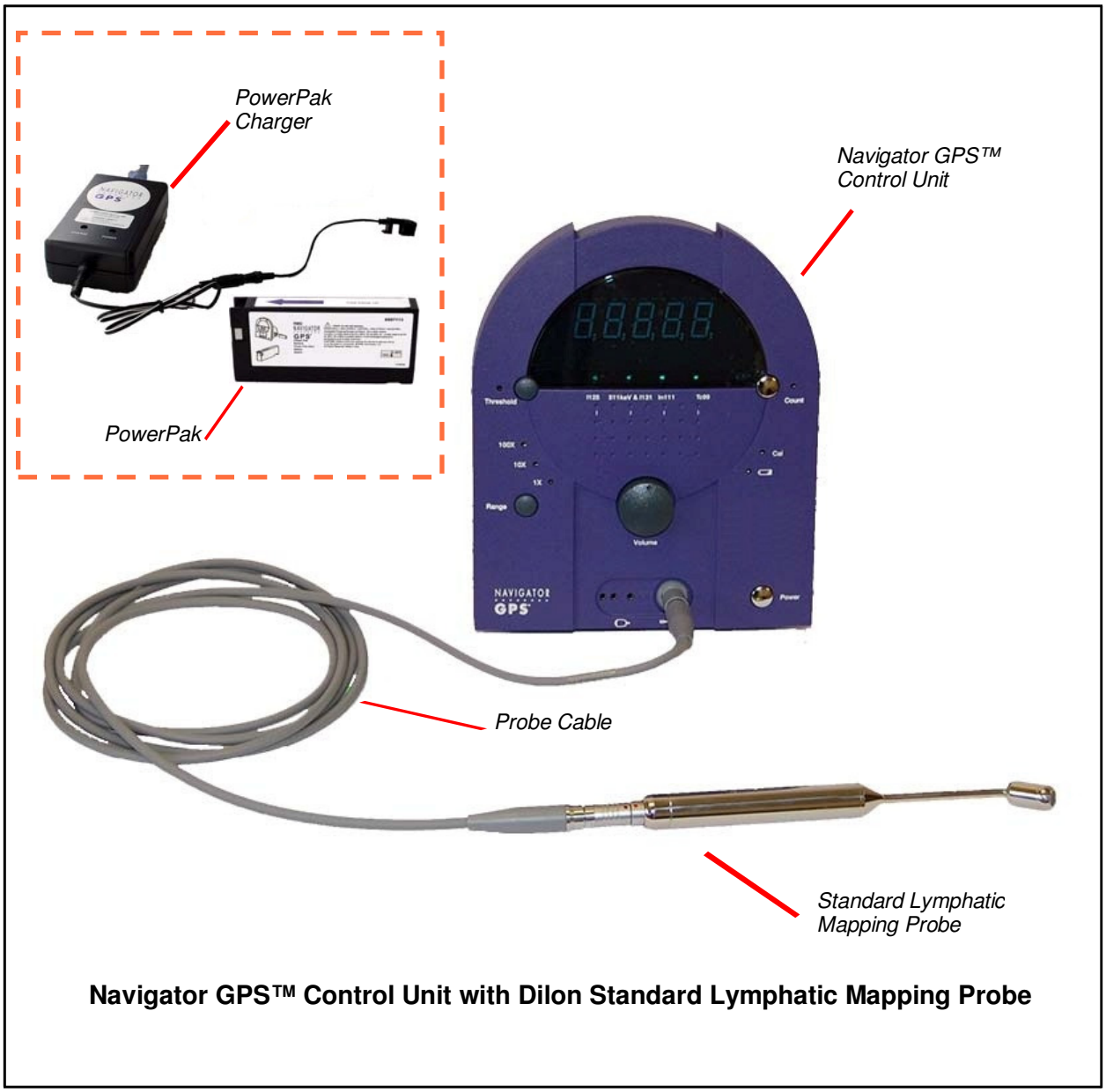
Table 1. Symbols (Continued)

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

2. System Overview and Components

Navigator GPS™ Control Unit with Dilon Navigator™ 12 mm Probe

The Navigator GPS™ Control Unit supports several Dilon Probe Models. The illustration shows each probe model available for use with the system. The Table gives probe model dimensions. Subsequent sections of this manual describe in detail probe and system use.



Navigator GPS™ Control Unit with Dilon Standard Lymphatic Mapping Probe

Table 2. Probe Dimensions

Probe	Tip Diameter	Tip Angle	Shaft Diameter	Shaft Length	Probe Length
Dilon Navigator™ 12 mm Probe	12mm	35	12mm	—	242mm
Gamma-PET™ Probe	22mm	0	14mm	—	157mm
Standard Lymphatic Mapping Probe	14mm	35	6mm	67mm	—
Straight Lymphatic Mapping Probe	14mm	0	6mm	67mm	—
Superficial Head and Neck Probe	11mm	0	6mm	53mm	—
Abdominal Probe	10mm	0	6mm	190mm	—
Thoracopic Probe	10mm	0	6mm	130mm	—
Daniel-Probe™	10mm	30	6mm	190mm	—

2A. Navigator GPS™ System - Probe Modes

Dilon Navigator™ 12 mm Probe (page 52)

Gamma-PET™ Probe (page 54)

Cable

Gain Module

Standard Lymphatic Mapping Probe (page 56)

Straight Lymphatic Mapping Probe (page 58)

Superficial Head and Neck Probe (page 60)

Abdominal Probe (page 64)

Thoracic Probe (page 62)

Daniel-Probe™ (page 66)

Cable

DataPak

Charger

3. Precautions

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

Control Unit, PowerPak, and Charger

- During system use, maintain electrical isolation of the patient. Do not connect either the probe, the cable, 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 probe cable surface 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.
- Do not defeat the electrical isolation between the control unit's external DATA PORT and the inside of the control unit. The external DATA PORT can be connected to earth ground. Electrical isolation between the DATA PORT and the internal circuit of the control unit maintains electrical isolation of 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 Gamma Probe drape, and a cart or stand.
- 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 PowerPak before use in the system.
- This system is not designed for use in an explosive atmosphere.
- Keep the Control Unit off when changing the PowerPak, and when changing connections between the Probe, Cable, Control Unit and Gain Module, if used.
- The Control Unit, PowerPak, and Charger are non-sterile. Do not sterilize these components.

Probes

Table 3. Precautions

	**DO NOT** put the Probe or Probe Cable in an autoclave
	**DO NOT** open the Probe. The Probe is tested and sealed at the factory. Attempting to open or opening the Probe may damage the Probe and will void the warranty.
	**DO NOT** drop the Probe. **DO NOT** strike the Probe tip against a hard surface. The detector element may become damaged. The Probe may no longer be able to measure radiation. This may also void the warranty.
	**DO NOT** place probe on or near a magnetic instrument pad.

Laparoscopic and Thoracoscopic Probe Use

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

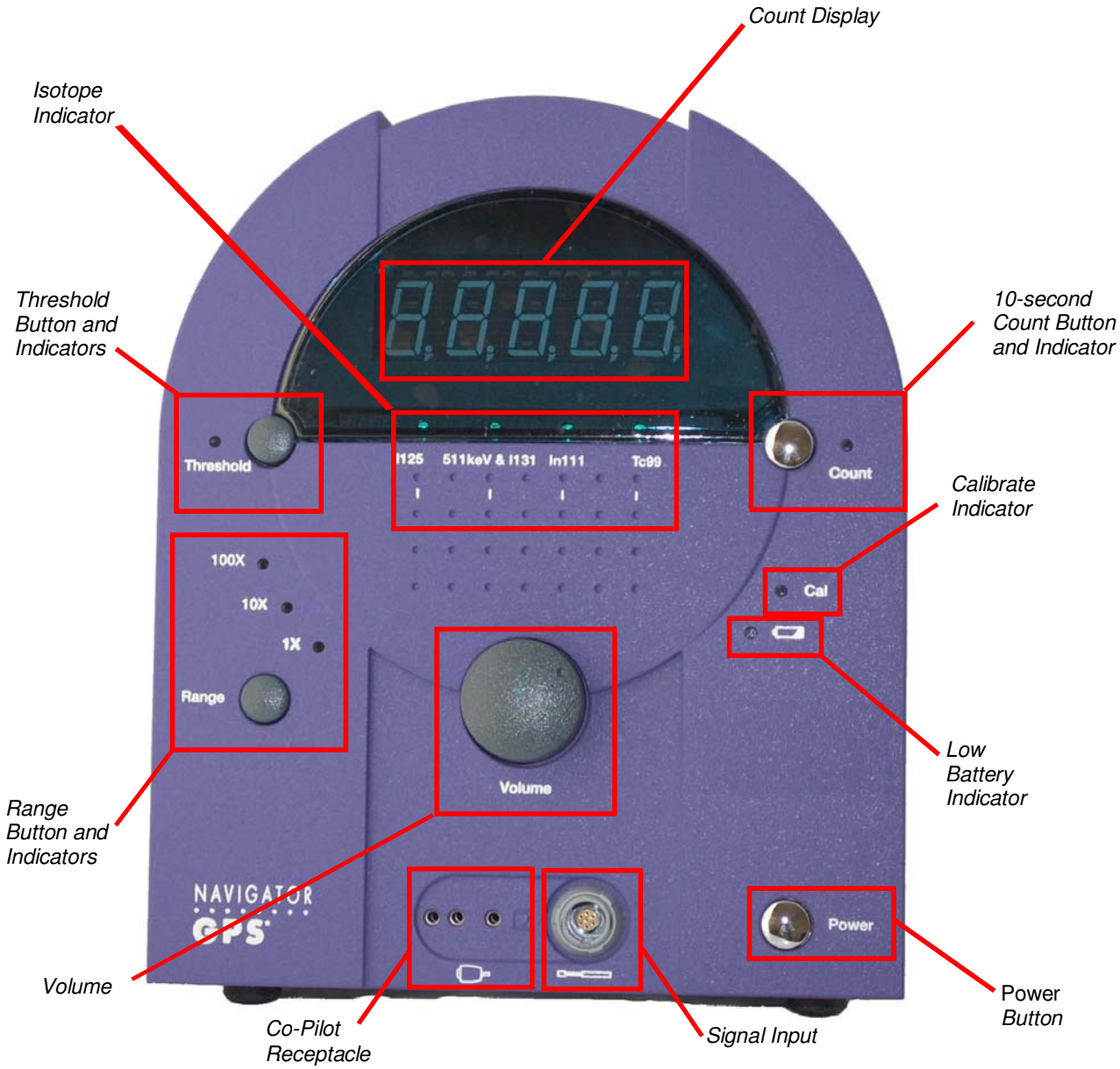
CAUTION
Endoscopic procedures should be performed only by Physicians having adequate training and familiarity with endoscopic techniques in addition medical literature should be consulted relative to techniques, complications and hazards prior to the performance of endoscopic procedures.

Contraindications

- This device is intended for use only as indicated. It is not intended for use when endoscopic techniques are generally contraindicated. Please see the book: 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 GPS™ 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.

4. Control Unit, PowerPak, and Co-Pilot

4A. Control Unit



The Control Unit contains the display, the PowerPak, and most of the controls. The 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 shown in the display and 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 4. Controls and Displays on the Front of the Control Unit

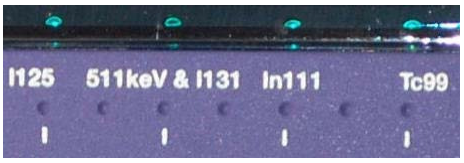
Control Display	Description
Power 	Turns on power
Volume 	Increases/decreases the volume of the audible signal
Display 	The photon count/second is normally shown. At the end of a 10-second count, the total photons detected is shown, then the display returns to showing counts/second.
Isotope Indicator 	Indicates the isotope selected.

Table 4. Controls and Displays on the Front of the Control Unit (Continued)

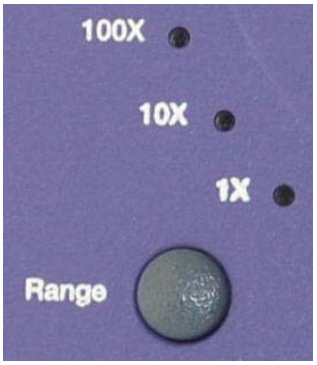
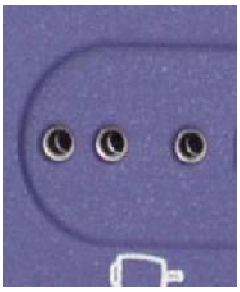
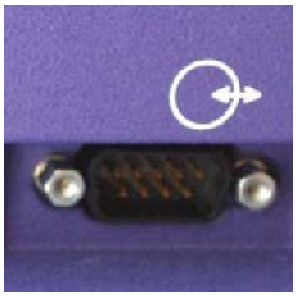
Control Display	Description
Range 	Controls when the audible pitch is heard: 1X – low event rates 10X – medium event rates 100X – high event rates Pressing the Range button cycles through the ranges; select the one most useful to the procedure being performed. **NOTE:** *Range Selection* **only** *controls the pitch of the sound generated by the unit.* *Range selection and the corresponding indicators have* **no** *effect on count rates or signal conditioning.* *Range Selection has* **no** *impact on the performance or counts displayed by the unit.*
Threshold 	Controls the range of the photon energy detected by the Probe. When the Threshold is off, all photon energy, including scattered photons, are detected. The indicator is not illuminated. When the Threshold is on the detection of the 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. The indicator is illuminated. **NOTE:** *The Threshold is normally on when using Probes. The Threshold may be set to off to count all events seen by a Probe.*
Count 	Starts a 10-second photon count. When Count has been pressed, the Count indicator is illuminated. When the 10 seconds is complete the Control Unit beeps and the total count is shown in the display for four seconds. After giving the total count, the Display goes back to showing counts per second.

Table 4. Controls and Displays on the Front of the Control Unit (Continued)

Control Display	Description
Cal 	Probes are used with the SCAN/Calibrate Control in the SCAN position only. The Calibrate Indicator blinks when the SCAN/Calibrate Control is in any position other than SCAN. **NOTE:** *The SCAN/Calibrate Control should be to SCAN for all uses of all Probes. The SCAN position is the only correct setting, and when the SCAN/ Calibrate Control is set to SCAN indicator is not illuminated.* See “Peak Procedure and Verification of Standard Gain” on page 79 for more information.
Low PowerPak 	Blinks when the PowerPak charge has only 30 minutes of useful charge remaining. Will change to a solid light before the useful charge is exhausted. See “PowerPak” on page 26 for more information.
Signal Input 	Signal Input For the Dilon Navigator™ 12 mm Probe and the Gamma-PET™ Probe, connect the Gain Module here. See “Connecting the Gain Module to the Control Unit” on page 43 for more information. For Standard Lymphatic Mapping probe, and similar probes, connects the Probe Cable here. See “6 mm Diameter Cable” on page 33 for more information.
Co-Pilot 	Connection for the Co-Pilot accessory. See “Optional Co-Pilot Device” on page 29 for more information.


Isotope Selector
Data Port
Scan/ Calibrate Control
SCAN
Calibrate
In111
Tc99
I131
I125
Fuse
Manufacturer's Serial Number Label

Table 5. Controls and Displays on the Back of the Control Unit

Control Display	Description
SCAN/Calibrate 	Set to SCAN/Calibrate when using Probes. The SCAN position is the only correct position when a Probe is being used. When set to SCAN, the CAL indicator on the front of the Control unit will not be illuminated, nor will it flash. See “SCAN/Calibrate Control” on page 25 for more information. See also “Peak Procedure and Verification of Standard Gain” on page 79.
Isotope Selector 	Selects the Isotope to be detected by the Control Unit. See “Isotope Control” on page 25 for more information.
Data Port 	Unused.

SCAN/Calibrate Control

This control should be in the SCAN Position. On some probe models, such as the Standard Lymphatic Mapping Probe, this control is temporarily placed in other positions during an optional VERIFICATION procedure

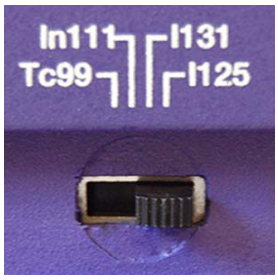
NOTE: *The SCAN/Calibrate Control has four positions. Make sure it is set to SCAN prior to a procedure.*
See "Verification of Standard Gain" on page 80 for information on Verification.

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

SCAN

low

center

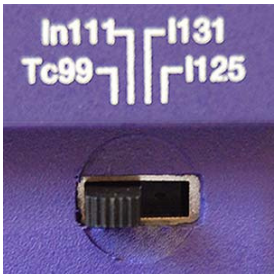


high

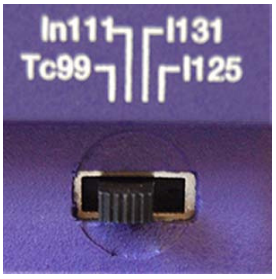
Isotope Control

The Isotope Control sets the Navigator™ to detect specific isotopes when in use.

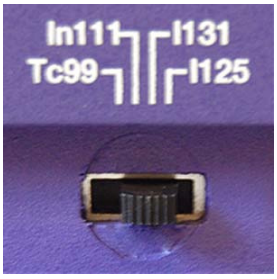
CAUTION
It is important that the Isotope Control is set to the isotope that is going to be used in the procedure. Setting the Isotope Control incorrectly will result in incorrect detection.



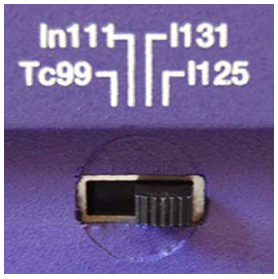
Tc99



In111



511keV & I131



I125

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.

Only one Isotope Indicator will light up at a time; the above image is for illustrative purposes only

4B. PowerPak

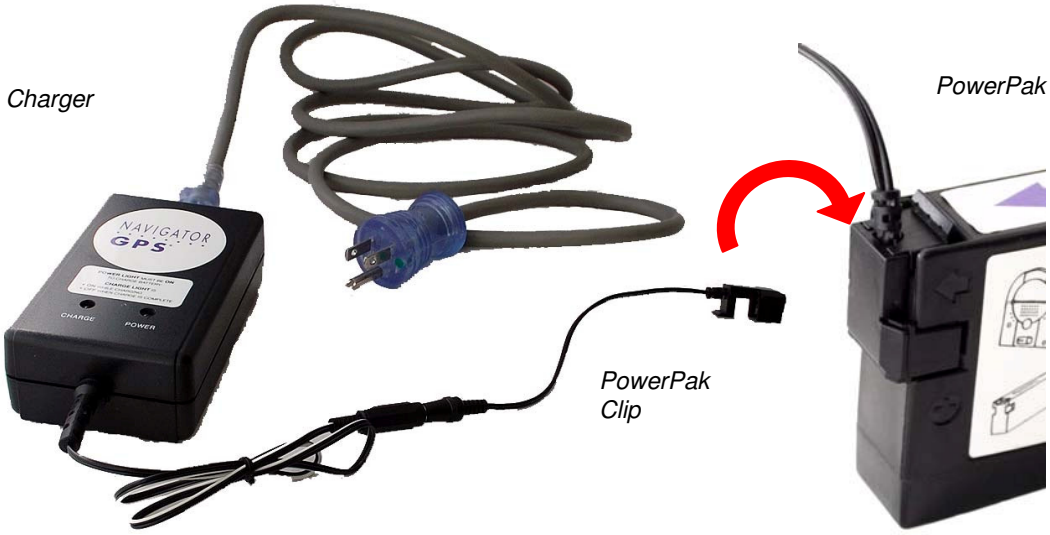
Inserting the PowerPak

Insert the PowerPak in the opening on the right side of the Control Unit. The notched end of the PowerPak is inserted first, notched corner on top. The Control Unit will “click” when the PowerPak is positioned properly.

Removing the PowerPak

Press the eject latch. The PowerPak will be released and will protrude slightly from the Control Unit.

Charging the PowerPak



1. Snap the PowerPak Clip onto the PowerPak, cord side up, at the corner of the PowerPak that has the purple arrow pointing to it. Ensure that the PowerPak Clip is connected to the Charger cable.

NOTE: *There is only one way to snap the PowerPak Clip to the PowerPak.*

2. Plug the Charger into a normal electrical outlet (110-240 VAC, 50-60 Hz).

NOTE: *It takes approximately two hours to charge a completely drained PowerPak. Having a fully charged spare PowerPak is recommended.*

The Charger has two indicator lights, Power and Status. Power is green, Status is yellow.

Table 6. PowerPak Charger Indicator Lights

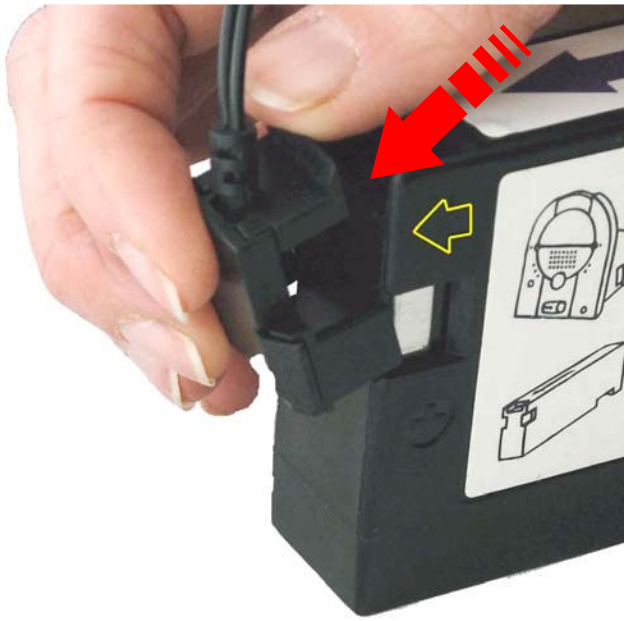
Indicator	Color	Condition	Meaning
Power	green	ON	Connected to power
Power	green	OFF	Not connected/No power
Status Light	yellow	ON	Charging the PowerPak
Status Light	yellow	OFF	PowerPak absent/fully charged

NOTE: *Use only PowerPaks supplied by Dilon. This PowerPak has the proper dimensions and a key feature that holds it securely in the Navigator GPS™ control unit.*

NOTE: *The PowerPak supplied with the Navigator GPS™ System contains lead. If the PowerPak requires disposal, recycle the PowerPak locally in a manner appropriate for its lead content.*

NOTE: *Consider using a second PowerPak. A second PowerPak may be kept in the Charger while the first PowerPak is being used in the Control Unit.*

Removing the PowerPak Clip

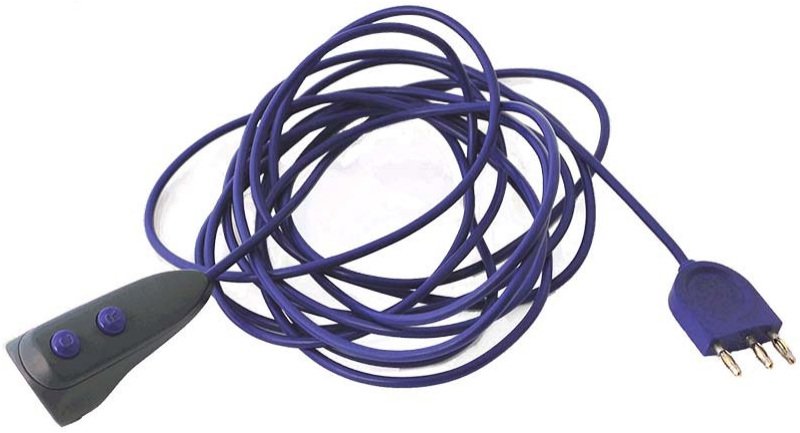


Push the PowerPak Clip off the PowerPak with your thumb.

4C. Optional Co-Pilot Device

The optional Co-Pilot Device initiates counting periods and changes the audible range. The Co-Pilot includes two small buttons, and a long, small-diameter cable.

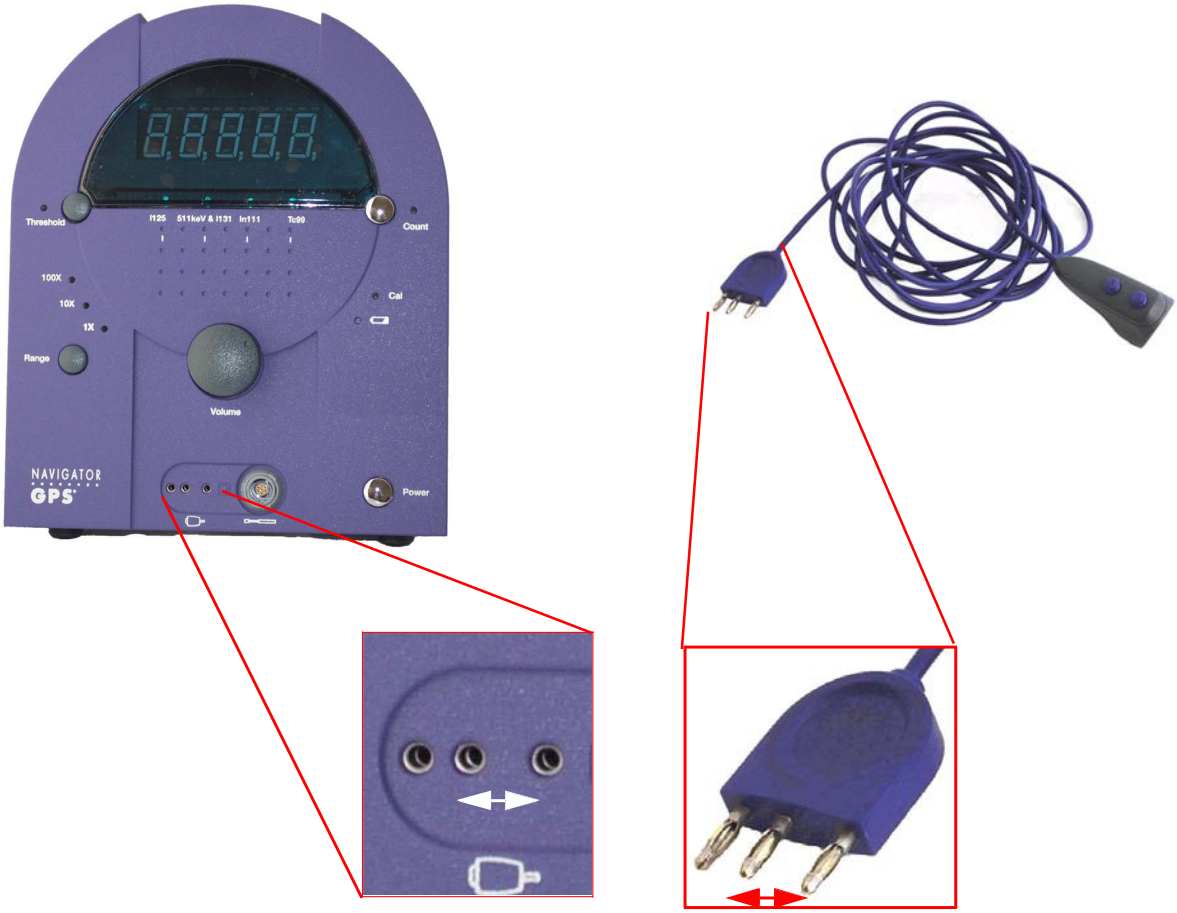
The Co-Pilot is clipped onto the end of a Probe, and connected to the Control Unit at the Co-Pilot receptacle.



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

The “C” button is the COUNT button. A one-second count is obtained by pushing and releasing this button once. A ten-second count is obtained by pushing this button twice, in quick succession. The total is shown in the DISPLAY on the Control Unit.

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



Match the spacing of the prongs with the spacing of the receptacles.

The Co-Pilot is attached to the Control Unit at the Co-Pilot receptacle.

CAUTION
The Co-Pilot can only be attached one way – the prongs are not evenly spaced.

4D. Useful Adjustments That Can be Made During Procedures

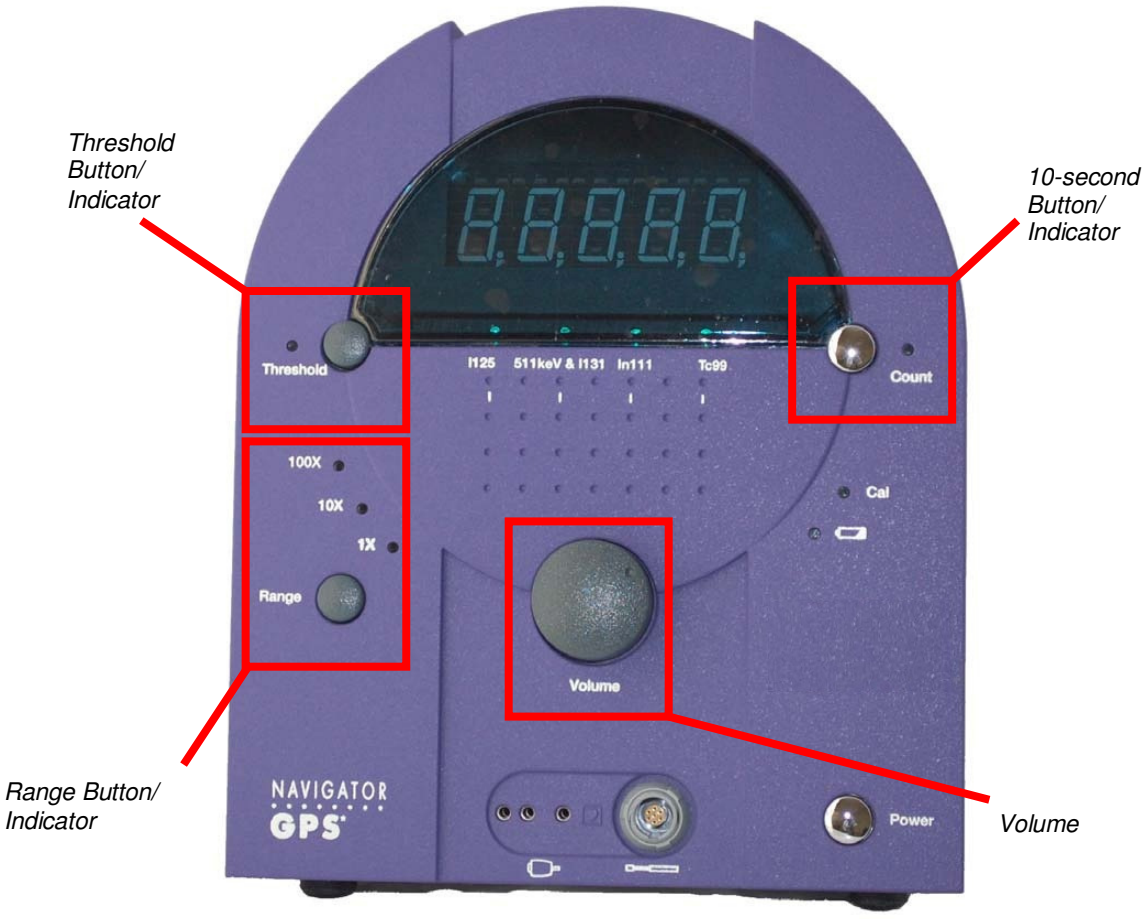


Table 7. Useful Adjustments

Adjustment	Benefit
Threshold	Increases signal when only a low number of events are observed. Threshold control is normally 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.
Range	You will be able to hear changes in high event rates. The Range is normally 1X. In the X10 position, every tenth signal produces an audible output. In X100, only every one hundredth 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. The total is displayed for at least four seconds so one may, if desired, record the total.
Volume	Adjust to desired loudness.

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

All Probes and Probe Cables require cleaning and disinfection immediately after and immediately before use.

Follow these steps to ensure that cleaning and disinfection is done correctly:

- "Clean/Disinfect Immediately Before Use" on page 34
- "Place Probe and Probe Cable in a Sterile Drape" on page 37
- "Clean/Disinfect/Store Probe and Probe Cable Immediately After Use" on page 37
- "Radioactive Decontamination Procedure – OPTIONAL" on page 41
- "Clean/Store Control Unit/Gain Module" on page 41

CAUTION
All Probes and Probe Cables are used inside a sterile drape. The Control Unit, Gain Module (if used), and PowerPak/Charger are used outside the sterile field. Probes and Probe Cables should be cleaned and disinfected separately from the other components.

Cables

One of two cables is used depending on the Probe.

3 mm Diameter Cable

The Dilon Navigator™ 12 mm Probe and the Gamma-PET™ Probe use a cable that has two conductors and a cable outside diameter of approximately 3 mm.

The connector is a locking connector. To disconnect the cable from the probe pull on the hood. Do not pull on the jacket. To disconnect the cable from the Navigator™ Gain Module, pull on the connector's hood. Do not pull on the connector jacket.

6 mm Diameter Cable

A different cable used for the Standard Lymphatic Mapping Probe, the Straight Lymphatic Mapping Probe, the Superficial Head and Neck Probe, the Thoracic Probe, the Abdominal Probe, and the Daniel-Probe™. This cable has five receptacles inside the probe end, and seven pins inside the plug that connects to the Navigator GPS™ control unit. The cable is approximately 6 mm in diameter.

The connector is a locking connector. To disconnect the cable from the probe pull on the hood. Do not pull on the jacket. To disconnect the cable from the Navigator GPS™ control unit, pull on the hood. Do not pull on the jacket.

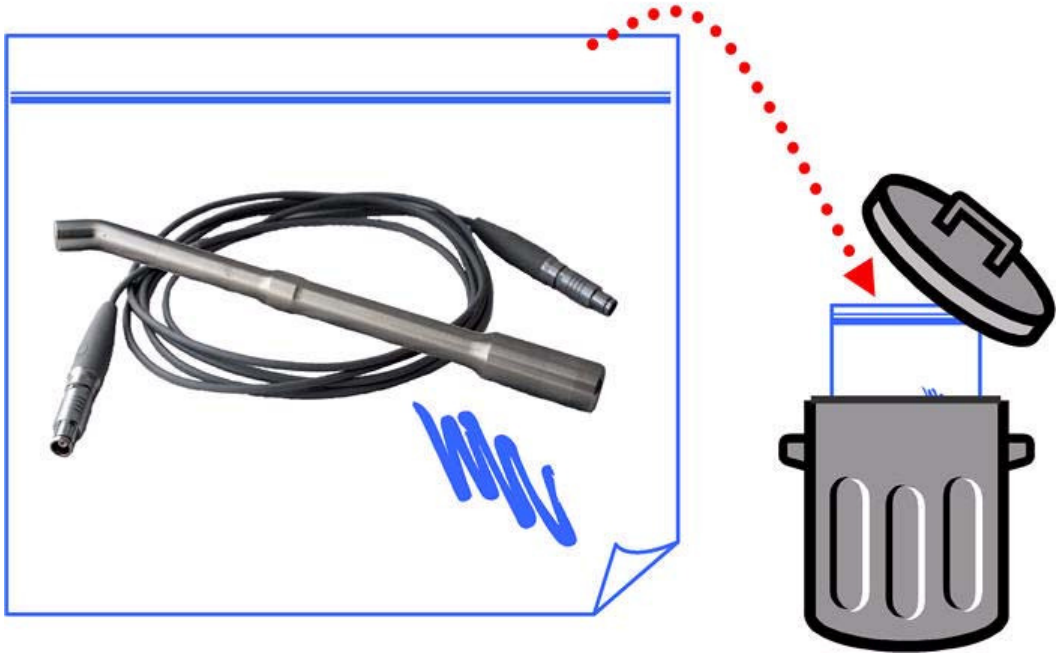
6mm Cable

6mm Cable - Navigator™ End

6mm Cable - Probe End

5A. Clean/Disinfect Immediately Before Use

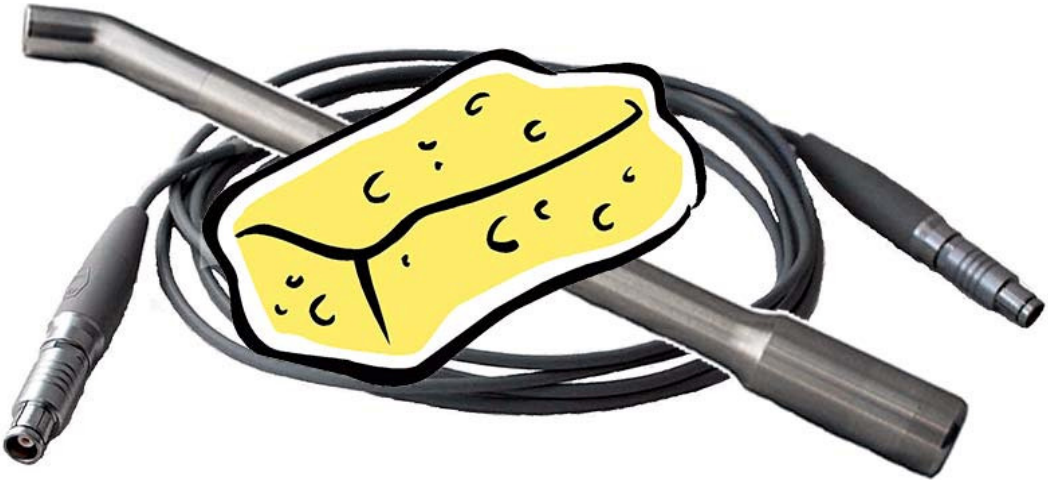
1. Remove Probe and Probe Cable from storage container. Discard container.



2. Visually inspect the Probe and Probe Cable for contamination.

If the probe or cable shows visual signs of contamination—or may possibly be contaminated—then proceed with Step 3 and Step 4, otherwise go to Step 5.

3. Wipe all visible contaminants from the Probe and Probe Cable with a clean sponge moistened with distilled water.



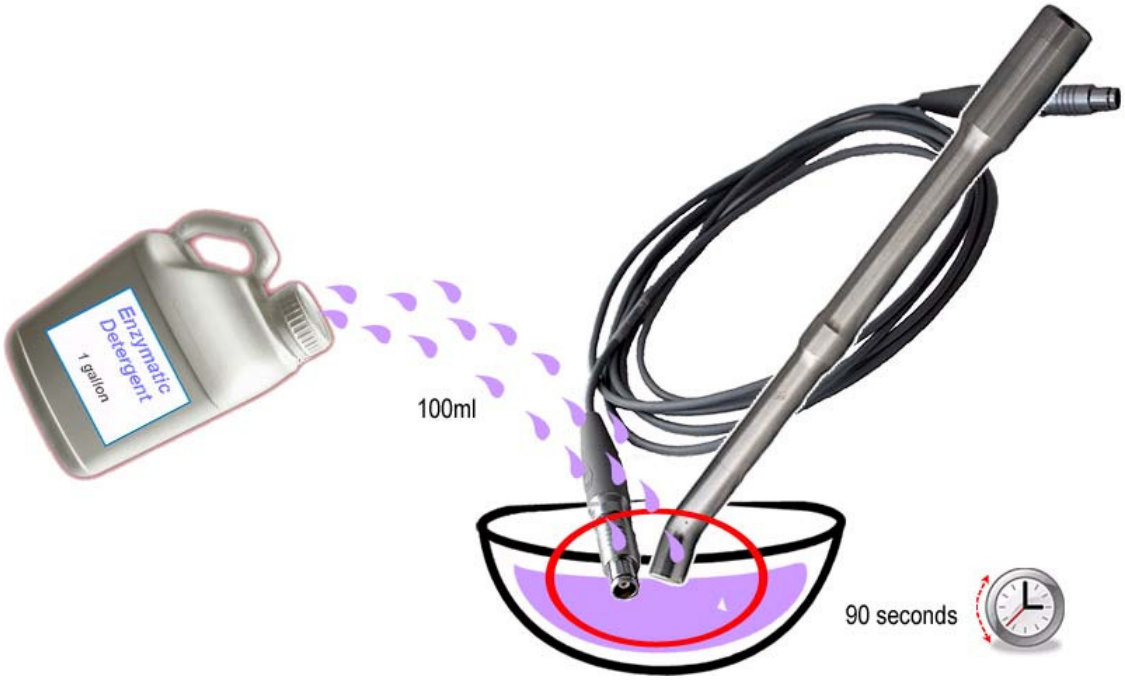
4. Wipe Probe and Probe Cable with a soft cloth soaked in an enzymatic detergent solution (suitable for surgical instruments) for approximately 30 seconds.

Visually inspect the Probe and Probe Cable for contamination.

Repeat Step 4 until visual inspection shows no contaminated areas.

5. If the probe tip and cable end show visual signs of contamination—or may possibly be contaminated—then proceed with this Step 5. Otherwise proceed with Step 6.

   Swirl the covered plug ends of the Probe and Probe Cable in 100ml of enzymatic detergent solution for 90 seconds.



CAUTION
Do not swirl the plug ends for more than two minutes.

6. Ensure that the connector ends of the Probe and Probe Cable are dry.
7. Connect the Probe to the Probe Cable.

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

5B. For Dilon Navigator™ 12 mm Probe and Gamma-PET™ Probe only

1 Run the Peak Procedure (see page 45). If the Peak Procedure was performed earlier in the day for the Probe, ensure that the Gain Module dial is in the same Peak Setting.

5C. Place Probe and Probe Cable in a Sterile Drape

1. Wipe the Probe and Probe Cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration).

2. Place the Dilon Navigator™ 12 mm Probe and Probe Cable into a suitable sterile drape (Spectrum Laboratories Inc., Part Number 719-03883-000 or equivalent).

WARNING! Do not drop the Probe, or strike the Probe tip against a hard surface. Doing so may damage the detector element, and the Probe may no longer be able to measure radiation.

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3. The Probe and Probe Cable are now ready for use.

   Refer to other sections of this manual, start with the section on the specific probe model.

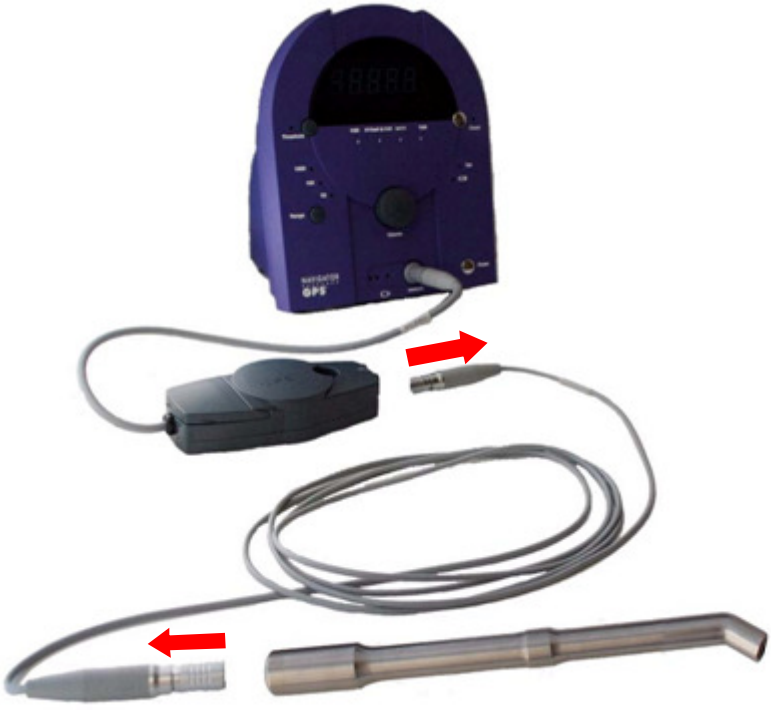
5D. Clean/Disinfect/Store Probe and Probe Cable Immediately After Use

1 Disconnect Probe Cable from Control Unit (or Gain Module if using).

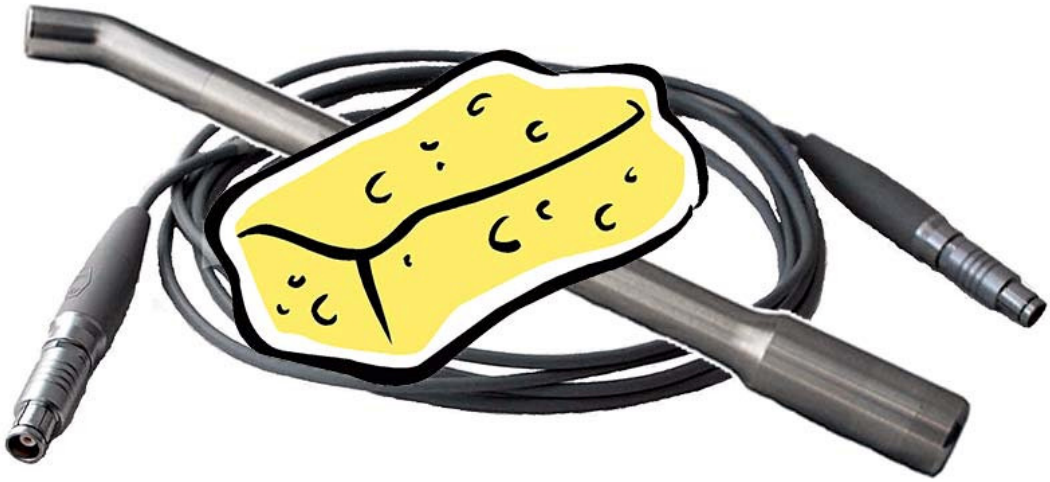
Put Control Unit (and Gain Module if using) to one side.

2 Disconnect the Cable from the Probe.

OR



3 Wipe all visible contaminants from the Probe and Probe Cable with a clean sponge moistened with distilled water.



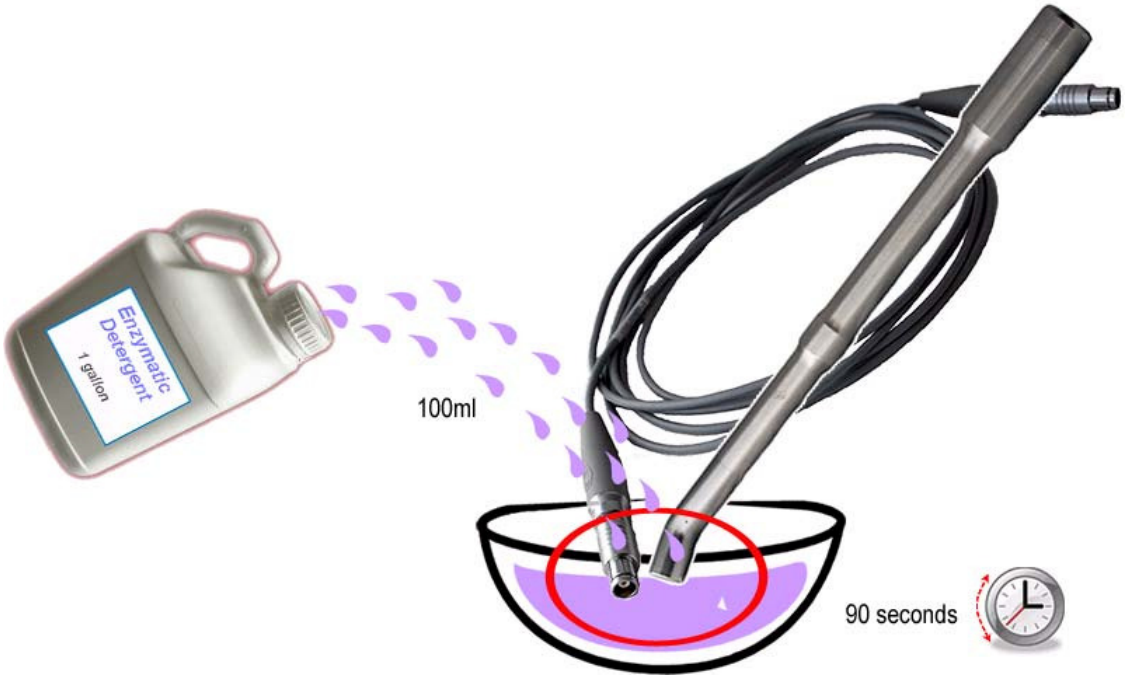
4 Wipe Probe and Probe Cable with a soft cloth soaked in an enzymatic detergent solution (suitable for surgical instruments) for approximately 30 seconds.

Visually inspect the Probe and Probe Cable for contamination.

Repeat Step 4 until visual inspection shows no contaminated areas.

5 If the probe tip and cable end show visual signs of contamination—or may possibly be contaminated—then proceed with this Step 5. Otherwise proceed with Step 6.

Swirl the covered plug ends of the Probe and Probe Cable in 100ml of enzymatic detergent solution for 90 seconds.



CAUTION
Do not swirl the plug ends for more than two minutes.

6 Ensure that the connector ends of the Probe and Probe Cable are dry.

CAUTION
Do not contaminate other items by wiping them with used cleaning solution. Dispose of used cleaning solution properly.

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

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7 When completely dry, loosely coil the Probe Cable (about six coils), and place the Probe and Probe Cable into a clean plastic bag/container, or other suitable storage container.

8 Store the container in a clean, safe environment.

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.

5E. Clean/Store 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.

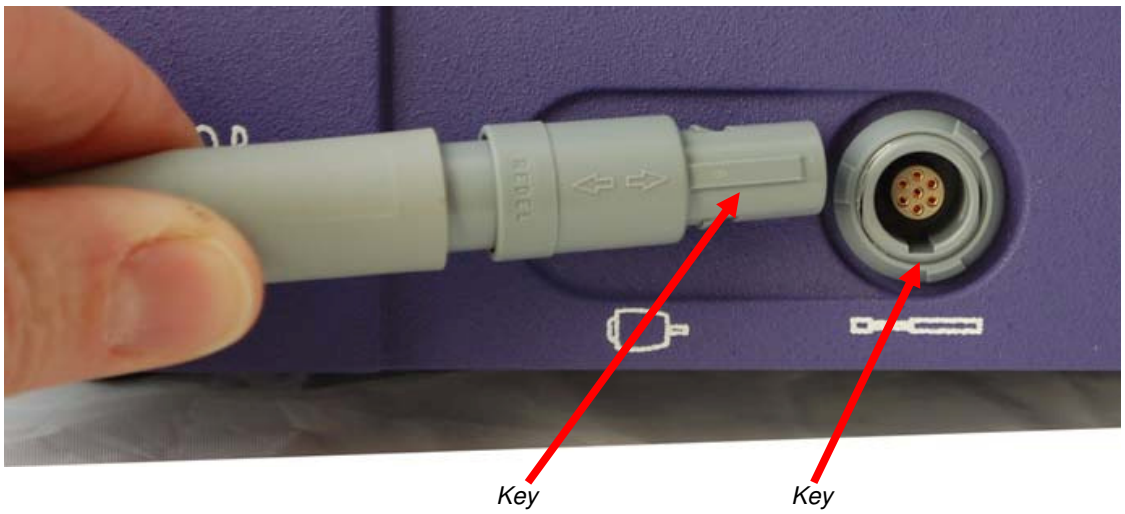
CAUTION
Follow universal, generally accepted practices when handling components that have come in contact with blood or tissue.

6. Gain Module and Peak Procedure

The Gain Module sits between the Control Unit and the Probe Cable of the Dilon Navigator™ 12 mm Probe or the Gamma-PET™ Probe.

6A. Connecting the Gain Module to the Control Unit

Line up the key on the Gain Module plug with the key on the Control Unit Probe receptacle, and insert the Gain Module plug into the Probe receptacle on the front of the Control Unit.



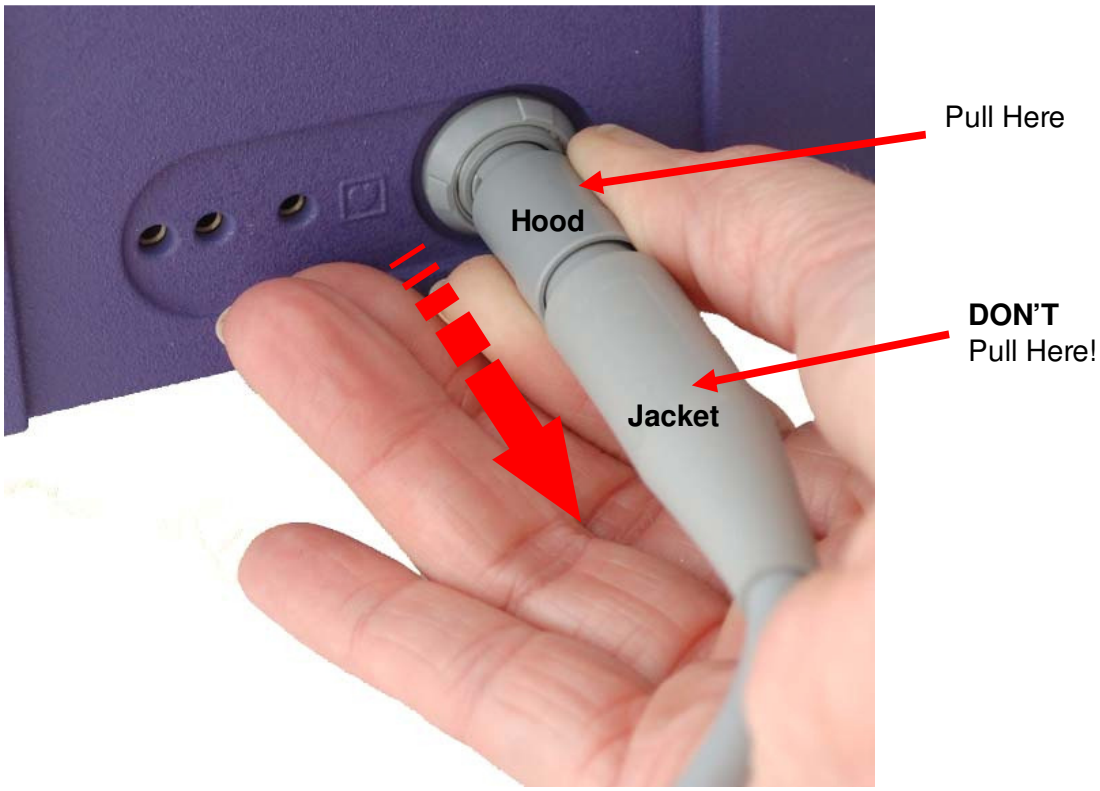
WARNING! The key on the plug MUST line up with the key on the receptacle. Do not try to jam the plug into the receptacle; this may damage the cable.

The plug will “click” when it is seated properly.

Removing the Gain Module

There is a hood at the end of the plug. Grasp the hood and pull straight out until the plug detaches from the Control Unit.

WARNING! Do not pull on the jacket of the Cable. You must pull on the hood at the very end of the Cable. Pulling on the jacket may damage the Cable.



6B. Connecting the Probe to the Gain Module

Connect the Probe end of the Cable to the Probe.

Connect the Gain Module End of the Cable to the Gain Module.

6C. Running a Peak Procedure

A Peak Procedure finds the best “sensitivity” of a probe - 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™ Display. Starting with the dial in the full clockwise position, the location on the Gain Module Dial where the count rate first reaches a maximum value is called the *Peak Setting*.

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 Dilon Navigator™ 12 mm Probe and the Gamma-PET™ Probe require a Peak Procedure, because they are the only probes that use the Gain Module.

EACH *Probe –*

1. Requires a Peak Procedure;
2. Needs a Peak Procedure run on EACH day-of-use, before the first surgical procedure;
3. Has its own Peak Setting on the Gain Module, which may have its Peak Setting change slightly day-to-day.

Dilon Navigator™ 12mm Probe - Technetium-99m isotope - Peak Procedure

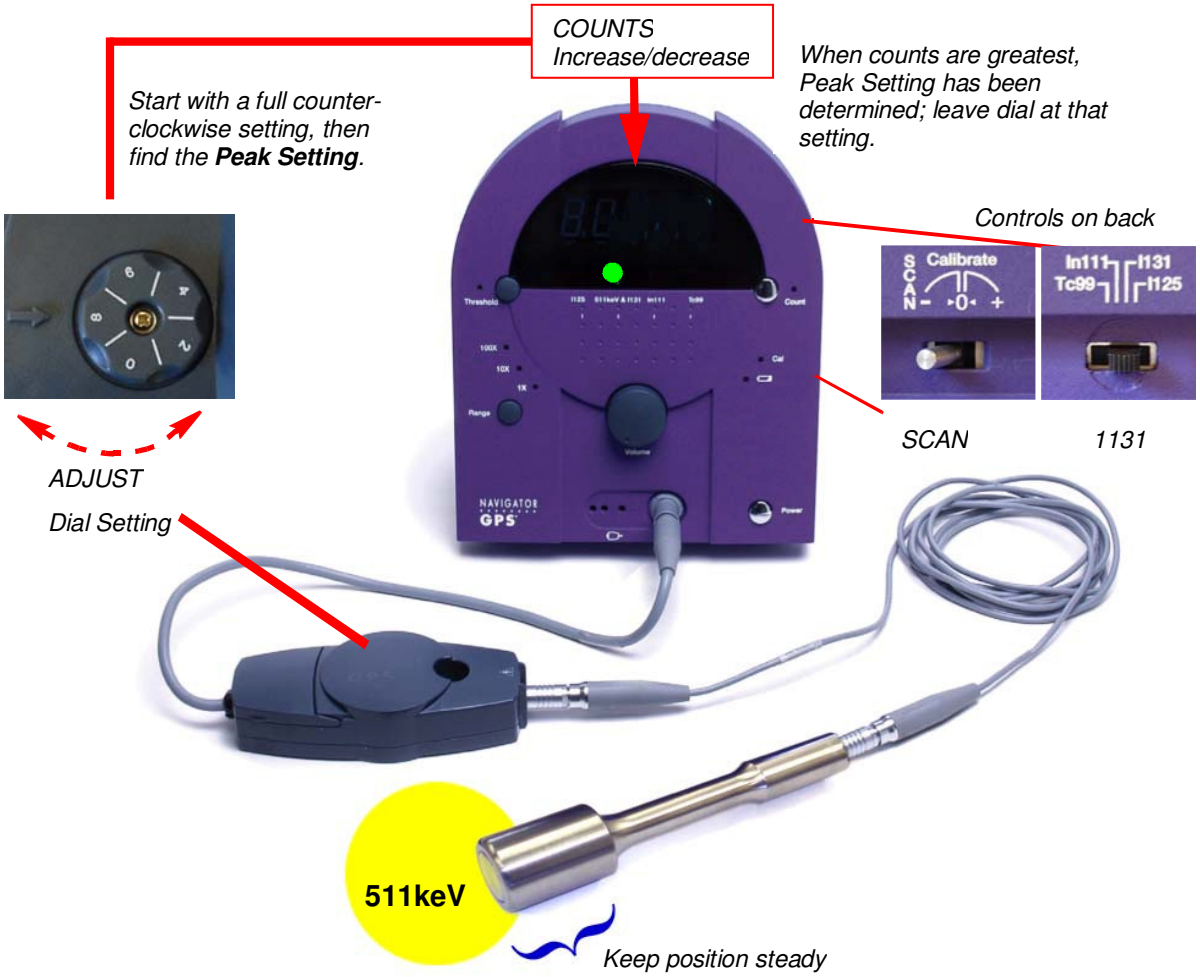
The Peak Procedure finds Peak Setting for the module's Dial, for that Probe for that day.

1. 99m technetium pharmaceutical is in patient.
2. On Control Unit, Isotope control set to Tc99, and Isotope indicator Tc99 is illuminated.
3. On Control Unit, SCAN/Calibrate control is set to SCAN.
4. On Control Unit, Threshold is ON, and Threshold Indicator is illuminated.
5. On Module, the Dial is at full counter-clockwise position. (near zero).
6. On Module, increase Dial to the first dial setting that maximizes the counts shown in the display.
   This is the **Peak Setting.**

NOTE: *On the module, the Dial can be set very closely to the **Peak Setting** for that Probe for that day.*

NOTE: *If uncertain about the **Peak Setting**, achieve it again. Remember the current dial setting as tentative. Remember the event rate shown in the display. Turn the dial to maximum, the event rate is typically lower than your tentative setting. Turn the dial to minimum, the event rate should be lower than your tentative setting. Then perform Step 6 again and achieve the **Peak Setting**.*

Gamma-PET™ Probe — 511KeV pharmaceutical — Peak Procedure



The Peak Procedure finds Peak Setting for the module's Dial, for that Probe for that day.

1. 511 keV pharmaceutical is in patient.
2. On Control Unit, Isotope control set to I131, and Isotope indicator 511keV & I131 is illuminated.
3. On Control Unit, SCAN/Calibrate control is set to SCAN.
4. On Control Unit, Threshold is ON, and Threshold Indicator is illuminated.
5. On Module, the Dial is at full counter-clockwise position. (near zero).
6. On Module, increase Dial to the first dial setting that maximizes the counts shown in the display.
   This is the **Peak Setting**.

NOTE: *On the module, the Dial can be set very closely to the **Peak Setting** for that Probe for that day.*

NOTE: *If uncertain about the **Peak Setting**, achieve it again. Remember the current dial setting as tentative. Remember the event rate shown in the display. Turn the dial to maximum, the event rate is typically lower than your tentative setting. Turn the dial to minimum, the event rate should be lower than your tentative setting. Then perform Step 6 again and achieve the **Peak Setting**.*

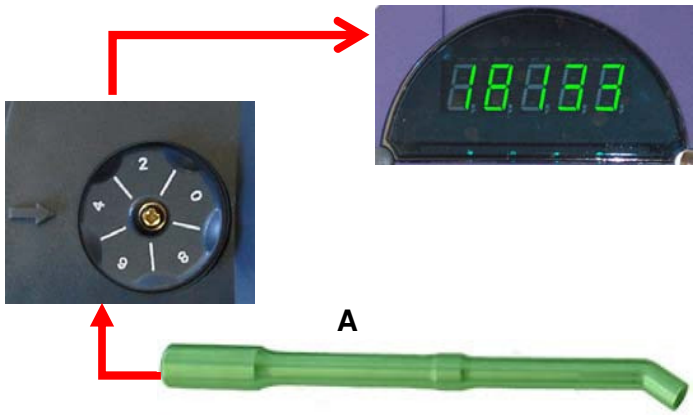
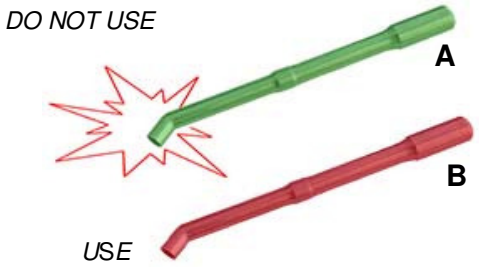
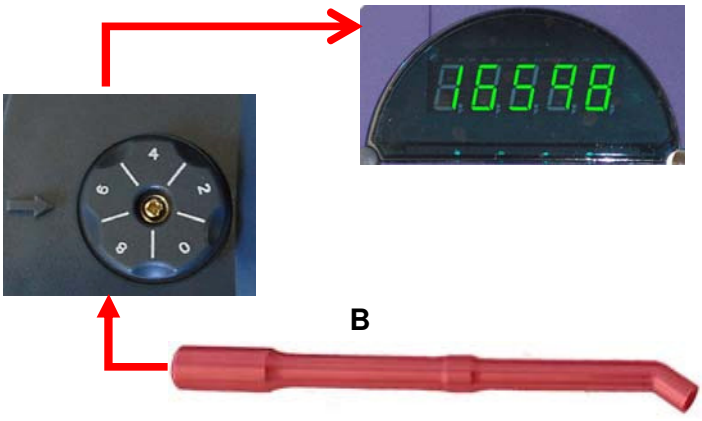
Example - Peak Procedure/Peak Setting for Probe A

1. Probe A is going to be used on Monday for surgical procedures.
2. Peak Procedure is run on Probe A, before the first surgical procedure of the day.
3. Probe A counts are highest when the Gain Module dial is set to just above 4.
4. The dial is kept at that location. This is the Peak Setting for that probe.
5. Probe A is now ready for surgical procedures.
6. The dial on the Gain Module is not adjusted for the rest of the day.

Example - Peak Procedure/Peak Setting for Probe B

1. Probe B is going to be used on Tuesday for surgical procedures.
2. Peak Procedure is run on Probe B, before the first surgical procedure of the day.
3. Probe B counts are highest when the Gain Module dial is set to just above 6.
4. The dial is left at that location. That is the Peak Setting for that probe.
5. Probe B is now ready for surgical procedures.
6. The dial on the Gain Module is not adjusted for the rest of the day.

Table 8. Using Multiple Probes During One Surgical Day

Control Display	Description
• **Probe A** is going to be used on Wednesday for all surgical procedures. • A Peak Procedure is run on **Probe A** before the first surgical procedure of the day. • **Probe A** counts are highest when the Gain Module dial is set to about 4 1/2. The dial is left at that location. • **Probe A** is ready for all surgical procedures.	
• **Probe A** is dropped. It cannot be used again until tested and disinfected. • The Surgical Team chooses to use **Probe B** for the rest of the procedures.	
• A Peak Procedure is run on **Probe B** before the next surgical procedure (or before continuing the current surgical procedure). • **Probe B** counts are highest when the dial on the Gain Module set to just above 6. The dial is left at that location. • **Probe B** is ready for the rest of the surgical procedures.	

7. Probe Assembly and Use

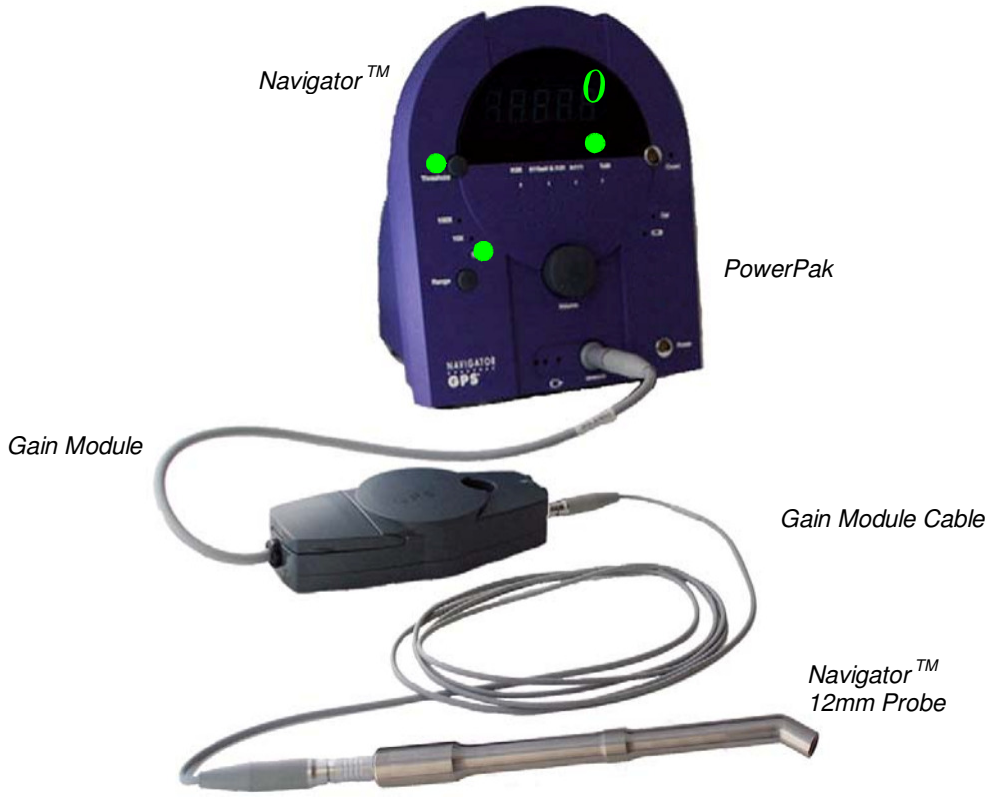
All Probes should be cleaned and disinfected immediately before and immediately after use. See “Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables” on page 33 for more information.

Also, the PowerPak should be charged prior to use.

See “PowerPak” on page 26 for more information.

NOTE: *A full charge for a discharged PowerPak takes two hours.*

7A. Dilon Navigator™ 12 mm Probe



The Dilon Navigator™ 12 mm Probe is used in various procedures. A typical sequence of setting up the Dilon Navigator™ 12 mm Probe for a procedure with a 99mTechnetium isotope (such as may be used in a lymphatic mapping procedure for a sentinel node) is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Gain Module to Control Unit.
- Run a Peak Procedure (page 45). You will see the system as shown above.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can Be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

NOTE: *A Peak Procedure must be performed before using the Probe in the first surgical procedure of the day. See page 45.*

NOTE: *Although the Peak Procedure is typically performed with no sterile drape around the probe and cable, the Peak Procedure may also be performed with the probe and cable inside a sterile drape.*

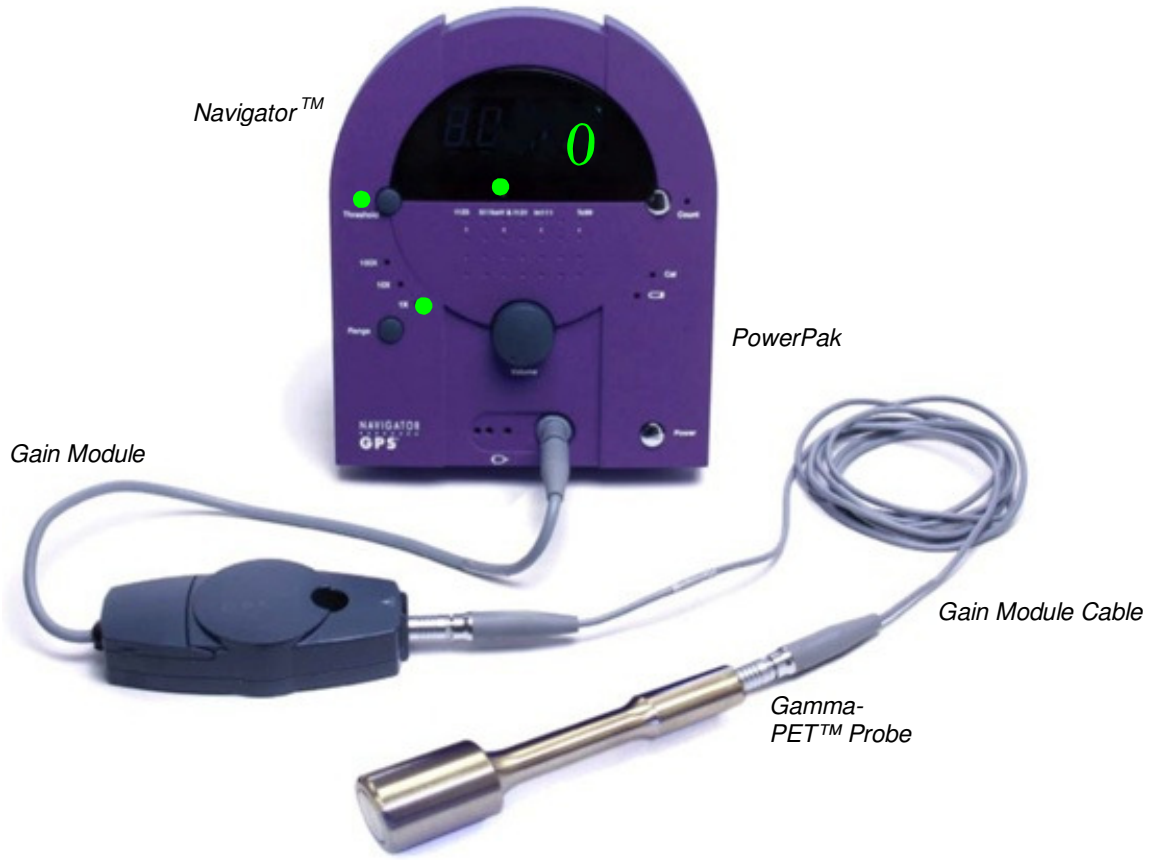
NOTE: *After a peak procedure has been performed, the control unit and Module settings are given in the table.*

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

Table 9. Dilon Navigator™ 12 mm Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99
Gain Module	
Dial at Peak Setting	Perform Peak Procedure on that Probe, that day

7B. Gamma-PET™ Probe



The Gamma-PET™ Probe is used in various procedures. A typical sequence of setting up the Gamma-PET™ Probe for a procedure with pharmaceutical that emits 511 keV Photons -- such as those that proceed from PET pharmaceuticals, such as ^{18}F-FDG is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Gain Module to Control Unit.
- Run a Peak Procedure (page 45). You will see the system as shown above.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

NOTE: *A Peak Procedure must be performed before using the Gamma-PET™ Probe in the first surgical procedure of the day. See page 45.*

NOTE: *Although the Peak Procedure is typically performed with no sterile drape around the probe and cable, the Peak Procedure may also be performed with the probe and cable inside a sterile drape.*

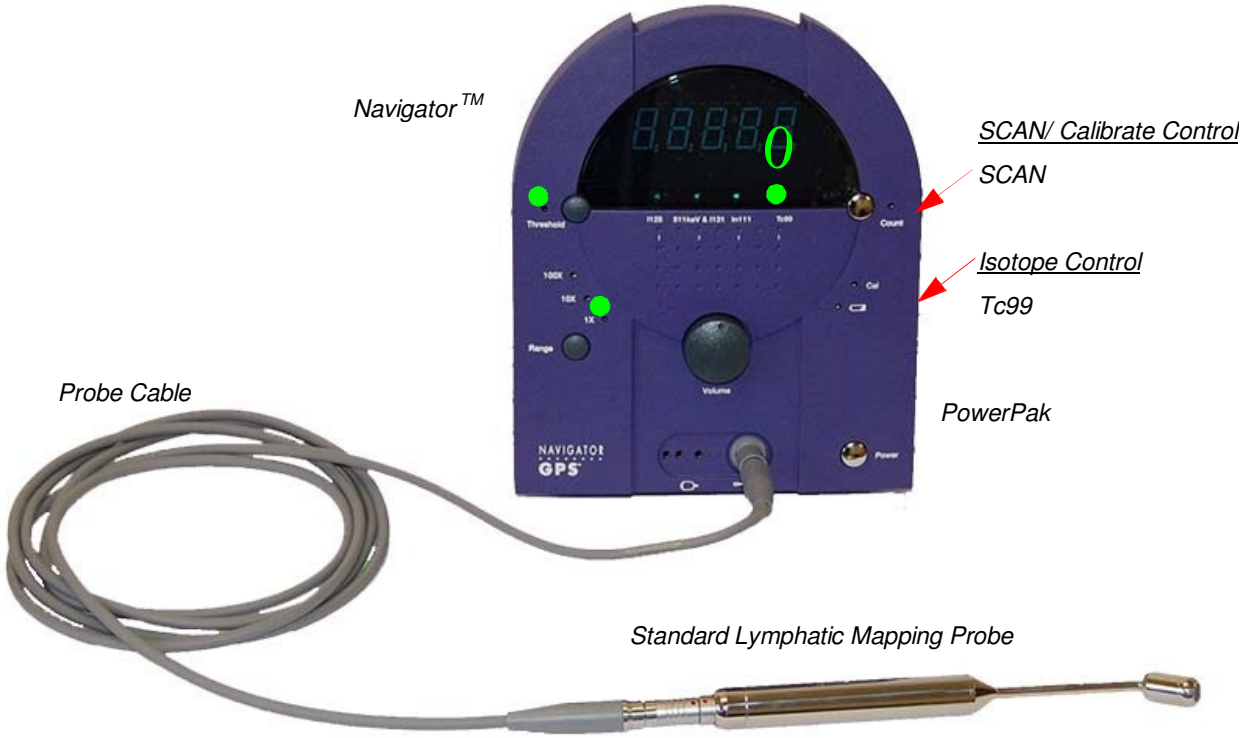
NOTE: *After a peak procedure has been performed, the control unit and Module settings are given in the table.*

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

Table 10. Gamma-PET™ Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	I131 (works for 511)
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	511keV & I131
Gain Module	
Dial at Peak Setting	Perform Peak Procedure on that Probe, that day

7C. Standard Lymphatic Mapping Probe



The Standard Lymphatic Mapping Probe is used in various procedures. A typical sequence of setting up the Standard Lymphatic Mapping probe for a procedure with a 99mTechnetium isotope (such as may be used in a lymphatic mapping procedure for a sentinel node) is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Control Unit.
- Set Control Unit rear-Panel SCAN/Calibrate control to SCAN.
- Set Control Unit rear-Panel Isotope control to Tc99.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

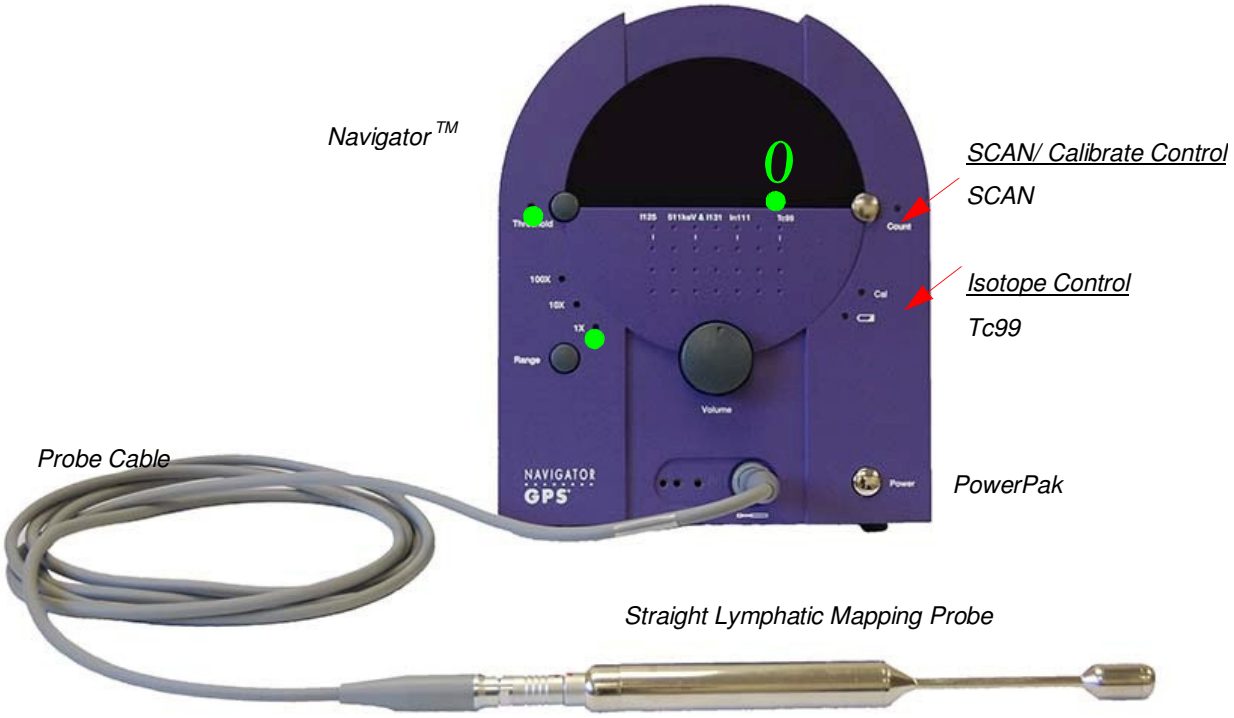
NOTE: *For 99mTechnetium, the Control Unit settings are also given in the attached table.*

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

Table 11. Standard Lymphatic Mapping Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99

7D. Straight Lymphatic Mapping Probe



The Straight Lymphatic Mapping Probe is used in various procedures. A typical sequence of setting up the Straight Lymphatic Mapping probe for a procedure with a 99mTechnetium isotope (such as may be used in a lymphatic mapping procedure for a sentinel node) is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Control Unit.
- Set Control Unit rear-Panel SCAN/Calibrate control to SCAN.
- Set Control Unit rear-Panel Isotope control to Tc99.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can Be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

NOTE: *For 99mTechnetium, the Control Unit settings are also given in the attached table.*

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

Table 12. Straight Lymphatic Mapping Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99

7E. Superficial Head and Neck Probe

The Superficial Head and Neck Probe is used in various procedures. A typical sequence of setting up the Superficial Head and Neck Probe for a procedure with a 99mTechnetium isotope (such as may be used in a procedure locating a hyperactive parathyroid gland) is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Control Unit.
- Set Control Unit rear-Panel SCAN/Calibrate control to SCAN.
- Set Control Unit rear-Panel Isotope control to Tc99.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can Be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

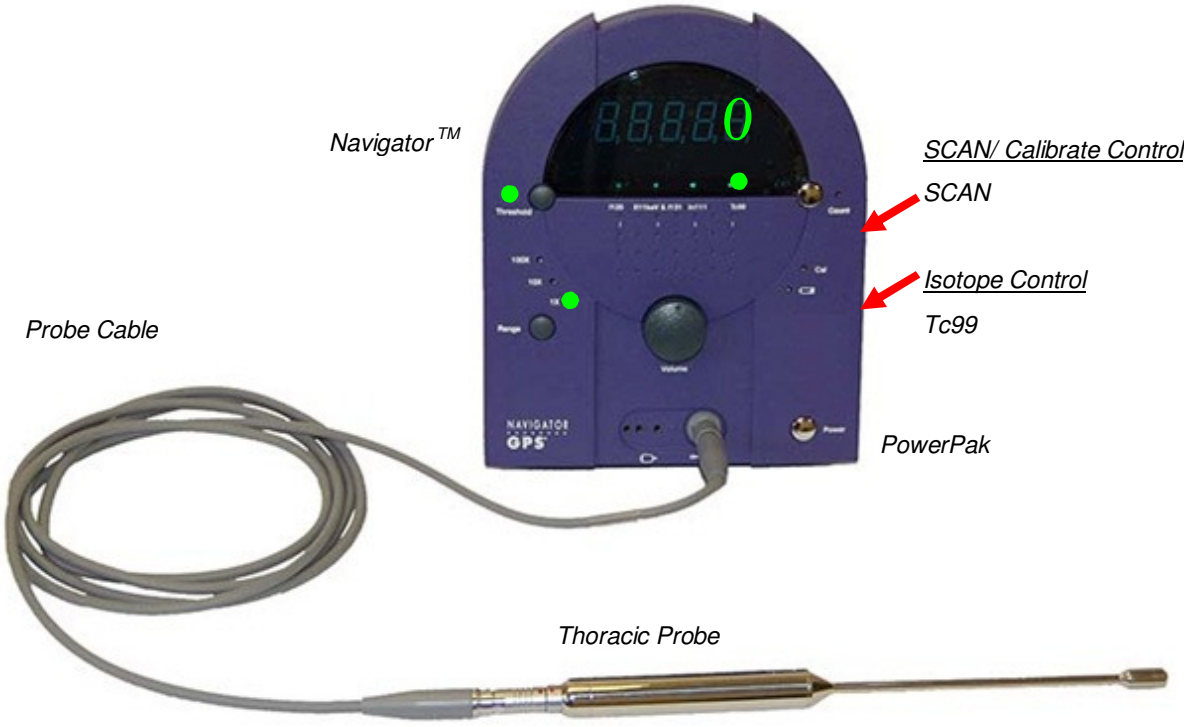
NOTE: *For 99mTechnetium, the Control Unit settings are also given in the attached table.*

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

Table 13. Superficial Head and Neck Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99

7F. Thoracic Probe



The Thoracic Probe is used in various procedures. A typical sequence of setting up the Superficial Head and Neck Probe for a procedure with a 99mTechnetium isotope is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Control Unit.
- Set Control Unit rear-Panel SCAN/Calibrate control to SCAN.
- Set Control Unit rear-Panel Isotope control to Tc99.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can Be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

NOTE: *For 99mTechnetium, the Control Unit settings are also given in the attached table.*

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

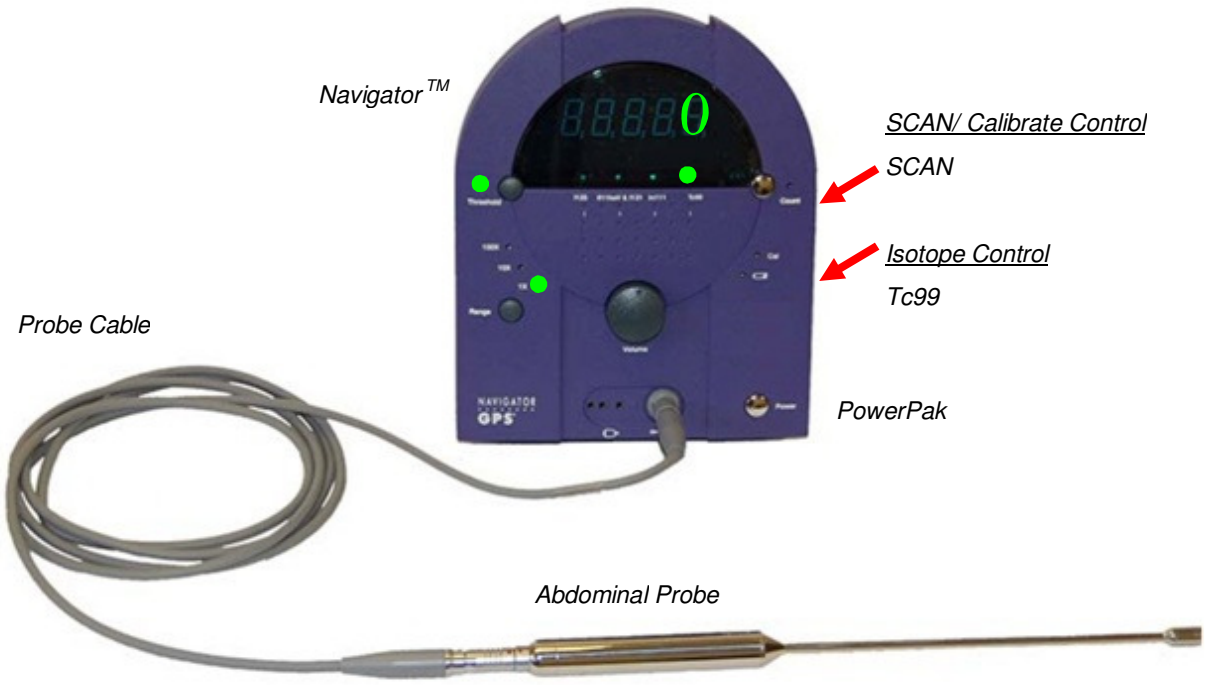
Table 14. Thoracic Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99

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.

7G. Abdominal Probe



The Abdominal Probe is used in various procedures. A typical sequence of setting up the Abdominal Probe for a procedure with a 99mTechnetium isotope is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Control Unit.
- Set Control Unit rear-Panel SCAN/Calibrate control to SCAN.
- Set Control Unit rear-Panel Isotope control to Tc99.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

NOTE: *For 99mTechnetium, the Control Unit settings are also given in the attached table.*

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

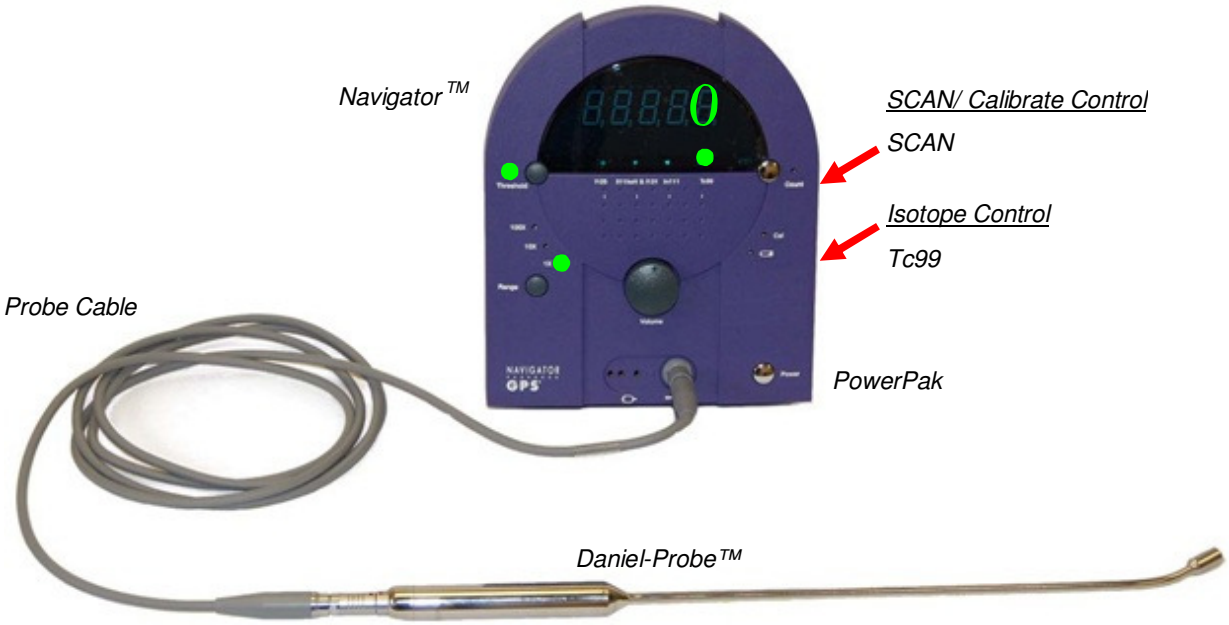
Table 15. Abdominal Probe - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99

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.

7H. Daniel-Probe™



The Daniel-Probe™ is used in various procedures. A typical sequence of setting up the Daniel-Probe™ for a procedure with a 99mTechnetium isotope is as follows:

Before Surgery

- Charge and insert the PowerPak into Control Unit (page 26).
- Connect the Probe, Cable, and Control Unit.
- Set Control Unit rear-Panel SCAN/Calibrate control to SCAN.
- Set Control Unit rear-Panel Isotope control to Tc99.
- Use Probe and Cable in a Sterile Drape (page 37).

During Surgery

- See also: Useful Adjustments That Can Be Made During Procedures (page 32).
- See also: Optional Co-Pilot Device (page 29).

After Surgery

- See: Cleaning, Disinfection, and Sterile Use of Probes and Probe Cables (page 33).

NOTE: *The time to charge a PowerPak by the Charger may take as long as two hours.*

NOTE: *Keep Control Unit Power off until all components are connected. This helps preserve component life.*

NOTE: *For 99mTechnetium, the Control Unit settings are also given in the attached table.*

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

Table 16. Daniel-Probe™ - Settings and Indicators

Control/Indicator	Setting
Controls (in back)	
Calibrate	SCAN
Isotope	Tc99
Indicators (in front)	
Range	1X
Threshold	Illuminated
Display	0
Isotope	Tc99

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.

Service Manual

8. Troubleshooting

Table 17. Troubleshooting: Problems, Causes, Remedies

Problem	Possible Causes	Remedies
1. Display is dark. No power to unit.	Power switch is Off, or broken.	Turn power on.
	Battery is dead.	Recharge battery.
	Fuse is missing.	Replace fuse.
	Damaged printed circuit board inside Control Unit	Contact Dilon for assistance.
2. Green 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 connections are secure.
	Isotope Control is incorrectly set to isotope I-131.	Change Isotope Control (on back of Control Unit) to TC-99
	Gain Module, if used, is set to zero.	Run Peak Procedure (page 45).
	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 for assistance.
	Probe is damaged.	Try a different Dilon Navigator™ 12 mm Probe. Contact Dilon for assistance.
3. Spurious high counts, such as 80000 counts a second (when Probe is held in air, for example)	Intermittent short in the cable.	Replace Cable.
4. Incomplete digits in display.	Display or display driver is damaged	Contact Dilon for assistance.

9. Specifications

The Navigator GPS™ system consists of the Control Unit, one or more Probes, and the system accessories.

9A. Navigator GPS™ Control Unit Specifications

Table 18. Navigator GPS™ Control Unit Specifications

Item	Description
Control Unit Power Source	Replaceable, internal PowerPak
PowerPak	Sealed, lead-acid, rechargeable 12V (nominal) voltage, 2.0Ah (nominal) capacity. Approximate weight: 590 g
New PowerPak Charge Life – full charge	4 hours continuous (nominal)
PowerPak Recharge Cycle – 100% discharge	150-200 cycles (80% of new PowerPak charge life)
Fuse – Control Unit	UL/CSA (198G) standards; 0.75 amp, Slow- blow. Glass Housing. 250 volt rating. 5x20mm IEC 127 standards: Type 7. 0.63 amp, 250 volts. 5x20mm T0.63AL250V
Sound Indicators	Pitch – sound. Frequency proportional to event rate. Beep – Indicates need to recharge PowerPak. Occurs when Lower PowerPak indicators comes on.
Visual Indicators	Digital Count – Vacuum Fluorescent Display Single Count – LED Sample Time Active – LED PowerPak Low – LED PowerPak Recharge Required – LED Range 1X/10X/100X – LED Isotope – LED (four)
Energy Range	Up to and including 511 keV
Storage Conditions	-15°C to 40°C (5°F to 104°F) 0% - 80% relative humidity
Maximum Count Rate	25,000/s
Control Unit Dimensions	20cm W x 24cm H x 18cm D

Table 18. Navigator GPS™ Control Unit Specifications (Continued)

Item	Description
Control Unit Weight w/ PowerPak	2.0kg
Accuracy	95% - 99% across the dynamic range of the instrument with probes

9B. Product Life

The products supplied by Dilon are non-sterile, durable goods. The product warranty is for a one-year time period consistent with use described in this user/service manual. Dilon defines the "end of life" of the product by the accumulation of wear, abrasion, and damage encountered during use.

The rate of wear, abrasion and damage varies among users. For practical purposes of record keeping, Dilon further defines the "life time" of the product components to these time periods given below:

Table 19. Product Life

Control Unit	3 years
PowerPak	2 years
Charger	2 years
Probe	2 years
Cable	2 years
Gain Module	2 years

The control unit contains a fuse. The "life-time" of the fuse is two years for normal use. The fuse is meant to be replaced when necessary (when the fuse is "blown") by the user. Instructions for replacing a fuse are given in the operating manual.

Consistent with Dilon's understanding of the current MDD, record retention is 5 years following the last production of the instrument.

9C. System Accuracy

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

10. Support Items

The Navigator GPS™ System is typically supplied as a complete system. Support items may be purchased from the local Dilon Navigator™ representative. At time of publication of this manual, some support items have the following order codes. Feel free to contact your local representative for additional information.

Table 20. Navigator GPS™ System Support Items

Item	Description	Marketing Order Code
Cable for 12mm Probe 	Connects Dilon Navigator™ 12 mm Probe and Gamma-PET™ Probe to Gain Module. Cable has two conductors, one central and one circular.	E097CBL
Cable for 14mm Probe 	Connects 14mm Probes to Control Unit. Cable has six conductors.	E097015
PowerPak 	See “PowerPak” on page 26 for more information.	E097113
PowerPak Charger 	Black color body. Rectangular shape. Includes cable that terminates in a circular receptacle. Supplied with two replaceable PowerPak clips. See “Charging the PowerPak” on page 27 for more information.	E097013
Spare PowerPak Clips 	Re-Usable. Set of Two. See “Charging the PowerPak” on page 27 for more information.	E297413

Table 21. Navigator GPS™ System Support Items (Continued)

Item	Description	Marketing Order Code
Co-Pilot 	See “Optional Co-Pilot Device” on page 29 for more information.	E098002

10A. Product Ordering Codes and Part Numbers

Items are typically ordered by the Marketing Order Code. The corresponding Dilon Engineering part number appears on some items.

Table 21. Marketing Order Codes/ Dilon Part Nos.

Marketing Order Code	Description	Dilon Part No.
E097113	DILON NVG GPS BATTERY ASSY	GP-5500-00
E297000	DILON, NVG, GPS SYS	GP-8500-00
E297400	NAV GPS SYS LEDS	GP-9000-00
E397400	NAV GPS SYS LEDS	GP-9100-00
E297500	12MM SYSTEM, US	GP-9200-00
E397500	12MM SYSTEM, EU	GP-9210-00
E097500	12MM PROBE UPGRADE	GP-9220-00
E097300	PET PROBE UPGRADE	GP-9320-00
E198003	TOP GUN COLLIMATOR 2	SP-1800-00
E097CBL	CABLE, 12mm, PET PROBES	PM-4000-20
E097002	PRB 14MM ANGLE 67MM SHAFT	SP-2A14-67
E097012	PRB 14MM STRHT 67MM SHAFT	SP-2S14-67
E097016	PRB 11MM STRHT 53MM SHAFT	SP-2S11-53
E097202	PRB 10MM STRT 310MM SHAFT	SP-2S10-31
E097102	PRB 10MM STRT 190MM SHAFT	SP-2S10-19
E097620	DANIEL PROBE	SP-2S10-31D
E097015	CABLE, 10mm, 11mm, 14mm PROBES	PM-4001-00

10B. Sterile Drape

A sterile drape is an accessory. A sterile drape is not sold or supported by Dilon Technologies.

Typical characteristics of a suitable intra-operative prove 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% latex Free-all components, including rubber bands, guaranteed Latex free
    - All available ETO Sterile
    - Strong and durable Anti-Static material

11. Maintenance

While the Navigator GPS™ System is virtually maintenance-free there are a number of steps the use should follow 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 22. Component Check

Component	Feature
Probe	Overall. Also tip and connector
Cable	Each connector, the connector pins, and integrity of cable
Module	(If present) dial, cable, and connector
Control Unit	Overall. housing, integrity of switches
PowerPak Charger	Battery clips

Should abnormalities be discovered by the user, the user should contact their sales representative or customer support person.

Do not use a damaged Probe, Cable, Gain Module, Control Unit, PowerPak or Charger.

2. The user should check each battery for function and charge before use. Should abnormalities be discovered by the user, they should contact their sales representative or customer support person.
3. To ensure proper functionality the user should follow each step as outlined in Chapter 4. “Control Unit, PowerPak, and Co-Pilot” on page 19 and the section on the Probe that is used. Should abnormalities be discovered by the user, they should contact their sales representative or customer support person.
4. In addition to the above, preventive maintenance suggests that every two years a new Cable, PowerPak, and fuse might be considered.

11A. Peak Procedure and Verification of Standard Gain

The Navigator GPS™ system is designed to minimize periodic maintenance, such as might 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.

Peak Procedure

Applies to the Dilon Navigator™ 12 mm Probe and Gamma-PET™ Probe. The Peak Procedure involves the Probe and Gain Module. This procedure is performed each day one these Probes is used. The procedure gives the Probe its maximum sensitivity for that day's use.

Verification of Standard Gain

Applies to the Standard Lymphatic Mapping Probe Family. These probes include the Standard Lymphatic Mapping Probe, Straight Lymphatic Mapping Probe, Superficial Head and Neck Probe, Thoracic Probe, Abdominal Probe, and the Daniel-Probe™. Some institutions perform this Verification of Standard Gain every six months or every year. The procedure does not change the system. The procedure reveals whether or not the Probe and Control unit are set to a common gain standard. 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 57Cobalt 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 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 position, as revealed by the highest count rate seen in the Control Units' display. The details of the test are given below.

Verification of Calibration Quick Test

1. Clean the PROBE and CABLE (page 34).
2. Charge the POWERPAK, and install it into the CONTROL UNIT (page 26).
3. Place the system controls as indicated in Table 23, “System Configuration - Cobalt-57 Alignment,” on page 81.
4. Align a 57 Cobalt source directly with the probe tip at a distance such that the total shown in the system display -- when the ENERGY THRESHOLD Control is off -- is in the range of 2,000 to 10,000 counts per second. For the remainder of the test, maintain this exact position between the source and the probe tip.
5. Place the system controls as indicated in Table 23, “System Configuration - Cobalt-57 Alignment,” on page 81.
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.

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 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: *When the SCAN/Calibrate Control is in either the BELOW position (-), the CENTERED position (>0<) or the ABOVE position (+), the CONTROL UNIT automatically disables the ISOTOPE control and the THRESHOLD control. These controls are enabled when the SCAN/Calibrate Control is returned to the SCAN position.*

NOTE: *Any probe in the Standard Lymphatic Mapping probe family can be used with any Navigator GPS™ Control Unit. The Verification of Standard Gain is an optional procedure that demonstrates this fact.*

Table 23. System Configuration - Cobalt-57 Alignment

Setting	Item
Navigator GPS™ Probe	connected to PROBE input
>0<	CALIBRATE control (rear panel)
Technetium-99m	ISOTOPE control (rear panel)
OFF	THRESHOLD control
ON	POWER switch
as desired	RANGE control
as desired	VOLUME control

Table 24. System Configuration - Verification of Standard Gain

Setting	Item
Navigator GPS™ Probe	connected to PROBE input
ON	POWER switch
Varies	CALIBRATE control (rear panel)
as desired	VOLUME control
as desired	RANGE control
no effect	ISOTOPE control (rear panel)
no effect	THRESHOLD control

12. Repair

The Probes are sealed at the factory. No user serviceable parts are inside the Probes. Damage to a Probe will result if a Probe is opened by the user.

The Navigator GPS™ control unit includes a Fuse which may be inspected and replaced by the user. The Control Unit may include a bracket by which the user affixes the Gain Module to the control unit. The Control unit includes a PowerPak which the user may remove and replace into the control unit. Beyond these three items, the control unit contains no user serviceable parts and should not be opened by the user.

Please contact Dilon for additional 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 plastic bags or film or other protective wrapping.

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. Indicate on the outside of the shipping carton that the items have been cleaned and disinfected.

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, Inc., (Dilon), warrants to its customers that, subject to the below provisions, the Navigator GPS™ 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 repair or replacement as set forth above. Dilon shall not be liable to anyone, under any circumstances, for any special, punitive, incidental or consequential damages 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.

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