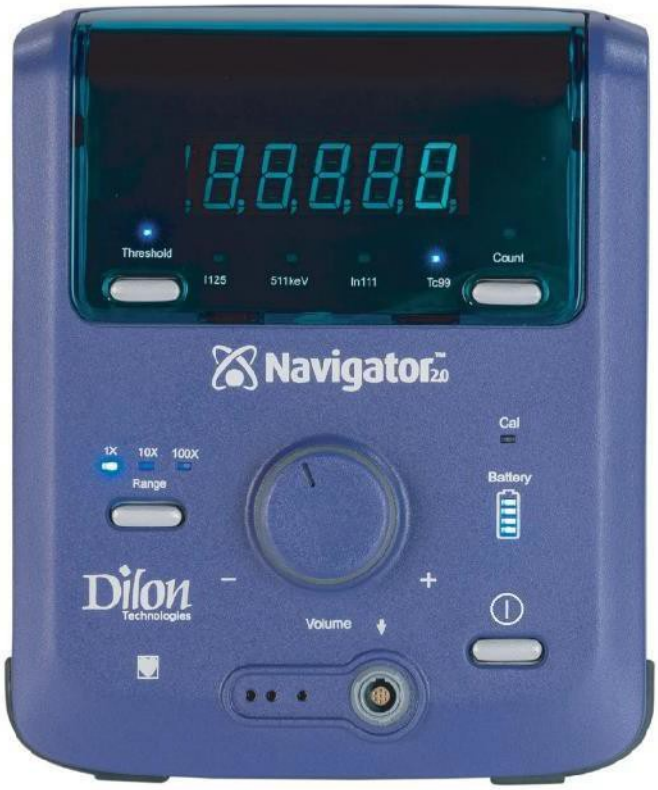
Navigator™ 2.0



User/Service Manual

Manufactured by:
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CE 0459

Important Notes

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.

Copyright Notice

Trademarks

Part Number

N2-5000-07-001 Rev 11 / 30April2020

User Manual: Table of Contents

USER MANUAL

1 Introduction

1.1 Operating Principle

The Navigator 2.0 System detects presence of gamma rays, emitted from radioactive isotopes in body organs or tissue. System use requires the Navigator 2.0 Control Unit, which allows the user to adjust the system's settings and produces a variety of signal outputs. The control unit is powered by a rechargeable battery. The system provides an increasing or decreasing sound and visual counts that vary as level of gamma radiation increases or decreases.
The control unit works in conjunction with a hand-held probe that is connected to the control unit either via a cable or wireless technology. Placing probe close to a radiation source increases number of counts detected and localization occurs. As the distance between the probe and the radiation source is increases, the number of gamma rays detected decreases.
The Navigator Control Unit is used with any of the following Navigator™ hand-held probe models. The probes differ primarily in their size, shape, detector technology and connection to the control unit.

- 14mm Wireless Pilot Probe™ (angled tip & straight tip)
- 14mm Standard Lymphatic Mapping Probes (angled tip & straight 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.

1.2 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.

1.3 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.

1.4 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.

1.5 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.

1.6 Regulatory and Safety Requirements

The Dilon Navigator 2.0™ System including Probes comply 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: 3 Ed: Amendment 1.
- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility – IEC 60601-1-2: 4th Ed.

Safety

- Medical Electrical Equipment - Part 1: General requirements For Safety 1: Collateral Standard: Safety Requirements For Medical Electrical Systems – IEC 60601-1: 3rd and 4th Ed.
- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – IEC 60601-1-2: 3rd and 4th edition.
- Medical Electrical Equipment - Part 1-6: General Requirements For Safety - Collateral Standard: Usability - IEC 60601-1-6: 2010 + Am. 1: 2013.
- CAN/CSA C22.2 No. 60601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety & Essential Performance; issued 2008-02-01 Ed. 2
- AS/NZS 3200-1-0, Deviations to IEC 601-1 for Application in Australia and New Zealand

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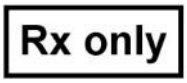
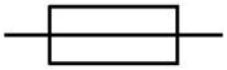
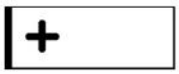
***CAUTION**:* Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

Table 1A. Explanation of Symbols

	Type-CF Applied Part		RX only Caution: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.
	Date of Manufacture		Follow Instructions for Use
	Manufactured by		Consult the Instructions for Use
	ON/OFF		Attention, consult accompanying documents
	Temperature limit		Serial number
	Humidity limitation		Catalogue number
	Wireless Capability		European Community Representative
	Fuse		WEEE
	Battery		

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.”

***CAUTION**: It is possible that cross communication may occur if two or more wireless devices are used in close proximity*

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

Probes are Type CF Applied Parts. See Table 2A below for a list of Probes.

Table 2A. Type CF Applied Parts and Probe Dimensions.

Probe	Tip Diameter	Tip Angle (degrees)	Length (mm)	Weight (grams)
Wireless Pilot Probes	14mm	0/30	257/260	255g
Standard Lymphatic Mapping Probes	14mm	0/35	224/220	185g
Superficial Head & Neck Probe	11mm	0	207	161g
Daniel Lung Probe™	10mm	30	465	195g
Laparoscopic Probe	10mm	0	467	195g

3 Precautions

3.1 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.
- This User/Service manual is designed to assist the use of the Navigator 2.0 system and is not a reference to surgical techniques.

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

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

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3.2 Control Unit, Battery, and Charger

- During system use, maintain electrical isolation of the patient. Do not connect the probe, cable (if used), or the internal circuit of the control unit to earth ground, or to other voltage potentials.
- Maintain patient electrical isolation. Do not defeat the electrical isolation of the surface of a probe cable (if used), and the control unit housing. These isolate the battery-power circuit inside the control unit, the conductors inside the probe cable, the probe surface, and the patient.
- The Line Cord of the 2-bay battery charger is used as the disconnect device for the charger.
- When optional system components are used with the system, maintain probe and patient electrical isolation from earth ground. The optional components include the probe drape, the Top Gun™ Collimator, Sterilization trays, and Navigator 2.0 roll stand.
- In the operating room, use the charger at a distance of six feet or greater from the patient.
- Fully charge the Control Unit battery before each use.
- Replace the wireless probe battery before ***each*** surgical procedure or prior to sterilization.
- This system is not designed for use in an 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.

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

3.3 Probe

- DO NOT put any probe or probe cable in an autoclave.
- With the exception of the Wireless Pilot Probe's battery holder, DO NOT attempt to open probes.
    - All probes are tested and sealed at the factory. Attempting to open the probe may cause damage and will void the warranty.
- DO NOT drop or strike the probe tip against a hard surface; this may result in damage to the probe.

3.4 Electromagnetic Compatibility IEC 60601-1-2:2014

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

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

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

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

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

WARNING: The Navigator Control Unit and Probes should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the Navigator Control Unit and Probes should be observed to verify normal operation in the configuration in which it will used.

3.5 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Navigator Control Unit and Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Navigator Control Unit and Probes should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11 Radiated	Group 1 Class A	The Navigator Control Unit and Probes uses RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Conducted	Class A	The Navigator Control Unit and Probes are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

3.6 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Navigator Control Unit and Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Navigator Control Unit and Probes should ensure that it is used in such environment.

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec cycle	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec cycle	Mains power quality for the Battery Charger should be that of a typical commercial or hospital environment. The Navigator Control Unit is powered from the internal battery. The Navigator 2.0 met criteria C.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated RF IEC 61000-4-3 80 MHz to 2.7 GHz 80 MHz to 2.7 GHz 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	3 V/m 3 V/m 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 3 V/m 80 MHz to 2.7 GHz 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	Recommended separation distance d = $1.2\sqrt{p}$ d = $1.2\sqrt{p}$ 80 MHz to 800 MHz d = $2.3\sqrt{p}$ 800 MHz to 2.7 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of the equipment marked with the following symbol: 

Guideline Notes
Note 1 - At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Assessment of the Electromagnetic Environment
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Navigator Control Unit and Probes are used exceeds the applicable RF compliance level above, the Navigator Control Unit and Probes should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Navigator Control Unit and Probes.
Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

4 Control Unit, Battery, and Cable

4.1 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 rear 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 on the display, as well as an audible pitch that correlates to the intensity of the measured gamma photons.
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 radioactive sire), and secondarily by the setting of the controls on the control unit.

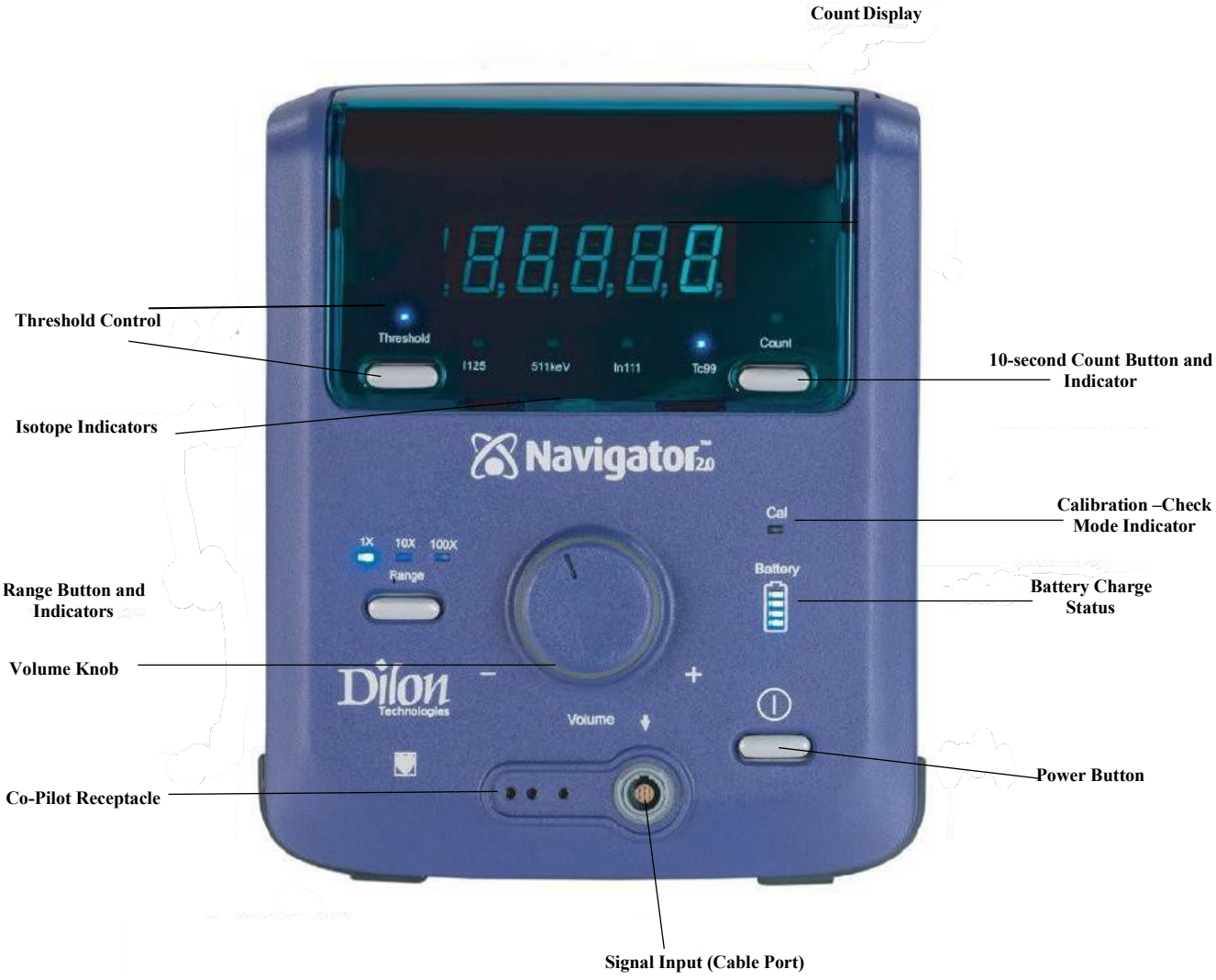
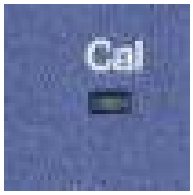
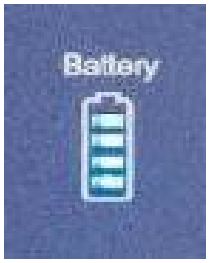


Table 4A-1. Controls and Displays on the Front of the Control Unit

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 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. When the Threshold is off, the indicator is not illuminated, and all photon energy, including scattered photons, is detected. For ***Wireless Probes only***: The Threshold functionality is not applicable for the Wireless Probes.

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 show the counts per second.
	**Cal-check:** This light indicates when the system is in 'Calibration-Check' mode on the rear of the unit. The light will be illuminated when in any of the 3 calibration-check settings and will not be illuminated when the system is set to the 'Scan' mode. The ***SCAN / Calibrate Control must be set to the SCAN position only, for all probes for all procedures. In this mode, the 'Cal' light will be turned off***. See Section 11B. Verification of Standard Gain (Calibration Quick Test) for more information on Calibration.
	The **Battery indicator on the Control Unit** 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 with a fully charged battery. Please note that the charge status on the control unit may differ from charge status reflected on the battery.
	**Signal input port**, for cable connection. For all cabled probes, connect the probe cable matching the arrow on the cable connector to the arrow above the signal input port. See "6mm Diameter Cable" for more information . The signal input port is **not** applicable when using the Wireless Pilot Probe with the Navigator 2.0.
	Connection port for the optional **Co-Pilot** accessory.

4.2 Control Unit Features: Rear

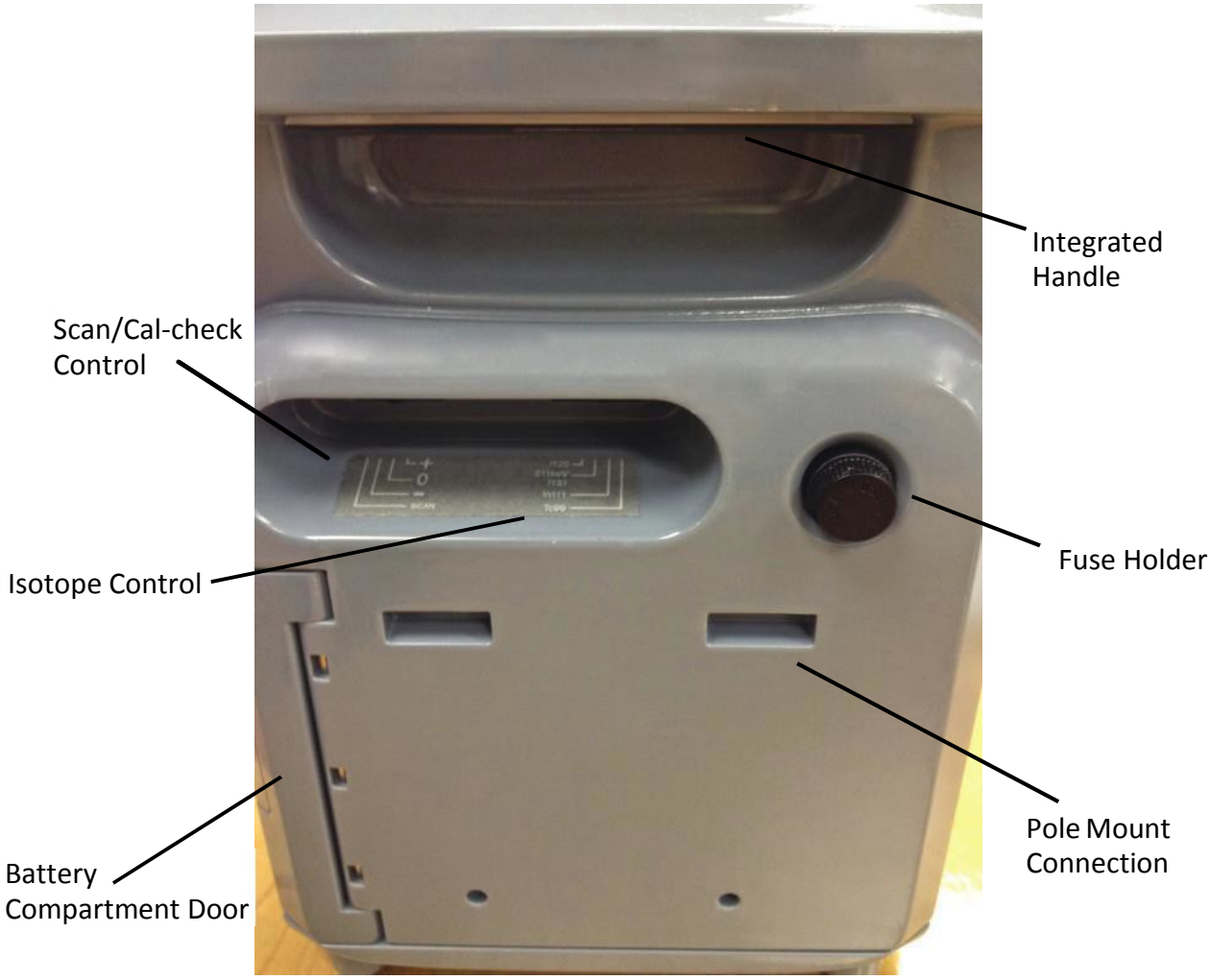
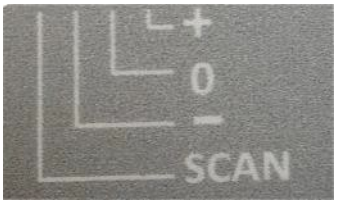
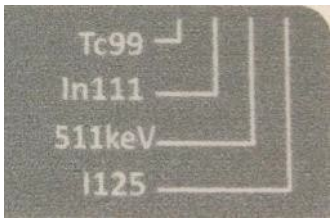


Table 4A-2. Controls and Displays on the Rear of the Control Unit

Control Display	Description
	*The SCAN/Calibrate Control has four positions.* The control unit should be set to SCAN when is normal use. 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, contact Dilon Customer Service or the local distributor for additional information.
	Allows the user to designate the specific isotope in use • I125 – Iodine-125 • 511keV – ^{18}F-FDG *(and I131)* • In111 – Indium 111 • Tc99 - *Technetium-99m* The Isotope Control setting on the rear of the control unit illuminates the corresponding light on the Isotope Indicator on the front of the control unit

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

CAUTION: The isotope control must be set to the isotope in use. Setting the isotope control incorrectly will result in incorrect counts displayed.

4.3 Battery (Part # N2-8500-02)

4.3.1 Inserting the Battery into the Control Unit

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

3. Close the battery door. The door will “click” when closed properly.

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

4.3.2 Removing the Battery from the Control Unit

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

4.4 Installing the Wireless Pilot Probe Battery

1. Hold the Wireless Pilot Probe firmly while turning the battery cap counterclockwise until the cap is removed.

2. Inspect O- ring on the cap. If O-ring is missing or damaged, do not use the Battery Cap. Contact Dilon Technologies or your distributor for a new cap, if required.
3. Remove the Wireless Battery Holder (Part # WP-9050-00) from the probe.

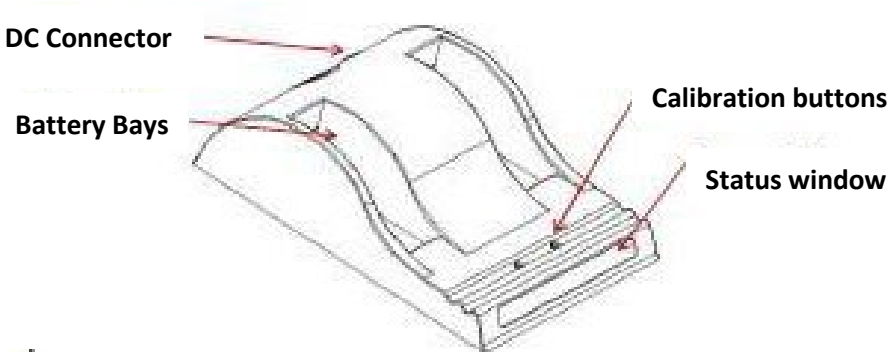
4. Install 3V CR 2 battery (Part # WP-8500-01) into the Wireless Battery Holder with positive (+) end of the battery aligned with the (+) as shown on the label.
5. Insert Wireless Battery Holder into probe with battery aligned with the serial number of the probe. Lightly turn until battery holder lowers into place.

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

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

4.5 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 only the cable provided.
All of the LEDs will flash momentarily to indicate that power is present.



Place the battery into either battery bay, ensuring that the 5-way connector is fully seated. The LEDs in the battery status window will provide charge status, and the charger will automatically begin charging. Each charge bay operates independently, providing simultaneous charge of each battery inserted. It takes approximately 3.5 hours to fully charge a discharged battery.

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

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.

4.6 Table 4B-4. Charge Bay LED Indications

Indication	Battery Charge Status
Green Flashing	Battery Charging
Green Solid	Battery Fully Charged
Blue Flashing or Solid	Not Used.
Red Flashing	Battery fuel gauge in need of calibration
Red Solid	Error. Refer to troubleshooting guide.

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

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

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

4.7 Flexible Probe Cable (Part # GP-4001-00)

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

CAUTION 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.

4.8 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. For ***Wireless Pilot Probe*** only. The Threshold feature is integrated into the probe. The Control Unit setting will not affect the wireless probe functionality.
Range	The Range function defaults to 1X. When Range is set to 1X, the audible signal fluctuates according to every event detected. The 10X position will fluctuate the audible signal every 10th event. The 100X position will fluctuate the audible signal every 100th event. **NOTE**: The Range control only affects the sound. The count shown in the display is independent of the range setting.
10-Second Count	Press to obtain a 10-second count, keeping probe in fixed position each time. The total is displayed for four seconds.
Volume	Adjust to desired volume.
Power	Press to turn on the control unit or to safely turn off the device.

5 Probe Connectivity and Use

5.1 Navigator 2.0 with Wireless Pilot Probe

14 mm Wireless Pilot Probe:	WP-9000-14 (Angled) WP-9000-14S (Straight)

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:

5A-1. Before Surgery

- Insert a charged battery into the Navigator Control Unit.
- Insert a new battery (Dilon Part # WP-8500-01) into the Wireless Pilot Probe. Refer to Section 4.4- Installing the Wireless Pilot Probe Battery:.

  Note: If Wireless Pilot Probe was sterilized, skip this step. Replacing the Wireless Pilot Probe battery may render the probe non- sterile.

  - Upon initial insertion of new Wireless Pilot Probe battery, lightly shake the Wireless Pilot Probe to activate. The LED on the Wireless Pilot Probe will illuminate when the probe is on and connected to a Control Unit.

  Note: Use of multiple Wireless Pilot Probe in close proximity may cause the Navigator

*Control Unit to connect with the Wireless Probe activated but **not in use**. If multiple Wireless Pilot Probes are present, ensure the Wireless Pilot Probe not in use is not activated.*

Table 5A-1. Pilot Probe LED Indicator

Indication	Status
On/Flashing	Probe is linked and ready for use.
On/Dim	Battery is low.
Off	Probe is in a resting position to conserve power when the Control Unit is off; to reactivate LED indicator, turn on the Control Unit and lightly shake probe. If no power upon ready to use, the battery needs to be installed or replaced.

NOTE: If battery has been replaced and LED light is still off, contact your distributor or Dilon Technologies directly.

5A-2. During Surgery

- See '*Useful Adjustments that can be made During Procedures*'.

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

Table 5A-2. Navigator 2.0 with Wireless Pilot Probe – Settings & Indicators

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

5A-3. After Surgery

- Refer to Section 7: "Probe and Cable Cleaning"

5.2 Navigator 2.0 with Cabled Probes

Standard Lymphatic Mapping Probe:	*SP-2A14-67* (Angled)
	*SP-2S14-67 (*Straight)
Superficial Head & Neck Probe:	*SP-2S11-53 (*Straight)
Daniel Lung Probe:	*SP-2S10-31D*
Laparoscopic Probe:	*SP-2S10-31* (310 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 is as follows:

5B-1. Before Surgery

- Refer to Section 7: “Probe and Cable Cleaning”
- Insert a fully charged battery into control unit.
- Connect the cabled probe and Flexible Probe Cable (Part # GP-4001-00) to Navigator Control Unit.

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

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

Table 5B-1. Navigator 2.0 with Standard Lymphatic Mapping Probes, Superficial Head & Neck Probe, Daniel Lung Probe, and Laparoscopic Probes - Settings and Indicators

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

5B-2. During Surgery

- See '*Useful Adjustments that can be made During Procedures*'.

5B-3. After Surgery

- Refer to Section 7: "Probe and Cable Cleaning"

6 Control Unit Cleaning

The Navigator Control Unit may be cleaned prior and after use. Before cleaning, inspect the control unit for signs of visual damage. If a damage is noticed, discontinue use and contact Dilon Technologies for service. The following wipes may be used to clean the control unit. Follow the manufacturer's Instructions for Use.

- Sani-Cloth ® Prime Germicidal Disposable Wipes
- Super Sani-Cloth® Germicidal Disposable Wipes
- Sani-Cloth® AF3 Germicidal Disposable Wipes
- Sani-Cloth® Plus Germicidal Disposable Wipes
- CaviWipes TM
- CaviWipes1TM

Note: If residue is observed, use a dry cloth to remove. Never submerge the Navigator Control Unit.

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

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

7 Probe and Cable Cleaning

GENERAL WARNINGS:
Failure to obey to these safety instructions may cause permanent damage to the systems and/or lead to inadequate cleaning and sterilization.

WARNING: Do not drop the Navigator probe. The reusable Navigator probe is a delicate surgical instrument. Mechanical shock can result in permanent damage to the probe.
WARNING: Follow universal, generally accepted practices when handling components that have come in contact with blood or tissue.
WARNING: The Probes and cables must be cleaned and sterilized only by qualified personnel.
WARNING: Do not clean or sterilize when the cap of the wireless probe is missing or not completely tightened. Attempting to do so will cause permanent damage to the probe.
WARNING: Do not scratch or abrade the probe when cleaning or sterilizing. Scratching / abrading the probe surface will damage the probe.
WARNING: Failure to properly clean the device prior to sterilization may lead to inadequate sterilization.
WARNING: Do not use unapproved methods of cleaning or sterilization. Use of cleaning or sterilization methods not listed in the Instructions for Use may cause permanent damage.
WARNING: The handling and storing of clean and sterile probes and cables should be conducted per your facility's guidelines.
WARNING: Do not immerse probe and cable in fluids, or place in an automated cleaning system as it may cause permanent damage to the probe and cable.

7.1 PREPARATION STEPS:

Preparation of probes and cables	**WARNING:** To avoid permanent damage of the Navigator Control Unit, do not sterilize the Navigator Control Unit or immerse it in fluids. **WARNING:** To avoid permanent damage of the probes and cables, prior to cleaning and sterilization, always inspect them for cracks, wear or other damages. **WARNING:** To avoid permanent damage to the wireless probe, do not clean with the battery cap open or not securely tightened. PREPARATION STEPS: Ensure the following for wireless probes, wired probes, and cables: 1. The probes are free of any damage. 2. The cables are free of cracks or cuts. 3. The connectors of the probe and cable are completely dry. 4. The cable is detached from the probe and the Navigator Control Unit. 5. (If available) The top gun collimator is removed from the probe. For wireless probe only: 1. Prior to each sterilization or use, insert a new CR-2 battery, part number WP-8500-00. 2. Ensure the cap is securely tightened to the Wireless Pilot Probe. The O-ring on the cap should not be visible.

Cleaning	Equipment: Enzymatic detergent
	Instructions: 1. Prepare enzymatic cleaner, suitable for surgical instruments, according to the manufacturer's recommendation. 2. Rinse the outside surfaces of the probe with a brisk stream of lukewarm tap water (98°F to 105°F / 36.5°C to 40.5°C). Wipe with soft cloth or sponge soaked in enzymatic cleaner. Repeat separately for collimator cleaning, if used. 3. Visually inspect device(s) for contaminated areas. 4. Repeat steps 1 & 2 until visual inspection reveals instrument(s) is clean. 5. 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. 6. Air-dry or dry with clean towel.

7.2 Sterilization of Navigator Gamma Probes

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

CDC Publication: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 Update May: 2019
Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

ISO 17664: 2017 Processing of health care products

Joint Commission Standards Related to Disinfection and Sterilization

Following are instructions for sterilization after following preparation and cleaning as indicated in Section 7:

Following are instructions for sterilization	Equipment: **Wireless probe, wired probe, and cable:** • STERRAD® NX - Standard Cycle • STERRAD® 100NX - Standard Cycle • STERRAD® 100S - Short Cycle • Steris V-PRO® 1 Plus - Non-Lumen Cycle • Steris V-PRO® maX - Non-Lumen Cycle • Steris V-PRO® 60 - Non-Lumen Cycle • Steris V-PRO® maX - Flexible Cycle • Steris System 1E® (US use only) • Steris System 1® (International use Only) • Steris System 1® Express (International use Only) • Steris System 1® Plus (International use Only) • STERIZONE® VP4 Sterilizer - Cycle 1 **Additional methods for wireless probe and wired probe (not for use on cable):** • Steris V-PRO® 1 - Standard Cycle • Steris V-PRO® 1 Plus – Lumen Cycle • Steris V-PRO® maX – Lumen Cycle • Steris V-PRO® 60 – Lumen Cycle **WARNING:** To avoid permanent damage of the cable, do not process the cable in the V-PRO 1 Standard Cycle or the VPRO-1 Plus, VPRO maX, or V-PRO 60 Lumen Cycles because the cable contains polyurethane. Instructions: 1. Please refer to the manufacturer's instructions to properly conduct the sterilization procedure. The probe cable can be loosely coiled and then placed together with the probe. 2. After the sterilization procedure is completed, handle and store the probes and cables per your facility's guidelines in packaging and

	storing sterile products. 3. The wireless probe with battery inside has a two-week shelf life of storage and no use after sterilization **WARNING:** Do not exceed the two-week shelf life after sterilization for a wireless probe with battery inside. A wireless probe with a shelf life longer than two weeks may not function properly due to a drained battery. If the probe has a shelf life of storage that is longer than two weeks, replace the battery and re-sterilize the probe.

7.3 Navigator Gamma Probes Used in Non-Critical Environments:

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

Navigator Gamma Probes Used in Non-Critical Environments such as to preform pre-operative scans should first be processed using the cleaning and preparation instructions identified in Section 7: “Probe and Cable Cleaning” before and after each procedure.

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

High-Level Disinfection

Following preparation and cleaning as indicated in Section 7.1:

High-level disinfection	Equipment: High-level disinfection OPA Instructions: 1. Please refer to the manufacturer’s instructions to properly prepare the sterilization mixture. 2. Immerse both the probe and cable in the solution for at least 12 minutes at 68°F or more to destroy all pathogenic microorganisms. 3. Rinse the outside surfaces of the probe with a brisk stream of lukewarm tap water (98°F to 105°F / 36.5°C to 40.5°C) for 1 minute. Rinse twice more. Air-dry or wipe with soft cloth. Do not exceed 60°C. 4. Air-dry or wipe with soft cloth. Rinse the probe connector with isopropyl or ethyl alcohol than air-dry. Make sure both cable ends are properly dried before storing them. The cable can take up to 24 hours before being completely dry. 5. The wireless probe with battery inside has a two-week shelf life of storage and no use after sterilization **WARNING:** To avoid health hazards, follow the instructions of the disinfectant manufacturer

NOTE: The instructions provided above have been validated by the medical device manufacturer as being capable of preparing the Navigator probe for re-use. It remains the responsibility of the facility to ensure that the probes and cables have been properly cleaned and sterilized. This requires validation and routine monitoring of the process. Any deviation by the facility from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

8 Specifications

8.1 Navigator 2.0 System Specifications

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

Table 8A-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
Industry Standard Wireless Operating Frequency	2.4 GHz.
Fuse – Control Unit	UL/CSA (198G) standards; 0.80 amp. Glass housing. 250 volt rating. 5x20m. (REF: SC-0099-00) IEC 127 standards: Type 7. 0.80 amp, 250 volts. 5x20m T0.63AL250V.
Sound Indicators	Pitch variations - Frequency proportional to event rate. Upon completion of 10-second count, device emits double-beep sound.
Visual Indicators	**Control Unit:** • Digital count – Vacuum fluorescent display • Single count – LED • Calibration-check - LED • 10-second count – LED • Battery energy level – LED • Range 1X/10X/100X – LED • Isotope – LED (four) **Battery:** • Battery state-of-charge – 4 LED's **Wireless Pilot Probe**: • Probe connection – LED
Energy Range	0 - 650 keV

Item	Description
Operating Conditions	Temperature: -15°C to 40°C (5°F to 104°F) Relative Humidity: 0%-80% relative humidity, non-condensing Atmospheric Pressure: 80 kPa to 106 kPa
Storage	Temperature: -15°C to 40°C (5°F to 104°F) Relative Humidity: 5%-95%, non-condensing relative humidity Atmospheric Pressure: 50 kPa to 106 kPa
Maximum Count Rate	99,999/s
Color of Housing	Purple
Control Unit Dimensions	20cm W x 24cm H x 12cm D
Control Unit Weight w/Battery	2.0kg

9 Accessories

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

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

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

Table 9A-1. Navigator 2.0 System Accessories

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

Cabled Probe Cover (10/BX)	SP-9004-DRC

10 Troubleshooting

The Navigator Control Unit, Probes, and Cables contain no user serviceable parts. Dilon offers Wireless Pilot Probe Battery Holders, Wireless Pilot Probe Batteries, and Navigator Control Unit Batteries and Fuses for sale for use with the Navigator System.
Contact your local representative or Dilon Technologies for additional assistance if more detail is required.

Table 10A-1. Navigator Control Unit - Settings and Indicators

Problem	Possible Causes	Remedies
1. Display is dark; No power to unit.	Power switch is off; Switch is broken. Unit may be damaged.	Turn power on; Contact Dilon Technologies for assistance.
	Battery is completely discharged.	Recharge battery or replace with new battery.
	Fuse is blown or missing.	Replace fuse.
	Damaged PCB (board) in control unit	Contact Dilon Technologies for assistance.
2. Incomplete digits in display.	Display, or display driver, is damaged. Unit may be damaged.	Contact Dilon Technologies for assistance.

Table 10A-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 rear of control unit) to appropriate setting for radiopharmaceutical in use.
	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.

Problem	Possible Causes	Remedies
	Probe is damaged / probe cap not secure.	Try a different probe or contact Dilon Technologies for assistance.
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.
3. Spurious counts, when probe not located adjacent to radio-pharmaceutical	Radiopharmaceutical may be present on probe.	Clean probe with Radiacwash or equivalent. Refer to Manufacturer's cleaning instructions.

Table 10A-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 rear of control unit) to appropriate setting for radiopharmaceutical in use..
	There is an open circuit in the probe cable.	Replace cable.
	Circuit inside the control unit has been damaged.	Try a different control unit. 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.
3. Spurious counts, when probe ***not*** located adjacent to radiopharmaceutical	Radiopharmaceutical may be present on probe.	Clean probe with Radiacwash or equivalent. Refer to Manufacturer's cleaning instructions.

11 Maintenance

11.1 Overview

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

1. Prior to each use, check each system component for any visible signs of damage or wear. This includes checking the following components and features:

Table 11A-1. Component Check

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

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

***CAUTION**:* Do not use damaged equipment.

3. Check each battery for function and charge before use. Discontinue use if abnormalities are observed.
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.

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

CAUTION: Modifications will void the warranty

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 SP2S10-31), 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, entitled "Running a Peak Procedure".*

11.2 Navigator Control Unit Fuse Replacement

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

***CAUTION**: Use of an unapproved replacement fuse may alter the performance of the Navigator Control Unit.*

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

1. Locate the fuse holder on the rear of the Navigator Control Unit.
2. Push-in and twist the fuse holder cap counterclockwise.

3. Remove the fuse from the fuse holder and discard.

4. Insert a new fuse (Part # SC-0099-00) into the holder.
5. Press-in and twist the fuse holder cap clockwise to lock in place

12 Repair

Serviceable parts for the Wireless Pilot Probes include a replaceable battery, battery holder, and end cap. The Wireless Pilot Probe contains no additional user serviceable parts.
The Cabled Probe contains no user serviceable parts. Damage to a probe may result if a probe is opened by the user and will void any remaining warranty, if attempted.
Serviceable parts on the Navigator 2.0 control unit include a fuse and a replaceable battery. The control unit contains no additional user serviceable parts and should not be opened by the user.
Please contact Dilon Technologies for service or to purchase user replaceable items. An authorization number is required for return to Dilon for service.

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

CAUTION: *If a system, or system components, are to be shipped from your institution for repair, then please clean and disinfect the components as described in this manual before packing for shipment**. Dilon Technologies require that the Navigator Service Sheet be attached to the outside of the shipping box, certifying that the items have been cleaned and disinfected to manufacturer's specifications. This form can be found on the Dilon Technologies website (www.Dilon.com) or by contacting your distributor or Dilon Technologies directly.***

13 Disposal

Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.
WEEE Directive 2012/19/EU - Do not dispose of WEEE products in general waste. At the end of life of the product, contact Dilon Technologies for return instructions.
Ensure the cleaning of the device and/or accessories prior to shipment.

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 orworkmanship.
This Limited Warranty does not apply to any product or replacement part or replacement product which has been subjected to any damage as a result of an accident or abuse, or that has not been used and maintained in accordance with the information contained in the literature accompanying the product, or that has been modified, repaired or serviced by any person or company other than Dilon or its authorized representative.
Dilon's sole liability for any defective product shall be repaired or replaced as set forth above. Dilon shall not be liable to anyone, under any circumstances, for any special, punitive, incidental or consequential 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.