Addendum to Navigator GPS™ System User and Service Manual
Wireless Upgrade

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EC REP

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User Manual

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USER MANUAL

1. Introduction

Description

This addendum to the *Navigator GPS™ System User/Service Manual (PN GP-9200-96EN)* details how to use the *Wireless Upgrade* option for existing Navigator Gamma Positioning Systems. This optional feature adds wireless gamma probe capability to Navigator GPS Control Units (PN-GP 2800-00).

Use this addendum as a supplement to the Navigator GPS™ System User/Service Manual. If this manual is not readily available, download the electronic version from www.Dilon.com.

The wireless receiver, when paired with the control unit, can only be used with the Wireless Pilot Probe™.

The system is supplied non-sterile. This addendum includes guidelines for the use of the Wireless Pilot Probe and accessories within the sterile field.

Intended Use

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

Indications for Use

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

Manufacture and Distribution

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

Trademarks

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

Navigator GPS® is a registered trademark of Dilon Technologies.

Regulatory and Safety Requirements

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

EC Directives

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

Reciprocal Interference

The Wireless Upgrade components were designed, manufactured, and tested in accordance to the following standards recognized for Medical Devices under Directive 93/42/EEC: 1993. This product has been certified and tested by 3rd party testing facilities.

- 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: General requirements For Safety 1: Collateral Standard: Safety Requirements For Medical Electrical Systems – IEC 60601-1: 2nd & 3rd Ed.
- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – IEC 60601-1-2: 3rd Ed.
- Medical Electrical Equipment - Part 1-6: General Requirements For Safety - Collateral Standard: Usability - IEC 60601-1-6: 3rd Ed.
- Information supplied by the manufacturer of medical devices- EN 1041:2008
- Symbols for use in the labeling of medical devices - EN 980 :2008
- CAN/CSA C22.2 No. 60601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety & Essential Performance; issued 2008-02-01 Ed. 2
- AS/NZS 3200-1-0, Deviations to IEC 601-1 for Application in Australia and New Zealand

CE 0459

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

Table 1. Explanation of Symbols

	Attention, consult accompanying documents
Rx only	RX only Caution: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.
	Probe
In111 Tc99 I131 I125	Isotope Control
40° C -15° C	Acceptable shipping/storage conditions: -15° C to 40° C
SN	Serial number
LOT	Lot #, or batch code

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

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

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

2. Product Overview and Components

Table 2A-1. Probe Dimensions

Probe	Tip Diameter	Tip Angle	Length	Weight
Wireless Pilot Probe	14mm	35°	260mm	255g

Table 2A-2. Receiver Dimensions

Receiver	Height	Depth	Weight
Wireless Pilot Probe Receiver	25mm	68 mm	15g

3. Precautions

3A. General

The output of this system is not to be considered a diagnostic measure of the extent of disease in the patient, nor the recommended source of therapy.

- Failure to thoroughly review and adhere to the information contained in this addendum and the Navigator GPS System User/Service Manual may pose a potential hazard to the patient and/or user and may void the warranty.

3B. Wireless Pilot Probe, Wireless Receiver and Navigator GPS Control Unit

- Replace the wireless probe battery with a new battery on EACH day of use, before the first surgical procedure.
- This system is not designed for use in an explosive atmosphere.
- Keep the control unit off while connecting the wireless receiver.
- The probes, probe batteries, receiver and control unit are sold non-sterile.
- No components should be sterilized.
- DO NOT put any probe in an autoclave.
- With the exception of the Wireless Pilot Probe's battery bay, DO NOT attempt to open probes.
    - All probes are tested and sealed at the factory. Attempting to open the probe may cause damage and will void the warranty.
- DO NOT drop the probe.
- DO NOT strike the probe tip against a hard surface; the detector element may become damaged and no longer be able to measure radiation.
    - This will also void the warranty.

4. Wireless Receiver

4A. Isotope Control

The wireless receiver allows the user to adjust the system's isotope setting, specific to the isotope in use. When the wireless receiver is connected to the control unit, and the control unit is turned on, the isotope control will automatically default to the Tc99 setting.

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

Table 4A-1. Isotopes

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

The Wireless Receiver and Navigator GPS Control Unit must both be set to the same isotope setting.

For Navigator GPS units built after 2006, the isotope control setting on the back of the device will illuminate the corresponding light on the control unit's isotope indicator.

For earlier Navigator GPS systems that lack the isotope indicator (built between 1999 and 2006), check the back of the control unit to ensure that the isotope setting switch matches the isotope specified on the receiver.

Table 4A-2. Controls and Displays on the Front of the Wireless Receiver

Control Display	Description
	Power LED: Indicates that the signal between receiver and Pilot Probe is connected. It will flash during receiving transmission from the probe
	Isotope Indicators: Select the isotope to be detected by the control unit. Be sure to select the same isotope on the back of the Control Unit as well. See "Isotope Control" section of Navigator GPS System User/ Service Manual for more information.

5. Cleaning, Disinfection, and Sterile Use of the wireless Pilot Probe

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

- **Before Use**, visually inspect probe to ensure that it is free of contamination
- **During Use**, place probe in a sterile drape
- **After Use**, Clean/Disinfect/Store Probe
- ***OPTIONAL***: Radioactive Decontamination Procedure –(see section 5B)

5A. Wireless Pilot Probe only

The Wireless Pilot Probe and all other Dilon probes and accessories are sold non-sterile.

WARNING! Before cleaning, inspect probe to ensure its integrity. Compromised probes can be further damaged as a result of the cleaning process. Probes in poor condition due to wear and fatigue should be returned to Dilon Technologies for repair.

Table 5A-1. Cleaning

Preparation for cleaning:	Remove battery from Wireless Pilot Probe, and secure battery cap to the bottom of probe before cleaning.
Cleaning Equipment:	Enzymatic detergent, OPA high-level disinfectant, running water
Cleaning Method:	1. Rinse the outside surfaces of the probe with a brisk stream of lukewarm tap water (98°F to 105°F / 36.5°C to 40.5°C). Prepare enzymatic cleaner, suitable for surgical instruments, according to the manufacturer's recommendation. 2. Swirl the proximal end of the probe in enzymatic cleaner for a minimum of 10 seconds. Thoroughly scrub the plastic end-cap with a toothbrush-style, latex-free nylon bristle cleaning brush (i.e. Key Surgical N-3000, or a similar brush). 3. Lightly scrub the probe and lens with a latex-free nylon bristle cleaning brush. Repeat separately for collimator cleaning, if used. 4. Wipe the entire probe with soft cloth or sponge soaked in enzymatic cleaner. 5. Visually inspect device(s) for contaminated areas. 6. Repeat steps 2 through 5 until visual inspection reveals instrument(s) is clean. 7. 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. 8. Prepare OPA high-level disinfectant solution according to manufacturer's instructions. 9. Immerse probe completely for a minimum of 12 minutes at 68°F (20°C) or higher, to destroy all pathogenic microorganisms. Note that probes that are compromised can be damaged if detergent seeps into them. 10. Rinse with a brisk stream of tap water (98°F to 105°F / 36.5°C to 40.5°C) for approximately 1 minute. Repeat rinse two additional times.
Drying:	Air-dry or dry with clean towel.

CAUTION:
Do not contaminate other items by wiping them with used cleaning solution.

CAUTION:
The cleaning instructions provided above have been validated by the medical device manufacturer, for preparing this device for re-use. It remains the responsibility of the re-processor to ensure that the reprocessing is actually performed using qualified equipment, materials, and personnel in the processing facility, to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

5B. Radioactive Decontamination Procedure – OPTIONAL

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

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

5C. Cleaning/Storing Wireless Receiver

1. If unclean, wipe wireless receiver with a soft cloth moistened with mild soap and water. Dry with a soft cloth.
2. Store the receiver in a clean, safe environment.

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

6. Probe Connectivity and Use

Navigator GPS System with Wireless Upgrade

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

6-1. Before Surgery

- Insert a fully charged PowerPak (battery) into the Navigator GPS control unit (see Navigator GPS System User/Service Manual for insertion instructions).
- Attach the wireless receiver to the cable port on the front of the control unit. Note that the isotope indicator will default to Tc 99 when turned on. An LED will illuminate on the receiver once the control unit is on.

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

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

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

4. Hold probe firm; push battery cap into probe and turn clockwise until O-ring is no longer visible.
    - Upon initial insertion of new Wireless Pilot Probe battery, probe may need to be lightly shaken to activate LED in probe base.
    - LED on the Pilot Probe indicates that it is linked with control unit and ready for use. When placed in a resting position, the LED turns off within seconds, to save energy. When the Pilot Probe is moved, it instantly powers up for immediate use.
    - For intraoperative use, insert the Pilot Probe into a sterile drape.

Table 6-1. Wireless Receiver - LED Power Indicator

Indication	Status
On/Flashing	Wireless receiver and Wireless Pilot Probe are linked and ready for use.
Off	The GPS system is off, or there may be a connection error between the receiver and the control unit.

Table 6-2. Wireless Pilot Probe LED Indicator

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

6-2. *During Surgery*

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

Table 6-3. Navigator GPS with Wireless Pilot Probe - Settings and Indicators w/ Tc 99 Example

Control/Indicator	Setting
Controls (back of Control Unit)	
SCAN/Calibrate	SCAN
Isotope	Tc 99
Indicators (front of the Control Unit)	
Range	1x
Threshold	Illuminated; this control is for ***CABLED PROBES*** *only*. The Wireless Pilot Probe features integrated threshold, which controls the count range of photon energy detected by the probe.
Display	0
Isotope	Tc 99
Probe LED Indicator (bottom of the Pilot Probe handle)	
Probe LED	Illuminated/Flashing
Wireless Receiver	
Receiver LED	Illuminated/Flashing
Isotope	Tc 99

6-3. After Surgery

- See: ‘Cleaning, Disinfection, and Sterile Use of Probe’ (Section 5).

SERVICE MANUAL

7. Troubleshooting

With the exception of the Wireless Pilot Probe's battery holder, there are no serviceable components within the Wireless Pilot Probe body, or wireless receiver. Contact your representative or Dilon Technologies for additional assistance if more detail is required.

Table 7-1. Navigator GPS 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 connection between probe, receiver and control unit.	Check that the connection between the receiver and control unit is secure.
	No connection between probe, receiver and control unit.	Replace the probe battery
	Isotope control indicates incorrect isotope.	Change isotope control (on front of wireless receiver) to desired isotope.
	Circuit inside the control unit has been damaged.	Try a different control unit. Contact Dilon Technologies for assistance.
	Probe is damaged.	Try a different probe, or contact Dilon Technologies for assistance.
	Wireless receiver is damaged.	Try a different receiver, or contact Dilon Technologies for assistance.
2. LED on wireless receiver does not illuminate when power is on.	No connection between wireless receiver and control unit.	Check that the wireless receiver is securely connected to the control unit.
	LED on wireless receiver is damaged.	Contact Dilon Technologies for assistance.
3. Isotope control on wireless receiver does not illuminate when power is on.	No connection between wireless receiver and control unit.	Check that the connection between the wireless receiver and control unit is secure.
	LED on wireless receiver is damaged.	Contact Dilon Technologies for assistance.
4. LED on Pilot Probe does not light as indicated	LED on probe is damaged.	Contact Dilon Technologies for assistance.
	Probe LED is illuminated but not transmitting signal to unit (LED flashes when transmitting)	Gently shake probe to activate connectivity.
	Probe battery is dead.	Replace with new battery.
	Battery was not installed.	Install new battery.

8. Specifications

The Wireless Upgrade consists of the wireless receiver, Wireless Pilot Probe, and probe batteries.

Table 8A-1. Wireless Upgrade Specifications

Item	Description
Wireless Pilot Probe Power Source	Replaceable, Internal battery
Battery	Single use CR2; 3 V Lithium; capacity 1550 mAh
Wireless Pilot Probe Transmission Distance	Up to 9 meters
Industry Standard Wireless Operating Frequency	2.4 GHz
Visual Indicators	Wireless Receiver: • Power On – LED • Isotope – LED (four) Wireless Pilot Probe: • Probe Connection – LED • Isotope – LED (four)
Storage Conditions	Operating Temperature Range: 15°C to 40°C (5°F to 104°F) Humidity: 0%-80% relative humidity Atmospheric Pressure: 50 kPa to 106 kPa

9. Support Items

The Wireless Upgrade is typically supplied as a complete system (Part # WP-9220-00). Support items may be purchased from the local Dilon Technologies Navigator representative. At time of publication of this addendum, the primary support items have the following part numbers. Feel free to contact your local representative for additional information.

9A. Product Part Numbers

Table 9A-1. Product Part Numbers

Item	Dilon Part Number
Wireless Receiver for Navigator GPS	WP-8000-01
Wireless Pilot Probe	WP-9000-14
Wireless Pilot Probe Batteries (Pack of 10)	WP-8500-01
Wireless Pilot Probe Battery End Cap	WP-2000-10
Wireless Pilot Probe Battery Holder	WP-9050-00
Optional Top Gun Collimator	SP-1800-00

9B. Sterile Drape

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

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

10. Maintenance

10A. Component Check

While Wireless Upgrade is virtually maintenance-free, a check of each system component for any visible signs of abuse, neglect, or wear, should be conducted before each use and storage. This includes checking the following:

Table 10A-1. Component Check

Component	Feature
Wireless Pilot Probe	Overall check - Also probe bay, battery cap and O-ring
Wireless Receiver	Overall check - Housing, integrity of its electrical connector and the connector pins

Do not use a damaged probe, wireless receiver, or probe batteries. *Should abnormalities be discovered, contact Dilon Technologies directly.*

11. Repair

The Wireless Pilot Probe is sealed at the factory. No user serviceable parts are inside the probes. Damage to a probe may result if a probe is opened by the user and will void any remaining warranty, if attempted.

Please contact Dilon Technologies for additional service. An RMA number is required upon return 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 plastic bags or film or other protective wrapping..

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

12. Limited Warranty

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

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

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

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

Dilon's sole liability for any defective product shall be repaired or replaced as set forth above. Dilon shall not be liable to anyone, under any circumstances, for any special, punitive, incidental or consequential 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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