



# Model 2059 Gamma Detection Probe for Laparoscopic and Thoracoscopic Applications

## Operation Manual



78NL  
UL2601 - 1  
CAN/CSA - C22.2 601.1  
Medical Electric Equipment

With respect to electrical  
shock, fire and mechanical  
hazards only

Manufacturer:  
Neoprobe Corporation  
425 Metro Place North, Suite 300  
Dublin, OH 43017-1367  
614-793-7500 800-793-0079  
fax: 614-793-7531

Authorized Representative:  
AR-MED, Ltd.  
Runnymede Malthouse  
Egham TW20 9BD, United Kingdom  
Tel: + 44 (0) 1784 708216  
Fax: + 44 (0) 1784 708103

**R<sub>x</sub> ONLY**

00-0280 Rev F

May 2002

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ENGLISH

# 1 Overview

## Model 2059 Gamma Detection Probe for Laparoscopic and Thoracoscopic Applications

### Purpose

This manual describes how to operate the Model 2100 **neo2000**<sup>®</sup> Gamma Detection System (**neo2000**), with the Model 2059 Gamma Detection Probe for Laparoscopic and Thoracoscopic Applications.

### Intended Use

The **neo2000** is an electronic device intended to detect and quantify gamma radiation.

### Indications

The **neo2000** is indicated for external, intraoperative, laparoscopic or thoracoscopic detection of radioactivity in body tissues or organs where radiopharmaceuticals are administered.

### Contraindications

The device is not rated for direct contact with cardiac tissue.

### Users

This manual is intended for physicians and operating room staff who must use the **neo2000** and ensure that it is functioning properly.

### Scope

This manual provides supplementary information for the **neo2000** Gamma System Operation Manual (Neoprobe document DOC 0780) for users of the Model 2059 Gamma Detection Probe. It does not provide detailed system repair and technical documentation; it does not discuss how to perform surgery and procedures related to nuclear medicine.

## 2 System Configuration



### **Trocar compatibility**

The Model 2059 Gamma Detection Probe is compatible with 11mm or 12mm trocars. Consult instructions for trocar selected.

### **Sterile sheath**

The Model 2059 Gamma Detection Probe may be placed in a commercially available Sterile Laparoscopic Transducer Cover, Cat. #610-658 (CIVCO Medical Instruments, 1-800-445-6741). The Model 2059 Gamma Detection Probe with CIVCO Laparoscopic Transducer Cover should be used with 12mm sized trocars.

## 3 Warnings, Cautions and Notes



### Overview



These Warnings, Cautions and Notes supplement the Warnings, Cautions, and Notes in the **neo2000**® Operation Manual for users of the Model 2059 Gamma Detection Probe.

### Warnings

- The use of the Model 2059 Gamma Detection Probe should only be attempted where there is adequate visualization and close accessibility of the target tissue.
- The Model 2059 Gamma Detection Probe should only be used with the “Type BF” Model 2100 **neo2000** console. The Model 2000 **neo2000** is rated “Type B” in accordance with EN60601-1 and may increase the risk of patient injury if other devices that come in contact with the patient fail.
- Do not use an electrocautery or other electro-surgical device in the patient when the Model 2059 Gamma Detection Probe is in the patient. Doing so may

increase the risk of patient injury if the electro-surgical devices contact the gamma detection probe.

- The reusable gamma detection probe is a delicate surgical instrument. **DO NOT DROP.**
- Only properly trained and qualified personnel should use the system.
- The gamma detection probe cannot be autoclaved or e-beam gamma sterilized. Use only recommended cleaning and sterilization methods.







### Cautions

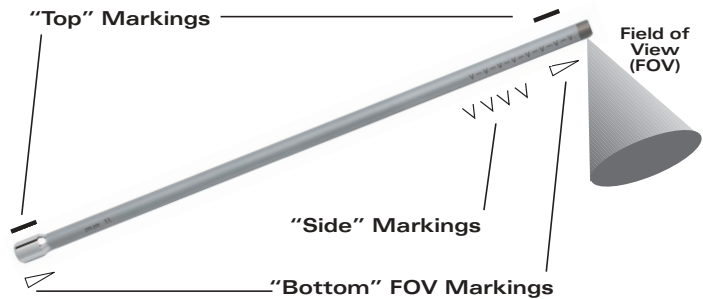
- The system components should not touch other electrical equipment during use.
- Use of this device in the vicinity of X-ray producing devices may cause false counts.
- Electrocautery and other electro-surgical devices may interfere with the operation of the **neo2000**. If interference is observed when operating the **neo2000** in the presence of these devices, the

user is advised not to operate these devices while the **neo2000** is in operation. If this can not be done, move these devices away from the **neo2000** to mitigate the effects of the electromagnetic interference.

- Always make sure probe connector pins and contacts are dry before use. Wet contacts may cause erroneous readings or operation.
- Use of this device in the vicinity of persons undergoing radiation therapy may cause false counts.

# 3.1 Symbols & Markings

	Type BF
	Caution: consult accompanying documents
	Consult instructions for use
	Temperature limitations
	Relative Humidity
	Atmospheric Pressure

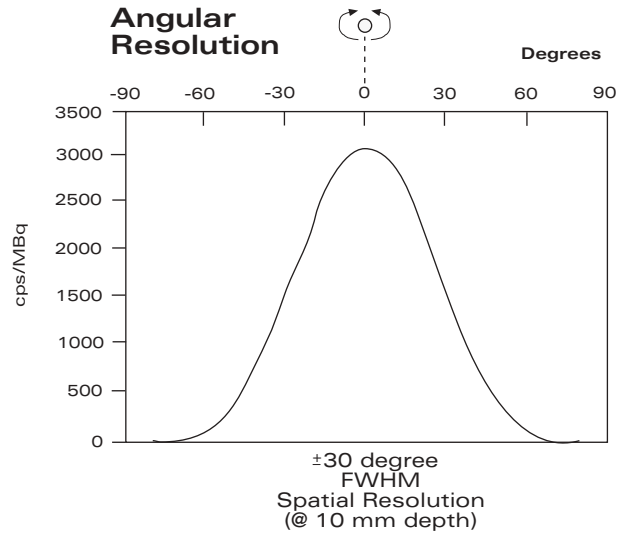
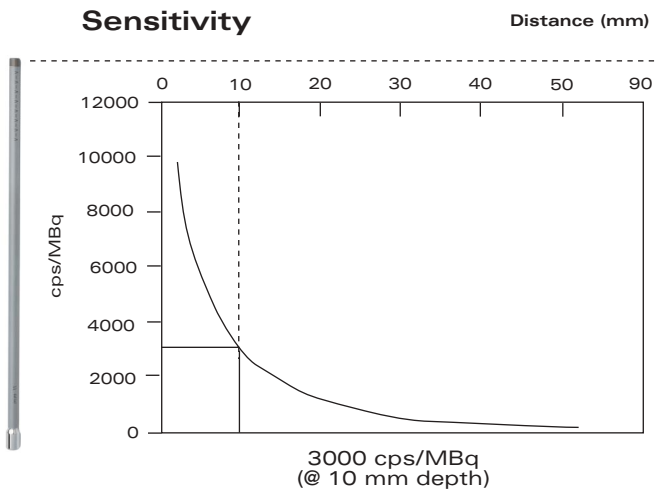


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## 4 Probe Specifications

Parameter	Specifications
Crystal	Cadmium Zinc Telluride, CdZnTe
Energy Range	27-364 keV
Detector Efficiency	> 90% <sup>125</sup> I, > 76% <sup>99m</sup> Tc, > 60% <sup>111</sup> In
Weight (including 3m Cable)	240 grams
Side/Rear Shielding	> 99.99% <sup>125</sup> I, > 99.5% <sup>99m</sup> Tc, > 90% <sup>111</sup> In
Operating Temperature Range	15° to 40° C (59° to 104° F)
Storage/Transit temperature	-20° to 60° C (-4° to 140° F)
Storage/Transit humidity	10 to 95%
Storage/Transit atmospheric pressure	500 hPa to 1060 hPa (7.3 psia to 15.4 psia)

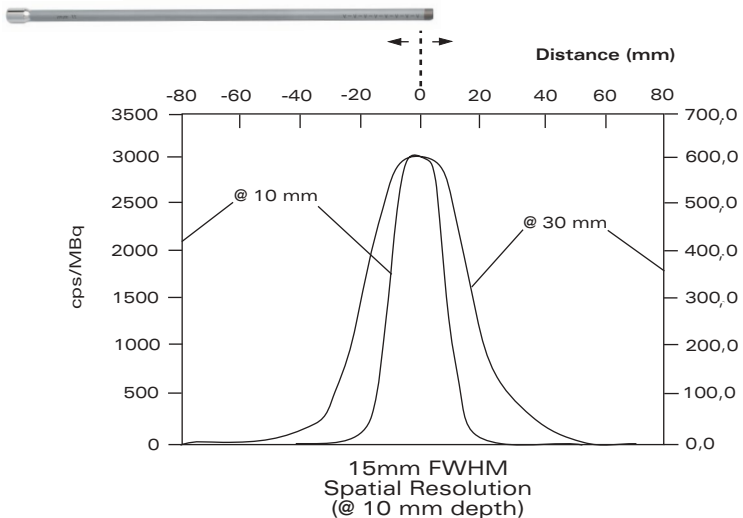
# 5 Performance Characteristics



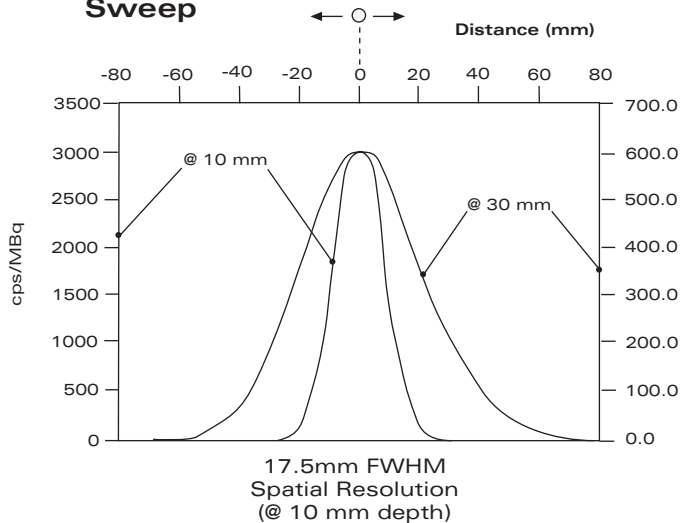
# 5 Performance Characteristics

## Spacial Resolution

### Thrust



### Sweep



## 6 Cleaning & Decontamination



### Overview

This section gives procedures for cleaning and inspecting the Model 2059 Gamma Detection Probe and the Model 2060 Detector Probe Cable. Refer to the **neo2000**<sup>®</sup> Operation Manual (DOC0780) for cleaning instructions for the **neo2000** console.



**Warning:** Adherence to universal precautions should be exercised when handling any device components that have been in contact with blood or blood components. All device components which were used in the operating field during laparoscopic, thoracoscopic or intraoperative applications must be cleaned prior to reuse or storage in Accessory Case, Model 2061.

If a high count is detected with the instrument in the absence of a radioactive source, then the detector probe and cable should be cleaned with a radioactive

decontamination solution. See section 4.3 of the **neo2000** Operation Manual for the recommended radioactive decontamination procedure.

Biohazard and radioactive decontamination procedures must be performed in accordance with your Institution's procedures for exposure and disposal of biohazard and radioactive waste.



**Warning:** Do not soak the detector probe or cable in liquids. Attempting to do so may cause permanent damage to the detector probe or cable. A soft brush should be used during cleaning procedures to avoid abrasion of the probe surfaces.



**Warning:** The reusable detector probe is a delicate surgical instrument. **DO NOT DROP.** Mechanical shock can result in irreparable damage.

## 6 Cleaning & Decontamination (Continued)

The following table lists cleaning and rinsing procedures.

Step	Procedure
1	Immediately after use disconnect the detector probe and cable from the <b>neo2000</b> . DO NOT disconnect the probe cable from the probe.
2	Wipe all visible soil from the detector probe and cable with a clean sponge moistened with distilled water.
3	Wipe the detector probe and cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration).
4	With the cable still attached to the detector probe, the outside surfaces should be rinsed with a brisk stream of tap water and wiped with a soft cloth soaked in an enzymatic detergent solution suitable for surgical instruments.
5	The outside surfaces should be brushed with a soft brush and enzymatic detergent and rinsed with a brisk stream of tap water for approximately 30 seconds.
6	Visually inspect the detector probe and cable for contaminated areas. Repeat steps 6-8 until no contaminated areas are visible.
7	Detach the probe cable from the probe.
8	The connector ends of the detector probe and probe cable should be swirled intermittently in 100 milliliters of enzymatic detergent solution for at least one minute but no more than two minutes. DO NOT SOAK.
9	Rinse these components in a brisk stream of tap water for approximately 30 seconds and dry them with a soft cloth.

## 7 Sterilization



This section describes how to sterilize the Model 2059 Gamma Detection Probe and the Model 2060 Detector Probe Cable.

### Sterilization Procedure

Ethylene oxide (EtO or EO gas)	YES
STERIS® SYSTEM I (liquid)	NO
STERRAD®	NO
E-Beam	NO
Autoclave	NO
Steam Flash	NO
PLAZLYTE®	NO
Gamma	NO



### General Warnings

- The Model 2059 Gamma Detection Probe and the Model 2060 Detector Probe Cable should only be sterilized by the ethylene oxide (EtO) method.
  - **DO NOT STEAM AUTOCLAVE, STERRAD, PLAZLYTE OR STERIS 1 STERILIZE.** These sterilization methods have not been validated.
  - Do not use gamma sterilization, which causes the probe to fail/degrade.
- Prior to EtO sterilization, the Model 2059 Gamma Detection Probe and Model 2060 Detector Probe Cable should be inspected to ensure:
- They are clean.
  - The cables are free of cracks or cuts.
  - The connectors are completely dry.
  - The probe is not attached to the cable.

The Model 2060 Detector Probe Cable should be loosely coiled and then placed together with the detector probe and a chemical indicator in a 76 cm x 76 cm (30" x 30") CSR wrapper or sterilization pouch. Sequentially wrap using the envelope method and secure the closure with a piece of ethylene oxide chemical indicator tape and label.

An SAL of  $10^{-6}$  was achieved in a hospital recommended cycle for 10% ethylene oxide following the AAMI (TIR 12-1994) protocol. The following table lists the recommended EtO sterilization cycle parameters for sterilization of the Model 2059 Gamma Detection Probe and Model 2060 Detector Probe Cable.

## 7 Sterilization (Continued)

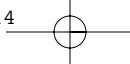
<b>EtO Process Phase</b>	<b>Parameter</b>	<b>Value</b>
Conditioning (in chamber)	Temperature	48.9 - 54.4 degrees C (120 - 130° F)
	Vacuum	610 - 660 mm (24 - 26 inches Hg)
	Humidity	40 - 80% RH
	Dwell	30 - 45 minutes
Sterilization	Temperature	48.9 - 54.4 degrees C (120 - 130° F)
	Pressure	690 - 827 hPa gauge (10 - 12 PSIG)
	Humidity	40 - 80% RH
	Sterilant Gas	10% EtO / 90% HCFC
	EtO Gas Concentration	600 +/- 30 mg/liter
	Dwell (exposure to gas)	120 minutes
Post Exposure Evacuation	Vacuum	610 - 660 mm Hg (24 - 26 inches Hg), Performed 2 times
Aeration	Time/Temperature	≥ 1 hour at 43.3 - 54.4 degrees C (110 - 130° F)

## 8 Warranty

Product Warranty: New equipment manufactured by Company is warranted against defects in workmanship and materials for a period of one year from the date of shipment by Company to buyer, subject to the limitations hereinafter set forth. Should any defects be found and reported during that period, Company, at its option, will repair or replace such defective equipment provided that Buyer ship the product containing the defect to Company, transportation charges prepaid, with notice of the defect and representation that the equipment has been properly installed, maintained, and operated within the limits or rated a normal usage. The repaired or replacement equipment will be shipped C.I.P. from the Company's plant. The terms of this product warranty do not extend to any product or part thereof which, under normal usage, has an expected useful life of less than one year.

This warranty shall not apply to any equipment where the installation, calibration or servicing of such equipment is improper, or where equipment is operated above rated load capability, or subjected to accident, tampering, alteration, or abuse. **THE COMPANY'S LIABILITY UNDER THIS WARRANTY OR ANY OTHER WARRANTY WHETHER EXPRESS OR IMPLIED IN LAW OR FACT SHALL BE LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE MATERIAL AND WORKMANSHIP, AND IN NO EVENT SHALL THE COMPANY BE LIABLE FOR CONSEQUENTIAL OR INDIRECT DAMAGES.**

THIS WARRANTY CONTAINS THE ENTIRE OBLIGATION OF NEOPROBE CORPORATION AND NO OTHER WARRANTIES INCLUDING, WITHOUT LIMITATION, WARRANTIES EXPRESSED, IMPLIED, OR STATUORY ARE GIVEN.



## 9 Contact Information

Manufactured by:  
Neoprobe Corporation  
425 Metro Place North, Suite 300  
Dublin, OH 43017-1367  
614-793-7500 800-793-0079  
Fax: 614-793-7520



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