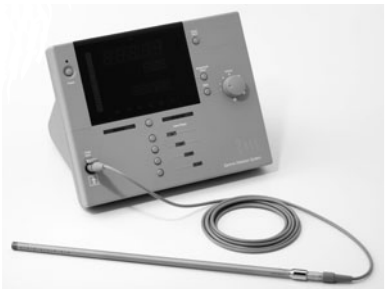
neoprobe

neo2000®

Manual

neo2000® Gamma Detection System

Operation Manual (Model 2100)



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CLASSIFIED C UL US
78NL
UL2601 - 1
CAN/CSA - C22.2 601.1
Medical Electric Equipment

With respect to electrical shock, fire and mechanical hazards only

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℞ ONLY

DOC0780 Rev C
English

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1 Introduction

Overview

Purpose
This manual describes how to operate the **neo2000**® Gamma Detection System (**neo2000**), which includes a control unit or console and a family of probes for detecting gamma radiation.

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

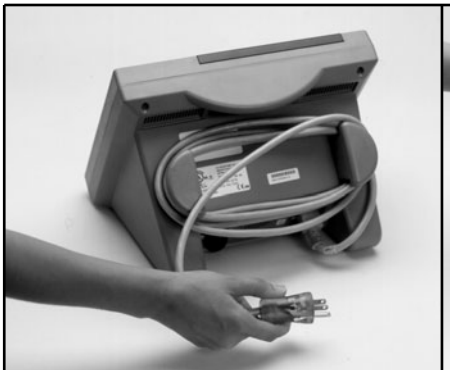
Indications
The **neo2000** is indicated for external and intraoperative detection of radioactivity in body tissues or organs, where radiopharmaceuticals are administered.

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 gives operating instructions for the **neo2000** as well as routine maintenance, safety, and troubleshooting instructions. It does not provide detailed system repair and technical documentation; it does not discuss how to perform surgery and procedures related to nuclear medicine.

In this chapter
The rest of this chapter covers the following:

1 Introduction



1. Plug in power cord.

2. Push power button.

3. Plug in probe cable.

1.1 System Warnings, Cautions and Notes

Overview
Read this section before operating the **neo2000®**. Included below are operational warnings, cautions and notes for safe operation of the **neo2000**.

Definitions
Warning: Specific information provided to the user to advise of situations where the misuse or unlabeled use of the device could present potential harm to the user or patient and/or could result in irreparable damage to the device or property.

Caution: specific information provided to the user to prevent the misuse of the device which may cause it to malfunction or produce erroneous readings.

Note: general information provided to the user to further explain or clarify the proper operation of the device and/or its accessories.

Warnings
- The reusable detector probe is a delicate surgical instrument. **DO NOT DROP**. Mechanical shock can result in irreparable damage.
- Only properly trained and qualified personnel should use the system.
- There are no user serviceable parts in the **neo2000** - **DO NOT OPEN**.
- The system is not to be used in the presence of flammable anesthetics or other explosive gases.
- The **neo2000** should only be cleaned after the power cord is disconnected from the console and the power outlet.
- Do not sterilize or immerse the console as permanent damage may result.
- Only Neoprobe approved accessory equipment shall be used with this device. Use of this device with unauthorized accessories may void the warranty with the user assuming all liabilities.
- When using Model 1017 14mm probes with the **neo2000** console, only use probes with serial numbers 1498600 or higher (gain-trimmed). Model 1017 14mm probes with serial numbers less than 1498600 (not gain-trimmed) are designed and can be used with the Neoprobe 1500 console, but are not recommended for use with the **neo2000** console.
- Do not use Model 1002 19mm probes with the **neo2000** console. The Model 1002 19mm probe is designed for use with the Neoprobe 1500 console, but is not compatible with the **neo2000**.
- No component, part, or accessory can be autoclaved. Use only recommended cleaning and sterilization methods (see Chapter 4).
- No component, part, or accessory can be gamma sterilized.
- Do not sterilize the disposable handle (Model 2025); discard after single use.

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 electrosurgical devices may interfere with the operation of the **neo2000**. If interference is observed 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.
- If the **neo2000** does not operate at all when the power is turned on, the user should check the user-accessible fuses on the back panel. The fuses should only be checked with the power cord disconnected from the **neo2000** console.
- Use of this device in the vicinity of persons undergoing radiation therapy may cause false counts.
- The **neo2000** has a radionuclide selection indicator for ^{18}F, which has a photo peak energy of 511 keV. The ^{18}F function is for future product development. For information on availability contact Neoprobe.
- Always make sure probe connector pins and contacts are dry before use. Wet contacts may cause erroneous readings or operation.

Notes
- Regarding Year 2000 compliance, the **neo2000** Gamma Detection System does not use a Real Time Clock, and subsequently will not be adversely affected by Year 2000.
- Inspect Model 2025 disposable handles and Model 2024 reusable cable for cracks or cuts before use; do not use if the cable or handle is damaged. If a cable is cut during surgery, it should be replaced immediately.
- Assure that reusable BlueTip™ probes (Models 2001,2002 or 2003) are securely attached to the disposable handle (Model 2025), and that reusable probes (Model 1017) are securely attached to the reusable cable (Model 2024) before use.
- The system generates no hazardous radiation but is designed to detect various radioactive materials. When using radioactive materials, use safe and proper handling techniques. See your institution's Radiation Safety Officer about Nuclear Regulation Commission and other requirements.
- When the reusable probe, (Model 1017) is used with the **neo2000** control unit, it is recommended that the probe always be placed in commercially available sterile surgical drape barriers [as noted on page 4.3-3].

- **Call Neoprobe Corporation immediately at 800-793-0079 or 614-793-7500 to report any incident or injury that occurred during use of the neo2000.**

1.2 Definitions

Overview
This section defines symbols and key terms used in this manual. Words in **bold** are defined in this section.

Count rate
A continuous counting rate of gamma radiation measured in counts per second (cps) and updated every half-second. Count rate is shown on the same line of the console display as **target count** and **target check** when these functions are not activated.

Background count
In Binary Pitch mode: baseline value measured in counts per second (cps) that is stored by the system for comparison with the **target count** to determine if the difference in radioactivity between background tissue and target tissue is statistically significant. In Dynamic Pitch mode: a baseline value measured in cps that is stored by the system, and is used as the threshold at which the sound is activated.

Compton scattering
Radioactive "noise" at an energy level lower than the photopeak of the injected radiopharmaceutical.

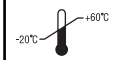
Dynamic pitch range
An operator-selected audible and counting range of radioactivity. If the **count rate** falls within the selected range, a variable-pitch sound is produced which is proportional to the level of gamma radiation present. Areas of tissue that generate higher pitch are associated with higher levels of radioactivity.

Ratio
A value indicating how likely it is that target tissue has been found (**target count** divided by **background count**).

Target check
A quick check of the level of radioactivity measured in counts per second detected by a probe held stationary for 2 seconds over target tissue; more accurate than **count rate**. The target check function does not display a ratio calculation.

Target count
A number indicating the level of radioactivity detected by a probe as measured held stationary for 6 seconds over target tissue; more accurate than **target check.** The target count activates and displays ratio calculation.

1.2 Definitions (Continued)

Symbol	Definition
	In the U.S.A., Caution: Federal Law restricts this device to sale by or on the order of a physician.
	Use by
	Do not reuse
	Storage and Transit Temperature
	Storage and Transit Pressure
	Type BF
	Underwriters Laboratory (UL) recognized component
	Sterile using Ethylene Oxide
	CE Mark, Class I
	CE Mark, Class II, Class I STERILE

Symbol	Definition
	Neoprobe Corporation logo
	UL Classified device
	Date of manufacture
	Storage and Transit Humidity
SN	Serial Number
REF	Catalog Number
LOT	Batch Code
	Caution: consult accompanying documents
	Consult instructions for use

For additional information on graphic symbols refer to section 1.3

1.2 Definitions (Continued)

Symbol	Definition
	Standby (push-push) (power on: connection to mains; power off: disconnection from mains)
	Alternating current
	Equipotentiality
IPX4	Splash-proof equipment
	Not for use in the presence of flammable anesthetics

For additional information on graphic symbols refer to section 1.3

1.3 System Functions and Features

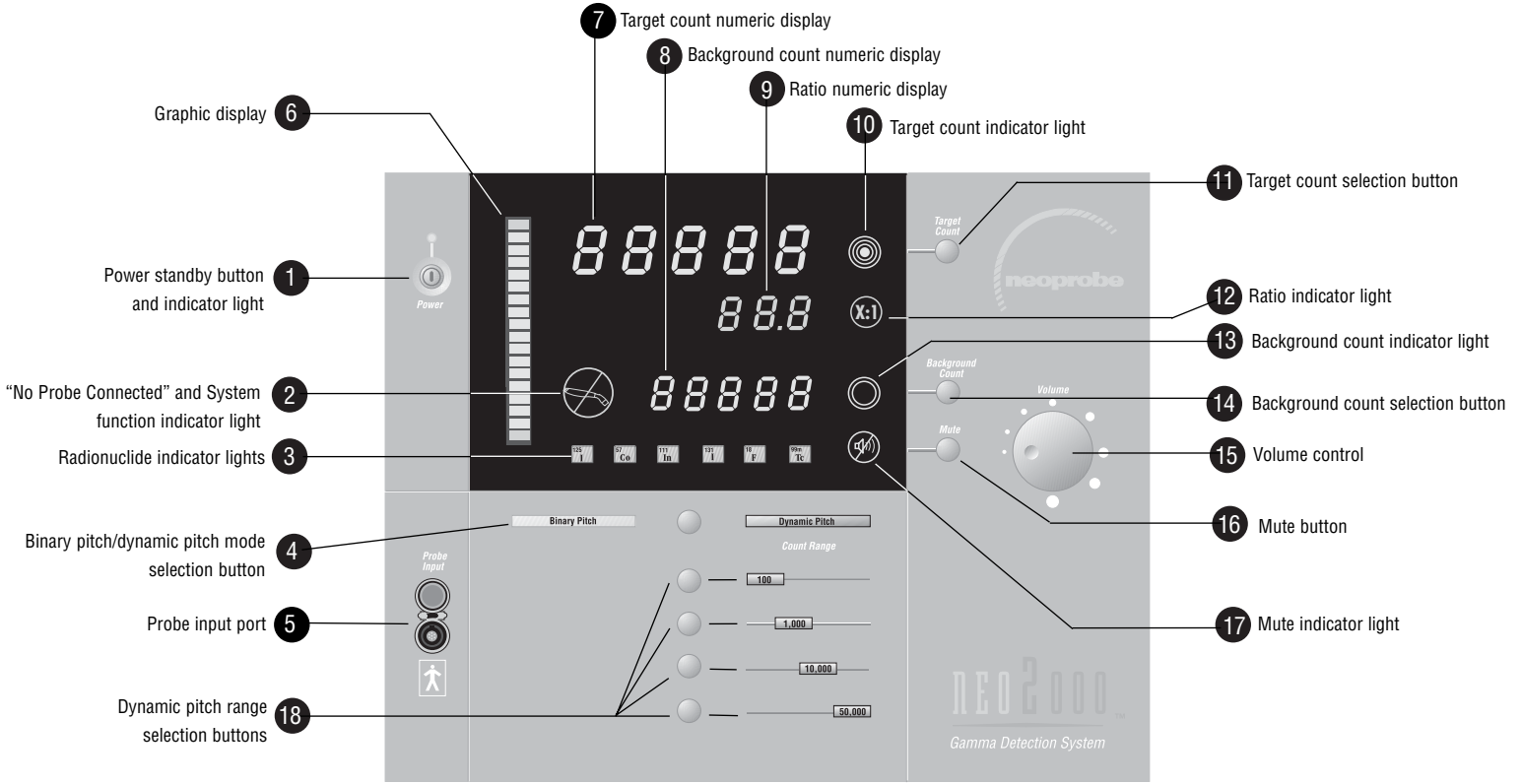


Figure 1 **neo2000®** console front panel

1.3 System Functions and Features (Continued)

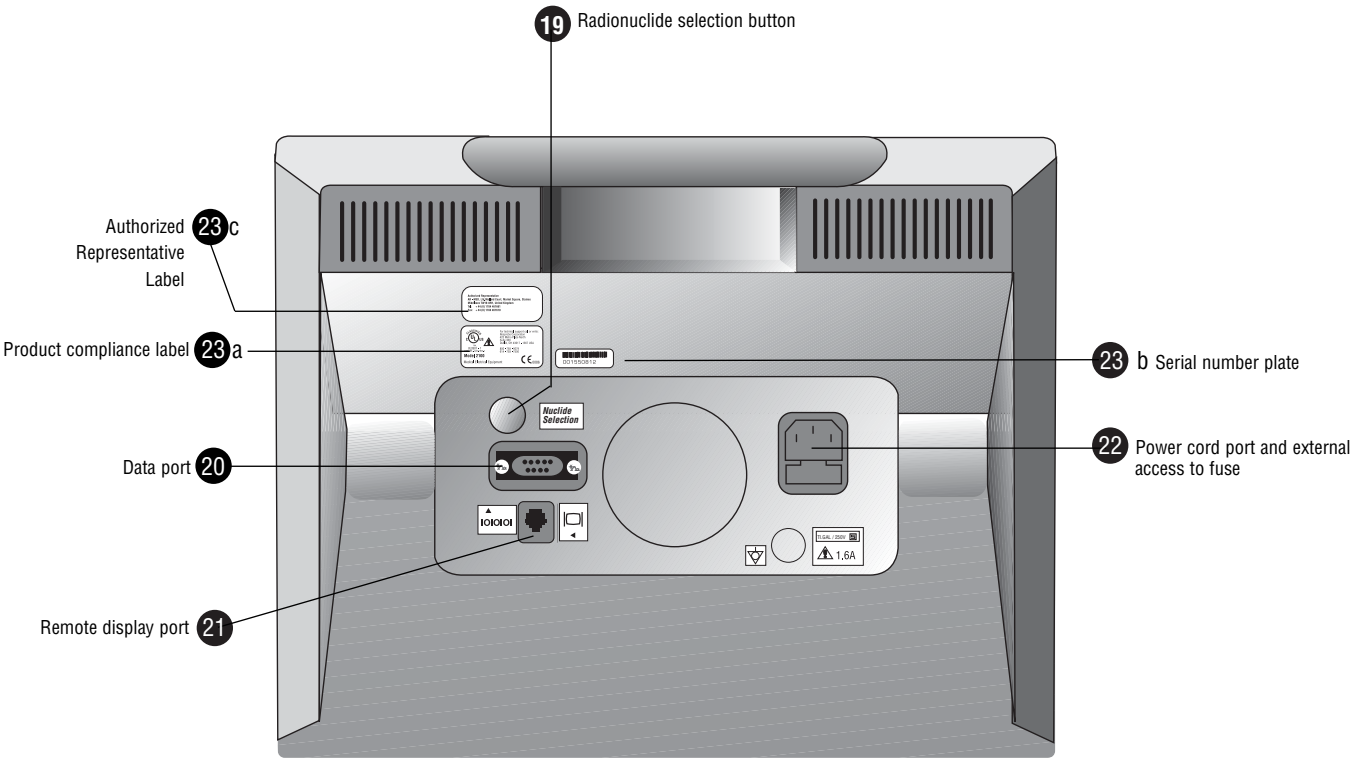


Figure 2 **neo2000®** console back panel

1.3 System Functions and Features (Continued)

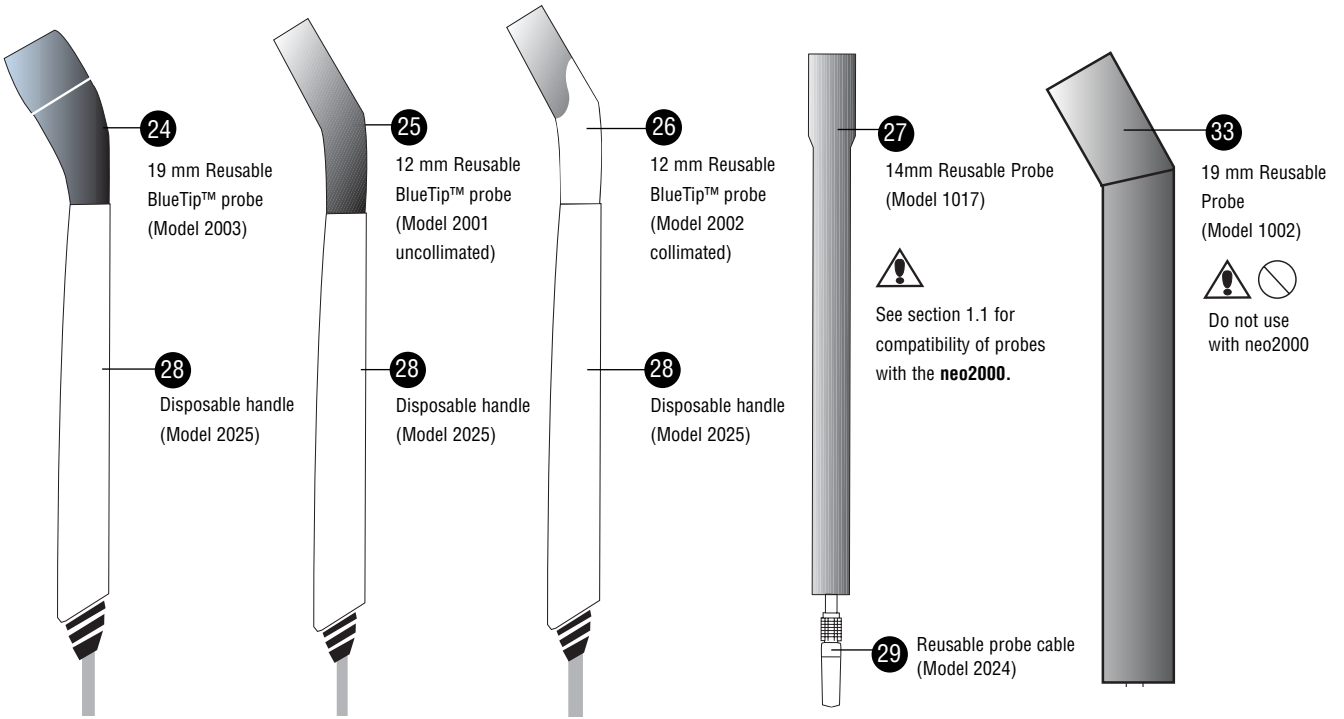


Figure 3

Cable connections

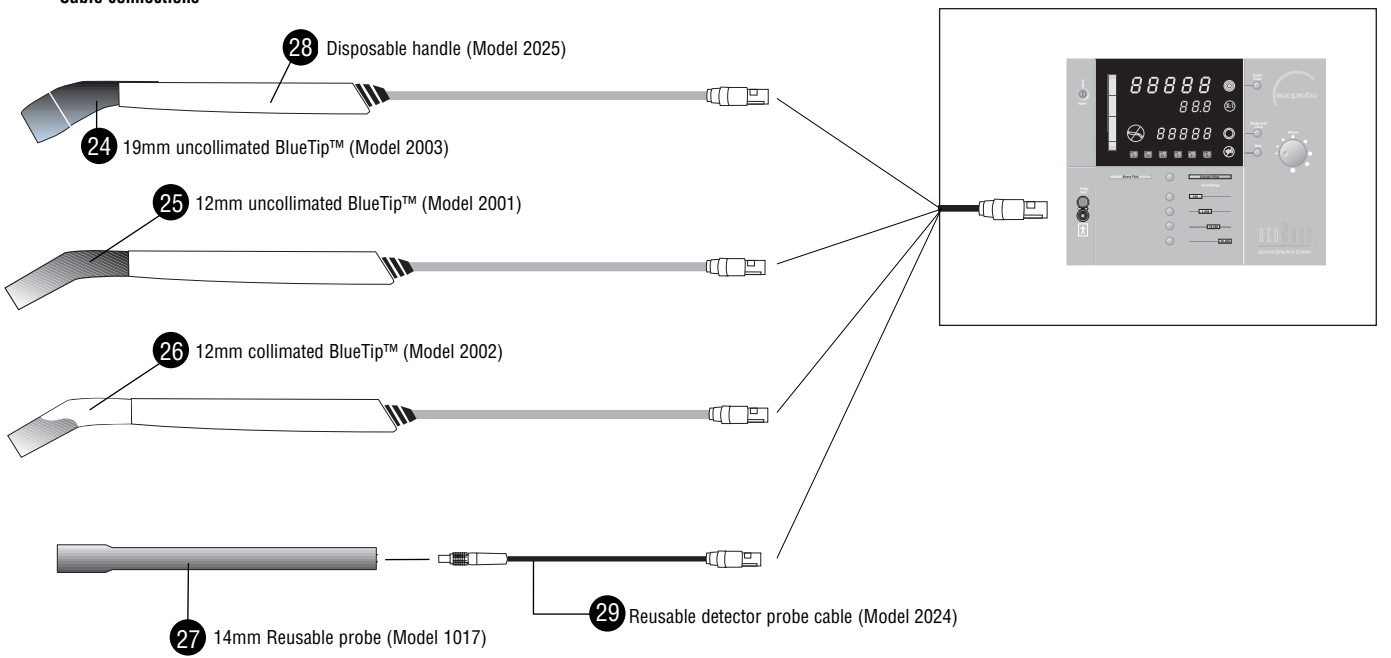


Figure 4. Alternate System Configurations

1.3 System Functions and Features (Continued)

Features

1 Power standby button and indicator light. Press and release to turn console on; press and release again to place in standby. Light is on when power is active.

2 "No Probe Connected" and system function indicator light. Lights up when no probe is attached or there is a problem with the console.

3 Radionuclide indicator lights. Lights up to indicate radionuclide selected.

4 Binary pitch/dynamic pitch mode selection button. Press and release to toggle between modes (binary pitch/dynamic pitch). Corresponding indicator lights up.

5 Probe input port. Attachment point on console for probe cables.

1.3 System Functions and Features (Continued)

6 Graphic display. Accumulates light bars starting from bottom as data is collected or time elapses during a count. Displays count rate in dynamic pitch mode.

7 Target count numeric display. Shows the radioactivity count detected by the probe either while scanning (count rate) or after taking a target count or target check.

8 Background count numeric display.
Shows default values or actual values of radioactivity counts detected after taking a background count.

9 Ratio numeric display. Lights up to show ratio calculated

10 Target count indicator light. Flashes when target count or target check is calculated and displayed.

11 Target count selection button. In Binary Pitch mode press and release to take a target check; press, hold, and release to take a target count. In Dynamic Pitch mode press and release to take a target count; press, hold and release to take a 10 second count.

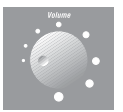
1.3 System Functions & Features (Continued)

12 Ratio indicator light. Lights up to indicate ratio is being calculated and displayed.

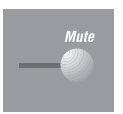
13 Background count indicator light. Flashes to indicate background count is in process.

14 Background count selection button. Press and release to take background count.

15 Volume control. Adjusts volume of system's audible signals.



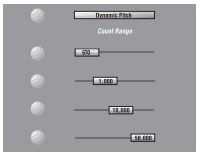
16 Mute button. Press and release to turn binary pitch alarm and dynamic pitch sound on and off.



17 Mute indicator light. Flashes to indicate mute is enabled. Remains lit continuously when mute is not enabled.

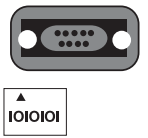
1.3 System Functions & Features (Continued)

18 Dynamic pitch range selection buttons. Press and release to select dynamic pitch range and corresponding indicator lights up.



19 Radionuclide selection button. Press and release to cycle to next radionuclide.

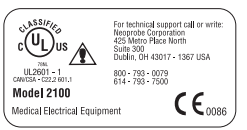
20 Data port. For use in software upgrades.



21 Remote display port. Provided for future expansion; not used on **neo2000**®.

22 Power cord port and fuse access. Attachment point on console for power cord. This receptacle also houses the user accessible fuses.

23a Product compliance label. Identifies regulatory compliance to standards and statutes.



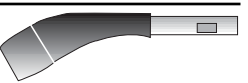
1.3 System Functions & Features (Continued)

23b Serial number plate. Identifies equipment by serial number.

23c European Union (EU) Authorized Representative Label

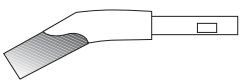
System Components

24 19 mm BlueTip™ probe (Uncollimated) Detects gamma radiation. The tip is reusable.



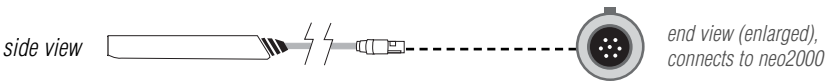
25 12 mm BlueTip™ probe (Uncollimated) Detects gamma radiation. The tip is reusable.

26 12 mm BlueTip™ probe (Collimated) Detects gamma radiation. The tip is reusable.

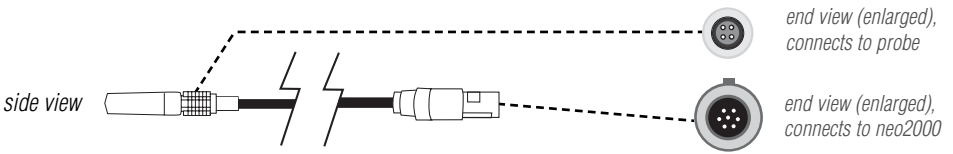


27 14 mm Reusable probe. Detects gamma radiation. The entire probe is reusable.

② **28 Disposable handle and cable.** This disposable unit includes a handle and cable for attachment to the console. The reusable BlueTip™ probes are inserted into this unit. The disposable handle is for single use only.



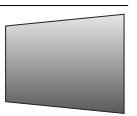
29 Reusable Detector probe cable. For use with 14 mm reusable probe. The cable is reusable.



30 14mm Detector probe collimator (snap on). For use with 14mm reusable probe. The collimator is reusable.

31 12mm BlueTip™ probe collimator. For use with 12mm uncollimated and collimated BlueTip™ probes. The collimator is reusable.

32 19mm BlueTip™ probe collimator. For use with 19mm BlueTip™ probe. The collimator is reusable.



1.4 New System Installation

Overview
This section describes how to install a **neo2000®** Gamma Detection System.

Removal from packaging
Remove the packing material carefully and save. Depending upon your precise order (check your purchase order and invoice), check for one or more of the following:

Item Description	**Model Number**
Console	2100
Manual Kit	2057
AC Power Cord, North America	2009
Probe Options	
14 mm reusable probe	1017
12 mm BlueTip™ probe (Uncollimated)	2001
12 mm BlueTip™ probe (Collimated)	2002
19 mm BlueTip™ probe (Uncollimated)	2003

1.4 New System Installation

Item Description	Model Number
Accessories	
14 mm detector probe collimator (snap-on)	1013
12 mm BlueTip™ probe collimator	2004
Accessories case	2010
19mm BlueTip probe collimator	2019
Detector probe cable	2024
Disposable handle and cable (case of 12 each)	2025

Calibration and Preventive Maintenance
The **neo2000®** is shipped set to factory specifications. Do not try to open the **neo2000** console; there is never a need for the user to calibrate or service the system. Preventive maintenance is limited to external cleaning of the **neo2000**, fuse replacement, and functional diagnostics.

1.4 New System Installation

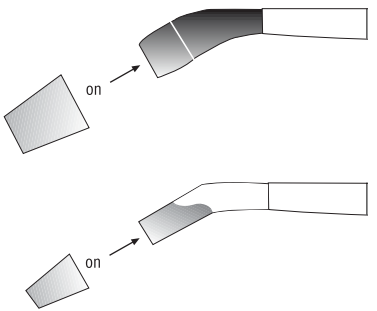
External Collimators
The gamma ray emitted by various isotopes differ in their ability to penetrate tissue. Under certain conditions the probes may require the use of an external collimator to make the probe more directional. All of the Neoprobe external collimators are designed to decrease the effective angle of probe detection, or field of view (FOV). In general, you should use an external collimator for applications where an increased sense of directionality is desired. It is the responsibility of the user to identify and determine when an external collimator meets his specific clinical requirements.

Hint: You should scan more slowly when using an external collimator.

Hint: Using an external collimator decreases the FOV and increases the spatial resolution of the probe. This makes it easier to distinguish between two radioactive sources that are close to one another.

Model 2004 and 2019 Collimators

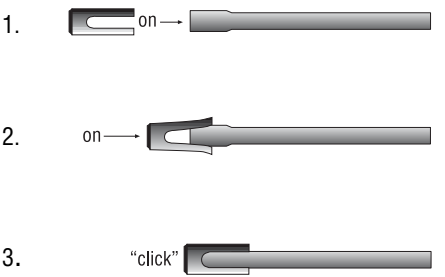
Installation
Insert the probe into the larger, open end of the collimator. Gently push these components together until the collimator is firmly seated, but do not use excessive force.



Removal
To remove the collimator, hold the probe stationary. Twist and pull the collimator off the probe. (See Chapter 4 for cleaning and sterilization instructions.)

Model 1017 Collimators

Installation
Insert the probe in between the two legs of the collimator. Push firmly to widen the legs until the collimator is fully seated on the probe.



Note: You should hear an audible click when the collimator in completely seated.

Removal
Use your thumb(s) to push up on one (or both) of the legs of the collimator. Continue pushing until the collimator is off of the probe. (See Chapter 4 for cleaning and sterilization instructions.)

2 Using the **neo2000**® in Dynamic Pitch Mode

Overview

Introduction
This chapter describes how to use the **neo2000**® Gamma Detection System in dynamic pitch mode to locate concentrated areas of radiopharmaceuticals such as may occur in lymphatic channels, lymph nodes, thyroid and similar tissues.

Operational principles
The **neo2000** detects the presence of gamma rays from gamma-emitting isotopes and distinguishes differences in the amount of gamma rays emitted from different areas of the body or an organ.

Using the **neo2000** in the dynamic pitch mode of operation, the physician can trace the flow of a radiopharmaceutical from a site of injection to other areas of concentration. The **neo2000** provides an audible signal that varies in pitch by increasing or decreasing as the level of radioactivity increases or decreases, respectively.

In this chapter
The following sections are included in this chapter:

2.1 Setting Up the System for Dynamic Pitch Mode

Overview
This section describes how to set up the system for use. Neoprobe recommends that you follow established hospital procedures to maintain a sterile environment.

How to set up the system
The table below lists the steps in setting up the system.

Step	Procedure for Reusable BlueTip™ Probes (Models 2001, 2002, 2003)
1	Plug the power cord into the console and into the wall receptacle. If needed, attach the appropriate external collimator to the probe.
2	Using aseptic technique, transfer the sterilized probe tip(s) by hand into the sterile field. **(DO NOT DROP)**
3	Remove the Model 2025 probe handle unit aseptically from sterile kit.
4	Verify that the probe tip is completely dry. Insert the probe tip into the handle and turn the probe tip clockwise 1/8 turn until it locks into place and the marks on the probe and handle align.
5	Have an assistant plug the probe cable into the probe input port on the **neo2000®** console. The **neo2000** is now ready for start-up.

Note: There are raised arrows on the cable connector and the probe input port. You should hear an audible click when you properly engage the cable.

2.1 Setting Up the System for Dynamic Pitch Mode (Continued)

See section 1.1 for compatibility of probes with the **neo2000®**.

Step	Procedure for Reusable Detector Probes (Model 1017)
1	Plug the power cord into the console and into the wall receptacle. If needed, attach the external collimator to the probe.
2	Using aseptic technique (unless you intend to use the detector probe with a sterile surgical drape), connect the probe to the Model 2024 reusable detector probe cable by aligning the red dot on the probe and the red dot on the cable connector, then gently insert the cable.
3	Have an assistant plug the other end of the probe cable (that has seven pins) into the probe input port on the console. Align the key of the cable connector and the groove in the probe input port, then gently insert the cable. The **neo2000** is now ready for start-up.

Note: The connector that engages the 14mm probe has four pins.

2.2 Starting the System in Dynamic Pitch Mode

Overview
This section describes how to start up the **neo2000®**.

Procedure
The table below lists the start-up procedures to prepare the system for use in dynamic pitch mode.

To . . .	Do the following…	And this happens. . .
Turn on the system	Press and release power standby button “on.”	• Power indicator lights up. System should begin normal operation within 15 seconds. • All lights illuminate as a system check. • If there is no probe attached or if there is a problem with the probe, the “No Probe Connected” and the system function indicator lights up, and Error “no ProbE” is displayed. If error messages “Error 2” through “Error 6” are displayed, then **see Chapter 5, Troubleshooting, for help.** • “Dynamic Pitch” indicator lights up. • Dynamic pitch range is automatically set to 0-100 count range, and default background count is 2cps.
Run performance check of system	See Section 4.7 for procedures.	• Radionuclide is automatically set to Technetium 99m, and this indicator lights up.

2.2 Starting the System in Dynamic Pitch Mode (Continued)

To . . .	Do the following…	And This Happens
Select dynamic pitch count range different from 0-100.	Press and release dynamic pitch count range selection buttons.	• Indicator for selected count range lights up; background count changes to default for selected count range, or last set background if it exceeds default and falls within 80% of upper limit of new range.
Select a radionuclide different from Technetium 99m.	On the back of the console, press and release the radionuclide selection button repeatedly until the desired radionuclide is lit.	The radionuclide selected lights up on the console.
Adjust the dynamic pitch audible tone.	Turn volume control to lowest setting. Turn volume control to highest setting.	Tone is at lowest volume level. Tone is at the highest volume. 
Turn the dynamic pitch sound on or off.	Press and release the mute button.	When sound is off, mute indicator light flashes. When sound is on, mute indicator light is lit constantly.

2.2 Starting the System in Dynamic Pitch Mode (Continued)

System status
When the system is first turned on, all indicators and displays are on for approximately 3 seconds.

Following this, the software version numbers of the system are displayed for approximately 3 seconds.

If there are no system errors and a probe is connected, the system will begin operation in the dynamic pitch mode, the 0-100 count range, and with the ^{99m}Tc isotope selected.

2.3 Acquiring the Background Count in Dynamic Pitch Mode

Overview
The background count can be used to compress the dynamic pitch range by using it as the minimum value for the selected range.

System status before background count
The background count display shows the default value for the selected dynamic pitch range; the ratio display is off; and the target count numeric display shows count rates as the physician moves the probe over tissue.

How to acquire background count

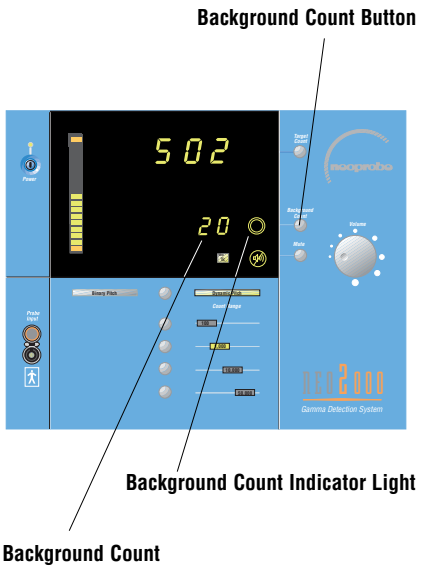
- Place the probe tip on tissue of interest.
- Press and release background count button (start beep); hold probe steady (between 2 and 6 seconds) until graphic display is full and a double bell sounds (stop beep).

Console display

- Background count indicator light begins flashing.
- Background count numeric display shows dashes.
- Count rate display is temporarily suspended.
- Graphic display fills from bottom as data is collected.

Background count display

- When a value is acquired, the background count numeric display shows the background count, and will retain this background count until a new background count is taken, the count range is changed, or the system is shut off.



2.3 Acquiring the Background Count in Dynamic Pitch Mode (Cont'd)

Set dynamic pitch range

The physician generally sets the dynamic pitch range based on the maximum count rates expected, in order to achieve the highest resolution for a given dynamic pitch range. The default background counts are shown in the table below:

Count Range	Default Background Count
100	2
1,000	20
10,000	200
50,000	1000

Operational notes

The table below explains what happens if certain events occur during system operation.

If . . .	**Then this happens . . .**
The background count value is greater than or equal to 80% of the maximum value for the selected count range.	The background count displays a value that is 80% of the maximum value for the selected count range, i.e. 800 is displayed for the 1,000 count range.
The background count value is less than or equal to 2% of the maximum value for the selected count range.	The background count displays a value that is 2% of the maximum value for the selected count range, i.e. 20 is displayed for the 1,000 count range. The ratio calculation is not performed when a target count is taken.
The background count button is pressed while the count is in progress	A beep sounds (start beep) and the background count starts over.
The background count button is pressed with background count displayed	The system begins another background counting calculation.

2.4 Scanning to Locate Concentrated Areas of Radiopharmaceuticals

Overview
When the background count and dynamic pitch range have been established, the physician scans target tissues to locate areas of significant localized radioactivity.

System status
The target count numeric display shows count rates; the graphic display is on and showing count rate value as scaled by the selected dynamic pitch range; the audible signal may be present, depending on count rate, dynamic pitch range selection, and volume setting.

Scanning procedure
It is recommended that the physician scan slowly by moving the probe over the tissue at a rate of 1-2 centimeters per second.

The audible signal rises in pitch as the count rates rise from the displayed background count to the dynamic pitch range maximum value.

Operational note
If the graphic display fully illuminates and flashes including pulsing audio feedback, this means that the count is too high to be displayed (out of range).

Press and release the range button for the next higher dynamic count range, and reset the background count if desired.

Another option is to press, hold and then release any range button to activate the autorange function. (See section 2.5).

2.5 Acquiring Target Count in Dynamic Pitch Mode

Overview

When scanning has identified target tissue with increased radioactive counts compared to adjacent tissue, the physician acquires the target count to qualify the intensity of the gamma radiation from the target tissue.

System status before target count

The target count numeric display shows count rates as the physician moves the probe over tissue; the graphic display is on and showing count rates.

How to acquire target count

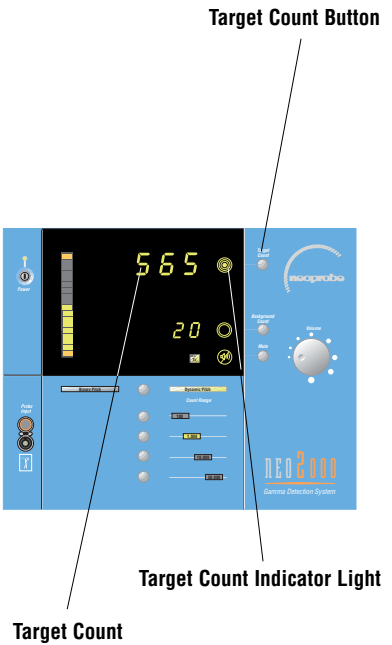
- Hold probe stationary over target tissue to achieve the highest numeric counts and the highest audible pitch.
- Press and release target count button (start beep); hold probe steady between 1 and 6 seconds until graphic display is full and a double bell sounds (stop beep).

Console display

- Target count indicator begins flashing in green.
- Target count numeric display shows dashes.
- Graphic display fills from bottom as data is collected.

Target count display

- Target count is shown in numeric display; target count indicator light flashes green.
- Graphic display is off.
- Target count is displayed for 5 seconds.
- After 5 seconds, a double bell sounds and the system returns to scan mode (Section 2.4), showing the last background count calculated and current count rates.



2.5 Acquiring Target Count in Dynamic Pitch Mode (Continued)

How to acquire a target count ratio

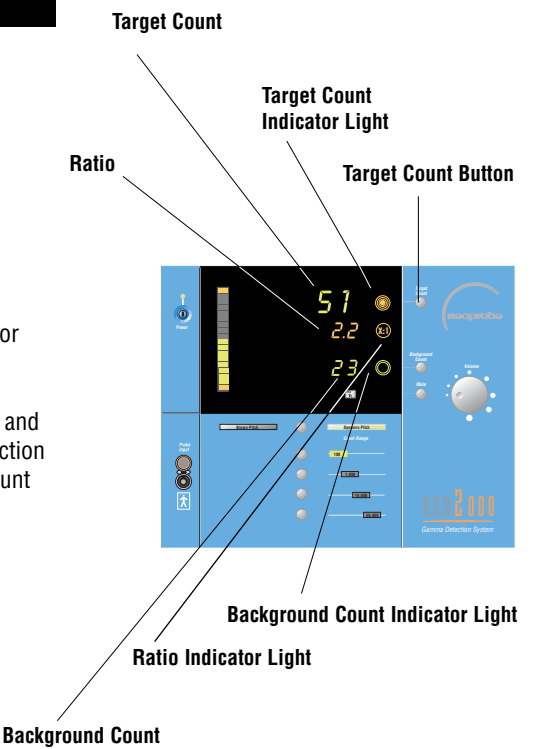
- Hold probe stationary over background or normal tissue. Press and release the background count button. The background count must be greater than the default value (2%) for the count range selected in order to activate the ratio calculation function.
- Hold probe stationary over target or suspicious tissue. Press and release target count button until the system beeps; hold probe steady between 1 and 6 seconds until graphic display is full and a double bell sounds. (stop beep)

Console display

- Target count indicator begins flashing in amber.
- Target count numeric display shows dashes.
- Graphic display fills from bottom as data is collected.

Target count display

- Target count is shown in numeric display; target count indicator light flashes amber.
- Ratio is shown below target count in amber.
- Graphic display is off.
- Target count and ratio are displayed for 5 seconds.
- After 5 seconds a double bell sounds and the system returns to scan mode (Section 2.4), showing the last background count calculated and current count rates.



2.5 Acquiring Target Count in Dynamic Pitch Mode (Continued)

How to acquire a ten second count

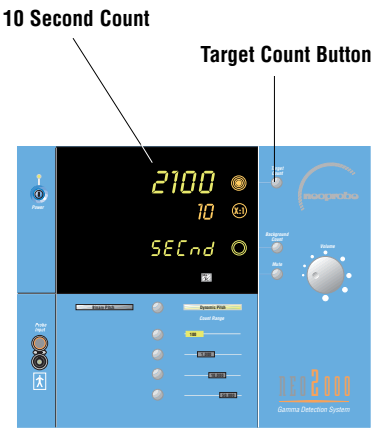
- Hold probe stationary over target tissue to achieve the highest numeric counts and the highest audible pitch.
- Press and hold the target count button until the system beeps; then release the button.
- Hold probe steady for 10 seconds until graphic display is full and a double bell sounds. (stop beep)

Console display

- Target count indicator begins flashing in green.
- Target count numeric display shows dashes.
- Graphic display fills from bottom as data is collected.

Target count display

- 10 second target count is shown in numeric display; target count indicator light flashes amber.
- “10” is shown below target count in amber, and “SECnd”is shown in green.
- Graphic display is off.
- The 10 second count is displayed for 5 seconds.
- After 5 seconds a double bell sounds and the system returns to scan mode (Section 2.4), showing the last background count calculated and current count rates.



2.5 Acquiring Target Count in Dynamic Pitch Mode (Continued)

How to use autorange feature

- The **neo2000®** has 4 preset ranges: 100, 1,000, 10,000, and 50,000. In certain instances the user may want to define a different range with the auto range feature.
- Hold the probe stationary over the target tissue to achieve the highest numeric counts and highest audible pitch.

Note: If the target counts are greater than the maximum value of the selected count range, then the graphic display is full and flashes while emitting an intermittent beep.

- Press and hold any one of the four count range buttons until the system beeps, then release the button; hold the probe steady until the graphic display is full and a double bell sounds.

Note: Press and release any of the count range buttons to return to default settings for the selected range.

Console display

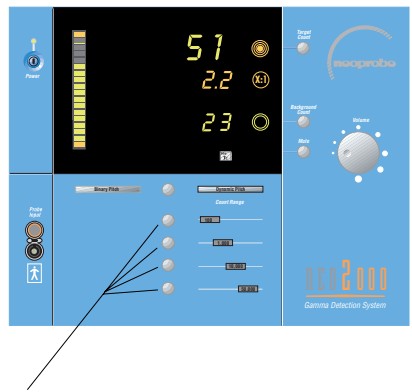
- Target count displays “rAnGE”. Background count display is blank. Graphic display; fills from bottom as data is collected.

Target count display

- Graphic display is approximately 80% full.

Note: Autorange sets the maximum value for the user defined range to 125% of the target counts acquired during the autoranging sequence.

- Background count is set to either 2cps or 2% of full scale, whichever is greater.
- The count range selection (that corresponds to the count range button pushed) flashes.



Count Range Buttons

2.5 Acquiring Target Count in Dynamic Pitch Mode (Continued)

Operational notes

The table below explains what happens if certain events occur during system operation.

If . . .	**Then this happens . . .**	
The target count button is pressed while a target count value is being calculated.	The target count starts over again.	
The target count is too high to be displayed.	Symbols " ⌐⌐⌐⌐⌐ " (non-numeric symbols for "overflow") appear on the target count numeric display and an audible alarm sounds.	
The target count button is pressed while either the target count or 10 second count is being displayed.	The target count numeric display reverts to scan mode and shows count rates.	
The ratio calculated is greater than 99.9.	The " ⌐⌐⌐ " overflow symbol appears in the ratio display.	

2.6 System Shutdown

Overview
This section describes how to shut down the system and prepare for its next use.

How to shut down the system
The table below gives the steps to shut down the system.

Step	Procedure for Reusable BlueTip™ Probes (Models 2001, 2002, 2003)
1	Press and release the power standby button.
2	Disconnect power cord from wall receptacle.
3	Disconnect probe handle from console.
4	Clean console and power cord (see Section 4.2).
5	Wrap power cord around posts on rear panel of console.
6	Remove probe tip from disposable handle by pulling back on the blue latch and turning the probe tip 1/8 turn counterclockwise.
7	Clean (see Section 4.2) and sterilize (see Section 4.3) probe tip.
8	Discard probe handle.

2.6 System Shutdown (Continued)

Step	Procedure for Reusable Detector Probe (Model 1017)
1	Press and release the power standby button.
2	Disconnect power cord from wall receptacle.
3	Disconnect cable from console by gently pulling on the gray plastic connector end of the cable.
4	Clean console and power cord (see Section 4.2).
5	Wrap power cord around posts on rear panel of console.
6	Separate and clean external collimator, detector probe and detector probe cable (see Section 4.2).
7	Sterilize external collimator, detector probe and detector probe cable, if necessary (see Section 4.3).

3 Using the **neo2000®** in Binary Pitch Mode

Overview

Introduction
This chapter describes how to use the **neo2000®** Gamma Detection System in binary pitch mode to locate tissue that has been tagged with a radiopharmaceutical.

Operational principles
The **neo2000** detects the presence of gamma rays from gamma-emitting isotopes and can be used to distinguish differences in the amount of gamma rays emitted from different areas of the body or an organ.

In the binary pitch mode of operation, the **neo2000** console can be used to emit an audible tone that indicates to the physician that the system has detected radioactivity in tissue that is significantly above the background radioactivity of normal tissue.

In this chapter
The following sections are included in this chapter:

3.1 Setting Up the System for Binary Pitch Mode

Overview
This section describes how to set up the system for use. Neoprobe recommends that you follow established hospital procedures to maintain a sterile environment.

How to set up the system
The table below lists the steps in setting up the system.

Step	Procedure for Reusable BlueTip™ Probes (Models 2001, 2002, 2003)
1	Plug the power cord into the console and into the wall receptacle. If needed, attach the appropriate external collimator to the probe.
2	Using aseptic technique, transfer the sterilized probe tip(s) by hand into the sterile field. **(DO NOT DROP)**
3	Remove the Model 2025 probe handle unit aseptically from sterile kit.
4	Verify that the probe tip is completely dry. Insert the probe tip into the handle and turn the probe tip clockwise 1/8 turn until it locks into place and the marks on the probe and handle align.
5	Have an assistant plug the probe cable into the probe input port on the **neo2000®** console. The **neo2000** is now ready for start-up.

Note: There are raised arrows on the cable connector and the probe input port. You should hear an audible click when you properly engage the cable.

3.1 Setting Up the System for Binary Pitch Mode (Continued)

See section 1.1 for compatibility of probes with the **neo2000®**.

Step	Procedure for Reusable Detector Probes (Model 1017)
1	Plug the power cord into the console and into the wall receptacle. If needed, attach the external collimator to the probe.
2	Using aseptic technique (unless you intend to use the detector probe with a sterile surgical drape) connect the probe to the Model 2024 reusable detector probe cable by aligning the red dot on the probe and the red dot on the cable connector, then gently insert the cable.
3	Have an assistant plug the other end of the detector probe cable (that has seven pins) into the probe input port on the console. Align the key of the cable connector and the groove in the probe input port, then gently insert the cable. The **neo2000** is now ready for start-up.

Note: The connector that engages the 14mm probe has four pins.

3.2 Starting the System in Binary Pitch Mode

Overview
This section describes how to start up the **neo2000®.**

Procedures
The table below lists the start-up procedures to prepare the system for use in binary pitch mode.

To…	Do the following…	And this happens…
Turn on the system.	Press and release power standby button “on.”	• Power indicator lights up. System should begin normal operation within 15 seconds. • All lights illuminate as a system check. • If there is no probe attached or if there is a problem with the system, the “No Probe Connected” and system function indicator lights up and “Error no ProbE” is displayed. If error messages “Error 2” through “Error 6” are displayed, then **see Chapter 5, Troubleshooting, for help.**
Run performance check of system.	See Section 4.7 for procedures.	

3.2 Starting the System in Binary Pitch Mode (Continued)

To…	Do the following…	And this happens…
Select binary pitch mode of operation.	Press and release binary pitch/dynamic pitch selection button.	•"Binary Pitch" indicator lights up. • Background count changes to 7cps. • Radionuclide is automatically set to Technetium 99m, and this radionuclide indicator lights up.
Select a radionuclide other than Technetium 99m.	On the back of the console, press and release the radionuclide selection button repeatedly until desired radionuclide is found.	The radionuclide selected lights up on the console.
Adjust the binary pitch audible sound.	Turn volume control to lowest setting (counterclockwise). Turn volume control to highest setting (clockwise).	Tone is at lowest volume level.  Tone is at highest volume level. 
Turn the binary pitch sound on or off.	Press and release mute button.	When sound is off, mute indicator light flashes. When sound is on, mute indicator light is lit constantly.

System status

•When the system is first turned on, all indicators and displays are illuminated for approximately 3 seconds.
•Following this, the software version numbers of the system are displayed for approximately 3 seconds.
•If there are no system errors, and a probe is connected, the system will begin operation in the dynamic pitch mode, the 0-100 count range, and with the ^{99m}Tc isotope selected.

3.3 Acquiring the Background Count in Binary Pitch Mode

Overview
The background count provides the capability to establish a baseline number for the radioactivity level of normal tissue; the system can be used to compare this background value to the radioactivity level for the tissue of interest when a target count is taken.

System status before background count
The background count display shows the number 7 as a default value; the ratio display is off; and the target count numeric display updates count rates every half-second as the physician moves the probe over tissue.

How to acquire background count

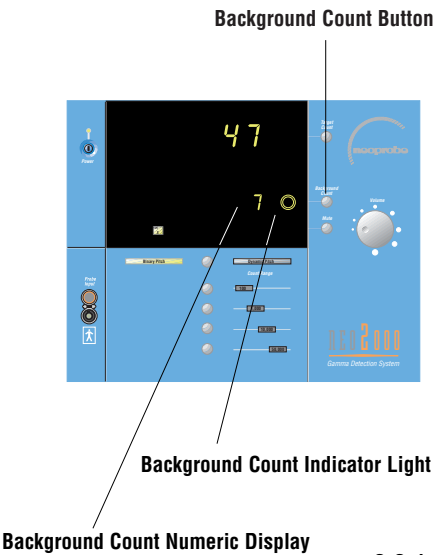
- Place the probe tip in area of normal tissue (e.g., bifurcation of aorta, normal adjacent tissue, etc.).
- Press and release background count button (start beep) and hold probe steady for 6 seconds (stop beep).

Console display

- Background count indicator light begins flashing.
- Background count numeric display shows dashes.
- Count rate display is temporarily suspended.
- Graphic display fills from bottom as data is collected for 6 seconds.

Background count display

- After 6 seconds, the background count numeric display retains the background count until a new background count is taken, or the pitch mode is changed, or the system is shut off.
- Count rate display is resumed.



3.3 Acquiring the Background Count in Binary Pitch Mode (Cont'd)

Operational notes

The table below explains what happens if certain events occur during system operation.

If . . .	**Then this happens . . .**	
The background count is too high to be displayed	Symbols " ⌐⌐⌐⌐⌐ " (non-numeric symbol for "overflow") appear on the background count numeric display and an audible signal sounds.	
The background count button is pressed while the count is in progress	A beep sounds (start beep), and the background count starts over.	
Background count button is pressed after background count value is displayed	The system begins another background counting calculation.	

3.4 Scanning to Establish Boundaries of Target Tissue in Binary Pitch Mode

Overview
When the background count has been established, the physician scans target tissues to locate areas of significant localized radioactivity.

Scanning procedure
It is recommended that the physician scans by moving the probe slowly over the tissue at a rate of 1-2 centimeters per second.

When the tissue being scanned exceeds the background count by a statistically significant amount, an audible tone sounds to indicate target tissue with localized radioactivity.

The physician marks the perimeter of suspicious tissue by an appropriate method.

Console display
Count rates are displayed. No target count or ratio is displayed during the scanning procedure.

3.5 Acquiring Target Count (6-Second Option)

Overview
This section describes how to acquire a target count which can be used to confirm the location of the target tissue.

System status before target count
The background count display shows the background count (Section 3.3); the ratio display is off; and the target count numeric display shows count rates as the physician moves the probe over tissue.

How to acquire target count

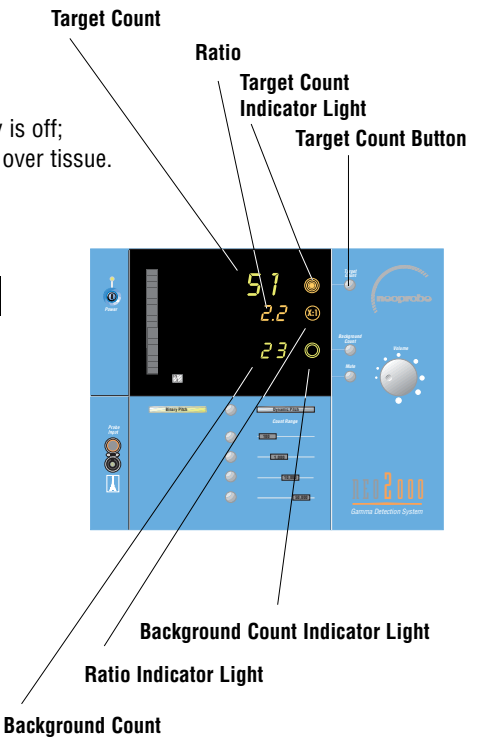
- Hold probe stationary over target tissue.
- Press and hold target count button until the system beeps (start beep), then release button; hold probe steady for 6 seconds until a beep sounds (stop beep).

Console display

- Target count indicator changes from green to amber and begins flashing.
- Target count numeric display shows dashes.
- Graphic display fills from bottom as data is collected for 6 seconds.

Target count and ratio display

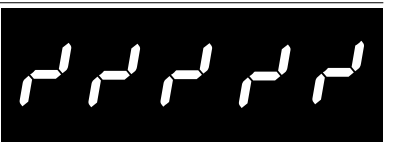
- Target count is shown in numeric display; target count indicator light is flashing amber.
- Ratio is displayed; ratio indicator is flashing.
- Target count and ratio are displayed for 5 seconds.
- After 5 seconds, the system returns to scan mode (Section 3.4), showing the last background count calculated and current count rates only.



3.5 Acquiring Target Count (6-Second Option) (Continued)

Operational notes

The table below explains what happens if certain events occur during system operation.

If…	**Then this happens…**	
The target count button is activated (press and hold) while a target count value is being calculated	The start beep sounds and the target count starts over again.	
The target count is too high to be displayed	Symbols " ⌐⌐⌐⌐⌐ " (non-numeric symbol for "overflow") appear on the target count numeric display and an audible alarm sounds.	
The target count button is pressed once while the count is being displayed	The target count numeric display reverts to scan mode and shows count rates.	
The target count button is pressed twice while the count is displayed	The target count starts over again.	
The ratio calculated is greater than 99.9	The " ⌐⌐⌐ " overflow symbol appears in the ratio display.	

3.6 Performing a Target Check (2-Second Option)

Overview
This section describes how to perform a 2-second target check to obtain a quick reading of the radioactivity level of the target tissue.

System status before target check
The background count display shows the background count (Section 3.3); the ratio display is off; and the target count numeric display shows count rates as the physician moves the probe over tissue.

How to perform target check

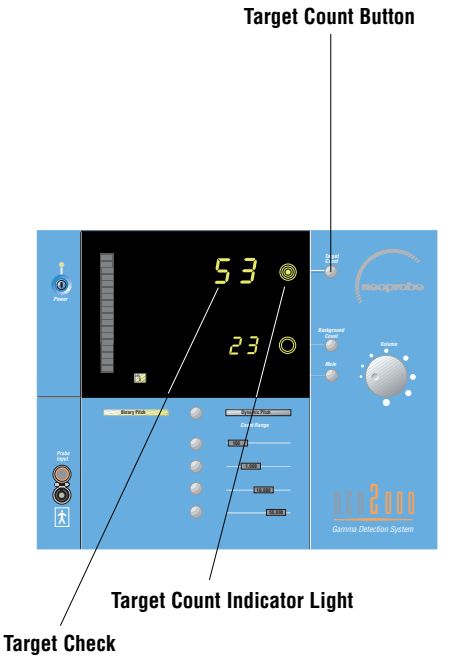
- Hold probe stationary over target tissue.
- Press and release target count button (start beep); hold probe steady for 2 seconds until a beep sounds (stop beep).

Console display

- Target count indicator light begins flashing.
- Target count numeric display shows dashes.
- Graphic display fills from bottom as data is collected for 2 seconds.

Target check display

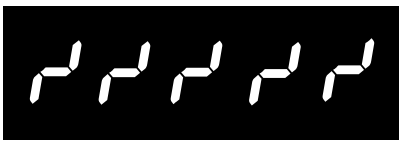
- Target check is shown in numeric display; target count indicator light flashes green.
- Target check is displayed for 5 seconds (ratio is not displayed).
- After 5 seconds, the system returns to scan mode (Section 3.4), showing the last calculated background count and current count rates only.



3.6 Performing a Target Check (2-Second Option) (Cont'd)

Operational notes

The table below explains what happens if certain events occur during system operation.

If…	**Then this happens…**	
The target check is too high to be displayed	Symbols " ⌐⌐⌐⌐⌐ " (non-numeric symbol for "overflow") appear on the target count numeric display and an audible alarm sounds.	
The target count button is pressed while the count is being displayed	The target count numeric display reverts to scan mode and shows count rates.	

3.7 System Shutdown

Overview
This section describes how to shut down the system and prepare for its next use.

How to shut down the system
The table below gives the steps to shut down the system.

Step	Procedure for BlueTip™ Reusable Probe Tips (Models 2001, 2002, 2003)
1	Press and release the power standby button.
2	Disconnect power cord from wall receptacle.
3	Disconnect disposable handle from console.
4	Clean console and power cord (see Section 4.2).
5	Wrap power cord around posts on rear panel of console.
6	Remove probe tip from disposable handle by pulling back on the blue latch and turning the probe tip 1/8 turn counterclockwise.
7	Clean (see Section 4.2) and sterilize (see Section 4.3) probe tip.
8	Discard disposable handle.

3.7 System Shutdown (Continued)

Step	Procedure for Reusable Detector Probes (Models 1017)
1	Press and release the power standby button.
2	Disconnect power cord from wall receptacle.
3	Disconnect cable from console by gently pulling on the gray plastic connector end of the cable.
4	Clean console and power cord (see Section 4.2).
5	Wrap power cord around posts on rear panel of console.
6	Separate and clean external collimator, detector probe and detector probe cable (see Section 4.2).
7	Sterilize external collimator, detector probe and detector probe cable, if necessary (see Section 4.3).

4 Maintenance

Overview

Introduction
This chapter discusses procedures for maintenance and servicing of the **neo2000®** Gamma Detection System.

Calibration and Preventive Maintenance
The **neo2000®** is shipped set to factory specifications. Do not try to open the **neo2000** console; there is never a need for the user to calibrate or service the system. Preventive maintenance is limited to external cleaning of the **neo2000**, fuse replacement, and functional diagnostics.

In this chapter
This chapter includes the following sections:

4.1 System Diagnostics

Overview
This section describes how to run diagnostics to verify that the **neo2000®** visual indicators and input controls are functioning properly.

Repair
If a diagnostic check indicates a fault, see Chapter 5, Troubleshooting, or contact Neoprobe for service (see Section 4.5). Do not use the **neo2000** until the fault has been corrected.

Visual indicator test mode
To verify that the visual indicators on the console are operating properly, do the following:

Step	Procedure	Result
1	Press and hold the binary pitch/dynamic pitch mode selection button and while holding it down, press and release the Mute button to enter the Base Diagnostic Mode of operation.	Background count display shows “dIAG”. 
2	Press and hold the binary pitch/dynamic pitch mode selection button. Press and release the dynamic pitch range 100 button to enter visual indicator test mode (VITM).	All indicator lights on the top half of the display (radionuclide indicators and above) are lighted. **Note: Indicators on bottom half of display are off.**
3	Press and release the Target Count button.	The color of the Target Count indicator changes from green to amber.

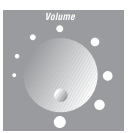
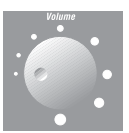
4.1 System Diagnostics (Continued)

Step	Procedure	Result	
4	Press and release the background count button.	All of the indicator lights on the bottom half of the display (binary pitch/ dynamic pitch mode selection button and below) are lighted. Background count displays “vItM”. **Note: indicators on top half of display are off.**	
5	To leave VITM and return to Base Diagnostic Mode: Press and hold the Binary pitch/ dynamic pitch mode selection button, and while holding it down, press and release the Background Count button.	A double chime tone is heard and the Background Count display shows “dIAG”.	
6	To exit the Base Diagnostic Mode, press and hold the binary pitch/dynamic pitch mode selection button, and while holding it down, press and release the Mute button.	**neo2000®** console exits the Base Diagnostic Mode.	

4.1 System Diagnostics (Continued)

Input controls test mode

To verify that all input controls on the console are operating properly, do the following:

Step	Procedure	Result	
1	Press and hold the binary pitch/ dynamic pitch mode selection button, and while holding it down, press and release the Mute button.	Background count display shows “dIAG”.	
2	To enter the input controls test mode (ICTM),press and hold the binary pitch/dynamic pitch mode selection button, and while holding it down, press and release the Dynamic Pitch range 1000 button.	Background count display shows “IctM” to verify that the **neo2000®** console is in IctM mode, and a continuous tone is heard.	
3	Turn volume control clockwise until it stops (maximum setting). Confirm that volume setting is at maximum.	Volume percentage is shown in ratio display. 100% is shown as “100”.	
4	Turn volume control counterclockwise until it stops (minimum setting). Confirm that volume setting is at minimum.	Volume percentage is shown in ratio display. 1% is shown as “1”.	

Step	Procedure	Result
5	Press and release the following console buttons in the order listed:	The **neo2000®** console displays the message for each button in the target count numeric display. A continuous tone is heard, and the operator then presses the next button in the list.

Button Description	Message Displayed
Radionuclide (on the back of the console)	Bu-0
Target count	Bu-1
Background count	Bu-2
Mute	Bu-3
Binary pitch/dynamic pitch mode	Bu-4
Count range 100	Bu-5
Count range 1,000	Bu-6
Count range 10,000	Bu-7
Count range 50,000	Bu-8

4.1 System Diagnostics (Continued)

Step	Procedure	Result
6	To exit the ITCM Mode, press and hold the binary pitch/dynamic pitch selection button, and while holding it down, press and release the Background Count button.	A double chime tone is heard and the Background Count display shows “dIAG”. 
7	To exit the Base Diagnostic Mode press and hold the binary pitch/ dynamic pitch mode selection button, and while holding it down, press and release the Mute button.	**neo2000®** console exits the Base Diagnostic Mode.

4.2 Cleaning and Decontamination

Overview
This section gives procedures for cleaning and inspecting the **neo2000®** console and components.

neo2000 console cleaning instructions
The console and AC power cord may be wiped clean. Use a soft cloth moistened and rinsed out in an acceptable cleaning agent. (See section 4.2)

WARNING: Do not clean when energized. Disconnect power cord from console and from power outlet before cleaning. Do not sterilize the console or immerse it in fluids. Attempting to do so will cause permanent damage.

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 intraoperative applications must be cleaned prior to reuse.

If the probe has been used in intraoperative applications without a sterile surgical drape, or if the drape was used and was compromised during the procedure and a high count is detected with the instrument the absence of a radioactive source, then the detector probe and cable should be cleaned with a radioactive decontaminant solution (e.g., Radiacwash®).

WARNING: Do not soak the detector probe or cable in cleaning solutions or water. 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.

The following tables list cleaning and rinsing procedures.

4.2 Cleaning and Decontamination (Continued)

Cleaning and rinsing methods for Model 1017 reusable probes, Model 2024 reusable probe cables, and accessories.

Step	Procedure
1	Immediately after use, remove the detector probe and cable from the sterile drape, if used. The sterile drape should be discarded. If the probe was used without a sterile sheath, or if the sheath was compromised, then confirm that the console registers low counts or no counts in the absence of a radioactive source. This confirms that there is no radioactive contamination of the probe.
2	Wipe all visible soil from the detector probe, cable, and external collimator with a clean sponge moistened with distilled water.
3	Disconnect the cable from the control unit. DO NOT disconnect the probe cable from the probe.
4	Wipe the detector probe and cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration).
5	Loosely coil the cable and place in a plastic container to protect the detector probe and cable from damage during transport.
6	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.
7	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.
8	Visually inspect the detector probe and cable for contaminated areas.
9	Repeat steps 6-8 until visual inspection reveals that no contaminated areas remain.
10	Detach the external collimator from the probe cable, then detach the probe cable from the probe.

4.2 Cleaning and Decontamination (Continued)

Cleaning and decontamination methods for Model 1017 Reusable probe, Model 2024 reusable probe cable, and accessories.(continued)

Step	Procedure
11	The connector ends of the detector probe, probe cable, and the external collimator should be swirled intermittently in 100 milliliters of enzymatic detergent solution for at least one minute but no more than two minutes.
12	Rinse these components in a brisk stream of tap water for approximately 30 seconds and dry them with a soft cloth.

4.2 Cleaning and Decontamination (Continued)

Cleaning and decontamination methods for Models 2001, 2002, and 2003 BlueTip™ probes, and Models 2004 and 2019 external collimators.

Step	Procedure
1	Immediately after use, remove the reusable probe tip and disposable handle and cable from the sterile drape, if used. The sterile drape should be discarded. If the probe was used without a sterile sheath, or if the sheath was compromised, then confirm that the console registers low counts or no counts in the absence of a radioactive source. This confirms that there is no radioactive contamination of the probe.
2	Disconnect the disposable handle and cable from the control unit. Separate the external collimator from the reusable probe tip. With the reusable probe tip still attached to the disposable handle and cable, wipe the exterior with a soft cloth soaked in enzymatic surgical detergent. Rinse thoroughly with a brisk stream of fresh tap water.
3	Inspect the collimator and reusable probe tip for any signs of soil.
4	Remove any visible soil, resistant to the soft cloth, with a soft brush and enzymatic surgical detergent. Repeat for the exterior and interior of the collimator. Rinse the collimator and reusable probe tip thoroughly with a brisk stream of fresh tap water.
5	When no visible soil remains, remove the disposable handle from the reusable probe tip. Discard the disposable cable. DO NOT DISCARD THE PROBE TIP OR THE COLLIMATOR.
6	Remove any soil now visible on the reusable probe tip with a soft cloth soaked in enzymatic surgical detergent.

Cleaning and rinsing methods for Models 2001, 2002, 2003 BlueTip™ probes and Models 2004 and 2019 external collimators.(continued)

Step	Procedure
7	Soak the reusable probe tip and collimator in a solution of enzymatic detergent according to the manufacturer's directions. (For example, Enzol enzymatic detergent, Johnson & Johnson, prepared by adding 60ml (2 ounces) Enzol to 3.8 liters (1 gallon) warm water. Soak for two minutes. Remove any soil with a soft cloth or soft brush soaked in enzymatic detergent.
8	Rinse thoroughly with a brisk stream of fresh tap water. Inspect for any signs of soil.
9	Dry with a soft cloth and reinspect for cleanliness.

4.2 Cleaning and Decontamination (Continued)

Cleaning methods for Model 2100 or neo2000 control unit.

Step	Procedure
1	Disconnect the cable from the control unit.
2	Disconnect power cord from the back of the control unit.
3	Wipe the exterior of the control unit with a soft cloth dampened with one of the following solutions:

Solution Name	Solution Preparation
Mild soap and water	30ml (1oz) mild soap in 30ml (1oz) warm tap water
Tor II	60ml (2oz) Tor II in 3.8 liters (1 gallon) warm tap water
MetriZyme	30ml (1oz) MetriZyme in 3.8 liters (1 gallon) warm tap water
Control III	30ml (1oz) Control III in 3.8 liters (1 gallon) warm tap water
Cidex	100% Cidex after activation
Ethyl Alcohol, denatured	95% ethyl alcohol, 5% water
Isopropyl Alcohol	70% isopropyl alcohol, 30% water
Clorox	100% Clorox
Septisol	100% Septisol

4.3 Sterilization Procedures

Overview
This section describes how to sterilize the **neo2000®** probes and accessories.

This table provides a quick reference guide to approved sterilization methods for Neoprobe probes. Refer to the rest of this section for additional process details and descriptions.

Sterilization Procedure	14mm Probe (Model 1017)	BlueTip™ Probes (Models 2001, 2002, 2003)
Place in sterile surgical drape barrier	YES	YES
Ethylene oxide (EtO or EO gas)	YES	YES
STERIS® SYSTEM I (liquid)	NO	YES
Autoclave	NO	NO
Steam flash	NO	NO
PLAZLYTE®	NO	NO
STERRAD®	NO	NO

4.3 Sterilization Procedures (Continued)

General warnings

The following general warnings apply to sterilization of the system components:

- Do not sterilize the console (see Section 4.2 for cleaning procedures).
- Do not use gamma sterilization, which causes the probe to fail or degrade.
- **DO NOT STEAM AUTOCLAVE, STERRAD OR PLAZLYTE STERILIZE.** These sterilization methods have not been validated.
- Reusable probes (Models 1017) and reusable probe cables (Model 2024) should only be sterilized by the ethylene oxide (EtO) method.
- Reusable BlueTip™ probes (Models 2001, 2002, and 2003) should only be sterilized by the EtO or Steris® methods.
- Do not re-use or sterilize the Model 2025 disposable handle; discard after single use.
- Use only the approved sterilization procedures described below.
- Neoprobe Corporation recommends that this equipment not be in contact with the patient or operator when any electrosurgical device is in use and energized.

Use of the Model 1017 reusable probes and Model 2024 cables inside a sterile surgical probe drape

For intraoperative use, the Model 1017 reusable probe, and Model 2024 reusable probe cable may be placed in a commercially available sterile surgical drape barrier, such as the

Microtek Probe Drape, Catalog #3787 (Microtek Medical, Inc., 1-800-824-3027). or outside the U.S.A., Catalog #3787 UK (Microtek Medical Europe, Ltd., 44 (0) 1782 561911).

Before inserting the detector probe and cable into the sterile drape, wipe the detector probe and cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration). Visually inspect the sterile probe drape before and after use to ensure its integrity. If the integrity of the sterile probe drape has been compromised, thus contaminating the detector probe and cable, follow the guidelines provided in Section 4.2 for proper cleaning procedures.

4.3.1 Model 1017 reusable probes, Model 2024 reusable probe cables, and accessories disinfection and sterilization methods

For intraoperative use, the Model 1017 reusable probe and cable can be wiped down with alcohol and subsequently inserted into a commercially available sterile surgical drape barrier or, alternatively, may be gas sterilized with ethylene oxide (EtO) as described in this section.

NOTE: If the reusable probe and cable are stored for extended periods of time between uses, it is recommended that EtO sterilization be performed just prior to use.

4.3 Sterilization Procedures (Continued)

When the reusable probe, Model 1017 is used with the **neo2000** control unit, it is recommended that the probe always be placed in commercially available sterile surgical drape barriers.

EtO sterilization

The Model 1017 reusable probes and Model 2024 cables can only be sterilized with ethylene oxide (EtO). **DO NOT AUTOCLAVE. DO NOT STERILIZE WITH STERIS®, STERRAD®, OR PLAZLYTE®.** Oxidizing agents may be harmful to the detector probe and cable.

Prior to EtO sterilization, the Model 1017 reusable probes and cables should be inspected to ensure:

- They are clean
- The cables are free of cracks or cuts
- The connectors are completely dry.
- All components are separate. The probe is not attached to the cable and the external collimator is not attached to the probe.

The Model 2024 cables should be loosely coiled (approximately six coils) and then placed together with the detector probe, external collimator, and a chemical indicator on a 76cm x 76cm (30" x 30") wrapper. Sequentially wrap using the envelope method and secure the closure with a piece of ethylene oxide chemical indicator tape. Label "NEOPROBE" and initial.

An SAL of 10^{-6} was achieved in a hospital recommended cycle for 10% ethylene oxide, Oxyfume 2000®/Oxyfume 2002® and Pengas 2® following the AAMI (TIR 12-1994) protocol. The following table lists the recommended EtO sterilization cycle parameters for sterilization of the Model 1017 reusable probe, Model 2024 reusable probe cable, and accessories.

Parameters for 10% Ethylene Oxide (EtO) 90% HCFC Sterilization Cycles for Models 1013, 1017, 2001, 2002, 2003, 2004, 2019, 2024.

EtO Process Phase	Parameter	Value
Conditioning (in chamber)	Temperature	48.9 - 54.4 degrees Celcius (120 - 130 degrees F)
	Vacuum	610 - 660mm Hg (24-26 inches Hg)
	Humidity	40-80% RH
	Time	30-45 minutes
Sterilization	Temperature	48.9 - 54.4 degrees Celcius (120-130 degrees F)
	Pressure	690 - 827 hPa gauge (10-12 PSIG)
	Humidity	40-80% RH
	EtO Gas Concentration	600 +/- 30 mg/liter
	Dwell (exposure to gas)	120 minutes
Post Exposure Evacuation	Vacuum	610 - 660mm Hg (24-26 inches Hg), performed 2 times
Aeration	Time/Temperature	≥12 hours at 50 - 57.2 degrees Celcius (122-135 degrees F) or 7 days at room temperature

4.3.2 Model 2001, 2002, and 2003 BlueTip™ probe disinfection and sterilization methods

The following components of the **neo2000®** device may be sterilized in accordance with the methods described below: Model 2001 (12 mm reusable BlueTip probe, uncollimated); Model 2002 (12 mm reusable BlueTip probe, internally collimated); Model 2003 (19 mm reusable BlueTip probe, uncollimated).

The Model 2001, 2002, 2003 reusable BlueTip probes and Model 2004, 2019 external collimators are to be sterilized prior to each use.

Prior to sterilization, the BlueTip probes should be inspected to ensure that they are clean and undamaged.

EtO sterilization
EtO sterilization, see section 4.3.1

STERIS SYSTEM 1® Sterile Processing System

To ensure sterile results for the Model 2004 and Model 2019 collimators, special positioning is required.

For STERIS SYSTEM 1 Sterile Processing, do the following:

1. Separate the collimators from the BlueTip probes. Place the collimators on their sides in the STERIS catalog number C1330 microsurgical rack, and orient the larger, open ends of the collimators toward the top of the STERIS C1200 processing tray. Placing the collimators in positions other than the one specified may may trap air bubbles and prevent proper sterilization.
2. Place the BlueTip™ probes in the microsurgical rack. Special positioning is not required for the probes.
3. Process the devices according to the instructions in your STERIS SYSTEM I Processor Operators Manual.

To receive additional copies of these instructions call STERIS Corporation Customer Service at:

800-JIT-4USE
800-548-4873

440-354-2600
(outside the U.S.A.)

The Model 2001, 2002, and 2003 reusable probe tips have achieved an SAL of 10^{-6} following the AAMI (TIR 12-1994) guidelines:

Concentration of peroxyacetic acid	0.2%
Temperature	50˚C to 55˚C (122˚F to 132˚F)
Exposure time	12 Minutes

Note: The STERIS SYSTEM 1 Process, including rinse, requires 20 to 30 minutes.

Radioactive decontamination procedures
An increase in counts in the absence of a known radioactive source may signal radioactive contamination of the environment, detector probe or accessories. By a process of elimination, establish exactly what is contaminated. Decontaminate following standard nuclear medicine techniques. In general, this consists of washing the probe with a decontaminant solution (e.g.,Radiacwash®) using a soft gauze pad. Pay particular attention to cleaning recesses, crevices and mating surfaces. Do not scratch or abrade the surfaces. This makes decontamination more difficult or impossible.

Treat spent cleaning solution as radioactive waste and do not allow it to contaminate other surfaces. Dispose of pads and cleaning solution in approved containers.

Caution: When using radioactive materials, use safe and proper handling techniques. See your institution's radiation safety officer about nuclear regulation commission and other requirements.

4.4 Fuse Maintenance

The fuses in the **neo2000®** console can be accessed and replaced through an external fuse link on the rear of the console.

The following table describes how to replace the fuses (2).

Caution: The fuses should only be checked with the power cord disconnected from the **neo2000** console.

Note: Both fuses are required for proper operation.

Step	Procedure
1	Using a flat blade screwdriver, remove the fuse holder on the rear of the power cord receptacle.
2	Replace the faulty fuse(s) with a new 1.6 Amp/250V slow blow, low breaking capacity, T1.6AL 250V. Do not replace the fuse with another fuse of a different rating. Doing so could impact the safe operation of the unit, could cause permanent damage to the unit, and void the warranty.
3	Reinstall the fuse holder.

4.5 Service Policy

Overview
This section describes how to obtain warranty and out-of-warranty service on the **neo2000**® Gamma Detection System. All service on the **neo2000** must be performed by an authorized service representative of Neoprobe Corporation ("the Company").

Warranty service
To obtain service under your warranty, do the following:

- Obtain advance authorization prior to returning any products to the Company. Before returning any equipment, either write or call Neoprobe Corporation at 614-793-7500 or 800-793-0079. Provide the part number and serial number for the defective product (if applicable), a technical description of the defect or malfunction, a no-charge purchase order number, and your appropriate shipping and billing addresses. At the same time, obtain a returned merchandise authorization (RMA) number from Neoprobe.
- Return the entire **neo2000** or other product in its original packing. The shipment must be clearly labeled with the RMA number and prepared in accordance with good commercial practices. Shipment to the Company shall be at Buyer's expense. Repaired or replacement equipment will be shipped C.I.P. from the Company's plant. Nonverified problems or defects are subject to an evaluation charge.

Out-of-warranty service
To obtain out-of-warranty service, do the following:

- Obtain advance authorization prior to returning the product to the Company. Before returning any equipment, either write or call Neoprobe Corporation at 614-793-7500 or 800-793-0079. Provide the part number and serial number for the defective equipment (if applicable), a technical description of the malfunction, a purchase order number covering the Company's estimate of the repair cost, and shipping and billing addresses for the Buyer. At the same time, obtain a returned merchandise authorization (RMA) number.
- Return the entire **neo2000** or other product in its original packing. The shipment must be clearly labeled with the RMA number and prepared in accordance with good commercial practices. Shipment to Company shall be at Buyer's expense. Repaired or replacement equipment will be shipped C.I.P. from the Company's plant. Nonverified problems or defects are subject to an evaluation charge.

All repairs of Company equipment are warranted for 90 days from the date of shipment to Buyer. This warranty applies only to items found defective and repaired and does not apply to products in which no defect was found and returned as is.

4.6 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 of rated and 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 capacity, 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 OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTIES EXPRESSED, IMPLIED, OR STATUTORY ARE GIVEN.

4.7 System Accuracy Check

The following procedure should be used to confirm that the system performance is stable and consistent with prior operation. The system uses inherently stable, solid-state sensor and electronics technology that does not require periodic high voltage adjustments to compensate for gain "drift" associated with photomultiplier tubes. When used and maintained in accordance with this Operation Manual, the probe and system are not expected to exhibit any performance drift over their expected lifetime.

Neoprobe recommends that individuals from the Nuclear Medicine department who are familiar with radioactive emissions and measuring equipment perform the System Accuracy Check to ensure that factors including source strength, distance from probe to source, stray radiation from other sources, scatter of fluorescent peaks from interaction with shielding materials do not adversely affect the measurements taken.

Before performing the following quality checks, make sure that the probe and cable are clean and free of sources of radioactive contamination. All other sources of radiation emissions should be removed from the proximity of the probe during this check. Shielding materials should be located to minimize the effects of scatter and fluorescence peaks from the radioactive source. Neoprobe recommends performing the following procedure with a ^{57}Co radioactive source with a known strength between 5 and 25 micro Curies (185 to 925 kBq) in a fixed position directly in front and approximately 20mm from the distal end of the probe. The user may adapt the System Accuracy Check to be performed with another radionuclide, source strength or source location if desired.

Test 1 – Photopeak Efficiency

1. Set the unit to Dynamic Pitch mode and press the Nuclide Selection button on the back of the unit to select the ^{57}Co radionuclide.
2. Position the ^{57}Co radioactive source at a fixed distance of 20mm in front of the distal end of the probe. Place the probe and source in air above a table or other surface to minimize the effects of scattered radiation on the measurement.
3. On the **neo2000®** press and hold the Target Count button to perform a 10 second count. Make sure the probe does not move during this count.
4. Press the Nuclide Selection button on the back of the unit to select an open energy window *(select the ^{125}I Radionuclide for units with v2.01 or earlier software or press and hold the Radionuclide button for an open energy window in units with v2.02 or later software)*.
5. On the **neo2000** press and hold the Target Count button to perform a 10 second count. Make sure the probe does not move during this count.
6. Divide the ^{57}Co 10-second count by the open energy window 10-second count. The results should be greater than 50%.

4.7 System Accuracy Check (Continued)

7. The count-rate ratio determined by this procedure should be stable and consistent over time within the expected ±10% statistical variation of radioactive emissions during the recommended counting intervals.

Should the results of this System Accuracy Check indicate a variation beyond the expected amount and that performance of the probe or system has changed or is not stable, check to make sure that the **neo2000** is properly set up with the desired Radionuclide selected, and that all external factors (source strength, source distance, stray radiation, etc.) have been properly determined and controlled. If an unexpected shift in system performance is still evident, contact an authorized representative of Neoprobe Corporation for technical support or service, or contact Neoprobe Corporation directly by calling 1-800-793-0079 or 614-793-7500.

4.8 Performance Check

Overview
The **neo2000®** device is shipped set to factory specifications. There is no field calibration required. The routine performance check shows whether the system is functioning properly. Periodic performance checks are also recommended to assure the proper performance of the system is within specifications.

Routine instrument performance check procedure
A performance check should be performed before each use. This check will indicate that the system is functioning properly. Regardless of the radioisotope in use, this performance check is a simplified procedure that will assure proper performance of your system. The procedure is:

1. Place the detector probe near an obvious source of radioactivity, i.e., the injection site on the patient. Verify that the registered counts are consistently greater than zero.
2. Point the detector probe opposite and several feet away from the source of radioactivity. Verify that the registered counts decrease substantially from the source counts.

If the detector probe performs as stated in Steps #1 and #2, proceed with operation of the device.

If the detector probe does not meet the performance parameters of Steps #1 and #2, consider the following:

- If the detector probe fails to detect appreciable levels of gamma emissions when over the source of radioactivity, assure that the device is on, and that all cables are properly connected, and check that the correct radionuclide is selected. If counts remain low, run a system diagnostics (see Section 4.1) to assure that all visual indicators and input controls are functioning properly. If no problem is confirmed, please contact Neoprobe Corporation (800-793-0079 or 614-793-7500).
- If the unit displays error codes “Error 2” through “Error 6” upon power up, or at any time during operating, power the unit down and attempt to power it on again. Contact Neoprobe Corporation at 800-793-0079 or 614-793-7500 if these Error codes persist.
- If the detector probe continues to count high levels of gamma emissions when pointed opposite and away from the source of radioactivity, look for another obvious source of radioactivity that may

be contributing to the counts. If no other source is obvious, move the **neo2000®** to another room and repeat the low count performance check. If counts go down appreciably, there must be another source of radioactivity in the first room or the patient source is overwhelmingly high. This will decrease the effectiveness of the **neo2000** in differentiating between target tissue radioactivity and background radiation. If the counts do not go down in the second room, then the detector probe and cables should be cleaned with a radioactive decontaminant solution (e.g., Radiacwash®). If the counts still do not go down then please contact Neoprobe Corporation at 800-793-0079 or 614-793-7500.

5 Troubleshooting

Overview
The table below gives solutions to correct some problems if the **neo2000**® Gamma Detection System is not operating properly.

In case of total operational failure
If the **neo2000** does not operate at all when the power is turned on, check the user-accessible fuses on the rear panel. The fuses should only be checked with the power cord disconnected from the **neo2000** console.

Questions
Questions about the **neo2000** Gamma Detection System and its use can be answered by contacting Neoprobe Corporation (800-793-0079, or 614-793-7500).

Symptom	Possible Cause	Corrective Action
Control unit does not turn on when power button is pressed “on.”	AC power cord not installed. Power button is damaged. Faulty fuse.	Plug the cord in. Return for service. Replace fuse.
Unit shows “Error no ProBE” on Power up.	Probe not connected. Probe cable damaged. Probe faulty.	Connect probe. Replace damaged cable. Return for service.

5 Troubleshooting (Continued)

Symptom	Possible Cause	Corrective Action
Unit shows “Error 2” through “Error 6 “.	Internal error codes.	Cycle power to unit. Return for service if condition persists.
Intermittent and unusually high readings.	Intermittent interference electrical source (e.g., electrosurgical unit, X-ray, fluoroscope, etc.). Damaged probe.	Track down source of interference. Turn off offending sources (if possible). Change probe.
Unexpected high readings (continuous).	Contaminated probe or collimator. Background too high. Damaged probe or cable. Incorrect Radionuclide selected.	Decontaminate probe and collimator. Shield background source. Change cable and probe. Select appropriate radionuclide.
Unexpected low readings.	Incorrect Radionuclide selected. Damaged probe or cable.	Select appropriate Radionuclide. Change cable and probe.
Erratic readings or no counts.	Damaged detector probe cable. Liquid contamination of connectors. Improper connection of cable to unit or probe.	Replace cable. Remove cable and dry. Check for proper connection.
Audible tone does not give expected sound indication of changes in count rate.	Volume turned down. Mute button is on. Wrong count range is active.	Turn volume up. Turn mute off. Lower count range.

6 System Specifications

Model 1017 14 mm Reusable Probe
and Models 2001,2002,and 2003 BlueTip™ Reusable Probe Tips.

Parameter	Specifications
Crystal	Cadmium Zinc Telluride, CdZnTe
Energy range	27-364 keV
Detector efficiency for I-125 (27-35 keV gamma-ray energy)	>80%
Detector efficiency for Tc-99m (140 keV gamma-ray energy)	>75%
Detector efficiency for I-131 (364 keV gamma-ray energy)	>25%
Operating temperature range	15˚ to 40˚ C (59˚ to 104˚ F)
Storage and transit temperature	-20˚ to 60˚ C (-4˚ to 140˚ F)
Storage and transit humidity	10 to 95%
Storage and transit atmospheric pressure	500hPa to 1060hPa (7.3 psia to 15.4 psia)

6 System Specifications (Continued)

neo2000® Console

Parameter	Specifications
Operating power	AC Line Power 100-240 VAC (50-60 Hz)
Power consumption	10 watts, nominal 36 watts, maximum (at high volume)
Heat output	Negligible (10 watts, nominal)
Audio	70 dB Sound Pressure Level at 1 meter
Counter	zero to $(2^{32}-1)$
Energy range	12-600 keV internal windowing resolution
Maximum count range	99,999 cps
Height	23.5cm (9.25 in.)
Width	31.1cm (12.25 in.)
Depth	25.7cm (10.10 in.)
Weight (approximate)	3.0kg (6.5 lb.)

6 System Specifications (Continued)

neo2000® Console, cont'd.

Parameter	Specifications
Operating temperature range	10˚ to 40˚ C (50˚ to 104˚ F)
 Storage and transit temperature	-20˚ to 60˚ C (-40˚ to 140˚ F)
 Storage and transit humidity	10 percent to 95 percent
 Storage and transit atmospheric pressure	500 hPa to 1060 hPa (7.3 psia to 15.4 psia)

7 Hazards

Overview
This section describes potential hazards associated with operation of the **neo2000®** Gamma Detection System.

Call Neoprobe Corporation Technical Service immediately to report any incident or injury that occurred while using **neo2000** Gamma Detection System (800-793-0079 or 614-793-7500).

General hazard warnings
The operator should observe all prescribed safety precautions when handling radioactive materials.

Do not open the control unit or tamper with the detector probe. Either activity may damage the system and will void the warranty.

Electrical

1. Ensure that all cables are securely attached before use. Exposure of the probe cable end to conductive fluids could result in an electrical shock hazard to the patient or operator.

   When using the Model 2001, 2002, or 2003 reusable probe tips, ensure that the disposable handle is securely attached to the probe tip before use. Exposure of the electrical contacts in the disposable handle to conductive fluids could result in an electrical shock hazard to the patient or operator.

2. Inspect probe cables for damage before use. DO NOT USE DAMAGED CABLES as they may present an electrical shock hazard. (See System Warnings, Section 1.1.)

3. Before cleaning or decontamination procedures are performed, unplug the control unit from AC power and disconnect the power cord from the console.

4. Only use fuses of the proper rating. (see fuse maintenance, Section 4.4)

Mechanical
The Model 1017 reusable probes should be securely connected to the detector probe cable and held firmly while in use. The Model 2001, 2002, and 2003 reusable probe tips should be securely connected to the disposable handle and held firmly while in use.

Fire/explosion
The **neo2000** device is not intended for use in the presence of flammable anesthetics or other explosive gases. Failure to heed this warning may result in fire or explosion.

Injury
In the unlikely event an incident occurs, leave the instrument undisturbed until an authorized representative of Neoprobe can inspect the instrument.

Note
When reusable probes, Model 1017 are used with the **neo2000** control unit, it is recommended that the probes always be placed in commercially available sterile surgical drape barriers [as noted on page 4.3-3].

8 Potential Applications

Overview
The **neo2000®** Gamma Detection System is useful for the detection and quantification of gamma radiation. It is indicated for external and intraoperative detection of radioactivity in body tissues or organs, where radiopharmaceuticals are administered. Some of the most commonly administered isotopes are listed in the following table, all of which are detected by the **neo2000** Gamma Detection System.

Radionuclide	Principal Photopeak Energy (keV)	Physical Half-life	Select this neo2000 Radionuclide indicator
Iodine-125	27-35, Te X-rays	60 days	^{125}I
Cobalt-57	122	270 days	^{57}Co
Technetium-99m	140	6.02 hrs.	^{99m}Tc
Indium-111	171/245	2.83 days	^{111}In
Iodine-131	364	8.07 days	^{131}I
Fluorine-18	511	110 min.	^{18}F

8 Potential Applications (Continued)

External applications
External gamma detection of an administered isotope can provide a noninvasive means of gathering important physiological and/or anatomical information. Some examples are: detection and localization of blood clot formation using I-125 or In-111 labeled platelets; evaluation of thyroid function by measuring radioactive iodine uptake; evaluation of skin or skeletal muscle blood flow using Xe-133; diagnosis of testicular torsion using Tc-99m; trancutaneous scanning for localization of sentinel lymph nodes.

Most of the protocols for external gamma detection techniques were originally designed to accommodate large, highly collimated scintillation detectors ("gamma cameras"). Therefore, minor modifications to standard protocols may be necessary when using the Neoprobe hand-held gamma detecting probe. It is the user's responsibility to determine the suitability of the **neo2000®** device for use in any procedure which may be of interest. However, Neoprobe Corporation may be contacted regarding any questions concerning an intended use of **neo2000** device for help in this determination.

Intraoperative applications
Various radiological and nuclear medicine procedures guide the surgeon during an operation, particularly in the localization, identification, and removal of a lesion. Localization occurs through the injection of a radiolabeled antibody or radiopharmaceutical with subsequent concentration in the area of a lesion. Detection during surgery occurs through the use of **neo2000** device to detect the localization. Excision of the lesion is then performed using standard surgical techniques.

The **neo2000** device overcomes one of the most significant limitations to lesion detection: the inability to place a gamma detector at the site of the radioactive source. The inverse square law which governs the detection of radiation from a small source is the central consideration. The inverse square law basically states that the number of gamma rays detected increases as the distance between the source of radioactivity and detector is decreased. By placing the detector probe immediately adjacent to a radioactive site in a way that is not possible with a scintillation camera, the number of counts detected increases and localization is enhanced.

Therefore, the portability and maneuverability of the **neo2000** detector allow the surgeon to gather important intraoperative information not readily available from large scintillation cameras. General descriptions of some intraoperative applications are given below. Because of the variety of radiopharmaceuticals available to the user, it is the responsibility of the physician to determine the suitability and clinical utility of the radiopharmaceutical or radiolabeled compound to be used, as well as the actual protocol for administering the drug and using the detector intraoperatively.

8 Potential Applications (Continued)

Intraoperative localization of lymphatic pathways and lymph node basin
Lymphoscintigraphy is a common medical procedure employed to define the lymphatic flow from a site of injection through the lymph channels to lymph nodes. As a complement to, or an alternative to lymphoscintigraphy, the **neo2000®** device may be useful in assisting a surgeon in the localization of regional lymph node basins draining a lesion site. This allows the surgeon to identify areas within the lymphatics where a biopsy of tissue may be taken to determine the histological status of lymph nodes.

Minimally invasive radioguided parathyroidectomy
A preoperative Technetium-99m-Sestamibi scan may be used on patients with primary hyperparathyroidism to localize the target parathyroid adenoma and enable limited exploration as an alternative to complete bilateral surgical exploration. The **neo2000** device may be useful in assisting the surgeon in the intraoperative localization of the target adenoma. The **neo2000** can be used to detect and localize the increased uptake of Technetium-99m-Sestamibi by the hyperparathyroid gland.

Evaluation of ischemic bowel
Strangulation of the gut is a cause of an ischemic bowel. The surgeon must revascularize it and then determine its viability as part of the surgical protocol. Determination of the viability of an intestine with poor blood supply is a problem that the surgeon faces frequently. The choice of the point of the resection is critical. Optimally, it will allow the surgeon to preserve as much intestine as possible to maintain good absorptive capacity while avoiding an anastomotic breakdown with its possibly fatal outcome.
The **neo2000** device can be used to detect the intra-arterial distribution of Technetium 99m labeled red blood cells as a means of determining if the gut is reperfused. Other tracers, such as Technetium 99m labeled DTPA for perfusion or Technetium 99m labeled pyrophosphate for muscle infarction, may require investigational drug status for this application.

Perfusion of anastomosis–assessment of compromised blood flow
When a surgeon creates an anastomosis, it must be determined that each side of the anastomosis has adequate perfusion; otherwise, the anastomosis will fail, and leakage will occur. A high degree of morbidity is associated with this failure.

The **neo2000** device gives a surgeon the opportunity to assess perfusion before and after creating the anastomosis.

Intravenous administration of stannous pyrophosphate followed by Technetium 99m automatically labels red blood cells in vivo. The labeled cells can be detected with the **neo2000** device, and blood flow to the anastomotic ends and across the anastomotic juncture can be verified.

Intraoperative localization of osteoid osteomas

Osteoid osteoma is a small, but painful, benign bone lesion. Surgical excision is curative. Modern radiographic techniques externally image the lesion with Technetium 99m labeled pyrophosphate. However, because of their size (rarely greater than 1 centimeter) and location within the cortical bone, it may be difficult for the surgeon to localize the lesion intraoperatively.

The **neo2000** device may be useful in localizing the lesion site intraoperatively. Additionally, checking the high concentration of radioactive isotope in removed bone fragments provides evidence that the nidus is being excised.

9 Equipment Classification and Description

Classification:

Type of protection against electrical shock:	
Control Unit	Detachable cord
Degree of protection against electrical shock:	
Applied Part:	Type BF
Protection against the harmful ingress of liquids:	
Console	Ordinary equipment
Models 2001, 2002, and 2003	IPX4
Protection against explosion:	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE
Mode of operation:	Continuous operation

The **neo2000®** Gamma Detection System complies with the requirements of domestic and international regulatory agencies.

Use only detachable power cords that comply with one or more of the following agency approvals, as indicated:

100VAC/50-60Hz	Dentori
125VAC/60Hz	CSA, UL
250VAC/50Hz	ASTA, CEBEC, CCEE, DEMKO, FIMKO, IMQ, KEMA, LCIE, NEMKO, OVE, SECV, SEMKO, SEV, VDE.

10 Notices

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