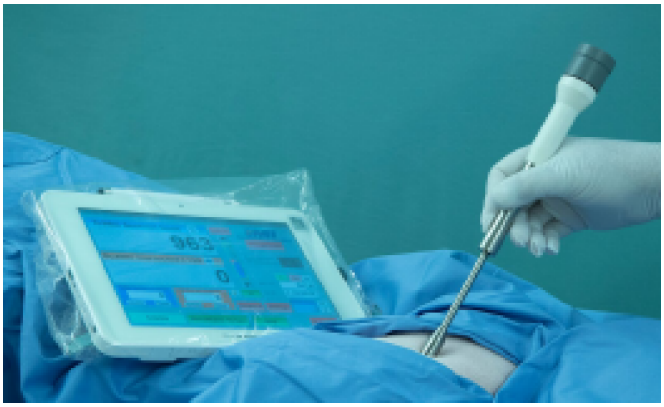
Node Seeker™ 2000
Operator's Manual

Document LC-0002Revision 3.0



Advanced Technology for Detection of Tumors and Lymph Nodes

For Service please call Intra-Medical Imaging at 1-844-426-6277
www.gammaprobe.com

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Section-1: Warnings

Please read this manual and follow its instructions carefully. The words **CAUTION, WARNING** and **NOTE** convey special meanings. When they are used throughout this manual, they should be carefully reviewed to ensure the safe and effective operation of this product.

CAUTION: A CAUTION indicates that particular precautions or service procedures must be followed to avoid possible damage to the product.

WARNING: A WARNING indicates that the personal safety of the patient or physician may be involved. Disregarding a WARNING could result in injury to the patient or physician.

NOTE: A NOTE indicates special information to improve the ease of maintaining the product, or to clarify important information.

⚠ The symbol of an exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the product's accompanying documents.

⚠**WARNING:** Read this instruction manual thoroughly and be familiar with its contents prior to using this equipment. Read the instruction manual completely before assembling or connecting the equipment.

⚠**WARNING:** Test this equipment prior to each surgical procedure or test the instrument for proper operation before use.

⚠**WARNING:** Turn the POWER OFF after turning off the probe. It is recommended that the probe battery be charged before and after use.

Usage

Only properly trained and qualified personnel should use the Intra-Medical Imaging (IMI) Node Seeker™. This device may be used under most hospital or physician office environmental conditions. Electro-cautery and other electro-surgical devices may interfere with the operation of the Node Seeker™, and X-Ray producing devices are likely to cause false counts. Do not use these instruments simultaneously with NodeSeeker™.

Electrical

There are no user-serviceable parts in the Node Seeker™. Only properly trained and qualified personnel authorized by IMI are permitted to access any internal parts.

Refer to Maintenance/Service at section 8 of the manual for detailed instructions.

Sterilization

The Node Seeker™ Control Unit **cannot** be sterilized or immersed for cleaning. Doing so may **cause permanent damage** to the unit.

The probe shall be sterilized in the Sterrad 100nx standard cycle or Steris V_PRO (see section-9). Alternatively, the probe can be placed in pre-sterilized probe jackets.

Cleaning of Probe and Control Unit

See Section 9.

Operational Warning

The Node Seeker™ has not been qualified for use outside the stated operating temperatures of 50º to 104 ºF (10º to 40 ºC).

Do not store the Node Seeker™ near a heat source or in any location where extreme heat, cold or dampness may be encountered.

The Node Seeker™ Control Unit should not come in direct contact with other electronic equipment during use.

Radiation Handling

This device does not generate any hazardous radiation, it is designed to detect various radioactive materials. When using radioactive isotopes or compounds, safe and proper handling techniques should always be observed. Refer to the institutional Radiation Safety Officer (RSO) regarding Nuclear Regulatory Commission (NRC) or equivalent requirements.

⚠**WARNING:** This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class A/B and EN 60601-1-2:2000). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and may radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
- Consult the manufacturer or field service technician for help.

NOTE: Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

⚠WARNING: This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.

⚠WARNING: Ground reliability can only be achieved when the equipment is connected to "Hospital Only" or "Hospital Grade" receptacle (i.e., approved for use in an operating room environment). Routinely inspect electrical plug and cord. Do not use if inspection reveals damage.

⚠WARNING: The electrical installation of the relevant operating room must comply with the applicable IEC, CEC and NEC requirements.

⚠WARNING: To reduce the risk of electrical shock, do not open the equipment's housing. Refer servicing to qualified personnel only. Removal of panels by unauthorized personnel will void the unit's warranty.

⚠WARNING: Read relevant sections of this manual before conducting any of the above operations. Disconnect power to the system before conducting any regular maintenance.

⚠WARNING: Keep out of reach of patients.

CAUTION: Federal law restricts the sale of this device on the order of a physician.

CAUTION: Do not store liquids on or above this system.

User Qualification

Only Physicians and medical assistants who have a corresponding specialized qualification and who have been instructed in the use of the equipment may use the equipment.

Safety precautions at the site of installation:

The Node Seeker may only be used in medical rooms installed according to applicable national standards.

Safety Precautions to be Considered When Operating the Equipment:

During use of this equipment, the patient must be treated and kept under observation with the usual medical care. This includes checking the progress of treatment, as well as monitoring sterile application conditions where required by the type of intervention.

The standard protocol for sentinel lymph node mapping recommends injection of radioactivity *and* blue dye into the tumor region. IMI strongly recommends this practice be followed when using the Node Seeker so that, in the unlikely event that the probe stops working and detection of radioactivity is not possible, the surgeon can use visual inspection of blue dye to find the sentinel lymph node.

Test the instrument for proper operation before use.

Should any liquid or solid object fall onto the system, unplug the unit and have it checked by qualified personnel before any further operation of the equipment. To disconnect the cord, pull it out by the plug. Never pull the cord itself. The wall outlet should be near the unit and easily accessible. The unit is not disconnected from the AC power source (main) as long as it is connected to the wall outlet, even if the unit itself has been turned off.

Allow adequate air circulation to prevent internal heat build-up. While the equipment is on, do not cover it or place the unit near materials (e.g., curtains, draperies) that may block the ventilating air circulation. Leave space of more than 10cm (4 inches) between the wall and the unit. Be aware that room heat rises to the ceiling; check that the temperature near the installation location is not excessive. Do not install the unit in a location near heat sources such as radiators or air ducts, or in a place subject to direct sunlight, excessive dust, or humidity, mechanical vibration or shock. To avoid moisture condensation, do not install the unit in a location where the temperature may rise rapidly.

To avoid electrical shock, do not attempt to open equipment. Refer servicing to qualified personnel only.

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EXPLANATION OF SYMBOLS:

	Alternating Current
	Attention, Consult Accompanying Documents
	USB Port
	Bluetooth ® Wireless Technology

Section2: Introduction

General Description

IMI has developed a series of radiation detection probes for identification of radiolabeled tissue. These probes are intended for use in procedures such as localization of sentinel lymph nodes in patients with breast cancer and melanoma, or localization of radioactive seeds of I-125. These probes are considered **radionuclide uptake probes**, and are used after the patient is injected with a specific radiotracer, or a seed of radioactivity is placed inside the patient's body.

The mechanism underlying these probes is the most common technique for the detection of radiation, i.e. scintillator and photomultiplier. This technology is used in almost all nuclear medicine uptake probes and cameras.

The design of these probes is based on the principle of maximizing sensitivity and spatial resolution, while minimizing the size and simplifying the operation of the system. The use of a computer provides a flexible system for human interface, checking various functions of the system and gives a platform for systematic quality control and calibration.

IMI has designed and manufactured a series of probe detector heads that are compatible with the Node Seeker™ Control Unit. These probe detector heads are either single detector probes for detection of gamma or beta rays, or dual detector probes for simultaneous detection of beta and gamma rays.

The electronics and data acquisition system (Control Unit) are contained in an enclosure. The Node Seeker™ 2000 model is equipped with a medical-grade computer (Cybernet Manufacturing; Model: CyberMed T10C). This computer was tested and approved in accordance with Standard UL-60601-3.

Wireless Gamma Probe for Low Energy Gamma Rays

(e.g. 140 keV emitted from Tc-99m, or 30 keV x-ray emitted by I-125)

This probe uses a scintillator and solid-state photomultiplier. The scintillator is shielded from detection of gamma rays coming from the sides or the back of the probe. A collimator allows entry of gamma rays only from the front of the probe. The solid angle of view of the probe is restricted such that full width at half maximum of the counts generated from a source at 5 cm distance is 50 degrees.

Control Unit

⚠**WARNING:** Accessory equipment connected to the analog and/or digital interfaces (signal inputs and signal outputs) must be certified according to the respective IEC/EN standards (i.e. IEC 950/EN60950 for data processing equipment and IEC 601-1/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anyone who connects additional equipment to the signal input parts or signal output parts is configuring a medical system, and is therefore responsible for that system's compliance with the requirements of the system standard IEC 601-1-1.

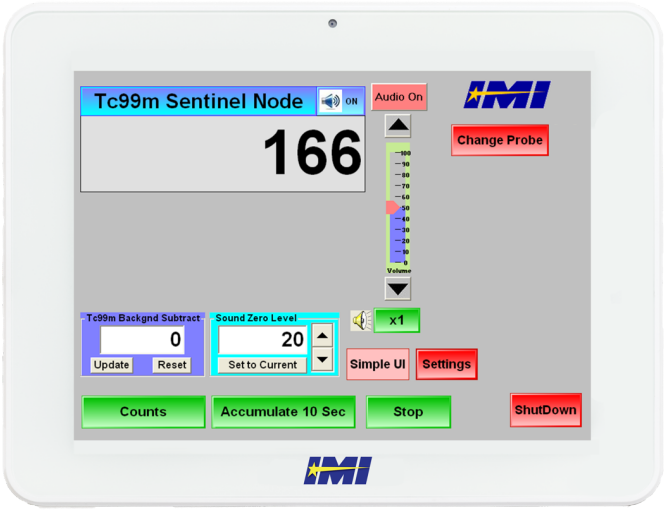


Figure 1: Front view of the Control Unit sowing the simplified user interface.

Section3:Operational Precautions and Limitations

General

This section outlines precautions that the user must observe and any limitations of instrument performance.

Before Use

Before using the instrument, it is imperative that you first become acquainted with how the instrument operates and is controlled. Please read this Operator Manual completely before starting to use the Node Seeker™.

If the unit is not operating, ensure that the power cord is connected properly and the Unit has been activated with the power switch.

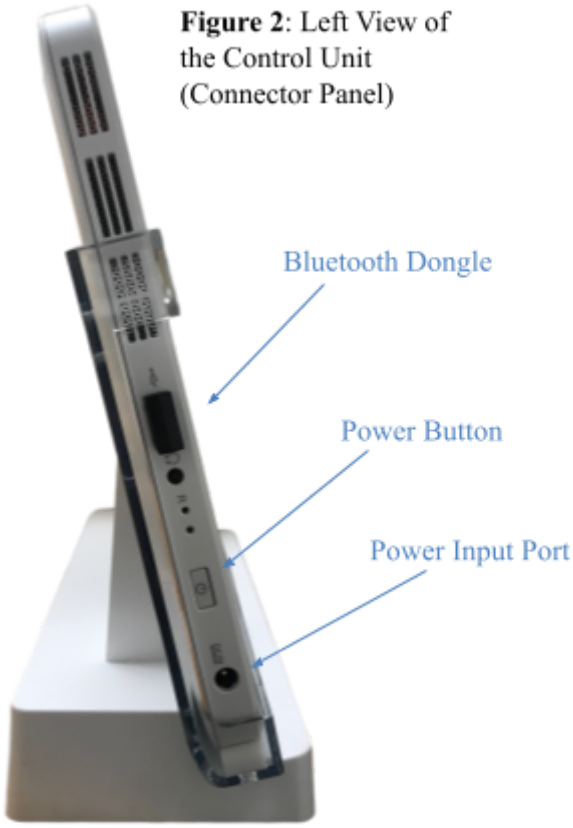


Figure 2: Left View of the Control Unit (Connector Panel)

Power Source for the Probe

The probe is powered by a one-time-use (non-rechargeable) Lithium type 123 battery. The battery can be installed by twisting off the gray battery housing located at the bottom of the probe.

During Use

1. Always move the detector probe slowly and carefully while scanning and positioning it close to the patient. It is recommended to use a scanning rate of about one centimeter per second.

Be alert for abnormal operations (e.g. zero, constant, or erratic very high counts). If abnormal operation is suspected, use of the Node Seeker™ for clinical applications is contraindicated. Discontinue use of Node Seeker™ if this occurs. Refer to Appendix A, Troubleshooting, which lists problems with possible causes and solutions.

2. Important: The detector probe is delicate. Avoid bumping or denting it. Dropping the detector probe may permanently damage it.

3. When using the Node Seeker™ device for intraoperative applications to detect and localize lesions, the surgeon should re-scan resection margins to determine if all desired targeted

tissues have been removed.

4. The Node Seeker™ is most sensitive for sources that are close to the detector probe. For deeper sources, the count rate is lower due to tissue attenuation and the Inverse Square Law.

5. When using the Node Seeker™ with tumor-specific targeting agents, such as radio-pharmaceuticals, maximum sensitivity is achieved when a minimum amount of background activity is present. Efforts should be made to wait for clearance of non-target activity to occur by normal bodily processes. In cases where a patient may have undergone previous diagnostic or therapeutic nuclear medicine procedures, or there is suspicion of obstructions in the kidney or bladder, the physician should monitor the patient for extremely high background counts. Use of this device in the presence of extremely high background counts is contraindicated, as this high background activity may mask small lesions.

Section4: Setup and Installation

Carefully unpack all components of the Node Seeker™.

Verify that the USB dongle is in the USB Port of the Control Unit.

Ensure that the probe is powered "on" prior to use; the red and green LEDs on the probe should flash. Replace the battery if neither LED flashes.

Connect the probes using Bluetooth® wireless technology. If you have obtained the Node Seeker™ and probes together, all probes are pre-calibrated with the Control Unit they shipped with. Before using the probes for the first time, verify that the probes are calibrated. Otherwise perform the calibration procedure outlined in Section 6 titled "Calibration."

Clean/Disinfect probe prior to use by wiping the probe with an alcohol wipe. Do not immerse in alcohol or any other liquid.

NOTE: Node Seeker™ uses the Bluetooth® wireless technology to connect to the wireless probe. The dongle must be installed in the USB Port (See Figure 2) for the Control Unit to receive signals from the probe. If the LEDs light up on the probe and the Control Unit cannot detect the probe when the Node Seeker™ software is started, check the Bluetooth® wireless connection.

Initial Setup

This section describes how to prepare the Node Seeker™ Gamma Probe for its first use.

Unpacking: Carefully unpack the Node Seeker™, ensuring that all the following components and supplies were received undamaged:

Wireless Detector Probe

Control Unit

USB Dongle (installed in the Control Unit)

Power Cord, Hospital Grade

Operator's Manual

Section5:

Starting the Node Seeker™

Node Seeker™ Software: The Node Seeker™ software uses many of the same conventions as are used in the standard Windows operating system and software applications. If you are familiar with using a Windows™ based personal computer, you are probably already familiar with these conventions. Here are some things you need to know to work effectively with the Node Seeker™ software.

A small movable arrow is displayed on the computer screen while the computer is operational. This arrow is called the *cursor*, and it can be moved around the display screen by touching the screen at the location where you want the cursor to be.

Some features of the Node Seeker™ software are accessed via a *pull-down menu*. Pull-down menus are located in a *menu bar* near the top edge of the screen, just below the *title bar*, the blue-colored bar at the very top of the currently active window. To activate a pull-down menu, press the menu's title. The list of possible selections in that menu will be displayed. Press one of the selections in the list to activate that function.

Areas of the screen where you are asked to enter information, called *fields*, have a white background. Areas of the screen where the software displays information that you cannot change have a colored background. There are several ways to enter information into the Node Seeker™ software:

When a numerical value is requested, there will usually be small up/down arrows located just to the right of the field. You may press on the up arrow to increase the value in that field, or press on the down arrow to decrease it.

When you are asked to select one choice from a predetermined list of possibilities, a *drop-down*

list box is used. This is a field with a small downward-pointing arrow at its right end. Press on the arrow to display the list of possible choices, and then press on one of the possible choices to select it.

Starting the Node Seeker™: To start the Node Seeker™, perform the following:

Press the Power switch on the Control Unit. See Figure 2. The pilot light should light. If it does not, check the power connection to the Control Unit

Wait while the computer "boots up." It will boot directly into the *Probe Finder* applet. See Figure 5, below. At this time, the Control Unit is looking for any IMI Wireless Probe and the yellow highlight will cycle through the three notes.

Figure 5: Probe Finder Screen, Looking for Probe

Turn on the IMI Wireless Probe by pressing its power switch at the large end of the Probe. The green light in the Probe will begin blinking at a slow rate approximately one half second on and one half second off. This indicates that the Probe is looking for the Control Unit.

After a period ranging from near-zero to a few seconds, the Probe and the Control Unit will recognize each other. The Probe will respond with a brief flash of the green light at a one second rate (approximately 50 milliseconds on and 950 milliseconds off). The Control Unit will respond with an image of the probe type and its serial number on the screen as shown in Figure 6, below. If more than one probe is active within the range of the Control Unit, multiple images and serial numbers will appear. Irrespective of the number of Probes detected, press the image of the desired probe to select it for use with this Control Unit.

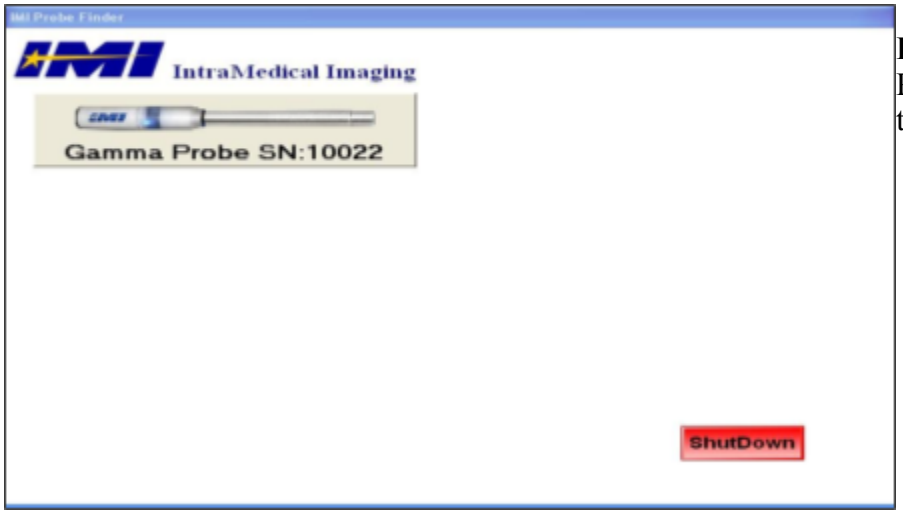


Figure 6: Probe Finder Screen, Probe Found, touch the icon of the probe on the screen to start.

When a Probe is selected (by touching the icon of the probe on screen), the Control Unit responds with the standard User Interface Screen, shown in Figure 7,below.

Figure 7: Wireless Probe User Interface Screen

The serial number of the active Probe is displayed on the title bar and after a few seconds, counting begins automatically. The User Interface screen is the "Home Base" for all Node Seeker™ operations. It displays the detected counts and the radioisotope used, along with other data related to the counts and the source radioisotope. There is a Volume Control and Mute switch for the audio tone which accompanies the counts and is approximately proportional to the count rate. Various available and active Probes may be selected with the *Change Probe* button. The *Settings* button allows the user to navigate to other screens to perform various Node Seeker™ operations. All these functions will be discussed in detail later in this document.

Using the User Interface Screen: The most commonly used functions can be adjusted from the User Interface screen, while other less frequently used functions are accessed with the *Settings* button.

Counting – Two buttons control counting: *Counts* and *Stop*. Pressing the *Counts* button enables counting, and is the default condition when the User Interface screen first appears. The numeric display(s) represent(s) counts per second, and are updated at the rate defined by the *Dwell Time*. Pressing the *Stop* button pauses counting and holds the last displayed counts on the screen.

Accumulated Counts – Pressing the *Accumulate 10 Secs* button causes counts to be accumulated for 10 seconds, and updated every 10 seconds irrespective of the *Dwell Time* setting. While in this mode, a yellow banner appears directly below the title bar identifying the accumulation mode with a count-down timer announcing the next display update. In Figure 8 at the right, there are four seconds to go until update.

This feature enables users to acquire a steady average count number. The average count number can be obtained by dividing the "10 Second Count" final display by 10.

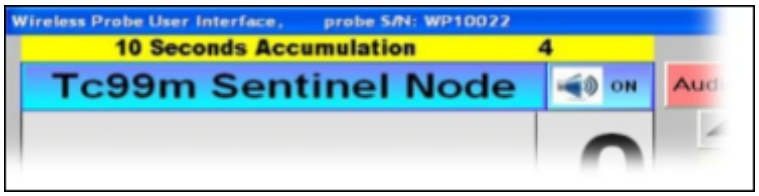
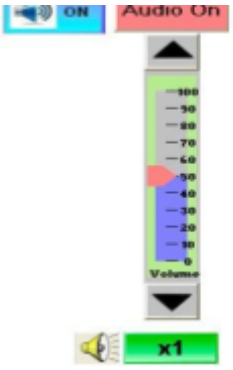


Figure 8: Accumulation Mode Banner

Volume Adjustment – The volume of the audio tone accompanying the counts can be adjusted in two ways, and muted in three ways. Above and below the volume slider are up and down pointing arrowheads. Pressing the up arrow increases the volume in 10% steps. Similarly, pressing the down arrow decreases it in 10% steps. There is a red pointer, the *Volume Indicator*, indicating the percent of maximum at which the volume is set, shown at 50% in Figure 9 at the right. The volume may be changed by large amounts quickly by pressing the *Volume Indicator* and dragging it to the desired position.



The audio tone may be muted by dragging the Volume Indicator down to 0%, by pressing the red button above the volume slider to cause it to read Audio Off, or by pressing the blue/white button, above and left of the slider, to cause it to read OFF.

x1/x10/x100 Button – Pressing this button repeatedly cycles through x1, then x10, then x100 and back to x1. The tone of the sound changes to higher frequencies if x10 or x100 are selected, thereby making identification of the maximum location easier.

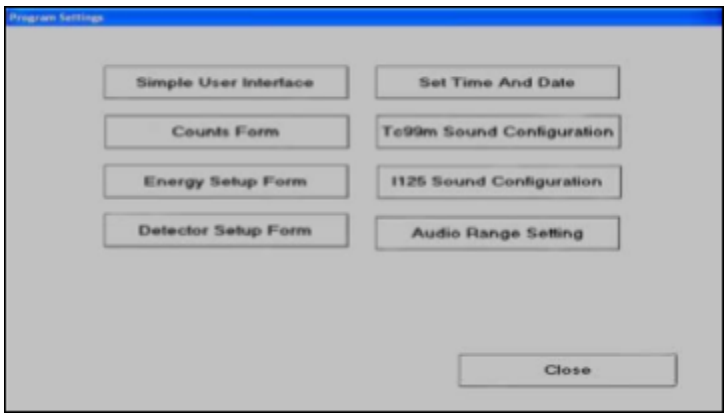
Figure 9: Volume control section in User Interface

Changing Probes – Pressing the *Change Probe* button generates a confirmation dialog box. When the user responds by pressing *Yes* (*I am sure*), the system goes back to the Probe Finder screen of Figure 5, allowing another selection to be made. Pressing *No* in the confirmation dialog cancels the operation and the same Probe remains in use.

Shutting Down the Control Unit – The function of the *ShutDown* button should be obvious. Pressing this button turns off the Control Unit (after the user responds in the affirmative to the confirmation dialog box). Note that any Wireless Probes in use must be turned off separately, with its/their own powers switch.

Using the Settings Button: Pressing the Settings button displays the Setup Selection screen. It is an array of buttons, each named for the setup function to be performed. Pressing one of the buttons displays the correct screen for the selected setup category. The Setup Selection screen is shown below in Figure 10.

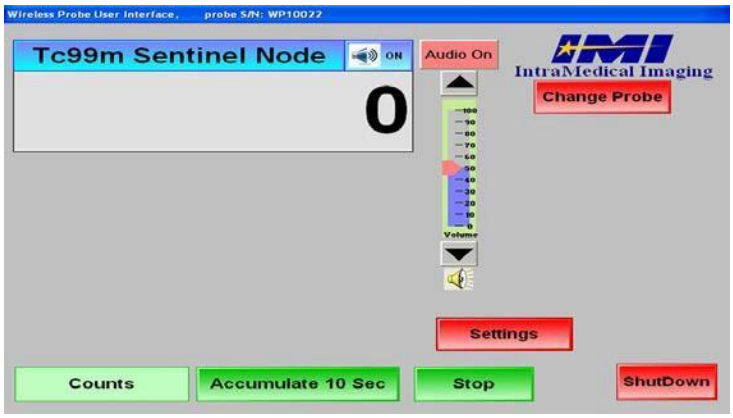
Figure 10: Setup Selection Screen



The Close Button – Pressing this button returns the user to the previously active User Interface screen.

Simple User Interface Button – Pressing this button removes some of the lesser used displayed information from the User Interface screen, leaving only the basic information required to use the Node Seeker™ system. The Simple Interface screen is shown below in Figure11.

Figure 11: Simple User Interface Screen



Counts Form Button - Pressing this button restores all of the displayable information to the User Interface screen, as shown in Figure7.

Energy Setup Form Button – Pressing this button displays the Energy Spectrum Chart and other associated information, along with several fields for the user to create a customized setup. The Energy Setup screen is shown below in Figure 12.

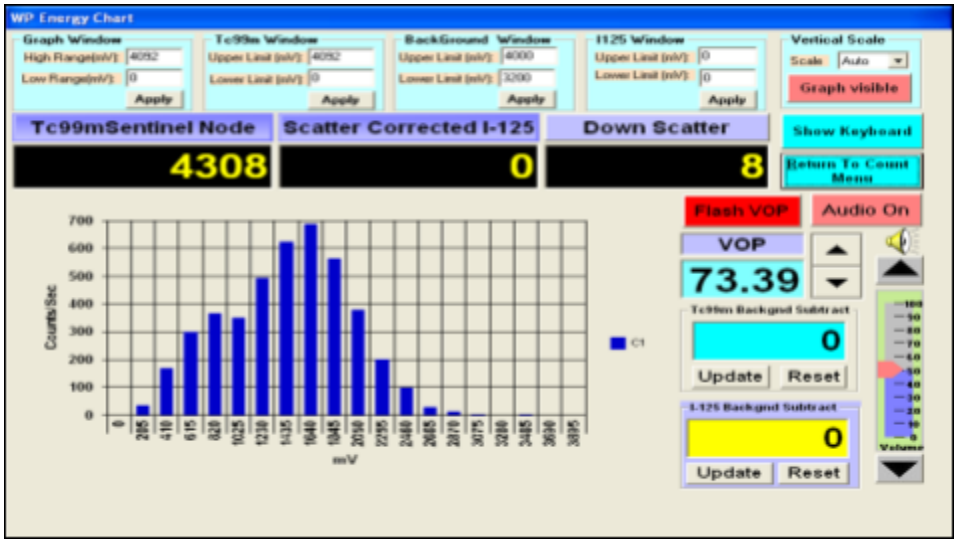


Figure 12: Energy Setup Screen for Co-57 radioactive source that emits gamma rays with 122 keV energy.

How to Set Graph Window Range:
Press the screen in the area of the "Low Range" field. A soft keyboard will appear. Erase the existing number by using the "Backspace" key then type "0". Now touch the "High Range" field and using the soft keyboard erase the existing number and the type 4095.

How to Set the Energy window for Tc-99m:
Note the channel that has the highest count. In Figure 12 it is the 1640 mV channel. Since the energy of the gamma rays of Co-57 that was used to generate the spectrum in Fig. 12 is slightly less than that of Tc-99m (140 keV), the "Low Range" of the Tc-99m energy window would be the channel before the maximum, i.e., 1435 mV, and the "High Range" two channels above the last readable channel of the Co-57 spectrum, i.e., 3280 mV.

How to Set Up the Energy Window for I-125:
Place a source of I-125 in front of the probe and acquire energy spectrum. Since the energy of the X-rays of I-125 is around 30 keV, then this spectrum would peak around 500 mV. Select the "Low Range" to be two channels below the maximum, and the "High Range" three channels above the maximum.

How to Set Up the Energy Window for Down Scatter of Tc-99m gamma rays:

The "Low Range is four channels above the maximum of I-125 spectrum, and the "High Range" is seven channels above the maximum of I-125 spectrum.

Detector Setup Form Button – The use of this function is reserved for IMI technical staff.

Set Date and Time Button – Pressing this button brings up the Windows Date and Time Properties dialog box. This is a tabbed dialog with the left tab used for setting date and time, the center tab facilitates selecting the user's time zone, and the right tab is not used as Node Seeker™ is not connected to the internet in normal use. The dialog box with the Date and Time tab active is shown at the right in Figure13.

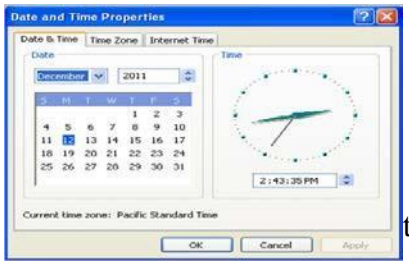


Figure 13: *Date & Time Dialog Box*

It is recommended to select the time zone first. Press on the center tab and select the correct time zone from the drop-down list, then press the Apply button. Next press the Date & Time tab. Select the month from the drop-down list if necessary, then adjust the year with the up/down arrows at the right edge of that field if necessary, then in the calendar page press the correct date unless it is already highlighted. Moving over to the digital clock field, press the hours to locate a cursor in that area and adjust to the correct setting with the up/down arrows at the right edge of that field. Then repeat that procedure with the minutes, seconds, and the AM/PM areas. Press the Apply button, then the OK button to close the dialog box.

Sound Configuration Buttons – There are two Sound Configuration dialog boxes: one for Tc-99m and the other for I-125. Pressing one of these buttons brings up the appropriate dialog, differing only in the isotope indicated in the title bar. They are represented in Figure 14, below.

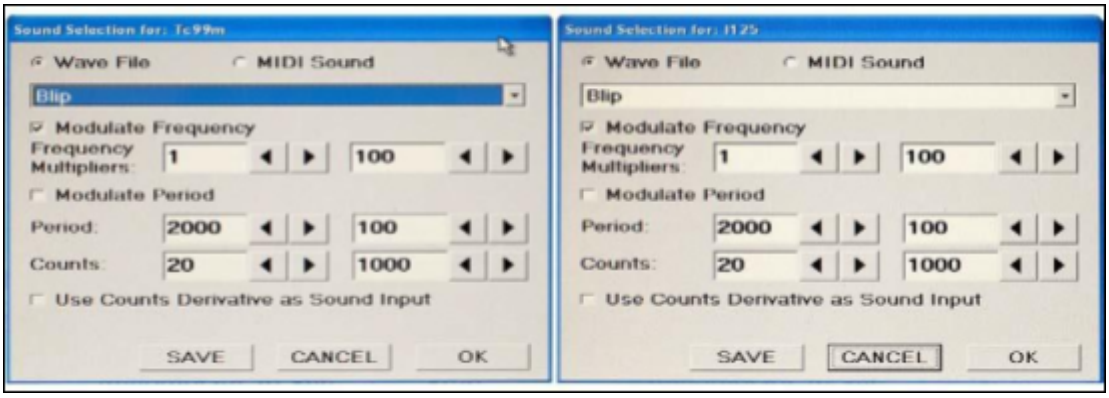
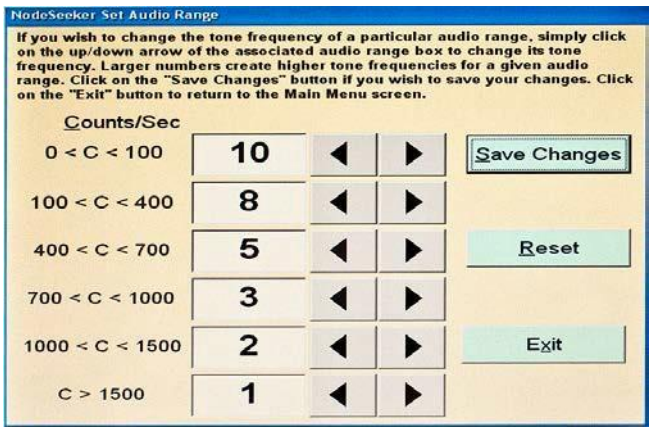


Figure 14: Sound Selection Dialog Boxes

As mentioned above, the two dialogs are identical except that the one on the left controls the sounds when Tc-99m is being used, and the one on the right controls the sounds for I-125. The user may select from a drop-down list of wav files or from a drop-down list of MIDI (musical instrument sound) files.

Audio Range Setting Button – Pressing this button brings up the Set Audio Range dialog box. In this case the instructions for use are at the top of the dialog shown in Figure 15,below.



Audio Sensitivity Adjustment

The frequency of the sound is proportional to the count rate.

Sound Frequency = (Sensitivity factor) × (Radiation Count-Rate) + 300

In order for the human ear to differentiate between two count-rates that are close to each other, for example 50 CPS versus 80 CPS, the Sensitivity Factor should be high (i.e. 7). Therefore:

Sound Frequency for (50 CPS) = 7 × 50 + 300 = 650 Hz and,

Sound Frequency for (80 CPS) = 7 × 80 + 300 = 860 Hz

When the Sensitivity Factor is set at 7, the ear can easily differentiate between 650 and 860 Hz.

If the surgeon wants to differentiate between 500 CPS and 600 CPS, a Sensitivity-Factor of 7 will result in very high pitch sounds that are not distinguishable by human ear. Therefore a lower Sensitivity-Factor is required (i.e. 3) resulting in:

Sound Frequency for (500 CPS) = 3 × 500 +300 = 1800 Hz and,

Sound Frequency for (600 CPS) = 3 × 600 + 300 = 2100 Hz

This difference is differentiated by human ear.

Section6: Clinical Operation

This section describes how to use the Node Seeker™ to assess radiation uptake of tissue during a clinical procedure. The following description assumes that a standard radioactive tracer has been administered and that it is desired to assess uptake of this tracer by tissue intraoperatively.

Preparation: To prepare the Node Seeker™ for clinical use, perform the following steps:

Interpreting the Count Rate Displays: While the Node Seeker™ is counting, the large count rate displays on the User Interface screen show the current measured count rate, in counts per second, as sensed by the handheld probe. These displayed count rates are adjusted by subtracting the current Background Count Rate from the "raw" count rates actually measured by the probe, resulting in displayed values that are the count rates above background. In case the background (shown on the small box) is zero, then this is the actual count rate (if Background Subtract display is activated).

The count rate is measured by accumulating the count during a time interval of 0.1 seconds, and divide it by this time interval to obtain the "count rate". The Smoothed Count Rate that is displayed shows the average count rate measured during several consecutive 0.1 seconds, known as the "Dwell Time". The length of the Dwell Time is user-adjustable, as described in the "Set Dwell" section. Note that the Dwell can be changed only when the system is not counting, that is, the Stop button has been pressed. If Dwell is set to 0.1 second (the shortest possible Dwell), the Smoothed Count Rate and Instantaneous Count Rate will be the same. If Dwell is set to a longer time value (such as 0.3 second), the Smoothed Count Rate display will be updated less frequently (every 0.3 seconds) and will be less reactive to rapid fluctuations in the measured radiation level.

When the Node Seeker™ is not counting, the Count Rate display retains its last displayed value from the end of the previous counting run.

Assessing Tissue Radiation Uptake: To use the Probe to assess tissue radiation uptake, perform the following steps:

Press the button labeled "Counts". The Node Seeker™ begins counting and displaying the current count rate.

Move the handheld probe above the tissue of interest and observe the visually displayed Count Rate and/or the audio output, searching for peaks in the count rate that indicate areas of higher radiation uptake.

To survey a broader area, hold the probe at a greater distance from the tissue and move it more rapidly. Monitor the primary Count Rate display to help locate when a sharp peak has been observed and passed over.

Once an area of higher activity has been found, hold the probe closer to the tissue and move it more slowly, to better localize the tissue regions with peak activity.

Dynamically adjust the audio output style as needed during the procedure to obtain the best discrimination between true activity peaks and statistical count-rate fluctuations. To adjust the Dwell, counts must be stopped, Dwell adjusted, then restart counts.

To stop or suspend the assessment process, press the button labeled “Stop” on the User Interface screen. The Node Seeker™ stops measuring and reporting count rate, and the Count Rate displays retain their last measured count rate values.

Ending Clinical Use: To end a clinical use session and shut down the Node Seeker™, perform the following steps:

To exit from the Node Seeker™ software completely and shut down the Node Seeker™, press the button labeled “Shut-Down” on the User Interface screen. The Control Unit will then complete power down.

Power off the wireless probe by pressing the button at the large end of the probe.

- **If sterile drape was used, remove it safely and discard it properly. Note if there is any puncture on the sterile drape or if there is any blood mark on the unsterilized probe. If yes, report to the surgeon as soon as possible that the sterility was broken.**

Regardless of using the sterile drape or sterilizing the probe before use, clean it with an alcohol wipe, or other equivalent or better disinfection method.

Section7: Hazards

General

The operator should observe all prescribed safety precautions when handling radioactive materials.
Do not attempt to 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 the USB dongle is securely attached before use.
2. Inspect probe before use.
3. Before cleaning or decontamination procedures are performed, turn off the power of the Control Unit.

Mechanical

DO NOT DROP THE PROBE. IT IS SENSITIVE AND FRAGILE.

Fire/Explosion

The Node Seeker™ 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, inform the local authorities.

To report any incident or injury that occurred while using Node Seeker™ please call IMI Customer Service immediately using the following numbers **(310) 428-4101**.

Section-8: Maintenance and Service

There is no requirement for regular maintenance of Node Seeker™ control unit or any of the gamma probes.

There are no user-serviceable parts in the Node Seeker™ Control Unit or Probes. Do not tamper with the system or any of its components. In case of any problem call IMI at 310-428-4101.

Routine quality control checks of the probes and control unit are described in section performance checks and calibration procedures have been described in this Manual to provide optimum performance.

The following tests are recommended and should be performed by the biomedical engineer of the hospital according to the local applicable regulation:

- Ground Continuity test is performed by using an ohmmeter to check continuity of the ground pin of the power cord and from a dead metal connector (or other dead metal point) to the power cord ground.
- Leakage Current Test – Enclosure leakage should be less than 100 microAmps. If this test fails, inform IMI at 310-428-4101.

SECTION-9: CLEANING AND DECONTAMINATION

WARNING: Do not clean when energized. Take the battery out and close the battery cap of the probe before cleaning. The probe shall be sterilized in the Sterrad 100nx standard cycle, or Steris V-PRO.

WARNING: Do not sterilize the control unit or immerse it in fluids. Attempting to do so may cause permanent damage.

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

STERRAD® 100NX™ Sterilization Cycle for the wireless gamma probe

The STERRAD 100NX Sterilization Cycle consists of two phases: Exposure 1 and Exposure 2.

The following information provides a brief description for each of the steps.

Exposure 1

- Delivery 1: The hydrogen peroxide is transferred via vacuum from the cassette into the vaporizer.
- Vaporization Pump down 1: The pressure within the chamber and vaporizer/condenser is reduced. Water is removed from the hydrogen peroxide solution, leaving behind a concentrated hydrogen peroxide solution in the condenser.
- Chamber Pump down 1: The chamber is isolated from the vaporizer/ condenser. The chamber pressure is reduced to remove air from the lumens.
- Transfer 1: The concentrated hydrogen peroxide solution is transferred to the chamber where it penetrates throughout the load.
- Diffusion 1: Chamber pressure is increased in order to drive hydrogen peroxide through the load packaging onto the surfaces of the devices and into the lumens of the load.
- Plasma Pump down 1 / Plasma 1: Plasma power is applied to the electrode screen and the plasma is lit.
- Vent 1: The chamber is vented to atmospheric pressure.

Exposure 2

The steps in Exposure 1 are repeated.

Cleaning process for Node Seeker Control Unit

1. Prepare a mixture of gentle kitchen-use detergent (one that does not contain abrasive powder or strong chemicals such as acid or alkaline)
2. Use water: detergent in ratio 5:1. Absorb the diluted detergent into a sponge.
3. Squeeze excess liquid from the sponge.
4. Wipe the surface with the sponge, using a circular motion and taking care not to let any excess liquid drip.
5. Rinse the sponge with clean running water.

6. Wipe the surface with a clean sponge.
7. Wait for the surface to dry completely and remove any cloth fibers from the computer surface.

SECTION-10: Quality Control

For Tc-99m a 10 microCi source of Cobalt 57 (CO-57) is placed in a tungsten cylindrical container.

This container shields workers from receiving radiation. The probe is inserted into this container and stops at 5 mm about the radioactive source.

1- Place the probe inside the tungsten tube
2- On the main menu, select 10 second accumulated counts
3- Write the count rate in the log sheet
4- Repeat three times.
5- Take the average of the three counts.
6- Decay correct the average count rate to the date written on the quality control source. Log this on the quality control log sheet.
7- If the recently decay-corrected count rate is within 10% of the original quality control count rate done in the factory, or done after energy window calibration (section 5), then the probe is accepted for operation. If not, perform a new energy window calibration (section 5) and repeat QC. If the energy calibration graph (Fig. 12) does not show a clear peak, then the probe is damaged and IntraMedical must be contacted.

Quality Control Report:

10-second Accumulation: _____

10-second Accumulation: _____

10-second Accumulation: _____

Average Accumulation Counts/10 s: _____

Original Activity of Isotope Source (N_o) _____

Isotope Creation Date (t_0): _____

Current Date (t_C): _____

Isotope Half-Life ($t_{1/2}$) (for Co-57=270 d): _____

Number of Half-Lives Expired ($T=(t_c - t_0) / t_{1/2}$) _____

Calculated Isotope Strength ($Nc=N_o * (1/2)^T$) _____

Average Accumulation / Calculated Strength: _____

Signature: _____

Print Name: _____

Appendix A: Troubleshooting

Symptom	Possible Cause	Corrective Action
Unusually high or zero counts observed.	Probe is not communicating with Control Unit.	Check Probe power and battery.
	Electrical interference source (X-ray, electro-cautery device, etc.).	Find source of interference and turn off if possible.
	Probe is contaminated.	Decontaminate the probe.
	Background level is too high.	Reduce background radiation or re-orient the probe.
Intermittent and unusually high readings.	Damaged probe.	Contact IMI*.
Continuous unexpected high readings.	System is not calibrated.	Re-calibrate the system.
	Background level is set too high in probe software.	Zero background (See Section 8).
Unexpected low readings.	Improper connection.	Contact IMI*.
		Check for proper connections.
No audio output, no sounds.	Volume off or system is set for silent operation	Turn sound mode on. Adjust sound volume.

Appendix B: Specifications

Count Display……CPS refreshed as low as every 0.1 sec.
Timed average over a dwell time, i.e. 0.7 sec. (CPS)
Energy Discrimination…….Selected on a graph of the acquired spectrum (15 to 600 keV)
Isotope Selection……Preset with variable windows
Audio Guidance……User selectable preset options include:
a) Variable Frequency Clicks
b) Variable Frequency Tones
c) MIDI Instrument Sounds
d) Peak Count Alert
Probe Dimensions…….Diameter at the tip = 13 mm
Overall Length = 280 mm
Probe Configuration…….Straight, 20 degree angled

Sensitivity……250 CPS/μCi (Co-57 at 1cm distance)

Sterilization……Sterile disposable drapes are available
Quality Assurance…….Automated QA Program with QC data retention
Power Rating……110-120/220-240V~, Max 0.75A, 50/60Hz
Classifications per IEC60601-3, EN60601-1, UL2601-1, and CSA C22.2 No. 601.1 Type of Protection against Electric Shock – Class I Equipment
Degree of Protection against Water – Ordinary
(IPX0) Mode of operation – continuous
Not suitable for the use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Storage/Shipping Conditions:
Humidity: 10 to 90% (non-condensing)
Temperature: -4º to 140ºF (-20º to 60ºC)
Atmospheric Pressure: 50kPa to 106kPa

Operating Conditions:
Temperature: 50º to 104ºF (10º to 40ºC)
Humidity: 30 to 75% (non-condensing)

Certification of Safety Testing

GENERAL REPORT SUMMARY

This product safety test report is generated by Compatible Electronics Inc., which is an independent testing and consulting firm. The test report is based on testing performed by Compatible Electronics personnel according to the measurement procedures described in the test specifications given below.

The measurement data and conclusions appearing herein relate only to the sample tested and this report may not be reproduced without the written permission of Compatible Electronics, unless done so in full. This report is issued errors and omissions exempt. This report can be subject to withdrawal, or alteration at Compatible Electronics' discretion.

This report must not be used to claim product endorsement by NVLAP, NIST, any NRTL or any other agency of the federal government.

The client Equipment referred to in this Test Report was found to comply with the requirements of standard,

- IEC 60601-1 (3rd Ed.): 2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1: 2006 +A1: 2012 - Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- AAMI ES 60601-1:2005 +A1: 2012 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Deviations from IEC 60601-1:2005

Test Specifications covered by accreditation:

NVLAP® TESTING
NVLAP LAB CODE 200527-0

ilac-MRA

Relevant Product Safety Medical Requirements
IEC 60601-1 (3rd Ed): 2005

Test Specifications not covered by accreditation;

AAMI ES 60601-1:2005 +A1:2012
IEC 60601-1: 2005 +A1:2012

Certification of EMC Testing

GENERAL REPORT SUMMARY

This electromagnetic emission and immunity test report is generated by Compatible Electronics Inc., which is an independent testing and consulting firm. The test report is based on testing performed by Compatible Electronics personnel according to the measurement procedures described in the test specifications given below and in the "Test Procedures" section of this report.

The measurement data and conclusions appearing herein relate only to the sample tested and this report may not be reproduced in any form except in full, without the written permission of Compatible Electronics.

This report must not be used to claim product certification, approval or endorsement by NVLAP, NIST, or any agency of the federal government.

Device Tested:	Node Seeker Model: NS-2000 S/N: None
Product Description:	The EUT is a radioactive isotope detector used in the medical industry to analyze internal tissue.
Modifications:	The EUT was not modified in order to comply with the specifications.
Manufacturer:	IntraMedical Imaging, LLC 12569 Crenshaw Blvd. Hawthorne, CA 90250
Test Dates:	June 15, 19, 21, 29, 2017

Test Specifications covered by accreditation:

NVLAP® TESTING
NVLAP LAB CODE 200527-0

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Emissions and Immunity requirements
European Standards EN60601-1-2 and IEC 60601-1-2
EN61000-3-2 & EN61000-3-3

The specification EN60601-1-2 and IEC 60601-1-2 are product family Medical standards which references the following specifications:
EN 61000-4-2 and IEC 61000-4-2
EN 61000-4-3 and IEC 61000-4-3
EN 61000-4-4 and IEC 61000-4-4
EN 61000-4-5 and IEC 61000-4-5
EN 61000-4-6 and IEC 61000-4-6
EN 61000-4-8 and IEC 61000-4-8
EN 61000-4-11 and IEC 61000-4-11

Appendix C: Potential Applications for the NodeSeeker™

External Applications

External gamma detection of an administered isotope can provide a non-invasive 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; and diagnosis of testicular torsion using Tc-99mpertechnetate.

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 Node Seeker™ hand-held gamma-detecting probe. It is the user's responsibility to determine the suitability of the Node Seeker™ device for use in any procedure that may be of interest. However, IMI may be contacted regarding any questions concerning an intended use of Node Seeker™ 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 the Node Seeker™ to detect the localization. Excision of the lesion is then performed using standard surgical techniques.

The Node Seeker™ overcomes one of the most significant limitations in lesion detection: the inability to place a gamma detector at the site of the radioactive source. The inverse square law that governs the detection of radiation from a small source is the central consideration. The inverse square law 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 Node Seeker™ 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 intra-operatively.

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. The Node Seeker™ 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.

Appendix D: Node Seeker™2000 Error Codes

There are three error severity levels in the Node Seeker™ 2000 software:
"Warning" only, allows operation to continue.
"Critical" error, halts operation in progress but allow system to continue running.
"Fatal" error, forces system to shutdown.

There are 81 User-defined errors in the Node Seeker™2000 application as shown below. The error number posted in the error box for these 81 errors is equal to the error number item listed below + 2147221504 + 512. Each error will also have one of the three severities posted in its severity box.

1. 'Run method of TimeDispatcherfailed
2. 'Unrecognized switch on commandline
3. 'Invalid scheduled time assigned to a TimeDispatcherScheduledAction
4. 'Invalid scheduling interval assigned to a TimeDispatcherScheduledAction
5. 'Halt method of TimeDispatcherfailed
6. 'StartMonitoring method of PowerMonitorfailed
7. 'StopMonitoring method of Powermonitorfailed
8. 'System settings were missing orinvalid
9. 'System settings could not besaved
10. 'Invalid dwell time value entered byuser
11. 'Periodic DoTimedAction method of PowerMonitorfailed
12. 'AC Power detected on probe and/or PC during clinicaloperations
13. 'Probe offline condition detected (disconnected or poweredoff)
14. 'Invalid main formstate
15. 'StartCounting method of ClinicalOpsCtlrfailed
16. 'StopCounting method of ClinicalOpsCtlrfailed
17. 'PC hardware does not support PerformanceCounter
18. 'Attempt to access invalid calibration/QCdata
19. 'Invalid or unrecognized line in cal/qc log entryfile
20. 'Invalid or unsuccessful attempt to update main form statusflags
21. 'StartNewEntry method of CalQCLogfailed
22. 'SaveNewEntry method of CalQCLogfailed
23. 'Invalid background count rateapplied
24. 'GetCount method of ProbeHardwarefailed
25. 'Invalid poll interval detected during dataacquisition
26. 'Invalid dwell interval detected during dataacquisition
27. 'StopAll method of AudioOutputfailed
28. 'Unrecognized audio outputstyle
29. 'StartTone method of AudioOutputfailed
30. 'ToneSmoothness method of AudioOutputfailed
31. 'ToneSensitivity method of AudioOutputfailed
32. 'StartClick method of AudioOutputfailed
33. 'SingleClick method of AudioOutputfailed
34. 'SayNumber method of AudioOutputfailed
35. 'Initialize method of ProbeHardwarefailed
36. 'Invalid internal state detected in Cal/QCform
37. 'Invalid or out of range High Voltagesetting
38. 'Invalid or out of range Energy Window scan rangesetting
39. 'Invalid state detected for Energy Window count ratechart
40. 'StartScanning method of CalibrationCtlrfailed

41. 'StopScanning method of CalibrationCtlrfailed
42. 'StartSampling method of QCCheckCtlrfailed
43. 'StopSampling method of QCCheckCtlrfailed
44. 'Calibration data collection aborted, data setincomplete
45. 'QC data collection aborted, data setincomplete
46. 'Invalid QC isotope dateentered
47. 'Invalid time interval for an energy channel duringcalibration
48. 'StartCounting method of ProbeHardwarefailed
49. 'StopCounting method of ProbeHardwarefailed
50. 'GetEntryList method of CalQCLogfailed
51. 'FetchEntryText method of CalQCLogfailed
52. 'Unable toprint
53. 'Invalid Probe typedetected
54. 'SoundAlert method of AudioOutputfailed
55. 'PurgeEntries method of CalQCLogfailed
56. 'GetEntryByID method of CalQCLogfailed
57. 'Timeout waiting for DAC Busy status bit toclear
58. 'Bad status return from a Wave Audiofunction
59. 'Bad value supplied for audiblethreshold
60. 'Attempt to set or get invalid data for a Probeobject
61. 'invalid port number specified toProbeHardware
62. 'GetProbeList method of CalQCLogfailed
63. 'GetIsotopeList method of CalQCLogfailed
64. 'GetProbeInfo method of CalQCLogfailed
65. 'GetIsotopeInfo method of CalQCLogfailed
66. 'Invalid/unsupported number of portsreported
66. 'Invalid/unsupported number of ports reported byProbeHardware
67. 'No eligible active port wasselected
68. 'AddProbe method of CalQCLogfailed
69. 'ModifyProbe method of CalQCLogfailed
70. 'DeleteProbe method of CalQCLogfailed
71. 'Attempt to use or access invalid isotopedata
72. 'AddIsotope method of CalQCLogfailed
73. 'ModifyIsotope method of CalQCLogfailed
74. 'DeleteIsotope method of CalQCLogfailed
75. 'Duplicate probe entered for two or moreports
76. 'Bad step number during Nuclear Uptake Probesetup
77. 'Invalid subject name entered during Nuclear Uptake Probesetup
78. 'Invalid duration entered during Nuclear Uptake Probesetup
79. 'Invalid warning threshold during Nuclear Uptake Probe datacoll.
80. 'GetOperatorList method of CalQCLogfailed
81. 'GetSurgeonList method of CalQCLogfailed

There are thousands of Visual Basic and Windows errors that are also trapped through a general “On Error Go To” statement. Every procedure and function in the Node Seeker™ 2000 has, as a minimum, this type of error trapping. Many of the Node Seeker™ 2000 procedures and functions also trap one or more of the 81 user defined errors as well. The Visual Basic and Windows errors will be displayed in a similar error box, however the error numbers will start at 1 and go through several thousand. That is why the user defined errors start at 1 + 2147221504 + 512. “Error 91” is an example of a Visual Basic error.