1 Important User Notes

1.1 Manual

This manual includes notes and information concerning the general safety and function of the Gamma Finder®II. Read all notes in the manual very carefully and comply with the information provided by these notes when using the device.

Symbols / Abbreviations

See operating manual

General warning sign

Protection degree of the used part against electrical shock: Type B

IP41

Protection degree of the Gamma Finder®II

These paragraphs include information concerning the intended and proper use of the device or accessories.

Here you will read information about the maintenance of the device or the accessories.

BBP-Mode Abbreviation for **B**ackground/**B**inary **P**itch Mode

Important User Notes

1.2 General Description

The Gamma Finder®II is a device used for the pre-operative and intra-operative detection of radioactive labeled substances (gamma maker). This battery-operated and autonomous handheld device without cable connections and additional external console, is extremely easy to use. The Gamma Finder®II provides an acoustic and visual signal when detecting gamma radiation. The LCD displays the numerical value in counts per seconds.

Standard Operating Mode

The Gamma Finder® II switches automatically into SLEEP-Mode after five minutes of inactivity (corresponds to count rate < 10 cps) by showing SLEEP on the Display and switches off 30 minutes later.
The device can be switched on anytime by pressing any key and is then immediately ready for normal operation.
A change of state will be noticed with three short beeps

Additional Functions

Special software functions are available for certain applications. This includes, for example, the

- **"10-s Count"** and the
- **"BBP-Mode"**
  Note: Default mode is "inactive". Pressing the (B) key the display shows nobbP.
  It can be activated in the user menu by pressing 7 x (1) key followed by **" + ".**
  The function BBP-Mode is now available and can be started at any time by pressing the (B) key.

1.3 Safety Notes

Device Use

Only trained technicians and qualified personnel may use the device.

Federal Law (only for U.S. market)

U.S. law stipulates that this device be used only by a physician or under supervision of a physician.

No Liability

The manufacturer does not assume any liability for direct or consequential damages if:

- the device or the accessories are improperly used, prepared, or maintained;
- the instructions and rules in the manual are not adhered to;
- unauthorized persons perform repairs, adjustments, or alterations on the device or accessories;
- unauthorized persons open the device;
- the prescribed inspection and maintenance schedules are ignored.

Receiving technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments, or alterations on the device.

Authorized Service Technician

Only an authorized service technician may perform repairs, adjustments, or alterations on the device or accessories and use the service menu. Authorized service technicians are only trained and certified by the manufacturer.

2 Intended Use

Always use this device only in accordance with its intended use.

2.1 Scope of Application

The application scope of the Gamma Finder®II in the clinical field ranges from the pre- and intra-operative detection of radioactive labeled substances in tumor cells, lymph nodes and parathyroid glands. For example, among these are the localization of the first drained lymph node (sentinel node) associated with malignant melanoma (skin cancer), ductal carcinoma (breast cancer), and special applications such as operative localization and total or partial resection of osteroid osteoma (nidus) and parathyroid. For further information concerning the diagnostic or therapeutic methods and processes, please consult the comprehensive medical literature or continuous education and training courses.

2.2 Indications

The Gamma Finder®II is designed for the intra- and extra-surgical detection for concentration differences of radioactive pharmaceuticals in the energy range between 140 keV and 360 keV (e.g. 57-Co; 99m-Tc; 123-I; 111-In; 131-I).

2.3 Contraindications

Dosimetric applications, detection of radiation other than gamma and detection of radiopharmaceuticals with radiation energies outside the above listed range are contraindicated.

2.4 Use in Sterile Field

The sterile disposable sleeve or sheath provided by the company SenoRx has to be applied when using the Gamma Finder®II in the operating room. Only this special cover can ensure the flawless function and optimal handling of the device.

- The sterile disposable sleeve serves to protect the Gamma Finder®II from becoming contaminated.
- Please read the instructions enclosed with the sterile sleeves for information on how to use the sleeves. The Gamma Finder®II is not approved for sterilization. Non-compliance may diminish or eliminate the functionality and safety of the Gamma Finder®II.
- Always handle the sterile sleeve with care. Insert the Gamma Finder®II slowly and carefully into the sleeve. Avoid contact with sharp objects or continuous friction with hard objects.
- Use the white self-adhesive strip to close the sterile sleeve and to keep the Gamma Finder®II securely in place. Make sure the display and keys are still easy to access and functional.
- The sterile sleeve can be used on and in the human body and is not damaged by contact with tissue or blood.

2.5 Distance to Center of Activity

The count rate is inversely proportional to the square of the distance to the measured source. The Gamma Finder®II should therefore be moved as close to the assumed center of activity as possible.

2.6 Spatial Resolution

The count rate depends on the angle of the Gamma Finder®II to the center of activity.
Therefore, it is advisable within a series of measurements to change probe's tip position keeping the angle constant or to change the angle keeping the position constant. It is recommended to train on this technique using experiments on models. Only when the disposable sterile sleeve is used it is possible to clearly and accurately assess the position of the tip of the Gamma Finder®II in relation to the tissue. Universal covers do not fit this specific device and the bulkiness occurring in some areas reduces the effective spatial resolution.

2.7 Corruption of the Count Rates

With breast cancer sentinel node detection procedures, the lymph nodes to be localized are frequently located in close proximity of the injection site . The injection site having an activity many times greater than those of the lymph nodes it may be difficult to locate precisely

the nodes.
Therefore, lymph node activity is best determined by guiding the Gamma Finder®II so that the injection site activity is not within its angle of detection and is completely shielded by the collimator.

2.8 Count Rates Aquisition

The acoustic and visual count rate output serves as general qualitative orientation. The numerical signal displayed may be used for quantitative statements.

2.9 Electrical Interference

The Gamma Finder®II may not be operated near high-frequency (HF) systems, defibrillators, mobiles phones and X-ray equipments The device has been shielded against harmful interferences. However, you may in some circumstances still detect or suspect such interferences, please follow these suggestions:

- Move this device, the other one or both devices to a different location
- Increase distance between devices
- Consult an electro-medical expert

3 Operating the Device

3.1 Using the Gamma Finder®II

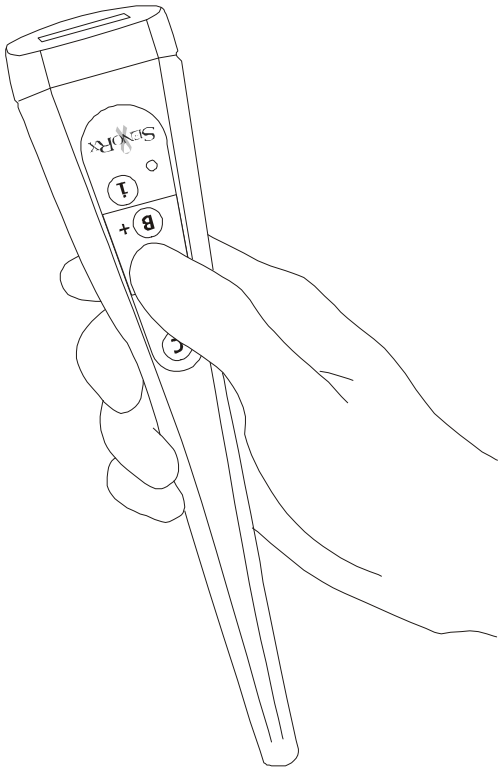


Fig. 3-1-1 How to hold the device during setup

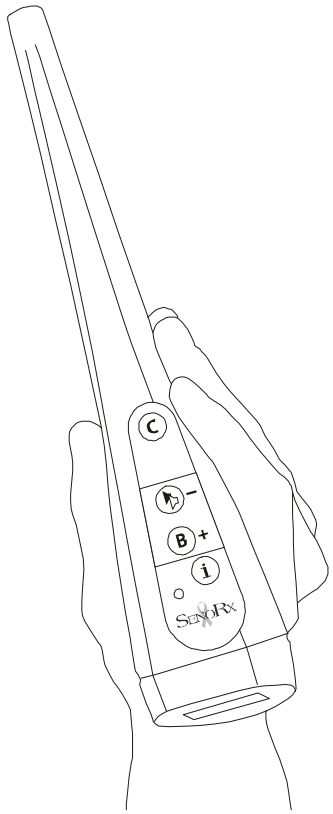


Fig. 3-1-2 How to hold the device during a measurement/surgery

3.2 Description of the Functions Assigned to the Keys

(C) Press this key to start the "10-s count"

Press this key to enable/disable the sound. A small loudspeaker symbol ◀ indicates on the LCD whether the sound is on or off. While in menu mode, this key has the function " **-** " (reduce value)

(B) Press this key to start the operating mode "Background/ Binary Pitch Mode" (BBP-Mode).
Note: Default mode is "inactive". Pressing the (B) key the display shows nobbP.
It can be activated in the user menu by pressing 7x (i) key followed by " **+** ".
The function BBP-Mode is now available and can be started at any time by pressing the (B) key.
While in menu mode, this key has the function "**+**" (increase value).

(i) Press this key to activate the menu mode to set different functions and parameters. Successive key press will access the different menu items. Use the " **+** " and " **-** " keys to change values in the respective menu items. The last set value is automatically activated and remains stored in memory after the device is switched off and on again.
Hold the device as shown in Fig. 3-1-1 "How to hold the device during setup", page 7.

Press 1 x (i) : Sets the acoustic dynamic. The symbol is shown on the display. This parameter's range, adjusted with the " **+** " and "**-** " -keys, is: 20, 40, 80, 160, 320, 640, 1280 and 2560.
Default value: 320

Press 2 x (i) **:** Sets volume. The loudspeaker symbol is shown on the display. This parameter's range, adjusted with the " **+** " and " **-** " -keys, is: 1, 2, 3, 4, 5, and 6 (max. value).
Default value: 6

Press 3 x (i) **:** Displays the remaining battery capacity as bar graph:
For example "ooooo" means full capacity and "____o" low capacity.

For more information please read chapter 3.11 "Battery Capacity Display", page 18.

Press 4 x (i) **:** "10-s Count" calculation mode. This parameter sets the calculation as an average of ten consecutive counts, shown as Std (Standard) or as a sum of the ten values which would be displayed as as totAL. To switch, use the " **+** " and " **-** " keys.

Press 5 x (i) **:** Switches LED on and off. Use " **+** " and " **-** " to change the status, which is indicated with On or OFF. When the LED is set to On the lamp symbol will be shown on the display during the standard operating mode.
Default value: OFF

Press 6 x (i) **:** Sets the calculation factor for the "Background/Binary Pitch Mode." The symbol bF represents the **B**ackground **F**actor on the display; use the "**+**" and "**-**" keys to select the factor to 0, 1, 2, 3, or 4.
Default value: 4

Press 7 x (i) **:** Switches the (B) key (BBP-Mode) on and off.
Use "**+**" and "**-**" to change the status which is indicated with b On and b OFF.

When switched to b On the BBP-Mode can be started in standard mode by pressing the (B) key twice

When switched to b OFF the BBP-Mode is deactivated and the dsplay shows nobbP by pressing the (B) key
Default value: b OFF

Press 8 x (i) **:** Displays "*RESET*" for Service only

Press 9 x (i) **:** Empty value

The device automatically returns to standard operating mode if no additional keys are pressed for about 5 seconds.

The Gamma Finder® II switches automatically into SLEEP-Mode after five minutes of inactivity (corresponds to count rate < 10 cps) by showing *SLEEP* on the display and switches off 30 minutes later.
The device can be switched on anytime by pressing any key and is then immediately ready for normal operation.
A change of state will be noticed with three short beeps.

3.3 Switching ON/OFF

Press any key to switch the device **on**. The Gamma Finder®II is immediately ready for use loading automatically the last set of parameters entered by the user (standard operating mode). The Gamma Finder®II will then detect continuously the gamma activity and display this activity with one measurement per second.
The Gamma Finder® II switches automatically into SLEEP-Mode after five minutes of inactivity (corresponds to count rate < 10 cps) by showing *SLEEP* on the display and switches off 30 minutes later.
He can be switched on anytime by pressing any key and is then immediately ready for normal operation.
If the device is set on "BBP-Mode", then the device will keep the background and binary mode parameters in memory for 30 minutes. Within those 30 minutes the device can resume its BBP measurements with the last calculated parameters once re-activated by pressing any key. The device resets automatically if switched off and will return to standard operating mode when switched on again.

A change of state will be noticed with three short beeps.

3.4 Display of Count Rates

The gamma radiation activity measured by the device is displayed once every second and its value is in cps/MBq.

Fig. 3-4-1 Example: Gamma radiation display

3.5 Switching Sound ON/OFF

Press the key to switch the acoustic feedback on or off. A small loudspeaker symbol on the LCD indicates whether the sound is activated or not.
Adjust the **volume** of the acoustic signal as described in chapter 3.6 "Adjusting Volume", page 12.
Setting the acoustic **dynamic** range impacts the characteristic of the acoustic signal; see chapter 3.7 "Adjusting Acoustic Dynamic", page 12 for additional information.

3.6 Adjusting Volume

While device is switched on, press the key twice and then use the "**+**" or "**-**" keys to set the desired value between 1 (minimum) and 6 (maximum).
Once set up, the device automatically returns to the standard operating mode after approx. 5 seconds.

3.7 Adjusting Acoustic Dynamic

Function principle:
The acoustic dynamic is used to adjust acoustic feedback or the **LED** flash rate to the level of activity. The beep frequency will be maximal when it is equal or superior to the acoustic dynamic range value.
For example, the setting x 160 means that only every 160th event is signaled with one LED flash or an acoustic signal with a rate of 1/s.
While the device is switched on, press the key once and then use the "**+**" or "**-**" keys to set the desired value. Once set up, the device

automatically returns to the standard operating mode after approx. 5 seconds.
The following table lists suggestions for setting the acoustic dynamic in function of the peak activity.

Value range (cps)	Dynamic setting	Application (example)
0-20	x20	--
0-50	x40	--
0-100	x80	Skin cancer
0-200	x160	Parathyroid
0-500	x320	Breast cancer
0-1000	x640	Breast cancer
0-2000	x1280	--
above 2000	x2560	--

3.8 Switching LED ON/OFF

In addition to the acoustic feedback, a visual feedback generated by an **LED** flash on top of the unit can be activated. The LED is enabled if a lamp symbol is shown the display.

- If needed, switch the Gamma Finder®II on by pressing any key.
- Then press the (i) key 5x.
- Press the "**+**" key to change the display from OFF to On.
- The lamp symbol appears in the display and the LED is enabled. The device automatically returns to the standard operating mode after approx. 5 seconds once the desired function has been adjusted.
- Follow the same steps to turn the LED **off** and set the display to OFF.

3.9 10-s Count

Function principle:
The "10-s Count" function once triggered runs automatically. During this process, ten individual activity measurements are stored and averaged. This generates a statistically verified average value of the activity. By default the average value is calculated based on the consecutive measurements with the smallest and greatest being taken off the average calculation.

For example, the values #3 and #6 in Fig. 3-9-1 would be removed from the average calculation.

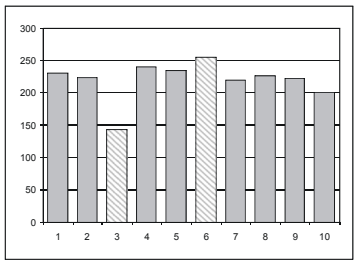


Fig. 3-9-1 10-s Count: Measuring series with 10 consecutive measurements resulting in an average 10s count of 220 (cps).

It is also possible to set the "10-s Count" mode to show the sum of 10 consecutive measurements. The result would then be 2197 (cps), in this example. If the calculated value exceeds the value 2^{16} (65536), an error symbol --E-- is shown on the display.

10s count sequence:

- Position of the (C) key on the Gamma Finder®II before starting the count (see Fig. 3-1-2 "How to hold the device during a measurement/ surgery", page 8).
- Press the (C) key and keep the Gamma Finder®II in position for the duration of the measurement (10 seconds) without moving your hand or the device.
- The word *count* flashes in the display every second. Acoustic feedback would still be audible.
- The result is then shown on the display for about four seconds accompanied by a short beep.
- The Gamma Finder®II returns to the standard operating mode after displaying the result.

3.10 Background/Binary Pitch Mode (BBP-Mode)

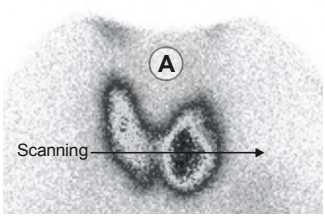
This function facilitates the finding of 99m-Tc maker in tissue areas where the background activity requires to be taken out of the measurement, e.g., when searching for "hot spots" in the thyroid or parathyroid gland localization procedures.
Default mode is "inactive". Pressing the (B) key the display shows nobbP.
It can be activated in the user menu by pressing 7x (1) key followed by **" + ".**
The function BBP-Mode is now available and can be started at any time by pressing the (B) key.

Function principle:
After the function has been triggered, the device calculates an average from five consecutive measurements of the background activity and then calculates the threshold above which the devices will emit an acoustic feedback or an LED flash. The relation between the background and threshold is an adjustable factor. When scanning "hot spots" only values exceeding this threshold will trigger the acoustic signal or the LED flash. The display shows the regular count rate without additional calculations for control purposes.
The adjustable factor bF (**B**ackground **F**actor) impacts the calculation of the threshold value in such a way that higher values raise the threshold and suppress lower activities from being visually or audibly detected.

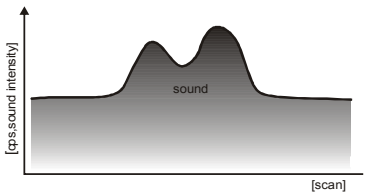
This function is especially intended for diagnostic applications used in such cases as hyperparathyroidism, for example. Since the acoustic display suppresses low active areas in "BBP-Mode", this function may not be used when searching for sentinel lymph nodes (breast cancer, malignant melanoma).

Operating the Device

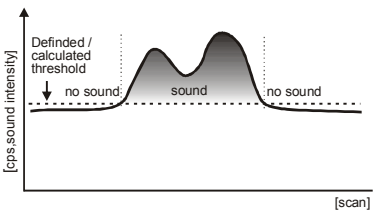
The following images and diagrams example the principle of the threshold limit:



Scintiscan of the human thyroid



Sound emission during the scan without "BBP-Mode"



Sound emission during the scan with "BBP-Mode"

"BBP-Mode" sequence

- Position the Gamma Finder®II onto the area where unspecified background activity can be assumed to exist such as the area (A) in the image of the scintiscan of the thyroid, for example.
- Press the (B) key. Device displays for 3 seconds:

  - bbP - or nobbP

  nobbP: The BBP-Mode has been deactivated in the user menu. To activate this function, press 7 x (1) and "**+**" to switch b OFF to b On.
  The BBP function is now available and can be started by pressing the (B) key in standard mode.

  - bbP -: Press the (B) key again to enter in the BBP mode. If (B) is not pressed again the device will return to the standard mode automatically after 3 seconds. The Gamma Finder®II enters the Background mode. Move the device with a Z scanning pattern, keeping the center of higher activity part of this pattern.
- Individual measurements are memorized for 5 seconds. The word count flashes in the display every second. When the 5 seconds are up stop the scanning.
- The device then shows the calculated threshold value (cps) for approx. 4 seconds.
- The Gamma Finder®II enters then the Binary mode and is ready for measurement again.
- In the Binary mode the acoustic signal is emitted only if the threshold value is exceeded. The value display flashes in the display during this measurement, which indicates that the device is in binary mode.
- If the device enters SLEEP mode due to inactivity, the "BBP" operating mode with the determined activity threshold value remains stored for 30 minutes.
- Press the (B) key again to end this operating mode. This switches the Gamma Finder®II back to the standard operating mode.

3.11 Battery Capacity Display

The remaining battery capacity can be checked at any time.

- Switch the device on if necessary and press the (1) key 3 times.
- The remaining capacity is displayed as bar graph.

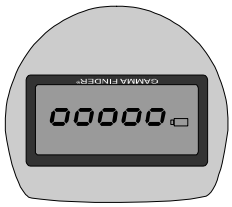


Fig. 3-11-1
Remaining battery capacity= full capacity

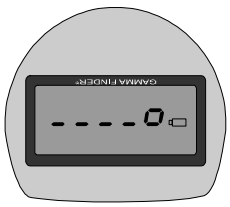


Fig. 3-11-2
Remaining battery capacity= low capacity

When the battery has nearly reached the end of its capacity, battery symbol ▭ is shown as a warning in the display of the Gamma Finder®II. The Gamma Finder®II may then still be used for approximately 20 hours. To avoid downtime, SenoRx should be contacted to request a replacement of the battery.
When the battery is completely depleted, the warning LOBAt is shown in the display in addition to the above mentioned battery symbol. The Gamma Finder®II is automatically switched off and can no longer be operated to prevent malfunctions. The battery has to be replaced if this is the case.

Fig. 3-11-3 LOBAT display

3.12 Battery replacement

Return the Gamma Finder ® to SenoRx when the battery warning is (or has been displayed) in the sensor's display. A "Return Goods Authorization" (RGA) number must be obtained from SenoRx Customer Service prior to returning the device. Refer to the back page of this manual for contact information.

3.13 Function Test

Before use the Gamma Finder®II can be checked with the help of a radioactive source (e.g. 57Co or 99mTc). This requires positioning the sensor of the Gamma Finder®II with the acoustic signal enabled over the source. If the device functions correctly, an activity-dependent acoustic signal is emitted and the LCD depicts the corresponding numerical value.

Calibration and setup are not necessary.

4 Care and Maintenance

The service and maintenance of the device and its accessories has to be carried out per instructions to ensure the safe operation of the device. Therefore, test function and presence of test certification after every service or maintenance activity ensures the safety of the patient and user/surgical team. Factory-new and repaired products must be prepared and tested prior to first use (see chapter 3.13 "Function Test", page 19).

4.1 Operating Time of the Gamma Finder®II

The Gamma Finder®II is a battery-operated device. With normal use, the capacity of the battery lasts approximatively 270 hours (approx. 1 year). The battery has to be replaced before it is completely depleted.

4.2 Storing the Gamma Finder®II

The Gamma Finder®II is delivered in a small metallic suitcase; safe transport is only ensured in this case. Make sure that the Gamma Finder®II is always stored in this case when not in use. For any kind of shipment (mail, parcel service, shipping company), the Gamma Finder®II must be in its case, which must then be wrapped in protective packing material. Non-compliance with this requirement may damage the Gamma Finder®II; SenoRx is not liable for damage caused by noncompliance.

4.3 Cleaning the Gamma Finder®II

The Gamma Finder®II can be wiped off with a cloth moistened with any solvent-free detergent or disinfectant. Immersion of the Gamma Finder®II in fluid is strictly prohibited and could lead to serious damage.

4.4 Maintenance and Repair

The Gamma Finder®II is to be serviced once a year, when the battery symbol appears in the display. The maintenance and service scope of the Gamma Finder®II consists of the following:

- Battery replacement
- Measuring sensitivity calibration and subsequent adjustment if

necessary
- Detector spectroscopic quality test
- Visual inspection and cleaning of device case

Only SenoRx service center is authorized to replace the battery and perform the maintenance of the Gamma Finder®. Opening the case or housing of the unit is expressly prohibited and can result in complete loss of device function. SenoRx is not liable for any damages or incidents based on the unauthorized opening of the Gamma Finder®II.

4.5 Contamination

Before shipping, decontaminate device and accessories in order to protect service personnel and to ensure safe transportation of the device. Follow the instructions listed in this manual.
If this is not possible,
- the product must be clearly marked with a contamination warning label and
- double-sealed in safety foil.

The manufacturer has the right to refuse carrying out repairs if the product is contaminated.

4.6 Non-sterile, reusable probe

The Gamma Finder®II is non-sterile. DO NOT STERILIZE. Sterilization of the Gamma Finder®II could have harmful consequence to its electronic and safety of the product.
SenoRx declines all responsibility for damage and undesirable incidents caused by the fact that this notice was not followed and the product sterilized following any known method.

4.7 Disposing of the Gamma Finder®II

Observe national waste management regulations when disposing of device and accessories.

The Gamma Finder®II is a compact, highly integrated device. It is made

of various materials and contains a battery as well as electronic components. At the end of its service life, it must be disposed in accordance with national, state and local requirements and may be returned to SenoRx.

Contact address for disposal:

SenoRx Inc.
1625 West 3rd Street
Tempe, AZ 85281 USA
Tel: 1-480-894-9515
1-800-321-4254
Fax: 1-480-966-7062
1-800-440-5376
www.bardbiopsy.com

5 Technical Data

Dimensions	Length: approx. 255 mm Height: max. 46 mm Width: max. 52 mm
Weight	approx. 210 g
Battery life Operating mode	270 hours (i.e. about one year use)
Current consumption	normal operation: max. of 80 mA
Storage and transportation conditions	-40°C to +70°C /-40°F to +158°F 10 to 90% rel. air humidity
[1] Absolute sensitivity for 99mTc (140 keV)	10000 cps/MBq
Discriminator threshold Tc 99m, I-123, In-111	110 keV
[2] Lateral shielding from 140 keV radiation	> 99.95 %
[3] Spatial resolution FWHM	14 mm
[4] Angular resolution FWHM	42°

1) For a point source in direct contact with the tip of the Gamma Finder®II
2) Preparation with lateral contact with distal end of the Gamma Finder®II
3) At distance of 10 mm
4) For far-field point sources (distance of 30 cm)

Subject to technical changes.

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK
FIRE; AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL2601-1/CAN/CSA C22.2 No. 601.1
2BD2