TruNode®

faxitron®

Surgical Gamma Probe

User Manual

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

User Manual P/N: 110015
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Table of Contents

1. INTRODUCTION

Description

The **TruNode®** Gamma Probe System is designed to detect and quantify Technetium-99m (Tc-99m) and Iodine-125 (I-125) in radio-guided localization medical procedures. A numeric display and audible signal convey the relative amount of radiation detected, allowing the user to localize radiolabeled tissue or structures.

The system is battery-powered, wireless, and portable. It consists of the **TruNode®** S-10 Gamma Probe and the **TruNode®** T-10 User Feedback Unit.

Intended Use

The **TruNode®** Gamma Probe System is intended to detect and quantify relative amounts of gamma radiation from Tc-99m and I-125 radionuclides in the body or tissues.

Indications for Use

The **TruNode®** Gamma Probe System can be used in non-imaging procedures to quantify relative amounts of Tc-99m or I-125 radionuclides in a particular organ or body region. It can be used in transcutaneous, open surgical, and laparoscopic procedures.

Potential Applications

The **TruNode®** Gamma Probe System can be used by physicians for radio-guided localization of tissues containing Technetium-99m (Tc-99m) and Iodine-125 (I-125). Potential applications include: radio-guided 'sentinel' lymph node localization with Tc-99m-labeled radiotracer, radio-guided parathyroidectomy with a Tc-99-labeled radiopharmaceutical such as Sestamibi, and radio-guided tumor localization with 'seeds' containing I-125 isotope.

Standards

The **TruNode®** system complies with the following standards:

Safety

- IEC 60601-1 (2005) 3rd Ed. Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

Biocompatibility

- ISO 10993 (including ETO residuals): Biological evaluation of medical devices: cytotoxicity, sensitization, irritation; externally communicating device; <24hrs exposure

Sterilization

- ISO 11135: Validation and routine control of ethylene oxide sterilization
- ISO 11607-1:2009+A1:2014: Packaging for Terminally Sterilized Medical Devices

Regulatory

- Medical Devices Directive 93/42/EEC amendment 2007/47/EC, Class IIa

Electromagnetic Compatibility

- EMC Directive 2004/108/EC Group l, Class B
- EN ISO 60601-1-2:2014 Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Wireless Operation

- Radio Equipment Directive 2014/53/EU
- FCC Part 15C: Intentional Radiators – FCC ID 2ADNA-S10
- Wireless: Bluetooth 4.0BLE

2. SYSTEM OVERVIEW

The **TruNode®** T-10 User Feedback Unit is used with the **TruNode®** S-10 Probe.

TruNode® User Feedback Unit (UFU)

The UFU is comprised of a tablet computer and a speaker all enclosed in a protective silicone rubber case. An IV pole clamp is attached to the back. The tablet computer uses the Android operating system and runs the **TruNode®** Application.

TruNode® T-10 UFU

A medical-grade power supply is included for re-charging the UFU battery.

Low-leakage Medical Grade Power Supply (EU Version Shown)

The UFU communicates bi-directionally with the **TruNode®** Probe over a Bluetooth Low Energy ('BLE') wireless link. It provides the visual display, sound feedback, and redundant controls for operating the probe.

The rate of gamma photons entering the Probe is displayed on the UFU in digits and with a log-scale meter. This rate is also represented by the audio feedback (pitch and beat frequency) coming from the speaker. The UFU will also announce the count rate upon request by the user via pushbutton on the Probe hand- piece.

The tablet computer controls for changing parameters such as the time zone or the announcements are accessed through the touch screen interface, as with any Android operating system. The ON/OFF control that turns launches the **TruNode®** application is located on the top of the UFU enclosure.

TruNode® Probe

The wireless **TruNode®** Probe is battery-powered (4.5V). It is completely sealed and supplied sterile for a single-patient use in a Tyvek™ peel-pouch. The pouch is designed for sterile handoff. The Probe can also be used in the pouch without breaking the seal prior to setting up the sterile field. Prior to use, the Probe must be stored in its unit box to prevent damage to the sterile pouch.

The Probe detects and quantifies gamma rays ('counts') from Tc-99m and I-125 isotopes and communicates this information to the UFU over the wireless link for user feedback. The Probe keypad provides the user with control of:

- activation status,
- detection energy window mode*,
- audio count-rate feedback volume,
- audio count-rate range scaling,
- announce instantaneous count-rate feedback, and

- announce integrated count-rate feedback*.

*see 'Using the Controls', Section 5.

3. WARNINGS and CAUTIONS

General

- Failure to thoroughly review and adhere to the information contained in this User Manual may pose a potential hazard to the patient and/or the user and may void the warranty.
- The **TruNode**® Gamma Probe System is not intended for use in the central nervous system.
- Do not modify this equipment without authorization of the manufacturer

User Feedback Unit

- Use only the Faxitron Power Supply provided with the UFU for recharging. Use of another power supply may increase the risk of electric shock
- Fully charge the UFU before using the system.
- Do not use the Charger in the operating room.
- Do not use the Charger in the presence of an oxygen-enriched environment or in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Keep the UFU off when charging.
- Remove the Charger when the UFU is fully charged.
- The UFU and Charger are non-sterile. Do not sterilize these components.
- If liquid is spilled on the UFU, remove it from service and contact Faxitron Bioptics for instructions to return for inspection. Ph: 1.520.399.8180.

- Securely mount the UFU to an IV pole.
- After connecting to a probe, the UFU must be turned ‘off’ then back ‘on’ before attempting to connect to a new probe.

Probe

- DO NOT activate the Probe until it is ready to be used. It is designed to be used immediately after activation.
- Keep a spare Probe at the ready in case of a failure, or of exceeding its 100-minute life after activation, or of exceeding its 4-hour life window.
- DO NOT reuse the Probe. It can be used on a single patient in a single surgical procedure only. Reuse poses a risk of cross-infection and cross-contamination.
- DO NOT attempt to re-sterilize the Probe.
- DO NOT drop the Probe. It may damage the detector element.
- DO NOT strike the Probe tip against a hard surface. It may damage the detector element.
- DO NOT simultaneously use the probe together with an electro-surgery device. It can disrupt the detector and produce spurious counts.
- DO NOT touch the probe to an energized electro-surgery device. It can damage the probe.

4. USING THE SYSTEM

Setting up the UFU (to be done prior to starting the procedure)

1. Turn on the UFU by pressing down on the ON-OFF control switch located on its top-left edge for approximately 5 seconds, until the boot screen appears.

   If only the battery-charge ICON  appears, the battery is fully depleted and the UFU must be recharged prior to use.

NOTE: A full charge for a fully-discharged UFU takes about three hours.

   Unless the UFU is fully-depleted, the Android 'Home' screen will appear after 20 seconds.

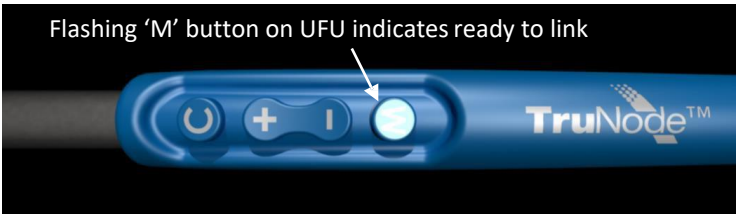
   After another 10 seconds, the **TruNode®** application will launch and the UFU will be ready to detect the **TruNode®** probe.

   Caution: If the battery charge is below 50%, turn off the UFU and charge it prior to use. Do not use the Charger in the operating room.

1. The UFU will announce a greeting followed by its charge status. Verify the UFU is at least 50% charged prior to starting the procedure.

2. When an image of the probe keypad with a flashing 'M' button is displayed, the UFU is ready to link with a **TruNode®** Probe.

3. Clamp the UFU securely to an IV pole in a location that is easy to see by the user.

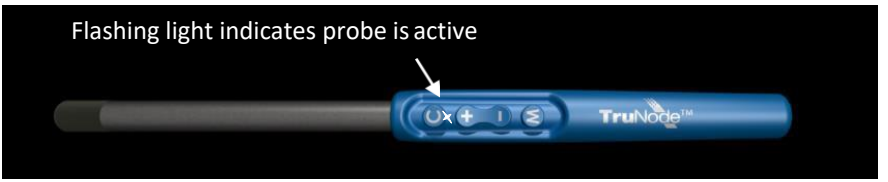


NOTE: After connecting to a probe, the UFU must be turned ‘off’ then back ‘on’ before attempting to connect to a new probe.

Deploying the Probe

1. Remove the Probe from the sterile peel-pouch, using aseptic technique.

2. Activate the Probe by pressing and holding ‘M’ button until the light on the Probe keypad flashes. This indicates the Probe has been activated. The live **TruNode®** application will start when the UFU senses the Probe.



*NOTE: The **TruNode®** Probe can be used preoperatively in its sterile pouch, prior to sterile deployment. Simply press through the clear poly film to access the controls. Use care not to damage the pouch seals, as this could disrupt its sterile barrier.*

*Note: The battery charge in the **TruNode®** Probe can also be tested as in step 2 by first assuring that there is no UFU in 'Ready' state nearby – a flashing light indicates the battery is not discharged. If no UFU is detected, the probe will turn off in 30 seconds.*

*NOTE: The useful life of the **TruNode®** Probe is the lesser of 100 minutes of continuous use, one patient procedure, or 4 hours, including preoperative use.*

*NOTE: The **TruNode®** Probe will hibernate after 10 minutes of inactivity. To awaken the probe, simply press and hold the 'M' button until the light on the keypad flashes.*

NOTE: The UFU will display the life of the probe when 15 minutes of use or less remain.

5. USING THE CONTROLS

NOTE: Each button can be: 1) momentarily 'clicked' or 2) held down for ~2 seconds to initiate a function. The UFU will announce the function.

- **To adjust the audio count-rate feedback volume:** Click the '**+**' or '**-**' button on the probe. A slider bar on the UFU displays the volume. The volume of the announcements cannot be adjusted.

- **To mute the audio feedback volume:** Repeatedly click the '**-**' button on the Probe until the UFU announces "Muting Probe." The audio level slider bar will be minimized and the speaker icon will be displayed in red.

- **To change the mode of the Probe from 'Scan' to 'Point':** Click the 'M' button on the Probe handle. The selected mode is displayed on UFU.

- **To change the mode of the Probe to 'Seed' from 'Scan' or 'Point':** Hold the 'M' button down 2 seconds. Seed mode is displayed on UFU.

- **To announce the instantaneous count rate:** Click the 'C' button. The UFU continuously displays the instantaneous count rate.

- **To get an averaged count rate:** Hold the 'C' button for 2 seconds – at which time "Recording Counts" will be announced – then a countdown to "Zero" while the integration completes – and finally the averaged count rate is announced and displayed on

the UFU. Up to 6 of the most recent average count rates can be displayed, and they can be removed by touching the stored count rate on the display.

- **To change the audio scale to match the count range:** Hold the '**+**' button for 2 seconds – at which time "High Range" will be announced, and the audio feedback will reflect the higher range. Clicking the '**-**' button will toggle back to low Range.

6. IN SURGERY

CHANGING MODES

Three photon energy-resolving modes are available -- 'Scan' and 'Point' modes are used for detecting Tc-99m and 'Seed' mode is used for detecting I-125.

Scan mode provides higher-sensitivity because it counts more gamma photons that have been scattered while in transit from their source to the probe's detector. This allows the user to survey wider areas more quickly than Point mode. The relatively higher number of gamma photons that are detected produce more rapid count-rate feedback information, and Scan mode accepts scattered gamma photons with lower energy than Point mode, and thus could have emanated from a wider region. Scan mode can be used for surveying larger areas, more quickly, especially when there is less background or scattered radiation (e.g. from the injection site or from nearby organs that uptake radiotracer). Scan mode can also be used to obtain more accurate ex-vivo specimen count rates because of its wider angle of acceptance for scattered gamma photons that may be emanating from the specimen.

Point mode provides higher-spatial resolution because it rejects low energy gamma photons that have been scattered while in transit from their source to the probe's detector. This allows the user to more precisely locate the source of the gamma photons: only those photons that have been minimally-scattered between their source and the probe's detector are counted, so the influence of background and scattered radiation is reduced. Point mode can be used when searching for hotspots where there is predominate background or scattered radiation (e.g. from the injection site or from nearby organs that uptake radiotracer), and when attempting to more accurately localize small radioactive hotspots.

Seed mode preferentially accepts photons from I-125, while rejecting the majority of photons from nearby Tc-99m. This can be useful for detecting I-125 seeds or other sources of I-125 isotope.

CHANGING THE AUDIO SCALE TO MATCH THE INCOMING COUNT RATE

A range of audio feedback is produced in proportion to the range of detected count rates. An increase in pitch and beat frequency indicates an increase in detected count rate. Two audio ranges are used to cover the range of count rates detectable by the **TruNode®** system. When the Probe is initialized, it defaults to the low range, producing audio feedback for count rates up to 2,000 counts per second. When more than 2,000 counts per second are detected, the very high pitched sound alerts the user that the high range may be needed. High range detects photons up to 10,000 counts per second.

NOTE: The selected range does not affect the digital count display or the count rate-meter.

OBTAINING AN AVERAGED COUNT RATE

The user can initiate the acquisition of an averaged, statistically- significant count-rate to improve the accuracy of the count rate reading for an exact target region. The user must hold the probe perfectly steady during this acquisition. When this feature is initiated, the **TruNode®** System will:

For count rates greater than or equal to 40 counts per second. The system will count for 2-10 seconds and return a count rate measurement with better than or equal to ±10% accuracy with 95% confidence. Very high count rates will be measured very quickly to very high accuracy (e.g. 1,000CPS target: 2 seconds counting time, ±10% accuracy with 99% confidence).

Or

For count rates below 40 counts per second. The system will count for 10 seconds and return a count rate measurement that is more accurate than the instantaneous reading but to less than +/-10% accuracy with 95% confidence. Very low count rates will have much lower accuracy (e.g. 5CPS target: 25% accuracy with 95% confidence).

7. AFTER SURGERY

- Dispose of the Probe in an appropriate bio-hazardous waste container.

- Turn off the UFU:
  - Press the ON-OFF control switch located on its top-left edge for approximately 2 seconds, until the power off options appear.
  - Follow the instructions that appear for powering off the UFU.

NOTE: The UFU must be turned off before the next procedure or it will not connect with another Probe.

- Wipe the surfaces of the UFU with a damp cloth or disinfectant wipe if they are soiled. Clean the display screen with a dry cloth to remove smudges.
- Charge the UFU. For maximum battery life, remove the charger when the UFU is fully charged.

8. SPECIFICATIONS

TruNode® S-10 Probe

Overall Dimensions: 17mm X 226mm

Reach: 103mm, Operative Diameter: 10mm

Weight: 70g

Wireless: Bluetooth® Smart

Integrated Tungsten Collimator

External Materials: Stainless Steel, Tungsten, Silicone Rubber

Shielding Efficiency: >99.9%

Energy Resolution: 10% FWHM (Tc-99m)

Selectable Energy Windows: Tc-99 'Point' Mode, Tc-99 'Scan' Mode, I-125 'Seed' Mode

Angular Resolution in Air: 46 degrees FWHM

Spatial Resolution @1cm in Air, Point Mode: 13mm FWHM

Spatial Resolution @1cm in Air, Scan Mode: 14mm FWHM

Sensitivity in Air, Point Mode: 18,000CPS/MBq max; 3,400 /MBq @1cm

Sensitivity in Air, Scan Mode: 27,000CPS/MBq max; 4,800CPS/MBq @1cm

Probe-Mounted Controls:

- Activate & Connect to UFU
- Mode (Hi-Sensitivity 'Scan', Hi-Resolution 'Point', I-125 'Seed'),
- Count Rate Reporting,
- Count Rate Averaging,
- Audio Feedback Scaling,
- Volume and Mute.

Probe Life: Lesser of 100-min continuous use, or 4-hr intermittent use, or 1-procedure

Use Condition Limitation: 15 to 37°C

Storage & Transit Condition Limitation: -15 to 50°C

TruNode® T-10 User Feedback Unit

Overall Dimensions: 25cm x 18cm x 2.3/13cm (without/with clamp)

Weight 1.4kg (with clamp)

Android operating system Maintenance free, no calibration

Power Supply: 100-240VAC, 56/60Hz input; 1A, 5VDC output

Storage & Transit Condition Limitation: -15 to 50°C

9. TROUBLESHOOTING

- Symptom: radiation count rate greater than zero even when no radiation present after contacting radioactive tissue

  Resolution: decontaminate probe tip of radioactive material using sterile process

- Symptom: spurious radiation counts in conjunction with energizing electrocautery device or other radio-frequency emitter

  Resolution: move electrocautery device cable or other radio-frequency emitter away from probe

- Symptom: spurious radiation counts not associated with radiation contamination or electrocautery device or other radio-frequency emitter

  Resolution: replace probe

- Symptom: insufficient or complete lack of radiation counts when locating the probe over a known source of high radioactivity

  Resolution: replace probe

- Symptom: new probe or probe that hasn't expired won't connect with a UFU.

  Resolution: turn the UFU off then back on – the UFU must be turned off prior to connecting to a new probe.

10. SYMBOLS

	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	*
	Splash-proof	*
	Type BF Applied Part	*
	Bluetooth®	*
	Use by date	*
	Read usage instructions	*
	Sterilized using ethylene oxide	*
	Not to be used in case package is damaged	*
	Re-use is not allowed	*
	Do not re-sterilize	*
	Does not contain natural rubber latex	*
	Contains alkaline battery	*
	USA Representative	*
	EU Authorized Representative	* **
	Manufacturer	* **
	Temperature limitation	* **
	Electronic Waste	**
	Serial number = Date of Manufacturer (YYMMDD-XX)	**
	Lot number	*
	Model	* **
	Caution, consult documents	**
	CE Mark, Class IIa	* **

*Affixed to Probe label **Affixed to UFU label

11. EMC DECLARATION

This product has been tested and verified to ensure that there are no issues or concerns regarding reciprocal interference. This includes EMI, EMC and RF. It has been certified and tested by 3rd party testing facilities. List of standards is as follows:

- Medical Electrical Equipment - Part 1: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests – EN 60601-1-2:2014
- CFR 47, Part 15, Section 15.247 (b): Effective Isotropic Radiated Power (EIRP)
- CFR 47, Part 15, Section 15.247 (d): Spurious Emissions
- EMC Directive 2004/108/EC Group l, Class B
- Radio Equipment Directive 1999/5/EC

The TruNode® Gamma Probe System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User Manual. The customer or user of the TruNode® Gamma Probe System should assure that it is used in such an environment. The following tables provide a guidance and declaration for the electromagnetic emissions and immunity of the TruNode® Gamma Probe System which requires the use of the supplied TruNode® Power Supply P/N 201029. The use of components other than these may result in increased emissions or decreased immunity. Similarly, the use of the supplied Power Supply and Cable with equipment and systems other than the TruNode® Gamma Probe System may significantly degrade emissions and immunity performance.

Portable and mobile RF communications equipment can affect the TruNode® Gamma Probe System.

The TruNode® Gamma Probe System should not be used adjacent to or

stacked with other equipment. If adjacent or stacked use is necessary, the TruNode® Gamma Probe System should be observed to verify normal operation in the configuration in which it will be used.
The Trunode® Gamma Probe System transmitter and receiver use Bluetooth® SMART technology, with a frequency band of 2.400 GHz-2.4835 GHz and GFSK modulation. The effective radiated power of the transmitter is 1.2mW.

The Trunode® Gamma Probe System may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

<table>
<tr><th colspan="3">Guidance and declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The TruNode® Gamma Probe System is intended for use in the electromagnetic environment specified below. The customer or the user of the TruNode® Gamma Probe System should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The TruNode® Gamma Probe System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The TruNode® Gamma Probe System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and declaration – electromagnetic immunity

The TruNode® Gamma Probe System is intended for use in the electromagnetic environment specified below. The customer or the user of the TruNode® Gamma Probe System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 2 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input line IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Dips: 0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 75 cycles Interruptions: 0 % U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TruNode® Gamma Probe System requires continued operation during power mains interruptions, it is recommended that the TruNode® Gamma Probe System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1 UT is the a.c. mains voltage prior to application of the test level.

NOTE 2 Compliance levels for IEC 61000-4-4, -5, -11 apply to the supplied power supply.

Guidance and declaration – electromagnetic immunity

The TruNode® Gamma Probe System is intended for use in the electromagnetic environment specified below. The customer or the user of the TruNode® Gamma Probe System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms	6Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the TruNode® Gamma Probe System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0{,}58\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz, $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3 The compliance levels for IEC 61000-4-6 applies to the supplied power supply.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TruNode® Gamma Probe System is used exceeds the applicable RF compliance level above, the TruNode® Gamma Probe System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TruNode® Gamma Probe System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the TruNode® Gamma Probe System

The TruNode® Gamma Probe System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TruNode® Gamma Probe System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TruNode® Gamma Probe System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 0{,}58\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,058	0,12	0,23
0,1	0,18	0,37	0,74
1	0,58	1,2	2,3
10	1,8	3,7	7,4
100	5,8	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

12. FCC INFORMATION

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

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

- FCC Part 15C: Intentional Radiators – FCC ID 2ADNA-S10

Caution: changes or modifications not expressly approved by Faxitron Bioptics, LLC. could void the user's authority to operate the equipment

13. TECHNICAL SUPPORT & PRODUCT COMPLAINTS

For any technical support and to report any complaints or problems in the quality, reliability, safety or performance of this product please contact Faxitron. If the device has caused or added to patient injury, immediately report the incident to Faxitron. Please contact Faxitron Bioptics, LLC via phone at +1.877.910.0030 (within United States of America and rest of the world) or + 32-27114680 (within Europe) or via email at sales@faxitron.com.