Node-O-Scope™

User Manual

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1. INTRODUCTION

Description

The Node-O-Scope™ system is designed to detect and quantify Technetium-99m radiotracer in radio-guided localization medical procedures. A numeric display and audible signal convey the amount of radiation detected, allowing the user to localize radiolabeled tissue.

The system is battery-powered, wireless, and portable. It consists of the Node-O-Scope™ S10 Gamma Probe and the Node-O-Scope™ T10 User Feedback Unit.

Intended Use

For the detection and quantification of gamma radiation from Tc-99m radionuclide in the body or tissues.

Indications for Use

Use in non-imaging procedures to measure relative amounts of Tc-99m radionuclide absorbed by a particular organ or body region. For transcutaneous, open surgical, and laparoscopic use.

Manufacture and Distribution

The system is manufactured by Cokiya Incorporated. Please direct all inquiries about the Node-O-Scope™ system to Cokiya Incorporated. The following are trademarks of Cokiya Incorporated: Node-O-Scope™ system and Node-O-Scope™ when used in context with the above.

Standards

The Cokiya Node-O-Scope™ system complies with the following standards:

EMC

- EN 60601-1-2: Medical Electrical Equipment Collateral Standard, Electromagnetic Compatibility - Requirements and Tests
- FCC Part 15C: Intentional Radiators – FCC ID 2ADNA-S10
- Wireless: Bluetooth 4.0BLE

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 11737: Tests of sterility
- ISO 11138: Biological indicators

Regulatory

- FDA Device Classification: Class 1

2. SYSTEM OVERVIEW

The Node-O-Scope™ T10 User Feedback Unit is used with the Node-O-Scope™ S10 Probe. A medical-grade battery charger is provided with the system for recharging.

User Feedback Unit

The User Feedback Unit is comprised of a tablet computer running the Cokiya Node-O-Scope™ application, a loudspeaker, and an IV pole clamp. It includes a medical-grade Battery Charger for recharging. It communicates bi-directionally with the Node-O-Scope™ Probe over a Bluetooth Low Energy ('BLE') wireless link.

The User Feedback Unit provides displays, sound feedback, and redundant controls for operating the probe.

The rate of gamma photons entering the Probe is displayed on the User Feedback Unit in digits and with a log-scale rate-meter. This rate is also represented by the audio feedback coming from the speaker.

The User Feedback Unit controls are accessed on the touch pad of the display or on the top of the User Feedback Unit. The ON/OFF control is located on the top left of the User Feedback Unit.

Node-O-Scope™ Probe

The wireless Node-O-Scope™ 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.

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

- activation status,
- detection energy window mode*,
- audio feedback volume,
- count-rate range scaling,
- voiced reporting of instantaneous count rate feedback, and
- voiced reporting of integrated count rate feedback*.

*****see 'Using the Controls', Section 4.

3. PRECAUTIONS

General

- *Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.*

- *The output of this system is not a diagnostic measure.*
- *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.*
- *This system is not designed for use 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*

User Feedback Unit

- *Fully charge the User Feedback unit before use of the system.*
- *Do not use the C10 Charger in the operating room.*
- *Keep the User Feedback unit off when changing the User Feedback.*
- *The User Feedback Unit and Charger are non-sterile. Do not sterilize these components.*
- *Securely mount the User Feedback to an IV pole.*

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 2-hour life after activation.*
- *DO NOT reuse the Probe. It can be used on a single patient in a single surgical procedure only.*
- *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.*
- *DO NOT touch the probe to an energized electro-surgery device. It can damage the probe.*

4. USING THE SYSTEM

Setting Up the User Feedback Unit

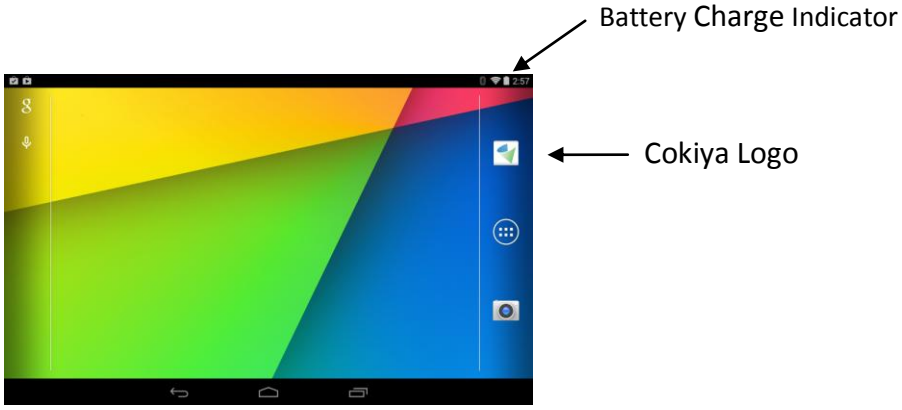
1. Turn on the User Feedback Unit by pressing ON-OFF control switch located on the Top-left edge of the User Feedback Unit. The ON-OFF switch button is the smaller, left-most button.

   If only the battery-charge ICON appears on the User Feedback Unit display, the battery is depleted and must be recharged prior to use.

   NOTE: A full charge for a discharged User Feedback Unit takes two hours.

2. Verify the User Feedback Unit is at least 50% charged as shown on the battery charge indicator. If it is not at least 50% charged, plug it into the charger for at least one hour prior to use.

   Caution: Do not use the Charger in the operating room

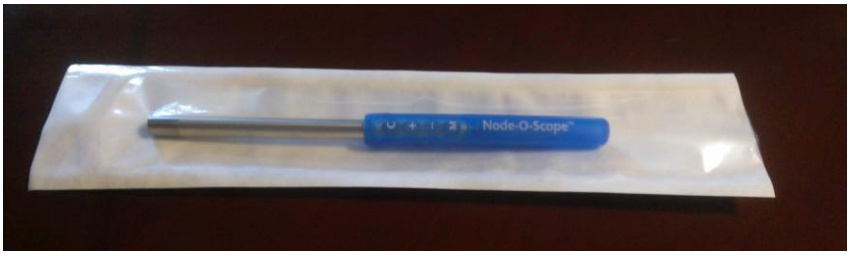


3. Launch the Node-O-Scope application by tapping on the Cokiya logo . 'Waiting for Probe' will be displayed.

4. Clamp the User Feedback Unit securely to an IV pole in a location that is easily viewable by the user.

5. The User Feedback Unit is now ready to link with a Node-O-Scope Probe.

Deploying the Probe



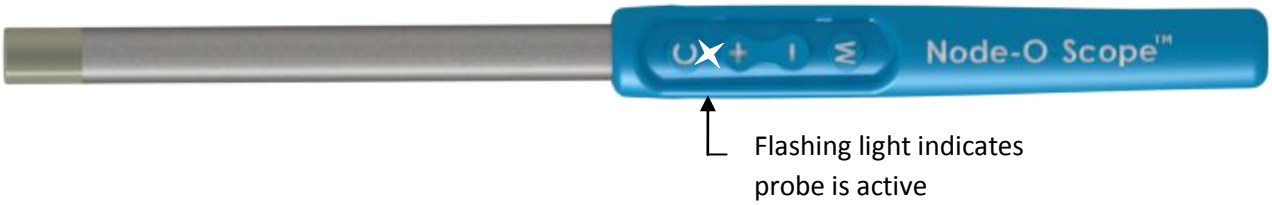
1. Remove the Probe from the sterile peel-pouch, using aseptic technique.

NOTE: The Node-O-Scope Probe can be used preoperatively in its sterile pouch, prior to sterile deployment. Simply release the tip cover from the detector end of the probe through the pouch and 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.

CAUTION: The Node-O-Scope battery lasts up to 2-hours after any initiation, including initiation for preoperative use.

2. Turn on the Probe by pressing down the 'M' button until the light on the Probe keypad flashes. This indicates the Probe has been activated. A greeting will be

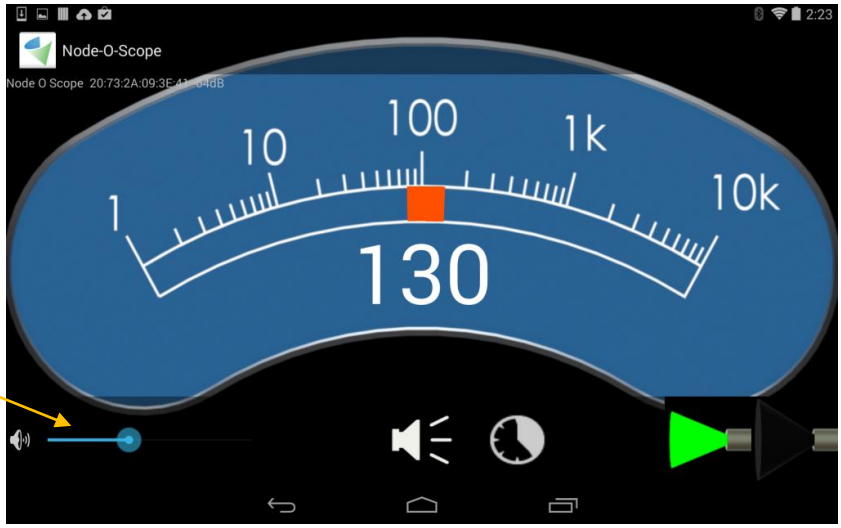
voiced and live Node-O-Scope application starts when the User Feedback Unit senses the Probe.



NOTE: Whenever a command is recognized, the User Feedback Unit will provide voiced feedback.

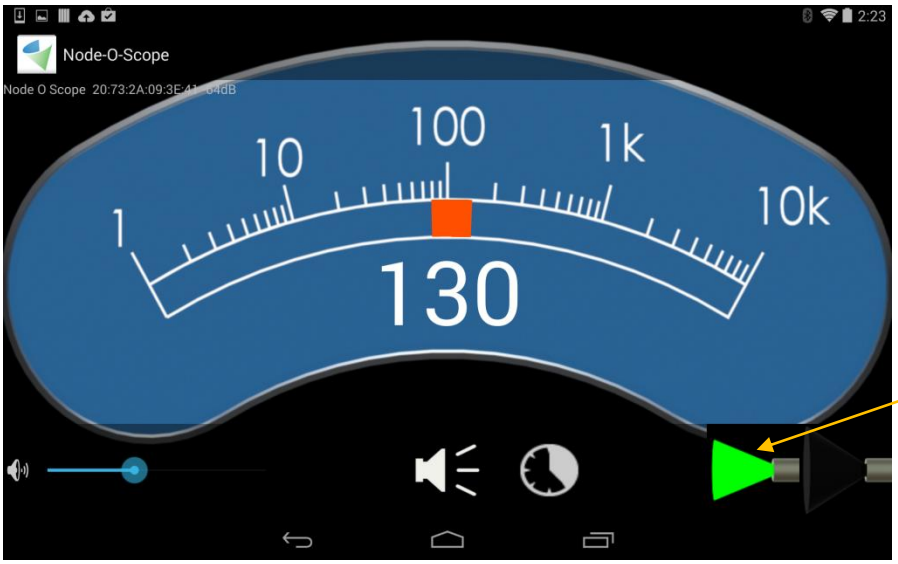
Using the Controls

- **To adjust the audio feedback volume:** Momentarily press on the '**+**' or '**-**' button on the probe. A slider bar on the User Feedback display next to the speaker icon displays the volume. Alternately, the audio volume can be adjusted directly from the User Feedback Unit display by pressing and sliding the audio level bar.



- **To mute the audio feedback volume:** Repeatedly press the '-' button on the Probe until the User Feedback voices "Muting Probe." The audio level slider bar will be minimized and the speaker icon will be displayed in red. Alternately, the audio volume can be muted directly from the User Feedback display by tapping and sliding the audio level bar to the left until the speaker icon is displayed in red.

- **To change the mode of the Probe from 'Scan' to 'Point':** Press the 'M' button on the Probe handle. The selected mode is displayed on User Feedback Unit.



- **To request a voiced indication of the instantaneous count rate:** Momentarily press the 'C' button on the Probe handle. The User Feedback Unit continuously displays the instantaneous count rate.

- **To get a statistically significant count rate:** Press and hold the 'C' button for 1-2 seconds – at which time "Hold Steady" will be voiced – then a countdown to "Zero" while the integration completes – and finally the statistically significant count rate is voiced and momentarily displayed in flashing numbers on the User Feedback Unit.

- **To change the audio scale to count range:** Press and hold the '**+**' button for 1-2 seconds – at which time "High Range" will be voiced, and the scale on the rate-meter will reflect the higher range. Pressing and holding the '**-**' button for 1-2 seconds will return to the lower range, and "low Range" will be voiced.

In Surgery

- **Changing Modes:** Two photon energy-resolving modes are available -- 'Scan' and 'Point'.

  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 when 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.

Changing the audio-to-count rate range

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 counts rates detectable by the Node-O-Scope system. When the Probe is initialized, it defaults to the low range, which detects counts up to 3,000 counts per second. When more than 3,000 counts per second are detected, an off-tone sound is produced to alert the user that the high range may be needed. High range detects photons from 2,000 to 10,000 counts per second.

NOTE: The selected range does not affect the digital count display.

Obtaining a statistically significant count rate

The user can initiate the acquisition of a 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 Node-O-Scope 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 greater than or equal to 95% accuracy with 90% confidence. Very high count rates will be measured very quickly to very high accuracy (e.g. 1,000CPS target: 2 seconds counting time, 99% accuracy with 90% 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 95% accuracy with 90% confidence. Very low count rates will have much lower accuracy (e.g. 5CPS target: 25% accuracy with 90% confidence).

After Surgery

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

- Close the Node-O-Scope application on the User Feedback Unit:
  - Tap the recent applications list icon  ,
  - Swipe the Node-O-Scope application  downward and off the screen to close the application.

NOTE: The Node-O-Scope application must be closed after use, or before the next procedure or it will not pair with another Probe.

- Hibernate the User Feedback Unit by pushing the ON-OFF button.

- Wipe the surfaces of the User Feedback Unit with a damp cloth or disinfectant wipe if they are soiled. Clean the display screen with a dry cloth to remove smudges.

- Charge the User Feedback.

5. SPECIFICATIONS

Node-O-Scope™ S-10 Probe

- Overall Dimensions: 17mm X 226mm
- Reach: 103mm, Operative Diameter: 10mm
- Weight: 70gm
- Wireless: Bluetooth Smart
- Integrated Tungsten Collimator
- Materials: Stainless Steel, Tungsten, Polyurethane, Epoxy (all biocompatible)
- Shielding Efficiency: >99.9%
- Energy Resolution: 10% FWHM (Tc-99m)
- Bi-Modal Selectable Energy Window: 10% in Hi-Res Mode, Open in Hi-Sens Mode
- Angular Resolution in Air: 46 degrees FWHM
- Spatial Resolution @1cm in Air, Hi-Res Mode: 13mm FWHM
- Spatial Resolution @1cm in Air, Hi-Sens Mode: 14mm FWHM
- Sensitivity in Air, Hi-Res Mode: 18,000CPS/MBq @1cm; 3,400 /MBq @1cm
- Sensitivity in Air, Hi-Sens Mode: 27,000CPS/MBq max; 4,800CPS/MBq @1cm
- Probe-Mounted Controls:
    - Power-on & Pair
    - Mode (Hi-Sens or Hi-Res),
    - Count Rate Reporting
    - Count Rate Averaging,
    - Audio Feedback Range,
    - Volume and Mute.
- Probe Life: Lesser of (100) Minutes or (1) Procedure
- Use Conditions: 10 to 40°C; 30 - 80% relative humidity; 50-70KPa pressure
- Storage Conditions -15 to 50°C; 0 - 80% relative humidity; 50 – 70KPa pressure

User Feedback Unit T10

- Nexus Android Tablet; OS 4.4 KitKat
- Maintenance free, no calibration
- Use Conditions: 10 to 40°C; 30 - 80% relative humidity
- Storage Conditions -15 to 50°C ; 0 - 80% relative humidity

6. TROUBLESHOOTING

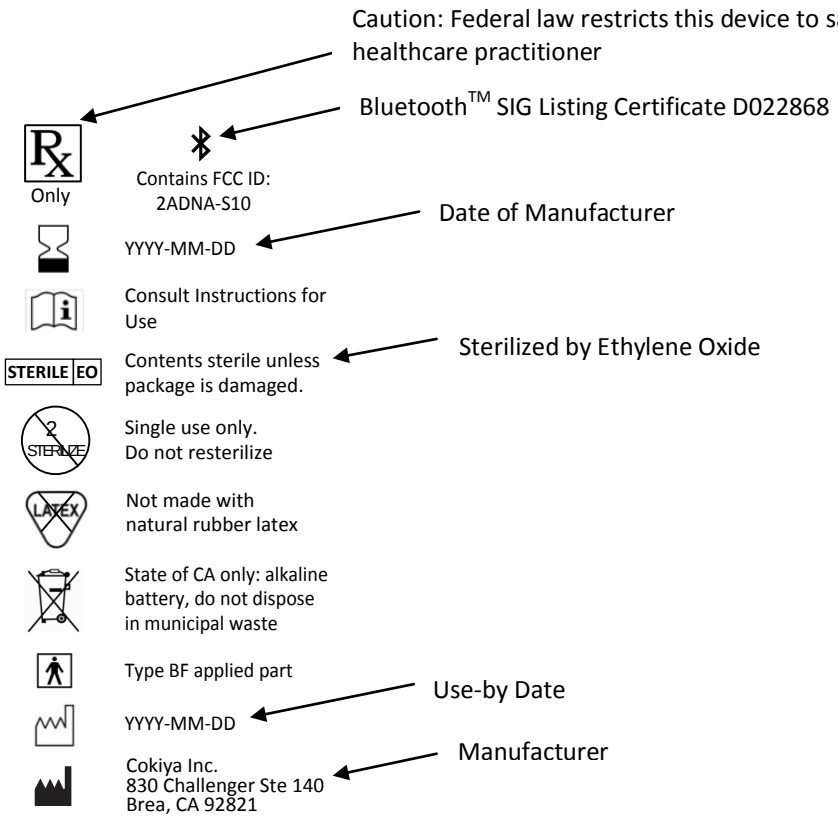
Symptom: radiation count rate greater than zero even when no radiation present after contacting radioactive tissue

Resolution: decontaminate probe tip of radioactive material using sterile process

Symptom: spurious radiation counts during in conjunction with energizing electrocautery device

Resolution: move electrocautery device cable away from probe tip

7. LABELING



8. 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 60601-1-2:2004
- CFR 47, Part 15, Section 15.247 (b): Effective Isotropic Radiated Power (EIRP)
- CFR 47, Part 15, Section 15.247 (d): Spurious Emissions

8. 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.

Caution: changes or modifications not expressly approved by Cokiya Inc. could void the user's authority to operate the equipment.