Optional Probe Check

Local regulations may require a series of tests be performed in specified time intervals to ensure that the functional performance of the equipment meets established criteria.

Note
TruNode® probes (p/n: 120-807605) are single-use and go through Quality testing during the manufacturing process. The functionality of the TruNode probe can be observed by confirming a positive count rate at the Tc-99m injection site and confirming a background count rate (away from radioactivity) of <5 CPS.

The following test procedure is an optional check of the sensitivity of the device.

Caution:
The useful life of the TruNode Probe is the lesser of 95-100 minutes of continuous use, one patient procedure, or 4 hours, including preoperative. Caution should be used with the timing of quality assurance testing if the user intends to use the same probe for both QA testing and a patient procedure.

Suggested Equipment

- Ruler (mm)
- Calibrated Co-57 point source (activity range 5-10 µCi)
- Use the "Optional Probe Sensitivity Record Form" on page 2 to record results.

Procedure

1. Power on the probe and connect to the UFU. Confirm that the probe is in Scan Mode.
2. Measure the background counts by orienting the probe far from any radioactive material and hold down "C" for 2 - 4 seconds to obtain a background count reading. Confirm that this background value is less than 5 CPS. Record the background Counts Per Second (CPS) value (B) in the record form.
3. Place the probe 1.5 cm away from the radioactive source with the center of the source in line with the center of the probe.
4. While maintaining the 1.5 cm distance from the source, hold down "C" for several seconds to obtain a reading and record the Counts Per Second (CPS) value with a radioactive source (R) in the record form.

Data Analysis

1. Record the current source activity of the radioactive source. If using a calibrated sealed source, calculate the Current Source Activity (A) from the half-life (T_h) of the radioactive source and the last measured activity (A_0), which may be obtained from the Calibrated Source Datasheet. Use the record form to calculate and record results.
2. Calculate the sensitivity by dividing the count rate of the radioactive source as measured by the TruNode probe (R) by the Current Source Activity (A) from step 1. This value should be a minimum of 0.5 CPS/KBq for calibrated Co-57 sources.

Note
The measurement is highly sensitive to alignment of the source and probe; this minimum value of 0.5 CPS/KBq accounts for variability in test setup.

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Technical Support and 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 Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic. Please contact Hologic Inc. via phone at +1.877.910.0030 (within the United States of America and the rest of the world) or +32-27114680 (within Europe) or a contact listed on www.hologic.com.

Optional Probe Sensitivity Record Form

TruNode Probe Measurements

Background count rate (B) = _____ cps

Count rate 1.5 cm away from radioactive source (R) = _____ cps

Current Source Activity Calculations

Last measured activity (A_0) = _____ µCi

Time (in days) since A_0 was measured (T) = _____

Current Source Activity (A) $= A_0 * e^{(-0.693*\frac{T}{271.8})}$ = _____ µCi

Sensitivity = (R – B)/A = _____ CPS/ µCi

Recommended Performance Criteria

Measured sensitivity for calibrated Co-57 sources should be ≥ 18.5 CPS/ µCi (0.5 CPS/kBq)

The following diagram is a reference of the expected minimum count rate (R – B) for a Co-57 source supplied at 10 µCi.