



UltraSPECT Reconfirms its Clinically Proven FDA-Cleared Dose-Reduction Solutions to the Technetium (Tc-99m) Shortage

Due to the impact of the Canadian reactor shutdown combined with the recently announced closure due to the six-month repair plan of the Dutch reactor, the global shortage of Tc-99m is expected to remain grave for the period covering February-August 2010, leaving the field of Nuclear Medicine in a very precarious position:

- Inability to provide patients with needed Nuclear Medicine tests
- Longer delays in scheduling of exams for most patients
- Use of reduced-dose imaging protocols with risk of inadequate clinical outcomes
- Loss of business to other imaging modalities such as CTA, Echo and cardiac PET.

The aim of this document is to outline clinically proven imaging alternatives using the FDA-cleared and CE Mark-approved UltraSPECT products to help weather this period; the products, installed in over 250 NM sites worldwide, allow the utilization of lower dose imaging protocols with no compromise in imaging acquisition times and outcomes, alleviating the impact of the Technetium shortage, while at the same time reducing patient radiation exposure.

UltraSPECT utilizes proprietary WBR image reconstruction technology for cardiac and bone applications. These products improve image quality and diagnostic efficacy, doubling the NEMA standard resolution for the currently installed camera systems. This improvement allows the reduction of scan times to one half-time or a quarter-time of the currently approved protocols, thereby enhancing clinical productivity and improving patient comfort. Moreover, UltraSPECT products are cleared to allow clinical protocols enabling reduced injection doses, thus ensuring a steadier delivery of the existing Tc-99m supplies while minimizing patient exposure to radiation. UltraSPECT WBR reconstruction presents the physician with a set of high-quality images which provide, according to a large number of peer-reviewed articles in professional journals and presentations at professional conferences, higher clinical efficacy.

As of today, UltraSPECT provides connectivity to the imaging systems of all three major NM camera manufacturers, supporting most existing camera hardware and workstation versions.

UltraSPECT's FDA-Cleared and CE Mark-Approved Dose-Saving Protocols:

A. The Xpress.Cardiac Product

Half-Dose Rest/Stress Single-Day Protocol

Applying the one-day Tc-99m Rest/Stress protocol with scan times as defined by the ASNC recommendations, but with injected doses that are approximately half the doses specified by ASNC:

Rest: 5-6 mCi; 8-9 mCi for patients weighing >100 kg.

Stress: 15-20 mCi; 24-27 mCi for patients weighing >100 kg.

B. The Xpress3.Cardiac Product

1. Half-Dose, Half-Time Single-Day Rest/Stress Protocol

As suggested by its name, the half-dose, half-time Tc-99m Rest/Stress protocol combines reduced injection doses with shortened scan times, enabling higher patient safety and comfort, while helping overcome the impact of radioisotope supply shortages and increasing patient throughput. A typical "half-dose half-time" same-day Tc-99m Rest/Stress protocol consists of:

Rest: 5-6 mCi; 15-20 sec. per stop.

Stress: 15-20 mCi; 10 sec per stop.

Note:

However, as in other protocols involving a shorter acquisition time, caution should be exercised when scanning larger patients. In patients with large chest circumferences and in women with large, dense breasts, doses should be increased proportionately for both the Rest and Stress scans, or the two-day Stress/Rest half-dose half-time scan protocol should be applied.

2. Dual-Isotope Single-Day Protocol

The one-day dual-isotope Tl-201/Tc-99m protocol combines reduced doses and shorter scan times. Reduced-dose shorter-time Rest Tl-201 imaging is followed by shorter-time reduced-dose Tc-99m Stress imaging:

Rest: Tl-201, 2 mCi (female) / 3 mCi (male); 20sec. per stop.

Stress: Tc-99m, 20 mCi (female) / 30 mCi (male); 10sec. per stop.

As attested by many users of dose-reduction protocols enabled by UltraSPECT's image reconstruction products, the negative impact of the reactor shutdowns can be substantially mitigated, freeing up Tc-99m supplies to accommodate all their patients.