Ultrasound Is a Safe, Highly Regulated Imaging Modality

- **Ultrasound does not use potentially harmful ionizing radiation.**
  - Diagnostic ultrasound uses extremely low intensity sound waves to generate images, unlike X-Ray, Computed Tomography (CT) and nuclear medicine, which require ionizing radiation, a potential carcinogen. Additionally, ultrasound does not require the use of contrast media, which are required for angiography and some CT studies, and cause adverse events in a significant number of patients.
  - An ultrasound system only generates a signal approximately 10 percent of the time the system is active; the rest of the time the ultrasound system spends passively listening for the returned echoes. This means that the actual time that a patient is exposed to ultrasound energy is very limited further reducing the chance of harm.

- **Ultrasound has a well-documented safety record with more than 50 years of widespread clinical use.**
  - In over 50 years of widespread clinical use, there have been no known adverse effects from exposure to diagnostic ultrasound. This is supported by the fact that the first babies who were exposed to ultrasound studies while in utero are now grandparents – there is no evidence that any of these three generations have experienced any adverse effect from exposure to ultrasound energy.
  - The American Institute of Ultrasound in Medicine, a prestigious multi-specialty professional society, issued the following statement on the safety of ultrasound: "There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments."

- **Ultrasound systems now incorporate numerous safety features that protect patients from unnecessary exposure to ultrasound energy.**
  - Current ultrasound systems incorporate numerous safety mechanisms including limiting the power output a system can generate and transducers that force a system to shut down if they detect an excessive operating temperature caused by a high power output.
  - Modern ultrasound systems are software driven enabling them to be programmed to shut down is they are performing outside of specifications.

- **Ultrasound is highly regulated by the Food & Drug Administration (FDA).**
  - Despite the excellent patient safety record for diagnostic ultrasound systems, the FDA imposes very strict pre-market and post-market requirements. These include obtaining Premarket Approval (PMA) and submitting Premarket Notification Applications (510k), which may include clinical trials.
  - The FDA responds to Medical Device Reports (MDR) and reports of adverse events filed by clinicians. The FDA can recall devices they find to be unsafe or defective and bring legal action against manufacturers to stop the sale, production and marketing of a medical device.