Chapter 16 - Safety

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Ultrasound: Hazard and Risk

Definitions of Hazard and Risk

- **Hazard** describes the nature of the threat (e.g., burning, electrocution).
- **Risk** considers the potential consequences of the hazard (e.g., death, scarring), probability of occurrence, and the type of tissue at risk (e.g., embryo, adult brain), along with timing (immediate or delayed effects).

Hazards Associated with Ultrasound Scanning

- **Thermal Hazard (Dominant)**:
  - Ultrasound energy converts partially into heat, causing temperature elevation in tissues.
  - Severity depends on:
    - Magnitude of temperature increase.
    - Duration of elevated temperature.
    - Nature and sensitivity of exposed tissues.
  - Temperature increase within normal physiological range poses negligible hazard and risk.
  - Exceeding normal physiological range requires careful risk assessment.
- **Mechanical Hazard (Acoustic Cavitation)**:
  - Arises from presence of gas in tissues (natural or introduced deliberately via contrast agents).
  - Gas may exist naturally (alveoli, intestines) or artificially (gas contrast agents, gas nuclei on renal calculi).
  - Ultrasound-induced oscillation of gas bodies termed:
    - **Acoustic cavitation** for free bubbles.
    - **Gas body activation** in general cases.
  - Risk of tissue damage depends on oscillation amplitude, gas location, and resulting cellular changes.

Risk Management and Safety Measures

- Sonographers must evaluate safety for each examination, weighing patient benefits against risks.
- Safety indices provided by ultrasound scanners help users make informed risk/benefit judgments.
- Chapter reviews:
  - Relationship between ultrasound output/exposure and hazard/risk.
  - Thermal and mechanical processes leading to potential biological effects.
  - Epidemiological evidence on safety of diagnostic ultrasound.
  - Role of manufacturers and users in maintaining safety standards.
  - Overview of regulations and standards governing ultrasound safety.
  - Specific scenarios posing unique safety challenges.

Recommended Further Reading and Resources

- Additional texts on ultrasound safety:
  - Barnett and Kossoff (1998)
  - McKinlay (2007)
  - AIUM (2008)
  - Duck (2008)
  - ter Haar (2012)
- EFSUMB safety tutorials freely available online at: www.efsumb.org/blog/archives/869

Ultrasound Exposure Measurements

Ultrasound Exposure and Acoustic Pressure

- During ultrasound scans, tissues are exposed to **ultrasound beams and pulses** forming the ultrasound field.
- Ultrasound is a **longitudinal pressure wave**, causing cyclic variations of pressure at each point it travels through.
- **Figure 16.1** illustrates a typical acoustic pressure variation with time for a pulsed Doppler ultrasound pulse near the focus in water:
    - Shows rapid transition from negative to positive pressure.
    - Positive pressure peaks are usually higher than negative pressure troughs.

Standard Quantities and Measurements

- Acoustic fields are characterized using specific standard quantities (detailed in Appendix B of original text).
- Direct measurement inside tissues is difficult; thus, a well-characterized, reproducible substitute medium (**water**) is used.

Water as a Substitute Medium

- Water is chosen for acoustic output measurements due to its similarity to soft tissues:
    - **70%** of soft tissues is water.
    - Ultrasound propagates in water similarly to soft tissue:
        - Similar acoustic speed and impedance.
        - Comparable reflection and refraction behavior.
- The primary difference is that **water absorbs significantly less ultrasound energy** compared to tissue:
    - Acoustic measurements in water yield higher values than in actual tissue scenarios.
- Measurements taken in water are termed:
    - **"Acoustic output measurements"** or more specifically, **"free-field acoustic output measurements."**
- The terms **"exposure measurements"** or **"exposure parameters"** specifically refer to what happens in real tissues, not water.

Estimating Tissue Exposure

- Actual tissue exposure values (**"estimated in-situ values"**) are approximations based on simplified models of tissue properties and structure.

Relationship Between Acoustic Output, Exposure, Hazard, and Risk

- **Figure 16.2** outlines this relationship clearly:
    - Moving from measured acoustic output parameters in water → estimated tissue exposures → hazard evaluations → risk assessments:
        - Each step introduces more uncertainty in assessment accuracy.
- A semi-formal evaluation of ultrasound hazard and risk has been detailed by Duck (2008).

Tissue Heating by Ultrasound

Thermal Hazard Overview

- **Tissue heating** is the most significant hazard associated with diagnostic ultrasound.
- Ultrasound energy absorbed by tissues converts to **heat**, causing temperature increases.

Acoustic Dose Rate

- The **rate of energy absorbed per unit mass (qmq_m)** depends on:
    - Ultrasound intensity II
    - Amplitude absorption coefficient α0\alpha_0
    - Tissue density ρ\rho

- Expressed mathematically as:
  $q_m = 2 \alpha_0 I$
- **Absorption coefficient** increases with ultrasound frequency; energy deposition at **10 MHz is approximately twice that at 5 MHz**.
- Acoustic dose rate is analogous to the **Specific Absorption Rate (SAR)** used in MRI.
- Ultrasound intensity is highest at the beam focus.

Temperature Increase Dynamics

- Initially, temperature increases fastest at the focus due to high intensity.
- Equilibrium is reached after about **one minute** of continuous exposure, as heat absorption balances heat conduction away from the area.
- Movement of the transducer reduces maximum temperature increase, as tissue cools upon motion.
- Greatest temperature typically occurs **midway between the skin and the focus** when stationary.

Influence of Scanning Motion

- For **stationary beams** (e.g., pulsed Doppler), maximum temperature rise occurs between the skin and focus.
- During active scanning (transducer movement), heat dissipates, preventing high temperature build-up.

Transducer Heating

- The transducer itself heats up during operation, further increasing temperature near its surface.
- Near-transducer temperatures can exceed focal region temperatures, especially in pulsed Doppler examinations.

Bone and Temperature Rise

- Bone absorbs ultrasound energy much more efficiently than soft tissue, causing rapid localized temperature increases.
- Large temperature gradients occur near bone surfaces due to concentrated absorption in a small area.

Perfusion and Temperature Regulation

- **Perfusion** can dissipate heat significantly in tissues like liver or during higher temperature elevations.
- Hyperthermic reactive perfusion (increased blood flow) typically occurs at much higher temperatures, rarely relevant in standard ultrasound scans.

Key Safety Consideration

- Temperature increase is the dominant hazard; the risk assessment must carefully consider factors like:
  - Beam intensity
  - Exposure duration
  - Tissue properties (soft tissue vs. bone)
  - Transducer-induced heating effects

TEMPERATURE IN ULTRASOUND: Measurement and Prediction

Challenges in Temperature Predictions

- Accurate prediction of temperature increases in tissues during ultrasound scans is difficult.
- Predictions require precise knowledge of:
  - **In situ intensity distribution** (challenging to estimate accurately).
  - Tissue properties (vary widely depending on age, tissue type, and individual differences).
- Acoustic output measurements provide only approximate predictions of actual tissue

intensity.

Alternative Methods for Assessing Temperature

- **Tissue-mimicking phantoms (TTOs)** are used practically to measure temperature increases:
    - They directly measure ultrasound-induced heating.
    - Cater automatically to complexities otherwise overlooked by simplified prediction methods.
- Another practical method includes simplified approaches like using **thermal indices**.

Temperature Measurement Using Tissue-Mimicking Phantoms (TTOs)

- **Tissue-mimicking phantoms (TTOs)** measure actual temperature rises caused by ultrasound equipment under controlled conditions.
- **Figure:** A schematic diagram of a typical TTO is provided (**Figure included in text**).
- Advantages of TTOs:
    - Directly measure heating potentials.
    - Account for complexities overlooked by simplified theoretical methods.
- TTOs provide a practical method to assess equipment heating potential.

Regulatory Limits and Importance

- Regulatory standards (IEC, 2007) define limits on the temperature of transducer faces:
    - **50°C** when transducer radiates into air (to simulate unintended radiation without patient exposure).
    - **43°C** when actively scanning patients.
- Ensuring compliance with these temperature limits is critical for patient safety, with TTOs providing a direct way to verify compliance.

Thermal Index (TI) in Ultrasound Imaging

- **Definition and Usefulness**:
    - The Thermal Index (TI) provides an estimate of the maximum possible temperature rise in tissue during an ultrasound scan.
    - Example: A TI value of 2.0 suggests a potential temperature increase of about 2°C.
    - TI is not an actual temperature measurement; it's more useful to observe changes (increasing or decreasing) during the scan to assess thermal hazard trends.
    - TI assists in weighing the risks versus benefits for an "average" patient but does not directly apply to individual patient specifics like physical conditions.
- **Standardization**:
    - TI was initially developed by the American Institute of Ultrasound in Medicine.
    - Now incorporated into international standards IEC60601–2–37 (2007) and IEC62359 (2010).
- **Calculation of Thermal Index**:
    - TI is the ratio of two power values:
        - Actual ultrasound power exposing the tissue (W).
        - Power required (W_deg) to increase tissue temperature by 1°C under stationary, worst-case equilibrium conditions (intended to be an upper limit in vivo).
- **Thermal Index Types**:
    - There are three distinct thermal indices, each based on specific tissue models:
        - **Soft-tissue Thermal Index (TIS)** – applicable for soft tissues.
        - **Bone-at-Focus Thermal Index (TIB)** – relevant when bone is at the focus of the ultrasound beam.
        - **Cranial (Bone-at-Surface) Thermal Index (TIC)** – relevant for cranial examinations where bone is near the transducer surface.
    - See **Figures 16.4 to 16.6** for illustrations of these three TI conditions.
- **Tissue Model Assumptions**:

- Assumptions for calculating TI include:
  - Uniform tissue attenuation coefficient of 0.3 dB cm^{-1} MHz^{-1}.
  - Small but finite tissue perfusion.
  - Fixed fraction of incident power absorbed by bone.
- All TI values scale linearly with acoustic power emitted; doubling power output doubles the TI value.

- **Frequency Dependency**:
  - The soft-tissue thermal index (TIS) depends additionally on the frequency because the absorption coefficient of soft tissue is frequency-dependent, influencing heating.
- **Limitations**:
  - TI calculations do not account for temperature rise caused by the transducer's heating.
  - Transducer heating must be assessed separately, typically with a thermal test object.
  - However, heating at deeper tissue levels usually does not exceed the surface temperature increase, making this omission less critical except under unusual circumstances.
- **Practical Recommendations**:
  - TI values typically appear on modern scanner screens, often at the top-right corner, labeled as TIS, TIB, or TIC.
  - If TI values aren't displayed, consult equipment manuals or suppliers for instructions to activate this feature.
  - Small or low-power portable devices might not display TI if values are consistently low. Verify this with the equipment manual or supplier.

DOES TEMPERATURE RISE MATTER?

- **Normal vs. Critical Temperature Levels**:
  - Normal human core temperature: approximately **36°C–38°C**.
  - Core temperature reaching **42°C** is described as "largely incompatible with life" (Miller and Ziskin, 1989).
  - Elevated temperature affects chemical reactions in cells, altering reaction rates and equilibrium positions.
- **Tissue-Specific Sensitivity to Heat**:
  - Although localized ultrasound exposure generally affects small volumes, some tissues are particularly sensitive:
    - Reproductive cells
    - Unborn fetus (especially during the first trimester, a critical period of organogenesis)
    - Central nervous system (brain and spinal cord)
- **World Federation for Ultrasound in Medicine and Biology (WFUMB) Recommendations**:
  - Developed approximately two decades ago from extensive reviews of thermal teratology.
  - Two key recommendations:

    Safe limit: Diagnostic ultrasound causing **no more than a 1.5°C rise** above the normal body temperature (37°C) is considered clinically safe.

    Hazardous limit: Temperature elevations of **4°C above normal (exceeding 41°C) lasting 5 minutes or more** in embryos/fetuses should be considered potentially dangerous.
- **Experimental Evidence on Temperature Rises**:
  - Shaw et al. (1998) demonstrated temperature rises in tissue-mimicking phantoms using clinical pulsed Doppler systems at maximum power.
    - Under typical soft-tissue conditions, temperature rise generally stayed below **1.5°C**.
    - **Special caution advised**:

- **First-trimester fetus** ultrasound through a full bladder can raise temperatures by up to **3°C**.
- **Intra-cavity probes** can cause significant temperature increases within **1 cm** of the transducer surface (Calvert et al., 2007).
- Presence of **bone** in the beam drastically increases heating:
  - **75%** of systems caused temperature rises between **1.5°C and 4°C** in bone-mimicking materials.
  - Particularly high temperatures possible when scanning through the full bladder during third-trimester fetal examinations.
  - Under extreme conditions:
    - **50%** of systems showed temperature rises exceeding **4°C**.
    - **15%** exceeded rises of **8°C**.

- **Important Considerations**:
  - The WFUMB guidelines primarily protect early fetal development (first trimester).
  - Temperature risks may be lower for other tissues or fetal stages, but precautions should still be considered due to potential tissue sensitivity.

Non-thermal mechanisms and effects

- **Two main non-thermal mechanisms** must be considered for a comprehensive ultrasound safety assessment:
  - **Cavitation-related effects**:
    - Occur when gas is present adjacent to tissues exposed to the ultrasound beam.
    - Commonly referred to as cavitation, but this category covers a broader range of conditions.
    - Most significant at **lower ultrasound frequencies**.
  - **Radiation force effects**:
    - Arise from mechanical forces exerted by ultrasound radiation on tissues.
    - Significance increases with **higher ultrasound frequencies**.

CAVITATION AND OTHER GAS-BODY MECHANISMS

- **Categories of Cavitation**:
  - Cavitation describes gas bubble activity caused by ultrasound and is classified into two types:
    - **Stable (Non-inertial) Cavitation**
    - **Inertial Cavitation**
- **Stable (Non-inertial) Cavitation**:
  - Bubbles exhibit a pulsating or "breathing" motion, contracting and expanding following pressure variations in the ultrasonic wave.
  - **Sources of cavitation nuclei**:
    - Microbubbles, solid particles in suspension, bubbles trapped on solid surfaces, and contrast materials introduced in vivo.
  - Typical diagnostic frequencies resonate with bubbles approximately **1 µm** in radius, given the simplified resonance formula.
  - **Potential biological effects**:
    - Can lead to cell damage (blood cells: erythrocytes, leucocytes, platelets) primarily through mechanical disruption (in vitro demonstrated), especially at high acoustic pressures.
    - Damage occurs more readily via shear (oscillations causing cell destruction) rather than simple compression or tension.
- **Inertial (Violent) Cavitation**:
  - Characterized by large bubble size variations, violent collapse, and occurs at

    higher peak acoustic pressures**.
  - Generated using short ultrasound pulses.
  - Produces strong local mechanical effects, extremely high temperatures, and pressures sufficient to generate **free radicals (H^+, OH^-)**.
- **Mechanical Index (MI)**:
  - Quantifies likelihood of inertial cavitation:

MI=prf\text{MI} = \frac{p_r}{\sqrt{f}}

- Where:
  - prp_r= Peak rarefaction pressure in situ
  - ff= Ultrasound frequency
- MI displayed on most scanners to indicate risk of inertial cavitation.
- **Biological Risks and Clinical Evidence**:
  - Cell damage from cavitation clearly demonstrated in vitro (e.g., erythrocytes, leucocytes, and platelets).
  - In vivo cavitation evidence mainly from extracorporeal lithotripsy treatments.
  - No substantial evidence that diagnostic ultrasound pulses typically cause cavitation damage in soft tissue under normal conditions.
  - **Special clinical scenarios for potential in vivo cavitation**:
    - Use of **extracorporeal lithotripsy**.
    - **Contrast-enhanced ultrasound** (introduced microbubbles).
    - Soft tissues adjacent to **solid concretions (e.g., renal stones)**.
    - Ultrasound exposure through structures containing gas (e.g., **fetal imaging through a full bladder**).

CAVITATION AND OTHER GAS-BODY MECHANISMS

Cavitation Risks with Gas-filled Contrast Agents

- Ultrasound exposure of contrast microbubbles in vivo can lead to:
  - Generation of **free radicals**.
  - **Cell lysis** (cell destruction).
  - **Sonoporation** (increased cell permeability).
- Extrapolating in vitro findings to in vivo conditions is challenging, particularly due to the presence of **free-radical scavengers** in blood that significantly reduce radical lifetimes.
- Use of contrast materials during **lithotripsy** (or the preceding day) is discouraged to minimize risks of fragments acting as cavitation nuclei.
- **Microvascular damage** is a proven risk with gas-filled contrast agents exposed to diagnostic ultrasound pulses in vivo.
- **Clinical guidelines for contrast-agent use** have been issued by:
  - AIUM (American Institute of Ultrasound in Medicine, 2008)
  - EFSUMB (European Federation of Societies for Ultrasound in Medicine and Biology, 2008)

LUNG CAPILLARY DAMAGE

- **Diagnostic-level ultrasound exposure** of lungs consistently results in **alveolar capillary bleeding** in experimental animal studies (small mammals).
- Similar bleeding also occurs in exposed **intestines**, likely due to adjacent gas.
- Damage occurs primarily in tissues adjacent to gas, indicating that the presence of gas bodies significantly contributes to vulnerability during ultrasound exposure.
- **Pressure Levels and Thresholds**:
  - Diagnostic pulse amplitudes sufficient to cause damage in animal studies involve fragile tissues (e.g., lungs, intestines) adjacent to gas-filled structures.
  - Observations have predominantly been made in small animals; therefore, clinical

relevance to humans might be limited.

- **Relevance to Clinical Practice**:
  - Clinical significance is generally minor, especially if bleeding is limited.
  - Greatest potential relevance applies to **neonatal cardiac examinations**, given the fragility of neonatal tissues.

CAVITATION AND OTHER GAS-BODY MECHANISMS

- **Cavitation-induced Artefacts (Stable Cavitation)**:
  - The "twinkling" artifact in ultrasound imaging (often discussed in clinical practice) is attributed to **stable cavitation**.
  - Cavitation nuclei trapped in crevices on solid surfaces (e.g., renal stones) oscillate or "breathe," potentially growing under ultrasound exposure.
  - This phenomenon explains the occurrence of the artifact in clinical scenarios.

RADIATION FORCE EFFECTS

- **Definition and Nature**:
  - Radiation force acts on all tissues within the ultrasound beam, directed **away from the transducer** along the beam axis.
  - The force magnitude is very small, directly related to the acoustic dose rate qmq_m(as per Equation 16.1).
- **Effects and Clinical Observations**:
  - Radiation force moves soft tissues slightly in the ultrasound beam's direction but typically does **not exceed forces capable of causing tissue damage**.
  - Most noticeable in vivo during **pulsed Doppler examinations**, where radiation force can cause movement of fluid (detectable via Doppler imaging).
  - Soft tissues typically resist significant movement due to internal structural integrity.
  - Despite theoretical concerns, **no evidence has confirmed harmful effects on embryonic tissues** from radiation force-induced movements.

Epidemiological Evidence for Ultrasound Safety

- Epidemiological studies explore possible associations between **prenatal ultrasound exposure** and subsequent developmental abnormalities.
- Despite extensive research, **no clear evidence** indicates harmful effects from diagnostic-level ultrasound during pregnancy.
- Caution remains advised due to theoretical risks, particularly during early developmental stages.

EPIDEMIOLOGICAL STUDIES ON ULTRASOUND EXPOSURE IN UTERO

BIRTH WEIGHT

- Several studies have investigated possible effects of prenatal ultrasound on **birth weight**.
- Current conclusion: **no evidence** of any association between ultrasound exposure and changes in birth weight due to inconsistent study outcomes.

CHILDHOOD MALIGNANCIES

- Three well-conducted, sufficiently large, case-control studies examined the potential link between ultrasound exposure in utero and **childhood cancers**.
- Findings consistently show **no association** between ultrasound use during pregnancy and childhood malignancies.

CHILDHOOD DEVELOPMENT AND MAL-DEVELOPMENT

- Studies have found **no confirmed associations** between prenatal ultrasound exposure and various developmental outcomes, including:
  - Dyslexia
  - Behavioural disorders
  - Cognitive dysfunction
  - Visual impairments
  - Childhood malignancies
- **Handedness** has been specifically studied:
  - Meta-analysis suggests a **small but statistically significant shift in handedness** associated with ultrasound exposure, though its clinical relevance remains uncertain.

SUMMARY OF EPIDEMIOLOGICAL FINDINGS

- Overall, **no robust evidence** exists linking diagnostic ultrasound exposure in utero to alterations in fetal development.
- Positive findings in some studies have generally been:
  - Unverified upon further investigation.
  - Resulting from poorly designed research methodologies.
- **Important gaps** in current research:
  - Lack of studies specifically on **pulsed Doppler** and **Doppler imaging**, techniques known to have higher intensities than standard pulse-echo ultrasound imaging.
- Current epidemiological evidence is reassuring but cannot fully eliminate all theoretical concerns, particularly regarding higher-intensity ultrasound exposures.

SAFETY MANAGEMENT OF ULTRASOUND EQUIPMENT

Roles in Ensuring Safety

- **Manufacturers**:
  - Responsible for meeting national and international safety standards.
  - Equipment must comply with established safety standards.
- **Users**:
  - Must operate equipment appropriately, ensuring patient safety.
- **Experts**:
  - Embryologists, biochemists, and physicists contribute to creating and maintaining ultrasound safety standards at national and international levels.

REGULATORY BODIES AND STANDARDS

International Electrotechnical Commission (IEC):

- Develops measurement and performance standards.
- Provides guidelines and measurement methods integrated into national directives.

US FOOD AND DRUG ADMINISTRATION (FDA):

- **FDA regulations** must be met by ultrasound equipment sold within the United States.
- FDA regulations are supported by standards set by the **International Electrotechnical Commission (IEC)**.
- Equipment must display ultrasound safety indices (**TI and MI**) based on IEC guidelines.
- FDA standards technically apply only within the United States, but manufacturers generally comply internationally, with no evidence of different safety standards outside the US.

ULTRASOUND SAFETY REGULATIONS AND GUIDELINES

European Medical Device Directive (MDD) and CE Marking

- **MDD Requirements**:
  - Medical devices (including ultrasound scanners) must comply with the **Medical Device Directive (MDD)** before being marketed within the European Community (EC).
  - Devices must clearly display warnings about potentially hazardous radiation emissions and indicate equipment accuracy.
- **CE Mark**:
  - Indicates that a device conforms to the MDD requirements.
- **Relevant IEC Standard for Ultrasound Equipment**:
  - Ultrasound scanners must comply with IEC standard:
    - **IEC60601–2–37** – details requirements for ultrasound diagnostic equipment.
  - Manufacturers must report **maximum acoustic indices (TI and MI)** for each operational mode (e.g., B-mode, M-mode, Colour Doppler).
- **Transducer Surface Temperature Limits**:
  - **43°C** maximum allowed for contact with adult skin.
  - **50°C** allowed if the transducer operates in free air.
- **Post-Brexit Regulatory Status**:
  - Post-Brexit regulations in the UK remain unclear, though a comparable regulatory system is expected.

User Responsibilities for Safe Ultrasound Use

- **Proper Equipment Usage**:
  - Users must choose the appropriate equipment and operational mode according to examination requirements and patient condition.
  - Responsible for equipment maintenance and compliance with safety standards.
- **Training and Good Clinical Practice**:
  - Essential for safe and effective ultrasound use.
  - Misdiagnosis remains a significant risk; thus, understanding image artifacts and accurate diagnosis is critical.
  - Users must be aware of ultrasound-induced hazards.
- **Safety Guidelines and Training Sources**:
  - Safety guidelines issued by professional bodies, such as:
    - **BMUS (British Medical Ultrasound Society)** – provides safety guidelines.
    - **NCRP (2002)** and **AIUM (2008)** offer further guidance.
  - Users must stay updated with current hazard assessments and guidelines.
- **BMUS Recommendations on TI Limits**:
  - **Prenatal scanning**:
    - TI $\leq$ 0.5: recommended for extended scans.
    - TI > 2.5: maximum limit of **1 minute**.
  - **Post-natal scanning**:
    - Limits similar but generally more permissive due to lower risks.
  - Graded exposure guidelines according to TI values:
    - TI > 2.5: exposure limited to **1 minute**.

US FDA Regulations

- Ultrasound equipment sold in the USA must comply with **FDA regulations**, aligned with **IEC standards**.
- FDA standards require on-screen display of safety indices (**TI, MI**).

ULTRASOUND SAFETY: APPROPRIATE EQUIPMENT USE AND GOOD PRACTICE

Appropriate Selection of Equipment

- Probes and scanners are designed specifically for certain clinical applications:
  - A probe safe for **adult cardiac** scanning may be unsafe for **obstetric** or **neonatal head** scans.
- Use equipment that clearly provides safety indicators (**TI and MI displays**).

Special Patient Populations (Extra Caution Needed)

Extra care is required when scanning:

- **Obstetric exams** (fetus and nearby maternal tissues)
- **Neonatal** patients
- Expectant mothers with **fever or elevated core temperature**
- Patients under **anesthesia or during surgery**
- When using **ultrasound contrast agents**
- TI and MI indices can sometimes underestimate actual heating or cavitation effects in these conditions.

Guidelines for Safe Clinical Practice

- **Clinical justification**:
  - Perform ultrasound examinations only when there are clear clinical reasons.
- **Reduce Exposure Time**:
  - Stop the exam once required clinical information is obtained.
  - Remove the transducer from the patient if the examination is temporarily paused or interrupted.
- **Prudent Use of Doppler Modes**:
  - Doppler modes (**PW, colour, or power Doppler**) typically cause more heating and should be used carefully.
  - Limit Doppler use to the shortest duration needed for accurate diagnosis.
- **TI and MI Displays**:
  - Prefer equipment providing clear safety indices (**TI, MI**).
  - Always use **TI ≤ 0.5** for prolonged prenatal examinations; higher values should have strictly limited exposure times (e.g., maximum **1 minute for TI > 2.5**).
- **Recommended TI use**:
  - General examinations: maintain **TIS ≤ 0.5**.
  - **Transcranial examinations**: use TIC.
  - For other exams, TIB or TIS as appropriate.

Guidelines for Safe Examination Practice

- **Clinical Necessity**: Only perform examinations when clinically justified.
- **Minimize Exposure Time**:
  - Stop examinations immediately once diagnostic information is achieved.
  - Remove the probe during breaks or pauses when attention is diverted.
- **Maintain Awareness**: Regularly consult displayed indices (TI, MI) during scanning to remain aware of potential thermal or mechanical risks.

PROPER MAINTENANCE AND ULTRASOUND EXPOSURE TRENDS

PROPER MAINTENANCE OF ULTRASOUND EQUIPMENT

- **User Responsibility**:
  - Users must ensure regular **maintenance and repairs** for ultrasound equipment.
  - Active user involvement encourages safer equipment and can lead manufacturers to address safety concerns proactively.
- Active participation by users in highlighting safety concerns:
  - Enhances the quality and safety of ultrasound devices.
  - Contributes to improved international standards via professional debates and discussions.

IS ULTRASOUND EXPOSURE ALTERING IN CLINICAL PRACTICE?

- Three key considerations:

    Current Exposure Levels: Have modern clinical practices increased ultrasound exposure?
    Technological Developments: Have new scanning methods or transducer types (e.g., trans-vaginal, trans-oesophageal) changed patient exposure?
    Clinical Trends: Have increased scan numbers or longer scan times altered exposure?

HISTORICAL CHANGES IN ULTRASOUND OUTPUT

- **1990s Trend**:
  - Relaxation of FDA intensity limits (particularly for non-cardiovascular and obstetric scanning) led to higher ultrasound intensities used clinically.
  - Manufacturers approached FDA-set upper limits more frequently, increasing patient exposure.
- **Present Concerns: Acoustic Pressure Limitations (MI)**
  - Due to physical limits in acoustic pressure achievable in water, actual in situ exposure may be **underestimated**, especially at higher frequencies (Duck, 1999).
  - In some situations, the FDA's MI limit (**1.9**) cannot be exceeded due to intrinsic physical constraints, masking true exposure levels and potentially hiding further increases in ultrasound output.
- **Potential Hidden Risk**:
  - At higher frequencies, actual in situ ultrasound exposure may surpass displayed MI values.
  - **FDA MI limit (1.9)** sometimes cannot be exceeded in water tests, potentially causing underestimation of real exposure.

Referenced Figures and Equations:

- Mentioned standards: **FDA MI limit of 1.9**.
- Duck (1999) noted inherent acoustic pressure limitations in water tests, affecting accuracy of MI readings.

Summary:

- Users must actively ensure equipment maintenance and engage in developing safety standards.
- Historical evidence shows increased ultrasound exposure due to relaxed regulations in the 1990s.
- **Currently, true exposure levels at higher frequencies might be underestimated due to limitations in water-based testing**, potentially masking increases in exposure.

OTHER DIAGNOSTIC MODES OF ULTRASOUND OPERATION AND TRENDS IN USAGE

Diagnostic Modes and Associated Intensities

- **Pulsed Doppler** modes produce the **highest intensities**.
- **Doppler Imaging** (including colour-flow and power Doppler):
  - Typically uses similar acoustic outputs to pulsed Doppler.
  - High intensities particularly occur with:
    - Narrow colour boxes
    - High line density
    - High frame rates
- **Pulse amplitudes (rarefaction pressures, prp_r, or MI)** for Doppler imaging are generally similar to those used in standard imaging, typically reaching about **2.5 MPa**.
- **Harmonic imaging** specifically requires higher pulse amplitudes for effective harmonic generation.

Plane-wave and Zonal Imaging

- Expected to **reduce peak intensities and acoustic pressures** due to absence of beam focusing on transmission.
- Conversely, other developments, especially higher-frequency and **intraluminal probes** (trans-rectal, trans-oesophageal, trans-vaginal), may **increase energy deposition and tissue heating**:
  - FDA limits apply in the US; manufacturers typically adopt similar limits globally, though it's not mandatory internationally.
  - Higher-frequency probes can achieve greater tissue heating without exceeding regulatory acoustic power limits.

Increasing Use of Diagnostic Ultrasound

- **Rapid growth** in ultrasound usage documented:
  - In England, ultrasound scans increased from about **6 million** per year (early 2000s) to nearly **10 million** (April 2013–March 2014).
  - Much of this increase involves **non-obstetric scanning**.
- Short scan durations are typical due to clinic time constraints, but certain conditions require **longer exposure times**, such as:
  - Fetal breathing assessments
  - Flow studies
  - Ultrasound-guided interventions
- Increased usage by **novice practitioners** might also extend exposure durations.

Conclusion:

- Population exposure to diagnostic ultrasound is **increasing significantly** and is expected to continue growing in the foreseeable future.

SAFETY CONCERNS FOR SPECIFIC TISSUES: FIRST TRIMESTER ULTRASOUND EXPOSURE

- **First-trimester embryonic sensitivity**:
  - The embryo undergoes rapid development, including organ formation and cell migration, making it particularly sensitive to external influences.
  - External agents during this critical phase can cause outcomes ranging from subtle biochemical disturbances to severe developmental abnormalities.
- **Thermal risks**:
  - Heat is known as a teratogen; temperature increases due to ultrasound absorption can impact embryonic development.
  - **Bone**, the tissue most prone to significant heating, typically starts forming **at the end of the first trimester**, reducing early heating risks.
  - Current evidence suggests that embryonic tissues generally do not experience temperature rises above **1.5°C** with typical diagnostic ultrasound exposures,

suggesting low risk.
    - However, biochemical processes, membranes, and signal-transduction pathways are temperature-sensitive; the effect of smaller temperature rises remains poorly understood.
- **Cavitation risks**:
    - No current evidence of cavitation occurring during first-trimester scans, due to the absence of gas bubbles (cavitation nuclei) in the uterus.
- **Radiation force risks**:
    - Ultrasound radiation force generates acoustic streaming (movement of amniotic fluid around the embryo), generally considered harmless.
    - A report by Ang et al. (2006) indicated possible **neuronal migration effects** in mouse embryos due to radiation force; however, this finding **has not been independently confirmed**.
- **Overall safety conclusion**:
    - Although existing knowledge suggests diagnostic ultrasound in early pregnancy is generally safe, sufficient gaps and uncertainties exist.
    - Current guidance therefore recommends continued caution, particularly considering unknown subtle biological interactions.

SAFETY CONCERNS: DIAGNOSTIC ULTRASOUND IN SPECIFIC CONDITIONS

Ultrasound During Second and Third Trimesters

- **Main safety concern**: Bone ossification.
    - Fetal **bone tissue** strongly absorbs ultrasound energy, causing local **temperature increases**.
    - Adjacent soft tissues (including sensitive neurological tissues like brain and spinal cord) can experience secondary heating by thermal conduction.
- **Risks associated with heating**:
    - Neurological tissues (**brain and spinal cord**) are highly sensitive to elevated temperatures.
    - In guinea pig studies, **abnormal neutrophil cell nuclei** occurred after a 6-minute exposure at a **2.5°C** temperature increase, achievable by modern pulsed Doppler systems.
- **Cavitation risks**:
    - Extremely unlikely due to the absence of gas nuclei.
- **Radiation pressure and streaming**:
    - Present but considered unlikely to cause damage due to increased structural integrity of fetal tissues (collagenous structures and extracellular matrix).

Obstetric Scanning in Febrile Patients

- WFUMB specifically advises caution when scanning pregnant patients who have a fever.
- **Increased baseline maternal temperature** already places the fetus at higher risk.
- Recommendations include:
    - Minimizing the **Thermal Index (TI)**.
    - Limiting **duration** of the scan.
    - Avoiding unnecessary use of **Doppler ultrasound** modes.

Neonatal Ultrasound Scanning

- **Special caution required**, especially in:
    - **Neonatal head scans**
    - **Neonatal cardiac scans**
- Scans often performed on seriously ill neonates; diagnostic needs must balance against

risks.

Neonatal Head Scanning Risks

- Similar concerns to **second and third-trimester fetal scans**:
  - Bone absorption of ultrasound leads to temperature rises that may affect developing neuronal tissues.
  - Brain tissues adjacent to bone (skull) may be heated by conduction.
- **Potential sources of heat in neonatal head scans**:

  Bone absorption: Ultrasound absorbed directly by the skull. The **Cranial Thermal Index (TIC)** estimates this risk.

  Transducer self-heating: May independently increase surface temperature by a few degrees, especially at high acoustic outputs.

Summary of Recommendations

- Vigilance and precaution remain important due to the sensitivity of developing neurological tissues.
- Monitoring TI and limiting ultrasound exposure duration are critical, especially in:
  - **Second and third-trimester fetal scans** (due to bone heating)
  - **Febrile obstetric patients** (due to already elevated maternal temperature)
  - **Neonatal head scanning** (due to proximity of brain tissue to skull bone and transducer heating risks)

SPECIFIC ULTRASOUND SAFETY CONCERNS: NEONATAL CARDIAC AND OPHTHALMIC SCANNING

Neonatal Cardiac Scanning

- Neonatal cardiac ultrasound, especially **Doppler blood-flow imaging**, may expose adjacent **pleural tissue** to ultrasound pulses.
- **Experimental evidence** indicates potential **alveolar capillary damage**:
  - Observed in small adult animals and juvenile larger animals.
  - No human evidence of similar lung damage yet identified, even in neonates.
- **Neonatal pleura** is immature, structurally weaker, and potentially vulnerable to ultrasound-induced mechanical stresses.
- **Recommended safety practice**:
  - Maintain **Mechanical Index (MI)** at the lowest level consistent with effective diagnostic imaging.

Ophthalmic Ultrasound Scanning

- The eye is uniquely regulated by the **US FDA** due to special sensitivity to ultrasound damage.
  - **Regulatory limits**:
    - **Intensity**: **50 mW cm^{-2}** (much lower than **720 mW cm^{-2}** for other tissues)
    - **Mechanical Index (MI)**: **0.23** (compared to **1.9** in general applications)
    - **Thermal Index (TI)** limit: **1.0**
- Reasons for strict regulation include:
  - **Unperfused tissues** (cornea, lens, vitreous body) dissipate heat solely via conduction, increasing susceptibility to thermal damage.
  - Poor blood supply limits tissue healing and repair capabilities after damage.
  - High acoustic attenuation in the lens (**8 dB cm^{-1} at 10 MHz**) results in significant local energy deposition (up to half incident power).
  - **Transducer self-heating** poses additional risks due to proximity to the lens during typical ophthalmic scans.
- **Recommended practice**:

- Ophthalmic ultrasound devices specifically designed to limit heating and acoustic output.
- Extreme caution required if general-purpose ultrasound scanners are used to avoid lens heating.