Non-ionizing radiation for diagnostic and cosmetic purposes

Adele GREEN, International Commission on Non-Ionizing Radiation Protection (ICNIRP)
Jacques ABRAMOWICZ, World Federation for Ultrasound in Medicine and Biology (WFUMB)
Emilie VAN DEVENTER, World Health Organization (WHO)

International Commission on Non-Ionizing Radiation Protection
ICNIRP aims to protect people and the environment against adverse effects of non-ionizing radiation (NIR) by developing and disseminating science-based advice on limiting exposure to NIR.

World Federation for Ultrasound in Medicine and Biology
WFUMB helps bring sustainable ultrasound programs to the underserved areas of the world to improve global healthcare through collaboration, communication, and education.
Outline

1. Introduction
2. Range of NIR diagnostic devices
3. Regulations and policies (patients, health care workers)
4. Potential risks from diagnostic use of NIR
5. Situations of potentially high NIR exposure
6. Conclusions
Electromagnetic field spectrum

Non-ionizing

Static fields
- 100 kHz
- 300 MHz
- 10 GHz
- 300 GHz

Ionizing radiation

Frequency

Low frequency fields
Radiofrequency fields
Optical radiation

Acoustic spectrum

Frequency (Hz)
- 1 Hz
- 1 kHz
- 1 MHz

Infrasound

Sonar

Ultrasound

Devices: EMF (0 - 300 GHz)

A. Intentional exposure of patient
   - Magnetic Resonance Imaging (MRI): static, LF, HF
   - Transcranial magnetic stimulation for diagnosis: LF
   - Volumetric EM phase shift spectroscopy: HF (26-166 MHz)
   - Microwave-induced thermoacoustic echography: HF (800 MHz), e.g. breast
   - Radar imaging: HF (4–10 GHz), superficial imaging, e.g. skin
   - Radar monitoring: HF (10–24 GHz), respiration, heart rate

B. Unintentional exposure of patient, worker
   - RFID: HF (120 kHz–400 MHz), storing of patient or device information
   - Wireless signal transfer: HF (400 MHz), miniature measurement device, e.g. heart rate, temperature, medication use
   - EMF movement tracking: HF, e.g. jaw
Devices: optical radiation

A. Detailed imaging of superficial structures via absorption, scattering, fluorescence
   - Terahertz imaging: IR (3·104–106 nm), e.g. breast
   - Tethered capsule endomicroscopy: IR laser (1220–1380 nm), gut
   - Catheter endomicroscopy: IR LED (822–842 nm), gut
   - Photoacoustic tomography: pulsed laser (532–770 nm), e.g. breast, skin

B. Illumination/Visualization
   - Opthalmoscopy: visible incandescent/halogen/LED, imaging during surgery, surgical microscope: visible incandescent/halogen/LED, imaging of retina

C. Measurement
   - Near-infrared spectroscopy (NIRS): laser/LED (700–1000 nm), oxygenation, lipid content, e.g. cerebral cortex
   - Diffuse correlation spectroscopy: IR laser (650–950 nm), blood flow, e.g. breast, skin, muscle, brain, prostate
Devices: ultrasound

A. Biometry (40 MHz)
   • A-scan, biometry of distances in eye

B. Imaging (1–20 MHz)
   • High frequency B-mode scanning, imaging of small structures
   • General body B-mode scanners, most common 2D body imaging
   • Real-time imaging at high frame rates, imaging of moving structures
   • 3D-imaging, computer synthesis of multiple 2D scans, foetus/labour

C. Doppler devices (1–6 MHz)
   • Continuous wave, low resolution blood velocity
   • Pulsed doppler, high-resolution blood velocity
   • Duplex doppler, combined imaging and blood velocity
   • Elastography, recording tissue motion associated with mechanical stress
Regulation

- **Patients**
  - Medical device (marketing) regulation and associated technical standards
  - Regulations of national regulatory agencies
  - National legislation with fixed limits for NIR-emitting devices
  - Guidelines issued by national or international professional associations

- **Health care workers**
  - Legislation with binding exposure limits (e.g. EU, Russia)
  - General health and safety legislation (e.g. Japan, USA)
  - Technical standards related to medical device legislation
  - Guidelines issued by national or international professional associations (e.g. ACGIH)
Risks (1)  
EMF

- **MRI:**
  - Acute perceptual, cognitive effects (vertigo, nausea)
  - Acute nerve stimulation effects
  - Acute heating effects
  - Possible delayed effects? (accidents in workers)
  - Developmental effects: few studies (no effect), confounding (e.g. contrast), suitable control group

- **Other applications:**
  - Few data on specific devices, would depend on exposure level vs. limits
  - TMS: magnetic fields can exceed occupational reference levels
  - Microwave tomography: patient and worker exposure expected to be below general population reference levels for thermal effects
**Risks (2)**

- **Optical radiation**
  - Acute damage to cornea, lens, retina
  - Acute damage to skin
  - Increased risk for skin cancer (UV)
  - No unexpected health risks in worker surveillance (laser)

- **Ultrasound**
  - Acute effects: no adverse outcomes for nervous system, haematological parameters
  - Reported adverse effects (heart, liver) may be due to contrast agent or interaction between ultrasound and contrast agent
  - Developmental effects: exposure almost universal, comparison high vs. low exposure gives no indications for effects on miscarriage, cognitive effects, childhood cancer, …
  - Workers: low or incidental (test) exposure, no risk expected
Research Gaps
Further research needs

● **EMF**
  - *MRI*: possible harmful (thermal) effects on foetus and possible long term effects in workers
  - *Other applications*: exposure/dosimetry of novel imaging techniques

● **Optical radiation**
  - risk threshold of repetitive short pulses and on internal exposure limits (gut)

● **Ultrasound**
  - potential risk of malformation after early exposure (1st trimester) and interaction between ultrasound and contrast media
NIR medical devices for non-medical purposes

- Use of medical devices for non-medical applications
  - Cosmetic purposes (laser removal of tattoos, body shaping with ultrasound, sunbeds)
  - Souvenir imaging of the foetus
  - "off-label" use of transcranial Direct Current Stimulation
  - Neuromarketing (MRI)

- No adequate regulatory framework

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