Zambia Perinatal Ultrasound Certification System

Although ultrasonic testing is an extremely safe testing method, depending on the intensity of the ultrasonic wave, it may cause adverse effects on the human body. Mechanical index (MI) and thermal index (TI) are measures of ultrasound safety. MI is related to the mechanical effect of ultrasonic waves on the human body, and is the value related to the cavitation, a phenomenon in which bubbles are activated by pressure changes. On the other hand, TI is related to the thermal effect of ultrasonic waves on the human body. The principle of ALARA (as low as reasonably achievable) exists in the use of ultrasound, and it is required that the ultrasound be performed at the lowest power within the range where the examination is adequate and in the shortest possible time.

Furthermore, infection control measures are essential for safe and effective use of ultrasonic testing and should be implemented in accordance with conventional infection control measures and measures against emerging infectious diseases such as new coronavirus infections. In general, bedside maintenance of ultrasound equipment is often inadequate, which poses a risk of spreading infection. After the examination, not only should the echo gel adhering to the probe be wiped off, but also decontamination of body fluids and blood should be carried out in accordance with the policies of the facility. Some types of disinfectants may damage ultrasound equipment, probes, etc., and there is no recommended disinfectant for all ultrasound equipment. Therefore, when selecting a disinfectant, it is necessary to refer to the manual of the device or contact the manufacturer. Portable ultrasound devices, which have become increasingly popular in recent years, are easy to use in the treatment of novel coronavirus infection because they are easy to keep clean and can be used entirely in a cover.

Laptop, tablet, and pocket-sized ultrasonic devices are functional, portable, and easy to wipe clean. This is easy to do, and infection control measures are easy to implement. In some cases, remote ultrasound may be used as an infection control measure, and recording and storage of ultrasound images are necessary in such cases. In order to reduce the risk of infection among healthcare workers, it is recommended to reduce the number of X-ray and CT examinations performed by introducing point-of-care ultrasonography (POCUS), and to perform POCUS in a shorter time and with more focused items. Disinfection of ultrasound equipment should be performed in the manner recommended by the manufacturer.

Basics of Ultrasonography

Objective

1. **Explain the relationship between the physical properties of the propagating medium and sound wave propagation.**

   Sound velocity: The velocity in solids (3,500 m/s) is the highest, followed by liquids (1,540 m/s) and gases (340 m/s). The speed of sound in a living body is considered to be basically liquid, and the speed of sound in soft tissues such as fat, organs, and muscles is almost the same as that in liquids.

   Acoustic impedance: Sound waves are partially reflected at boundaries with different acoustic impedances of the medium.

* Acoustic impedance (Z) = sound velocity in the medium (c) × density of the medium (ρ)

2. **Explain reflection, transmission, and refraction of sound waves.**

   Reflection: reflection intensity (Ri) = $\left(\frac{Z2-Z1}{Z2+Z1}\right)^2$ The higher the density of material deeper than the boundary, the higher the reflection intensity.

medium	Speed of sound (m/s)	Acoustic impedance ($\times 10^6$ kg/m^2・s)
air	340	0.0004
blood	1,570	1.62
fat	1,450	1.35
average soft tissue	1,540	-
bone	4,080	7.80
water (esp. cool, fresh water, e.g. drinking water)	1,480	1.52

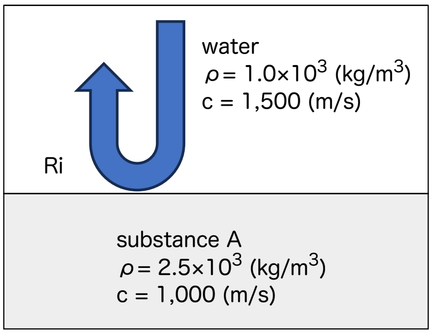

Figure 1. Reflection

Since the acoustic impedance of air and bone is extremely different than that of soft tissue, most ultrasound waves are reflected at the boundaries.

Refraction: Ultrasonic waves are refracted at boundary surfaces where the sound quality of the medium differs.

Incident angle ($\frac{sin\theta 1}{C1}$), Reflection angle = ($\frac{sin\theta 2}{C2}$)

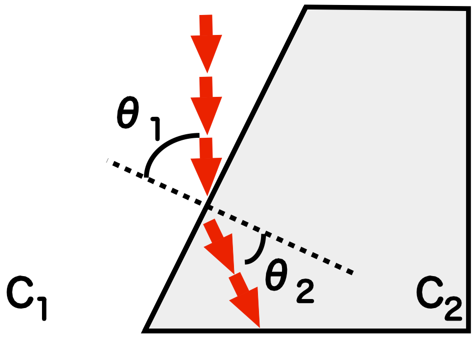

Figure 2. Refraction

Transmission: All non-reflective ultrasonic waves are transmitted.

Transmission Intensity (TI) = 1 - Ri $=\frac{4 \cdot Z2Z1}{(Z2+Z1)^2}$

Acoustic properties of living organisms

Objective

1. **Explain frequency-dependent attenuation of sound wave propagation in vivo and its effect on diagnosis.**

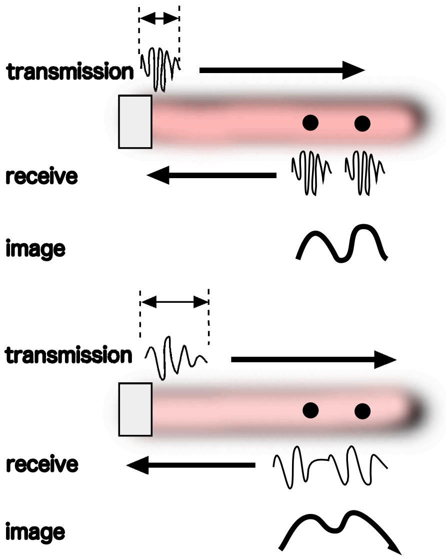

Figure 3. frequency-dependent attenuation of sound wave propagation

High ultrasound frequency increases the directivity, which improves the resolution. Although the area near the probe becomes more visible, the attenuation rate is higher, so the transmissivity is lower, and the ultrasound cannot reach deeper. The pulse width must be shorter than the distance between the two substances in order to distinguish between them.

2. **Explain the influence of the acoustic structure of a living body on sound wave propagation.**

   Ultrasonic pulses are highly directional, so ultrasonic waves travel straight ahead. In vivo, the speed of ultrasound is almost constant (almost equal to the speed of ultrasound in water) except in bone and lung.

3. **Explain the relationship between the distribution of scatterers in vivo and ultrasound image characteristics.**

   When ultrasonic waves strike irregular tissue boundaries or minute reflective objects, they diffuse (scatter) in all directions. Scattering reduces the intensity of ultrasonic waves that travel deeper into the body. If the ultrasonic frequency is a few MHz, the ultrasonic waves are hardly scattered by the biological tissue (scatterers).

Diagnostic

Objective

1. **Explain the signal flow from ultrasound transmission and reception to image display.**

   The ultrasound imaging system propagates ultrasound waves from the probe into the living body and irradiates them into the tissue. The echoes from the scatterers in the tissue are reconstructed as the distance and direction to individual scatterers according to their propagation time and orientation to visualize the tissue in the body.

2. **Explain the relationship between the displayed image and gain, dynamic range, STC, etc.**

   Gain: This function changes the signal level of the entire ultrasound image to create a brighter or darker image. Too much gain causes noise to appear, and too little gain causes information to be missing in weak areas of the ultrasound image.

   Dynamic Range: The range between the upper and lower limits of the received signal strength. Lowering the dynamic range displays a narrower range of signals with a larger difference in luminance. (The contrast between black and white becomes stronger, resulting in a harder image. (outlines are emphasized)

   STC (Sensitivity Time Control): Because ultrasound attenuates in vivo, reflected echoes are weaker when the tissue is farther away from the probe and stronger when it is closer. STC can balance echo brightness by applying gain correction to reflected signals from various depths.

   Echo Enhancement: to enhance the rising edge of the signal to make it easier to see the contours of organs.

3. **Explain the relationship between repetition frequency, scanning width, diagnostic distance, etc.**

   Repetition frequency: Pulse waves are repeatedly emitted at intervals to produce an ultrasound image; the number of pulse waves repeated in one second is called the repetition frequency.

Ultrasound equipment has a defined upper limit of energy output (age range 720 mW/cm^2). Ultrasound operators should pay close attention to the power output indications (MI and TI) and perform examinations in compliance with the ALARA (as low as reasonably achievable: as low as necessary to achieve the necessary medical judgment) principle.

MI and TI may be higher with pulsed Doppler.

MI (Mechanical Index): An index for the potential of non-thermal actions, such as cavitation, to induce adverse biological effects. (An index to evaluate the safety of non-thermal effects of ultrasound, recommended to be used when MI<1.0)

This is less of a problem in perinatal ultrasound, where few bubbles are present in the object.

Cavitation: When ultrasound is applied to a liquid and the ultrasound intensity is increased, bubbles are generated in the low-pressure area, and when the peak sound pressure exceeds the static pressure, the bubbles collapse and disappear. This phenomenon occurs in a short period of time and is used in ultrasonic cleaners and extracorporeal shock wave lithotripsy devices because of the extremely high pressure generated by the generation and collapse of bubbles. When cavitation occurs in vivo, it can cause bleeding from tissues containing bubbles and rupture of tissue structures.

TI (Thermal Index): An index that evaluates the potential for tissue temperature increase and is an important index for perinatal ultrasound examinations. (an index to evaluate the safety of thermal effects of ultrasound)

Ratio of ultrasound output to power required to raise the temperature of in vivo tissue by 1°C

Acoustic Safety

Ultrasonic Intensity

Ultrasonic wave intensity = Ultrasonic wave output [W] / irradiated area [cm^2] (sound energy passing through a unit area perpendicular to the direction of sound wave travel in a unit time)

Ultrasonic Output = Total energy of ultrasonic waves emitted from the probe in unit time

Safety indicators of ultrasound output (TI & MI)

	MI	**TI**
important	• Contrast medium is used • Irradiation of lungs during echocardiography • Intestinal gas during abdominal echocardiography	• Early pregnancy examination (Soft tissue): TIS • Testing in the 2^{nd} and 3^{rd} trimester of pregnancy (Bone): TIB • Fetal Cranial (TIC) and spinal cord • Patient with fever • Ultrasound irradiation to the ribs and Bones: TIB
unimportant	No air bubbles are present	

【Probe】

Objective

a-1) Explain the basic structure of a probe and the roles of its components.

The probe generates ultrasound and transmits and receives ultrasound beams.

The internal structure of the probe consists of an "acoustic lens," "acoustic integration layer," "transducer," and "backing," in order from the tip (the surface in contact with the living body).

Transducer is the part that transmits and receives ultrasonic waves. When voltage is applied, it vibrates to generate ultrasonic waves, and when it vibrates, it generates voltage. It is made of a material that has a piezoelectric effect (piezoelectric effect).

Backing: Placed behind the transducer to suppress backward ultrasonic wave propagation.

Acoustic integration layer: A multilayer arrangement to reduce the acoustic impedance difference between the transducer and the living body and to transmit and receive ultrasound waves efficiently.

Acoustic Lens

Although the purpose is to reduce friction with the biological surface during examination, it is also positioned to focus the ultrasound beam using refraction and to improve resolution in the thickness direction of the slice. Generally, a material that is convex and slower than the speed of sound in vivo (about 1000 m/sec: silicone rubber) is used.

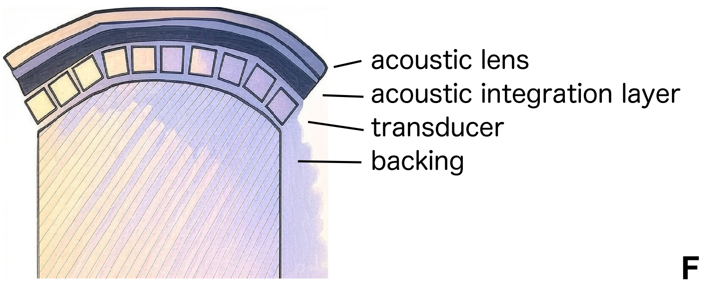

Figure 4. Echo probe

Type of probe

Linear, convex, and sector types are commonly used, but there are also intracorporeal probes for transesophageal echocardiography and transrectal ultrasonography, and special probes used for puncture and other procedures.

probe	Array of piezoelectric elements	Frequency (MHz)	Depth (cm)	Resolution (mm)
Linear	Linear	7 – 15	3 − 6	0.5 − 1.0
convex	curved	3 – 7.5	15 – 20	2 − 3
sector		3 – 5	15 − 18	1.5 − 2

A linear probe is used to view shallow areas through the epidermis, a convex probe is used to view large areas in the abdomen and elsewhere, and a sector probe is used to view narrow areas between the ribs in the circulatory system.

a-2) Explain the types of arrays and the principles of imaging.

Array: An ultrasonic inspection probe that incorporates elements that simultaneously transmit ultrasonic waves in a specific direction. Multiple elements in a row emit and receive ultrasonic pulses. The multiple beams form a single wave.

a-3) Explain the principles of electronic focus and scanning.

Electron scanning: Scanning is performed by arranging a large number of transducers in a strip of paper and shifting the transducers that are simultaneously driven (transmitted and received) in turn.

Azimuth resolution (focus): The ability to discriminate reflected waves from two points orthogonal to the beam. The larger the beam width, the better the discrimination capability. To improve the azimuth resolution at the focus point, increase the transducer diameter and shorten the wavelength.

Electronic focus: Timing is controlled so that ultrasonic waves transmitted from each element reach the focus point simultaneously.

B: Average ultrasonic velocity in the human body is 1,530 m/sec (344 m/sec in air and 1,520 m/sec in water)

D: Distance resolution: the ability to discriminate reflected echoes from two reflection sources aligned in the beam direction. Shorter transmission pulse widths can discriminate smaller objects. To improve the distance resolution, shorten the wavelength when the wavenumber is constant. When the wavelength is constant, the wavelength is decreased.

G: Convert the intensity of the reflected echo into a change in brightness. This is repeated to form a B (Brightness) mode image.

Operation and operation of diagnostic equipment

Objective

a-1) Explain coupling media.

Also called contact medium. A substance placed between the probe and the specimen to improve ultrasound propagation. Jelly, saline solution, isodine solution.

a-2) Explain the calibration of diagnostic equipment using phantoms.

Ultrasound phantoms are used for quality control of ultrasound imaging systems, in which variously different specimens are placed in a hydrophilic urethane rubber or gel substrate that has the same sound velocity as the skin and muscle tissue of the human body.

Acoustic safety

Objective

a-1) Explain how to display ultrasonic intensity.

The intensity of ultrasonic waves is the acoustic energy that the ultrasonic waves pass through a unit area perpendicular to the direction of travel in a unit time, expressed in [W/m^2]. If the ultrasonic beam is moving, the intensity is dispersed, thus reducing the possibility of temperature increase.

a-2) Explain cavitation and its effects.

Ultrasound produces two physiological effects when irradiated on a living body: thermal and nonthermal effects.

Thermal action: The attenuation of ultrasound in vivo causes energy to be converted into heat, which increases the element temperature.

Non-thermal action: **Cavitation** Caused by mechanical vibration. Bubbles repeatedly contract, expand, and collapse, causing tissue damage. **Non-cavitation** Micro vibration stimulates cell membranes, improves cell functions, and repairs tissue damage. Promotes blood circulation and reduces inflammation and edema.

Safety: There is no concern about radiation exposure, and the test can be repeated with little burden to the body. High safety. No pain.

Electrical and other safety

Objective

Explain the safety of the main unit. Explain the safety of probes.

1. **Explain the safety features of the main unit.**

   Mechanical index (MI): The mechanical effect of ultrasound on a living body. When the negative sound pressure exceeds a certain value, bubbles are generated in the body (**cavitation**), and when these bubbles burst, they cause mechanical damage to the organism. MI increases as the negative peak sound pressure increases. MI increases as frequency decreases.

   Thermal index (TI): Thermal energy effect produced by the absorption of ultrasound by a living body. In vivo, protein denaturation occurs at temperatures above 42°C (TI 1 is the ultrasound power required to raise the temperature in vivo by 1°C). (TI 1 is the ultrasound power required to raise the temperature in vivo by 1°C.) TI is dependent on the total acoustic power.

2. **Explain the safety of probes.**

   The probe is set not to exceed 43°C.

   Do not use the probe if it is scratched, as it may cause electric shock.

a-1) Explain the concept of patient leakage current and protective grounding.

The standard for patient leakage current: Leakage current is a current that flows from the adhesive part of the probe to the patient to the surface of the equipment. Leakage current is a current that should not flow and is caused by poor insulation performance of wiring and equipment. If the patient leakage current is too large, there is a risk of damaging the patient. Normally, electric shock is prevented by releasing the leakage current to the ground through a ground wire (**protective grounding**), but if grounding is not obtained and a large leakage current is generated, the patient may be shocked.

Reduce the leakage current of the power supply supplied from the power supply unit to several tens of μA or less.

Electrical safety of ultrasound: An important electrical safety issue in ultrasound systems is "leakage current". Leakage current is a so-called electric leakage current, which can cause electric shock to the patient or examiner. An electric shock of 100 mA received from the body surface can cause ventricular fibrillation. Leakage current includes "ground leakage current," "exterior leakage current," and "patient leakage current." Ground leakage current that is grounded is safely handled, but electricity that flows through the enclosure to the patient or examiner or through electrodes or probes is a problem.

a-2) Explain the concept of micro shocks and macro shocks.

There are two types of electric shock in the medical field.

Macro shock: Electric shock through the skin.

Micro shock: Electric shock is given directly to the heart or other parts of the body through a cardiac catheter or other device placed inside the body. In the case of micro shock, the electric current is 1/1000 of that of macro shock.

a-3) Explain B-type, BF-type, and CF-type equipment. (Classification of mounting parts according to the degree of protection against electric shocks)

Classification of Mounting Area	Patient leakage current (normal state: mA)	Applicable parts	External current inflow protection
B-type	0.1 (anti-macro shock)	Body surface only	No protection
BF-type	0.1 (anti-macro shock)	Body surface only	floating
CF-type	0.01 (anti-macro shock)	heart-directed	floating

i type B (blood, influenza, hepatitis, etc.)

A device that is worn only on the body surface (the wearing part) and has the lowest safety grade. Only one device is used per patient.

ii BF type

Although the device (wearing part) is applied only to the body surface, it is intended to be connected to a number of devices at the same time. It is protected against leakage current from other devices. It is designed so that a patient who enters between devices will not be electrocuted.

iii CF type mounting section

The highest grade, where the device's sensors and leads are inserted directly into the heart (the wearing part).The B or BF fitting should never be connected directly to the heart.

B- and BF-type wearing parts: The "B" in the symbol is the initial letter of Body.

Devices with a CF-type fitting: Devices that can be applied to the heart, such as pacemakers that may come into direct contact with the heart, must be used with a CF-type fitting. The "C" in the symbol stands for Cardial.

Floating: F is an acronym for Floating. Floating means floating, i.e., insulated. The electrodes and lead wires connected to the patient and the power supply unit of the device itself are electrically insulated, and the leakage current flowing into the patient can be kept low.

Maintenance management

Objective

a-1) Explain how to maintain and manage the main unit.

Check the probe cable and power cable for kinks, bends, or insulation damage. Also check the connections. Is the LAN cable properly connected to the LAN outlet? Are there any damages?

a-2) Explain the maintenance of probes.

Check for scratches, cracks, or other abnormalities on the acoustic lens surface, etc. Check for cracks, damage, or broken pins on connectors.

a-3) Explain maintenance of diagnostic equipment using phantoms.

Control the deterioration of instruments and probes. When the equipment or probe is purchased or changed, the imaging conditions and parameters are controlled, and subsequent changes are managed by phantoms.

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