FAMILIE DOKTOR
MEDIZINTECHNIK

Model: BABYGERÄUSCH

FETAL DOPPLER EN
FETAL DOPLER TR
DOPPLER FŒTAL FR
DOPPLER FETAL ES
FETALER HERZMONITOR DE

Instruction Manual EN
Kullanım Kılavuzu TR
Mode d'emploi FR
Manual de instrucciones ES
Bedienungsanleitung DE
Руководство Пользователя RU
KU Rêbera Bikaranînê KU
كتيب التعليمات AR
دستورالعمل راهنما FA

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CONTENT

Section 1 : Introduction

1.1 Product description

The product is mainly used to detect the sound of the fetal heartbeat (SFH. Fetal heart rate (FHR is important basis for checking whether a fetus is healthy. Recording the changes in FHR helps detecting signs of fetal hypoxia, fetal distress, fetal umbilical cord around neck, and so on. Fetal monitoring at home or department of gynaecology and obstetrics and clinic environment mainly includes listening to fetal heartbeat and checking FHR changes, which help greatly increase fertility safety.

1.2 Operating principle

Fetal Doppler consists of probe (transmitter and receiver and signal process unit. Ultrasonic wave is transmitted from one piezoelectric ceramic at the front of the probe to the uterus of the pregnant women. Echo is received by the other piezoelectric ceramic at the front of the probe when ultrasonic wave reaches the fatal heart. Then it is converted into voltage. This doppler signal is detected and demodulated from the received signal. And the doppler frequency is consistent with the rhythm of the fetal systole and diastole. Once cardiac valves vibrate and a doppler frequency excursion is formed. It is transmitted an output signal of cardiac valves vibrating, and it is sent to the loudspeaker for getting a rhythmical sound with the fetal heartbeat. Simultaneously, it is sent to a counter which calculate periods of heartbeat that is fetal heartbeat rate (bpm=beat per minute.

1.3 Intended use

The Fetal Doppler Babygeräusch is a hand-held, battery powered audio Doppler device used for detecting fetal heartbeats. The patient is an intended operator.

1.4 Indication for use

The device is ultrasonic fetal heart beat detector, which can detect the Fetal Heart Rate. The built in speaker of the device allows for listen to the fetal heartbeat. The Product normally is applied to fetus of above 16 weeks growth, difference in pregnant mater. The normal range of fetal heart rate: 110bpm-160bpm.

Listen to SFH:

Operator can listen to the sound of fetal heartbeat from the headset.

Audio record:

The sound of fetal heartbeats can be recorded by a recorder which is connected with the product. As a safety advisement that can only be connected with a recorder complied with the safety requirements of IEC 60601-1.

1.5 Contraindications for Use

The device has no side-effects if administered correctly and residual risk is acceptable.

1.6 Note for home use

This device cannot replace a professional fetal monitor. If the fetal heart rate is abnormal or cannot be located by using this monitor,the pregnant woman should immediately go to the hospital to seek the doctor's help.If fetal movement is not felt by the pregnant woman, immediately go to the hospital to seek the doctor's help.

Section 2 : Safety guidance

2.1 Safety terms and conditions

The signal words shown below, left, identify the potential hazard categories. The definition of each category is as follows:

⚠ **DANGER:** This alert identifies hazards that will cause serious personal injury or death.

⚠ **WARNING:** This alert identifies hazards that may cause serious personal injury or death.

⚠ **CAUTION:** This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

2.2 Safety alert descriptions

The following is a list of product safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the product.

	⚠ DANGER
◆	Fire and Explosion Hazard Do not operate the product in the presence of flammable gases to avoid possible explosion or fire hazard.
	⚠ WARNING
◆	Strangulation resulting from baby or child entanglement in monitoring cables.
◆	Do not modify this equipment without authorization of the manufacturer.
◆	Dust, light may affect the safety and performance of the instrument.
◆	Degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems.
◆	The effects caused by pets, pests or children
◆	Use only Approved Equipment Do not use batteries, gel, cables, or optional equipment other than those approved by manufacturer which may cause the product to function improperly during a rescue.
◆	Adjacent and/or Stacked Equipment The Product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Product should be observed to verify normal operation in the configuration in which it will be used.
	⚠ CAUTION
◆	Check that the equipment does not have visible evidence of damage that may affect personnel's safety or examining capability before use. If damage is detected, replacement is recommended.
◆	The surface of the probe in contact with the patient may cause discomfort due to biocompatibility issues. The coupling agent may cause skin allergies in users. If the patient experiences any discomfort or allergic reactions, usage should be immediately discontinued and medical attention sought if necessary.
◆	Do not wrap the probe wire to avoid suffocation.
◆	Don't touch patient, power port ,and probe at the same time.
◆	This product is not recommended for use on ships and aircraft.

◆	Please keep the Fetal Doppler and batteries out of the reach of children to prevent them from playing with them. In the event that a child accidentally swallows a battery, seek immediate medical attention.
◆	Temperature/Humidity/Pressure extremes Exposing the Product to extreme environmental conditions outside of its operating parameters may compromise the ability of the Product to function properly.
◆	Battery Disposal Recycle or dispose of the battery in accordance with the local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.
◆	Possible Radio Frequency (RF) Susceptibility RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause interference with the product. Do not operate wireless radiotelephones in the vicinity of the Product – turn power OFF to the radiotelephone and other like equipment near the Product.
◆	Systems Statement Equipment connected to the product must be certified to the respective IEC Standards (IEC 60601-1 for medical equipment).
◆	Case Cleaning Solutions When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.
◆	Environment of use The product is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.
◆	Cold Environments If the product is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.
◆	Do not use the device with HF surgical equipment.

2.3 Symbols

The following symbols may appear in this manual, on the product, or on its accessories. Some of the symbols represent standards and compliance associated with the product and its use.

Symbol	Description

	Consult instructions for use of the product and/or it's accessories.
MD	Medical Device
EC REP	Authorized Representative in the European Community
	Date of manufacture.
	Manufacturer information
	Storage Temperature limit
	Humidity limitation
	Atmospheric Pressure limitation
CE 0598	This product complies with the Regulation (EU) 2017/745 requirements.
	Type BF applied part.
	Caution. Refer to the document accompanying the device.
IP22	Ingress Protection.
	When end users abandon this product, they must send the product to the collection places designed in environment protection regulations for recycling.

Section 3 : Getting started

This section presents information on unpacking and setting up the product.

3.1 Unpacking check

Please open the package carefully before use, check whether all accessories are available or not and whether any component is damaged during transportation, and perform installation and operation following this user manual. In case of any

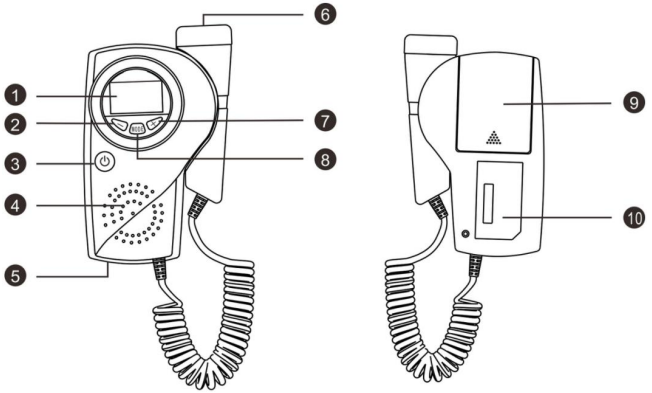
damage or operation problem, please contact the dealer or contact Jumper directly. You will need the following information when making your claim: device model, serial number, purchase date, and your contact information and address.

3.2 Packing list:

No.	Item	Quantity	Packed or Unpacked
1	Instruction Manual	1	√
2	Mainframe(including Probe)	1	√
3	AA Batteries	3	√

Section 4 : Appearance and structure

4.1 Appearance



① LCD display

② Volume down button

③ Power on/off button

④ Loudspeaker

⑤ Audio output socket

⑥ Probe ⑦

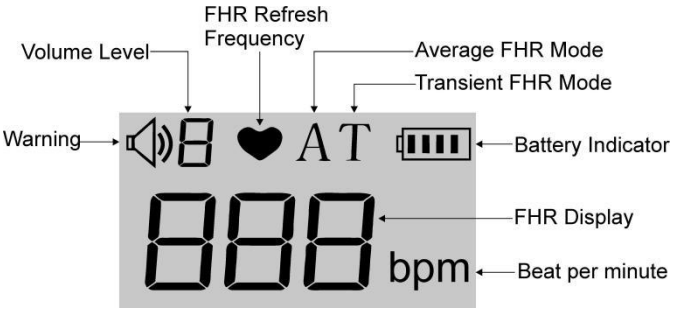
⑦ Volume up button

⑧ Mode button

⑨ Battery cover

⑩ Label

4.2 Display panel



FHR refresh frequency:

When monitoring, the heart shape symbol will appear and disappear. When it appeared or disappeared one time, the fetal heart beats one time.

FHR Display :

Here displays the fetal heart rate value, whose unit is bpm(beat per minute)

Warning:

When open the lower and higher restrict warn sound, and the FHR is in the restrict scope, the symbol will twinkling. And the warn sound will sound.

Average FHR mode:

When the symbol is appeared, the working mode is Average FHR mode.

Transient FHR mode:

When the symbol is appeared, the working mode is Transient FHR mode.

Battery Indicator:

Display the quantity of electricity in batteries now. When the four black small rectangles are all appeared, it responses batteries are fulfill. As decreases of the

quantity of electricity in batteries, the rectangles will disappear from left to right gradually.

Volume Level :

Display the Volume Level.

4.3 Buttons

Power on/off button "⏻"

Function: power on or off the Doppler

Volume up button "+"

Function: increase the volume.(more detail refer to 5.3 Modes Setting)

Volume down button "—"

Function: decrease the volume. (more detail refer to 5.3 Modes Setting)

MODE button "MODE"

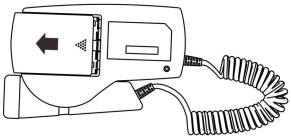
Function: switch working mode. (more detail refer to 5.3 Modes Setting)

Section 5 : Operation

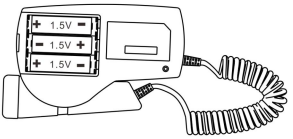
This section provides the description for operation

5.1 Installation battery

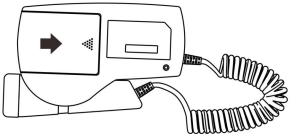
1. Open the battery cover in the direction show by the arrow .



2. Install batteries in the correct polarity.



3. Close the battery cover.



WARNING: Don't throw batteries in fire because this may cause it explode.

CAUTION: The battery must be proper disposed according to local regulation after their use

CAUTION: You must shutdown the doppler before installing battery or replace battery.

5.2 Replace battery

Take out other batteries, Repeat the above steps.

5.3 Operation instruction

1. Turn on

Press and hold the Power on button for 2 seconds, the device will turn on and self check, when the FHR display "---" , the self-check is finished and get into use.

2. Detect FHR

Put the gel on the surface of the ultrasonic probe, then press the probe on the detect position softly, and ensure it has a good touch surface. When the probe is on the right position, you can hear the fetal heart beat. Wait until the sounds is clear and consecutive seconds later, the LCD screen will display the right FHR.

3.Volume Control

Under the FHR display state, you can control the volume by volume up button and volume down button. Volume level has 9 level , "0" is silent , "8" is loudest.

4.Turn off

After detecting, press and hold the power off button for 2 seconds, the device will turn off. The device will power off automatically without singal one minute.

5.4 Guidelines for manual calculation FHR

After turn on the Doppler, press " MODE" button and enter the interface for manual calculation FHR.

1. Calculation FHR

When hear the clear fetal heart beat. Press down"+" or "-" button, calculate 15 heart beats, then press once more "+" or "-", the screen will display fetal heart rate. If you continue to detect, you can repeat.

2. Switch to automatic calculation

Press "MODE" button four times.

5.5 Modes setting

Function Menu:

Turn on the Doppler. Press the "MODE" button for function set. Operation as follows:

Press first time:

Enter the function of " Manual Calculate FHR", the Screen flickers " 000".Press once "+" button or "-" button and calculate 15 heart beats, then press once more "+" or "-" button, the screen will display Fetal Heart rate.

Press second time:

Enter the interface of FHR display mode options, the screen flickers "A" or "T". "A" display the Average Fetal Heart Rate ,"T" display Transient Fetal Heart Rate .Default factory settings is: "T". press "+"or "-" button, select the "A" Mode or "T" Mode.

Press third time:

Enter the interface of backlight switch settings, and ♥ is flicking, press"+" or "-" button, select the switch backlight, Default factory settings is: " ON"

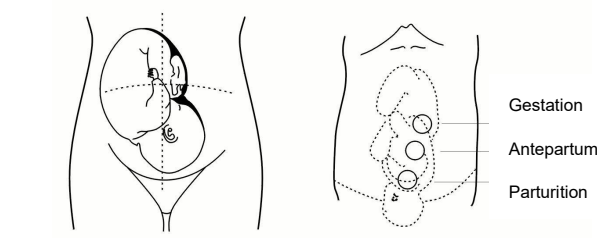
Press fourth time:

Enter the alarm setting interface, and 🔊 (Upper left corner) is flicking. Press "+" or "-" button select to turn on or off the alarm. Default factory setting is: "OFF". Notice: This interface is only to set the alarm on or off, so you can't detect the fetal heart rate.

5.6 Detecting

Locate the position of the fetus by hand touching, firstly to find out the best direction to the fetal heart. Place the faceplate of probe at the best position for detecting fetal heartbeat. Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Generally, the site of heart of fetus is 1/3 below of navel line at its earlier stage, it then moves upward with increasing of gestational period, and the site of heart of fetus will be a little deviation to left or right with different fetus. Please make sure that the surface of probe should be contacted fully with the skin. After the sound become clear, it is the proper functioning. If no coupling gel, water can be used.

Note: The normal range of fetal heart rate is 110 bpm-160 bpm. Abnormal value of FHR may appear during the searching of fetal heart.



Section 6 : Maintenance and cleaning and disinfection

6.1 Maintenance

6.1.1 The transducer acoustic surface is frangible and must be handle with care .Gel must be wiped off from the transducer after use. These precautions will prolong the life of the unit.

6.1.2 To ensure the product is always functional when required, the following maintenance shall be performed.

● Visual Inspection

● Clean the product and its accessories

● Check the battery fuel gauge

● Test product performance

● Remove the battery if it is not used for a long time.

● The product requires no calibration.

Note: No service and maintenance while the equipment is in use.

Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions ,or other information that will assist to service personnel in parts repair.

6.2 Cleaning product and accessories

The following cleaning products may be used to clean the exterior surfaces of the product.

● Isopropyl alcohol (70% solution in water)

● Mild soap and water

● Sodium hypochlorite (chlorine bleach) (3% solution in water).

● Quaternary ammonium compounds (such as Lysol) (10% solution in water).

WARNING: Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.

WARNING: Do not use mixing disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

WARNING: Do not use acid, alkaline, or corrosive detergent.

WARNING: Do not clean electrical contacts or connectors with bleach.

6.3 Cleaning instructions

1. Before cleaning the product, turn off the product.

2.Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.

3.When cleaning, do not immerse. Keep the exterior surface of the device clean and free of dust and dirt, clean exterior surface of the unit with a dry, soft cloth, if necessary, clean it with a soft cloth soaked in a solution of soap and wipe dry with a clean cloth immediately. Wipe the transducer body with soft cloth to remove any remaining coupling gel .Clean with soap only.

CAUTION: To prevent damage to the product, do not clean any part of the Product or Accessories with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the Product or accessories.

CAUTION: Cleaning liquids: do not submerge the product in liquids or pour cleaning liquids over, into or onto the product.

6.4 Disinfection

Cleaning the unit surface and the transducer as the above mentioned, then wipe the surface of transducer with 75% ethanol or alcohol, clean the transducer surface with a dry, soft cloth.

WARNING: Don't use low temperature steam sterilization or other way to sterilize.

WARNING: Don't use high temperature sterilizing process.

After cleaning or disinfection, check if the Doppler function well. If any problem is detected, please contact the manufacturer for service before reusing them.

Checking Item	Checking Method
Visual Check	Check if the Doppler probe and host are damaged
Function Check	1.Check if the Doppler can be switched on or off properly; 2.check if the screen works normally; 3. Rub the surface of the probe with your hand to check if the Doppler is producing sound properly

Section 7 : Technical specifications

This section presents the specifications and safety standards of the product.

NOTE: The following specifications are subject to change and are only noted as a point of reference.

Product name: Fetal Doppler
Mode: Babygeräusch
Safety: Complies with IEC 60601- 1, EN 60601- 1, EN60601-1-2, IEC 61266
Physical Dimensions: 135mm W x 83mm D x 33 mm H, Wt: 0.24kg (not including battery)
Classification: Anti-electric Shock Type: Internally powered equipment Anti-electric Shock Degree: Type BF applied part 
Degree of Protection against Harmful Ingress of Water: Main Unit : IP22 Probe: IP22 Water Ingress Protection Code
Degree of Safety IN Presence of Flammable Gases: Equipment not suitable for use in presence of flammable gases
Working Mode: Continuous operation
Product service life: 5 years
Recommended battery type: DC 4.5V 3×AA batteries
Technical parameters: Ultrasonic emitting frequency: 3MHz Overall sensitivity at the distances 200mm from the face of the probe (Doppler frequency: 500±50Hz, Target velocity: 10cm/s~40cm/s): 92.9dB Spatial-peak temporal-peak acoustic pressure: 20.8KPa Output power: 8.6mW Effective area of the ultrasonic transducer active element: 3.07cm2 The acoustic coupling medium for normal use: ph: 5.5~8, Acoustic impedance: ≤1.7*105g /cm2·s Working mode: Continuous wave Doppler Audio
Audio output: Audio output power: <0.5 W Audio out Socket: Φ3.5mm
Performance: Sensitivity: 16 weeks gestation FHR Measuring Range:50bpm -210bpm (beat per minute) Resolution: 1bpm Accuracy: ±2bpm
Environmental Requirements: Operating Conditions: Temperature: 5°C to 40°C

Atmospheric pressure: 86kPa to 106kPa Storage and Shipping Conditions: Temperature: - 20°C to 55°C Humidity: 10%-93% RH, non-condensing Atmospheric pressure: 50kPa to 106kPa
Equipment heating time -the time required for me equipment to warm from the minimum storage temperature between uses until it is ready for intended use: 30min. -the time required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use: 30min.

Section 8 : Troubleshooting

What appearance to be a malfunction may not always serious, if your unit should not perform as expected, consult the table below to see if the problems can be corrected before seeking help from your dealer or service representative.

Symptom	Cause	Remedy
Audio scream	● Audio volume too high ● Too much Gel on the probe surface ● Battery is exhausted	● Turn down the volume ● Use less Gel ● Change or charging the battery
Weak sound output	● Audio volume too low ● Insufficient Gel ● Battery is exhausted	● Turn up the volume ● Add Gel ● Replace the battery
Low sensitivity	● Incorrect probe position ● Insufficient Gel	● Locate the correct position ● Add Gel

Appendix 1 EMC information

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in

increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000 -4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m

	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

Appendix 2 Ultrasound intensity and safety

2.1 Ultrasound in medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. The ultrasound output of the device is controlled internally and cannot be changed by the user during the inspection process. Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

2.2 Explanation of MI/TI

2.2.1 MI (Mechanical Index)

When ultrasound waves penetrate and contact tissues, cavitation effects may occur, causing local instantaneous high temperatures. The occurrence of this effect depends on various factors and has a threshold phenomenon. Currently, there are no reports of harmful mechanical effects from human use of ultrasound diagnostic equipment, and the threshold for cavitation effects is unclear. As the peak sound pressure of ultrasound waves increases, the occurrence rate of mechanical effects increases, but decreases with increasing frequency. The American Institute of Ultrasound in Medicine and the National Electrical Manufacturers Association have established the Mechanical Index (MI) to characterize the probability of ultrasound mechanical effects.

2.2.2 TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermophysical properties of the tissue.

According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.

TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

2.3 Ultrasonic output limitation

The acoustic output parameter meets the provision freedom from publication in IEC 61157 Requirement for the declaration of the acoustic output of medical diagnostic ultrasonic equipment: Pr<1MPa; the output power divided by the 12dB output beam area is not less tan 20mW/cm2; Ispta<100mW/cm2.

Note: For all equipment settings, the thermal index and mechanical index are less than 1.0.

Statement:

The lay operator or lay responsible organization should contact the manufacturer or manufacturer's representative on the following issues：

Assistance in setting up, using, or maintaining the equipment or system when needed.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authorities of your Member State.

Made in China

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