imv TECHNOLOGIES

Safety Guidance

IMAGo™
IMAGo™ Flex

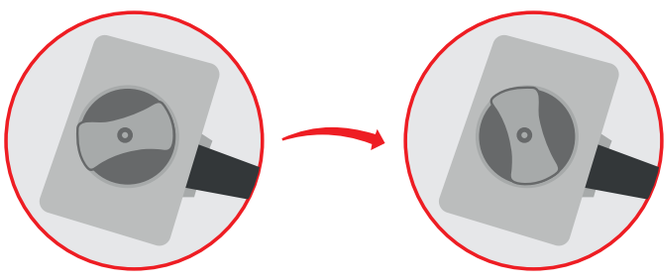
CE

Contents

1. Start Up

1.1 Connection and disconnection of probes (only applicable to ImaGo Flex)

To connect a probe, place the probe connector in the opening at the back of the scanner, with the cable pointing outwards. Turn the lock situated in the middle of the connector with slight pressure in order to engage the locking mechanism. When the locking mechanism is engaged, make a quarter turn clockwise so that the probe is connected.



After connecting a probe, always place the probe in a safe place in order to avoid any damage of the probe from a shock or drop. The probes can be changed during the examination without restarting the device.
To disconnect a probe, make a quarter turn anti-clockwise in order to unlock the connector. Take the connector out of the device and store the probe, protected from shocks.

- Before disconnecting the active probe, make sure you freeze the image.
- When starting the device, always make sure to have a probe connected on the scanner.
- The name of the connected probe is indicated on the screen in the top left corner

1.2 Charging Battery

The Imago L/C and Flex battery can be removed of the scanner. When inserting the battery pack in the device, check that it is securely connected.The battery can be only charged in the charging dock, powered by a standard outlet

A fully discharged battery should be fully charged within 4 hours. While in a good condition, the battery run time will be 5 hours (assuming 50% idle time between scans).

Scanner will enter low power mode when idle.

For optimal battery longevity, avoid letting the battery run completely down and recharge at approximately 20 Celsius/68 Fahrenheit.

Electrical connection to the power pack is through the gold pads on battery and scanner. Power pack output is protected but care should be taken to prevent short circuiting the gold connector pins and pads.

LED sequence	
One blue flashing	Charging, charge level below 33%
First LED solid blue Second LED flashing blue	Charging, charge level below 66%
First and second LEDs solid blue, third LED flashing blue	Charging, charge level below 100%
All LEDs solid blue – fully charged.	Fully charged
All LEDs flashing yellow	Temperature is too high (more than 45 Celsius, 113 Fahrenheit) for safe charging
All LEDs flashing blue	Temperature is too low (less than 0 Celsius, 32 Fahrenheit) for safe charging.

Warning:
To reduce the risk of burns, fire, electric shock, or injury to persons the appliance should never be left unattended when plugged into mains or 12 V cigarette lighter.

1.3 Accessories

2. Safety instructions

2.1 Safety instructions for ultrasound equipment

2.1.1 User profile

Warning

The ImaGo range devices for Veterinary Use is intended for use on animals only and is prohibited to be used on humans.

Warning

The diagnostic ultrasound equipment or ultrasound scanner must be used only by a user trained to the ultrasound imaging technique. This training allows the understanding of displayed ultrasound images, the understanding of how to perform measurements on images or on Doppler spectrums. The user must have read the complete user's manual in order to know the instructions needed to operate the equipment. He must refer to the user's manual at any time in case of doubt about the use of the device.

Warning

It is mandatory to read the user's manual before starting an examination. People which are not trained to ultrasound diagnostic imaging technique must not use the ImaGo range equipment.

2.1.2 Care

Whilst every measure has been taken to ensure the probes are robust and fit for purpose, the probe head is still fragile and care should be taken to protect it from any knocks.

2.1.3 Acoustic power

The AIUM (American institute of Ultrasound in Medicine) has stated on the use of ultrasound for medical diagnostic that "no confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound equipments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefit to patients of the safe use of diagnostic ultrasound outweigh the risks, if any, that may be present". The institute indicates that the benefits of a safe use of diagnostic ultrasound outweigh the risks, if any, which may be present.

References: Bioeffects considerations for the safety of Diagnostic Ultrasound; Journal of Ultrasound in medicine; Vol. 7, Number 9; American Institute of Ultrasound in Medicine – Bioeffects Committee

Warning

"Safe use" means that the ultrasound scanner must be used according to the ALARA principle, meaning that the operator must maintain the transmit power level and the length of the exposure at the lowest possible level (As Low As Reasonably Achievable).
The operator should maintain the transmit power and the exposure time at the lowest possible level.

Consequently, the operator must use the ultrasound in a safe way, in order to ensure the maximum protection of the patient. This means that the operator must assume that there might be unidentified risks during the use of ultrasounds, and therefore reduce the exposure time of the patient as well as the transmit power. This can be done by following the ALARA principle (As Low As Reasonably Achievable), which associates some simple rules for obtaining a diagnosis while using the least amount of acoustic energy.

How to perform a safe examination:

- When starting an examination, always adjust the transmit power at the lowest possible level. Increase the power during examination if necessary in order to obtain a satisfactory image or Doppler signal, while keeping the review of MI and/or TI indexes.
- Do not hold the probe in a fixed position longer than necessary. As soon as the image has been frozen, take the probe away from the patient's skin.
- Do not continue the examination longer than necessary: It is important to reduce the time of patient exposure to ultrasounds as much as possible.

2. Safety instructions

2.1.4 Interpretation of MI and TI parameters

It is the operator's responsibility to foresee the risks linked to the output energy of the device, and to act appropriately in order to obtain the necessary diagnostic information with a minimum risk for the patient.

In order to do this, the operator has two indexes displayed on the screen (MI and TI, respectively Mechanical Index and Thermal Index) enabling him to continuously have an indication of the acoustic transmit power level.

The relationship between different parameters of acoustic power and biological evaluation criteria is not well known today. Two fundamental phenomena have been identified, mechanical and thermal, through which ultrasounds might have biological effects. The MI and TI indexes have been developed to take these phenomena into account and to give the user immediate information on the potential mechanical or thermal biological effects. Please notice that these indexes do not take accrued effects into account.

The MI index (mechanical index) is related to the spatial peak of the maximum rarefaction pressure, providing an indication according to the cavitation effect. There is a strong agreement that biological effects can possibly occur with an increase of the maximum rarefaction pressure.

The TI index (thermal index) is related to the tissue temperature rise and corresponds to the ratio between the total acoustic power and the acoustic power required to raise the tissue temperature by one degree Celsius. There is no simple model to represent the temperature rise in all conditions and for all type of tissues. A TI index of 2 represents a higher temperature rise than a TI index of 1, but cannot be considered as a temperature rise of 2°C. The TI index is intended to advise the user of a possible temperature rise in a specific area.

2.1.5 Accuracy of MI and TI parameters display

The mechanical and thermal indexes are displayed permanently and explicitly on the screen in the upper corner.

During the use of the device, the operator must survey the effect of the controls which are influencing the acoustic power and, if necessary, write down the values of the indexes.

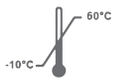
As indicated above, the operator must permanently try to maintain the indexes at their lowest possible level and to reduce the exposure length.

The preciseness of the display of the mechanical and thermal indexes (MI and TI) is at 0.1.

The maximum possible MI and Ispta on the ImaGo range is within the limits set in Track 3 in the FDA guidance of June 27, 2019 for diagnostic ultrasound systems and transducers, MI <1.9 and Ispta <720 mW/cm.

2.2 Safety symbols

Please notice the meaning of the following safety symbols:

Symbol	Signification
	Isolated patient. Type BF patient applied part (B=body, F=floating applied part) The probe complies with the class "BF" Medical Electric equipment compliant with the standard IEC 60601-1
	Warning: Read the user manual before using the device bearing this symbol.
	Power On/Off
	Collect separately from other waste (see European Commission Directive for electronic waste)
	Storage temperature limit
	CE Mark
	ImaGo version and serial number • IMGX01YYYYY • X:L or C or F • YYYYYY: Serial number (5-digits)
	Model number
	Manufacture's name and address
	Date of manufacture (YYYY-MM): • YYYY: Year (4-digits), • MM: Month (2-digits)
IP Code (IPX-)	Degree of protection (IEC60529)

Warning

Do not attempt to disassemble or modify any part of the ImaGo range, battery, power adapter and accessories. Disassembly or modification may result in electrical shock.

2. Safety instructions

2.3 Environmental conditions of use

The device shall be operated in a clean atmosphere, with as little dust and smoke as possible.

The device is designed and tested to be operated at the following temperatures:

- From 0°C to +35°C in discharge mode

The length of the battery life is increased if the storage takes place in a temperate atmosphere and if the battery is stored on an intermediate charging level.

The device is designed to be operated with a relative humidity range from 10 to 95% including condensation.

The device is designed for the following atmospheric pressures:

- 700 hPa to 1060 hPa while in operation
- 500 hPa to 1060 hPa during transportation and storing.

The device must be transported in the following environmental conditions:

- temperatures from -10°C to +60°C
- humidity range from 10% to 85%

Warning

Never use the device if the environmental conditions described above are not respected. Stop operation of the device if one of these conditions is no more respected. The device can be used in any room or place respecting these environmental conditions.

Do not place the equipment against a wall or in a confined area, this will result in a bad cooling of the equipment. A minimal distance between walls and the device must be respected, typically 30 cm.

2.4 Electrical safety

The ImaGo device includes a Lithium-Ion battery with a voltage of 3.6 V and a capacity of 6.7 Ah. It is powered by an AC adapter.

This equipment is compliant with the article 6 of the IEC standard 60601-1, Safety for Medical Electrical Equipment.

According to the standard, the equipment is classified as:

a) According to the type of protection against electrical shock: Class B Group 1

b) According to the degree of protection against electrical shock: Type BF

c) According to the degree of protection against harmful water ingress: IPX0 (device without protection against water ingress)

d) According to the degree of safety of application in presence of flammable anaesthetic mixture with air, oxygen or nitrous oxide. Device not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide

e) According to the mode of operation: Continuous operation

In order to ensure patient safety, please observe these warnings:

Warning

The equipment must be maintained in the exact same configuration as it was delivered by IMV Technologies. It is forbidden to bring any change to the equipment without permission of IMV Technologies.

Warning

The external battery charger must be powered by using the provided power cord including a connection to ground.

Warning

Do not charge the battery near a fire or heater.

Warning

The equipment uses an external Lithium battery. The battery should be replaced exclusively by an identical type of battery provided by IMV Technologies. Replacing the battery by an incorrect type may cause excessive temperatures, fire or explosion. The battery is a Lithium-Ion battery rating a voltage of 3.6 V and a capacity of 6.7 mAh.

Warning

If the battery leaks or emits an odor, disconnect the battery and contact your distributor or IMV Technologies' service center. The details of the IMV Technologies can be found on the back of the safety guide.

Warning

The probes are the only applied parts of the ImaGo range system according to the standard CEI 60601-1. No other part of the equipment is intended to be in contact with the patient in order to guarantee the electrical safety.

Warning

In order to guarantee the electrical safety for the patient, the user must not touch the equipment (or any accessible parts of the equipment) and the patient at the same time.

Warning

Never touch a non-medical device situated near the patient at the same time as the patient.

Warning

Always inspect the probe head, housing, cable and power cord before use (see section 2.8: probe information). Any crack or damage to the probe head can lead to electrical shock. Never use a probe that is damaged, that has been dropped or has been suffering a severe shock until it has been inspected by an IMV Technologies customer service engineer.

Warning

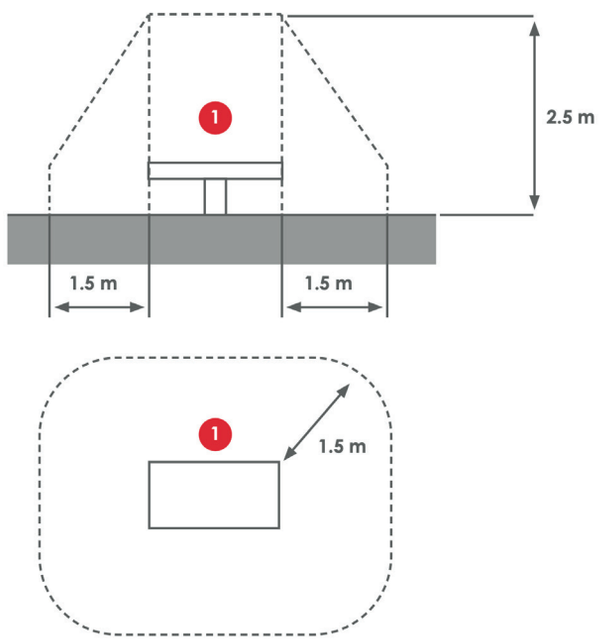
Do not soak the transducer connector in any liquid. Soaking it can destroy its electrical safety features.

Warning

Always disconnect the system prior to cleaning.

2.5 Patient Environment

The ImaGo ultrasound scanner is designed to be used in an environment as defined on the figure below:



2.6 Electromagnetic compatibility

The ImaGo range ultrasound scanner is compliant with the standard EN 60601-1-2 concerning electromagnetic compatibility (EMC).

Warning

The ImaGo ultrasound scanner is a medical electrical device which needs special care regarding the EMC. The equipment should be installed and started by a trained person according to the detailed information in this manual (refer to annex II).

2. Safety instructions

Warning

Portable communication devices can affect the normal function of the ImaGo range equipment (refer to table 6 of annex II).

Warning

The use of cables or accessories other than those specified by IMV Technologies may result in an increase of emission or a reduction of immunity of the ImaGo range devices.

Warning

The equipment should not be used close to other equipment, and if it is not possible to do differently, the functioning of The ImaGo range devices should be monitored in order to check that it is working normally.

2.7 Environmental conditions of use

The probes supplied with the ImaGo range equipment are intended to be used only with this system.

Warning

Never try to connect the supplied probes to any other ultrasound system. This can lead to irreversible damage on the probe connector and to the possibility of much higher acoustic output than required. This can also lead to patient burn due to overheating of the probe. The ImaGo range devices is designed to be used exclusively with probes supplied by IMV Technologies together with the device.

Warning

Never try to connect a probe to the ImaGo range device which is not supplied by IMV Technologies. This can lead to irreversible damage on the ImaGo range probe connector and to the possibility of much higher acoustic output than required. This can also lead to patient burn due to overheating of the probe.

Warning

Check the cleanliness of the probes before starting an examination. Also check the probe in order to detect any shock, crack or damage on the casing and the acoustic lens. Never use a damaged probe for an examination.

Warning

For safety reasons and in order to keep the probes in a good state, never disconnect a probe from the device without freezing the image first.

2.8 Removable Accessories

IMV Part Number	Description
90-3532	Linear Rectal (LR664V)
80-3088	Chest harness
90-3514	Convex Abdominal (C360S)
90-3529	Convex Rectal (CR460V)
ESG-BATT-V2	Battery for ultrasound devices
22-3229	Bumper
ESG-CHARGER-V2	Charger for ultrasound devices
IMG-STRAP-RIGHT	Arm-strap-Right
IMG-STRAP-LEFT	Arm-strap-Left
IMG-CASE	Carry bag
IMG-HOOD	Sun hood
90-3445	Linear meat probe (L3130B2)
90-2254	Linear meat probe (L3180B)
90-2990	Bovine / Equine ovum pick up probe (E610B)

2.9 Error messages

The ImaGo range devices can display error messages which have all been designed in order to be easily understood.

2.10 End of product life of the device

At the end-of-life of the device, due to a reject or a definitive end of use, the device must be recycled. Take care of bringing the device to a certified recycling center or return it to the distributor. The distributor's address is found on the first page of this manual.

2.11 Probe Information

The probes supplied with the ImaGo range equipment are intended to be used only with this system.

2.11.1 Probe types and corresponding applications

The probes provided with the ImaGo range equipment are the following:

LR664V
Linear Rectal

CR460V
Curved Rectal

E610B / E614B
Ovum pick up probe

C360S
Convex

L3130B2 / L3180B
Linear abdominal

- C360S Convex probe, central frequency 3.5 MHz. This external probe is used for the Veterinary applications (Musculo-skeletal, cardio on horses, abdominal, small parts on small animals).
- LR664V Rectal linear probe, central frequency 6.5MHz. This probe is used through the rectum or through the vagina for the veterinary applications (Foetal sexing, Ovarian diagnosis, follicles visualization).
- CR460V Rectal convex probe, central frequency 4 MHz. This probe is used through the rectum or through the vagina for the veterinary applications (Foetal sexing, Ovarian diagnosis, follicles visualization).
- L3130B2 Linear abdominal probe, 3.5 MHz, 128 elments, 130 mm. External probe used for veterinary applications (back-fat and intramuscular measurements on pigs).
- L3180B Linear abdominal probe, 3.5 MHz, 128 elements, 180 mm. External probe used for veterinary applications (back-fat and intramuscular measurements on cows).
- E610B Micro convex probe, 5-7,5 MHz, 128 elements, radius 10. Internal probe used for veterinary applications (Ovum-pick up in small horses and heifers).
- E614B Micro convex probe, 5-8 MHz, 128 elements, radius 14. Internal probe used for veterinary applications (Ovum-pick up in larger horses and cows).

The indicated applications can be examined in:

- Scanning modes: black/white (B-mode), CFM mode, combined (B + Color Doppler),

2.11.2 Inspection of probes

Warning

Do not use the probe for any other application than the one specified, since the probe type and frequency are related to the clinical application. This can lead to bad diagnostic resulting from a non-adapted image quality. It can also lead to useless irradiation of the patient, which is contrary to the ultrasound imaging safety guidelines.
All probes provided with the ImaGo range devices are compliant with the standard ISO 10993-1 concerning biocompatibility of components used for probe manufacturing.

Warning

Do not bend or twist the transducer cable. If the transducer housing becomes cracked or broken or if there are cuts or openings in the cable, the electrical safety features of the transducer might be compromised

Warning

Any crack or damage to the probe head can lead to electrical shock. Never use a probe that is damaged, that has been dropped or has been suffering a severe collision until it has been inspected by an IMV Technologies customer service engineer.
In case of failure or replacement of a probe, the damaged probe must be recycled. Take care of bringing the probe to a certified recycling center or return it to the distributor. The distributor's address is found on the first page of this manual.

2. Safety instructions

2.11.3 Handling of probes

Warning

The probe is fragile and requires proper handling, care and cleaning. Transducer care includes daily inspections, cleaning and disinfections between each patient. Please refer to the chapter about cleaning and disinfection instructions.

Warning

Always store the probe in a secure place when not in use in order to avoid it from falling either on the patient or on the floor. Any crack or damage to the probe head can lead to electrical shock. Never use a probe that is damaged, that has been dropped or has been suffering a severe collision until it has been inspected by an IMV Technologies customer service engineer.

Warning

Do not immerse the transducer connector in any liquid. Immersing it can destroy its electrical safety features.

2.11.4 Ultrasound coupling gel

Some ultrasound coupling gels and lotions can damage the probes. Agents containing the following chemicals are known to damage transducers:

- Acetone
- Methanol
- Denatured ethyl alcohol
- Mineral oil Iodine
- Any lotion or gel that contains perfume.

Warning

Check the gel contents with your gel supplier.

Warning

To avoid any problems regarding the use of ultrasound coupling gel, please respect the rules:

- Always check the expiry date on the gel bottle prior to use on a patient. Always throw expired bottles away.
- Choose 250ml conditioning rather than 5 liters. Never use a 5 liters bottle to fill smaller bottles each day.
- Throw away all started bottles at the end of the day.
- Before the probe disinfection procedure between each examination, wipe off all gel residues on probe head, housing and cable.

Warning

Neither the ultrasound coupling gel nor the external probes are intended for use on a damaged skin.

2.11.5 Surface temperatures

The probes provided with the ImaGo range devices are compliant with the security standards concerning surface temperatures. The probes have been designed in order to never let the surface temperature exceed 41°C.

Warning

The ImaGo range devices has not been designed to be used together with a high frequency surgical device. A risk of patient burn might exist in case of failure in connection of the neutral electrode of the surgical high frequency device.

3. Installation of the equipment

Warning

Never try to open the equipment. Only an IMV Technologies qualified customer service engineer is authorized to open the system and service it.

Warning

When moving the device, take care of avoiding any mechanical shock or collision due to the important inertia of the equipment.

Warning

After installation check that the mechanical components are properly attached and that there is no risk for them to fall or move in unexpected ways.

4. Peripheral connectivity

The Imago cannot be connected wired to peripherals (no external connector) but only to wireless display devices (phone, tablet or BUG goggles)

5. Updating the software

The ImaGo L, C and Flex show the software version at the top left of the screen just after turning on.

To update the system to the latest version, use the Imago Connect app

Process:

- Download the ImaGo Connect app from the app store
- Connect a charged battery (> 70%) and turn the Imago on
- Launch the app and follow all the prompts.
- Wait untill the Imago LEDs stop flashing and the device turns off.
- Turn the Imago on again and check the software version.

6. Cleaning and disinfection instructions

The protection of patients and staff from risks of infections is essential for all health care institutions. A treatment level corresponds to each risk level in order to obtain the needed level of microbiological quality.

Warning

Before cleaning the system and probe, shut down the system and disconnect the battery. System failure and electric shock could result.

6.1 Cleaning and disinfection of the device

The cleaning and maintenance of the ultrasound equipment and all connected devices are essential. It is important to do this very carefully on a daily basis. All your equipment can be exposed to dusty and humid environments that can damage the functioning and reliability of the equipment if cleaning and maintenance is not done in accordance with our instructions.

The device has a low infection risk. This risk level corresponds to the use of so-called non-critical medical devices, which means devices which are not in direct contact with the patient.

The needed treatment for this type of medical device is a low-level disinfection, especially bactericidal.

The following disinfection solutions have been tested and their compatibility with the components of the device has been proved:

- Mild soap solution
- Isopropyl alcohol 70%
- T-spray II (quaternary ammonium)
- Opti-Cide 3 (quaternary ammonium / isopropyl alcohol)
- Cidex (glutaraldehyde 2%)
- Cidex plus (glutaraldehyde 2%)
- Cidex OPA (glutaraldehyde 2%)
- Anios Wipes (Incidin Plus 1%)
- Cidalkan wipes (Sani-Cloth HB)

It is strongly recommended to use one of these solutions in order to avoid any deterioration during the cleaning and disinfection procedure.

Warning

The use of any other disinfecting solution than the ones indicated above is dangerous as it may damage the components of the device. Check the list of specified agents carefully.

6. Cleaning and disinfection instructions

In order to ensure proper cleaning and disinfection, please follow the following procedure:

1. Switch off and disconnect the device together with all connected peripherals.
2. After every examination, wipe off the screen and the external surfaces of the device to remove any traces of coupling gel.
3. Wipe the keyboard and the external surfaces of the device with a clean soft cloth damped in a solution of mild soap and water.
4. Carefully follow the instructions for low level disinfection indicated by the disinfectant manufacturer. The disinfectant content of the cleaning solution and the exposure time must be appropriate for the ongoing disinfection.
5. Remove any cleaning solution residue with a clean soft cloth damped in sterile water.
6. Air dry or dry with a soft, clean and dry cloth.

Warning

If you use any other disinfection method than the one described above, you might damage the equipment and cancel the warranty.

Warning

Before cleaning the equipment, check that it has been turned off and that all connected peripherals and electric devices has been disconnected.

Warning

Don't use any strong solvents or chemical agent which may damage the external surfaces of the equipment.

Warning

Don't vaporize any liquid directly on the equipment or on the probe connectors.

Warning

Don't use any sharp items on the equipment or the screen as these might damage the equipment. Don't use absorbent paper or paper towels (containing wood fibers) for cleaning the screen as these might scratch or damage the screen.
The use of a clean micro-fiber cloth for cleaning the screen of the equipment is highly recommended.

Warning

The use of any product containing bleach is forbidden for cleaning and disinfecting the equipment.

6.2 Cleaning and disinfection of probes

Warning

It is essential to clean the probes after each use. The disinfection of the probes cannot be done before a cleaning of the probes has been done.

Warning

The use of any other disinfecting solution than the recommended ones or used improperly and not in accordance with the manufacturer's recommendations may damage the probes and invalidate the warranty.

Warning

Please follow the cleaning and disinfection procedures according to the infection risk linked to their use.

Warning

During cleaning and disinfection procedures of the probes, the use of any sharp item that could damage the probes, cables or connectors is strictly forbidden.

Warning

The probes are sensitive to shocks and dropping. It is therefore important to handle the probes very carefully during cleaning and disinfection.

External probes

External probes have a low infection risk. This risk level corresponds to the use of so-called non-critical medical devices, which means devices which are not in direct contact with the patient or which are in contact with intact skin.

The needed treatment for this type of medical device is a low-level disinfection, especially bactericidal.

Low level disinfection procedure: The probes supplied with The ImaGo range devices must be used only on intact skin.

The following disinfection solutions have been tested and their compatibility with the components of the probes has been proved

- Cidex
- Cidex plus
- Cidex OPA
- ANIOS wipes
- Endosporine
- Echo Clean wipes
- Incidin
- Metricide
- Mild soap solution
- Oxivir wipes
- PerCept wipes
- Sani-Cloth AF
- Sani-Cloth AF3
- Sani-Cloth wipes
- T-spray
- T-spray II
- Steranios 2%
- Nu-Cidex
- Salvanios PH10
- Alkazyme
- Klenzyme
- Cidezyme

It is strongly recommended to use one of these solutions in order to avoid any deterioration during the cleaning and disinfection procedure.

Warning

The use of any other disinfecting solution than the ones indicated above is dangerous as it may damage the probe components. Kindly pay attention to the list of specified agents.

In order to ensure proper cleaning and disinfection, please follow the below procedure:

1. Unplug the probe connector from the system.
2. After every patient examination, wipe the ultrasound transmission gel off the probe.
3. Wipe the probe and cable with a clean soft cloth that has been damped in a solution of mild soap and water.
4. Carefully follow the low level disinfection instructions indicated by the disinfectant manufacturer.
5. Remove any cleaning solution residue with a soft clean cloth damped in sterile water.
6. Air dry or dry with a soft clean and dry cloth.

Endo-cavity probes

Endo-cavity probes have a medium infection risk. This risk level corresponds to the use of so-called semi-critical medical devices, which means devices which are in contact with mucus membranes or superficially injured skin.

The needed treatment for this type of medical device is a medium-level disinfection.

Medium level disinfection procedure:

Warning

The endo-cavity probe supplied with the ImaGo range devices must be used with a sterile cover over the probe casing which will be in contact with the mucus membranes. This cover is for single use only.

The following disinfection solutions have been tested and their compatibility with the components of the probes has been proved:

- Cidex
- Cidex plus
- Cidex OPA
- ANIOS wipes
- Endosporine
- Echo Clean wipes
- Incidin
- Metricide
- Mild soap solution
- Oxivir wipes
- PerCept wipes
- Sani-Cloth AF
- Sani-Cloth AF3
- Sani-Cloth wipes
- T-spray
- T-spray II
- Steranios 2%
- Nu-Cidex
- Salvanios PH10
- Alkazyme
- Klenzyme
- Cidezyme

It is strongly recommended to use one of these solutions in order to avoid any deterioration during the cleaning and disinfection procedure.

Warning

The use of any other disinfecting solution than the ones indicated above is dangerous as it may damage the probe components. Check the list of specified agents carefully.

6. Cleaning and disinfection instructions

In order to ensure proper cleaning and disinfection for endo-cavity probes, please follow the following procedure:

1. After every patient examination, remove the single use sterile cover and throw it away.
2. Wipe the ultrasound transmission gel off the probe.
3. Unplug the probe connector from the system.
4. Wipe the probe and cable with a soft clean cloth that has been damped in a solution of mild soap and water.
5. Follow carefully the medium level disinfection instructions indicated by the disinfectant manufacturer.
6. Remove any cleaning solution residue with a soft clean cloth damped in sterile water.
7. Air dry or dry with a soft clean and dry cloth.

Warning

During cleaning or disinfection, it is important to avoid any liquid from entering the permeable parts of the probe. Please pay attention so that no cleaning or disinfection liquid enters through the cable muff, the connector muff, the electrical contacts or the locking system. Any liquids having entered one of these parts will immediately invalidate the warranty of the equipment.

Warning

Do not soak the probe in a solution any longer than the disinfection agent manufacturer's recommendation. Follow the disinfection agent manufacturer's recommendations for disinfection.

Warning

Use a sterile probe cover and sterile ultrasound coupling gel for biopsies and peroperative examinations.

Warning

Do not rub the probe with an abrasive sponge. Use a soft cloth or towel.

Warning

The following procedures are known to damage transducers. They can damage both the electrical safety features and the acoustic performance of the probes. Do not use the following procedures:

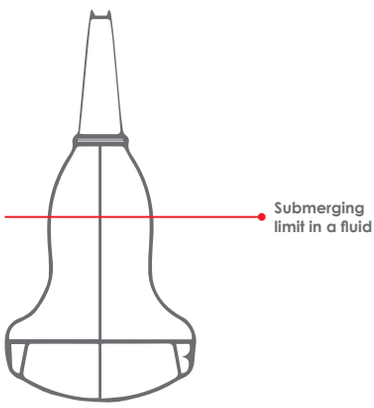
- Gas sterilization.
- Ultraviolet sterilization
- Dry heat sterilization
- Autoclaving
- Soaking a transducer in a chlorine bleach solution

Submerging limits

Warning

During cleaning and disinfection of probes, take care of never exceeding the submerging limits indicated on the following figures.

Probe C360S:



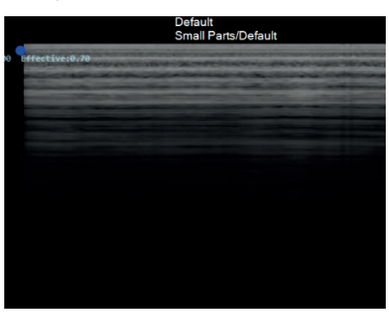
7. Maintenance of the device

Repairing of the device:

None of the parts of the device can be repaired by any person who has not been authorized by the manufacturer. Only a technician who has been trained and qualified by IMV Technologies can intervene for reparation of the device. In case of breakdown or fault in the functioning of the device, contact your distributor. You will find the address of your distributor on the first page of this manual.

Before each use, check the probe is recognized by the ultrasound system. The name of the probe is visible at the top left of the screen.Visually check that the echo from the lens on B image is homogeneous across the entire array by setting the shortest image depth.

Example of defect.

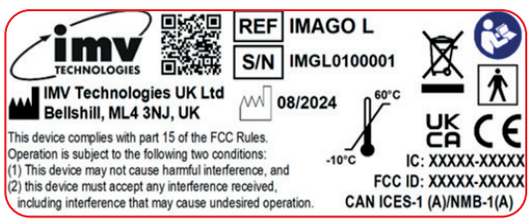


Warning

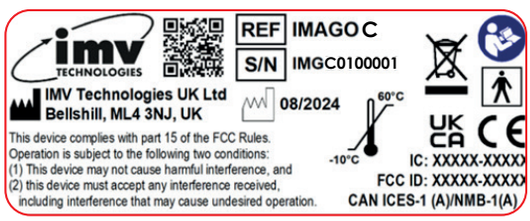
Always inspect the B image.
Never use a probe that is damaged, that has been dropped or has been suffering a severe shock until it has been inspected by an IMV Technologies service engineer.

8. Labelling of ImaGo range

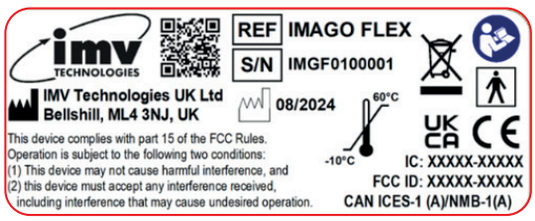
Imago L



Imago C

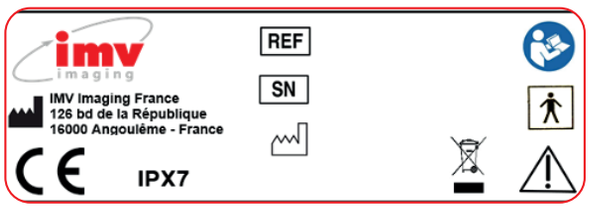


Imago Flex

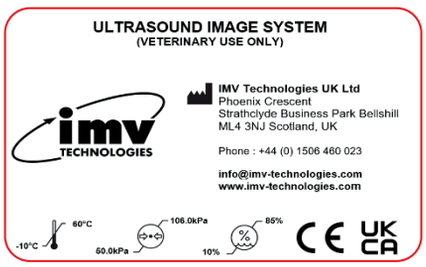


Battery labels:

Probe label for ImaGo Flex



Packaging label



SN: YYDDDNNN

- YY: year (2-digits)
- DDD: day of the year (3-digits)
- NNN: Daytime battery number (3 digits)

9. FCC Compliance statement

Warning

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning

The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

10. Annex I: Measure accuracy

TABLE 1

Symbol	Signification	Signification
Distance and ellipse perimeter	Up to 30 cm	< ± 5% or < 1mm, below 2 cm. See note 2
Trace perimeter	Up to 100 cm	< ± 5% or < 1mmww, below 2 cm
Surface	Up to 1000 cm2	< ± 10% or < 40 mm², below 4 cm²
Volume	Up to 3000 cm³	< ± 16% or < 1.3 cm3, below 8 cm3
Time	Up to 30 secs	< ± 5% of full scale

11. Annex II: Electromagnetical compatibility

TABLE 2

Guidance and manufacturer's declaration – electromagnetic emissions		
The ImaGo range equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ImaGo range equipment should assure that it used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The ImaGo range equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ImaGo range equipment is suitable for use in all establishments other than domestic and can be used in domestic establishments and those directly connected to the public low-voltage power supply network under the condition of the following warning Warning: This equipment/system is intended to be used by health professionals. This equipment/system can cause radio-electric perturbations or it can affect the behaviour of a nearby electronic equipment. It may be necessary to take attenuation measures, like re-orienting or relocating the ImaGo range equipment or shielding the location.
Harmonic emissions CEI 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions CEI 61000-3-3	Complies	
Note 1: The use of cables or accessories different from those specified by IMV Technologies may have as a consequence an increase of emission or a decrease of immunity of the ImaGo range equipment		

11. Annex II: Electromagnetical compatibility

TABLE 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The ImaGo range equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ImaGo range equipment should assure that it used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (DES) **IEC 61000-4-2**	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kVcommon mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	<5 % UT (>95 % dip of UT) for 0,5 cycle 100 % UT (0 % dip of UT) for 1 cycle 70 % UT (30 % dip of UT) for 25 cycles <5 % UT (>95 % dip of UT) for 5 s	<5 % UT (>95 % dip of UT) for 0,5 cycle 100 % UT (0 % dip of UT) for 1 cycle 70 % UT (30 % dip of UT) for 25 cycles <5 % UT (>95 % dip of UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ImaGo range equipment requires continued operation during power mains interruptions, it is recommended for the ImaGo range equipment to be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field **IEC 61000-4-8**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note 1:UT is the a.c. mains voltage prior to application of the test level..

Note 2: The use of cables or accessories different from those specified by IMV Technologies may have as a consequence an increase of emission or a decrease of immunity of the ImaGo range equipment.

Note 3: The essential performance of the equipment considered for the compliance to the standard is defined as the correct visualization on the screen of an area of interest centered at 5 cm's depth with the L738V probe using default settings on a ATS model 539 phantom. The ultrasound image includes both hypoechogenic and hyperechogenic targets that should stay visible without any possible confusion

11. Annex II: Electromagnetical compatibility

TABLE 4

Guidance and manufacturer's declaration – electromagnetic immunity

The ImaGo range equipment is intended for use in the electromagnetic environment specified below.
The customer or the user of the ImaGo range equipment should assure that it used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ImaGo range equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ 150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380–390 MHz	27 V/m	
	28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz	28 V/m	
	9 V/m 704–787 MHz, 5100–5800 MHz	9V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: The use of cables or accessories different from those specified by IMV Technologies may have as a consequence an increase of emission or a decrease of immunity of the ImaGo range equipment.

a. Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Imago equipment is used exceeds the applicable RF compliance level above, the Imago equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Imago equipment.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 5

Recommended separation distances between portable and mobile RF communications equipment and the ImaGo range equipment

The ImaGo range equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the ImaGo range equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ImaGo range equipment as recommended below, according to the maximum output power of the communication equipment.

Separation distance according to frequency of transmitter w	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3: The use of cables or accessories different from those specified by IMV Technologies may have as a consequence an increase of emission or a decrease of immunity of the ImaGo range equipment.

TABLE 6

Radio Regulatory Compliance -Wi-Fi Parameters	
Operating Frequency	2412-2462 5150-5250
Modulation	BPSK
Transmitter Output Power (dBm)	< 18

12. Annex III: Acoustic power

Probe model: CR460V B Mode (mode 2D)

Table 201.103 – Acoustic output reporting table

CR460V MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,799	0,066		0,662		0,662
Index component value				0,066	0,066	0,662	0,066	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,409					
	P	(mW)		23,434		23,434		23,434
	P_{1x1}	(mW)		2,836		2,836		
	z_s	(cm)			3,328			
	z_b	(cm)					3,328	
	z_{MI}	(cm)	3,328					
	$z_{pii,\alpha}$	(cm)	3,328					
	Dim - 6dB	X (cm)		0,264		0,264		0,264
		Y (cm)		0,293		0,293		0,293
	f_{awf}	(MHz)	3,763	3,762		3,762		3,762
Other Information	pw	(us)	0,359					
	prr	(kHz)	3,99					
	srr	(Hz)	17,64					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	89,01					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	5,86					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	13,90					
	p_r at z_{pii}	(MPa)	2,17					
Operating control conditions			Preset 2	Preset 1		Preset 1		Preset 1
			Preset 3					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Probe model: LR664V B Mode (2D)

Table 201.103 – Acoustic output reporting table

LR664V MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,799	0,066		0,662		0,662
Index component value				0,066	0,066	0,662	0,066	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,409					
	P	(mW)		23,434		23,434		23,434
	P_{1x1}	(mW)		2,836		2,836		
	z_s	(cm)			3,328			
	z_b	(cm)					3,328	
	z_{MI}	(cm)	3,328					
	$z_{pii,\alpha}$	(cm)	3,328					
	Dim - 6dB	X (cm)		0,264		0,264		0,264
		Y (cm)		0,293		0,293		0,293
	f_{awf}	(MHz)	3,763	3,762		3,762		3,762
Other Information	pw	(us)	0,359					
	prr	(kHz)	3,99					
	srr	(Hz)	17,64					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	89,01					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	5,86					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	13,90					
	p_r at z_{pii}	(MPa)	2,17					
Operating control conditions			Preset 2	Preset 1		Preset 1		Preset 1
			Preset 3					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

12. Annex III: Acoustic power

Probe model: C360S B Mode (mode 2D)

Table 201.103 – Acoustic output reporting table

C360S MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,666	0,085		1,014		1,014
Index component value				0,085	0,085	1,014	0,085	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0,975					
	P	(mW)		35,890		35,890		35,890
	P_{1x1}	(mW)		4,343		4,343		
	z_s	(cm)			2,812			
	z_b	(cm)					2,812	
	z_{MI}	(cm)	2,680					
	$z_{pii,\alpha}$	(cm)	2,680					
	Dim - 6dB	X (cm)		0,272		0,272		0,272
		Y (cm)		0,882		0,882		0,882
	f_{awf}	(MHz)	2,596	3,134		3,134		3,134
Other Information	pw	(us)	0,497					
	prr	(kHz)	3,30					
	srr	(Hz)	12,87					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	67,00					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	5,66					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	9,15					
	p_r at z_{pii}	(MPa)	1,24					
Operating control conditions			Preset 2	Preset 0		Preset 0		Preset 0

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Probe model: L3130B2 B Mode (Mode 2D)

Table 201.103 – Acoustic output reporting table

L3130B2 MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,726	0,074		1,214		1,214
Index component value				0,074	0,074	1,214	0,074	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,112					
	P	(mW)		53,320		53,320		53,320
	P_{1x1}	(mW)		4,212		4,212		
	z_s	(cm)			4,196			
	z_b	(cm)					4,196	
	z_{MI}	(cm)	4,196					
	$z_{pii,\alpha}$	(cm)	4,196					
	Dim - 6dB	X (cm)		0,206		0,206		0,206
		Y (cm)		0,684		0,684		0,684
	f_{awf}	(MHz)	2,837	2,837		2,837		2,837
Other Information	pw	(us)	0,462					
	prr	(kHz)	5,06					
	srr	(Hz)	19,75					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	115,81					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	5,45					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	12,38					
	p_r at z_{pii}	(MPa)	1,68					
Operating control conditions			Preset 0					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC*

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

12. Annex III: Acoustic power

Probe model: L3180B B Mode (mode 2D)

Table 201.103 – Acoustic output reporting table

L3180B MODE: B SIMPLEX

Index label			*MI*	*TIS*		*TIB*		*TIC*
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,679	0,081		1,767		1,767
Index component value				0,081	0,081	1,767	0,081	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,026					
	P	(mW)		100,557		100,557		100,557
	P_{1x1}	(mW)		4,726		4,726		
	z_s	(cm)			4,840			
	z_b	(cm)					4,840	
	z_{MI}	(cm)	4,840					
	$z_{pii,\alpha}$	(cm)	4,840					
	Dim - 6dB	X (cm)		1,05		1,05		1,05
		Y (cm)		0,544		0,544		0,544
	f_{awf}	(MHz)	2,759	2,759		2,759		2,759
Other Information	pw	(us)	0,583					
	prr	(kHz)	3,98					
	srr	(Hz)	15,56					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	48,75					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	7,12					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	17,90					
	p_r at z_{pii}	(MPa)	1,63					
Operating control conditions			Preset 0					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Probe model: OPU 610B B Mode (mode 2D)

Table 201.103 – Acoustic output reporting table

OPU610B MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,667	0,204		0,792		0,792
Index component value				0,204	0,204	0,792	0,204	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,501					
	P	(mW)		14,199		14,199		14,199
	P_{1x1}	(mW)		5,353		5,353		
	z_s	(cm)			1,468			
	z_b	(cm)					1,468	
	z_{MI}	(cm)	1,468					
	$z_{pii,\alpha}$	(cm)	1,468					
	Dim - 6dB	X (cm)		0,19		0,19		0,19
		Y (cm)		0,364		0,364		0,364
	f_{awf}	(MHz)	6,142	6,142		6,142		6,142
Other Information	pw	(us)	0,260					
	prr	(kHz)	8,33					
	srr	(Hz)	32,55					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	84,17					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	13,78					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	25,66					
	p_r at z_{pii}	(MPa)	2,05					
Operating control conditions			Preset 0					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

12. Annex III: Acoustic power

Probe model: OPU614B B Mode (mode 2D)

Table 201.103 – Acoustic output reporting table

OPU614B MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,849	0,234		1,190		1,190
Index component value				0,234	0,234	1,190	0,234	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,866					
	P	(mW)		13,955		13,955		13,955
	P_{1x1}	(mW)		6,461		6,461		
	z_s	(cm)			1,428			
	z_b	(cm)					1,428	
	z_{MI}	(cm)	1,428					
	$z_{pii,\alpha}$	(cm)	1,428					
	Dim - 6dB	X (cm)		0,21		0,21		0,21
		Y (cm)		0,185		0,185		0,185
	f_{awf}	(MHz)	5,847	5,847		5,847		5,847
Other Information	pw	(us)	0,259					
	prr	(kHz)	8,33					
	srr	(Hz)	32,55					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	137,43					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	29,99					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	53,36					
	p_r at z_{pii}	(MPa)	2,49					
Operating control conditions			Preset 0					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

Probe LR664V Mode B plus CFM

Table 201.103 – Acoustic output reporting table

OPU614B MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,849	0,234		1,190		1,190
Index component value				0,234	0,234	1,190	0,234	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,866					
	P	(mW)		13,955		13,955		13,955
	P_{1x1}	(mW)		6,461		6,461		
	z_s	(cm)			1,428			
	z_b	(cm)					1,428	
	z_{MI}	(cm)	1,428					
	$z_{pii,\alpha}$	(cm)	1,428					
	Dim - 6dB	X (cm)		0,21		0,21		0,21
		Y (cm)		0,185		0,185		0,185
	f_{awf}	(MHz)	5,847	5,847		5,847		5,847
Other Information	pw	(us)	0,259					
	prr	(kHz)	8,33					
	srr	(Hz)	32,55					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	137,43					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	29,99					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	53,36					
	p_r at z_{pii}	(MPa)	2,49					
Operating control conditions			Preset 0					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

12. Annex III: Acoustic power

Probe CR460V Mode B plus CFM

Table 201.103 – Acoustic output reporting table

OPU614B MODE: B SIMPLEX

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0,849	0,234		1,190		1,190
Index component value				0,234	0,234	1,190	0,234	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	1,866					
	P	(mW)		13,955		13,955		13,955
	P_{1x1}	(mW)		6,461		6,461		
	z_s	(cm)			1,428			
	z_b	(cm)					1,428	
	z_{MI}	(cm)	1,428					
	$z_{pii,\alpha}$	(cm)	1,428					
	Dim - 6dB	X (cm)		0,21		0,21		0,21
		Y (cm)		0,185		0,185		0,185
	f_{awf}	(MHz)	5,847	5,847		5,847		5,847
Other Information	pw	(us)	0,259					
	prr	(kHz)	8,33					
	srr	(Hz)	32,55					
	n_{pps}		1,00					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	137,43					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ *or* $z_{sii,\alpha}$	(mW/cm^2)	29,99					
	I_{spta} at z_{pii} *or* z_{sii}	(mW/cm^2)	53,36					
	p_r at z_{pii}	(MPa)	2,49					
Operating control conditions			Preset 0					

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to *TIS* or *TIB* .

NOTE 3 Information need not be provided regarding *TIC* for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS* , *TIB* or *TIC* .

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to *MI*

NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and z_{pii}, apply to NON-SCANNING MODES, while the depths z_{sii} and z_{sii}, apply to SCANNING MODES.

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