User Manual

Version 1.12

Exago reference: 90-1119 Indice A
User Manual reference: 70-2705

Warning:

This manual must be read before using the equipment.

Manufacturer's address:
ECM
126 bd de la République
F-16000 Angoulême
Tél : +33 5 45 92 03 57

Distributor's address:
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SUMMARY

1. Introduction

This manual includes all necessary information for installing and using the Exago ultrasound equipment (ECM ref. 90-1119), used alone or with the Exago trolley (ECM ref. 90-1541).
Exago is an ultrasound device for diagnostic imaging.
Entirely digital, using FPGA technology, Exago provides imaging in B, M and CFM modes as well as Doppler spectrums.
Exago is designed for the following applications: Abdominal, General, Gynecology, Obstetrics, Orthopedics, Small parts,musculo squelletic,back fat & muscle & loin eye & IMF.

2. Safety instructions

2.1 Safety instructions for ultrasound equipment

2.1.1 User profile

 Warning:

This equipment 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 Exago equipment.

2.1.2 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).

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.

2.1.3 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.

2.1.4 Accuracy of MI and TI parameters display

The mechanical and thermal indexes are displayed permanently and explicitly on the screen in the upper right corner. See chapter 5.2.
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.

2.2 Safety symbols

Please note the meaning of the following safety symbols:

Symbol	Signification
	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.
	Warning : do not sit on the equipment
	Warning : do not push the equipment if the castor wheels are locked
	ON / OFF switch
	Collect separately from other waste (see European Commission Directive for electronic waste)
	CE Mark

2.3 Environmental conditions of use

The device shall be operated in a clean atmosphere, without dust and smoke.

The device is designed and tested be operated within this range of temperature:

- -20°C to +60°C during transportation and storing
- +10°C to +40°C during operation.

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.

 Warning:

Never use the device if these environmental conditions 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.
In order to ensure proper cooling of the device, do not block the ventilation fans or obstruct the air exhaust. 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.

 Warning:

Never block the fans or obstruct air exhaust, this will lead to overheating of the device and compromise proper operation of the system.

2.4 Electrical safety

This equipment is compliant with 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 I equipment

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 ECM. It is forbidden to bring any change to the equipment without permission of ECM.

 Warning

The equipment must be supplied by using the provided power cord including a connection to ground.

Warning:
The equipment must be used with the power adapter supplied by ECM, reference Protek PMP120-13-2-B2. The use of any other power adapter is forbidden. The power adapter is considered as a part of the medical device.

Warning:
The equipment uses an internal Lithium battery. The battery should exclusively be replaced in the equipment by the identical type of battery provided by ECM. Replacing the battery by an incorrect type may cause excessive temperatures, fire or explosion. The Battery is a Lithium-Ion Polymer battery rating a voltage of 14.8 V and a capacity of 8400 mAh.

Warning:
All connected peripherals requiring power (printer, monitor, USB peripherals or others) must use an insulation transformer or must comply themselves with the standard EN 60601-1-1. Otherwise the global configuration can no longer be considered patient safe.

Warning:
A risk of electrical shock may exist if the system is not properly grounded. The system must be connected to the electrical power network by a three-hole outlet with a connection to ground.

Warning:
Removing the power cord from the equipment may be used a s a safety action. Always place the equipment in a situation where the operator can easily access to the power cord to remove it quickly and safely if needed.

Warning:
The probes are the only Applied parts of the Exago system. No other part of the equipment is intended to be in contact with the patient.

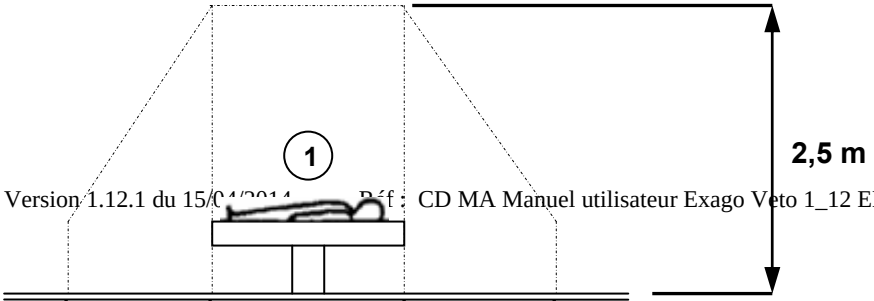
Warning:
Always inspect the probe head, housing, cable and power cord before use (see section 2.8: probe information). Any crack or damage to the probe head can lead to electrical shock. Never use a probe that is damaged, that has been dropped or has been suffering a severe shock until it has been inspected by an ECM 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 Exago ultrasound scanner is designed to be used in an environment as defined on the figure below:



2.6 Electromagnetic compatibility

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

 Warning:

The Exago 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).

 Warning:

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

 Warning:

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

2.7 Probe and equipment compatibility

The probes supplied with the Exago 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 Exago device is designed to be used exclusively with probes supplied by ECM together with the device.

 Warning:
Never try to connect a probe to the Exago device which is not supplied by ECM and described to fit the Exago equipment. This can lead to irreversible damage on the Exago 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 and maintenance reasons, never disconnect a probe from the device without freezing the system first.

2.8 Probe information

2.8.1 Probe types and corresponding applications

The probes provided with the Exago device are the following:
- LR760P Linear rectal probe, central frequency 7,5 MHz. This probe is used for the following applications : general, reproduction, gynecology.
- C360A Convex probe, central frequency 3.5 MHz. This external probe is used for the following applications: general, abdominal, gynecology, obstetrics.
- L738P Linear probe, central frequency 7.5 MHz. This external probe is used for the following applications: general, orthopedics, abdominal, small parts .
- C614P Micro-convex probe, central frequency 6 MHz. This external probe is used for the following applications: general, abdominal, small parts, gynecology.
- C320A Convex probe, central frequency 3,5 MHz. This external probe is used for the following applications : general, abdominal, gynecology.
- E610A Endo-cavity probe, central frequency 6.5MHz. This probe is used through the vagina (with the guide) for the following application: Ovum Pick Up.
- L3130 B Linear probe, central frequency 3.5 MHz. This external probe is used for back fat, muscle, loin eye measurements and even IMF (Biotronics software compatible with the Exago) on pigs.
- L3180 B Linear probe, central frequency 3.5 MHz. This external probe is used for back fat, muscle, loin eye measurements on cattle.

The indicated applications can be examined in B, PW or CFM modes or in combined modes.

 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 Exago device are compliant with the standard ISO 10993-1 concerning biocompatibility of components used for probe manufacturing.

References for Biopsy needle guides:
Provider CIVCO: www.civco.com
Linear L738P: Bracket reference Civco 612-085, to be used with needle guide 610-608, compatible with the needles 8.5FR and gauge 14 to 23 (except gauge 19). This bracket reference is a re-usable bracket; needle guides are disposable.

Endo-cavity E610A: Reference (bracket and needle guide) Civco 610-604 (or 610-605), compatible with needles gauge 16 to 18.

Provider PROTEK: www.protekmedical.com
Convex C360A: Bracket reference Protek 7138, to be used with needle guide ref 4222 (22 Ga), ref 4218 (18 Ga), ref 4216 (16 Ga). This bracket reference is a re-usable bracket; needle guides are disposable.

Nb : Micro convex probe C 614 P is recognized with Biopsy line.

2.8.2 Inspection of probes

 Warning:
Before each use, inspect the transducer lens, case and cable. Check for cracks or other damages that may allow liquids to enter the transducer.
If you find any damage, do not use the probe until it has been inspected and either repaired or replaced by an authorized ECM customer service engineer

 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 ECM 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.

2.8.3 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 chapter 7.2 about how to perform proper care to the probe.

 Warning:
Always place the probe in the probe holder placed on the trolley or in another secured place when not used on a trolley 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 ECM customer service engineer.

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

2.8.4 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 following 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.

2.8.5 Surface temperatures

The probes provided with the device 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 Exago device 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.

2.9 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.

3. Installation of the equipment

The Exago device must be installed on site by a person authorized by ECM.

 Warning:

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

 Warning:

After installation with the Exago trolley, check that the mechanical components (optional LCD screen, additional screen arm) are properly attached and that there is no risk for them to fall or move in unexpected ways.

 Warning:

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

 Warning:

When closing the locking system on the Exago trolley, take care of avoiding pinching your fingers between the locking mechanism and the upper part of the equipment.

4. Getting started

4.1 Connection and disconnection of probes

To connect a probe, put the probe connector in the opening provided for this purpose. Turn the locker situated in the middle of the connector with a slight pressure in order to engage the locking mechanism. When the locking mechanism is engaged, make a quarter turn so that the probe is connected.

After connecting a probe, always place the probe in a safe place (in one of the probe holders if the system is used with its trolley) in order to avoid any damage of the probe due to a shock or falling down.

The probes can be changed during the examination without restarting the device.

To disconnect a probe, make a quarter turn in order to unlock the connector. Take the connector out of the device and store the probe in an appropriate place protected from shocks.

 Warning:
Before disconnecting the active probe, make sure to freeze the image.

When starting the device, always make sure to have a probe connected on the connector.
The label of the connected probe label is displayed on the screen (top right of the image).

4.2 Use of Exago trolley

If the equipment is used with the Exago trolley, check that a probe is connected to the right hand side connector. To start the device, use the same procedure as below for the Exago equipment.

4.3 Starting of the device

 Warning:
Only the power cord supplied by ECM with a ground connection must be used to power the device. Never use a power cord without proper ground connection.

To start the equipment, turn on the power switch situated on back panel of the device.

Then wait until the system starts and displays the user interface on the screen.

The Exago equipment starts in B mode with the probe connected on the probe connector. If no probe is connected to the probe connector, the system will display a label “No probe”. In this case, connect a probe to the connector and press “Freeze”, or restart the equipment.

To stop the equipment, press again the power switch situated on the back panel of the device. A shutdown procedure will be performed until the complete stop of the equipment.

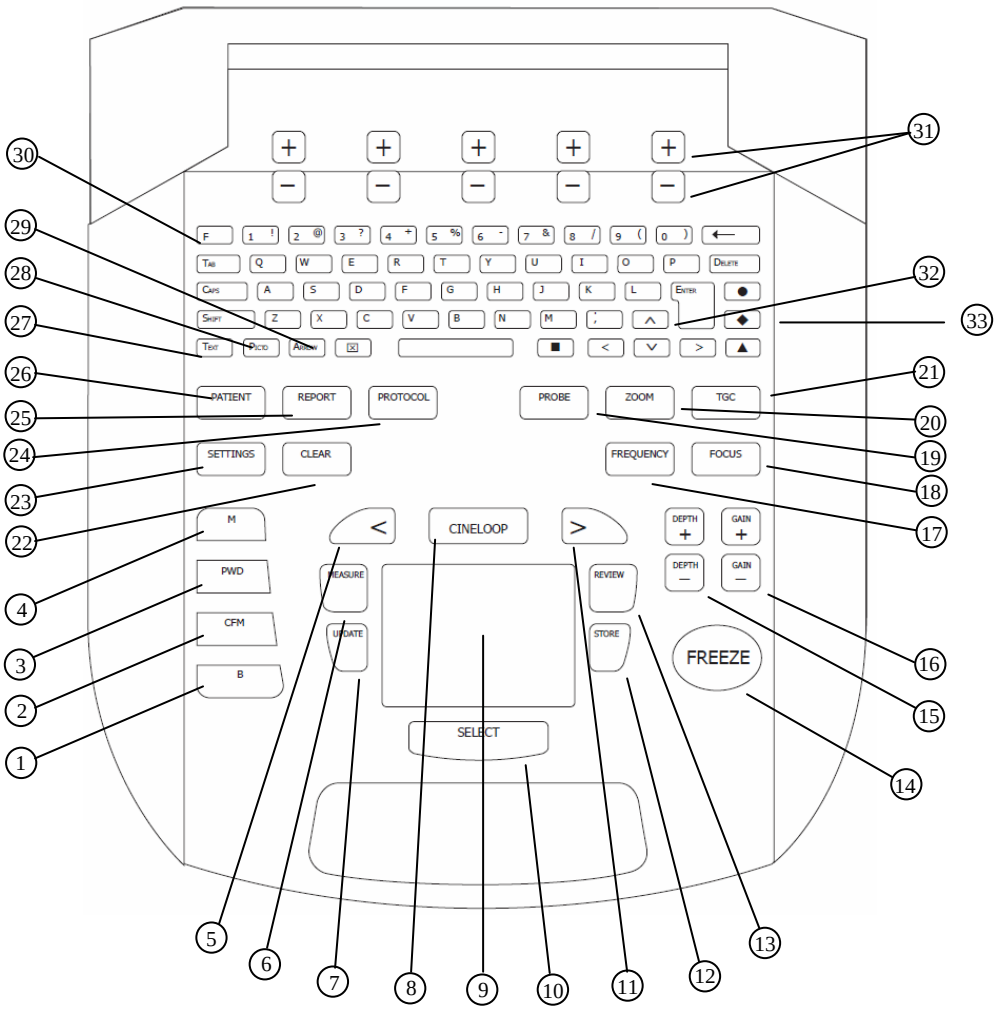
4.4 Battery operation

The Exago battery can be removed from the equipment by pressing the two clips located on the rear of the product. When inserting the battery back in the device, check that it is securely fastened.

When the device is powered on the main network, the battery is charging whatever the device is running or not. While the battery is charging, a charging indicator is visible on the back panel of the device (yellow led).

5. Presentation of the device

5.1 Keyboard description



5.2 Keyboard function

1. **B:** access **B** mode operation and **B** contextual menu. When operating in **M, CFM** or **PW** mode, return to **B** mode.

B contextual menu includes:

- **Dynamic**: select **Dynamic** Range of B image (35-70dB). Displayed on screen with “Dyn” label.
- **Power**: select transmit Power (30-100%). Displayed on screen with “Power” label.
- **Brightness**: adjust screen brightness (3-100%). Displayed temporarily on screen with “Bright.” label.
- **Dual**: access **Dual** B imaging mode. Use Select to switch between left and right images. A round dot on display indicates the active image, or if in Freeze mode the image that will be unfrozen. Use B to exit Dual mode.
- **L/R, U/D**: invert displayed image orientation (**Left/Right** or **Up/Down**). A round dot on display indicates probe element n°1.Keys UP & DOWN allow also to move in the protocol list.
- **Frame Average**: select frame averaging level among SLOW, SLMED, MFAST, FAST values. Displayed temporarily on screen with “FAvg” label.
- **Noise Reject:** activate the **Noise Reject** window on the screen. The window position can be adjusted by the touchpad control. After pressing Select, the window size can be adjusted by the touchpad control. The **Noise Reject** level (0-15) is displayed in the window and can be adjusted by pressing the “+” and “-“ contextual **Noise Reject** keys. All signals below the selected level will be filtered to provide a cleaner image. Press **Clear** to exit.
- **Biopsy:** activate the display of biopsy needle guiding channel on the screen. The needle channel is shown with two dotted lines within which the needle should travel. Before using this feature, it is recommended to test this function in a water tank before use on a patient. The mechanical tolerances of the biopsy guide may exceed the expected values and the guiding channel is purely indicative. Press **Biopsy** or **Clear** to remove the Biopsy guiding channel display.

 Warning:

This biopsy needle guide is only valid if the operator uses the biopsy guide recommended by ECM and listed for each probe (See chapter 2.8).

 Warning:

The user must check that the biopsy guide is properly attached to the probe to ensure secure guidance of the needle.

 Warning:

On probe C360A and C614, check that the biopsy needle is situated at the same side as the orientation marker of the probe.

 Warning:

On probe E610A, check and confirm by clicking OK that the system will display a biopsy guideline dedicated to medical application.

- **Exa Cross:** activate the Cross Beam function. The angle can be adjusted with the arrow cursors (see item 32). Exa Cross can be used in B and Dual B. Active only on the linear probe. Press **Exa Cross** again to exit.
- **Large image:** activate the function **Large Image** where the images use a maximum of the screen. Large Image can be used in B and Dual B. Active only on the linear probe. Press **Large Image** to exit.

- **Smooth +/- :** 3 levels 0 = no smoothing – 1 & 2 = smoothing, level can be modified with contextual menu +/-, active in B and Dual mode but not in Zoom ; the "Smooth" function can be saved in a preset.
- **Next, Previous:** used to explore next and previous levels of the contextual menu. The key "Next" allows to come back to first page of the menu and a page gauge indicates in which of the 3 pages you work.

B gain is adjusted with the "Gain" keys (see item 16).

2. CFM: access **CFM** display and menu. The CFM box **Position** can be adjusted using the touchpad.
Press **Update** to go to **Pre-trace CFM** mode for adjustment of the **CFM** box size, position and **Steering** angle.

Pre-trace **CFM** contextual menu includes**:**

- **Position:** activate CFM box **Position** control. The **Position** adjustment can be done using the touchpad or the Cursor keys (see item 32).
- **Size:** activate CFM box **Size** control. The **Size** adjustment can be done using the touchpad or the Cursor keys (see item 32).
- **Steering** (only active on linear probe)**:** Activate the Steering of the CFM box. Select CFM box Steering angle by pressing "+" and "-" keys. By default, the Steering angle is equal to previous PW or CFM selected Steering angle value. The **Steering** function is only available on linear probes.

Press **Select** to switch from **Pre-trace CFM** to **Active CFM** mode operation and contextual menu.

Active CFM contextual menu includes:

- **PRF**: select PRF value (500-11313 Hz). Displayed on screen with "PRF" label.
- **Wall Filter**: select the Wall Filter index (1-7). Rejection of movements from vessel walls and tissues. With a high Wall Filter index, slow speeds are rejected. Displayed temporarily on screen with "WFilter" label.
- **MinVelocity**: select MinVelocity index (1-5). Rejects the color on slow velocities. A high Min Velocity index cuts the color on slow velocities. Displayed temporarily on screen with "MinVel" label. Max & Min velocities are displayed on the color scale of the CFM.
- **Vessel Size**: select Vessel Size index (1- 5). Optimisation of color sensibility according to the vessel size. Index 1 for small vessels, index 5 for big vessels. Displayed temporarily on screen with "VesSize" label.
- **PacketSize**: select the PacketSize index (1-3). Higher PacketSize index increases CFM sensitivity and slightly decreases CFM Frame Rate. Displayed temporarily on screen with "Packet" label.
- **Burst**: select the number of cycles in the transmit burst with **Burst** index (1-3). Higher Burst index increases CFM sensitivity and slightly decreases CFM spatial resolution. Displayed temporarily on screen with "Burst" label.
- **Power**: select the CFM transmit power (30-100). Displayed temporarily on screen with "Power" label.
- **Persistence**: select the Persistence index (1-8). Persistence is a Frame averaging on CFM image. Displayed temporarily on screen with "Persist." label.
- **Spatial Filter**: select the SpatialFilter index (1–3). Smoothening of the CFM image. Displayed temporarily on screen with "SFilter" label.
  Invert: select inversion of color and CFM scale color is also inverted. Max & Min velocities are displayed on the color scale of the CFM.

  CFM gain is adjusted with the "Gain" keys (see item 16).

Press **Update** to switch from **Active CFM** mode to **Pre-trace CFM** mode. Press **Select** to return to **Active CFM** mode.

3. PWD: access **Pre-trace PW** display and menu. **Pre-trace PW** mode allows to adjust the **PW** gate **position** and size on the **B** image or **B/CFM image**, and to adjust **Steering** and **Angle** parameters before starting **PW** active mode.

Pre-trace **PW** contextual menu includes**:**

- **Gate Size:** select Gate Size by pressing "+" and "-" keys. Selected Gate Size is displayed on screen.
- **Steering:** select Steering angle by pressing "+" and "-" keys. The PW line is updated on the display. By default, the Steering angle is equal to previous PW or CFM selected Steering angle value. The **Steering** function is only available on linear probes.
- **Angle:** select position of the **Angle** correction marker. The **Angle** value is displayed on screen with the label "Angle" and the marker is shown in the PW Gate. Angle marker is displayed in red if the angle is not valid, and in white if angle is valid. Once the **Angle** marker is selected, the frequency/velocity scale in Active PW mode will include velocity labels. To cancel **Angle** correction, press **Clear** in Pre-trace or active PW mode.

The PW gate **Position** can be adjusted using the touchpad or the Cursor keys (see item 32) in the **Pre-trace PW** mode.

Press **Select** to switch from **Pre-trace PW** to **Active PW** mode.

Active PW mode contextual menu includes:

- **PRF:** select PRF value (2000-11313 Hz). Displayed on screen with "PRF" label.
- **Baseline:** select the spectrum Baseline. The frequency/velocity scale is updated on the display.
- **Invert:** invert the frequency/velocity scale. The frequency/velocity scale is updated on the display.
- **Audio:** select the audio output volume.
- **Filter:** select the PW Wall Filter (50, 100, 200 Hz). Displayed on screen with "WFilter" label.
- **Power:** select the PW transmit power (50-100%). Displayed on screen with "Power" label.

PW gain is adjusted with the "Gain" keys (see item 16).

Press **Update** to switch from **Active PW** mode to **Pre-trace PW** mode. Press **Select** to return to **Active PW** mode.

4. M: display M line, set M line position with **Touchpad**, press **Select** to start M mode display. Press **Update** to return to M line adjustment. Press **Select** again to start M mode display.

5. <: in Freeze mode, move to previous **Cineloop** image. Current image index is displayed on screen.

6. Measure: freeze the system (if operating live) and access **Measure** menu. Accessing the **Measure** menu will automatically initiate a first **Distance** measurement.

Measure contextual menu includes:

- **Distance:** start a new **Distance** measurement with display of first calliper. Adjust first calliper position with **Touchpad** and click on **Touchpad** for first calliper position validation and display of next calliper. Adjust second calliper. Press **Select** to go back to first calliper adjustment or click on **Touchpad** to terminate the **Distance** measurement. **Distance** values are displayed on screen with identification and color code. Four distances can be acquired on the same image. If the option **Tools: Distances in sequence** in the Setting menu is active, once a distance measurement is completed, the system automatically displays the first calliper of the next distance measurement (see item 23).
- **Ellipse:** start a new **Ellipse** measurement with display of first calliper. Adjust first calliper position with **Touchpad** and click on **Touchpad** for first calliper position validation and display of next callipers. Adjust second calliper. Press **Select** to validate second calliper and go to third calliper to adjust this. Press **Select** to go back to first calliper adjustment or click on **Touchpad** to terminate the **Ellipse** measurement. **Ellipse** values are displayed on screen with identification and color code. Two ellipses can be acquired on the same image.
- **Trace:** start a new **Trace** measurement with display of first calliper. Adjust first calliper position with **Touchpad** and click on **Touchpad** for first calliper position. Draw the **Trace** contour on image using the **Touchpad** and click on **Touchpad** to terminate the **Trace** measurement. If the drawn contour is not closed, a straight line will be used to close the contour and allow surface and perimeter calculation. **Trace** values are displayed on screen with identification and color code. One single **Trace** can be acquired on the same image.

- **Select:** select one distance, ellipse or trace among all items displayed on screen. Selected item and related measurements are highlighted.
- **Delete:** delete the selected measurement on screen.

Press **Measure** to exit the measurement menu and Freeze to unfreeze and return to live imaging.

7. **Update:**
   - **M:** in operating **M** Mode, freeze **M** display and return to live operation of **B** mode for **M** line adjustment by **Touchpad**. After adjustment, **Select** is used to return to **M** mode display**.**
   - **CFM:** in operating **CFM** Mode, return to CFM Pre-trace mode (**Position**, **Size**, **Steering**). After adjustment, **Select** is used to return to **CFM** mode display**.**
   - **PW**: in operating **PW** Mode, freeze **PW** display and return to live operation of **B** mode for **PW** gate adjustment by **Touchpad** and **PW Pre-trace** menu (**Gate Size**, **Steering**, **Angle**). After adjustment, **Select** is used to return to **PW** mode display**.**
   - When **PW** is activated from **CFM**, the "**Update**" key allows to come back to the **CFM mode** with the gate active.

8. **Cineloop:** freeze the system (if operating live) and access **Cineloop** menu.
   Cineloop contextual menu includes:

   - **Cineloop key** freezes the image and makes also stop/play of the cineloop sequence.
   - **First Image:** set current image to first frame in Cineloop memory. Index of current image is displayed on screen.
   - **Play/Pause:** play/pause the sequence of stored images from the Cineloop memory.
   - **Last Image:** set current image to last frame in Cineloop memory. Index of current image is displayed on screen.
   - **StoreClip:** Store current clip on external USB device (if any) or in internal memory.

9. **Touchpad:** pointing device used for menu selection, measurement cursors, validation of measurements etc.

10. **Select:** used to confirm selection of items, to activate **Active CFM** mode, **Active PW** mode and **M** mode, to go from one calliper to another in measurement mode, to display zoomed image, to switch from one image to another in **Dual B**.

11. **> :** in **Freeze** mode, move to next **Cineloop** image. Current image index is displayed on screen.

12. **Store:** store current image on external USB device (if any) or in internal memory.

13. **Review:** access to **Review** menu for reviewing stored images or clips from external USB device or internal memory. System will explore the USB in priority before exploring the internal memory. In order to access to internal memory, remove any connected USB device. **Review** display includes an Image List and a Clip List in which the file to be reviewed should be selected using **Touchpad**.
    Review contextual menu includes:

    - **Load:** display the selected image or clip.

      For a loaded image in format .bmp or .jpeg (see item 23):
      - **Previous:** display the previous image in the image list.
      - **Next:** display the next image in the image list.
      - **Rename:** rename the selected image.
      - **Delete:** delete the selected image.
      - **Back:** return to the upper level menu.

      For a loaded image in format .imag (raw data format, see item 23):
      - Cineloop menu, possibility of making new measurements or adjusting existing measurements in post-processing and storing of this.

      Press **Freeze** to exit the cineloop mode.

      For a loaded clip:
      - **First image:** display the first image of the selected clip.
      - **Play/Pause:** play or pause the reading of the selected clip.

- **Last image:** display the last image of the selected clip.
- **Store clip:** Store current clip.
- Possibility of making measurements on a paused image in post-processing and storing of this.

Press **Freeze** to exit the cineloop mode.

- **Rename:** rename the selected image or clip.
- **Delete:** delete the selected image or clip.
- **Exit:** exit the **Review** menu.

14. Freeze: freeze and unfreeze system. In **Freeze** mode, 3 contextual menus are available: **Cineloop, Measure** and **Protocol**. See details of **Measure** in item 6, of **Cineloop** in item 8 and of **Protocol** in item 24 descriptions.

15. Depth + and - : adjust image **Depth**. Image **Depth** is displayed on screen (bottom of depth scale).

16. Gain + and - : adjust **Gain** of current imaging mode **(B, PW or CFM)**. **Gain** is displayed on screen (label "Gain").

17. Frequency: access **Frequency** selection menu. Three available transmit frequencies are selectable in each mode using the contextual keys. The operating **Frequency** is displayed on screen (label "Freq"). Same key is used to exit the **Frequency** selection menu. If no contextual keys are used for 15 seconds, the system automatically exits the **Frequency** menu. If the option **Tools: Circular selection (Focus & Frequency)** in the Setting menu is active, the Frequency button automatically brings the frequency from one step to the next in a circular way ; also valid in CFM and PW mode.

18. Focus: access transmit **Focus** selection menu. Five available transmit **Focus** are selectable in B mode using the contextual keys. The operating **Focus** is displayed on screen by a triangular marker on the depth scale. Same key is used to exit the **Focus** selection menu. If no contextual keys are used for 15 seconds, the system automatically exits the **Focus** menu. If the option **Tools: Circular selection (Focus & Frequency)** in the Setting menu is active, the Focus button automatically brings the focus from one step to the next in a circular way.

19. Probe: access to **Probe** selection (if system used on dual port trolley) and to **Preset** menu for factory and user-defined preset selection. This key is only active when in live imaging. If image is frozen, press **Freeze** to access this menu.

Probe contextual menu includes:

- **Probe 2:** Only active if the device is used on dual port trolley**.**
- **Probe 1:** this contextual key displays the connected probe identification (for example L738P).
- **Preset:** access the Preset selection menu. This menu displays a Factory Preset list and a User Preset list.
  - **Load:** load the selected Preset.
  - **New:** save the current system settings into a user **Preset** file. Enter a file name in the "Save as" field and press the **Enter** key. The new user **Preset** is listed in the User **Preset** list.
  - **Rename**: rename the selected User Preset. Enter a file name in the "Rename as" field and press the **Enter** key. The new user **Preset** is listed in the User **Preset** list.
  - **Delete**: delete the selected User **Preset**. Factory Presets can not be renamed or deleted.
  - **Exit:** exit the **Preset** menu**.**

If no contextual keys are used for 15 seconds, the system automatically exits the **Probe** menu.

20. Zoom: display **Zoom** box on image and access **Zoom** menu. The ROI position can be adjusted by the touchpad control. Select **Zoom** scale factor (x1.5, x2, x3) using contextual keys and press **Select** to display zoomed image. **Zoom** scale factor is displayed on screen (label "Zoom"). Same key is used to exit the **Zoom** menu and to get back to normal non-zoomed image. If no contextual keys are used for 15 seconds, the system automatically exits the **Zoom** menu.

21. TGC: access to **TGC** menu. For every image depth, the **TGC** can be adjusted at 4 different levels within the current image depth, corresponding to the blue dots on the curve. Adjust **TGC** levels using the "+" and "-" contextual keys. The active level is highlighted in yellow during the modification and values (from -120 up to

+120) are displayed on each of the 4 contextual menu keys. Press **Reset** to return to initial TGC level. Press **TGC** again to exit the **TGC** menu. If no contextual keys are used for 15 seconds, the system automatically exits the **TGC** menu.

22. Clear: clear all annotations, arrows from current image**.** Clear Biopsy guide and Noise Reject from current image.

23. Settings: access to the **Settings** menu**.** This menu is made of 3 folders and 3 functions from the contextual menu.

User folder:

- **Hospital name:** selection of the Hospital Name as a free text. The Hospital Name is displayed on screen.
- **User Name:** selection of the User Name (Doctor name) as a free text. The User Name is displayed on screen.
- **Patient Identification:** selection of patient identification by patient name or Patient ID.
- **Language:** selection of system language. (Chinese version is available and key • selects or not the Chinese input and ▲ selects the input for digits and other symbols non-ideogram.
- **Image format:** selection of stored image files (uncompressed bitmap, compressed jpeg, raw data image and/or Dicom format images).DICOM "only" allows to save the images only on Dicom format.
- **M/PW Scroll speed:** duration in seconds of scrolling M/PW display (2, 4 or 6 seconds). 4 sec. by default.
- **M/PW Refresh:** refresh frequency of B image (every 1, 2 or 4 M/PW scrolls). 1 scroll per default.
- **Tools / Distances:** selection of automatic distance measurements in sequence. If this option is active, once a distance measurement is completed, the system automatically displays the first calliper of the next distance measurement. Active by default.
- **Tools / Freq/Focus Auto Select:** selection of AutoSelect function. When enabled, B mode transmit focus and transmit frequency are selected automatically by the system depending on image depth. These functions can still be adjusted manually during the active imaging.
- **Tools / Centimetre grid on B:** When enabled, a centimetre grid is active on B and Dual B images.
- **Tools / PW Pretrace/CFM:** this selection authorizes the display of PW pre-trace mode (displaying the PW Gate line) on an active CFM image. Active by default.
- **Tools / Circular selection (Focus & Frequency):** When enabled, the Frequency and Focus buttons automatically bring the frequency and focus from one step to the next in a circular way. Active by default ; circular frequency is also available in CFM and PW mode . See item 17 and 18.
- **Tools / Logo at the bottom :** on frozen image "EXAGO" logo can be displayed either on top or bottom of the image.
- **Auto / Real Time Tools - Follicles :** automatic measurement of the diameter or ellipse of the dominant follicle (in live or frozen mode) – 1 or 2 scans.
- **Auto / Real Time Tools - Back Fat :** automatic measurements of back fat and muscle (on live or frozen mode), both measurements can be adjusted manually with Fat+/- and Muscle +/-. In PIG application and with the probe L 3130 B dedicated for back fat & muscle & loin eye and even IMF (with the Biotronics software compatible with the EXAGO) we have included a Biotronics preset entitled Biotronics DDI.

Annotation folder:

- **Annotation key F1 to F10:** selection of user defined annotations, as a free text. These annotations can be used in the **Text** function and can be selected using the F+ numeric keys as shortcuts. See **Text** function (item 27).
- **Restore last annotation:** Repeat the latest free text (not from the annotation list) entered with the Text function (item 27) automatically when pressing Text.
- **Annotations are saved in raw data such as measurements.**
- **Annotation of a saved image can be modified and new annotations can be added on that image.**

System folder:

- **Date format:** selection of date format (DD/MM/YYYY, YYYY/MM/DD, MM/DD/YYYY).
- **Time format:** selection of time format (24 H or 12 H).
- **System date:** selection of current date.
- **System time:** selection of current time.
- **Auto Freeze:** selection of Auto Freeze time period, after which the system will automatically freeze if no key has been used. Can be selected as 5 min, 10 min, 15 min and also Never.
- **About:** displays system information as software revision level.
- **USB: Force store clip:** Improves storing of clips on some USB flash sticks (old or not correctly formatted)
- **Network:** selection to activate DHCP or not (by default DHCP is activated). In case DHCP is activated, the IP address shown in the screen is the one provided by the network. If DHCP is not activated, user should enter a valid IP address, enter the standard subnet mask as 255.255.255.0 and press "Apply".

Dicom folder:

- **Store Menu** :

Host: Storage server IP address. Provided by the network administrator.
Port: Storage server Port (default value is 104). Provided by the network administrator.
AE: Storage server Application Entity name Provided by the network administrator.
Local AE: Exago system Application Entity name. Allocated by the network administrator.
Interpretation: image format. Pallete by default. If not accepted by the server, select RGB (Red Green Blue) or Monochrome (no color).
Compression: image compression type. None by default. RLE: compressed.

Immediate Storage: If the box is ticked, the transfer to the DICOM server is immediate when pressing store. When not ticked, the Dicom images can be saved in a Patient Report in Dicom format on the internal memory or on an external USB device and transferred later to the Dicom server by the key Dicom Store in the contextual report menu. It is recommended to enter a Patient ID if Dicom storage is used.

To enable the storage on the Dicom storage server, the Enabled checkbox should be ticked.

The Ping key allows, in case the network authorizes it, to check IP connection to the server.

The Echo key allows to check the Dicom connection to the server using Port and AE identification.

Log enabled: Information about the network communication. To be used in case of problems.

- **Print Menu**:

Host: Print server IP address. Provided by the network administrator.
Port: Print server Port (default value is 104). Provided by the network administrator.
AE: Print server Application Entity name. Provided by the network administrator.
Local AE: Exago system Application Entity name. Allocated by the network administrator.
Interpretation: image format. Pallete by default. If not accepted by the server, select RGB (Red Green Blue) or Monochrome (no color).
Orientation: to be selected as portrait or landscape

To enable the print on the Dicom print server, the Enabled checkbox should be checked.

Print: Pressing the Print key (black square located on the right of the space bar) will print the image on the Dicom storage server.
Printing of images is possible during the examination or when the images are stored in .imag format.

The Ping key allows, in case the network authorizes it, to check IP connection to the server.

The Echo key allows to check the Dicom connection to the server using Port and AE identification.

User Protocol: access to the **User Protocol** menu to create user-defined protocols.

The contextual menu includes:

- **Create:** add a new line in the "User Protocols" list. Start by selecting the Application with the Touchpad in the list to the left in which the user protocol should be created. User can select which measurements from the "Protocol Items" list will be included in the user protocol by clicking on the corresponding box with the Touchpad. For measurements having multiple authors, user can select the author from the "Authors" list. Protocol name can be modified by typing the new name in the text field located in the lower left part of the menu. Press **Save** when selection is finished.
- **Delete:** delete the selected **User Protocol** from the "User Protocols" list.
- **Save:** save the created **User Protocol**.
- **Tables:** in Obstetrics application, display the current protocol table in data or graphical mode (**Data/Graph** control). Next and Previous controls are used to review equivalent table with different authors (if any).
- **Back:** exit the **User Protocol** menu and return to the **Settings** menu.

To activate a user protocol, click on **Patient** and select the application and protocol for the examination in the "Exam" box to the right. The application and protocol selection can be done with or without opening a patient file (see item 26).

Reset: reset all system settings to default factory settings.

Exit: exit from the Settings menu.

24. Protocol: open and display a measurement **Protocol**. The **Protocol** menu can be used during an examination or independently of an examination. Protocols are either factory protocol or user protocol if any (see item 23). Selection of protocol is made by clicking on **Patient** and selecting the application and protocol for the examination in the "Exam" box.

In case of use during an examination with a patient file, user should first through the Patient menu create and/or select a patient, select an application, select a Factory or User protocol and then start an examination (see item 26).

Protocol will display on the left side of image:

- the list of measurements to be performed in the protocol. When frozen, use the contextual key "Page +/-" or the cursors (see item 32) to scroll the protocol list up and down;you may use also the UP & DOWN key to scroll the list.
- the current measurement result
- the author reference of the current table (if any)
- in Application Obstetrics: the reference gestational age (weeks+days) if any, the estimated gestational age (weeks+days), the date of LMP and the estimated date of birth (edd).
- In Horse application, and for the Protocol "tendons disease", it is possible to use 2 times 2 Trace measurements on the same image (B image) and also on Dual Mode.

Use of Protocol measurements: Freeze the image. Select measurement to be performed in the protocol list using the touchpad, click on **Select** to initiate first calliper on the image. After adjusting position of the first calliper, click on touchpad to validate this and to activate the second calliper. After adjusting position of the second calliper, click on **touchpad** to validate the measurement or press **Select** to return to the previous calliper for readjustment before validating the measurement by clicking on the touchpad.

Measurement result and estimated Gestational Age (in Application Obstetrics) are displayed on screen.

To confirm storing of these results in the report, press **Add**. The number of validated and added results for each measurement is indicated in the protocol list after each item in parenthesis.

When pressing Add after validation of the protocol measurement, this measurement is included in the examination report.

In case of use without starting an examination, user can use the protocol list to select available measurement, perform measurement on the image, and obtain an estimated Gestational Age (in Application Obstetrics) without selecting a Patient and opening an examination report. The information can be stored or printed with the corresponding image without using the Report feature.

Volume protocol measurements: Make first two measurements (Width and Height) on a frozen image. Defreeze, find the second cut and freeze again. Click Select to get first calliper of third measurement (Depth) and do as usually for making the measurement. After validation, the result of volume measurement is displayed. If an examination is in progress, this measurement can be added to the report pressing **Add**.

25. Report: access to **Report** menu allowing to review images, clips and examination reports from USB device (if connected) or from internal system memory. Text reports can be reviewed as well as stored images and clips.

When no examination is under progress **Report** will display the following:

- **Export USB:** exports selected data (image, clip, patient, complete examination or report) on an external USB device.
- **View:** display selected items from the menu main list (text report, images or clips).
  For an image or a clip: See item 13 on Review.
  For a report: see below, like for a report under progress.
- **Rename:** rename the selected data (image or clip).
- **Delete:** delete the selected data (image or clip).
- **DICOM store:** Transfer of previously stored Dicom files to the Dicom server. Only possible when the images are stored in a patient report. Select the report and press Dicom Store. If no ID has been allocated before, the device will ask you to do it. See item23 about Dicom folder, Immediate Storage.

Exit by pressing Report.

If an examination is under progress, **Report** will directly access viewing the current report under progress.

- **Page 1/…:** move to next report page.
- **View:** display stored image from the current report under progress.
  - **Previous:** display the previous image in the image list from the current report.
  - **Next:** display the next image in the image list from the current report.
  - **Rename:** rename the selected image.
  - **Delete:** delete the selected image.
  - **Back:** return to the upper level menu.
- **Directories:** return to **Directories** selection menu: USB device (if connected) or internal memory. See above.
- Press **Report** to exit and return to current examination

26. Patient: access to the **Patient** menu, allowing to review and store Patient data, examination information including Application and Protocol selection.

- **Patient List:** access to stored Patient data from USB device (if connected) or internal system memory. Click with touchpad to select an existing patient.
  - **Search:** Easy search of existing patients by name or ID. Patients can be sorted out by Animal, Name or ID selecting the headline list.
  - **Delete:** delete selected patient with all attached reports, images and clips.
  - **Previous:** Return to the New Patient page.
- **New Patient:** create a new patient in the patient list. Patient data are typed by user in the "Patient" box.
  In the "Exam" box, select the Application and the protocol (Factory or User protocol, see item 23) to be used for the examination.
  In OB application, the patient's LMP date can be entered. This date will be used for the reference gestational age.
  To validate patient data and confirm patient creation, press **Exit** or proceed to start an examination.

- **Start Exam:** start an examination and opens an examination report. All stored images, clips and protocol measurements will be included the current report.
- **End Exam:** stop current examination and closes examination report.
- **Exit:** exit from the **Patient** menu.

27. Text: In Freeze mode, display a text field for writing an annotation on the current image. Shortcuts can be used to display user pre-defined annotations in the Settings menu, by pressing "F" function key and one numeric key (F and 1, for example). See item 23. Free text can also be entered. . If the option **Annotations: Restore last annotation** in the Setting menu is active, the last entered text will automatically be displayed in the Text field. Press enter to validate.

28. Picto: not active.

29. Arrow: display an arrow in active imaging mode or a calliper for drawing arrows In Freeze mode. Same key is used to delete the arrow in active imaging mode. Use **Clear** to delete arrow in Freeze mode.

30. F: special "function" key used in combination with numeric keys (1-9) for annotation shortcuts (see item 23).

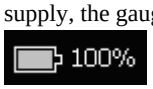
31. Contextual keys: keys used to activate functions included in contextual menus.

32. Cursors: Up, down, left and right cursors to be used to scroll text lists (for example in protocol measurement list), to move cursor in a text field, to adjust position and size of CFM box or to adjust position of PW gate.

33. When the Chinese version is selected on the Setting page, the key • activates and deactivates the Chinese input ; the key ▲ activates and deactivates the larger space for numbers and other symbols.

5.3 Screen icons

An icon in the upper right part of the screen indicates the battery capacity. When the device is connected to the main power supply, the gauge is getting filled up. When battery goes down to 20% and 10% low battery warning appears.



When the battery is lower than 20%,a warning appears on the screen and you have to validate it.

The icon in the lower right part of the screen indicates the state of the memory, on either the internal memory (marked Exago) or on a connected USB stick (marked USB). If the indicator is red, the memory is full.

During storage of images or clips, the following icons are displayed on the screen according to the storage media:

 The arrow downwards indicates a storage on the internal Exago memory.

 The arrow upwards indicates storage on a USB stick.

 The arrow towards the right indicates a storage on the Dicom server.

6. Connection of peripherals

The Exago equipment can be connected to several peripherals like:

- composite video printers
- USB peripherals (flash stick)
- External screen (DVI connection)

To ensure the electrical safety of the equipment:

 WARNING: All peripherals requiring a power input (printers, monitors etc.) must also use a medical isolation transformer or comply themselves with the electrical safety standard EN 60601-1. Otherwise, the patient electrical safety is no longer ensured.

 WARNING: To ensure the electrical safety of the device, never touch any parts of an electrical non-medical device situated in the patient's environment at the same time as the patient.

To ensure the electromagnetic compatibility of the equipment:

 WARNING: This equipment is intended to be used only by health professionals. This equipment can cause electromagnetic perturbations and alter the behavior of another equipment. It may be needed to move the equipment or change his orientation in order to reduce this perturbation.

7. 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.

7.1 Cleaning and disinfection of the device

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:

- Cidex
- Cidex plus
- Cidex OPA

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.

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

1. After every patient examination, or as often as necessary, wipe the keyboard and the external surfaces and casings of the device off to remove any traces of coupling gel.
2. Switch off and disconnect the device together with all connected peripherals.
3. Wipe the keyboard and the external surfaces and casings of the device with a clean soft cloth damped in a solution of mild soap and water.
4. Follow carefully instructions for low level disinfection indicated by the disinfectant manufacturer.
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: Before proceeding to any cleaning of the equipment, check that the system is switched off and all electrical connections and peripherals are unplugged.

 WARNING: Do not use alcohol, or other strong chemicals agents that may damage the casings of the equipment. Do not poor or spray liquids directly on the equipment.

7.2 Cleaning and disinfection of probes

7.2.1 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 Exago device 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:

- Alkazyme
- Klenzyme
- Cidezyme
- Nu-Cidex
- Anioxyde
- Gigasept-FF
- Steranios
- Cidex OPA

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.

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

1. After every patient examination, wipe the ultrasound transmission gel off the probe.
2. Unplug the probe connector from the system.
3. Wipe the probe and cable with a clean soft cloth that has been damped in a solution of mild soap and water.
4. Follow carefully 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.

7.2.2 Endo-cavity probes(LR 760 P & E610A)

Endo-cavity probes have a medium infection risk. This risk level corresponds to the use of so-called semi-critical devices, which means devices which are in contact with mucus membranes or superficially injured skin.
The needed treatment for this type of device is a medium-level disinfection.
Low level disinfection procedure:

 WARNING: The endo-cavity probes supplied with the Exago could be used with a sterile cover over the probe casing which will be in contact with the mucus membranes.

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

- Alkazyme
- Klenzyme
- Cidezyme
- Nu-Cidex
- Anioxyde
- Gigasept-FF
- Steranios
- Cidex OPA

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.

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:** The specified disinfectants have been tested for compatibility with the probe components, but not for their efficiency in producing the required level of disinfection. For information about the efficiency of each solution, please consult the respective disinfectant manufacturer.

 **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**: 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:

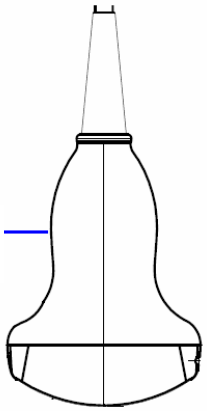
- Gas sterilization.
- Ultraviolet sterilization
- Dry heat sterilization
- Autoclaving
- Soaking a transducer in a chlorine bleach solution.

7.3 Submerging limits

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

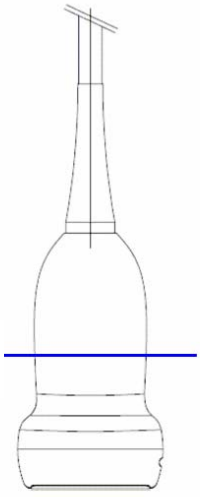
Probe C360A :

Submerging limit in a fluid



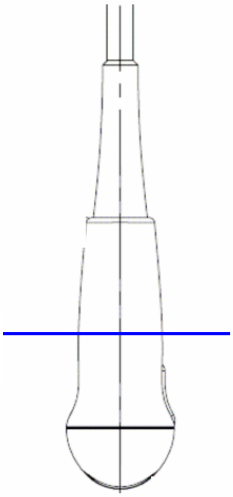
Probe L738P:

Submerging limit in a fluid



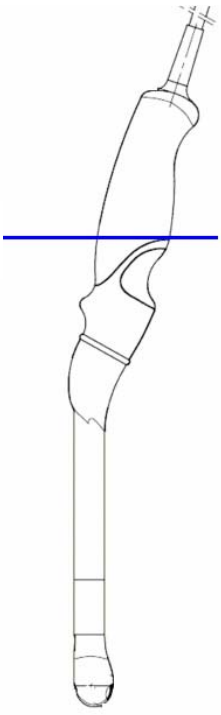
Probe C320A / C614P:

Submerging limit in a fluid



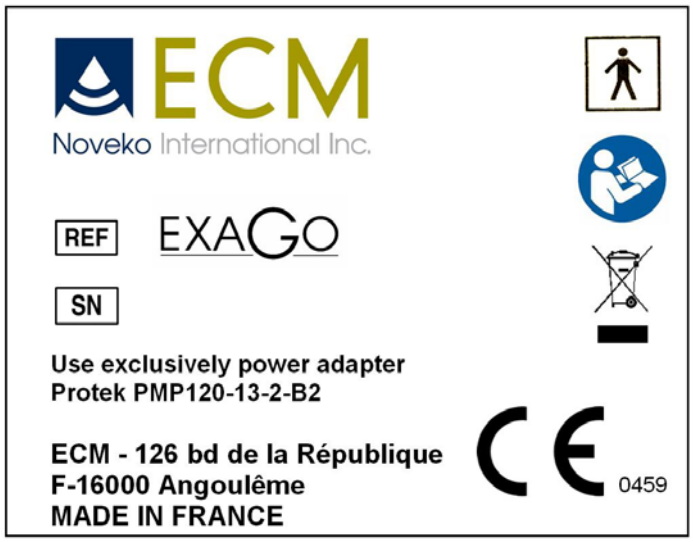
Probe E610A:

Submerging limit in a fluid



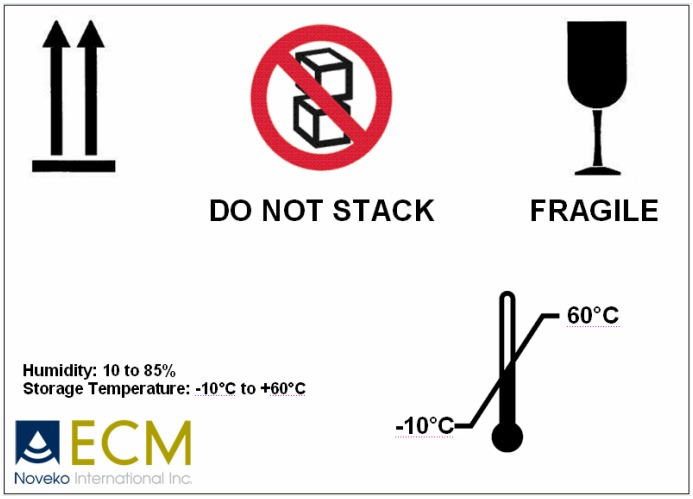
8. Labeling of the device

Reference label for Exago with indication of serial number:



Battery label:

Protection packaging label with temperature and humidity precautions for transport and stocking:



9. Annex I : Measure accuracy

Measurement	**Range**	***Accuracy***
Distance and ellipse perimeter	Up to 30 cm	< ± 5% ou < 1mm, below 2 cm See note 2
Trace perimeter	Up to 100 cm	< ± 5% ou < 1mm, below 2 cm
Surface	Up to 1000 cm^2	< ± 10% ou < 40 mm^2, below 4 cm^2
Volume	Up to 3000 cm^3	< ± 16% ou < 1.3 cm^3, below 8 cm^3
Time	Up to 30 sec	< ± 5% of full scale
Speed	Up to 10 m/s	N/A : see note 1
Cardiac beat frequency	0 <= value < 600 BPM	< ± 5%

Note 1: The PW (Pulsed Wave Doppler) speed information provided by the equipment is only indicative. The equipment is performing an accurate measurement of the Doppler frequency shift, but speed indication is obtained by a computation based on the angle correction information which is manually entered by the user. As an indication only, the speed information would be accurate at ± 5% of the full scale speed in the hypothetical case where there would be absolutely no uncertainty on the angle correction estimation.

10. Annex II: Electromagnetical compatibility

TABLE 1

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Exago equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Exago equipment should assure that it used in such an environment.</td></tr>
<tr><th>Emission tests</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The Exago 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.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Exago 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 radioelectric 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 Exago equipment or shielding the location.</td></tr>
<tr><td>Harmonic emissions
CEI 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
Flicker emissions
CEI 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">NOTE 1: The use of cables or accessories different from those specified by ECM may have as a consequence an increase of emission or a decrease of immunity of the Exago equipment.</td></tr>
</table>

TABLE 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Exago equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Exago equipment should assure that it used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environnement - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 kV common 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 % *U*T (>95 % dip de *U*T) for 0,5 cycle 40 % *U*T (60 % dip de *U*T) for 5 cycles 70 % *U*T (30 % dip de *U*T) for 25 cycles <5 % *U*T (>95 % dip de *U*T) for 5 s	<5 % *U*T (>95 % dip de *U*T) for 0,5 cycle 40 % *U*T (60 % dip de *U*T) for 5 cycles 70 % *U*T (30 % dip de *U*T) for 25 cycles <5 % *U*T (>95 % dip de *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Exago equipment requires continued operation during power mains interruptions, it is recommended for the Exago 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: *U*T 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 ECM may have as a consequence an increase of emission or a decrease of immunity of the Exago 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 C360 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.			

TABLE 4

Guidance and manufacturer's declaration –electromagnetic immunity			
The Exago equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Exago equipment should assure that it used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environnement - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Exago 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 survey[a], 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 : 

NOTE 1: À t 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 ECM may have as a consequence an increase of emission or a decrease of immunity of the Exago 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 Exago equipment is used exceeds the applicable RF compliance level above, the Exago 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 Exago equipment.

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

TABLE 6

Recommended separation distances between portable and mobile RF communications equipment and the Exago equipment

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

Rated maximum output power 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 ECM may have as a consequence an increase of emission or a decrease of immunity of the Exago equipment.

11. Annex III: Acoustic power

Probe model: C360A **Mode B (mode 2D)**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		0,93	0,21				(a)
Associated acoustic parameters	pra MPa	1,75					
	P mW		12,46				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	8					
	deq(zb) cm						
	fawf MHz	3,54	3,54				(a)
	Dim Aaprt X		21				(a)
	Y		11				(a)
Other information	td µs	0,38					
	prr Hz	32					
	pr at max Ipi	4,78					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	106					

Probe model: C360A **Mode CFM**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,29	0,33				(a)
Associated acoustic parameters	pra MPa	2,43					
	P mW		20,32				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	8					
	deq(zb) cm						
	fawf MHz	3,54	3,41-3,54				(a)
	Dim Aaprt X		21				(a)
	Y		11				(a)
Other information	td µs	0,38					
	prr Hz	8					
	pr at max Ipi	5,73					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	154					

Probe model: C360A **Mode PW**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,27			5,34	5,92	(a)
Associated acoustic parameters	pra MPa	2,24					
	P mW					590,98	(a)
	Min[Pa(zs),Ita,a(zs)]				360,58		
	zs cm				2,6		
	zbp cm				2,6		
	zb cm				6,5	6,5	
	z at max Ipi, a cm	8					
	deq(zb) cm						
	fawf MHz	3,11			3,11	3,11	(a)
	Dim Aaprt X				21	21	(a)
	Y				11	11	(a)
Other information	td µs	1,77					
	prr Hz	5120					
	pr at max Ipi	1,89					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	20					

Probe model: C360A **Mode M**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		0,93			1,41	1,62	(a)
Associated acoustic parameters	pra MPa	1,64					
	P mW					161,86	(a)
	Min[Pa(zs),Ita,a(zs)]				95,21		
	zs cm				2,6		
	zbp cm				2,6		
	zb cm				6,5	6,5	
	z at max Ipi, a cm	8					
	deq(zb) cm						
	fawf MHz	3,11			3,11	3,11	(a)
	Dim Aaprt X				21	21	(a)
	Y				11	11	(a)
Other information	td µs	1,77					
	prr Hz	5120					
	pr at max Ipi	1,89					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	20					

Probe model: L738P **Mode B (mode 2D)**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,3	0,36				(a)
Associated acoustic parameters	pra MPa	3,67					
	P mW		9,50				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	7,96	7,96				(a)
	Dim Aaprt X		0,9				(a)
	Y		4,3				(a)
Other information	td µs	0,16					
	prr Hz	64					
	pr at max Ipi	6,83					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	371					

Probe model: L738P **Mode CFM**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		5,67	0,18				(a)
Associated acoustic parameters	pra MPa	16,00					
	P mW		4,74				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	7,96	7,97-8,06				(a)
	Dim Aaprt X		0,9				(a)
	Y		4,3				(a)
Other information	td µs	0,16					
	prr Hz	11					
	pr at max Ipi	6,8					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	371					

Probe model: L738P **Mode PW**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		2,62		1,65		2,56	(a)
Associated acoustic parameters	pra MPa	6,50					
	P mW			56,25		56,25	(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm					1	
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,16		6,16		6,16	(a)
	Dim Aaprt X			0,9		0,9	(a)
	Y			4,3		4,3	(a)
Other information	td µs	1,84					
	prr Hz	5120					
	pr at max Ipi	3,44					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	110					

Probe model: L738P **Mode M**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,3		0,97		1,50	(a)
Associated acoustic parameters	pra MPa	3,23					
	P mW			33,07		33,07	(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm					1	
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,16		6,16		6,16	(a)
	Dim Aaprt X			0,9		0,9	(a)
	Y			4,3		4,3	(a)
Other information	td µs	1,84					
	prr Hz	5120					
	pr at max Ipi	3,44					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	110					

Probe model: E610A **Mode B (mode 2D)**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		0,79	0,29				(a)
Associated acoustic parameters	pra MPa	1,98					
	P mW		9,68				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z au max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,29	6,29				(a)
	Dim Aaprt X		0,92				(a)
	Y		0,58				(a)
Other information	td µs	0,27					
	prr Hz	64					
	pr at max Ipi	4,2					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	228					

Probe model: E610A **Mode CFM**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,25	0,18				(a)
Associated acoustic parameters	pra MPa	3,13					
	P mW		6,14				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,29	6,16- 6,29				(a)
	Dim Aaprt X		0,92				(a)
	Y		0,58				(a)
Other information	td µs	0,27					
	prr Hz	18,9					
	pr at max Ipi	4,2					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	230					

Probe model: E610A **Mode PW**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,17		1,38		2,14	(a)
Associated acoustic parameters	pra MPa	2,90					
	P mW			47,05		47,05	(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm					2,5	
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,16		6,16		6,16	(a)
	Dim Aaprt X			0,92		0,92	(a)
	Y			0,58		0,58	(a)
Other information	td µs	1,84					
	prr Hz	5120					
	pr at max Ipi	2,18					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	40					

Probe model: E610A **Mode M**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		0,79		0,77		1,19	(a)
Associated acoustic parameters	pra MPa	1,96					
	P mW			26,25		26,25	(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm					2,5	
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,16		6,16		6,16	(a)
	Dim Aaprt X			0,92		0,92	(a)
	Y			0,58		0,58	(a)
Other information	td µs	1,84					
	prr Hz	5120					
	pr at max Ipi	2,18					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	40					

Probe model: C614P **Mode B (mode 2D)**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,12	0,19				(a)
Associated acoustic parameters	pra MPa	2,77					
	P mW		6,51				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,12	6,13				(a)
	Dim Aaprt X		1,06				(a)
	Y		0,55				(a)
Other information	td µs	0,2					
	prr Hz	64					
	pr at max Ipi	2,42					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	56					

Probe model: C614P **Mode CFM**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,47	0,3				(a)
Associated acoustic parameters	pra MPa	3,64					
	P mW		10,33				(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm						
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,13	6,10-6,13				(a)
	Dim Aaprt X		1,06				(a)
	Y		0,55				(a)
Other information	td µs	0,2					
	prr Hz	12,4					
	pr at max Ipi	2,42					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	56					

Probe model: C614P **Mode PW**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,16		0,73		1,13	(a)
Associated acoustic parameters	pra MPa	2,88					
	P mW			24,89		24,89	(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm					3	
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,16		6,16		6,16	(a)
	Dim Aaprt X			1,06		1,06	(a)
	Y			0,55		0,55	(a)
Other information	td µs	1,85					
	prr Hz	5120					
	pr at max Ipi	1,49					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	17					

Probe model: C614P **Mode M**

Index label		MI	TIS			TIB	TIC
			Scan	Non scan		Non scan	
				Aaprt ≤ 1 cm²	Aaprt> 1 cm²		
Maximum Index Value		1,12		0,52		0,81	(a)
Associated acoustic parameters	pra MPa	2,78					
	P mW			17,73		17,73	(a)
	Min[Pa(zs),Ita,a(zs)]						
	zs cm						
	zbp cm						
	zb cm					3	
	z at max Ipi, a cm	3					
	deq(zb) cm						
	fawf MHz	6,16		6,16		6,16	(a)
	Dim Aaprt X			1,06		1,06	(a)
	Y			0,55		0,55	(a)
Other information	td µs	1,85					
	prr Hz	5120					
	pr at max Ipi	1,49					
	deq at max Ipi cm						
	Ipa, a at max MI (W/cm²)	17					

12. 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 ECM 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.