DRAMIŃSKI
TECHNOLOGY

# ULTRASOUND SCANNER
# FAST


## User manual

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Manufactured by:

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Dramiński S.A. has established and maintains a full quality management system compliant with the requirements of **EN ISO 13485:2012/AC:2012**. The system is periodically reviewed along with the technical documentation by the notified body No. **0197** – **TUV Rheinland LGA Products GmbH**, Tillystrasse 2, 90431 Nuremberg, Germany participating in the conformity assessment.

**Declaration of conformity**

Available in our Sales Department

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**We wish you and the users of our product every success in caring for your patients and we are convinced you will be able to serve your patients well with our product.**

DRAMIŃSKI S.A. will be pleased to receive any comments and remarks from our

customers regarding t e device and t is manual.

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# I. INTRODUCTION

### Information on this user manual

This manual is intended to provide information to identify the technical properties of the scanner. It is written in an accessible way to make the information contained herein as useful as possible.
However, reading of this manual cannot replace even a basic course in ultrasonography. It is necessary for the user to undergo appropriate ultrasonography training through authorized courses.
The individual chapters of this manual describe the design, any accessories used in normal operation and the preparation of the scanner for operation as well as the features and operation of the portable ultrasound scanner.

### Warnings and notes used in this manual

To draw attention to the important content of this manual, the following symbols are used:

**Caution! - used to draw the reader's attention to ensure the safety of the patient or the user of the scanner.**

**Attention**! - used to draw the reader's attention to protect the scanner from damage or to ensure the proper operation of the scanner.
**Text in bold** - used to draw the reader's attention to important parts of this manual or to enhance clarity or legibility.
**Descriptions of drawings and illustrations** - to facilitate the recognition of the details.

**The symbols used in this manual do not include all the safety hints, therefore it is necessary to read carefully the hints and follow them!**

## General information on ultrasonography

Ultrasound devices have been widely used in medical diagnostics for a number of years. What is particularly popular and useful is the real time imaging which enables the two-dimensional visual presentation of tissue cross-sections.
The quality of the image produced by the equipment of this kind depends on the frequency of waves emitted by the head: the higher the frequency the better the image quality. However, the penetration depth decreases and the absorption and wave dispersion ratio increases in a nearly linear way as the frequency increases.
The diagnostic efficiency of ultrasonography is highly rated but it is significantly influenced by the quality of the instruments, the user's individual experience and knowledge as well as compliance with the ultrasound testing standards and observation of the instructions of this manual.

## Preliminary information on the portable FAST ultrasound scanner

FAST ultrasound scanner is a modern, specially designed and compact device, which, together with an external battery pack and the PC plug-in feature for image transfer purposes, is a practical medical device for ultrasound diagnostics. A special feature of the device is its low weight and very robust aluminium casing, which protects the technologically advanced electronics to guarantee very high image quality.
DRAMIŃSKI FAST is a unique ultrasound scanner. Compact design and the battery power supply feature make a flat LCD LED monitor-equipped device a new tool for any doctor, particularly where conditions require high mobility (e.g. point-of-care testing, disaster medicine examinations, medical rescue teams - on-site examinations).
DRAMIŃSKI FAST is a portable device intended for diagnostic use on people to carry out ultrasound examinations:
- in intensive care and critical conditions including focused abdominal examination in trauma (FAST - focused assessment with sonography in trauma) and ultrasound lung examination;
- for diagnosing the physiological and pathological conditions and monitoring the course of disease using the ultrasound technology for basic examination purposes;
- of abdominal organs and lesser pelvis;
- urological examinations;
- gynaecological examinations.

# II. EQUIPMENT

**List of components and standard equipment of DRAMINSKI FAST ultrasound scanner**

| | *Description* | *Quantity* |
|---|---|---|
| 1 | Scanner incl. LCD LED screen and membrane keyboard | 1 |
| 2 | Mechanical probe (type as agreed with the supplier) | 1 |
| | Additional probe – to be agreed with the supplier | -- |
| 3 | Li-Ion battery pack 14.4 V / 3.1 Ah | 2 |
| 4 | Battery charger 230 V with power cord | 1 |
| 5 | Adapter for the external memory terminal to transfer images to the external memory | 1 |
| 6 | Explorer type carrying case including foam lining | 1 |
| 7 | Stand (table support) | 1 |
| 8 | User's manual and warranty card | 1 |

# III. DESIGN OF DRAMIŃSKI FAST ULTRASOUND SCANNER

**The scanner is composed of the following main parts:**

1. Casing with membrane keyboard and LCD LED display.
2. Ultrasound probe to be connected to the multi-pin connector.
3. Battery pack for multiple charging - external battery pack.
4. 110-240 V/ 50-60 Hz mains-powered battery pack charger.

### 1. Casing of the ultrasound scanner

The casing is made of high quality aluminium and features high level of protection from dust and water (IP65). The rear wall incorporates a mounting system for the battery pack.

The following connectors are located in the side walls of the casing:

**External memory terminal** (round 6-pin connector) and a 12–pin **probe connector**. The connectors are secured with special protection plugs if not in use.

Description and location of the casing parts are presented on the following pages of this manual.

**Attention!**

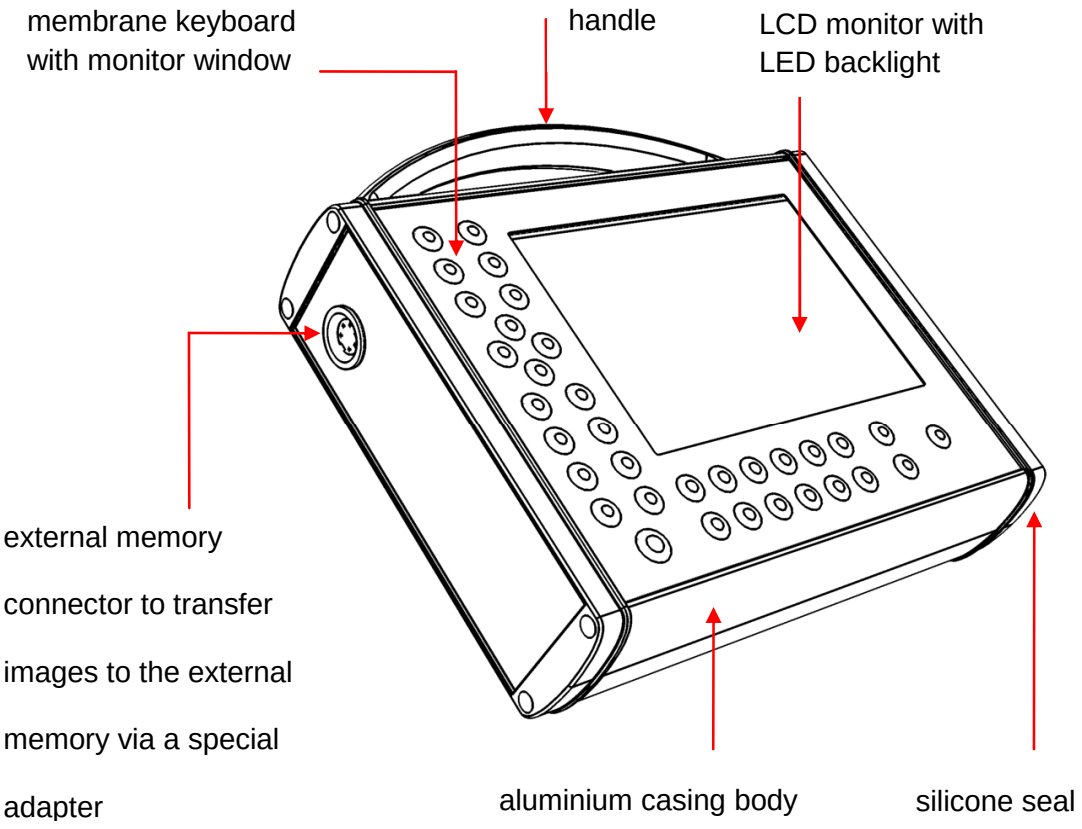
**The ultrasound scanner is of robust design. Nevertheless, be careful during the use and handling so as to avoid any strong impacts, which might lead to damage. Protect the probe connectors from dust or moisture.**

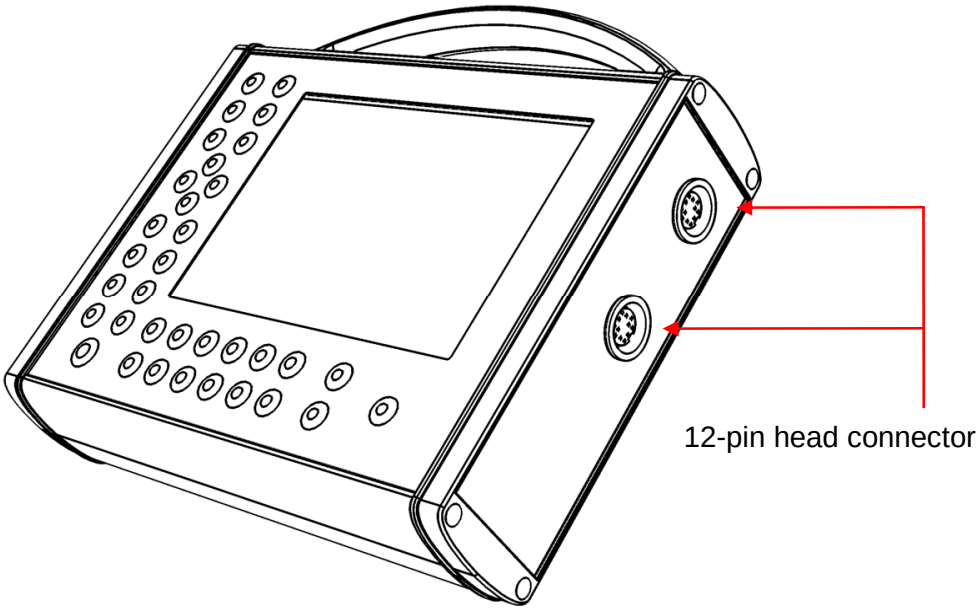
The 7" high quality LCD monitor with LED backlight offers very wide viewing angles, excellent contrast and brightness and resolution, which guarantee very good imaging of the ultrasound image. The brightness of the monitor can be adjusted by the user using a corresponding menu item.

The membrane keyboard functions and location as well as the description of the keys are presented in the illustrations included in this manual.

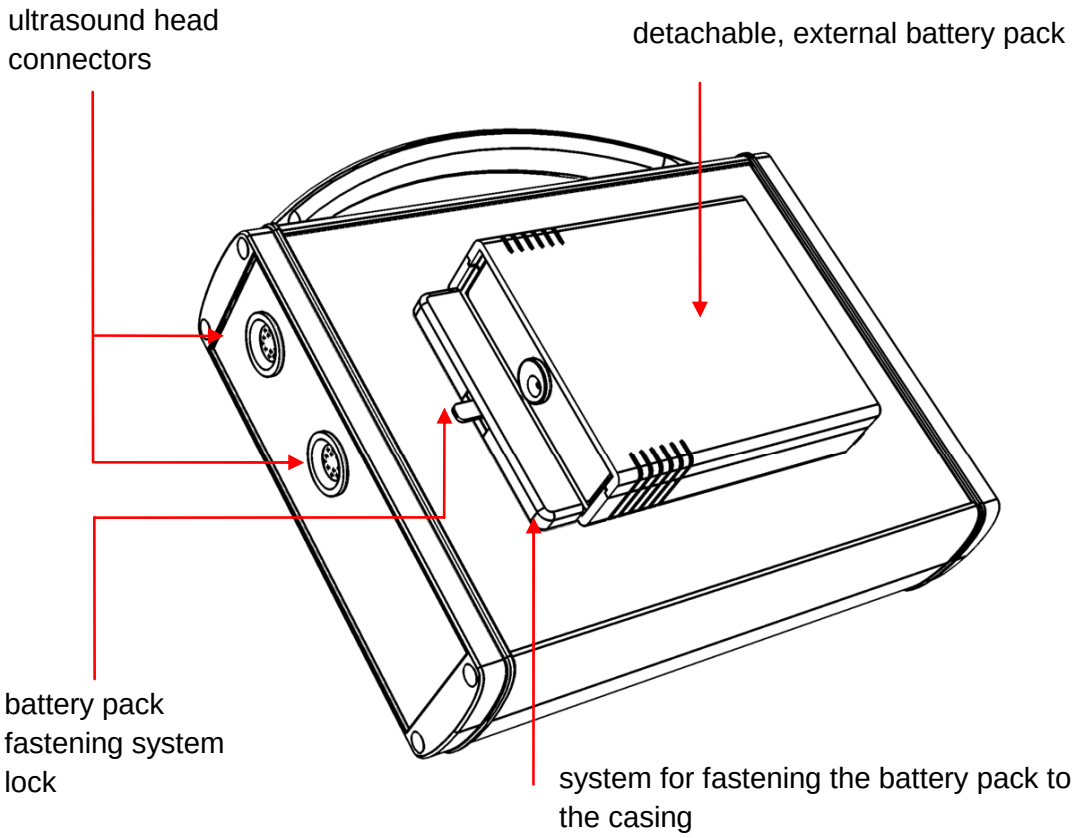
**The ultrasound scanner is a technologically advanced device. The compact design and the independent power supply of the scanner assure full mobility and freedom of use even under adverse conditions.**

**General view and description of casing components**



**Rear casing wall with the battery pack connected**

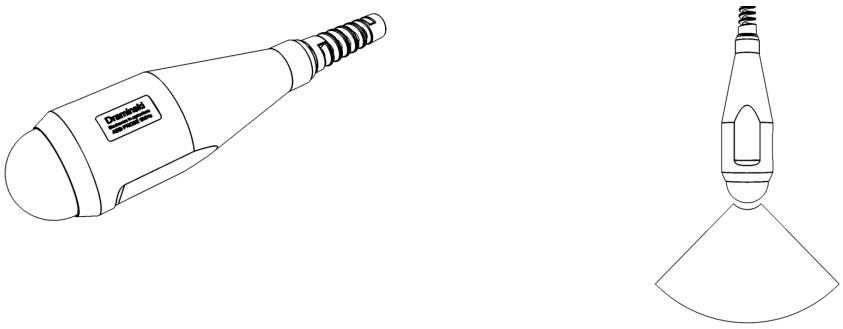


## 2. Ultrasound probe

**The probe** (head) is an important part of the scanner.

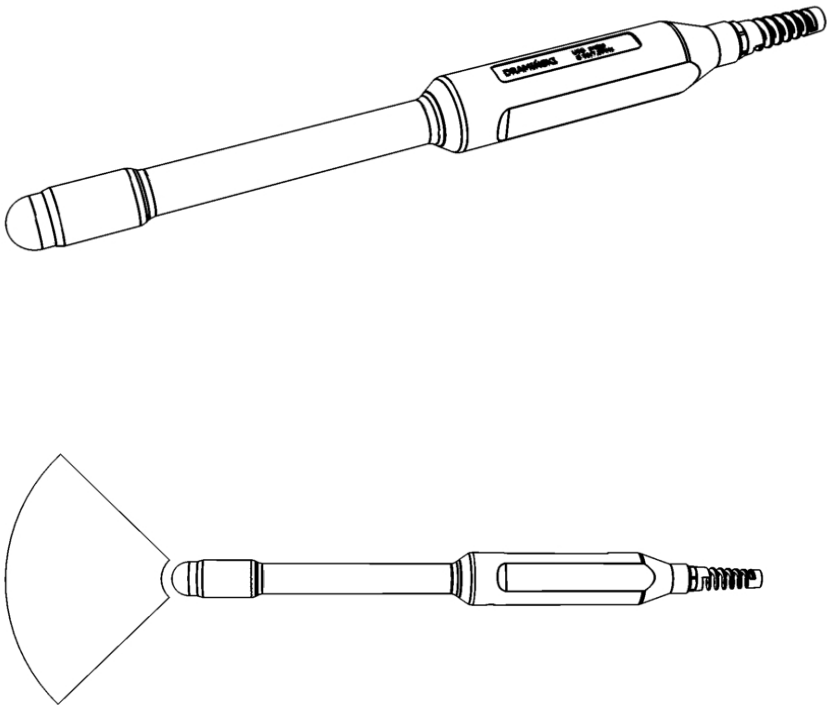
**DRAMIŃSKI FAST** ultrasound scanner is equipped with two ports and can operate with two types of mechanical sector probes at the same time:

1. **DA-90 abdominal sector probe 5.0 MHz** (3-7 MHz), scanning angle: 90°

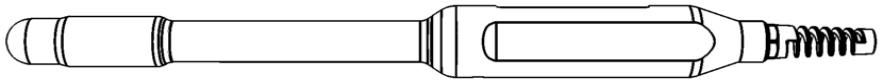


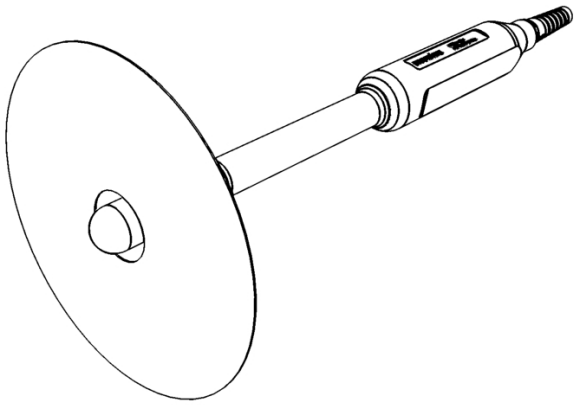
2. **DG-90 endovaginal sector probe 7.5 MHz** (4-9 MHz), scanning angle: 90°

**Attention! Disposable probe covers must be used during examination.**



**3. DR-360 endorectal sector probe 7.5 MHz** (4-9 MHz), scanning angle: 180°
**Attention! Disposable probe covers must be used during examination.**





**As the probe mechanism is technically advanced, appropriate care must be taken during operation and the probe needs to be protected from falling from significant height or from strong impact. Protect the probe dome covering the piezoceramic element immersed in a special oil from damage and scratching.**

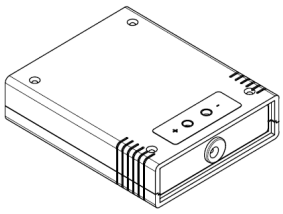
**The protection grade of the probes is IPX1, while the grade of each of the head face is IPX7, which allows the part to be fully immersed in water or disinfectants.**

## Batteries

The specially configured Li-Ion batteries form a pack including a thermal fuse to protect them from overheating during charging.

The pack housing incorporates a socket for connecting the charger cable and dedicated openings for connection to the ultrasound scanner. During operation, the pack is attached to the scanner bottom using a special clip system with a lock.

Li-Ion battery pack



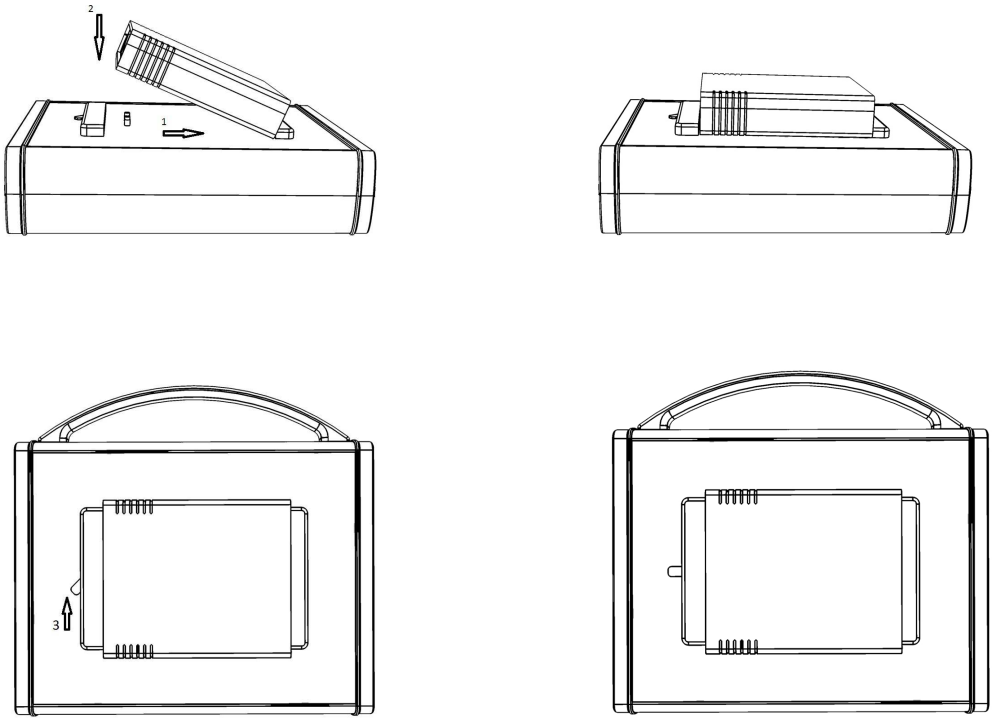



*Fig. Battery attachment diagram*

The estimated life of the batteries is 500 charging cycles. The use of modern high capacity batteries (3.1 Ah) allows an operating time of more than 4 hours.

**Precautions for handling the Li-Ion battery packs are described later in this manual - see the BATTERY CHARGING section.**

## 4. Charger

An especially adapted 110-240 V / 50-60 Hz mains-powered charger is used to charge the batteries. The charger is equipped with cables and a colour LED to indicate the stage of the charging process.

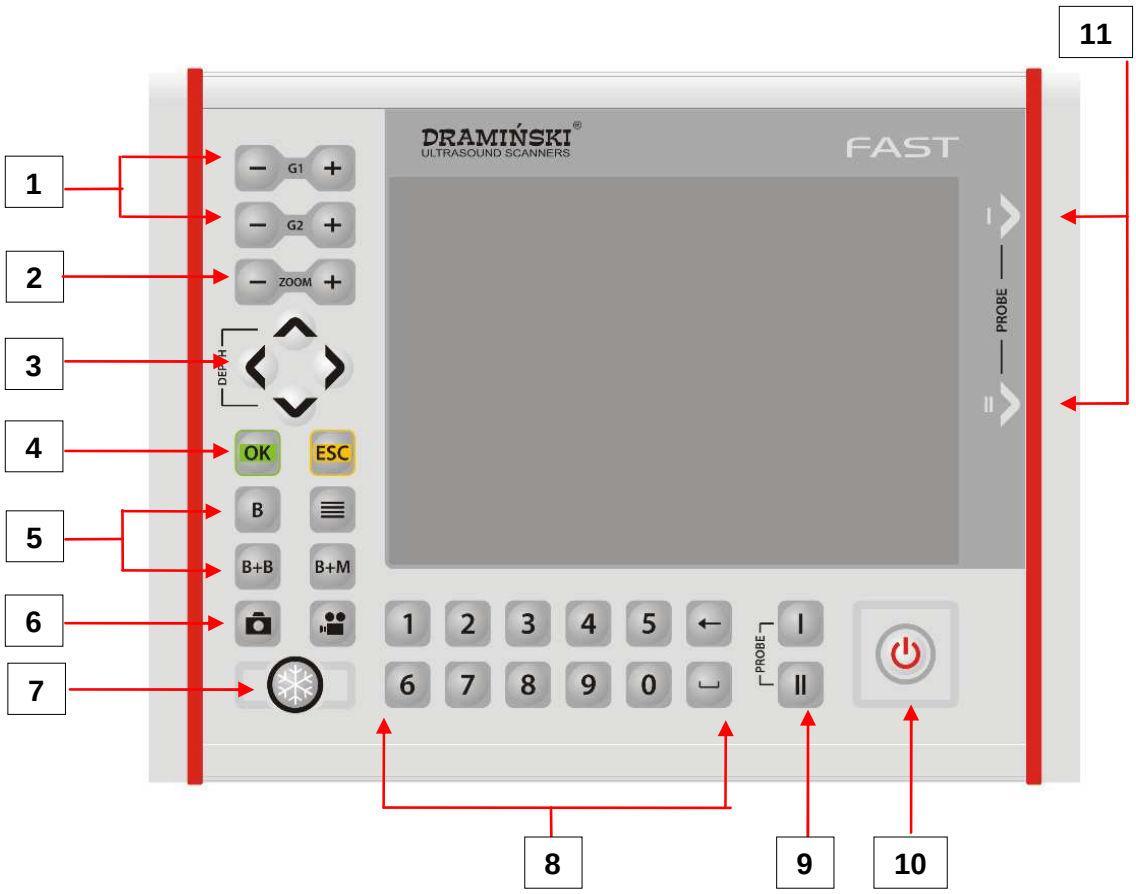
**Attention: Use only the original charger supplied with the ultrasound scanner to charge the battery pack.**

More details on the battery pack charging and the use of the charger - see the **BATTERY CHARGING** section.

Li-Ion battery pack charger

## Membrane keyboard and keyboard layout

The keys of the keyboard are arranged so as to facilitate the use of the ultrasound scanner during operation. Most of the keys are assigned specific functions to make access to various options and setting the picture parameters easier and faster. The functions of the individual keys are described later in this manual




**1** G1 – setting the signal gain in the nearer field
G2 – setting the signal gain in the further field

**2** ZOOM setting

**3** Navigation keys to perform the following operations:

- ▲▼ scan depth setting DEPTH (with menu closed)
- ◄► head frequency setting in MHz (with menu closed)
- ◄►/▲▼ navigation in the menu and setting the parameter values
- ▲▼ „Cine loop” function - automatic scrolling of the frames forward and backward
- ◄► „Cine loop” function - manual scrolling of the frames one by one
- ◄►/▲▼ set the markers for dimensioning
- ◄►/▲▼ selection of characters when describing the pictures or cine loop before saving in memory
- ◄► highlight selected pictures and cine for sending to external memory

**4** OK 1. open the main menu and accept the selected option or settings
2. confirm the marker position for dimensioning
ESC exit the menu and cancelling the change in parameter settings

**5** B Mode, B+B Mode B+M Mode. Keys to select the imaging mode

 Key to open an additional menu to manage pictures and cine loops (save to the scanner memory or load the pictures or cine loops and send them to external memory i.e. memory stick or delete them from the memory).

**6** Quick save of a / Cine loop in the memory (without opening the additional menu)

7 Freeze the picture and start imaging

**8** Numerical keys to describe images

**9** Keys to select the port activity (head connector)

**10** Power ON/OFF key

**11** Designation of locations of the individual head ports

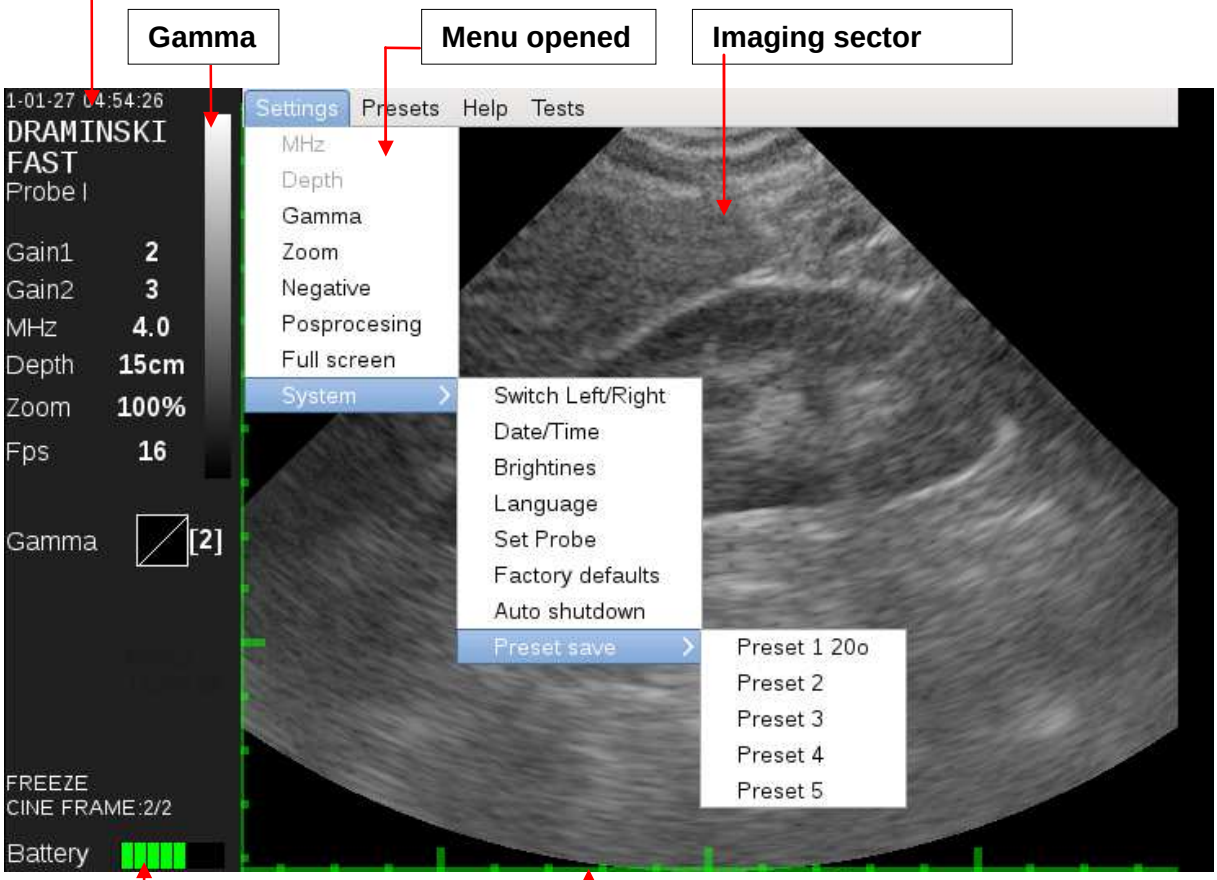
**Attention!** When selecting some of the menu options, information is displayed on the keys that can be used in that specific situation**.**

## Screen layout

**Messages and information presented on the screen during the operation of the scanner**

An example of the **FAST** ultrasound scanner screen view with the picture frozen and description of messages and the information displayed:

**Information bar** presenting the current settings: date and time, type of probe connected, G1 and G1 gain level, preset probe frequency, scanning range, zoom, refreshing (Fps), gamma level, picture freezing, battery status, results of measurements.



# IV. PREPARATION FOR USE

**Connection of probe by the user**

**Attention!** Protect the probe connectors from mechanical damage, dirt and moisture.
Protect the probe cable from excessive load, repeated over-bending and yanking.
Carefully connect the round probe connector to the housing socket and tighten it while holding the metal part to ensure full and proper contact between the probe connector and the housing socket.
**DRAMIŃSKI FAST** ultrasound scanner is equipped with two multi-pin sockets for probe connection.
**Attention! Replace the probe only with the scanner turned off**.
To replace the probe, unscrew and remove the connector, connect a new probe and re-tighten the connector.
Once connected, the head will be automatically recognized by the system and the imaging sector will change according to the type of the head connected, provided that the number of the port where the probe is connected is selected using the keyboard.
If two probes are connected to the probe sockets at the same time, the selection of the probe to be used for the image evaluation is made by pushing the corresponding key on the keyboard.


probe connected to port No. 1

probe connected to port No. 2

**If no head is connected to the port when the port has been selected by the user using the keyboard the following message will be displayed on the No head No. 1 (2) connected**

# V. MENU STRUCTURE

### Menu navigation rules

The menu of the **FAST** ultrasound scanner is composed of two blocks, i.e.:

**Main menu** opened with the button  and

**Additional menu** opened with the key  ; each menu contains several items with drop-down option lists.

The navigation buttons are used to navigate in the menu options:

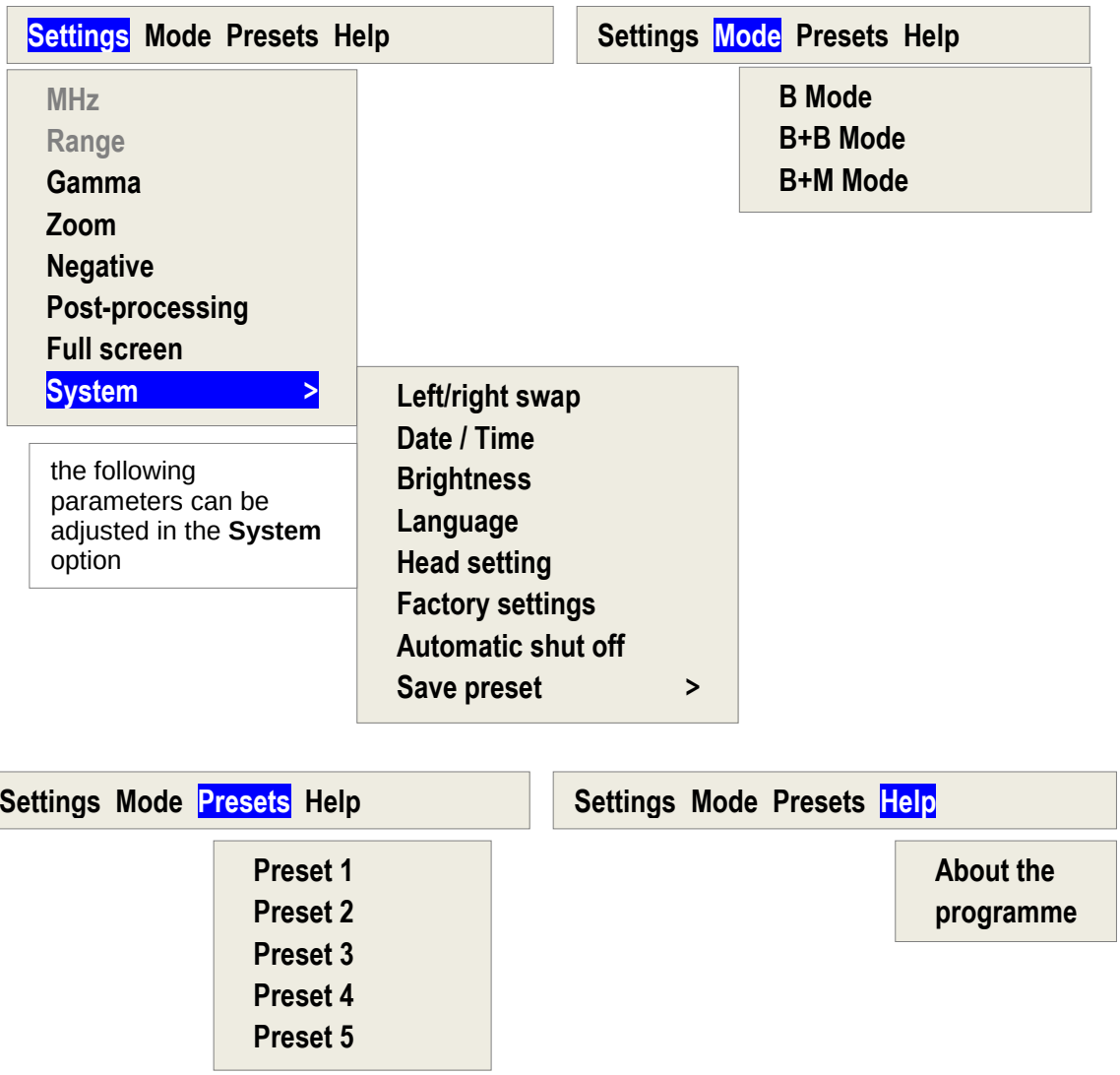
The selected item or option is highlighted in blue.

To confirm the selected menu option, press  .

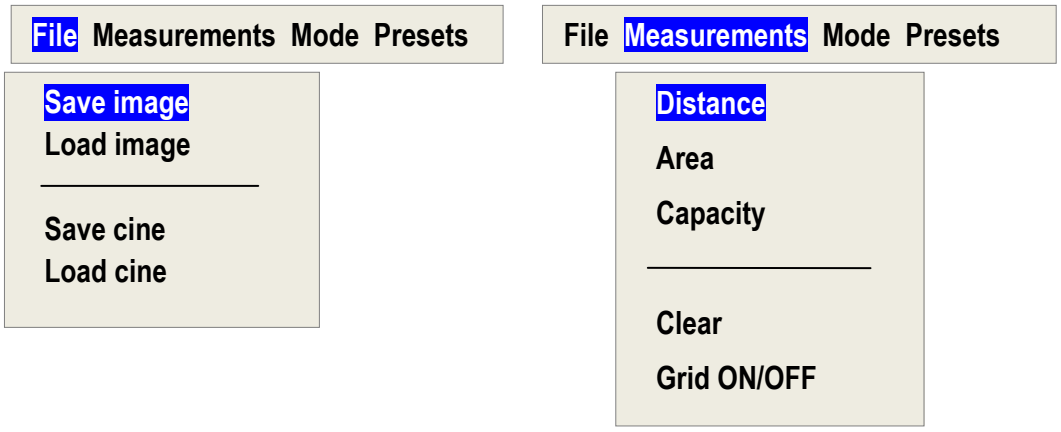
To exit the selected menu option, press  .

**When selecting some of the options, additional messages (hints) are displayed indicating which buttons can be used to set or change the selected parameter.**

**Main menu** includes several items with drop-down lists to enable the user to set or change the following parameters:

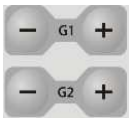
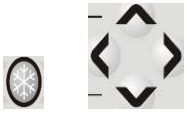


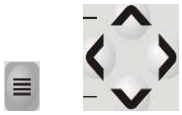

**Additional menu** allows the management of images and image sequences (cine loop) i.e. saving, loading, transferring via the external memory connector, and deleting. Additionally, the menu allows dimensioning (with the available presetting and imaging mode selection options).



# VI. MOST FREQUENTLY USED FUNCTIONS

The table below includes the basic functions and those most frequently used during the operation of the ultrasound scanner and the keys to use the functions:

| | | |
|---|---|---|
| Scanner ON/OFF |  | The ultrasound scanner is turned off by pressing the ON/OFF button. If pressed and held for longer than 2 seconds, the scanner will turn off. |
| Picture freezing |  | Picture freezing/unfreezing during examination is performed by pressing either of the buttons. The picture is frozen and a "FREEZE" message is displayed in the information bar. |
| Gain adjustment |    | Signal gain adjustment.<br>G 1 button = **gain in the nearer field**. When pressing G1, the level is adjusted with the navigation buttons.<br>G 2 button = **gain in the further field**. When pressing G2, the level is adjusted with the navigation buttons. The value of the preset G1 and G2 levels is presented in the information bar. |
| Zoom |   | **Zoom**. Magnification (or reduction) function (in percent) from the standard 100% in increments within the range of– 60% to +200%. |
| Range - change of penetration depth |   | The penetration range is set using the navigation buttons ▲▼. The depth is adapted according to the needs depending on the examination and the probe type. The value of the range set is presented in the information bar. |
| MHz - filtering the transducer signal |  | The MHz level (**quick access**) is adjusted using the navigation buttons ◀ ▶, with the Menu off. The heads are equipped with broadband transducers and the function allows the transducer signal filtration in the range between 3.0 MHz and 9.0 MHz. The option is also available at **MENU / MHz (frequency)**. The value of the parameter set is presented in the information bar. |
| GAMMA |   | **MENU / GAMMA**. The function allows the adjustment of the grey scale level within a broad range to optimize the picture during the examination. |
| Cine loop |  | The function allows the playback of up to 256 last frames from the picture freezing. By using the navigation buttons ◀ ▶ you can manually scroll the sequences of the examination frame by frame or automatically playback the cine loop forward or backward using the arrow buttons (▲▼). |

| | | |
|---|---|---|
| Measurements |  | **ADDITIONAL MENU /MEASUREMENTS**/ Once the picture is frozen, the objects can be dimensioned using the navigation buttons by placing the marks and confirming their positions with OK button. This menu additionally includes the grid ON/OFF feature. |
| Operating modes<br>B Mode<br>B+B Mode<br>B+M Mode |  | **B MODE**<br>**B+B MODE**. Division of the monitor into two sections (B+B Mode) to enable comparison of the frozen picture with the one being scanned.<br>**B+M MODE** |
| Saving the pictures and cine |  | **ADDITIONAL MENU / Save picture / Save cine**<br>The function allows saving a picture or a loop of up to 256 frames in the scanner memory (with the possibility to add a description before saving). |
| Loading pictures and cine to the screen and picture management |  | **ADDITIONAL MENU / Load picture / Load cine**<br>The function allows loading pictures or cine loops stored in the memory to the screen from a list with preview thumbnails.<br>The pictures or cine loops loaded can be transferred to an external memory drive or deleted after highlighting. |

## Picture freezing

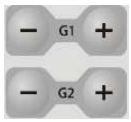
This is a basic feature used during examination.

To freeze or unfreeze the picture, press either of the two buttons:  .

A "FREEZE" message will appear in the bottom part of the information bar. If you press either of the buttons, it will immediately reactivate the imaging process.

Freezing enables further picture management (e.g.: saving, dimensioning).

## Gain adjustment




During the adjustment of the gain in the near (G1) and the far (G2) field (using dedicated buttons). The current Gain1 and Gain2 levels are presented in the information bar next to the imaging sector in the form of a value from 1 to 8. The signal gains are adjusted to optimize the diagnostic quality and clarity of the picture depending on the type of the examination being carried out and the examination conditions.

## Range - penetration depth adjustment


This feature is frequently used during examination. The penetration range can be set simply and quickly using the navigation buttons (up and down arrow).

The depth is adjusted to optimize the picture parameters depending on the examination and the probe type used. The value of the set range is shown in the information bar. Additionally, there is a ruler with a 1 cm scale displayed at the bottom of the screen and next to the imaging sector. The ruler scale is automatically changed as the scanning depth changes.

## MHz – head frequency setting

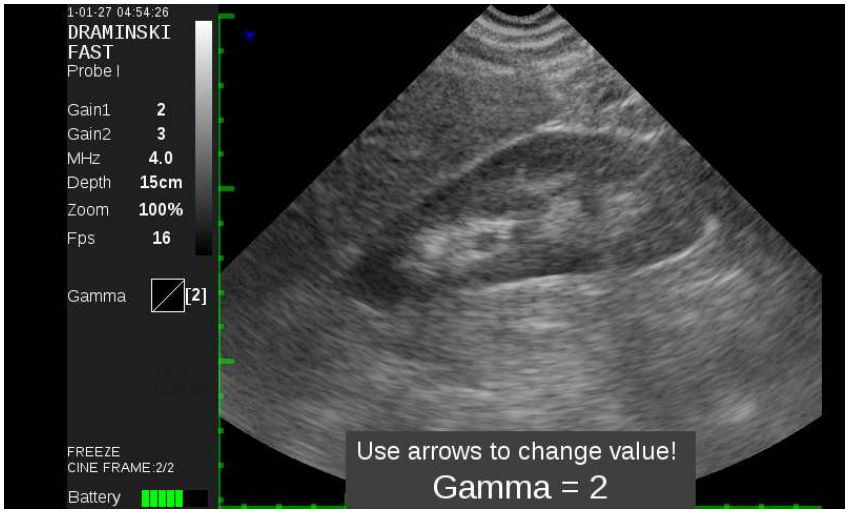
The FAST ultrasound scanner operates with broadband (multi-frequency) probes. The probe signal frequency can be changed simply and quickly using the navigation buttons.

The current MHz frequency is displayed in the information bar. It has to be noted that as the frequency goes up the signal strength and the ultrasound wave penetration depth go down.

## Gamma – grey scale correction

Gamma level is set to optimize the diagnostic quality of the image. This option allows changing the image contrast and brightness (gamma correction). A vertical greyscale bar is presented in the information bar. Additionally, a numerical value of the gamma level (1 to 8) and an additional graphic indicator are shown in the information bar. Gamma correction is possible in real time during scanning or after freezing and loading a saved image or a cine loop to the screen.

To change the gamma level, select the corresponding option from the main menu. Once the dialogue box appears, use the navigation buttons and confirm the setting by pressing "OK".

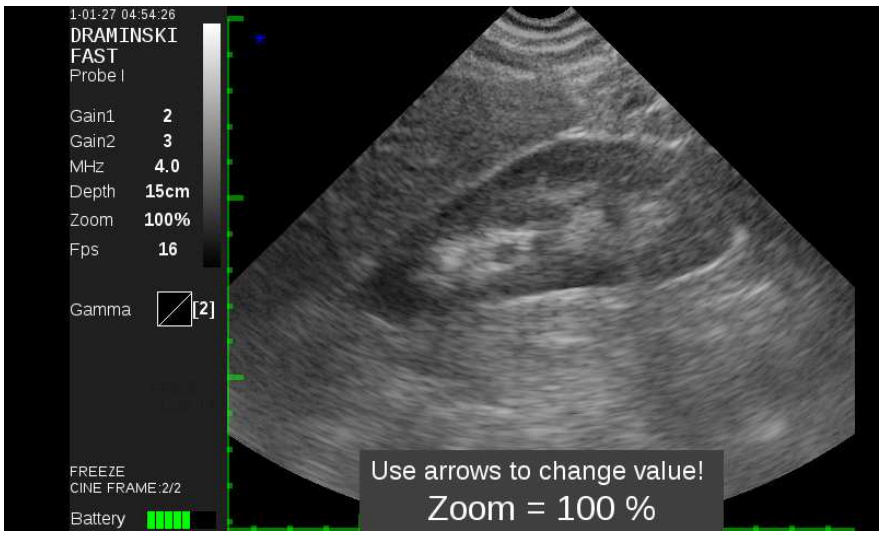



**Example of a screen with adjusted gamma level**

## Zoom (Magnification)

During an active imaging or freezing of 100% of the size, the image can be zoomed in or out within the range of -60% to +200%. The option is available in the main menu or by using the dedicated keys in the keyboard.

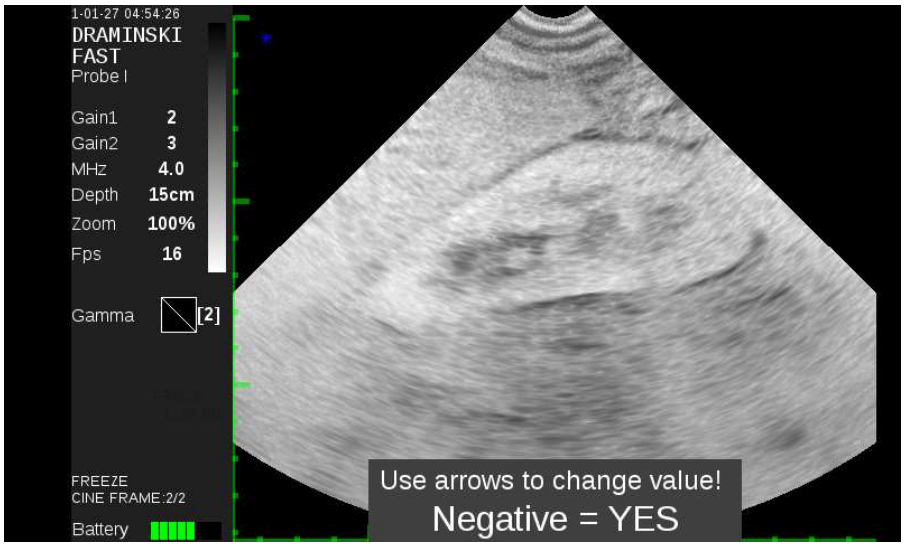
A window with a message about the set zoom level is displayed in the bottom of the screen. The window will automatically disappear after 2 seconds or after the setting is confirmed by pressing "OK". The current zoom level is displayed in the information bar.




**Example of a screen with adjusted zoom**

## Negative

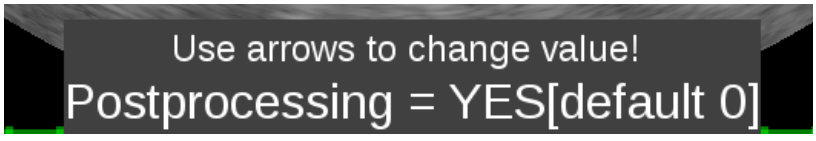
This is the option of image presentation with reversed greyscale. This option is used less frequently.




## Post-processing – digital picture processing

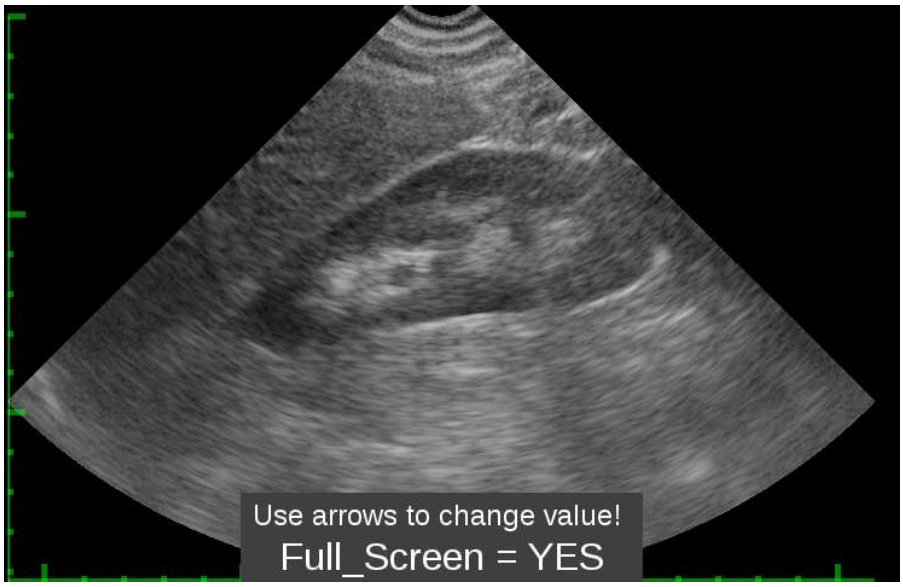
FAST ultrasound scanner is a compact but technologically advanced device. To optimize the picture quality and enhance its diagnostic value, an option of digital real-time processing of the picture being displayed and the frozen pictures or the pictures or cine loops loaded from the memory is available.

The post-processing option can be turned off at any time or restarted from the main menu after confirmation of "Post-processing=Yes" message in the dialogue box.



## Full screen

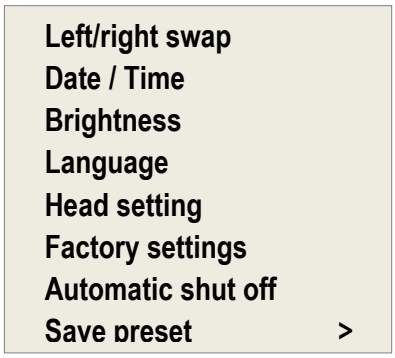
Once this option is selected and confirmed with "OK", the information bar is hidden and the imaging sector is displayed in full screen mode.




**Full screen view**

## System - Settings

This option in the main menu allows setting of additional available ultrasound scanner parameters which are used less frequently:

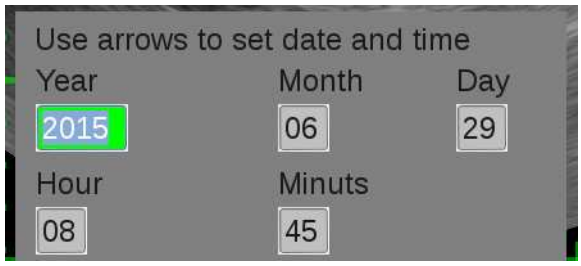



**Left/right swap**

This option makes it possible to change the display of the head picture on the right or the left side according to the actual scanning side. This is of particular importance for examination with the use of the endocavity probe. The set scanning side is marked at the top of the scanning sector with an asterisk.

**Date and time setting**

This option is used to update the date and time according to the user's calendar. Once the option is selected, a dialogue box is displayed in which the date and time fields can be set. You can move to the next fields by pressing the left/right navigation buttons and change the individual values of date and time by pressing the up/down navigation buttons.




**Time and date setting dialogue box**

**Brightness**

This is used to adjust the monitor screen brightness. Please note that the brightness level has an impact on the operating time of the batteries. The adjustment range is 10% to 100%.

**Language**

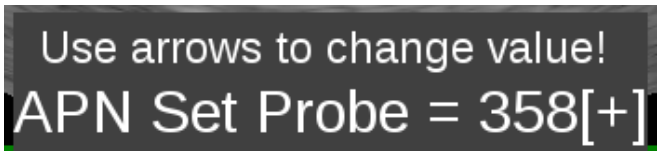
Once this option is selected, a window with a table of available languages appears.

Once the language is selected and OK is pressed. The system will automatically switch to the selected language version.

**Head setting**

This option is very rarely used. The setting is performed at the repair shop or in case the head index is mechanically changed as a result of a strong impact or dropping the head onto the floor.

A typical symptom of the head being out of adjustment is a slightly blurred picture. Once this option is selected, a dialogue box appears to set the numerical value (index) that stabilizes the probe picture as much as possible. After the probe picture is stabilized, confirm the value displayed by pressing "OK".



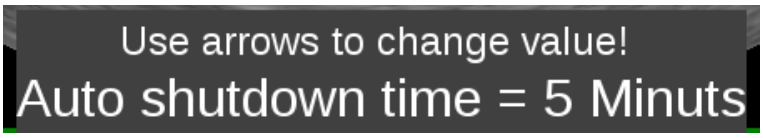

**Factory settings**

This option restores the default settings for the individual picture parameter if they are misadjusted by the user and the average parameters need to be restored quickly.


**Automatic shut-off**

This option is used to preset the time after which the system will be automatically shut off if no keys are pressed.

An example of a window for setting the automatic system shut-off time:




The following time periods can be set: ***never, after 5 min, 15 min, 30 min, 60 min***.

Sixty seconds before the automatic shut-off the following message will be displayed: "**Auto power OFF, 60 seconds"** and the system will start the countdown. The message disappears if any button is pressed and the system will restart the preset countdown time.

**Presets**

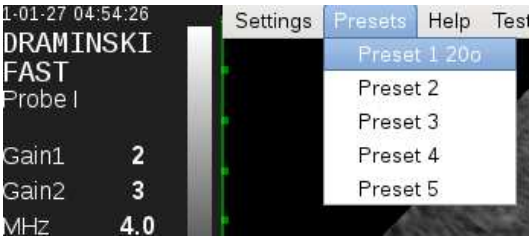
With this option the user can save the favourite settings under the "preset" name. This function can be also used to save the optimum settings for a specific organ examination (5 presets can be saved).

To add a new preset the scanner settings have to be optimized first (gain 1 and 2, frequency, scanning depth, focus, zoom and Gamma). From the Main Menu → Settings select as follows: →System and →Save Preset and confirm the Preset number the settings should be assigned to.



After confirmation, the dialogue box with the preset name appears. The name can be edited and finally confirmed.

The "Presets" saved can be accessed by the user from the main menu bar → "Presets".



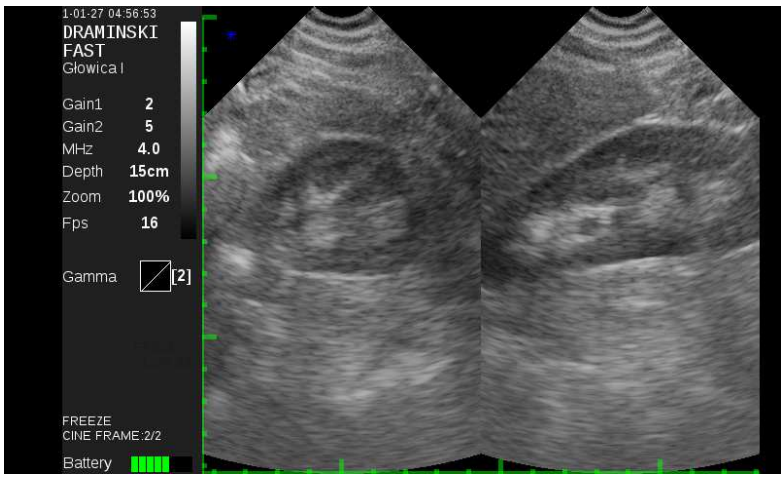

## B+B and B+M modes

In addition to the traditional and most frequently used B Mode of operation, there are other modes available. All the imaging modes can be quickly accessed from the dedicated keys in the keyboard.


B+B and B+M modes can be also activated by selecting the specific item in the main menu bar.

**B+B mode**

This option allows comparison of two pictures displayed on the screen at the same time. Once the B+B mode is activated, the screen will be divided into two windows (left and right window) and the picture will be frozen and moved to the right window. The division of the monitor in the B+B mode makes it possible to compare the frozen picture with that being currently scanned.



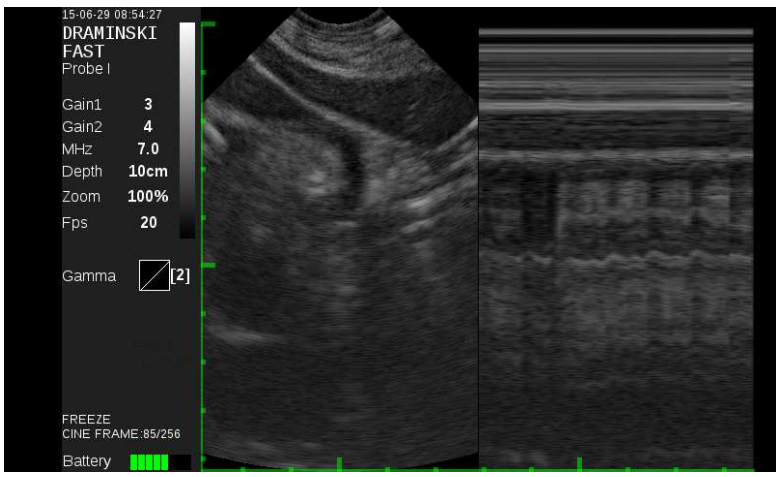

**Example of a screen with the B+B mode turned on**

**Swapping the B+B mode windows**

To move the picture currently viewed to the right window press **B+B** button. This will result in moving the picture to the right side. Once the B+B mode is activated during an examination, the picture being moved will become frozen immediately. To unfreeze the picture in the active window use the "Freeze" buttons.

**B+M mode**

When in this mode the movement of the individual structures and tissues is imaged in time integrated together with the B image. It can be used to assess quickly moving structures. Two images are displayed in the monitor at the same time. One of them is the presentation in B mode while the other presents the image changes in time (M mode).




**Example of a screen with B+M activated (change the picture)**

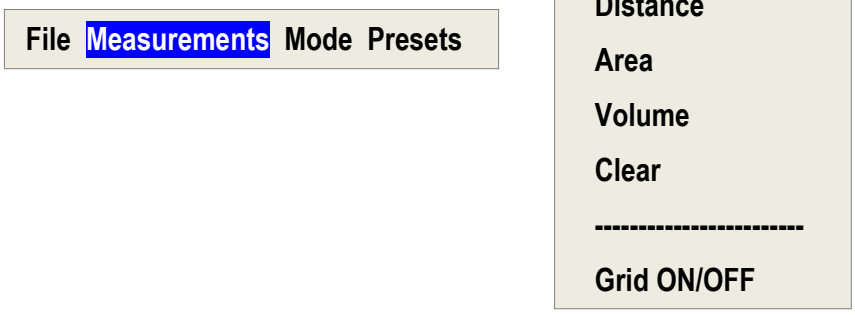
## Cine loop

The FAST ultrasound scanner is equipped with a very useful feature of reviewing the examination results directly after completion of the examination. The "cine loop" option makes it possible to replay up to 256 frames before the picture was frozen.

By using the navigation buttons ◄ ► , the subsequent sequences of the examination can be viewed frame by frame. By using ▲ ▼ buttons, the cine loop can be replayed forward or backward (up to 256 frames i.e. approx. 20 seconds of the examination).
The number of the frame being displayed is indicated at the bottom of the information bar.

## Measurements

After the picture is frozen, the object being diagnosed can be dimensioned. This is an item available on the additional menu including the list of the available measurement options and it is opened with a dedicated button .




**Attention! To remove the individual measurements from the screen you can also press ESC.**

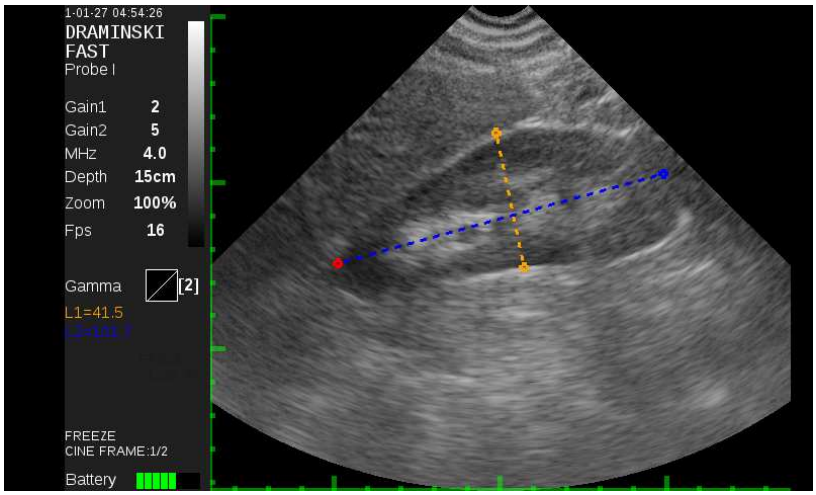
**Measurements - Distance**

Once this option is selected, a red marker appears on the screen, which can be moved and set using the navigation buttons ◄ ► ▲▼. The position of the marker is confirmed by pressing "OK". Once the position is confirmed, another red marker appears which can be placed at an appropriate position and the distance between the two markers can be measured.

After the "OK" button is pressed, a new cursor is displayed and the distance between another pair of markers can be measured.

The cursors can be moved only by pressing the navigation buttons or pressing the navigation buttons and holding them for longer if the marker is to be moved over a longer distance.

The user can carry out 4 measurements on a single picture. Each measurement is marked in a different colour. The values in mm are displayed in the bottom part of the information bar for the individual distance measurements.




**Measurements - Area**

Once this option is selected, a red marker appears on the screen and all the operations are carried out the same way as in the case of the distance measurement. To calculate the area automatically two measurements need to be made to provide the width and the height of the object.

The resulting area is given (in $cm^2$) in the information bar.

**Measurements - Volume**

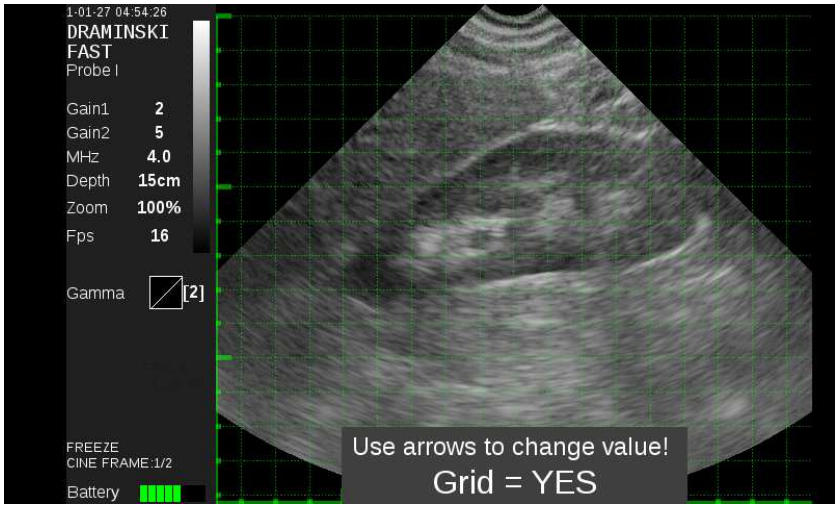
Once this option is selected, a red marker appears on the screen and all the operations are carried out the same way as in the case of the distance measurement, but to calculate the volume three measurements need to be performed (height, width and depth of the object). The most suitable mode for the volume measurement is the B+B mode with the dimensioning being carried out on a frozen picture.

**Measurements - Clear**

By selecting this option measurements carried out previously will be deleted from the screen. This operation is performed to complete the dimensioning process. Additionally, the measurement results can be quickly cleared by pressing the “ESC" button.

**Measurements – Grid ON/OFF**

Once this option is selected and confirmed by pressing "OK", a grid is superimposed on the imaging sector to facilitate an approximate dimensioning of the objects. The resolution of the grid is 1.0 cm and it is automatically scaled as the scanning depth is changed during magnification (zooming).



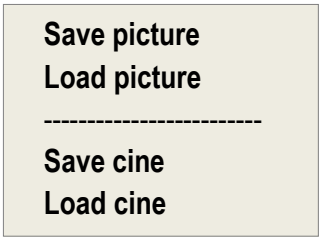

**Example of a screen with the grid displayed**

## Additional menu - management of pictures and cine loop

- save in the memory,
- load onto the screen,
- search,
- transfer to external drive,
- delete pictures and cine loop.

The options are available in the additional menu list and can be opened by pressing  .

The list includes several items:



**Save picture/cine**

To save a picture or a cine loop in the memory, the appropriate option needs to be selected in the additional menu and confirmed by pressing "OK". The picture (cine) will be automatically saved in the list and assigned to the next available number and a message with the number will be displayed shortly after the saving process is completed (saving the sequence of 256 frames takes approx. 5 seconds).

The ultrasound scanner memory can store up to 200 pictures and 200 full cine loops.

**Attention!** One or more pictures can be saved from one cine loop, if necessary.

Pictures or cine loops can be quickly saved using the dedicated buttons. 

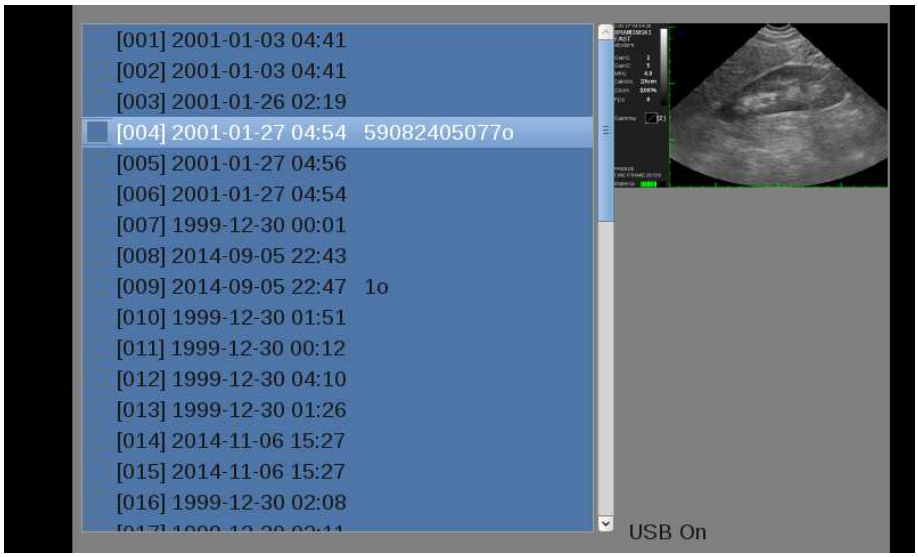
Pressing one of these buttons during the scanning process will result in the automatic saving of the picture or the cine loop in the memory.

Describing the picture or cine loop being saved

It is possible to add a description to the picture while saving. By using the navigation buttons ▲▼, ◄► individual digits or letters can be entered into the description field. Up to 30 characters can be entered. The description process is completed after the "OK" button is pressed. The picture or the cine loop will be stored in the memory together with the date and the description.


**Load picture/cine**

To load a picture or a cine loop saved in the memory, open "Load picture / Load cine" option, mark the selected item from the list and confirm it by pressing "OK". The list includes the basic data on the picture, e.g. the date of saving and a preview in the form of a thumbnail of the item being highlighted. After the cine loop is loaded onto the screen, the individual frames or sequences of frames can be scrolled forward or backward.




**View of the screen with the list of pictures or cine loops saved and a preview of the selected picture**

**Searching the pictures and cine loops in the list**

Pictures and cine loops saved in the memory and specified in the list can be searched by a string of characters, provided that such a description was made when saving in the memory.

The searching option is opened by pressing the additional menu button and selecting "Load picture" or "Load cine ".

After the selected list is opened, press the additional menu button again .
The list of available functions including "Search" will be displayed on the screen.


Selection and confirmation of the "Search" item will result in opening a window where a string of characters being searched for can be entered. Individual characters to be searched for are entered the same way as in the case of the description.

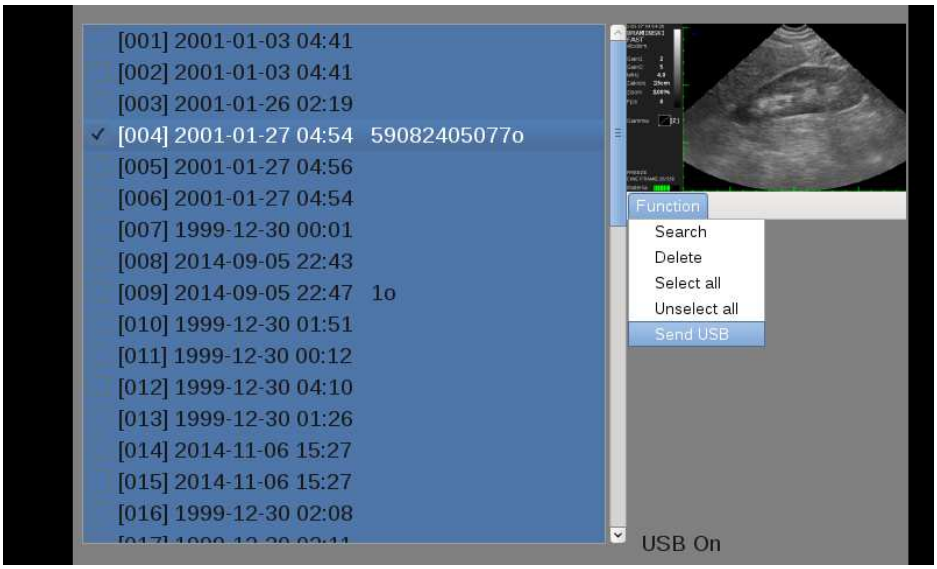
**Transferring and deleting pictures and cine loops to an external drive**

Pictures and cine loops stored in the memory and specified in the list can be transferred to an external drive. To do so, connect (by screwing on) a special adapter to the external memory connector located on the side wall of the housing and insert an external memory stick to the adapter socket.

External memory connector adapter for connecting an external memory stick

After opening the "Load picture" ("Load cine") option, select an item using ▲▼buttons and mark the selected item using◀ or ▶ button from the list of pictures (cine loops).

Press button to recall the auxiliary menu including a couple of functions to perform the appropriate operations including "Send to USB". Once the item is selected and confirmed by pressing "OK", the highlighted items will be transferred to an external memory drive.




**Screen with highlighted picture or cine loop ready for transferring to an external drive**

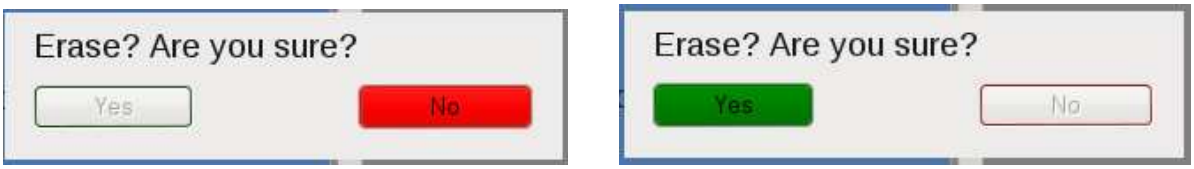
After the "Send to USB" operation is confirmed, the data transfer process will be started and a corresponding message will be displayed in the centre of the screen indicating the transfer progress (which is the number of the frame being transferred or converted to AVI in case of a cine loop).


**Delete picture/cine**

Pictures and cine loops stored in the memory and specified in the list can be deleted at any time. The preparation of a listed item for deletion is performed the same way as in the case of transferring to external memory.


**Part of the screen with the list of functions including deletion of pictures or cine loops from the memory**

After the items are highlighted and the "Delete" option is selected, a warning of the ultimate deletion is displayed which requires a conscious selection and confirmation of the appropriate message.




**Confirmation of the decision by selecting YES will result in the permanent deletion of the items highlighted in the list and stored in the memory.**

# VII. SPECIFICATIONS

| | |
|---|---|
| Application | diagnostic medical sonography |
| Imaging modes | Black and white imaging (B, B+B, B+M) |
| Picture management | - Freeze<br>- Cine loop<br>- Zoom 60 - 200% of the original image, in 20% increments<br>- Full screen function<br>- Saving pictures and cine loops in the memory (256 frames)<br>- Loading pictures and cine loops from the memory onto the screen<br>- Dimensioning (distance, area, volume) |
| Monitor | LCD LED display, 7" diagonal screen size |
| Feature control | membrane keyboard |
| Picture and cine loop memory | memory capacity: min. 200 pictures and 200 cine loops with date and description |
| Picture transmission | to an external drive – possibility to connect an external memory to the USB port via a special adapter |
| Type of operating heads | sector, mechanical, multi-frequency |
| Number of head ports | two independent ports (connectors) |
| Power source | external Li-Ion battery pack, 14.4V, 3.1Ah |
| Continuous operating time with battery supply | 4 h 30 min using a single fully-charged pack |
| Battery pack charging time | approx. 2.5 h (charger type: 2541 LI) |
| Low battery indicator | graphic colour-coded indicator and a sound signal before auto shut-off |
| External dimensions | 23 cm x 17 cm x 6.0 cm |
| Scanner weight | 1530 g excl. probe and battery pack |
| Battery weight | 280 g |
| Operating temperature | + 10 ℃ to + 45 ℃ |
| Storage temperature | + 5 ℃ to + 45 ℃ |
| Power consumption | approx. 0.71 A |

**Attention! If the storage temperature was lower than 5 ℃ the head must be warmed up before the scanner is turned on.**
**Operating the DRAMIŃSKI FAST scanner in extremely high and low temperatures is contraindicated and may lead to damage to the unit.**

# VIII. CHARGING THE BATTERIES

**A Li-Ion battery is a rechargeable battery pack. The battery life depends on the manner of operation. It is recommended that it be used in full cycles, i.e. full charging followed by a full discharging.**

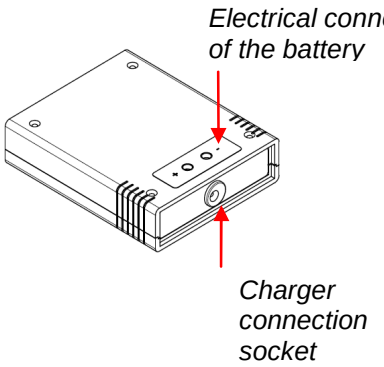
The estimated life of the DRAMINSKI BATTERY PACK is about 500 charging cycles.

The use of high-capacity batteries allows a long operating time (more than 4 hours).

The battery level is indicated at the bottom of the screen of the DRAMIŃSKI FAST scanner. Shortening of the battery level bar and changing from green to yellow indicates an expected full discharge in about 1.5 hours. If the bar has turned red, the battery will be fully discharged in about 10 minutes. If the scanner remains on, the battery pack will become deeply discharged and the scanner will finally turn off automatically with a message being displayed in the middle of the screen shortly beforehand.

**Charging DRAMIŃSKI BATTERY PACKS (3.1Ah)**

A specially adapted charger with parameters that ensure proper charging is used to charge the battery package.




**Li-Ion battery pack**
14.4V, 3,1Ah


**Charger, type 2541 LI**

To charge the battery pack, carry out the operation below in the following order

a) turn the ultrasound scanner power off,
b) connect the charger cable to the battery pack socket,
c) connect the charger to the mains (110-240 V / 50-60 Hz),
d) observe the LED in the charger – change from red (with deeply discharged battery) to green indicates the battery is properly and fully charged.

It takes about 2.5 hours to charge a fully discharged battery. Once the battery is fully charged, the charger stops the operation and the LED turns green.

**Caution! – Repair of the charger or disassembly of the scanner by unauthorized persons is prohibited. The battery pack can be charged using the charger supplied by the manufacturer only.**

**To ensure the user's safety and the durability of the charger, the charger must not be used in humid or damp places.**

**Before using the charger, always check the main charger components (including cables) for any damage.**

If any defect is found, immediately disconnect the appliance from the power source and have the damaged part replaced with a new one by an authorized repair shop.

**Attention!** The charger is an auxiliary appliance to be used for charging the batteries only. It is not an integral part of Dramiński FAST ultrasound scanner to be used during operation.

**Attention!**
Connecting the charger to the battery pack attached to the ultrasound scanner will result in automatic disconnection of the power supply and prevent examination.

**Li-Ion battery handling precautions**

- Do not disassemble the battery packs, which form an integrated unit.
- Do not short the pack housing contacts with metal objects.
- Do not throw the battery packs into fire or heat them up.
- Do not use mechanical impact on or throw the battery packs.
- If the leakage of electrolyte from the battery pack is observed, immediately cease the use of the battery pack.
- Prevent any liquids from penetrating the battery pack as this may result in a sudden increase of the battery pack temperature and pose a danger.
- Do not leave the battery pack in high temperature environments, e.g. exposed to direct sunlight inside a car, near heat sources etc. Failure to observe these rules may lead to the leakage of electrolyte from the battery pack or shortening battery life.
- The battery should be charged in an ambient temperature between 0 ℃ and 40 ℃. Charging the battery outside that temperature range may pose a hazard and result in permanent damage to the battery pack.
- If any charging problems occur after a longer use (approx. 500 cycles), replace the battery pack with a new one.
- Used battery packs must be recycled according to the regulations in force.

# IX. MAINTENANCE OF THE DEVICE AND THE HEADS

After a longer period of use, the appliance may become heavily contaminated also with contagious pathogens. Clean the instrument directly after use with a moist and soft cloth or a paper towel and a mild detergent. When cleaning, protect the housing sockets from moisture using special plugs (screw caps).
Disinfect the surface of the unit with a disinfectant intended for medical products.

**Attention! Disinfect the ultrasound probe thoroughly after each use**.
If necessary, after wet cleaning wipe the probe and the ultrasound scanner dry with a soft paper towel.

**Caution! - Do not use concentrated, aggressive or abrasive agents as they may permanently damage the probe surface, monitor windows or the housing surface.**
**The probe protection grade is IPX1 while that of the head face is IPX7; therefore, protect the probe connector from moisture when wet-cleaning. The probe face can be immersed in water or disinfectants.**

Users are recommended to carry out regular inspections of the ultrasound scanner at least every two years. This will ensure the highest safety level and the reliability of the unit during operation.

## Operating and technical advice

Prepare the appliance and the accessories before starting work.

- Turn the power on and check if there is no indication of the battery pack being discharged.
- A special gel is indispensable to carry out the examination (please use certified ultrasound-recommended gels preferably after making sure they are certified for use). Application of different agents may result in side effects. The use of high quality gel significantly improves signal penetration and ensures clearer images. Before starting work it is recommended to check if the amount of gel is sufficient for the scheduled number of examinations.
- The quality of pictures produced during the examination is affected by a number of factors like the area of head application, plane of penetration (i.e. the head application angle), quantity of gel and, certainly, the experience and skills of the operator.
- During examination the keyboard is used to set the best working parameters in the specific conditions. Take advantage of the possibility to adjust the gain. The appliance will "remember" the most recent gain settings for individual scanning depths. Take advantage of the possibility to change the frequency to obtain clearer images in the area of the examined object.

| **Problem** | Possible solution |
|---|---|
| No power - the appliance does not turn on | 1. Check if the battery pack is properly connected.<br>2. Check the operation with other battery pack. |
| Irregular or blurred image or no image | 1. Check if the head is properly connected or check the head setting (Menu option). |
| Image is too light or too dark | 1. Check the settings for gain, gamma, MHz or restore the factory settings (Menu option). |
| No charging indication in the charger | 1. Check the connections.<br>2. Check the mains power. |
| Short operating time of the battery. | 1. Battery not fully charged.<br>2. Very low ambient temperature.<br>3. The battery is used up (a normal occurrence, resulting from the design and the operating principles of the battery). |

If none of the basic actions proves effective, please contact the repair shop at DRAMIŃSKI, tel. +48 89 675 26 00 or e-mail: info@draminski.com.

# X. SAFETY OF USE

1. The DRAMIŃSKI FAST ultrasound scanner is an appliance, which should be used for diagnostics by qualified and trained personnel only (persons trained in ultrasound diagnostics).

2. It is necessary to disinfect the abdominal probe before each examination and disposable covers must be used for endocavity probes. Application of covers should be performed in line with the recommendations provided in the information leaflets.
   The remaining parts of the ultrasound scanner should be disinfected when necessary in case they might have come in contact with infectious agents.

3. It is prohibited to use the ultrasound scanner along with the high frequency-based (HF) technique.

4. The ultrasound scanner must never be used in transesophageal examinations.

5. For safety reasons the use of the ultrasound scanner is strictly prohibited in places where the explosive gases are present.

6. **The users of the ultrasound scanner are recommended to have the scanner regularly inspected by the manufacturer (DRAMIŃSKI, Olsztyn) every other year. This will help ensure the safety of patients**.

7. Ultrasound diagnostics must not be performed during defibrillation.

8. It is prohibited to disassemble the scanner and carry out repairs or adjustments except for the operations described in this manual.

9. Users of the ultrasound scanner are recommended to inspect the ultrasound head periodically for cracks which might cause the leakage of the propagation fluid.

10. Users of the ultrasound scanner are recommended to periodically inspect the head cable and the head cable connectors for mechanical damage.

11. If any mechanical damage to the head, cable or the connectors is found, the scanner must be repaired at an authorized repair shop.

12. Despite the robust design of the scanner, follow the instructions provided in this manual to avoid any mechanical damage.

13. Avoid exposure to intense sunlight. It is recommended to observe the temperature ranges indicated on the scanner labels and components.

14. Any modification of the scanner by the user is prohibited.

15. The DRAMIŃSKI FAST ultrasound scanner is an electrical appliance, which may be a source of electromagnetic radiation and its operation can be disturbed by other electrical devices. Therefore, it is recommended to minimize, as much as possible, the number of other electrical devices being operated in the vicinity of the unit.

16. At the end of the operational life of the scanner it should be disposed of by qualified units according to the regulations in force or returned to the manufacturer.

17. Guidelines and manufacturer's declaration - electromagnetic emissions

| **Guidelines and manufacturer's declaration - electromagnetic emissions** | | |
|---|---|---|
| The ultrasound scanner is intended for use in the electromagnetic environment described below. The owner or the user of the ultrasound scanner should ensure it is operated in such an environment. | | |
| Electromagnetic emission measurements | Conformity | Electromagnetic environment – guidelines |
| High frequency emissions acc. to CISPR 11 | Group 1 | The ultrasound scanner uses electromagnetic energy for internal functioning. The energy is very low hence the risk of disturbance to the nearby electronic equipment is very low. |
| High frequency emissions acc. to CISPR 11 | Class B | The ultrasound scanner is intended for use in all buildings including flats etc. connected to the public grid which supplies power to buildings used for residential purposes. |
| Harmonic vibration acc. to IEC 61000-3-2 | Class A | |
| Voltage variation / flicker acc. to IEC 61000-3-3 | conforms | |

| **Guidelines and manufacturer's declaration - electromagnetic immunity** | | | |
|---|---|---|---|
| **The ultrasound scanner is intended for use in the electromagnetic environment described below. The owner or the user of the ultrasound scanner should ensure it is operated in such an environment.** | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidelines** |
| Electrostatic discharge acc. to IEC 61000-4-2 | Contact discharge +/- 6 kV<br><br>Air discharge +/- 8 kV | Contact discharge +/- 6 kV<br><br>Air discharge +/- 8 kV | Floors should be made of wood and concrete or be covered with tiles. If the floor is lined with synthetic material the relative humidity of air must be min. 30%. |

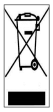
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidelines** |
|---|---|---|---|
| bursts acc. to IEC 61000-4-4 | +/- 2 kV for mains cables<br>+/ 1 kV for input and output cables | +/- 2 kV for mains cables<br><br>not used | Quality of the power supply voltage should be compliant with the standard commercial or clinical environment. |
| surges acc. to IEC 61000-4-5 | non-return voltage +/- 1 kV<br>common mode voltage +/- 2 kV | non-return voltage +/- 1 kV<br>common mode voltage +/- 2 kV | Quality of the power supply voltage should be compliant with the standard commercial or clinical environment. |

| | | | |
|---|---|---|---|
| switching overvoltages, short interruptions and power supply voltage variations acc. to IEC 61000-4-11 | <5% $U_T$ (>95% dip $U_T$) for ½ of the period<br>40% $U_T$ (60% dip $U_T$) for 5 periods<br>70% $U_T$ (30% dip $U_T$) for 25 periods<br><5% $U_T$ (>95% dip $U_T$) for 5 s | <5% $U_T$ (>95% dip $U_T$) for ½ period<br>40% $U_T$ (60% dip $U_T$) for 5 periods<br>70% $U_T$ (30% dip $U_T$) for 25 periods<br><5% $U_T$ (>95% dip $U_T$) for 5 s | Quality of the power supply voltage should be compliant with the standard commercial or clinical environment.<br>If continuous operation of the ultrasound scanner is required by the user even in case of power supply interruptions, it is recommended to supply the scanner with power using a UPS or a battery. |
| Power Frequency Magnetic Fields (50/60 Hz) acc. to IEC 61000-4-8 | 3 A/m | 3 A/m | Mains frequency magnetic fields should correspond to typical values in the commercial or clinical environment. |

Note: $U_T$ is an alternating mains voltage before the application of the control level.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidelines |
|---|---|---|---|
| High frequency conduction disturbance acc. to IEC 61000-4-6<br><br>High frequency radiation disturbance acc. to IEC 61000-4-3 | 3 Vrms<br>from 150 kHz to 80 MHz<br><br>3 V/m<br>from 80 MHz to 2500 MHz | 3 Vrms<br><br>3 V/m | Portable or mobile radio frequency equipment including cables must not be used in the vicinity of the ultrasound scanner at a distance less than the recommended separation distance calculated from the equation applicable to the operating frequency of the transmitters.<br><br>Recommended separation distance:<br>d = (3,5/3) <br><br>d = (3,5/3)  for the range of 80 MHz to 800 MHz<br><br>d = (3,5/3)  for the range of 800 MHz to 2.5 GHz<br><br>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 metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveys, should be less than the compliance level in each frequency range b.<br>Interference may occur in the vicinity of equipment marked with the following symbol.<br><br>  |
| 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 buildings, objects and people. | | |
| a | Field strengths from fixed transmitters, such as base stations 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 device is used exceeds the applicable RF compliance level, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ultrasound scanner. | | |
| b | Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | |

## XI. SYMBOLS AND DESIGNATIONS USED ON THE LABELS

| | |
|---|---|
| CE 0197 | CE mark indicating conformity of the product with the Medical Devices Directive certified by a notified body of TUV. |
|  | BF type for parts in direct contact with the patient's body. B= body, F= Floating applied part |
|  | Attention, read the user's manual. |
|  | Warnings against risks to the users' safety. |
|  2014 | Date of manufacture |
|  DRAMIŃSKI | Product manufacturer name and address |
|  | Dispose of separately from other household waste according to the EU Commission Directive 93/86/EEC or local regulations. |
| IP65 | Water resistant. Resistant to water jet flowing from all directions at the rate of up to 12.5 litres per minute. |
| IPX7 | Water resistant. Resistant to immersion in water up to 30 minutes at a depth up to 1 metre. Applicable to the probe. |
| SN- | Product serial number for identification purposes. |
| MAX 40 ℃  MIN 10 ℃ | Product storage temperature. |
|  | Caution! Fragile! |

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