DRAMIŃSKI
TECHNOLOGY

# DermaMed

## USB 2.0 System


# User manual

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The Draminski Company has established and maintains a complete quality control system according to the requirements of **EN ISO 13485:2012/AC:2012.** This system and the technical documentation are periodically revised by notifying unit No. **0197 – TUV Rheinland LGA Products GmbH**, Tillystrasse 2, 90431 Nuremberg, Germany, which takes part in compliance assessment.

**Declaration of conformity**
It can be obtained at our Sales Department:
ph: +48 89 675 26 00
e-mail: ultrasound@draminski.com

We wish the users of this product lot of success in taking care of your patients and we are sure that using our product you will provide good service to your patients.

All possible comments and notes of your customers concerning the device and this user manual will be accepted by DRAMINSKI Company with necessary attention.

Please feel free to call us at: + 48 89 675 26 00
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# 1. INTRODUCTION

Congratulations on your purchase of Derma Med USB 2.0 system that can work with any computer or tablet with the required technical specifications, including USB 2.0 plug. Please read this manual carefully before using the machine.

Derma Med USB 2.0 system is a modern skin imaging device based on a specialized high frequency probe. Thanks to its construction, it is possible to observe changes and the nature of these changes with high precision.

# 2. WARNINGS, SAFETY INFORMATION

This manual uses warning signs and safety symbols and it is important to adhere to these instructions. These codes, symbols and their meanings are as follows.

| Codes and symbols | | COMMENTS |
|---|---|---|
|  | **WARNING** | Indicates a potentially hazardous situation which, if not avoided, may cause damage to the equipment. |
|  | **ATTENTION** | Indicates a potentially hazardous situation which, if not avoided, may result in minor injury or damage to the device. |

General remarks and warnings

| | |
|---|---|
|  | **ATTENTION** |
| | Probes should be cleaned after each use. Cleaning the probe is an important step for effective disinfection. Follow the manufacturer's instructions when using disinfectants. |
| | The probe used in DermaView system has a very low noise output, and ultrasound in many tests were identified as safe when used correctly. It is important to use the lowest possible power settings and the shortest times for the skin examination, while gathering the necessary information for the personnel. |
|  | **WARNING** |
| | There must be no mechanical damage, e.g. through contact with sharp objects. Prevent the probe and the cable from contact with flammable or aggressive substances. |
| | To ensure safety, connecting the probe to other devices is not permitted. |
| | Do not use the device in the presence of flammable anaesthetics or other flammable materials. |

## 3. QUALIFICATIONS OF THE OPERATOR

The operator of the system must have a general knowledge of the use of imaging devices.

It is recommended to previously undergo a training on skin imaging with the use of heads of high frequencies.

## 4. MAINTENANCE AND OPERATION OF THE PROBE

Although the DermaView system probe is very durable, make sure it is not damaged, be particularly careful about the probe tip to be covered with a plastic membrane and the socket on the other end of the probe. The probe should work in a reliable manner for many years if these simple precautions are observed.

| | |
|---|---|
|  | **WARNING** |
| | Always disconnect the probe from the machine during maintenance or cleaning. |
| | Always follow the manufacturer's instructions when cleaning and disinfecting the probe. |
| | Do not use sharp brushes when cleaning the probe, use only a soft cloth or tissue paper. |

## 4.1. WASHING

1. Put protective gloves on to wash the probe.
2. Disconnect the probe from the system.
3. Use a soft cloth slightly moistened with a soapy water, detergent or special agent to remove any dirt or body fluids that remain on the probe or cable.
4. To remove residual disinfectant, rinse the probe with water protecting the USB plug,
5. Wipe the probe with a moist cloth to remove any residual of e.g. soap, then wipe the surface of the probe housing with a dry cloth.

## 4.2. DISINFECTION OF THE PROBE

Approximately 60% of the pathogens should be destroyed after the disinfection, according to the procedure set out in the manual, using the following recommended agents.

The following disinfectants are recommended due to both: their biological effectiveness and their chemical compatibility with the materials of which the probe is made:

| Solution | Country | Type | Active ingredient | |
|---|---|---|---|---|
| Cidex® | USA | Fluid | Glutaraldehyde | |
| Cidex Plus® | USA | Fluid | Glutaraldehyde | |

1. Wear protective gloves during the process of disinfection.
2. Check the expiration date of the solution. Use only solutions whose best before date has not expired.
3. Prepare a solution for disinfection in accordance with the instructions on the label. It is recommended to use a disinfectant registered and approved for use by relevant authorities.
4. Immerse the probe into disinfectant for the time recommended by the manufacturer.
5. When immersing the probe, follow the instructions on the label of the product.
6. Using the cleaning and sterilization instruction on the label, rinse the probe protecting the USB plug and dry it in the air or wipe it with a clean towel or a tissue**.**
7. Check probe for damage such as crack, or sharp protruding edges. If damage is evident, do not use the probe and contact the service department of Dramiński as soon as possible.

| | |
|---|---|
|  | **WARNING** |
| | Do not immerse in hot liquids, do not heat or expose the probe to radiation during sterilization. This will cause permanent damage to the probe and the loss of warranty. |

| | |
|---|---|
|  | Instructions and other data are available at: http://www.medical.draminski.com after contacting us using "ask about this product" section. |

## 5. ACOUSTIC ENERGY

According to many studies, the impact of acoustic energy on human tissue is considered as absolutely safe but it is recommended that the system settings are at the lowest possible levels and the test time is as short as possible.

## 6. LABELLING

### SYMBOLS

The below symbols can be used on the labels:

| | |
|---|---|
|  | The symbol for "Serial Number" |
|  2014 | The symbol indicating the "date of manufacture" |

## 7. TRAINING

DermaView system is intended to be used by trained personnel. Proper training will allow the appropriate use of the system and will enable to achieve satisfactory effect. The functions of the device are described in this manual.

## 8. GENERAL REMARKS

Before using the system, be sure to read the instructions describing the service. DermaView system is a unique solution where the probe plays the main role and a computer or a tablet performs imaging and provides user control panel via a special software installed.

DermaView system allows the user to observe the skin in real time and review a sequence of images (cine-loop) or evaluate the still-image on the screen.

## 9. SOFTWARE INSTALLATION

Before you start to use the system, make sure to install the DermaView USB 2.0 system on your PC (laptop) using the included software on a CD or the installation software provided individually.

9.1. Basic hardware requirements for the computer are as follows:

- Operating System: Windows XP, VISTA, Windows 7, Windows 8 or 8.1 in version x86 or x64
- RAM: 2 GB
- Graphic card supporting DirectX 9c
- Hard drive: about 500 MB to install the application

1. Insert the attached CD into the CD reader in your computer.
2. Open the installation software by clicking on the DermaView.exe file and follow the instructions.
3. Drivers needed for the software operation will be installed automatically, if necessary.

## 10. CONSTRUCTION OF THE EQUIPMENT AND SYSTEM

**CONSTRUCTION**

DermaView system consists of three basic elements:

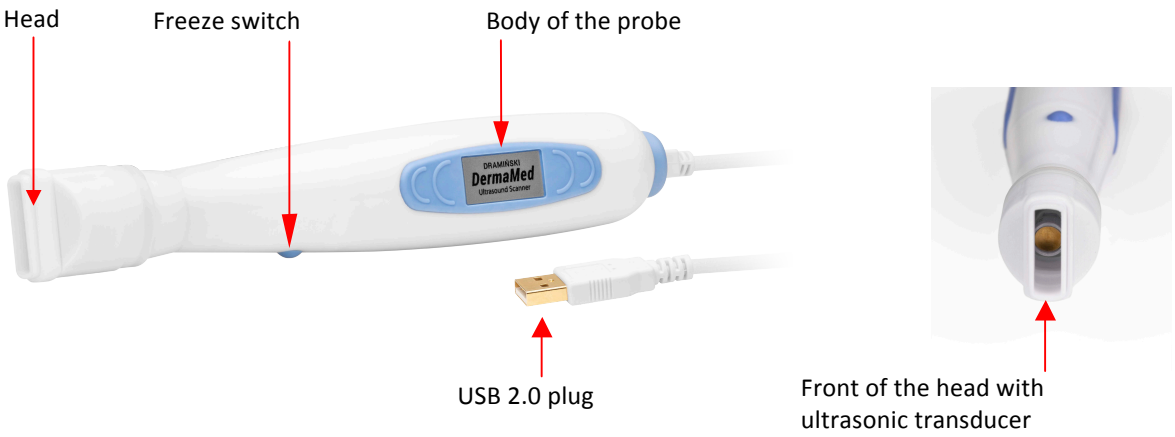
1. **Ultrasound head**
2. **Specialized software** with a user control panel
3. **PC** with a monitor/or a notebook

All the aforementioned elements are necessary for the proper operation and use of the DermaView system.

**Ultrasound head (probe)**

The most important from the above elements is the probe that was made of carefully selected materials to ensure comfort of use.

The construction of the probe is shown below:




**PREPARATION OF THE HEAD FOR TEST**

Before the commencement of the test, the head should be properly prepared:

1. The head, in which the transducer is located, should be held upright and fully filled with deionized water.
2. Place a formerly prepared film (cling film) on the top of the head, and stretch it.
3. Protect the applied film and secure it with a special O-ring (rubber ring), placing it in the trough.

The front part of the probe with stretched film, protected with an O-ring. Deionized water is under the film.

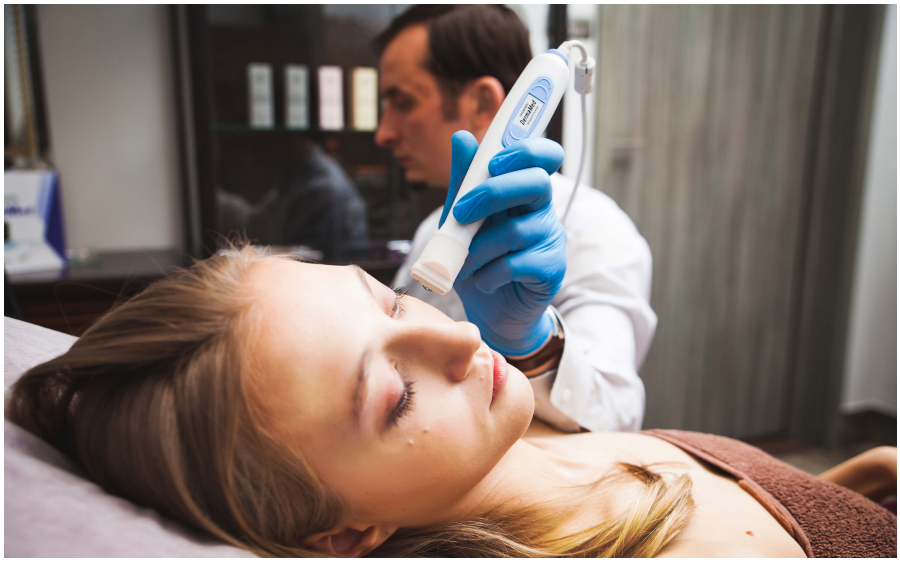
The probe inside the body contains electronic components. Please be careful when using or cleaning and do not expose it to shocks or impacts.

## ACTIVATION OF THE SYSTEM AND PREPARATION FOR TEST

To launch the system, make sure you have completed a few simple steps listed below starting with turning on the computer with the software installed.

1. Plug the power cord connecting the probe to a USB port on a PC or tablet. Start the computer by pressing the ON/OFF (according to the manual of the hardware).
2. Prepare the head according to the preceding steps.

3. Open DermaView USB 2.0 system and click on the icon of the installed software to start imaging.
4. Place the front of the probe to the desired spot on the skin previously moisturised with an ultrasound gel (to facilitate the contact of the head with the skin).



**Note:** the quality and clarity of the image are achieved through a combination of several factors, such as placing the probe at a right angle, correct and complete filling of the probe chamber with distilled water, right application of the probe tip to the surface of the skin, adequate skin moistening (gel application) and well-chosen set of operating parameters of the system. Please refer to the available reference images to find out what can be achieved through an appropriate screening technique. If you do not have experience with positioning, orientation and adjusting the angle of the probe and the correct pressure force of the tip of the probe, it is recommended to undergo a training under the guidance of an experienced user and continue to practice regularly, until obtaining good results.

## 11. USER CONTROL PANEL OF DERMA MED SYSTEM

The computer screen (tablet screen) is divided into three main parts (see figure and descriptions below):

1. On the left there is an imaging window. It shows the sector with the image and additional information on the performance of the system.
2. On the right side of the screen there is a user interface window. It contains control elements that allow the user to set the preferred working parameters to conduct skin imaging procedure.
3. At the bottom of the panel, there is a toolbar with buttons for current management of images while scanning the skin and management of the images stored in the system memory.

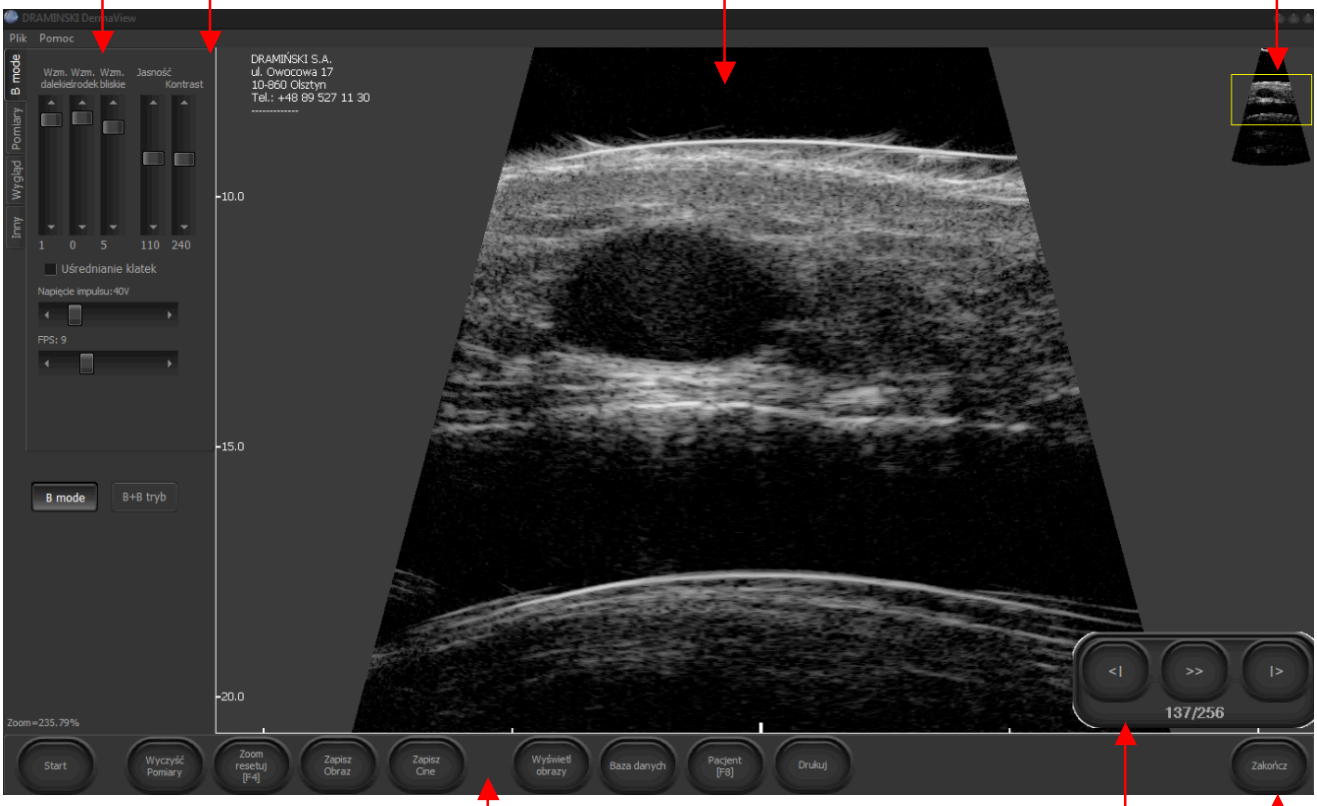
**General view of the user control panel with an imaging windo**

User interface

Ruler – 1 mm divider

Imaging sector

Preview of the position of the enlarged area in the imaging sector




Toolbar with buttons to manage images

Buttons to manage cine loop - rewind and freeze-frame

Closing button

**The view of the user interface window with features to control the operating parameters of the system:**

**"B mode" section.**

**B mode**
Section of the adjustment of operating parameters of the system in B-mode imaging (or B+B mode)

The set of sliders to adjust the intensification of the image in the far, middle and near field

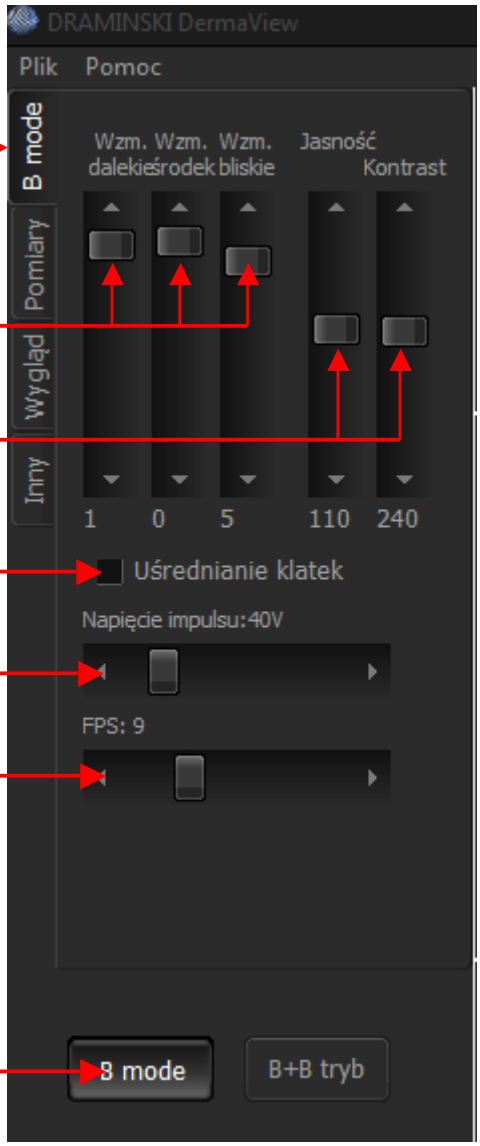
The set of sliders to adjust the brightness and contrast of the image

Button that activates averaging of image frames

Slider to adjust the voltage level of the impulse supplied to the ultrasonic transducer

Slider to adjust the level of image refreshing (number of frames per second)

Buttons to switch imaging mode B mode/B+B mode




The B section mode is the primary window of the user interface with tools for the optimization of the parameter settings of the system performance in order to obtain the best possible skin image quality.

**The view of the user interface window with features to control the operating parameters of the system: the "Measurements" Section.**


**Measurement** Section for measurements

Switches activating the corresponding types of measurements:

No measurements

Pixels measurements

Length measurements

Surface measurements

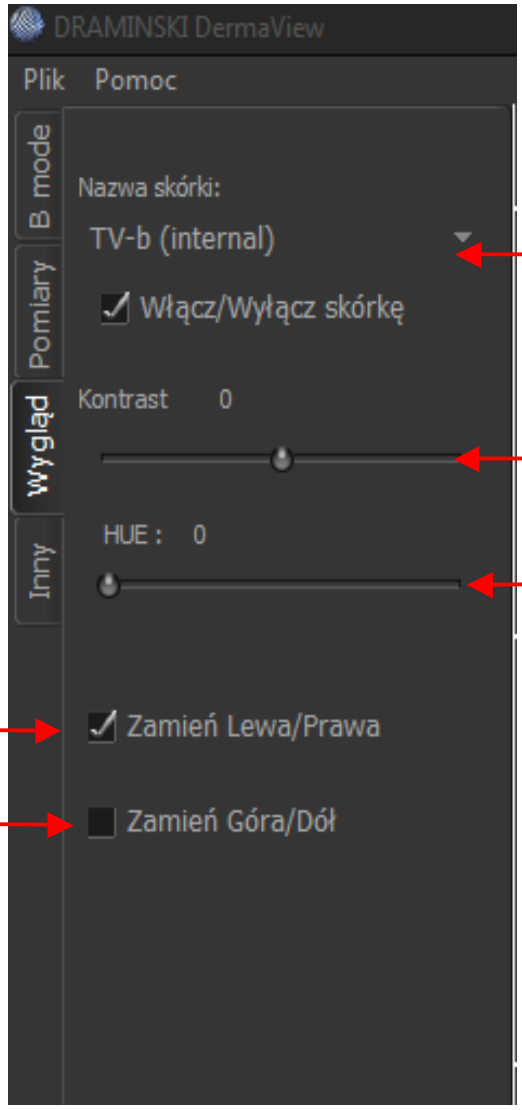
Sliders to adjust the level of grey pixels in skin echogenicity measurement

Button of the automatic measurement of the observed structure thickness

Setting of the frames (Inactive)

More information on the measurements is provided further in the manual. (FREQUENTLY USED FUNCTIONS)

**The view of the user interface window with features to control the operating parameters of the system: the "Layout" Section.**




**Layout**
Section to configure the layout of the user control panel

Selecting from the drop-down list and setting the panel background layout

Slider to adjust the contrast

Slider for the adjustment of colour brightness (background)

Rearranging the panel left/right

Rearranging the panel up/down

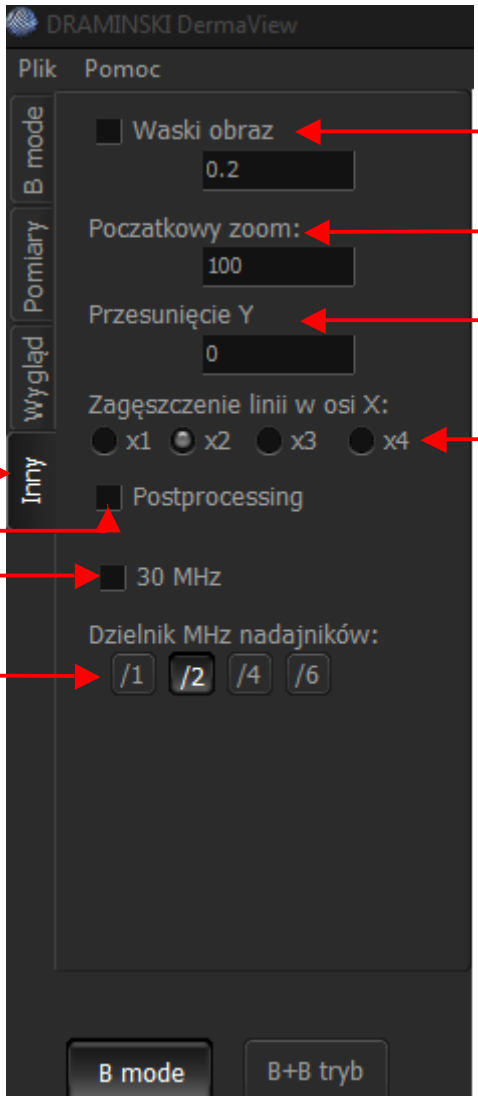
**The view of the user interface window with features to control the operating parameters of the system: the “Other” Section.**

**Other**
Section to configure the parameters and the location of the imaging sector to optimize the image.

Post-processing switch

Filter of transmitter frequency changes from 48

Change of the frequency of the converter using the method of dividing 48 MHz by 2/4/6




Setting the narrow image level

Setting the preferred initial zoom of the image

Setting the preferred start position of image sector

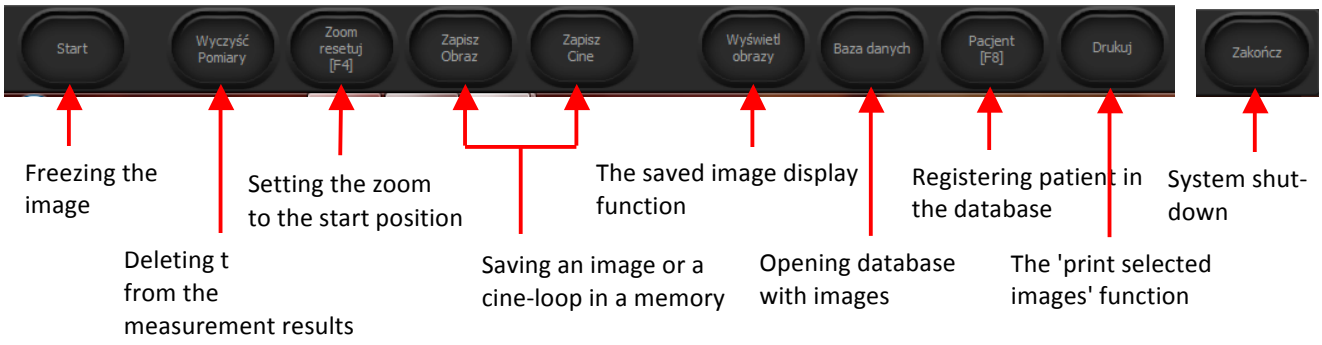
Setting the line density level of the image in order to improve its clarity

The "Other” Section allows the user to perform additional operations in order to improve the characteristics of the image and the settings of the imaging sector. This section is intended for advanced system operators.

## TOOLBAR TO MANAGE IMAGES

At the bottom of the user panel, there is a toolbar with buttons used to freeze the image and to manage the images obtained when scanning skin with images.

The button layout is shown below:




When working with DermaView USB 2.0 system, the user will regularly use a computer mouse. Therefore, please make sure you have comfortable conditions to use this tool.

The above-presented set of buttons that are a part of user control panel allows to perform functions available in the system.

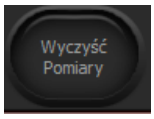
# 12. FREQUENTLY USED FUNCTIONS

### FREEZING IMAGE AND MEASUREMENTS

After freezing the image with Freeze/Start button in the imaging window, a set of control buttons will appear to control cine loop in order to scroll and set a stop-frame on the image that the operator wants to measure (or save).


A set of buttons to scroll the loop and to move forward and backward, frame by frame. On a selected stop-frame, it is possible to perform several types of measurements available in the "Measurements" Section:

- Measurements of pixels
- Length measurements
- Surface measurements
- Measurement of thickness (of the observed structure - automatic measurement)

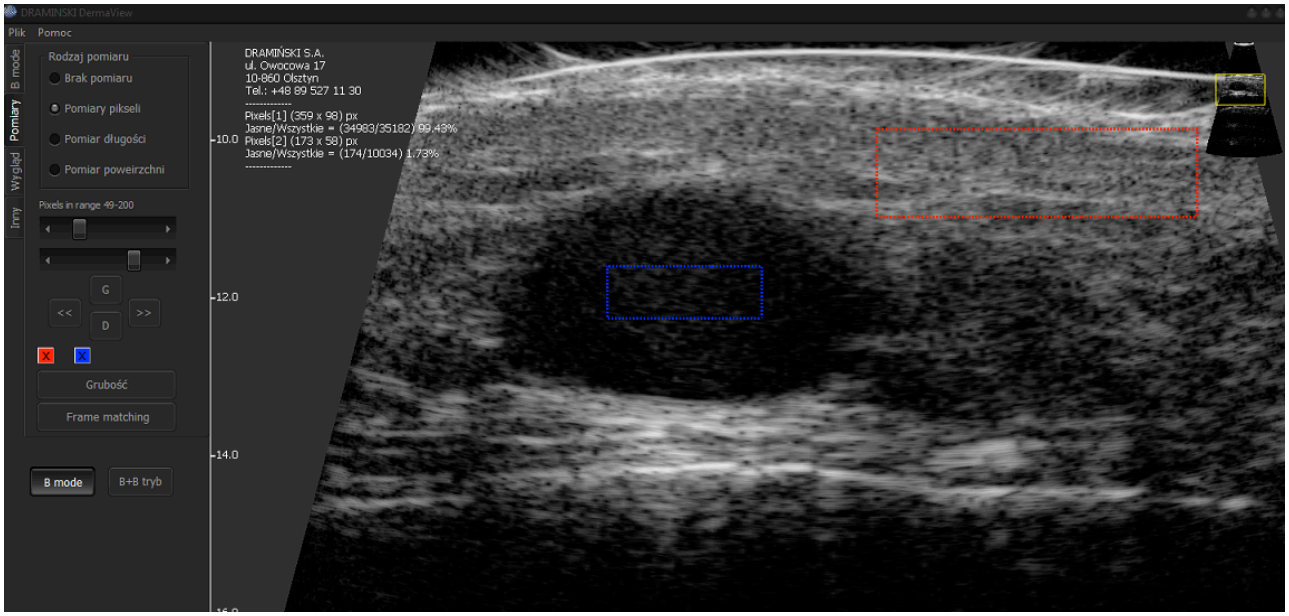



**Remember!** If necessary, it is always possible to delete the measurement results using the "clean" button on the toolbar at the bottom of the user profile.


**Remember!** Most frequently, you will perform imaging and measurements on a highly magnified image. A quick return to the standard zoom (100% zoom) or an individually preferred zoom is possible by pressing "Zoom reset F4" or by pressing the F4 key on a computer keyboard.

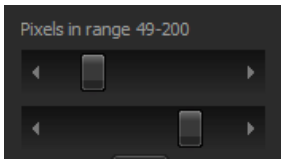
### Measurements of pixels

1. Select this option by drawing a rectangular area of the imaged skin structure.
You can select multiple areas at the same time (up to 4).

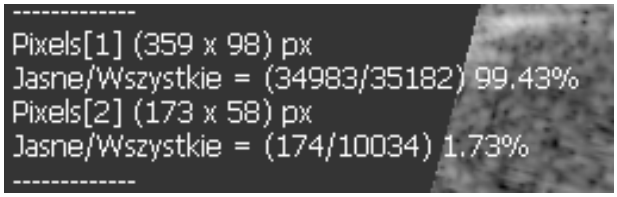



You can set the selected area (rectangle) using the available navigation buttons in the user interface: Up/Down/right >>/<< left:


2. After setting the selected area, determine the scope according to which the value of the pixels measurement will be calculated. You can operate in the range of 49 to 200.



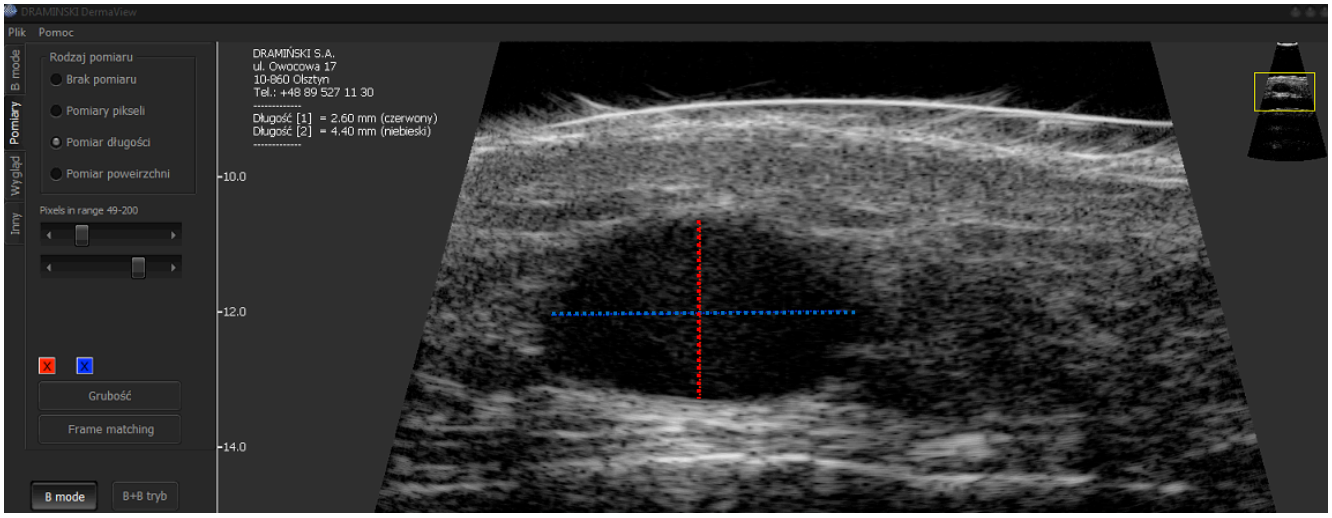

3. The measurement results are shown in the upper corner of the imaging field in the form of a ratio of bright pixels to all pixels found in the framed area and as a percentage value of this ratio:




**Length measurement**

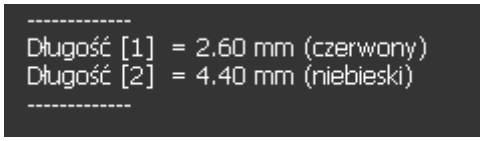
It is a frequently used measurement that consists of measuring the distance between pairs of markers on the selected image object.

1. After choosing this option, select the initial place of the measurement of the imaged skin structure and the final spot of the distance measurement as shown below:




2. You can measure the length of the imaged structure for several marker pairs (up to 4) that are colour-coded.

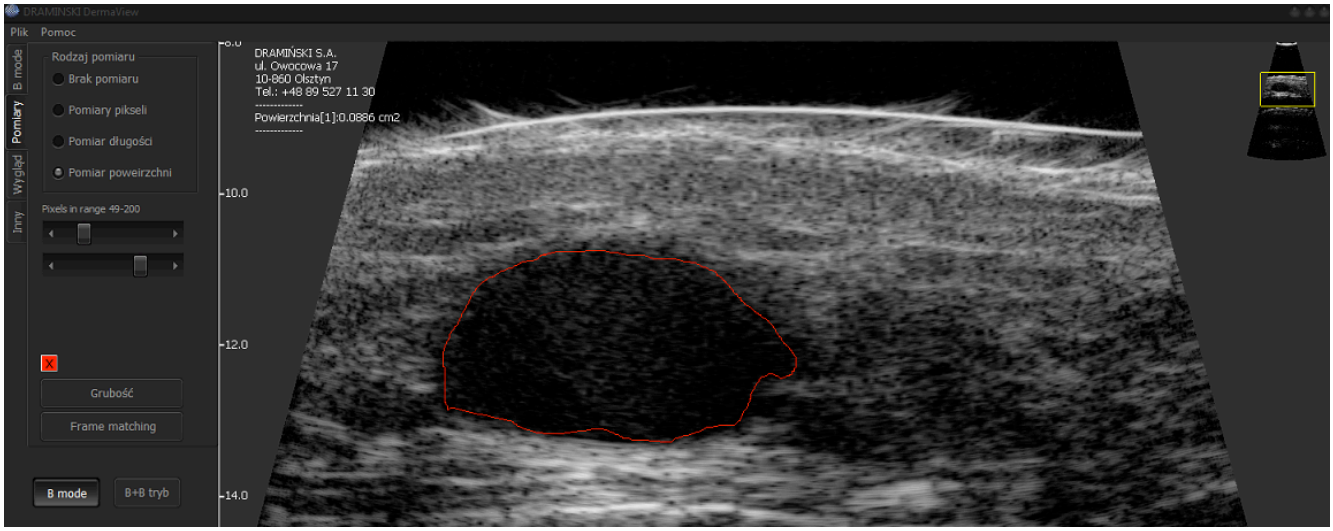
3. The result is given with a resolution of 0.01 mmm and shown in the upper corner of the imaging field.



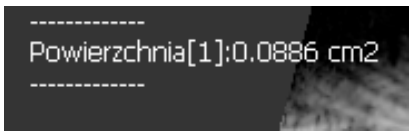

**Surface measurement**

It is a frequently used measurement that consists of measuring the field of the structure on the selected image. Thanks to this option, it is possible to observe the changes of the size of the structure in time.

1. After selecting this option, outline the imaged skin structure in a precise manner as depicted below:



2. During outlining the system will automatically make calculations and show the score in the top corner of the imaging field for the area selected with the red curve. The result of the measurements is given in $mm^2$ with an accuracy of 4 decimal places.




**Measuring the thickness of the structure**

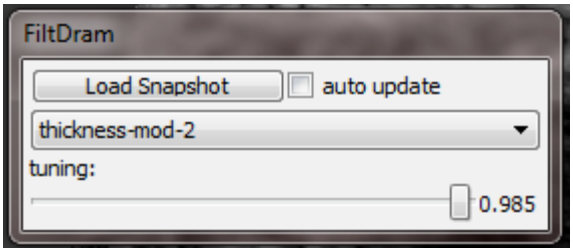
It consists in automatic measurement of the average thickness of the selected structure on the chosen image object. This option requires some experience from the operator and setting a correct level of pixels brightness with a suitable tool.

1. After selecting the “Thickness" measurement option, select the initial line (straight or polygonal line) around the centre line of the analysed area. It is important that the line runs through the area without entering the adjacent structures.

**Attention!** The selection operation is performed with the right mouse button or by dragging the mouse while holding down the right button, or by holding down the left ALT key and clicking different points belonging to the profile of the structure (polygonal line).

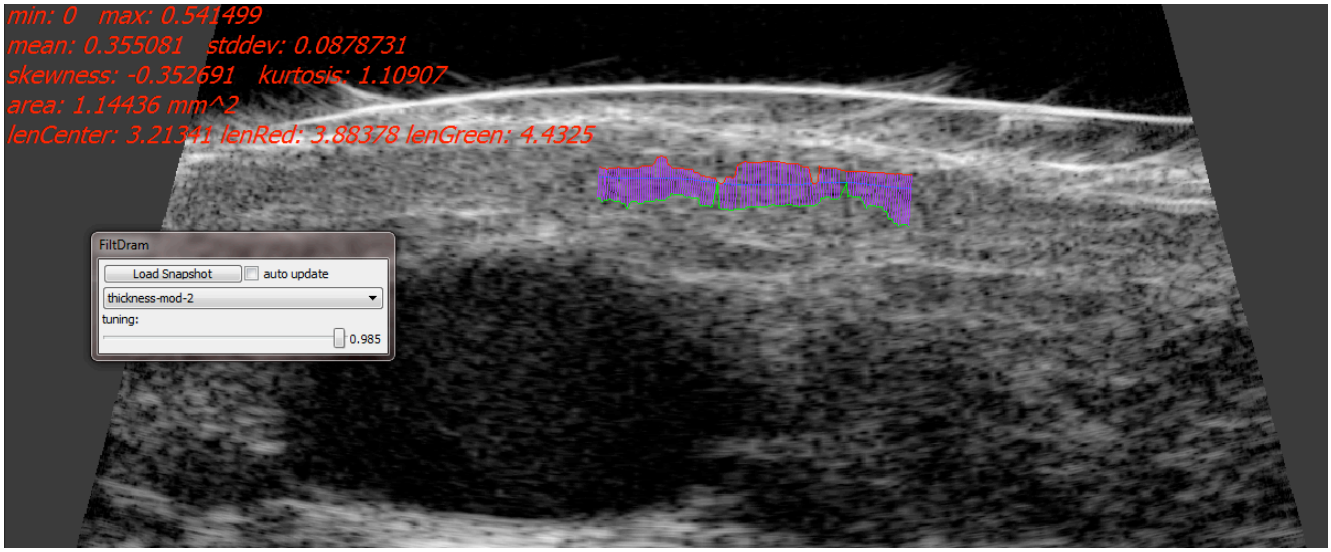
2. After determining the initial (polygonal) line, the software will automatically calculate the statistics of the intensity along the polygonal line.

A toolbox (FitDram) is displayed on the screen:




**Tuning slider** stands for the probability (range between 0-1). For the value of 0, all image points belong to the alleged thickness; for a value of 1 only those within the profile selection. Usually the values at the level of 0.8xx - 0.9xx are appropriate and should be adjusted individually. The use of statistics (probability maps of belonging to the area) enables the algorithm to work in non-linear situations - in case of typical algorithms, the intensity range is selected by the lower and upper threshold. In this case, the range values do not have to be next to each other - they can be freely distributed.

Below there is a designated area with an automatically determined average.




**Thickness-mod-x** - a drop-down list with a choice of invisible parameters. Thickness-mod-x tool allows the operator to select from various options tailored to the specific type of an image. Parameter sets include pre-processing, filtering, smoothing, sampling density.

3. The results of the measurement of thickness of the area designated by the line are shown in the upper corner of the imaging field as in the following example:


Particular messages of statistical calculations:

**-min/max** - the highest and the lowest thickness value in mm.

**-mean** - the average thickness value.

**-stddev** - standard deviation from the average value.

**-skewness/kurtosis** - statistical values allowing for the analysis of the thickness of collected samples (e.g. if the values above the average are predominant or vice versa, etc.).

**- area** - the selected area .

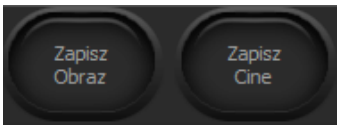
**- len center** - the length of the centre line.

**- len red/green** - the length of the red/green line – it allows defining the diversity of the external and internal edges.

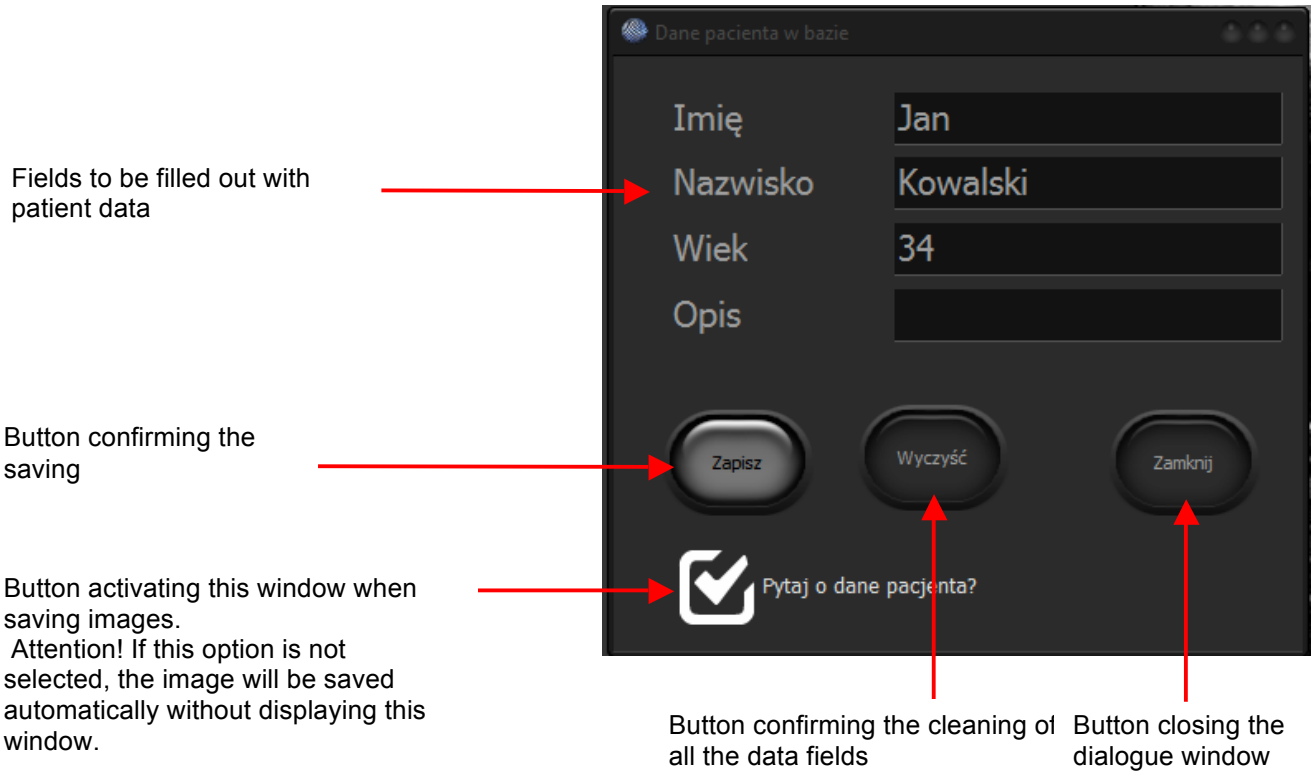
## SAVING, DISPLAYING AND PRINTING IMAGES

After freezing the image with Freeze/Start button, it is possible to save the image or the sequence of images (cine loop) in the memory of DermaView system. The memory capacity depends on the computer capacity that was used to create the DermaView system.

To select the save images option or cine loop option, use the corresponding buttons on the toolbar




After selecting Save Image/Cine option, a dialogue window with fill-in boxes will appear, as well as a set of buttons to perform the available options:



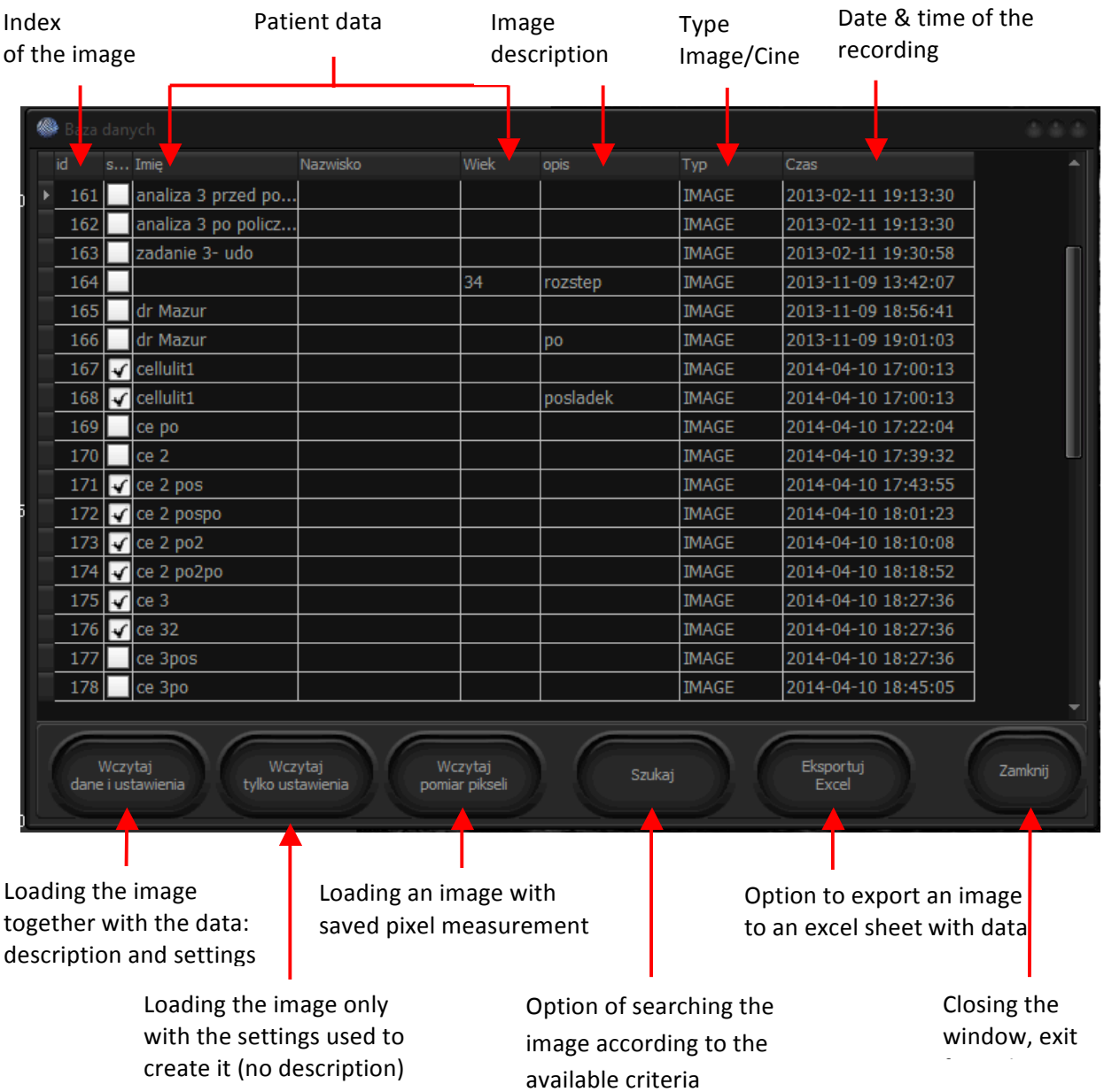

**Printing images is carried out with the use of a printer installed on a computer connected to the DermaView system.**

## DATABASE OF DERMA MED SYSTEM

On the toolbar, there is a "Database" button that is used to open the window presenting the database that contains images stored in the memory and related data along with a description.

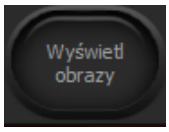
At the bottom of the window, there are buttons to activate options that allow loading an image along with the parameters of DermaView system settings that were used to create the image.
This is important when comparing the current and previously saved images of a patient.

The "database" window's outlook and description is shown below



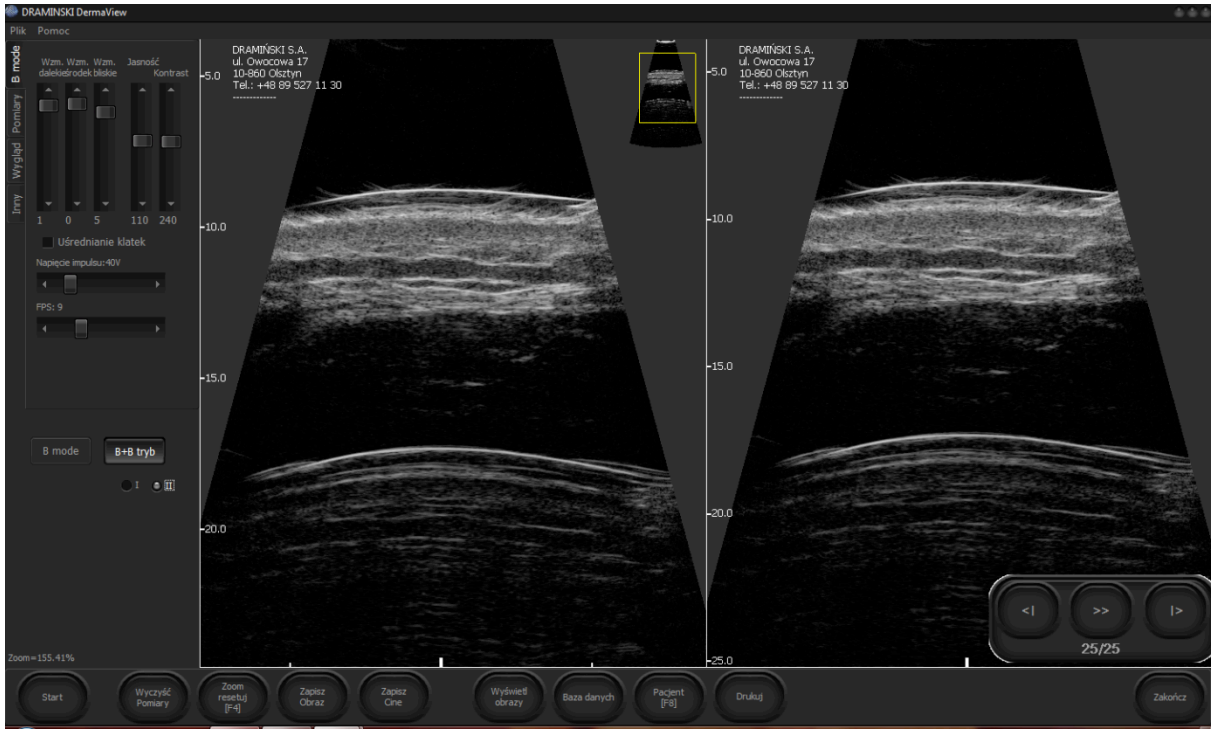
## DISPLAYING IMAGES

On the toolbar, there is a "View Images" button that is used to load onto the screen cine or images stored in memory.




Clicking the button will open a window containing a catalogue of images that were previously stored in the computer memory.

After being displayed, the image can be used to compare it with the currently performed test by B+B mode selected on the user interface.



## 13. ELECTROMAGNETIC COMPATIBILITY

Like any device, DermaView USB 2.0 system requires special safety precautions to ensure electromagnetic compatibility with other electrical devices. To ensure electromagnetic compatibility (EMC), the system shall be installed and operated in accordance with the EMC information contained in this manual. The device has been designed and tested for compatibility with PN-EN 61000-6-3:2008+A1:2011 and PN-EN 61000-6-1:2008 and the requirements for electromagnetic compatibility with other devices.

|  | **ATTENTION** |
|---|---|
| | Portable and mobile radio frequency equipment may affect the normal functioning of the DermaView system. |
| | Do not use cables or accessories other than those supplied with the DermaView head as they may result in the increased electromagnetic emissions or reduced resistance to such emissions. |

## 14. STORAGE AND TRANSPORT

### STORAGE

When the probe is not in use, store it in a clean, dry place.

|  | **ATTENTION** |
|---|---|
| | Do not send the probe, unless it has been properly disinfected. The probe can be a source of infection. |

To avoid damage to the probe, do not store it in places where it can be exposed to:

• Excessive vibration

• Excessive dust and dirt

Keep the probe in the following environment conditions:

• Temperature: 0 °C to 50 °C

• Relative humidity: 20% to 80% (without condensation)

• Atmospheric pressure: 700 hPa to 1060 hPa

### TRANSPORT

Never carry the probe by the cable. The cable could disconnect from the probe allowing it to drop and possibly damaging the probe.

Never bend the USB cable in a tight radius. This could result in damage to the cable.

Transport the probe under the following ambient conditions:

- Temperature: -10 °C to 50 °C (14 °F to 122 °F)
- Relative humidity: 20% to 80% (no condensation)
- Atmospheric Pressure: 700 hPa to 1060 hPa

When transporting the probe to a different field location or being returned for repair and / or maintenance, use of the disinfected carrying case or enclosure that the probe was originally packaged in. Call Interson for an RMA number before returning probe.

If the original package is not available, pack in such a way that the probe is protected.

Never carry the probe by the cable as it may detach from the probe, causing its dropping and possible damage.

Do not bend the USB cable at an acute angle as it may damage the cable.

The probe should be transported in a case in the following environment conditions:

• Temperature: -10 °C to 50 °C

• Relative humidity: 20% do 80% (without condensation)

• Atmospheric pressure: 700 hPa to 1060 hPa

When transporting the probe, e.g. for the purpose of repair and/or maintenance, use a special case, so that the probe is originally packed. If for some reason you do not have this special transport packaging, pack the probe in such a way so that it is well protected.

## 15. PRECAUTIONS FOR THE PROBE

The probe and the cables are completely sealed. The probe can be submerged in water up to the cable during normal use.

**Do not attempt to open the probe body.**

**Do not disconnect the USB cable from the probe body**.

Always be very careful when handling the probe because dropping the probe onto a hard surface can damage it.

Be sure that the USB plug is always dry.

The probe must be cleaned after each use. Regularly check the cable. Any cuts, cracks and fractures may adversely affect the operation of the probe.

## 16. DISPOSAL

If you are unsure how to dispose of equipment after its use, please contact the manufacturer or your local distributor.

Remember, however, to always follow the applicable disposal regulations of your country.

## 17. PROTECTING THE PRIVACY OF THE PATIENTS

As the stored images and patient database files may contain information identifying the patient, you should always take necessary steps to protect the data.
There may be situations during the use of the system which will put the patient data stored in the system memory at risk. Ask yourself the following questions:
What is my responsibility in the event that someone steals a laptop (computer)?
What should I do if the computer's drive is damaged?
It is always the responsibility of the user to ensure the safety of data.

Here are some procedures that can be used to protect the data:
1) The computer used for Derma Med system should always be locked at all times when the system is stored on it, if it is under the direct control of the user.
2) Access to the computer should be limited only to authorized users.
3) The computer should be protected by a password that requires login.
4) The folder with the files containing patient information should be password protected.
5) Back-up copies of data should be performed regularly and kept in a safe place.

## 18. LIST OF EQUIPMENT ELEMENTS

| No. | Name and description | Amount |
|---|---|---|
| 1 | Probe with USB 2.0 cable | 1 |
| 2 | Case with foam insert | 1 |
| 3 | User Guide | 1 |

## 19. TECHNICAL DATA

| | |
|---|---|
| Probe dimensions | 19.0 x 3.5 cm |
| Weight of the probe | 300 g |
| Frequency of transducer | 48 MHz |
| USB cable length | 178 cm |
| Power | from the computer through USB 2.0 port |

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